### Number 181

# **Outcomes of Community Health Worker Interventions**

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### **Preface**

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to **epc@ahrq.gov.** 

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## Structured Abstract

**Objectives.** To conduct a systematic review of the evidence on characteristics of community health workers (CHWs) and CHW interventions, outcomes of such interventions, costs and cost-effectiveness of CHW interventions, and characteristics of CHW training.

**Data sources.** We searched MEDLINE<sup>®</sup>, Cochrane Collaboration resources, and the Cumulative Index to Nursing and Allied Health Literature for studies published in English from 1980 through November 2008.

**Review methods.** We used standard Evidence-based Practice Center methods of dual review of abstracts, full-text articles, abstractions, quality ratings, and strength of evidence grades. We resolved disagreements by consensus.

**Results.** We included 53 studies on characteristics and outcomes of CHW interventions, 6 on cost-effectiveness, and 9 on training. CHWs interacted with participants in a broad array of locations, using a spectrum of materials at varying levels of intensity. We classified 8 studies as low intensity, 18 as moderate intensity, and 27 as high intensity, based on the type and duration of interaction.

Regarding outcomes, limited evidence (five studies) suggests that CHW interventions can improve participant knowledge when compared with alternative approaches such as no intervention, media, mail, or usual care plus pamphlets. We found mixed evidence for CHW effectiveness on participant behavior change (22 studies) and health outcomes (27 studies): some studies suggested that CHW interventions can result in greater improvements in participant behavior and health outcomes when compared with various alternatives, but other studies suggested that CHW interventions provide no statistically different benefits than alternatives. Low or moderate strength of evidence suggests that CHWs can increase appropriate health care utilization for some interventions (30 studies). The literature showed mixed results of effectiveness when analyzed by clinical context: CHW interventions had the greatest effectiveness relative to alternatives for some disease prevention, asthma management, cervical cancer screening, and mammography screening outcomes. CHW interventions were not significantly different from alternatives for clinical breast examination, breast self-examination, colorectal cancer screening, chronic disease management, or most maternal and child health interventions.

Six studies with economic and cost information yielded insufficient data to evaluate the cost-effectiveness of CHW interventions relative to other community health interventions.

Limited evidence described characteristics of CHW training; no studies examined the impact of CHW training on health outcomes.

**Conclusions.** CHWs can serve as a means of improving outcomes for underserved populations for some health conditions. The effectiveness of CHWs in numerous areas requires further research that addresses the methodological limitations of prior studies and that contributes to translating research into practice.

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Appendixes cited in this report are available at

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# **Executive Summary**

## Introduction

The United States has experienced remarkable improvements in public health and medical progress throughout much of the twentieth century, including major advances in pharmaceutical and medical device innovation and gains in life expectancy. These improvements, however, have not been accessible to all parts of U.S. society. Substantial disparities in life expectancy, health, and health care persist. Although many actors—including health care systems, insurers, health care providers, and patients—contribute to these disparities, bias, discrimination, and stereotyping during the clinical encounter also explain health care disparities. Experts recommend reducing fragmentation in health care systems, improving awareness on the part of health care providers of these problems, strengthening culturally competent approaches to the delivery of health care, and increasing the diversity of the health care workforce, as strategies to reduce health care disparities. A core component in recommendations to address healthcare disparities is the involvement of the community: specifically, the involvement of community health workers (CHWs).

The RTI International—University of North Carolina at Chapel Hill Evidence-based Practice Center (RTI-UNC EPC) conducted a systematic review on outcomes of CHW interventions. The review addressed four key questions (KQs):

- KQ 1. How do CHWs interact with participants? Specifically, what is the place of service, type of service, type of educational materials used, duration of interaction with participants, and length of followup?
- KQ 2. What is the impact of CHWs on outcomes, particularly knowledge, behavior, satisfaction, health outcomes, and health care utilization?
- KQ 3. What is known about the cost-effectiveness of CHWs for improving health outcomes?
- KQ 4a. What are characteristics of training for CHWs in the outpatient setting?
- KQ 4b. Are particular training characteristics associated with improved outcomes for patients?

#### **Methods**

We searched MEDLINE®, Cochrane Collaboration resources, and the Cumulative Index to Nursing and Allied Health Literature for studies published in English from 1980 through November 2008 in the United States. We refined KQs in collaboration with a panel of technical experts. We searched data sources using more than 10 terms for CHWs, including the Medical Subject Heading term "community health aides." We used standard Evidence-based Practice Center methods of dual review of abstracts, full-text articles, abstractions, quality ratings, and strength of evidence grades. We resolved disagreements by consensus. We identified 53 studies addressing KQ 1 and KQ 2, 6 studies addressing KQ 3, and 9 studies addressing KQ 4.

#### Results

# **KQ 1: Characteristics of Community Health Worker Interaction with Participants**

KQ 1 asks for descriptions of the interaction between CHWs and participants; specifically, we examined place of service, type of service, type of educational materials used, duration of interaction with participants, and length of follow-up. CHWs interacted with participants in a broad array of locations, using a spectrum of materials at varying levels of intensity. Studies usually described the place of service and type of intervention in some detail. Across the studies, one-on-one interventions generally occurred in the home, over the telephone, or in a medical setting; by contrast, group interventions tended to take place in a community setting. Studies described types of educational materials poorly or not at all. Studies inconsistently reported duration of interaction with participants and length of followup (the number and length of sessions), and studies did not always clarify whether their reporting was based on protocol or on actual experience.

We synthesized the variety of ways in which CHWs can interact with participants into a single measure of intensity that serves as a proxy of resource allocation. We classified interactions that reported at least four of six elements suggesting a higher resource utilization (one-on-one, face-to-face, 1 hour per session or more, 3 or more months' duration, three or more interactions, and tailored materials) as high intensity; interventions with two or three elements as moderate intensity; and interventions with only one or none of the elements as low intensity. Of the total of 53 studies, we classified 27 as high intensity, 18 as moderate intensity, and 8 as low intensity. The intensity of CHW interventions varied by clinical context: maternal and child health and chronic disease management interventions were all moderate or high intensity, whereas prevention and screening studies were more likely to include low-intensity interventions.

## **KQ 2: Outcomes of Community Health Worker Interventions**

KQ 2 asks about the impact of CHWs on outcomes, with specific attention to the following five domains: knowledge, behavior, satisfaction, health outcomes, and health care utilization. In addition, we summarize results by a key source of heterogeneity, the clinical context of the CHW intervention.

## **Summary by Outcomes**

**Knowledge.** The five studies reporting information on knowledge together provided moderate strength of evidence that CHW interventions improve the knowledge of participants on disease prevention and cancer screening, compared with other alternatives, and provided low strength of evidence that CHW interventions improve knowledge of label reading among diabetics, compared with usual care, but these studies gave insufficient evidence for knowledge of other issues related to the management of diabetes. This literature did not compare CHWs with a comprehensive range of usual care providers; we cannot therefore conclude that CHWs outperform all alternatives in improving participant knowledge. For the small subset of comparators and outcomes included in this literature, the studies together suggest that CHW

interventions can improve participant knowledge when compared with alternative approaches such as no intervention, media, mail, or usual care plus pamphlets.

**Behavior.** Twenty-two studies reported on the effect of CHW interventions on participant behavior. The evidence for workplace safety, diabetes mellitus, and the use of bedding encasements for asthma, from five studies, suggested that CHW interventions result in improvements in participant behavior when compared with alternatives such as a community intervention, a lower-intensity CHW intervention, and usual care combined with a pamphlet. The strength of evidence is moderate for the use of bedding encasements for asthma and low for workplace safety and diabetes mellitus. The evidence for disease prevention, improving the environment for child well-being, planned use of cancer screening tests, and breast self-examination, from 14 studies, is mixed, with some studies demonstrating a statistically significant benefit of the CHW arm, and others demonstrating a lack of significant difference. The strength of evidence for these outcomes is low. The evidence for health promotion among Latinas, injury prevention at home, and smoking cessation to reduce asthma, from five studies, failed to demonstrate that CHW interventions resulted in significantly different outcomes than alternatives; the strength of evidence for these outcomes is low.

Together these studies suggest that CHW interventions can, in some instances, result in greater positive changes in participant behavior when compared with a range of alternatives (including no intervention, community intervention, usual care plus a newsletter, media, print, a less intense or delayed CHW arm, or a combination of interventions). In other instances, CHW interventions provided no statistically different benefit when compared with a range of alternatives. When the alternative requires greater resource allocation, as with the use of health care professionals, the absence of statistically significant differences may favor the use of CHWs.

**Satisfaction.** A single study, focusing on mental health among the homeless, found no differences between study arms in participant satisfaction; the strength of evidence for this outcome is low.

Health outcomes. The literature examined CHW effectiveness on a range of outcomes: 27 of 53 studies reported health outcomes. Moderate strength of evidence exists that CHW interventions improve health outcomes for two clinical areas (improving back pain and improving psychosocial outcomes among caregivers of children with asthma) when compared with either a lower-intensity CHW intervention or a delayed-intervention control group (three studies). The evidence for other outcomes (pediatric immunizations, prenatal care and perinatal outcomes, child development, environment conducive to child well-being, mental health, diabetes, and asthma symptoms), from 22 studies, is mixed, with some studies suggesting that CHW interventions are more effective than alternatives (including no intervention, usual care, and nurses), and other studies showing no difference between CHW interventions and alternatives. For disease prevention (specifically, reduction in body mass index), hypertension, and mental health, the evidence from five studies suggests no difference between CHW interventions and alternative approaches, including the use of CHWs in a lesser capacity, nurses, and print materials; the strength of evidence for these outcomes is low.

Together these studies showed that CHW interventions had a greater effect on some health outcomes when compared with alternatives such as no intervention, usual care, and nurses, but these findings were not consistent across all studies; several studies found no statistically significant benefit of the CHW arm when compared with alternative approaches.

**Health care utilization.** More than one-half of the identified studies reported on health care utilization. Fifteen studies provided moderate strength of evidence that CHW interventions increase appropriate health care utilization for disease prevention, mammography, infectious diseases, and asthma when compared with a range of alternatives such as no intervention, mail, print, or a less intense CHW arm. Two studies offered low strength of evidence that CHW interventions provide statistically significant benefits in health care utilization for two outcomes: prenatal and perinatal care (when compared with nurses) and hypertension (when compared with usual care). For Pap smears, six studies provided mixed evidence, with some studies suggesting a statistically significant benefit for the CHW arm, and other studies suggesting no significant differences; the strength of evidence for this outcome is low. For health promotion among Latinas, child well-being, clinical breast examination, colorectal cancer screening, and mental health, evidence from nine studies suggested no difference between the CHW intervention and alternatives; the strength of evidence for these outcomes is low.

Together these studies provided low to moderate evidence that CHW interventions increase appropriate health care utilization (e.g., more use of cancer screening tests, less use of emergency services) when compared with a range of alternatives for disease prevention (specifically, medical follow-up for elevated blood pressure), mammography, infectious diseases, and asthma; for other reported outcomes, the evidence was mixed or does not show a statistically significant benefit of the CHW arm.

## **Summary Findings by Clinical Context**

Health promotion and disease prevention. Eleven studies addressed health promotion and disease prevention, including pediatric immunizations, cardiovascular disease, diabetes prevention, HIV prevention, secondhand smoke exposure, colorectal cancer prevention, and general preventive care. Two studies on disease prevention found that CHW interventions versus print or no intervention were more effective in changing knowledge. Results for CHW interventions on behavior outcomes were mixed, with one-half of the studies favoring CHW intervention versus control groups, which consisted of no intervention, media, print, or a combination of interventions. None of the studies evaluated outcomes in the area of satisfaction. Results for CHW interventions on health outcomes, available from four studies, were also mixed.

The results suggest that CHW interventions may serve as an effective means of improving knowledge outcomes and possibly other outcomes related to preventing disease in underserved, minority populations.

**Injury prevention.** Three studies assessed injury prevention measures and associated behavioral outcomes: two focused on home injury prevention, and one considered workplace injury prevention. One study found improvements in behavior associated with CHW interventions when compared with a minimal community intervention, and one found mixed results with CHW interventions showing a statistically significant benefit in some measures but controls (with no intervention) showing a statistically significant benefit over CHW interventions for other measures. One study showed no significant difference in behavior between CHW interventions and health care professionals. The mixed results preclude any firm conclusions regarding the benefit of CHW interventions for injury prevention behaviors.

**Maternal and child health.** Fifteen studies meeting our inclusion criteria involved primarily maternal health, child health, or both and reported mainly on health outcomes. A statistically significant benefit of CHWs over standard care was shown most prominently in rapidity of metabolic control for mothers with phenylketonuria (PKU) and in the mental development of

infants of mothers with PKU. CHW interventions were associated with a greater likelihood of initiating breastfeeding among African Americans, more frequent use of nonviolent discipline methods by parents, and higher parenting efficacy scores when compared with video-intervention or no-intervention controls. CHWs were also associated with significant attenuation in the decline of cognitive and motor development among infants with failure to thrive and with a lesser degree of increase in depressive symptoms among postpartum women when compared with no intervention. No significant advantage to CHW intervention was seen for improvements in incidence of low birth weight, presence of neonatal or infant health problems, language development, maternal stress or self-esteem, continuation of breastfeeding beyond 1 week, tobacco exposure for children of smokers, continued drug use among mothers with known prior drug use, growth of children with failure to thrive, or incidence of child maltreatment when compared with nurse interventions, multidisciplinary specialty clinical care, video or print intervention, routine health care, or no intervention.

Most studies involving CHWs for maternal and child health have been concerned with high-risk populations. For maternal and child health, CHWs appear to be most beneficial when addressing existing health conditions instead of potential conditions (i.e., primary prevention). Of the 15 studies that were evaluated, 8 studies reported statistically significant benefit to CHWs, compared with nurse interventions, multidisciplinary specialty clinical care, video or print intervention, routine health care, or no intervention. CHWs have not yet been shown to improve key health outcomes relating to maternal and child health such as prematurity, low birth weight, sustained breastfeeding, or child maltreatment relative to other alternatives such as video or print intervention, routine health care, or no intervention. The lack of such findings suggests that either further research is needed to demonstrate benefits or that there is a true lack of benefit for CHWs in this domain.

**Cancer screening.** Fifteen studies examining knowledge or health care utilization outcomes of CHW interventions for improving breast, cervical, or colorectal cancer screening met inclusion criteria for this systematic review. Together the 15 studies suggest limited evidence of improvement in knowledge in the CHW arm, compared with alternative approaches such as media or mail, and these studies also suggest conflicting findings on the effect of CHWs on planned or actual behavior changes—specifically, breast self-examination—when compared with no intervention, delayed intervention, mail, minimal CHW, or usual care. The volume of evidence on these outcomes is limited; the quality and design of the studies limit the interpretation of available evidence. Regarding health care utilization, our findings from limited evidence suggest that CHW interventions are not effective in comparison with other alternatives (such as no intervention, mail, tailored print and video, and minimal CHW) in raising the rates of clinical breast examination or colorectal cancer screening. More substantial evidence exists on Pap smears and mammography. The evidence suggests that the CHW arm is at least as effective as other alternatives (such as mail or lower-intensity CHW interventions) in improving Pap smear rates, but more effective than other alternatives (such as no intervention, media, print, community interventions, and usual care) only with low- and moderate-intensity interventions (rather than high-intensity interventions). Studies demonstrated significantly greater improvements in the CHW arm, compared with the alternative (no intervention, mail, print, or minimal CHW) in the main analysis or in subgroup analysis among low-income, minority, or other underserved subsamples.

CHW interventions were not demonstrated to be more effective than alternatives for increasing the utilization of breast self-examination, clinical breast examination, or colorectal

cancer screening. CHWs can serve as a means of improving utilization of Pap smear tests and mammograms for underserved populations; the effectiveness of CHWs for other outcomes requires further research.

Chronic disease management. Thirteen studies addressed disease management, including diabetes mellitus, hypertension, asthma, back pain, mental health, and tuberculosis. Only one of the studies in the area of chronic disease management addressed knowledge outcomes. Two of four CHW interventions on diabetes and two asthma studies addressed behavior changes, comparing the CHW arm with usual care or a less intense CHW arm. These studies found that CHW interventions provided statistically significant benefit for diabetes and for use of bedding encasements in asthma, but not for smoking cessation. Only the mental health study addressed satisfaction outcomes, and this study did not demonstrate a difference between the CHW group and the control. Regarding health outcomes, two of four studies focusing on diabetes management found that a CHW intervention was more effective than usual care in decreasing hemoglobin A1c. None of the studies addressing hypertension management showed a significant difference in blood pressure control between groups. Two asthma studies demonstrated that CHW interventions were more effective than alternatives in reducing unscheduled health care services, improving psychological outcomes, and changing behavior, although symptom measures improved equally in each group. With the exception of asthma, the majority of CHW interventions for chronic disease management (specifically, diabetes, hypertension, and mental health) failed to show consistently greater improvement in health outcomes than usual care. By contrast, four of five studies on chronic disease management found that a CHW intervention was more effective than usual care or a less intense CHW arm in improving health care utilization.

## KQ 3: Cost-Effectiveness of Community Health Worker Interventions

We identified six studies in the literature providing economic analyses of CHW interventions. All of the studies included in our review estimated intervention program costs, but not all reported the specific components of those costs or the year for which costs were estimated. None of the CHW intervention evaluations that included an economic analysis reported a standard measure of costs per quality-adjusted life year saved, as recommended in recent guides for performing economic evaluations. One study did report on the costs per life-year saved of the CHW intervention, but potential biases in measurement limit the interpretation of results. We found insufficient evidence to evaluate whether CHW interventions are a cost-effective alternative to clinical interventions to promote health and prevent disease.

## **KQ 4: Training of Community Health Workers**

We found only nine studies meeting our inclusion criteria that described the training of CHWs. All included studies reported evidence of improvement in knowledge or skills, and many focused on aspects of training relevant to the specific health concern. Few reported on training for cultural competence, recruitment and retention process skills, intake and assessment, or protocol delivery. The failure to report on these elements presents a roadblock to identifying critical elements of a standardized curriculum applicable to all CHWs.

No studies reported on the effects of CHW training on health outcomes. The question of how to tailor CHW training to improve health outcomes is a significant gap for future studies to address.

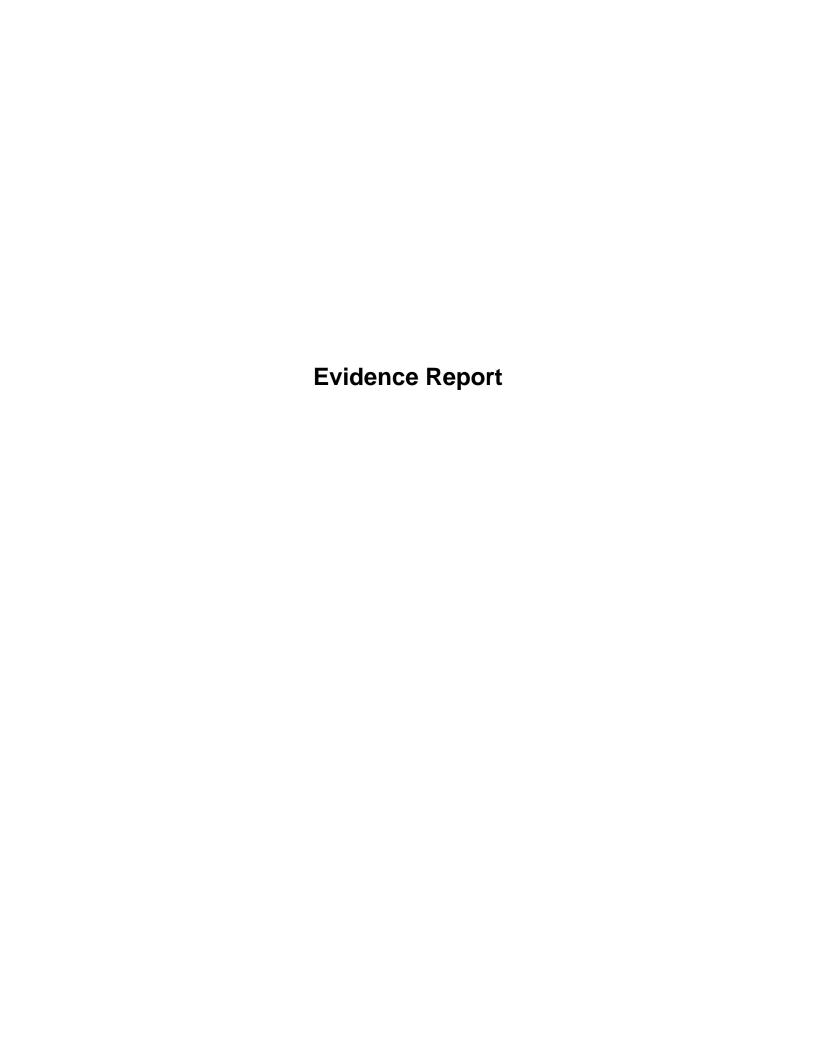
### **Discussion**

CHW interventions have the potential to address two fundamental imperatives for improving health care in the United States: the need to address substantial and persistent health care disparities, and the need to translate more research into practice. CHWs, by virtue of their role as a bridge to the health care system, can help to disseminate widely efficacious interventions to populations that rarely benefit from health care advances.

Evidence about the effectiveness of CHWs relative to other choices is, however, mixed. Some studies demonstrated statistically significant benefits of the CHW approach, compared with other choices; other studies showed mixed results or no statistically significant differences between study arms. For the latter studies, one explanation is a lack of true benefit of the CHW arm relative to other choices. In addition, the choice of controls (including health professionals and CHWs in a lesser capacity), inadequate study power, and the Hawthorne effect may explain the lack of significant differences between CHWs and alternatives. The variation in and inadequate reporting on components of CHW interventions limit assessments of whether high-intensity interventions deliver greater value than low- or moderate-intensity interventions.

We found limited evidence that suggests that CHW interventions can improve participant knowledge when compared with alternative approaches such as no intervention, media, mail, or usual care plus pamphlets. We found mixed evidence for CHW effectiveness on participant behavior change and health outcomes: some studies suggested that CHW interventions can result in greater improvements in participant behavior and health outcomes when compared with various alternatives, but other studies suggested that CHW interventions provide no statistically different benefits. Low or moderate strength of evidence suggests that CHWs can increase appropriate health care utilization for some interventions. The literature showed mixed results of effectiveness when analyzed by clinical context: CHW interventions had the greatest effectiveness relative to alternatives for some disease prevention, asthma management, cervical cancer screening, and mammography screening outcomes. CHW interventions were not significantly different from alternatives for clinical breast examination, breast self-examination, colorectal cancer screening, chronic disease management, or most maternal and child health interventions. We found insufficient evidence to evaluate the cost-effectiveness of CHW interventions relative to other public health interventions.

Our review suggests that CHWs may serve as a means of improving outcomes for underserved populations for some health conditions, as described above. Other health concerns require further research that addresses the methodological limitations of prior studies to fully evaluate the effectiveness of CHW interventions.



## **Chapter 1. Introduction**

## **Background**

## **Health Disparities in the United States**

The United States experienced remarkable improvements in public health and medical progress throughout much of the twentieth century. These advances, which have continued into the twenty-first century, have been accompanied by significant increases in medical spending. In 2003, total health care spending reached approximately \$1.7 trillion, accounting for nearly 16 percent of the gross domestic product. An estimated 5.6 percent of total health care spending was on biomedical research, a proportion unmatched by any other country. Some experts note associations between US expenditures on biomedical research and major advances in pharmaceutical and medical device innovation and accompanying improvements in life expectancy.

These improvements have not been accessible to all parts of US society. Substantial disparities in life expectancy,<sup>4</sup> health, and health care persist.<sup>5-9</sup> Repeated measures of disparities in quality of care and access to care since 2003 demonstrate, at best, only minor improvements.<sup>5-9</sup> According to an Institute of Medicine (IOM) committee report, *Unequal Treatment*, these seemingly intractable differences cannot be explained by clinically appropriate care, differing needs of patients, or patient preferences.<sup>10</sup> Moreover, access-related factors such as insurance status and income also cannot alone explain differences in quality of care or outcomes.<sup>10</sup>

Although many actors, including health care systems, insurers, health care providers, and patients, contribute to these disparities, bias, discrimination, and stereotyping during the clinical encounter also explain health care disparities. Recommendations of the IOM report, echoed by other publications, focus on reducing fragmentation in health care systems, improving awareness on the part of health care providers of these problems, strengthening culturally competent approaches to the delivery of health care, and increasing the diversity of the health care workforce. On the strength of the health care workforce.

# Role of the Community Health Worker in Addressing Health Disparities

A core component in recommendations to address health disparities is the involvement of the community, specifically the involvement of community health workers (CHWs). <sup>10</sup> Models of care using CHWs vary from making them an integral part of the care delivery team to involving them as community navigators, education providers, or outreach agents. <sup>13</sup>

A key variable along this spectrum is the extent to which CHWs operate within their own social networks. For example, CHW interventions using natural helpers rely on the specialized knowledge and expertise of CHWs working within their own social networks, whereas an outreach worker model may operate across social networks. <sup>14</sup> The nomenclature for CHWs reflects this variation; it includes terms such as natural helpers, lay health advisors, patient navigators, and community health aides, among others. The disease conditions that CHWs help to address also reflect a wide spectrum, from AIDS prevention to smoking cessation, hypertension management to pediatric immunization, and asthma management to maternal and child care.

Common attributes across CHWs, regardless of nomenclature, health condition, or intervention include: (1) their role as health workers who share a relationship with their community (e.g., shared language, ethnicity, geography, race, or disease condition) and (2) the absence of professional training. The relationship that CHWs share with the community in which they work has long identified them as a natural bridge to the health care system.

Explanations for the anticipated outcomes of CHW interventions typically cite theories of individual behavior change. <sup>15-23</sup> Theories of individual behavior change draw upon many ideas. Among them are the stages of change or the transtheoretical model (a framework for understanding motivational readiness to address problem behaviors<sup>24</sup>), social learning or social cognitive theory (an explanation of individual learning as operating through the observation of others within the context of behavioral, environmental, and personal factors<sup>25</sup>), and the health belief model (an explanation of individual health behaviors through attitudes and beliefs toward perceived susceptibility, severity, benefits, and barriers<sup>26</sup>).

Less frequently, authors acknowledge that these interventions also operate within the context of community change. 27-29 According to Minkler and Wallerstein, collaborative models of community change range from community organizing (externally driven and motivated by community needs) to community building (internally generated and drawing upon community strengths) with variants in between. 30 Several ideas help explain the drivers and mechanisms of community change: theories of social justice and human rights (the idea of health as a human right that CHWs can help to achieve in the interest of social justice 28,31), collaborative empowerment (grantmakers, support organizations, local leaders, and individuals working together in a reciprocal manner 32), and critical consciousness (the process of critical awareness by which community members become aware of their own agency and create spaces to work with others to bring about changes in individual and community health 33,34).

CHW engagement is expected to diffuse community change to individuals; in addition, CHWs are postulated to reduce disparities through improving access to care, providing culturally competent health education, counseling, and sometimes rendering direct health services. Additionally, as trusted members of the community, CHWs may help to minimize barriers to care resulting from health beliefs and health values. <sup>10</sup>

## **History of Community Health Workers**

The history of CHWs supports the role that they continue today in providing services to marginalized populations. Perez and Martinez<sup>28</sup> note that the earliest records of CHWs date back to a shortage of doctors in early 17th century Russia, when lay people, called "feldshers," received training to provide basic medical care to military personnel.<sup>35</sup> Later a similar model arose in China, where farmers with minimal medical training served as "barefoot doctors" to provide basic primary care, including vaccinations and treatment of minor illnesses, to rural underserved regions.<sup>28</sup> Today, thousands of health programs employ CHWs worldwide for similar reasons.<sup>36</sup>

Internationally, a global shortage of medical workers has increased the call for these types of personnel. Significant health care workforce shortages are present in 57 countries, including countries in sub-Saharan Africa, Bangladesh, India, and Indonesia. Figures for the number of physicians per 100,000 people range from a low of 2 in Malawi to a high of 591 in Cuba; the number in the United States is 256. These figures represent overall physician proportions; the proportion of primary care physicians is far lower worldwide.

The AIDS epidemic in developing countries that already face a critical shortage of professional health care workers has strengthened the need to make greater use of CHWs. Task shifting allows CHWs to take on jobs that were previously performed by nurses; this phenomenon holds promise for rapidly filling the health care workforce deficit. One advantage of employing CHWs is the relatively short amount of training time they need, ranging from hours to weeks. This quick turnaround in training allows CHWs to be ready to provide services years before new nurses or doctors can complete their own training. Ultimately, the hope is that task shifting will improve access to primary care and, thus, serve to strengthen health care systems around the world.<sup>37</sup>

In the United States, despite the relatively high ratios of physicians to patients in this country, a significant percentage of the population remains underserved, particularly for primary care. An estimated one in five Americans are medically disenfranchised due to the shortage of primary care physicians, meaning they have inadequate or even no access to these physicians. The need to reduce health disparities among the underserved has led to an interest in CHW interventions within the United States. The 2007 Community Health Worker National Workforce Study suggests that the development of the CHW workforce in the United States occurred over four important time periods: early documentation (1966-1972), utilization of CHWs in special projects (1973-1989), state and federal initiatives (1990-1998), and public policy options (1999-2007). Few references to CHW interventions appear in the literature before the mid-1960s.

During the period of early documentation (1966-1972), CHWs were used to address problems of the poor rather than in specific health improvement models. The New York City Health Department first documented CHW use in a 1960s-era tuberculosis program that involved "neighborhood health aides." One early effectiveness study on CHWs (published in 1970) consisted of a CHW intervention with nurses and physicians to improve compliance in treating pediatric infections. <sup>40</sup>

Public and private funding of projects involving CHWs continued to grow from 1973 to 1989, in turn prompting more publications. <sup>13</sup> Further attention was brought to CHWs as a result of a World Health Organization (WHO) declaration in 1978, proposing the development of national CHW programs as important for promoting primary health care. <sup>41</sup> Another significant step for dissemination of CHW programs occurred when the "Resource Mothers" curriculum, prepared for the Virginia Task Force on Infant Mortality during the 1980s, became one of the early CHW curricula distributed nationally. <sup>42</sup>

From 1990 to 1998, several state and federal bills proposed CHW interventions; none, however, was enacted. Despite this lack of legislative support, training centers dedicated to CHWs opened in Boston<sup>43</sup> and San Francisco.<sup>44</sup> Support remained high for the promise of CHW interventions with the expectation that the widespread incorporation of CHWs into the health delivery system would offer opportunities to improve the delivery of preventive and primary health care in the United States.<sup>45</sup>

The state of Texas passed the first legislation addressing the CHW workforce in 1999, starting the public policy options period (1999-2006). During this time, several associations called for expansion of CHW roles and projects, including the National Rural Health Association, the American Association of Diabetes Educators, and the American Public Health Association. As noted earlier, the 2003 IOM report also made recommendations regarding the role of CHWs in addressing health care disparities. Finally, during this same period the first national legislation on CHWs was passed: The Patient Navigator Outreach and Chronic Disease

Prevention Act of 2005. Additionally, the state of Minnesota passed legislation allowing for Medicaid coverage of CHW services in December of 2007.<sup>47</sup>

In 2000, an estimated 86,000 CHWs were supporting American communities.<sup>13</sup> The number of CHWs has continued to grow since then to an estimated 121,000 CHWs in 2005, representing a 41 percent increase from 2000.<sup>13</sup>

## **Key Questions and Analytic Framework**

## **Key Questions**

Numerous recent reviews have examined the effectiveness of CHWs, but their scope has often been limited to specific disease conditions, <sup>48,49</sup> subpopulations, <sup>50,51</sup> or study designs. <sup>52,53</sup> The Agency for Healthcare Research and Quality (AHRQ) commissioned the RTI International—University of North Carolina Evidence-based Practice Center (RTI-UNC EPC) to conduct a systematic review on outcomes of CHW interventions. The nominator for this work was the Minnesota Department of Human Services (MDHS).

The EPC received and revised key questions (KQs) after discussions with internal technical staff, AHRQ staff, MDHS staff, and our Technical Expert Panel (TEP, see below). The final KQs are as follows:

- KQ 1. How do community health workers interact with participants? Specifically, what is the place of service, type of service, type of educational materials used, duration of interaction with participants, and length of followup?
- KQ 2. What is the impact of community health workers on outcomes, particularly knowledge, behavior, satisfaction, health outcomes, and health care utilization?
- KQ 3. What is known about the cost-effectiveness of community health workers for improving health outcomes?
- KQ 4a. What are characteristics of training for community health workers in the outpatient setting?
- KQ 4b. Are particular training characteristics associated with improved outcomes for patients?

# **Analytic Framework for Outcomes of Community Health Worker Interventions**

Based on our discussion with TEP members, we used the following operational definition of CHWs: A CHW:

- Performs health-related tasks to create a bridge between community members, especially hard-to-reach populations, and the health care system (i.e., performs tasks extending beyond peer counseling or peer support alone).
- Has health training associated with the intervention; training is shorter than that of a professional worker (i.e., training does not form part of a tertiary education certificate).
- Is recognized (or can be identified) as a member of the community in which he or she works, defined by but not limited to, geographic location, race or ethnicity, and exposure or disease status.

As reflected in Figure 1, KQ 1 and KQ 4a are descriptive questions. The information obtained through KQ 1 will inform KQ 2. KQ 3 evaluates cost information for the subset of evidence identified in KQ 1 as effective. The heterogeneity of health conditions, CHW intervention types, and comparators will be explicitly addressed in all KQs.

CHW Characteristics: Motivation, setting, ethnic concordance, integration with health care system Training (KQ4) Health Care and Utilization Outcomes Intervention Population with **CHW-Client** KQ2 with CHW Health Concern Interaction Component Cost-Effectiveness (KQ3) Patient Characteristics: Demographics (age, sex, race, education), cointerventions, income, immigration status Population Characteristics: Appropriateness of intervention, eligibility of population Societal Characteristics: Socio-economic policy, insurance, cultural barriers, availability of services, health benefits

Figure 1. Outcomes of community health worker interventions: conceptual framework

## **Production of This Evidence Report**

## **Organization**

Chapter 2 describes our methods, including our search strategies and inclusion/exclusion criteria; we also document our approach to grading the quality of articles and rating the strength of evidence. In Chapter 3, we report the results of literature searches and synthesis of retained articles for KQs 1, 2, 3, and 4. Chapter 4 presents our conclusions and offers our recommendations for future research.

References and included studies follow Chapter 4. Appendixes include a detailed description of our search strings (Appendix A\*), data collection forms (Appendix B), detailed evidence tables (Appendix C), excluded studies (Appendix D), and acknowledgments (Appendix E).

## **Technical Expert Panel (TEP)**

In designing the study questions and methodology at the outset of this report, we consulted several technical and content experts, seeking broad expertise and perspectives. We identified

<sup>\*</sup> Appendixes are cited in this report and provided electronically at <a href="http://www.ahrq.gov/downloads/pub/evidence/pdf/comhealthwork/comhwork.pdf">http://www.ahrq.gov/downloads/pub/evidence/pdf/comhealthwork/comhwork.pdf</a>

seven technical experts to provide assistance throughout the project (Appendix E); two were employed by the Minnesota Department of Human Services (the nominator for this topic). The TEP contributed to AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of its products. Thus, the TEP was both an additional resource and a sounding board during the project.

Divergent and conflicting opinions are common; we perceive them as healthy scientific discourse that contributes to a thoughtful, relevant systematic review. Nonetheless, in the end, study questions, design, and/or methodologic approaches do not necessarily represent the views of individual technical and content experts.

To ensure robust, scientifically relevant work, we called on the TEP to provide reactions to work in progress and advice on substantive issues or possibly overlooked areas of research. Specifically, TEP members participated in conference calls and discussions through e-mail to:

- refine the analytic framework and KQs at the beginning of the project;
- discuss the preliminary assessment of the literature, including inclusion/exclusion criteria; and
- provide input on the information and categories included in evidence tables.

Because of their extensive knowledge of the literature, including numerous articles authored by TEP members themselves, and their active involvement in the field, we also asked TEP members to participate in the external peer review of the draft report.

## **Uses of This Report**

We anticipate that this report will be useful to primary care and public health practitioners; community health workers; national, state, and local health policy makers; Medicaid and other public and private insurers; and community-based researchers. As noted above, we will explicitly consider CHW effectiveness by clinical concern; specialists in these areas may also find this report to be of use in designing and allocating resources for future CHW interventions.

## **Chapter 2. Methods**

In this chapter, we document the procedures that the RTI International—University of North Carolina Evidence-based Practice Center (RTI–UNC EPC) used to develop this comprehensive evidence report on community health workers (CHWs). The team was led by a senior health services researcher (Meera Viswanathan, Ph.D., Study Director), and included a physician trained in internal medicine and pediatrics (Dan Jonas, M.D., M.P.H.), a general internist (Jennifer Kraschnewski, M.D.), a preventive medicine physician (Brett Nishikawa, M.D.), an economist (Amanda Honeycutt, Ph.D.), and two EPC staff members, Laura Morgan, M.A., and Patricia Thieda, M.A.

We describe our inclusion and exclusion criteria, search and retrieval process, and methods of abstracting relevant information from the eligible articles to generate evidence tables. We also discuss our criteria for grading the quality of individual articles and for rating the strength of the evidence as a whole.

### **Literature Review Methods**

#### Inclusion and Exclusion Criteria

Our inclusion and exclusion criteria are documented in Table 1. As noted in Chapter 1, this systematic review focuses on characteristics, outcomes, cost-effectiveness, and training of CHWs. We restricted our searches to the United States so that we could have data relevant to domestic health care concerns. We also restricted our searches to studies published in 1980 or thereafter to ensure that results had relevance to current practice.

We excluded studies that (1) were published in languages other than English (given the available time and resources); (2) did not report information pertinent to the key clinical questions; (3) had fewer than 40 subjects for randomized controlled trials (RCTs) or nonrandomized cohorts with comparisons; and (4) were not original studies.

A key criterion for inclusion was the requirement that the effect of the CHW had to be abstractable. As a result of this criterion, our review is limited to studies for which the effect of the CHW intervention can be isolated; we excluded 38 studies in which the outcome of the intervention could not be attributed to the CHW. These studies often compared usual care to a combination of interventions that may have included CHWs as one of several components and did not distinguish between the effect of the CHW and other components. Another key criterion was the requirement that the intervention included CHWs. As a result, we excluded studies that relied on peer counselors (13 studies).

For key questions (KQs) 1, 2, and 3, we required that the CHW intervention be compared with an alternative; we excluded 70 studies without comparison arms. For KQ 4, we required that the description of training for CHWs be supported by pre- and post-training evaluation data; we excluded 34 studies without such data.

Table 1. Inclusion/exclusion criteria

Category	Criteria		
Populations	All study populations with a CHW intervention		
Interventions	Intervention must be delivered by CHWs, not peer counselors or health care professionals. A CHW:		
	<ul> <li>Performs health-related tasks to create a bridge between community members, especially hard-to-reach populations, and the health care system (i.e., performs tasks extending beyond peer counseling or peer support alone).</li> <li>Has health training associated with the intervention; training is shorter than that of a professional worker (i.e., training does not form part of a tertiary education certificate).</li> <li>Is recognized (or can be identified) as a member of the community in which he or she works, defined by but not limited to, geographic location, race or ethnicity, and exposure or disease status.</li> </ul>		
Comparisons	KQs 1, 2, 3: CHW intervention must have a comparison arm; all comparisons admissible as long as the effect of the CHW intervention can be abstracted		
	KQ 4: No comparisons required		
Outcomes	KQ 1: Interaction with clients		
	KQ 2: Knowledge, satisfaction, behavior, health outcomes, and health care utilization		
	KQ 3: Cost data		
	KQ 4: Training characteristics		
Time period	1980 to November 14, 2008		
Study settings and geography	United States		
Publication languages	English only		
Admissible evidence (study design and other criteria)	Admissible designs controlled trials ( $n \ge 40$ ), nonrandomized controlled trials ( $n \ge 40$ ), systematic reviews, meta-analyses, prospective trials with historical controls ( $n \ge 40$ )		
	Other criteria		
	<ul> <li>Original research studies must provide sufficient detail regarding methods and results to enable use and adjustment of the data and results</li> </ul>		
	<ul> <li>Relevant outcomes must be able to be abstracted from data presented in the papers</li> </ul>		
	<ul> <li>Effect of CHW intervention must be abstractable</li> </ul>		
	<ul> <li>KQ 4: CHW interventions must provide pre-training and post- training evaluation of CHW knowledge or skills</li> </ul>		

### **Literature Search and Retrieval Process**

**Databases**. We searched three electronic databases—MEDLINE<sup>®</sup>, Cochrane Collaboration resources, and Cumulative Index to Nursing and Allied Health Literature (CINAHL). We also hand-searched the reference lists of relevant articles to make sure that we did not miss any

relevant studies. We consulted with our Technical Expert Panel (TEP) about any studies or trials that were currently under way or that had not yet been published.

**Search terms**. Based on the inclusion/exclusion criteria above, we generated a list of Medical Subject Heading (MeSH) search terms (Table 2 and Appendix  $A^{\dagger}$ ). Our TEP also reviewed these terms to ensure that we were not missing any critical areas, and this list represents our collective decisions as to the MeSH terms used for all MEDLINE searches.

Table 2. MEDLINE search strategy and unduplicated results for April 2008

Search number	Search Term	Yield
#2	Search "Community Health Aides"[MeSH] OR "health advisor" OR "health worker" OR "health advocate" OR "health paraprofessional" OR "community health representative" OR "outreach worker" OR dumas OR promotoras OR embajadores OR consejeras	6,051
#3	Search "Community Health Aides" [MeSH] OR "health advisor" OR "health worker" OR "health advocate" OR "health paraprofessional" OR "community health representative" OR "outreach worker" OR dumas OR promotoras OR embajadores OR consejeras Limits: Humans, English	3,031
#6	Search (("Outcome Assessment (Health Care)"[MeSH] OR "Pregnancy Outcome"[MeSH])) OR ("Treatment Outcome"[MeSH] OR "Outcome and Process Assessment (Health Care)"[MeSH] OR "Fatal Outcome"[MeSH]) Limits: Humans, English	369,350
#7	Search #3 AND #6 Limits: Humans, English	175
#17	Search ("Patient Education as Topic"[MeSH] OR "Patient Education Handout "[Publication Type]) OR "Professional-Patient Relations"[MeSH]) OR "Office Visits"[MeSH] Limits: Humans, English	109,582
#18	Search #3 AND #17 Limits: Humans, English	90
#26	Search ("Costs and Cost Analysis" [MeSH] OR "Economics" [MeSH] OR "economics "[Subheading] OR "Cost-Benefit Analysis" [MeSH] OR "Cost Allocation" [MeSH] OR "Cost of Illness" [MeSH] OR "Cost Control" [MeSH] OR "Cost Sharing" [MeSH] OR "Cost Savings" [MeSH] OR "Health Care Costs" [MeSH] OR "Direct Service Costs" [MeSH] OR "Hospital Costs" [MeSH] OR "Employer Health Costs" [MeSH] OR "Drug Costs" [MeSH]) Limits: Humans, English	257,114
#27	Search #3 AND #26 Limits: Humans, English	254
#28	Search United States Limits: Humans, English	606,881
#29	Search #27 AND #28 Limits: Humans, English	71
#33	Search (("Education"[MeSH] OR "education "[Subheading])) OR "Education, Professional"[MeSH] OR training Limits: Humans, English	370,579
#34	Search #3 AND #33 Limits: Humans, English	1,013
#35	Search #34 AND #28 Limits: Humans, English	241
#41	Search ("Randomized Controlled Trials as Topic"[MeSH] OR "Randomized Controlled Trial "[Publication Type]) OR "Single-Blind Method"[MeSH]) OR "Double-Blind Method"[MeSH]) OR "Random Allocation"[MeSH] Limits: Humans, English	303,728
#42	Search #3 AND #41 Limits: Humans, English	165
#44	Search control OR controlled Limits: Humans, English	1,368,901
#45	Search #3 AND #44 Limits: Humans, English	908
#46	Search #45 AND #28 Limits: Humans, English	154
	Total unduplicated PubMed records	640

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<sup>†</sup> Appendixes cited in this report are available at <a href="http://www.ahrq.gov/downloads/pub/evidence/pdf/comhealthwork/comhwork.pdf">http://www.ahrq.gov/downloads/pub/evidence/pdf/comhealthwork/comhwork.pdf</a>

Our initial searches in MEDLINE produced 640 unduplicated records. Searches in other databases (CINAHL, Cochrane, and Cochrane Clinical Trials Registry) yielded 169 new records (unduplicated across all databases) for a total of 809 records. We conducted update searches in all databases in November, 2008 and supplemented electronic searches with manual searches of reference lists. In addition, we received recommendations for studies of interest from the TEP and conducted a supplemental search on patient navigators after peer review. In all, we identified 1,076 unduplicated references from all searches (Table 3).

Table 3. Overall unduplicated results and sources of all searches

Original search of MEDLINE, Cochrane, Cochrane Clinical Trials Registry, CINAHL (April 2008)	809
Update search of MEDLINE, Cochrane, Cochrane Clinical Trials Registry, CINAHL (November 2008)	59
TEP recommended references	10
Handsearches of reference lists	173
Supplemental search (Patient Navigator) of MEDLINE, Cochrane, Cochrane Clinical Trials Registry, CINAHL	25
TOTAL	1,076

Figure 2 presents the yield and results from our searches, which we conducted from April through November 2008. Beginning with a yield of 1,076 articles, we retained 89 articles that we determined were relevant to address our KQs and met our inclusion/exclusion criteria (Figure 2). We reviewed titles and abstracts of the articles against the basic inclusion criteria above; we retained relevant articles and used them as appropriate in the discussion in Chapter 4.

**Article selection process.** Once we had identified articles through the electronic database searches, review articles, and reference lists, we examined abstracts of articles to determine whether studies met our criteria. Each abstract was independently, dually reviewed for inclusion or exclusion, using an Abstract Review Form (Appendix B).<sup>‡</sup> If one reviewer concluded that the article should be included in the review, we retained it.

Of this entire group of 1,076 citations, 590 required full review. For the full article review, one team member read each article and decided whether it met our inclusion criteria, using a Full-Text Inclusion/Exclusion Form (Appendix B). Reasons for article exclusion are listed in Appendix D.

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<sup>‡</sup> Appendixes cited in this report are available at <a href="http://www.ahrq.gov/downloads/pub/evidence/pdf/comhealthwork/comhwork.pdf">http://www.ahrq.gov/downloads/pub/evidence/pdf/comhealthwork/comhwork.pdf</a>

Titles and abstracts Citations identified through excluded: searches: n = 477n = 1,076Unable to retrieve full text: n = 3Full text articles excluded: n = 384Published as 27 Non-US population abstract-only 41 No health or economic outcomes n = 6 59 Not about CHWs 30 Wrong publication type Full-text articles 3 Sample size < 40 retrieved: 70 No comparison arm/data n = 59038 Comparison arm/data not about CHW (or CHW only) 13 CHW component insufficiently described to distinguish from other Background n = 117 peer-led models 69 Published prior to 1980 34 No pre-post data on training Articles included in review n = 89\*KQ1: n = 79 KQ2: n = 79 KQ3: n = 6 KQ4a: n = 10 KQ4b: n = 0\*Articles were included for more

Figure 2. Results of literature search

than one KQ

## **Literature Synthesis**

## **Development of Evidence Tables and Data Abstraction Process**

The team jointly developed the evidence tables. We designed the tables to provide sufficient information to enable readers to understand the studies and to determine their quality; we gave particular emphasis to essential information related to our KQs. We based the format of our evidence tables on successful designs that we have used for prior systematic reviews.

We trained abstractors by having them abstract several articles into evidence tables and then reconvening as a group to discuss the utility of the table design. The abstractors repeated this process through several iterations until they decided that the tables included the appropriate categories for gathering the information contained in the articles.

Four members of the team (Jennifer Kraschnewksi, Brett Nishikawa, Laura Morgan, and Patricia Thieda) shared the task of initially entering information into the evidence tables. Authors

of individual sections reviewed the articles and edited all initial table entries for accuracy, completeness, and consistency. Abstractors reconciled all disagreements concerning the information reported in the evidence tables. The full research team met regularly during the article abstraction period and discussed global issues related to the data abstraction process.

The final evidence tables are presented in their entirety in Appendix C. Studies are presented in the evidence tables alphabetically by the last name of the first author. A list of abbreviations and acronyms used in the tables appears at the beginning of that appendix.

## **Quality Rating of Individual Studies**

Quality rating forms for RCTs have been validated and in use for several years; a similarly well-validated form for observational studies does not exist. RTI has been developing a form to rate observational studies. This form, which can be used to rate the quality of a variety of observational studies, was based on a review of more than 90 AHRQ systematic reviews that included observational studies; we supplemented this review with other key articles identifying domains and scales. We structured the resultant form largely on the basis of the domains and subdomains suggested by Deeks and colleagues; we then adapted it for use in this systematic review (Appendix B).

The form currently includes review of nine key domains for observational studies: background, sample selection, specification of exposure, specification of outcome, soundness of information, followup, analysis comparability, analysis of outcome, and interpretation. An additional domain for RCTs is the quality of randomization. We used these dimensions of quality to assess the overall quality of the study. We did not attempt to construct a quantitative scale for quality. Previous scales have been critiqued for their lack of inter-rater reliability. An additional concern is scales do not account for a single flaw that may substantially bias results, despite meeting standards for all other aspects of study quality. Each study was dually evaluated for quality; abstractors reconciled all disagreements.

## **Strength of Available Evidence**

We evaluated the strength of evidence based on the AHRQ Comparative Effectiveness Methods Guide. The strength of evidence for each outcome incorporates risk of bias, consistency, directness, precision, and the presence of other modifying factors. As described in Owens et al., the evaluation of risk of bias includes assessment of study design and aggregate quality of studies. We judged good quality studies with strong designs to result in evidence with low risk of bias. We graded evidence as consistent when effect sizes across studies were in the same direction and had a narrow range. When the evidence linked the interventions directly to health outcomes, we graded the evidence as being direct. We graded evidence as being precise when results had low degree of uncertainty. When considering the effect of confounders, we evaluated whether the degree of intensity of interventions in both arms could have explained the effects (or absence of effects); additionally we considered whether other sources of effect modification or confounding had been accounted for. We dually evaluated the overall strength of evidence for each outcome based on a qualitative assessment of strength of evidence for each

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<sup>§</sup> Appendixes cited in this report are available at <a href="http://www.ahrq.gov/downloads/pub/evidence/pdf/comhealthwork/comhwork.pdf">http://www.ahrq.gov/downloads/pub/evidence/pdf/comhealthwork/comhwork.pdf</a>

domain and reconciled all disagreements. The levels of strength of evidence are shown in Table 4.

Table 4. Strength of evidence grades and definitions

Grade	Definition
High	High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
Moderate	Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
Low	Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.
Insufficient	Evidence either is unavailable or does not permit estimation of an effect.

## **Applicability of the Evidence**

We evaluated the applicability of the evidence based on a qualitative assessment of the population, intensity, or quality of treatment, choice of the comparator, outcomes, and timing of followup. We based our parameters for evaluation on guidance provided by AHRQ's Comparative Effectiveness Methods Guide. Specifically, we consider whether enrolled populations differ from target populations and how this might affect risk of benefits or harms, whether studied interventions compare to those in routine use and how this might affect risk of benefits or harms, whether comparators reflect best alternative treatment and how this may influence treatment effect size, whether measured outcomes are known to reflect the most important clinical benefits and harms, and whether followup is sufficient to detect clinically important benefits.

## **External Peer Review**

AHRQ's Scientific Resource Center requested review of this report from a wide array of outside experts. We received three external reviews and revised the report as appropriate.

## **Chapter 3. Results**

This chapter presents the results of our evidence review for the following four key questions (KQs): KQ 1, interaction of CHWs with participants; KQ 2, outcomes of community health worker (CHW) interventions; KQ 3, cost-effectiveness of CHW interventions; and KQ 4, training of CHWs and the relationship between CHW training and patient health outcomes. We note that KQ 3, on cost-effectiveness of CHW outcomes, is derivative of KQ 2 and is limited to studies demonstrating effectiveness. As noted in Chapter 2, a total of 53 studies qualified for inclusion for KQ 1 and KQ 2, 6 for KQ 3, and 9 for KQ 4.

Appendix C-1\*\* provides the detailed evidence tables for KQs 1, 2, and 3. Appendixes C-2 and C-3 present individual quality ratings for randomized clinical trials (RCTs) and observational studies, respectively. Appendix C-3 provides detailed abstractions for KQ 4. All evidence tables are presented in alphabetical order by last name of the first author.

As noted in earlier chapters, an overall assessment of the effectiveness of CHW outcomes requires evaluation of sources of heterogeneity, including clinical context, intensity of interaction between CHWs and participants, and type of comparator. CHW interventions operate in a variety of clinical contexts; summarizing the effects of these interventions on varied outcomes requires an explicit consideration of the clinical context. For this reason, we have organized the results for KQs 1, 2, and 3 by the clinical context of the interventions identified. These are, specifically, health promotion and disease prevention, injury prevention, maternal and child health, cancer screening, and chronic disease management.

An additional source of heterogeneity is the degree of intensity of the intervention, which can vary by clinical context. We synthesize the evidence from KQ 1 to develop a measure of the intensity (low, moderate, or high) of the interaction between CHWs and participants, and we then include the measure in describing results for KQ 2 and KQ 3. We also record other sources of heterogeneity such as the type of comparator. Chapter 4 discusses the effectiveness of CHW interventions and the potential impact of sources of heterogeneity on effectiveness more fully.

This literature is characterized by several articles together constituting a single study. We refer to studies in the text and cite all relevant articles for each study; article and study counts, therefore, frequently do not match. Our summary tables below feature groups of studies addressing each outcome. Unless otherwise stated, these tables are organized alphabetically by the last name of the first author. The summary tables for KQ 2 and KQ 3 provide information to identify the study (author, and date of publication), study design, population and setting, sample size, study quality, intervention and comparators, and results.

# **KQ 1: Interaction of Community Health Workers and Participants**

KQ 1 focuses on how CHWs interact with participants, specifically the place of service, type of service, type of educational materials used, duration of interaction with participants, and length of contact. We categorize place of service as over the telephone or based in the clinic, the community, home, or workplace. Interventions often employed multiple settings to interact with

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<sup>\*\*</sup> Appendixes cited in this report are available at <a href="http://www.ahrq.gov/downloads/pub/evidence/pdf/comhealthwork/comhwork.pdf">http://www.ahrq.gov/downloads/pub/evidence/pdf/comhealthwork/comhwork.pdf</a>

participants. The type of services ranged from one-on-one interactions to group interactions. All CHW interventions included some element of education; we sought to understand the degree to which these materials were standardized or tailored for each participant. We identified three elements of duration of interaction: the number of sessions, time per session, and the length of time from the first interaction to the last interaction (length of contact). We report summary findings below, for each descriptor, of the interaction between CHWs and participants across all studies and clinical contexts. These characteristics vary greatly across CHW interventions, but a common element is the overall intensity of the intervention. Interventions of lower intensity will require fewer resources than interventions of moderate or high intensity. As a proxy measure of resource allocation, we employ characteristics of the CHW-participant intervention to develop a measure of intensity of interaction. As noted earlier, a key organizing principle for understanding the effectiveness of CHW interventions is clinical context; we conclude this section by describing characteristics of CHW-participant interactions and their intensity by clinical context. Summary tables describing the characteristics of CHWs are provided by clinical context; within each table, studies are presented in order of intensity and then in alphabetical order, by the last name of the first author.

# Overview of Interaction Between Community Health Workers and Participants

**Place of service.** CHWs interacted with participants over the telephone or provided services in one or more of four locations: home, community, clinic, or workplace. CHWs provided home, telephone, and clinic interventions on a one-on-one basis; community interventions were more likely to be oriented toward groups than to individuals. Thirty-two studies had at least one home visit but may have involved telephone and community components as well. <sup>15,17,18,23,59-102</sup>
Interventions in five studies occurred primarily by telephone. <sup>19-22,69,70,103-106</sup> In nine studies, interventions included at least one meeting in a community setting and were primarily group-oriented. <sup>27,59,60,107-115</sup> Interventions taking place in the community generally occurred in churches or in other neighborhood or community locations. <sup>27,102,109-114,116-122</sup> Eight studies involved community interventions but did not specify the location; <sup>27,109-115,118-120</sup> of these, only two were one-on-one interventions. <sup>118-121</sup> One intervention occurred in a neighborhood beauty salon, <sup>116</sup> and four occurred on the street or in shelters. <sup>117-122</sup> Five studies took place within clinics or health care settings. <sup>23,77,99,123-125</sup> One intervention occurred in the workplace. <sup>126</sup> We could not determine the place of service for one intervention. <sup>16,127</sup>

**Type of service.** The type of services varied greatly across included studies. CHWs provided a wide range of services including one-on-one counseling (face-to-face and by telephone), education, support, information on health and community resources, transportation, appointment reminders, and other forms of assistance. The type of service ranged from brief one-time interactions to intensive one-on-one interactions over a span of years. The minimal service provided was a brief, one-time interaction such as distributing condoms and providing prevention literature 117 or a single telephone call to promote cancer screening. At the other end of the spectrum, many interventions had multiple face-to-face counseling sessions, often in the home, to address specific needs.

**Type of educational materials used.** The least described characteristic of the interaction between CHWs and clients is the type of educational material used. As many as twenty-seven studies did not report any details on the type of educational materials utilized. <sup>16,19-23,67-74,78,79,83,85-</sup>

<sup>92,96,97,99,101,104-108,117,120-122,124,125,127</sup> Several studies did not describe educational materials per se but did report that they distributed "materials" as part of the intervention (e.g., safety glasses, materials to reduce exposure to asthma triggers, smoke detectors). The remainder provided minimal descriptions that ranged from the use of a postcard<sup>66</sup> to complex systems, including audio and written formats to appeal to the broadest range of subjects.<sup>63</sup>

**Duration of interaction (time per session and number of sessions).** The duration of interaction varied broadly overall. Interactions lasted from quite brief (5 minutes to an hour) one-time meetings to extensive multiple interactions totaling several hours in all.

**Length of contact.** The length of contact—that is, the length of time that CHWs were directly involved with participants (which may have differed from the length of the study, or the length of time between measurement of pre- and postintervention health outcomes)—was inadequately reported in many cases. Length of contact ranged from 1 day <sup>15,103,108,116,117</sup> to 2.5 years. <sup>98</sup>

## **Intensity of Interaction**

Based on the type of interaction, the duration of interaction (time per session, number of sessions, and length of interaction), and the tailoring of CHW interactions, we classified the intensity of an intervention into three categories: low, moderate, or high. Interactions that had at least four of six elements suggesting a higher intensity (one-on-one, face-to-face, an hour per session or more, 3 or more months' duration, three or more interactions, and tailored materials) were classified as high intensity. Interventions with two or three elements were classified as moderate intensity. Interventions with only one or none of the elements were classified as low intensity.

In making these classifications, we relied, whenever possible, on the protocol intentions rather than what actually occurred. When no information was available for the protocol, we relied on reported interactions in the field. When interactions in the field were also not reported, we assumed lower intensity for that aspect for the intervention. For instance, when studies did not report the time spent in each session, we assumed that the time per session did not exceed an hour on average. Similarly, if studies did not report specifically that the materials were tailored for each participant, we assumed that the interventions used generic materials for all participants.

Low-intensity interventions were generally one-time interactions, usually in a group setting. Moderate-intensity interventions occurred in a variety of settings but typically involved only one or two interactions with CHWs over shorter periods of time. High-intensity interventions included multiple interactions, face-to-face, for 3 months or more. Each category varies internally: for instance, within the high-intensity interventions, the number of interactions could vary from 3 to more than 20 in a year, depending on the nature of the intervention. Of the total of 53 studies, we classified 8 studies as low intensity, 19-22,59,60,103,104,107,108,113,117,126 18 as moderate intensity 106,125 15,23,63,66,69,70,99,101,102,105,109-112,114,116,118,119,122-124 and 27 as high intensity. 16-18,27,61,62,64,65,67,68,71-98,100,120,121,127,128

## **Community Health Worker-Participant Interaction by Clinical Context**

Community health worker-participant interactions for health promotion and disease prevention intervention. We included 11 studies on health promotion and disease prevention (Table 5). Six studies occurred in the home and by telephone;<sup>64-71</sup> one additional study was by telephone and mail.<sup>105</sup> Three studies were conducted in community settings—one in a

nonclinical site, <sup>118,119</sup> one in churches, <sup>107</sup> and one on community streets. <sup>117</sup> For one study, the place of service was not reported. <sup>16,127</sup> The majority of studies did not report the educational materials used; one of these studies provided condoms as part of the intervention. <sup>117</sup> Only four studies provided some description of the educational materials used during the intervention. <sup>64-66,117-119</sup>

Table 5. CHW-participant interactions for health promotion and disease prevention

Author, Date of Publication	Place of Service	Type of Service	Educational and Other Materials Provided	Number of Sessions, Time per Session, and Length of Contact with Participants	Intensity— Low, Moderate, High
Auslander et al., 2002 <sup>16</sup> Williams et al., 2001 <sup>127</sup>	NR	Counseling adults for diabetes prevention: group and individual sessions	NR	6 group sessions and 6 individual sessions weekly, 45-90 minutes per session, over 3 months	High
Barnes et al., 1999 <sup>68</sup>	Home and telephone	Information and assistance, NR referral, transportation to clinic if needed for childhood immunizations		Unspecified number of calls and visits, over 6 months (time per session NR)	High
Barnes-Boyd et al., 2001 <sup>71</sup> Nacion et al., 2000 <sup>72</sup>	Home	Family-focused care plan; support, model problem- solving skills, promote self- development of mother, provide instruction in infant care; transportation; find community resources for childhood immunizations	NR	12 monthly visits, over 1 year (time per visit NR)	High
Conway et al., 2004 <sup>67</sup>	Home and telephone	Problem-solving techniques to reduce environmental tobacco smoke exposure to children	NR	6 home and telephone visits over 4 months (time per session NR)	High
Elder et al., 2005 <sup>64</sup> Elder et al., 2006 <sup>65</sup>	Home and/or telephone	Home visits or phone calls for Latinas to make healthful dietary behavior changes	Tailored newsletters with homework assignments	12 home visits or telephone calls over a 12-week period, 12 weekly tailored newsletters (time per session NR)	High
Becker et al., 2005 <sup>118</sup> Cene et al., 2008 <sup>119</sup>	Community nonclinical site	Counseling for adults with risk factors for cardiovascular disease	Written, culturally sensitive	Multiple (number unspecified) 30- minute sessions over 1-year period	Moderate
Hunter et al., 2004 <sup>66</sup>	Home	Facilitated appointment scheduling for annual preventive exams for Latinas	Postcard	1 initial home visit and 1 final followup visit 8 weeks after postcard mailing to begin intervention (time per session NR)	Moderate

NR, not reported.

Table 5. CHW-participant interactions for health promotion and disease prevention (continued)

Author, Date of Publication	Place of Service	Type of Service	Educational and Other Materials Provided	Number of Sessions, Time per Session, and Length of Contact with Participants	Intensity— Low, Moderate, High
Krieger et al., 1999 <sup>105</sup>	Telephone and mail	Referral to medical care; appointment scheduling assistance; appointment reminder letter; followup to determine whether the appointment was kept; a new appointment for each missed appointment (up to 3); and assistance in reducing barriers to care through referral to community transportation, child care, or other services	NR	Various, brief interactions over 3 months (time per session NR)	Moderate
Rask et al., 2001 <sup>69</sup> LeBaron et al., 2004 <sup>70</sup>	Home and telephone	Appointment reminder, assistance in overcoming barriers to appointment for pediatric immunizations if needed	NR	At least 1 telephone call, followed by repeat calls and home visit if no telephone contact, over 15 months or less (time per interaction NR)	Moderate
Campbell et al., 2004 <sup>107</sup>	Community – churches	Provide information through existing networks; organize and conduct at least three church-wide activities focused on spreading information for colorectal cancer prevention	NR	3 church- based activities during 12 months (time per session NR)	Low
Wendell et al., 2003 <sup>117</sup>	Community — streets	Interview on sexual disease risk factors and prevention in at-risk adults; survey interaction	Condoms	Brief one-time interaction handing out condoms and prevention literature (time of interaction NR)	Low

Five studies were of high intensity,  $^{16,64,65,67,68,71,127}$  four of moderate intensity,  $^{66,69,70,105,118,119}$  and two of low intensity.  $^{107,117}$ 

Community health worker-participant interactions for injury prevention interventions. We included three studies in injury prevention (Table 6). Two took place primarily in the home and one on farms. Two studies involved the distribution of materials to improve safety; one study did not report the educational materials used. Two studies were of moderate intensity; one was of low intensity.

Table 6. CHW-participant interactions for injury prevention

Author, Date of Publication	Place of Service	Type of Service	Educational and Other Materials Provided	Number of Sessions, Time per Session, and Length of Contact with Participants	Intensity— Low, Moderate, High
Gielen et al., 2002 <sup>101</sup>	Home	Assessed home for injury hazards such as falls, burns, and poisonings; made recommendations about appropriate safety products and practices; referred families to the Child Safety Center	NR	1 home-safety visit sometime between the patient's 6- and 9- month well-infant visits (time of session NR)	Moderate
Schwarz et al., 1993 <sup>102</sup>	Home and community	Recruitment of volunteer representative from each block to identify neighborhood resources, facilitate contacts with residents, and reinforce safety messages through monthly block meetings. Home safety inspections in the presence of residents consisting of provision of safety materials; instruction on correcting safety hazards, simple household repairs, use of ipecac and bathwater thermometer, safety behaviors; identification of community resources	smoke detectors, batteries, bathwater thermometer, nightlight, ipecac, sticker for telephone with emergency numbers, and a poster with	1 home visit and monthly block meetings over 18-month period (time per session NR)	Moderate
Forst et al., 2004 <sup>126</sup>	Workplace (farms)	Distribution of eyewear, training on use and on eye health and safety	Reference manual on agricultural eye illness and injury; enlarged photos and fotonovelas; tool kit to demonstrate eye injuries and hazards; protective eyewear	At least 1 individual and at least 1 group session during farming season (time per session NR)	Low

NR, not reported.

**Community health worker-participant interactions for maternal and child health interventions.** Overall we included 15 studies in maternal and child health (Table 7). All of the studies occurred primarily in the home, but 1 had opportunities for interactions in health care clinics. To Only 4 studies provided some description of educational materials used during the intervention; the remaining 11 did not report any details. All the maternal and child health studies were of high intensity.

Table 7. CHW-participant interactions for maternal and child well-being

Author, Date of Publication	Place of Service	Type of Service	Educational and Other Materials Provided	Number of Sessions, Time per Session, and Length of Contact with Participants	Intensity— Low, Moderate, High
Barnes- Boyd et al., 2001 <sup>71</sup>	Home	Family-focused care plan; support, model problem- solving skills, promote self- development of mother, provide instruction in infant care; transportation; find community resources	NR	Monthly visits over 12 months (time per session NR)	High
Barnes et al., 1999 <sup>68</sup>	Home and telephone	Information and assistance, referral, transportation to clinic if needed for childhood immunizations	NR	Unspecified number of calls and visits over 6 months (time per session NR)	High
Barth et al., 1988 <sup>73</sup>	Home			hours per session, over 6	High
Barth et al.,1991 <sup>74</sup>	Home	Task-directed approach to reduce the risk of parenting problems	NR	On average 11 visits (range 5-20) over 6 months (time per session not reported but ≈ 4 hours implied)	High
Black et al., 1995 <sup>75</sup> Hutcheson et al., 1997 <sup>76</sup>	Home	Develop individualized family service plan with specific goals; support mother's needs; promote maternal-child relationship	Handouts, developmental assessment toys	Weekly visits (≈ 1 hour per visit) for 1 year	High
Caulfield et al., 1998 <sup>77</sup>	Community (WIC clinics), home or telephone	ommuni- (WIC participants' attitudes toward incs), infant feeding, correcting me or misconceptions, group		3 or more meetings during pregnancy (from 24 weeks of gestation) and then weekly up to 16 weeks postpartum if they continued breast feeding (time per meeting NR)	High
Conway et al., 2004 <sup>67</sup>	Home and telephone	Problem-solving techniques to reduce environmental tobacco smoke exposure to children	NR	6 home and telephone visits over 4 months (time per session NR)	High
Duggan et al., 1999 <sup>78</sup> Duggan et al., 2000 <sup>128</sup>	Home	Building relationships with families; active assistance to address existing crises; model problem-solving skills and effective parent-child interaction; link families with needed resources; provide parenting education; ensuring presence of medical home for children	NR	≈22 visits (1 hour each) over 2 years	High

 $<sup>\</sup>approx$ , approximately; NR, not reported; WIC, Special Supplemental Nutrition Program for Women, Infants, and Children.

Table 7. CHW-participant interactions for maternal and child well-being (continued)

Author, Date of Publication	Place of Service	Type of Service	Educational and Other Materials Provided	Number of Sessions, Time per Session, and Length of Contact with Participants	Intensity— Low, Moderate, High
Graham et al., 1992 <sup>79</sup>	Home	Psychosocial support; educate family about pregnancy; advocate; link to community services for stress reduction; information on health risks during pregnancy and on nutrition	NR	4 visits (1 hour each) at 2-4 week intervals for 2-5 months (until birth of child)	High
Nacion et al., 2000 <sup>72</sup>	Home	Intensive home visits for assessment, problem-solving, emotional support, and information	NR	NR	High
Olds et al., 2002 <sup>80</sup> Korfmacher et al., 1999 <sup>81</sup> Olds et al., 2004 <sup>82</sup>	Home	Intensive home visitation: promoting healthy behaviors, competent child care, pregnancy planning, education, employment, linking to social and health services; promoting healthy family/friend relationships	Visit-specific protocol, adapted to individual needs of mother	Every other week (except for weekly visits during the first 4 weeks after enrollment and the first 6 weeks after delivery) through the child's 21st month, followed by monthly visits during the final 3 months, ≈ 75 minutes per session	High
St. James et al., 1999 <sup>83</sup>	NR (most likely home, based on activities like cooking)	Counseling, meal planning, pregnancy education, shopping, discuss medical recommendations	NR	≈20 sessions of 2 hours each (weekly in beginning then less frequently) throughout pregnancy	High
Schuler et al., 2000 <sup>84</sup>	Home	Teaching and counseling on infant development, health education, mother-infant interaction	Activity sheets	Weekly visits (mean duration 30.1 minutes per visit) for 6 months	High
Silver et al., 1997 <sup>85</sup>	Home	Counseling; share information on child health and behavior; link families with existing community resources	NR	6 meetings (1 hour each) with at least biweekly telephone calls and 3 group social activities over 12 months	High
Tessaro et al., 1997 <sup>86</sup> Navaie- Waliser et al., 2000 <sup>87</sup>	Home	Counseling, assistance in applying for government benefits, housing, employment, education, general advocacy for families	NR	One visit per month (more if needed) for approximately 14 months (time per visit NR)	High

### Community health worker-participant interaction for cancer screening interventions.

Overall 15 studies concerned cancer screening: 7 took place primarily in the home (visits or telephone) and 8 in community locations 59,60,107-113,116,125 (Table 8).

Nine studies described some of the materials used during the intervention; 15,17,18,59-63,103,109-113 six did not report the educational materials used. 19-22,104,106-108,116,125 We found two studies of high intensity, 17,18,61,62 seven of moderate intensity. 15,63,106,109-112,116,125 and six studies of low intensity. 19-22,59,60,103,104,107,108,113

Table 8. CHW-participant interactions for cancer screening

Author, Date of Publication	Place of Service	Type of Service	Educational and Other Materials Provided	Number of Sessions, Time per Session, and Length of Contact with Participants	Intensity— Low, Moderate, High
Paskett et al., 2006 <sup>17</sup> Katz et al., 2007 <sup>18</sup>	Home and telephone	Education and barrier- specific counseling to promote screening; scheduling assistance	Individualized health education program	2 visits at 45-60 minutes and 30-45 minutes, 2 intervening telephone calls, and a final visit (time of final visit NR) over 9 to 12 months	High
Sung et al., 1997 <sup>61</sup> Sung et al., 1992 <sup>62</sup>	Home	Education on breast and cervical cancer, breast self-exam, educational materials on screening, facilitation to address logistical barriers to screening	Video of Pap and breast exam; printed materials	3 visits (months 1, 2, 4) over 4- month period, visits 1 and 2 for 1.5 hours each, time for visit 3 NR	High
Dignan et al., 2005 <sup>15</sup>	Home	Barrier-specific counseling to promote screening	Tailored brochure	One-time session of 20-90 minutes	Moderate
Hiatt et al., 1995 <sup>125</sup>	Community (various locations)	One-on-one support; education: contact with clients was ongoing and personal	NR	Unspecified # of interactions (time per interaction NR) over 2 years	Moderate
Jandorf et al., 2005 <sup>106</sup>	Telephone	One-on-one support and NR education on screening techniques and barriers to screening; assistance scheduling procedures		At least 3 telephone calls (time per call NR) over 6 months	Moderate
Mock et al., 2007 <sup>109</sup>	Community	2 small group gatherings and individual direct contacts to help access medical services and schedule appointments	Language- specific flip charts and booklets	2 sessions of 90 or 120 minutes each over 3 to 4 months	Moderate

NR, not reported.

Table 8. CHW-participant interactions for cancer screening (continued)

Author, Date of Publication	Place of Service	Type of Service	Educational and Other Materials Provided	Number of Sessions, Time per Session, and Length of Contact with Participants	Intensity— Low, Moderate, High
Navarro et al., 1995, 1998, 2000 <sup>110-112</sup>	Community	12 weekly small group educational sessions	Pamphlets, worksheets, posters developed for project and pamphlets from other organizations	12 sessions of 90 minutes each over 3 months	Moderate
Taylor, et al., 2002 <sup>63</sup>	Home and telephone	Tailored responses to individual barriers to cervical cancer screening, clinic referral and scheduling assistance, translation services, transportation assistance	Video, motivational pamphlet, educational brochure, fact sheet, tailored counseling	One-time visit with followup telephone call (time per interaction NR)	Moderate
Wilson et al., 2008 <sup>116</sup>	Community— beauty salon	Education, counseling, and information on location of screening services during salon appointment	Written materials (not described)	1 visit (time of session NR)	Moderate
Andersen et al., 2000 <sup>103</sup>	Telephone	Barrier-specific telephone counseling to promote screening	Standardized script	1 interaction (time of interaction NR)	Low
Campbell et al., 2004 <sup>107</sup>	Community— churches	Provide information through existing networks; organize and conduct at least 3 church-wide activities focused on spreading information	NR	3 church-based activities during 12 months (time per session NR)	Low
Derose et al. 2000 <sup>19</sup> Duan et al., 2000 <sup>20</sup> Derose et al. 2000 <sup>21</sup> Fox et al., 1998 <sup>104</sup> Stockdale et al., 2000 <sup>22</sup>	•	Barrier-specific telephone counseling to promote screening, discussion of resources for free- and reduced-cost mammograms, translation services, transportation, and childcare assistance	NR	2 telephone calls (1 per year over 2 years), time per session 7-11 minutes on average	Low
Earp et al., 2002 <sup>113</sup>	Community	Presentations to community groups and events; one-on-one conversations; use of informational/ motivational materials	Brochures, posters, church fans, holiday cards	2 community activities per month; one-on- one conversations once a week over a 24-month period, time per session NR	Low

Table 8. CHW-participant interactions for cancer screening (continued)

Author, Date of Publication	Place of Service	Type of Service	Educational and Other Materials Provided	Number of Sessions, Time per Session, and Length of Contact with Participants	Intensity— Low, Moderate, High
Erwin et al., 1997 <sup>108</sup>	Church	Motivational speeches based on cancer survivor experience of CHWs, breast self-exam lessons using a breast model, discussion of resources for free- and reduced-cost mammograms	NR	1 presentation, time NR	Low
Sauaia et al., 2007 <sup>59</sup> Welsh et al., 2005 <sup>60</sup>	Community (church) and home	Personal education sessions to deliver health promotion messages	Newsletter	At least bimonthly meetings (time per meeting NR) over 5 years	Low

Community health worker–participant interactions for chronic disease management interventions. Overall, 13 studies focused on chronic disease management (Table 9). Seven took place primarily in the home, <sup>23,88-100</sup> 2 in health care settings <sup>123,124</sup> and 4 in community locations. <sup>27,114,120-122</sup> Eight described some of the materials used during the intervention; <sup>27,93-98,100,114,123</sup> five did not report the educational materials used. <sup>23,88-92,99,120-122,124</sup> Two studies provided materials to households to reduce exposure to asthma triggers (bedding, vacuum cleaners, etc.). <sup>96,97,100</sup> Eight were of high intensity <sup>27,88-98,100,120,121</sup> and five studies were of moderate intensity. <sup>23,99,114,122-124</sup>

Table 9. CHW-participant interactions for chronic disease management

Author, Date of Publication	Place of Service	Type of Service	Educational and Other Materials Provided	Number of Sessions, Time per Session, and Length of Contact with Participants	Intensity— Low, Moderate, High
Batts et al., 2001 <sup>88</sup> Gary et al., 2003 <sup>89</sup> Gary et al., 2005 <sup>90</sup> Gary et al., 2000 <sup>91</sup> Vetter et al., 2004 <sup>92</sup>	Home and telephone	Offer to schedule appointments and visits, provide education, mobilize social support for adults with diabetes mellitus	NR	3 visits (45-60 minutes each) per year over 2 years (and additional contacts as needed)	High
Beckham et al., 2008 <sup>93</sup>	Home or clinic (site chosen by participant; majority preferred home)	Diabetes self- management education; referrals to registered dieticians, healing center	Visual aids (majority of participants illiterate)	Up to 15 home visits over 1 year, lasting 1-1.5 hours per visit	High

NR, not reported.

Table 9. CHW-participant interactions for chronic disease management (continued)

Author, Date of Publication	Place of Service	Type of Service	Educational and Other Materials Provided	Number of Sessions, Time per Session, and Length of Contact with Participants	Intensity— Low, Moderate, High
Frate et al., 1985 <sup>94</sup> Frate et al.,1983 <sup>95</sup>	Home or community	Monitor blood pressure; provide health education and support; self- management of hypertension for adults	Pamphlets, scale, low-salt cookbook, AHA and NHLBI pamphlets	Monthly visits over 18 months (time per session NR)	High
Krieger et al., 2005 <sup>96</sup> Krieger et al., 2002 <sup>97</sup>	Home	Environmental assessment; individualized action plan; education and social support; deliver materials to reduce trigger exposure for asthma	Materials to reduce asthma-trigger exposure	4 to 9 visits over 12 months (time per session NR)	High
Levine et al., 2003 <sup>98</sup>	Home	Education, counseling, referrals, providing information on access to health care, answered questions for adults with hypertension	Wallet-sized blood pressure tracking card, educational pamphlet	6 visits over 2.5 years (time per visit NR)	High
Lujan et al., 2007 <sup>27</sup>	Community (classroom), telephone, and mail	Deliver participative classes for adults with diabetes mellitus, answered questions, reinforce education, promote behavior change, send biweekly postcards	Audiovisual teaching aids (flip charts, food models, food labels) and handouts	8 weekly 2-hour classes + biweekly telephone calls for 8 weeks followed by biweekly postcards for 16 weeks  24 weeks' total duration of interaction with participants	High
Morse et al., 1997 <sup>120</sup> Wolfe et al., 1997 <sup>121</sup>	Community— unspecified locations (homeless population)	Assistance with activities of daily living and leisure activities for homeless people with psychiatric diseases	NR	Face-to-face meetings (time per meeting and number NR) over 18 months	High
Parker et al., 2008 <sup>100</sup>	Home	Environmental assessment; asthma action plan based on allergy tests; education and social support; mattress covers, pillows, vacuum, cleaning supplies; counseling on environmental tobacco smoke; integrated pest management services	Asthma booklet; materials to reduce asthma trigger exposure	At least 9 visits over 12 months (time per session NR)	High

Table 9. CHW-participant interactions for chronic disease management (continued)

Author, Date of Publication	Place of Service	Type of Service	Educational and Other Materials Provided	Number of Sessions, Time per Session, and Length of Contact with Participants	Intensity— Low, Moderate, High
Bone et al., 1989 <sup>123</sup>	Emergency room and telephone	Measured pulse and blood pressure (in emergency room session); provided educational counseling; identified barriers related to referrals, appointment keeping, and adherence to the treatment plan for adults with hypertension	Wallet-sized BP record card	1 face-to-face session (≈20 minutes) and at least 1 pre-followup appointment reminder telephone call (5-10 minutes) (time period over which this occurred NR)	Moderate
Corkery et al., 1997 <sup>124</sup>	Hospital clinic	Liaison between patients and health care providers for adults with diabetes mellitus; attended clinic sessions with patient; provided translation, appointment reminders; rescheduled missed appointments; reinforced self-care instructions	NR	Varied (mean = 3.4 months, range: 0.9-5.4), time per session equal to clinic visit duration	Moderate
Morisky et al., 2002 <sup>23</sup> Ward et al., 2000 <sup>99</sup>	Home and/or clinic	Counseling regarding lifestyle, medication-taking, and appointment-keeping; tailored to patient need for adults with hypertension	NR	Number of visits, time per session, time period over which interactions occurred NR	Moderate
Pilote et al., 1996 <sup>122</sup>	Community— shelters (homeless population)	Transported participants to clinic appointment for homeless people with tuberculosis; assisted with paperwork and doctor's recommendations	None	Met participants and went to clinic within a 3 week period (time per session NR)	Moderate
Von Korff et al., 1998 <sup>114</sup>	Community— unspecified locations	Led classes on self- managing back pain, discussed strategies and barriers to achieve goals for managing pain		4, 2-hour classes held once a week for 1 month	Moderate

# **KQ 2: Outcomes of Community Health Worker Interventions**

KQ 2 asks about the impact of CHWs on outcomes, particularly knowledge, behavior, satisfaction, health outcomes, and health care utilization. As noted earlier, the effect of CHW interventions will vary by clinical context (e.g., diagnosis or health concern), so as with KQ 1, we present results by clinical context for each of the outcomes described above. The areas of

clinical concern are health promotion and disease prevention, injury prevention, maternal and child health, cancer screening, and chronic disease management.

We also assessed each study for quality; in general, we present results for higher quality studies first, followed by findings for moderate and then lower quality studies. We also give the level of intensity of the interaction between CHWs and participants and the type of comparator for each study, using the three intensity categories introduced in KQ 1. As noted there, the intensity of the interaction between CHWs and participants varied by clinical context. For example, maternal and child health interventions were solely high intensity whereas cancer screening studies ranged across high, medium, and low intensity. Because of this variation for cancer screening, we discuss those studies categorized first by intensity, then by quality. For all other clinical contexts, we did not find meaningful patterns by intensity of intervention, either because of lack of variation in intensity, or because the number of studies was insufficient to draw conclusions.

Variation in aims and clinical contexts of the studies, populations and settings, measures of health outcomes, and health care utilization information precluded quantitative synthesis of the results of studies. As with other questions, the number of articles exceeds the number of distinct studies. In all cases, tables list studies by quality (good, fair, then poor) and then alphabetically by last name of the first author of the article(s).

### **Outcomes for Health Promotion and Disease Prevention**

Health promotion and disease prevention: pediatric immunizations. *Study characteristics*. Two RCTs, one good<sup>69,70</sup> and one fair quality,<sup>68</sup> and one poor-quality prospective cohort study (REACH-Futures<sup>71,72</sup>) examined outcomes of CHW interventions to improve pediatric immunization rates in inner cities (Table 10). The RCTs used moderate-intensity interventions and the cohort study used a high-intensity intervention.

Both RCTs used CHWs to provide reminder telephone calls for upcoming clinic appointments. The good-quality RCT, targeting children < 12 months of age in a county public health clinic in metropolitan Atlanta, had CHWs make home visits only if a child remained behind on his or her immunization schedule. Additionally, this study compared four groups of children receiving: (1) automated telephone call reminders, (2) CHW outreach, (3) a combination of a CHW and automated telephone call reminders, and (4) a control group defined by normal clinic procedure. Outcomes were assessed after 22 months.

The fair-quality trial, targeting low-income children in Manhattan, also used CHWs to provide basic immunization education and referral, in addition to assisting in obtaining immunization services through a combination of telephone and home visits. <sup>68</sup> It compared outcomes after 6 months for children receiving the CHW intervention with those for a control group comprising parents who were informed of their child's immunization status at enrollment and instructed to reschedule the missed appointment. <sup>68</sup>

Table 10. CHWs and health promotion and disease prevention: pediatric immunization interventions

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Rask et al.,, 2001; <sup>69</sup> LeBaron et al., 2004 <sup>70</sup>	Moderate	G1: Autodial – automated telephone call delivered recorded message from health department medical staff; if no number or	Vaccine series completed per immunization registry after 22 months:
RCT		nonworking – then postcard to remind	No statistical difference
Pediatric Immunizations		families 7 calendar days before child was due to be immunized	between CHW and control groups
Children <12 months in a county public health clinic in metropolitan Atlanta, Georgia		G2: Outreach – Following standardized protocol, outreach worker contacted patient within 1 week and made reminder call before appointment; if child still not up to date, monthly home visits attempted	
N: 3,050		G3: Combination of G1 and G2	
Good		G4: Normal clinic procedure (control)	
Barnes et al., 1999 <sup>68</sup>	Moderate	G1: Basic immunization education and referral. During subsequent contacts	Up-to-date on immunizations after 6
RCT		(home visits or telephone calls) throughout the remainder of followup,	months:
Pediatric Immunizations		families were reminded of upcoming vaccinations and were recontacted to	G1: 75% G2: 54% ( <i>P</i> = 0.03)
Low-income children in Manhattan, New York		ensure that requisite vaccines were received. Contact with the clinic or escort	Late for immunization:
N: 434		to appointments provided if a family required support or assistance to obtain immunization services.	G1: 18% G2: 38% ( <i>P</i> < 0.05)
Fair		G2: Informed of their child's immunization status at the enrollment visit by the contro group interviewer and were instructed to reschedule the missed appointment.	
Barnes-Boyd et al., 2001 <sup>7</sup>	<sup>1</sup> High	G1: Monthly home visits over 1 year; visits at prenatal, 1, 6, and 12 months	Percent fully immunized at 12 months:
Prospective Cohort		teamed with a nurse.	G1: 77%
Pediatric Immunizations		G2: Historic controls with nurse home visits.	G2: 63% ( <i>P</i> <0.001)
Low-income inner-city African-American women and infants in Chicago, Illinois			
N: 1,922			
Poor			

CHW, community health worker; G, group; N, number; RCT, randomized controlled trial.

REACH-Futures, a prospective cohort study, compared a group receiving a high-intensity intervention of CHW and nurse visits with historic controls of nurse-only home visits. <sup>71,72</sup>

Monthly home visits started prenatally and ended at 1 year. <sup>71,72</sup> We rated this study poor because of high potential for secular trends, given the time difference between the two groups, and for other confounding problems. <sup>71,72</sup>

Overview of results. These three studies<sup>68-72</sup> evaluated the impact of CHWs on vaccine series completion rates and showed different CHW effectiveness. The good-quality study found no difference between groups receiving the CHW intervention and the control group.<sup>69,70</sup> In contrast, the fair-quality study demonstrated that children in the CHW group were more up-to-date and less likely to be late for their immunizations than the controls.<sup>68</sup> The control group for this study received more intervention directed at improving immunization rates, which would diminish the apparent effectiveness of the CHW. This study was more intensive than either of the other two projects (regular home visits or telephone calls over 6 months to ensure that requisite vaccines were received); this factor may have produced the difference in effectiveness between studies. REACH-Futures<sup>71,72</sup> also found that the CHW-intervention group had a higher proportion of fully immunized participants at 12 months than did the historic controls who had received a nurse-only home visit.

*Knowledge*. No study reported outcomes for improved knowledge of pediatric immunization. *Behavior*. No study reported outcomes for behavior changes.

Satisfaction. No study reported outcomes for satisfaction.

Health outcomes. All three studies evaluated immunization rates. The good-quality trial evaluated vaccine series completion rate from an immunization registry and found no difference between the CHW and control groups. The fair-quality trial found that children in the CHW arm were more up-to-date on immunizations than in the control arm (75 percent versus 54 percent, P = 0.03) and that fewer children were late for immunizations (18 percent versus 38 percent, P < 0.5). The poor-quality study evaluated vaccine series completion rates at 12 months and found that a higher proportion of children receiving the CHW and nurse home visits were up-to-date than historical controls (P < 0.001). The fair-quality trial found that a higher proportion of children receiving the CHW and nurse home visits were up-to-date than historical controls (P < 0.001).

Health care utilization. No study reported outcomes for health care utilization.

**Health promotion and disease prevention: health promotion – Latina health.** *Study characteristics.* Two RCTs, one fair<sup>66</sup> and one poor quality,<sup>64,65</sup> examined outcomes of CHW interventions in comparison with mailings for health promotion in Latinas (Table 11). The fair-quality study used a moderate-intensity CHW intervention in uninsured Hispanic women age 40 years and older living at the US-Mexico border (Agua Prieta, Sonora, Mexico, and Douglas, Arizona, United States) with the aim of increasing return to clinic for an annual preventive examination. <sup>66</sup> It compared a group receiving CHW home visits in addition to reminder postcards with a group getting reminder postcards alone.

The poor-quality study, Secretos de la Buena Vida, used a high-intensity CHW model in the same target population living in San Diego County, California. 64,65 It evaluated the effectiveness of weekly CHW home visits and telephone calls in addition to tailored print materials against that of tailored materials alone or off-the-shelf materials for changing dietary behavior. We rated this a poor-quality study because of a high potential for selection bias, measurement bias, and confounding. 64,65

Table 11. CHWs and health promotion and disease prevention: Latina health promotion interventions

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Hunter et al., 2004 <sup>66</sup> RCT  Annual preventive exams  Uninsured Hispanic women, aged 40 and older, living at the US-Mexico border  N: 103	Moderate	G1: Received postcards in the mail 2 weeks before the month their annual exams were due, printed in language used to complete original questionnaire  G2: Received G1 intervention and were visited by a promotora 2 weeks after the postcard had been mailed. Promotora facilitated appointment scheduling and contacted them to facilitate rescheduling if appointment was missed.	Return to clinic for a second comprehensive annual exam:  G1: 48% (n = 24) G2: 65% (n = 33) RR, 1.35; 95% CI, 0.95-1.92
Fair			
Elder et al., 2006; <sup>65</sup> Elder et al., 2005 <sup>64</sup>	High	G1: CHW home visits and/or telephone calls + tailored print materials	Total fat gm, total fiber gm (Nutrition Data System 24-hour dietary recall interview) (validated):
RCT: Secretos de La Buena Vida		G2: 12 weekly tailored newsletters and homework G3: 12 weekly off-the-shelf dietary	No significant difference between groups at 6 and 12 months postintervention
Dietary behavior, changes		printed material	
Latinas in San Diego County, California			
N: 357			
Poor			

CHW, community health worker; CI, confidence interval; G, group; N, number; RCT, randomized controlled trial; RR, risk ratio.

Overview of results. The fair study found that a moderate-intensity CHW intervention was more effective than a reminder postcard in increasing preventive exam appointments.<sup>66</sup> The poor-quality study demonstrated that a high-intensity CHW intervention group was different from those receiving weekly tailored dietary printed material in terms of dietary intake immediately post-intervention. This difference was no longer apparent after 6 months, although all three groups improved.<sup>64,65</sup>

*Knowledge*. Neither study reported outcomes for improved knowledge of health promotion. *Behavior*. The Secretos de la Buena Vida project examined behavioral changes. <sup>64,65</sup> The CHW arm and the tailored print arm did not differ significantly at 6 and 12 months postintervention in dietary intake of fat or fiber, based on a validated measure for 24-hour diet recall.

Satisfaction. Neither study reported outcomes for satisfaction.

*Health outcomes.* Neither study reported outcomes for improved health.

*Health care utilization*. The fair-quality, moderate-intensity CHW study reported on the percentage of women returning to clinic for a second annual preventive examination. <sup>66</sup> The CHW arm had a higher percentage of women returning than the postcard-only arm (65 percent versus 48 percent; RR, 1.35; 95percent CI, 0.95-1.92), but the difference was not statistically significant.

**Health promotion and disease prevention: disease prevention.** *Study characteristics.* Six studies, five RCTs<sup>16,67,105,107,118,119,127</sup> and one prospective cohort study, <sup>117</sup> examined outcomes of CHW interventions for disease prevention in underserved populations throughout the United States (Table 12). Two studies were both high intensity and fair quality; <sup>16,67,127</sup> two studies were moderate intensity, one fair <sup>105</sup> and one poor quality; <sup>118,119</sup> and two studies were low intensity, one fair <sup>117</sup> and one poor quality. <sup>107</sup> Studies focused on a broad range of disorders, including cardiovascular disease prevention, <sup>105,118,119</sup> diabetes prevention, <sup>16,127</sup> HIV prevention, <sup>117</sup> colorectal cancer prevention, <sup>107</sup> and second-hand smoke exposure. <sup>67</sup> Of the five RCTs, three were of fair quality <sup>16,67,105,127</sup> and two were poor. <sup>107,118,119</sup>

The Missouri study was a fair-quality RCT evaluating a high-intensity CHW intervention focused on diabetes prevention in a low-income, African-American female population. <sup>16,127</sup> This study compared 3 months of weekly sessions, alternating between group and individual sessions, targeting stages of change to tailor dietary patterns, with a control group that received a book to read. <sup>16,127</sup> The San Diego study was a fair-quality RCT evaluating a high-intensity CHW intervention focused on decreasing secondary tobacco smoke exposure in Latino neighborhoods in San Diego County, California. <sup>67</sup> The intervention consisted of six home and/or telephone visits by CHWs over 4 months using culturally tailored behavioral problem-solving techniques to reduce secondary tobacco smoke exposure; controls received no intervention. <sup>67</sup> The Seattle, Washington, study was a fair-quality RCT evaluating moderate-intensity CHW assistance with medical followup against verbal advice to see a medical provider in low-income neighborhood participants who were found to have elevated blood pressure. <sup>105</sup>

The sole prospective cohort study, rated fair quality, evaluated the effectiveness of a low-intensity CHW intervention in HIV prevention by street outreach to at-risk community members in Louisiana compared with a control group in a neighborhood receiving no intervention. 117

The poor-quality Baltimore, Maryland, trial evaluated a moderate-intensity intervention consisting of a nurse practitioner and CHW team at a nonclinical site with exercise equipment; CHWs provided dietary, smoking cessation, and exercise counseling. This strategy was compared with "enhanced" primary care, in which the same risk-specific materials and information on local programs were given to the intervention group and results and recommendations were provided to the patients' primary care physicians. We rated it poor because of a high potential for measurement bias. The WATCH trial was a poor-quality RCT of low intensity conducted in rural, predominantly African-American churches in North Carolina. This study had four arms: (1) control churches offered a health education session and speakers not related to study objectives; (2) CHW intervention, consisting of organization and presentation of at least three church-wide activities on educating and enhancing support for healthy lifestyle and colorectal cancer screening; (3) four personalized computer-tailored newsletters and four targeted videotapes focused on healthy lifestyle and colorectal screening mailed bimonthly to participants' homes; and (4) both the CHW and the videotape components. The provided results are provided to the patients of the church and the videotape components.

Overview of results. These six disease prevention studies reported on outcomes of knowledge, behavior, health outcomes, and health care utilization. Overall, four studies found that a CHW intervention was more effective in achieving outcomes than the respective control group. <sup>16,105,117-119,127</sup> Two fair-quality studies (the Missouri trial <sup>16,127</sup> and the prospective cohort study <sup>117</sup>) reported improved knowledge of the respective diseases in the CHW intervention as compared to respective controls. Two fair-quality studies (the Missouri trial <sup>16,127</sup> and the prospective cohort study <sup>117</sup>) and one poor-quality study (the Baltimore trial <sup>118,119</sup>) demonstrated that moderate- and low-intensity CHW interventions were more effective than controls in changing health behaviors.

Table 12. CHWs and health promotion and disease prevention: disease prevention interventions

Author, Year Study Design Population Setting Sample Size	Intensity of CHW		Passita
Quality Auslander et al.,	Intervention High	Study Groups G1: 6 group sessions (approximately	Results Food Frequency Questionnaire –
2002; <sup>16</sup> Williams et al.,	riigii	6 to 8 participants per group) and 6 individual sessions targeting stages of	Validated:
2001 <sup>127</sup>		change to tailor, dietary pattern with a	
RCT		peer educator, meeting weekly over a 3-month period	by percentage of calories from total fat (baseline/6 months):
Diabetes		G2: A book (control)	G2: 36.0/34.5
prevention			G1: 35.9/32.3 ( <i>P</i> < 0.05)
Low-income African-American women in a large			BMI: No significant difference between groups
city (unspecified) in Missouri			Knowledge of Label Reading Questionnaire (unvalidated)
N: 294			baseline/6 months: G2: 5.4/5.7
Fair			G1: 5.5/6.3 ( <i>P</i> > 0.0001)
Conway, 2004 <sup>67</sup>	High	G1: Culturally relevant home and	RIA of child's hair for nicotine and
RCT	•	telephone visits on problem-solving techniques to reduce ETS exposure	cotinine (validated):
Cocondon		C2: No intervention (control)	No significant difference between
Secondary tobacco smoke		G2: No intervention (control)	groups
Latino neighborhoods in San Diego County, California			
N: 143			
Fair			

BMI, body mass index; CBC, community-based care; CHW, community health worker; CI, confidence interval; EPC, enhanced primary care; ETS, environmental tobacco smoke; LHA, lay health advisor; MET, metabolic equivalent; N, number; NP, nurse practitioner; OR, odds ratio; PCP, primary care physician; RCT, randomized controlled trial; RIA, radioimmunoassay; SE, standard error; YMCA, Young Men's Christian Association.

Table 12. CHWs and health promotion and disease prevention: disease prevention interventions (continued)

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Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Krieger, 1999 <sup>105</sup>	Moderate	G1: CHW assistance with medical followup related to a date when blood pressure was determined to	Self-report of completed followup appointment within 90 days (validated by medical provider
Hypertension		be elevated	report):
		G2: Advice to see medical provider,	
Low-income neighborhoods in Seattle, Washington		list of public and community clinics	G2: 46.7% ( <i>P</i> = 0.001)
N: 421			
Fair			
Wendell, 2003 <sup>117</sup>	Low	G1: Discussions with community members during which they	Condom use (intervention vs. comparison):
Prospective cohort study		assessed the client's needs, imparted a risk- or harm-reduction message, answered questions,	OR, 1.37 (95% CI, 1.20 to 1.56; <i>P</i> < 0.001)
HIV prevention		made referrals, and negotiated and reinforced behavior change	7 < 0.001)
At-risk		-	
neighborhoods in Louisiana		G2: No intervention (control)	
N: 6,547			
Fair			
Becker et al., 2005; <sup>118</sup>	Moderate	G1: EPC- received risk-specific materials (same as intervention	Smoking cessation (self-report):
Cene et al., 2008 <sup>119</sup>		group), PCP received results and recommendations, sent info on	G1: 7% reduction G2: 16.2% reduction ( <i>P</i> < 0.001)
RCT		local programs (e.g., YMCA)	52. 15.270 Toddolloff (1 < 0.001)
Cardiovascular disease prevention		G2: CBC - received care in 1 nonclinical site in the community	
		from a NP and CHW. CHW provided dietary counseling,	
Baltimore, Maryland		smoking cessation, and exercise	
N: 267		counseling lasting 30 minutes.	
Poor			

Table 12. CHWs and health promotion and disease prevention: disease prevention interventions (continued)

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Campbell, 2004 <sup>107</sup>	Low	G1: Control churches were offered health education sessions and	Dietary change—daily fruit and vegetable servings
RCT		speakers on topics of their choice not directly related to study	(baseline/followup):
Colorectal cancer screening		objectives	G1: 3.3/3.4 G2: 3.5/3.5
African-American		G2: Organize and conduct at least 3 church-wide activities on	G3: 3.3/3.9 G4: 3.4/3.7
rural churches in		spreading info and enhancing	No significant change across
North Carolina		support for healthy lifestyle and CRC screening (LHA)	arms for LHA interventions
NR (12 churches;			Physical activity—recreational
completers/dropouts of individual	<b>3</b>	G3: 4 personalized computer- tailored newsletters and 4 targeted	(moderate-vigorous) activity MET hours/week, M (SE)
participants from each church not		videotapes corresponding to the same behaviors mailed to	(baseline/followup):
reported)		participants' homes bimonthly for first 6 months after baseline data	G1: 9.3(0.88)/8.4(0.69)
Poor		collection; 4th mailing was 9 months baseline	G2: 10.5(0.9)/10.6(0.70) G3: 9.5(0.80)/10.9(0.61) G4: 9.7(0.76)/9.7(0.60)
		G4: LHA + targeted print and videotape	No significant change across arms for LHA interventions

The two studies that targeted tobacco cessation found opposing results regarding CHW effectiveness. <sup>67,118,119</sup> The fair-quality study (San Diego trial <sup>67</sup>) found no difference in smoking cessation between a high-intensity CHW intervention group and a group receiving nothing based on validated radioimmunoassay (RIA) of children's hair for nicotine and cotinine. The poorquality study (Baltimore trial <sup>118,119</sup>) found a significant difference between a moderate-intensity CHW intervention and enhanced usual care; however, this outcome was based on self-report. The fair-quality Seattle trial measured health care utilization and demonstrated that a moderate-intensity CHW intervention increased medical followup compared with only verbal advice to seek medical care for elevated blood pressure. <sup>105</sup>

Overall, most (four of the six) disease prevention studies demonstrated that various levels of CHW intervention intensity (low, moderate, or high) were more effective than the comparator, which ranged from nothing to enhanced usual clinical care, in changing a variety of outcomes.

Knowledge. Two fair-quality studies  $^{16,117,127}$  reported outcomes for improved knowledge of the respective diseases. The Missouri study  $^{16,127}$  found that participants in the high-intensity, diabetes-oriented CHW intervention, compared with a control group receiving a book to read, had an improved knowledge of label reading as assessed by an unvalidated questionnaire (P < 0.0001); this improvement remained statistically significant at 6-month followup. The prospective cohort study  $^{117}$  demonstrated that a low-intensity CHW street outreach program was effective at increasing knowledge of where to obtain free condoms as determined by an unvalidated questionnaire (90 percent versus 74 percent, odds ratio [OR], 3.2, P = 0.001).

Behavior. Five RCTs, three fair  $^{16,67,105,127}$  and two poor quality,  $^{107,118,119}$  examined a variety of behavioral changes. Three demonstrated CHW effectiveness  $^{16,105,118,119,127}$  and two  $^{67,107}$  showed no difference compared with their respective controls. The Missouri trial on diabetes prevention evaluated dietary change following high-intensity, CHW-led group and individual sessions;  $^{16,127}$  it found a reduction in fat intake with a validated food frequency questionnaire compared with intake in a control group (P < 0.0001). The San Diego trial, a high-intensity CHW intervention of home and telephone visits to reduce second-hand tobacco smoke exposure to children, found no difference from baseline by self-report or validated RIA of children's hair for nicotine and cotinine. The San Diego trial evaluated a CHW intervention and found a difference in self-reported smoking cessation as compared to a standard of care group (16.2 percent reduction versus 7.0 percent, P < 0.001). Both groups reported less smoking, confirmed by measures of hair cotinine. The North Carolina trial did not show a difference in either fruit and vegetable intake or increased physical activity between intervention and control groups. The prospective cohort low-intensity study targeting HIV prevention demonstrated an increase in condom use reported in the intervention group (OR, 1.37; 95 percent CI, 1.20-1.56).

Satisfaction. No study for health promotion evaluated outcomes focused on satisfaction. *Health outcomes*. The Missouri trial found no difference within or between arms when comparing the high-intensity CHW intervention and the control group in terms of body weight and body mass index (BMI) at baseline (BMI 35.7 versus 35.3) and after 6 months (BMI 35.7 versus 35.4). 16,127

*Health care utilization*. The Seattle trial evaluated self-reported medical provider followup within 90 days of determined elevated blood pressure. <sup>105</sup> It demonstrated a higher rate of completed medical followup in the CHW group than in the control group (65.1 percent versus 46.7 percent, P = 0.001). The number needed to treat in order to bring 1 person to medical care was 5 (95 CI, 3-13). <sup>105</sup>

## **Outcomes for Injury Prevention**

**Injury prevention: home safety.** *Study characteristics*. One fair-quality RCT<sup>101</sup> and one poor-quality RCT randomized at the community level (called the Safe Block Project)<sup>102</sup> assessed the effect of low-intensity CHW interventions on injury prevention in homes, either for children<sup>101</sup> or for all ages.<sup>102</sup> Both studies involved CHW home visits. The fair-quality RCT consisted of assessment of safety hazards and recommendations for appropriate products and practices compared with safety counseling in a pediatric clinic.<sup>101</sup> The poor-quality RCT also included direct implementation of several safety features into homes compared with no intervention in control households; we rated this trial poor because of its high potential for measurement bias and not masking those who assessed outcomes.<sup>102</sup>

Overview of results. The fair-quality RCT showed no benefit to CHW intervention, <sup>101</sup> but the poor-quality trial had mixed results <sup>102</sup> (Table 13.). Significant benefit was seen for household features that did not require participants to change behaviors (e.g., continued presence of a smoke detector, as installed in intervention homes); conversely, no benefit was observed for other household features that did require behavior change (e.g., maintaining a working light bulb in stairways).

Knowledge. Neither study assessed knowledge-related outcomes.

Table 13. CHW injury prevention interventions and home safety

Author, Year Study Design Population Setting Sample Size	Intensity of CHW		
Quality		Study Groups	Results
Gielen et al., 2002 <sup>101</sup> Parents and infants 6 months or younger in large	Moderate	G1: Safety counseling and referral by pediatrician to children's safety center	No significant difference between groups in home safety practices:  Hot water temperature controlled: Pre/Post G1: 39%/47%; G2: 39%/47%
urban teaching hospital pediatric clinic		G2: Standard care plus offer of CHW home visit;	· ·
Baltimore, Maryland		assessed injury hazards; made recommendations about appropriate safety	Working smoke alarm: Pre/Post G1: 92%/84%; G2: 92%/81%
N: 187		products and practices; referred families to the	Safety gates used: Pre (planned use)/Post (actual use) G1: 84%/23%; G2: 84%/27%
Fair		children's safety center; 1 visit between 6 and 9 months	Poisons latched/locked: Pre/Post G1: 26%/12%; G2: 26%/10%
			Ipecac present: Pre/Post G1: 12%/27%; G2: 12%/31%
Schwarz et al., 1993 <sup>102</sup> (Safe Block Study)	Moderate	G1: Safety inspections, home modifications and education; myriad safety	G1 more likely than G2 to retain intervention modifications such as presence of ipecac ( <i>P</i> < 0.001), hot water temperature control
Inner city residents in neighborhoods with high		devices (e.g., smoke detectors, ipecac,	(P < 0.001)
injury rates		emergency telephone numbers, light bulbs)	No difference between groups for adequate lighting at stairs
Philadelphia, Pennsylvania		,	
N: 2,722		G2: Control (details NR)	
Poor			

CHW, community health worker; G, group; N, number.

*Behavior*. In the fair-quality RCT,<sup>101</sup> groups did not differ significantly in maintaining adequate stairway lighting (83.1 percent versus 80.1 percent; adjusted odds ratio [AOR], 0.90; 95 percent CI, 0.69-1.16) or in following any of the home safety practices assessed. Hot water temperature control and presence of ipecac increased from baseline in both groups, but presence of a working smoke alarm, use of safety gates on stairs, and latching or locking of poisons declined from baseline. In the poor-quality trial,<sup>102</sup> following the CHW intervention a significantly higher proportion of households continued to have ipecac (which was recommended at the time of the study for households with young children) (81.0 percent versus 9.8 percent; AOR, 0.04; 95 percent CI, 0.02 to 0.07) and smoke detectors (96.0 percent versus 77 percent; AOR, 0.14; 95 percent CI, 0.09 to 0.20) than did controls. These interventions were provided by the CHWs and required no behavior change by participants. In contrast, intervention households were actually less likely than control households to have retained hot water temperature controls (63.2 percent versus 73.2 percent; AOR, 1.73; 95 percent CI, 1.39 to 2.15).

Satisfaction. Neither study assessed satisfaction.

*Health outcomes*. Neither study assessed direct health outcomes.

Health care utilization. Neither study assessed health care utilization.

**Injury prevention: workplace safety.** *Study characteristics.* One prospective cohort study, rated poor quality for high potential for selection and measurement bias and lack of description of baseline characteristics, examined the effect of a low-intensity CHW intervention for migrant farm workers to prevent work-related eye injury. The CHW intervention involved distribution of protective eyewear either with or without specific training provided by the CHWs; it was compared to distribution of eye protection not involving CHWs. Outcomes were assessed during the same growing season in parts of the Midwest.

*Overview of results.* The CHW intervention increased the likelihood of protective eyewear use, particularly when coupled with CHW-led training (Table 14). 126

Table 14. CHW injury prevention interventions and workplace safety

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Forst et al., 2004 <sup>126</sup>	Low intensity	G1: CHW distributed protective eyewear, conducted at least 1	G1 were more likely to increase use of protective eyewear
Latino migrant and seasonal farm workers		each individual and group training sessions	. ,
Southeast Michigan and northeast Illinois		G2: CHW distributed eyewear, did not provide training	Any CHW intervention increased likelihood of protective eyewear use vs. no CHW ( <i>P</i> = 0.0004)
N: 786		G3: No CHW component	use vs. 110 CITIV (F = 0.0004)
Poor			

CHW, community health worker; G, group; N, number.

Knowledge. Knowledge was not assessed.

Behavior. The presence of any CHW component related to receiving protective eyewear was significantly associated with increased self-report of continued use of the eyewear on a 5-point Likert scale compared with having received the eyewear without CHW involvement (difference in average change in Likert scale value 0.6452, P < 0.01). Incorporation of CHW-led training was associated with greater self-reported eyewear use compared with CHW eyewear distribution alone (difference in average change 0.7663, P < 0.01) and with no CHW involvement (difference in average change 0.5241, P = 0.03). Observed use of eyewear increased in all groups during the study period (CHW trained 1.1 to 36 percent; CHW distributed 0 to 5.2 percent; no CHW 0 to 14 percent,

*P*-value not reported).

Satisfaction. Satisfaction was not assessed.

*Health outcomes*. Although the investigators measured the incidence of pterygium, they did not compare groups on this variable and in fact reported it as only inadequately identified.

Health care utilization. No measure of health care utilization was reported.

### **Outcomes for Maternal and Child Health**

Maternal and child health: overview. We identified 15 studies that met inclusion criteria and involved maternal or child health outcomes (or both). All the studies utilized high-intensity interventions, usually involving some series of home visits. All but 1 study were rated either fair (8 studies) or poor (6 studies). The 1 good-quality study found no significant differences associated with interventions employing CHWs. Among the other studies, results were mixed, some showing benefit of CHW interventions and some showing no effect attributable to CHWs. This distribution was found in both fair- and poor-quality studies. Significant associations were most commonly found for existing conditions (e.g., phenylketonuria [PKU] or failure to thrive) rather than primary prevention and in the area of health care utilization (e.g., immunization rates) and behavior (e.g., parenting measures).

Maternal and child health: prenatal care and perinatal outcomes. *Study characteristics*. Six studies assessed prenatal care and perinatal outcomes associated with CHWs. 71,72,77,79,83,86,87 Of these, three were rated fair quality: one RCT involving prenatal care in Cleveland and two cohort studies (one on the Resource Mothers Program for Maternal PKU and one evaluating REACH-Futures 2. The remaining three studies, rated poor, included one RCT on promotion of breastfeeding in African-American mothers in Baltimore, rated poor for high attrition and lack of specific or validated outcome measures; one cohort study (the Baby Love Maternal Outreach Worker study 31,32), rated poor for high attrition, high potential for selection bias and confounding, and lack of specific or validated outcome measures; and a second study on REACH-Futures 1 rated poor for high potential for secular trend and other confounding.

Most studies focused on interventions for low-income families, usually from racial or ethnic minority groups. Most CHW interventions involved home visits. The Resource Mothers Program for Maternal PKU<sup>83</sup> involved coaching in activities of daily living unique to mothers with PKU infants including meal planning and medical recommendations concerning pregnancy. The Maternal Outreach Worker program also provided direct assistance to families for obtaining benefits and services. <sup>86,87</sup>

Studies generally compared outcomes for families receiving CHW interventions with outcomes for those receiving usual clinical care (Table 15). The Baltimore breastfeeding study compared CHW intervention with video and other literature and against both interventions combined;<sup>77</sup> the Resource Mothers Program<sup>83</sup> used as controls mothers who had completed pregnancy in the 5 years before the start of the program; and REACH-Futures<sup>71,72</sup> used historic controls of nurse home visits. Outcomes were typically assessed months to years after the interventions.

Overview of results. Improvements over usual care were demonstrated to be associated with CHWs in breastfeeding, 77 maternal control of PKU, 83 and prenatal care. However, birth outcomes in mothers with PKU, 83 low birth weight incidence, 86,87 continuation of breastfeeding, 77 and overall presence of infant health problems 11 were not significantly improved by use of CHWs compared with usual care 77,83,86,87 or with health professional intervention. 11

Knowledge. No study measured knowledge-related outcomes.

Behavior. No study assessed behavior change.

*Health outcomes*. Peer CHW counseling in the Baltimore study was associated with greater initiation of breastfeeding than standard care (OR, 3.84; 95 percent CI, 1.44-10.21), but the statistically significant difference between groups in the proportion of participants still breastfeeding by 7 to 10 days disappeared. <sup>77</sup> For the Resource Mothers Program, <sup>83</sup> mothers

receiving the CHW intervention needed less time to reach metabolic control (blood phenylalanine level consistently below 10 mg/dL) than those who had not received the intervention (8.5 weeks versus 16 weeks, P < 0.05). The head circumference of infants born to participating mothers did not differ significantly between cohorts (mean Z-score of head circumference: intervention -0.56; 95 percent CI, -0.88 - -0.24 versus control -1.4; 95 percent CI, -1.56 - -1.2; P = 0.08). The Maternal Outreach Workers program

Table 15. CHW maternal and child interventions and prenatal care and perinatal outcomes

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Graham et al., 1992 <sup>79</sup> RCT Pregnant inner-city African-American women Cleveland, Ohio N: 145 Fair	High	G1: Home visits with psychosocial support and encouragement, education, link to community resources, information on health risks; 4 visits of 1 hour each at 2-4 week intervals  G2: Routine prenatal obstetric care (control)	No statistically significant difference between groups in incidence of low birth weight: 12.9% intervention, 7.5% controls ( $P = 0.51$ )
Nacion et al., 2000 <sup>72</sup>	High	G1: Home visits by	G1 more likely than G2 to receive problem-
Cohort		CHW G2: Home visits by	solving services ( $P < 0.01$ ) and to have problems identified in women's health ( $P = 0.01$ ), well-child health care deficits
REACH-Futures		nurse (historic control)	(P = 0.02), parenting $(P = 0.02)$ , and socioeconomic issues $(P < 0.01)$
Low-income inner-city African-American pregnant women and infants			G1 less likely than G2 to receive emotional support services ( $P < 0.01$ ), to have referrals placed for women's health ( $P = 0.01$ ), well-woman ( $P = 0.02$ ),
Chicago, Illinois			emotional/interpersonal ( $P < 0.01$ ), parental support ( $P < 0.01$ ), or for socioeconomic
N: 213			issues ( <i>P</i> < 0.01)
Fair			
St. James et al., 1999 <sup>83</sup>	High	G1: Historic control; women who completed	Metabolic control achieved in 8.5 weeks for G2 vs. 16 weeks for G1 ( <i>P</i> < 0.05)
Cohort		pregnancy in the 5	, ,
Mothers with PKU		years prior to project onset	Infant mental scale on Bayley Developmental Quotient was 108 for G2 vs. 95 for G1 ( <i>P</i> < 0.05)
New England		G2: Resource mothers	
N: 69			No difference in head circumference at birth $(P = 0.08)$
Fair			

CHW, community health worker; PKU, phenylketonuria; WIC, Special Supplemental Nutrition Program for Women, Infants, and Children.

Table 15. CHW maternal and child interventions and prenatal care and birth outcomes (continued)

Author, Year Study Design Population Setting Sample Size	Intensity of CHW	Shada Ossansi	Desuite
Quality	Intervention	Study Groups	Results
Barnes-Boyd et al., 2001 <sup>71</sup> Cohort	High	G1: Monthly home visits over 1 year; visits at prenatal, 1, 6, and 12 months teamed with nurse	Proportion fully immunized at 12 months: CHW 77%, nurse 63% ( <i>P</i> < 0.001)  No significant difference between groups
REACH-Futures		G2: Historic controls with	in presence of neonatal or postneonatal health problems (27% CHW vs. 25%
Low-income inner-city African-American pregnant women and infants		nurse home visits	nurse)
Chicago, Illinois			
N: 1,922			
Poor			
Caulfield et al., 1998 <sup>77</sup>	High	G1: Standard WIC services only	Initiation of breastfeeding: G1: 26% (referent)
RCT		G2: WIC plus video and	G2: 50% (OR, 1.36; 95% CI, 0.52-3.54) G3: 62% (OR, 3.84; 95% CI, 1.44-10.21)
African-American women receiving prenatal care		literature	G4: 52% (OR, 1.92; 95% CI, 0.78-4.76)
Baltimore, Maryland		G3: WIC plus peer counseling	Breastfeeding at 7-10 days: G1: 14% (referent) G2: 30% (OR, 0.79; 95% CI, 0.25-2.52)
N: 548		G4: WIC plus peer counseling plus video and	G3: 38% (OR, 1.11; 95% CI, 0.34-3.61) G4: 38% (OR, 1.52; 95% CI, 0.50-4.59)
Poor		literature	·
Tessaro et al., 1997 <sup>86,87</sup>	High	G1: CHW intervention	Maternal depression score increased by 2.1 in G1 vs. 5.1 in G2 ( $P = 0.01$ )
Cohort		G2: Matched controls, not otherwise defined	Prenatal care, African Americans:
Maternal Outreach Workers		outerwise defined	G1: 60.7% adequate, 32.6% intermediate, 6.7% inadequate G2: 63.8% adequate, 31.5%
Medicaid-eligible pregnant women with 1 or more pregnancy risk factors			intermediate, 4.7% inadequate  Prenatal care, Whites:
North Carolina			G1: 77.4% adequate, 19.7% intermediate, 2.9% inadequate
N: 705			G2: 75.1% adequate, 22.8% intermediate, 2.1% inadequate
Poor			No difference between groups in maternal self-esteem ( $P = 0.19$ ) or perceived stress ( $P = 0.75$ )
			No difference in observed vs. expected incidence of low birth weight or very low birth weight: African Americans -13 $(P = 0.12)$ , Whites +1 $(P = 0.58)$

demonstrated a trend toward lower incidence of adequate prenatal care for African-American women receiving CHW intervention than for controls (significance not reported);<sup>86,87</sup> neither the observed nor the expected incidences of low birth weight or very low birth weight infants differed significantly. REACH-Futures found no difference between CHW intervention and controls in incidence of neonatal or postneonatal infant health problems.<sup>71</sup>

Health care utilization. The Cleveland study showed a significant increase in the ratio of actual to expected numbers of prenatal visits for women receiving CHW intervention (P = 0.029);<sup>79</sup> the investigators did not compare the intervention findings to those from women in the control group.

Other. The fair-quality analysis from REACH-Futures found that CHW home visits were more likely than nurse home visits to include identification of problems in women's health (P = 0.01), deficits in well-child care (P = 0.02), parenting issues (P = 0.02), and socioeconomic issues (P < 0.01) and that participants were more likely to receive problem-solving services (P < 0.01). However, CHWs were less likely than nurses to provide emotional support services (P < 0.01) or to place referrals for women's health (P = 0.01), well-woman care (P = 0.02), emotional/interpersonal support (P < 0.01), parental support (P < 0.01), or socioeconomic issues (P < 0.01).

**Maternal and child health: Child development.** *Study characteristics.* Four studies considered the impact of CHWs on child development (Table 16). Three were rated fair quality and one poor quality; all used high-intensity interventions. One RCT focused on children with nonorganic failure to thrive in Baltimore, Maryland; <sup>75,76</sup> another RCT examined the Home Visitation 2000 program in Denver, Colorado; <sup>80-82</sup> and a cohort study involved the Resource Mothers Program for Maternal PKU in New England. <sup>83</sup> The RCT assessing the Hawaii Healthy Start Program was rated poor for high potential for site-specific bias.

Overview of results. Variation in timing and specific outcomes among studies precludes much summarization of results. Two of the studies demonstrated some significant benefit of CHW intervention over usual care; the other two showed no significant difference between CHW intervention and controls. The failure-to-thrive study demonstrated that the CHW home visiting program was effective in mitigating declines in cognitive and motor development, but not language, if implemented during the first year of life (Table 16). The PKU Resource Mothers Program study found higher mental development for infants born to mothers who participated than for those born to historic controls. By contrast, the Home Visitation 2000 trial showed more improvement in language development with nurse visits rather than CHWs, and the Hawaii trial found no difference in mental or psychomotor development between children receiving CHW intervention and controls.

*Knowledge*. No study assessed knowledge about child development issues. *Behavior*. No study included health behaviors in the outcomes measured. *Satisfaction*. No study considered satisfaction outcomes.

Table 16. CHW maternal and child interventions and child development

Author, Year Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Black et al., 1995; <sup>75</sup> Hutcheson et al., 1997 <sup>76</sup> Low-income urban	High	G1: Weekly CHW home visits with community health nurse supervision for 1 year, addressing various child health and development needs, nutrition	Smaller postintervention decline in cognitive and motor development for G1 vs. G2 only for children recruited in infancy
children with nonorganic failure to thrive		intervention, and concerns raised by mothers	Bayley cognitive development (SD):
Baltimore, Maryland		G2: Clinic-based multidisciplinary services; no CHW intervention	G1: 96.9 (SD 15.8) to 89.3 (17.4) G2: 96.2 (12.1) to 86.1 (18.7)
N: 130 Fair			Bayley motor development: G1: 91.1 (18.7) to 92.0 (14.6) G2: 95.3 (17.7) to 91.5 (18.7) (P = 0.02)
			No significant differences between groups for language development
Korfmacher et al., 1999; <sup>81</sup> Olds et al., 2002; <sup>80</sup> Olds et al., 2004 <sup>82</sup>	High	G1: Developmental screening plus intensive home visitation: promoting healthy behaviors, competent child care, pregnancy planning, education,	Preschool Language Scales at 21 months (G3 mean 99.49): G1 vs. G3 +0.40 (95% CI, -1.94 to +2.74)
Home Visitation 2000		employment; linking to social and health services; promoting healthy family/friend relationships; variable	G2 vs. G3 +1.73 (95% CI, -0.64 to +4.11)
Medicaid-eligible pregnant women		frequency from weekly to monthly up to 24 months of age	Mental Development Index at 24 months (G3 mean 89.38):
Denver, Colorado N: 735		G2: Developmental screening plus nurse home visits	G1 vs. G3 +0.07 (95% CI, -2.39 to +2.53) G2 vs. G3 +0.75 (95% CI, -1.77 to +3.28)
Fair		G3: Developmental screening and referrals	10 +3.20)
St. James et al., 1999 <sup>83</sup>	High	G1: Historic control; women who completed pregnancy in the 5 years	Infant mental scale on Bayley Developmental Quotient was
Mothers with PKU (PKU Resource Mothers Program)		before project onset  G2: Resource mothers	G1: 95 G2: 108 ( <i>P</i> < 0.05)
New England			
N: 69			
Fair			

CHW, community health workers; CI, confidence interval; G, group; PKU, phenylketonuria; SD, standard deviation.

Table 16. CHW maternal and child interventions and child development (continued)

Author, Year Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Duggan et al., 1999; <sup>128</sup> Duggan et al., 2000 <sup>78</sup>	High	G1: Home visiting with individualized service plans, child developmental screenings, and mother-child	All outcome measures at 2 years postintervention
Families at high risk for child maltreatment		interaction assessments; family support plan within 45 days of initial visit,	Development –
Oahu, Hawaii		reviewed every 6 months, revised annually; periodic screening for developmental delays, observational	Mental Development Index: G1: 90.0 G2: 89.2 ( <i>P</i> = 0.60)
N: 730		assessment of parent-child interaction and home environment; ensure	Psychomotor Development Index:
Poor		existence of medical home, link to other needed resources	G1: 92.1 G2: 90.4 (P = 0.12)
		G2: Control (details NR)	

Health outcomes. All four studies examined various health outcomes. In the Baltimore, Maryland, failure-to-thrive study, the decline in cognitive development over 1 year as measured by the Bayley Scales of Infant Development was less severe for the home intervention group than for the clinic-only group (P = 0.02) for children recruited during infancy. Groups of children recruited at older ages did not differ using the Battelle Developmental Inventory, although all groups demonstrated some degree of decline in cognitive function. Whether this decline was attributable to failure to thrive or to some other factor was not assessed in the study. Children in the intervention group showed less severe decline in receptive and expressive language than did age-matched controls (P = 0.05), but all groups experienced relative declines in language over the course of the study. All groups showed significant improvements in weight for age, weight for height, and height for age, but the groups did not differ significantly.

The Home Visitation 2000 study in Denver, Colorado, found slightly greater improvement over controls with nurse home visits than with CHW visits for the Preschool Language Scales at 21 months and the Mental Development Index at 24 months. 80-82

Infants in the intervention cohort of the Resource Mothers Program in New England had higher mean Bayley Developmental Quotient (mental scale) values than those in the control cohort (108 versus 95) at 12 months of age (P < 0.05). 83

At 2 years postintervention, children in the Hawaii Healthy Start Program<sup>78,128</sup> who received CHW intervention had a mean Bayley Mental Development Index score of 90.0 versus 89.2 for controls (P = 0.60) and a Psychomotor Development Index score of 92.1 versus 90.4 for controls (P = 0.12).

Health care utilization. No study assessed health care utilization.

Maternal and child health: Environment conducive to child well-being. Study characteristics. Factors contributing to an environment conducive to the health and well-being of children were assessed directly in 10 studies; 6 rated as fair quality and 4 as poor quality. The five fair-quality RCTs covered the following populations and interventions: smokers in San Diego; low-income urban children with nonorganic failure to thrive; the Parent to Parent Network for mothers of children with chronic conditions; a trial targeting children in New York

with missed immunization visits;<sup>68</sup> a trial involving drug-using mothers in Maryland;<sup>84</sup> and the Home Visitation 2000 RCT. <sup>80-82</sup> Finally, of the four poor-quality studies, two RCTs (both involving the Child-Parent Enrichment Project, or CPEP<sup>73,74</sup>) were rated poor for lack of relevant outcome measures; the Hawaii Healthy Start Program was rated poor for high potential for site-specific bias; and on the REACH-Futures trial was rated poor because of high potential for secular trend and for other confounding.

*Overview of results.* The variety of outcomes assessed by the studies precludes much summary of results. Of the 10 studies in this category, only 4 reported significantly beneficial outcomes for CHWs over usual care.

The New York study<sup>68</sup> and REACH-Futures trial<sup>71</sup> did find CHW-associated improvements in immunization status. Home Visitation 2000 showed greater improvement with nurse than with CHW interventions for mother-infant interaction, home environment, and tobacco smoke exposure.<sup>80-82</sup> The Hawaii study found that CHW intervention significantly increased appropriate parental coping and discipline methods and decreased injuries from partner-related violence.<sup>78,128</sup>

As to the remaining studies: the San Diego study found no significant impact by CHWs on exposure to environmental tobacco smoke among children of smokers. The failure-to-thrive study found no effect of CHWs on outcomes related to home environment or parenting behavior. The Parent to Parent Network study showed no significant difference between intervention and control groups for maternal psychiatric well-being postintervention; however, the results were potentially confounded by differences at baseline. No differences were found in the Maryland study for maternal drug use or mother-child interaction. Other studies on substance abuse, child maltreatment, and improving psychiatric outcomes among caregivers of children with chronic diseases also did not report significant differences between study arms.

Knowledge. No study assessed measures of knowledge.

*Behavior*. The failure-to-thrive study found no differences between groups for parent-child interaction behavior during feeding using a modified Parent Child Early Relational Assessment. Assessment. It did show improved interactive communication with parents during feeding among children over time for all groups (P < 0.001), but no differences were apparent according to intervention status. Developmental appropriateness of the home environment, as assessed postintervention by the Home Observation for Measurement of the Environment Scales, was slightly higher for the CHW intervention group than for the clinic-only group (31.6 [SD 3.6] versus 29.3 [SD 4.2] for infants; 32.4 [SD 5.1] versus 30.3 [SD 5.7] for older children; P = 0.05 [significance not reported by age strata]). However, no baseline scores were reported for this measure to ascertain the true effect of CHWs.

In the Maryland study on substance-abusing mothers, self-reported postintervention substance use was similar for mothers receiving CHW interventions and for those in the control group (65 percent versus 68 percent for alcohol, 46 percent versus 44 percent for cocaine and/or heroin, and 25 percent versus 38 percent for marijuana;  $P \ge 0.1$ ).

The Hawaii study found that parents who received CHW intervention had a greater postintervention use of nonviolent discipline strategies (see Table 16), reported less parenting-related stress, and had higher parenting efficacy scores than those receiving usual care alone. \*\*78,128\*\* Satisfaction\*\*. No study assessed satisfaction outcomes.

*Health outcomes*. Among children of smokers in the San Diego study,<sup>67</sup> no reduction was seen in parental report of children's tobacco exposure or in nicotine or cotinine levels in children's hair for either CHW or control participants. The Parent to Parent Network demonstrated no difference between groups in postintervention Psychiatric Symptom Index

scores (intervention 22.1 versus control 20.1). <sup>85</sup> However, the baseline score for the intervention group was significantly higher than for the control group (24.1 versus 20.3, respectively; P < 0.05). Adjustment for this baseline difference revealed a greater degree of improvement in the intervention group than in controls, except for the depression subscale, which was improved in both groups. However, whether this reflected true improvement attributable to CHWs or was simply a regression to the mean could not be determined. The New York study showed that children receiving CHW intervention were more likely than control children to be current on their immunizations (P = 0.03) and less likely to have received immunizations behind schedule (P < 0.05) (Table 17). <sup>68</sup>

Table 17. CHW maternal and child interventions and environment conducive to child health

Author, Year			
Study Design			
Population	Internalty of		
Setting Sample Size	Intensity of CHW		
Quality	Intervention	Study Groups	Results
Barnes et al., 1999 <sup>68</sup> Low-income immigrant	High	G1: Basic immunization education and referral; home visits with reminders of immunizations due,	Immunizations up to date: G1: 75% G2: 54% ( <i>P</i> = 0.03)
children from Dominican Republic		followup to ensure compliance	Late for immunizations:
NW Manhattan, New York		G2: Information provided on child's missed immunizations, encouraged to reschedule missed appointments	G2: 38% (P < 0.05)
N: 434		(control)	
Fair			
Conway et al., 2004 <sup>67</sup>	High	G1: Home and telephone visits on problem-solving techniques to	No difference between groups for parent report of child's tobacco
Latino families with smokers and children between 1 and 9 years old		reduce environmental tobacco smoke exposure; 6 visits over 4 months	exposure or child's hair nicotine or cotinine levels (no reduction in either group)
San Diego County, California		G2: Participated in surveys but received no other intervention (control)	
N: 143		(control)	
Fair			
Black et al., 1995 <sup>75</sup> ; Hutcheson et al., 1997 <sup>76</sup>	High	G1: Weekly CHW home visits with community health nurse supervision for 1 year, addressing	No significant differences between groups for parent-child interaction
Low-income urban children with nonorganic failure to thrive		various child health and development needs, nutrition intervention, and concerns raised by mothers	HOMES home environment scores not reported pre-intervention
Baltimore, Maryland		by mouncis	
N: 130		G2: Clinic-based multidisciplinary services; no CHW intervention	
Fair			

CHW, community health worker; CI, confidence interval; G, group; N, number; ng/dL, nanograms/deciliter; SD, standard deviation.

Table 17. CHW maternal and child interventions and environment conducive to child health (continued)

Author, Year Study Design			
Population Population			
Setting	Intensity of		
Sample Size	CHW		
Quality	Intervention	Study Groups	Results
Korfmacher et al., 1999;81	High	G1: Developmental screening plus	Greater improvement in mother-infant
Olds et al., 2002;80	· ·	intensive home visitation:	interaction and home environment
Olds et al., 2004 <sup>82</sup>		promoting healthy behaviors,	with intervention vs. controls for nurse
(Home Visitation 2000)		competent child care, pregnancy	home visits (least squares mean
		planning, education, employment;	1.32, <i>P</i> ≤0.05) than for CHW visits
Medicaid-eligible pregnant		linking to social and health	(least squares mean 1.16, P < 0.1)
women		services; promoting healthy	
		family/friend relationships; variable	Urine cotinine among smoking
Denver, Colorado		frequency from weekly to monthly	mothers reduced in all groups, more
0-		up to 24 months of age	so for nurse intervention:
N: 735		00.0	CHW vs. control -76.19 ng/dL (95%
Fata		G2: Developmental screening plus	CI, -302.21 to -149.82)
Fair		nurse home visits	Nurse vs. control -246.68 ng/dL (95%
		C2: Dayalanmental careening and	CI, -466.19 to -27.16; $P \le 0.05$ )
		G3: Developmental screening and referrals (control)	
Schuler et al., 2000 <sup>84</sup>	High	G1: 9 visits of 30 minutes each to	No difference between groups in self-
Schaler et al., 2000	riigii	enhance mothers' ability to manage	
Women with known history	1	self-identified problems by using	infant warmth on observed mother-
of drug use plus their		existing services and family and	child interactions
infants		social supports; modeling infant	
		development behavior/activities	65% of intervention and 68% of
Unspecified inner city,		·	controls reported alcohol use
Maryland		G2: 3 monthly visits of 17 minutes	postintervention, 46% of intervention
		each for tracking purposes only	and 44% of controls reported cocaine
N: 192			and/or heroin use, 25% of
			intervention and 38% of controls
Fair Silver et al., 1997 <sup>85</sup>	High	G1: Intervention	reported marijuana use (P ≥ 0.1)
Sliver et al., 1997	підп	G1. Intervention	Psychiatric Symptom Index scores higher at baseline in G1 than G2 ( <i>P</i> <
Inner-city, low-income,		G2: Usual care (control)	0.05), but no difference between
minority women with		GZ. GSual care (control)	groups postintervention
children who have a			groups postinion vention
chronic disease			
Bronx or Lower			
Westchester, New York			
N: 365			
Fair	Lliab	C4. Monthly home visite ever 4	Dropostion fully improvided 4.40
Barnes-Boyd et al., 2001 <sup>71</sup>	High	G1: Monthly home visits over 1	Proportion fully immunized at 12
(REACH-Futures)		year; visits at prenatal, 1, 6, and 12 months teamed with nurse	(P < 0.001)
Low-income inner-city		months touried with Huise	(, < 0.001)
African-American pregnant	ŀ	G2: Nurse home visits (historic	
women and infants	-	controls)	
		,	
Chicago, Illinois			
N. 4 000			
N: 1,922			
Poor			

Table 17. CHW maternal and child interventions and environment conducive to child health (continued)

Author, Year			
Study Design			
Population	Intensity of		
Setting Sample Size	Intensity of CHW		
Quality	-	Study Groups	Results
Barth et al., 1988 <sup>73</sup>	High		er Child Abuse Potential Inventory pre-
Families referred for high		6 months with links to other community resources	vs. postintervention: G1: 116.33 (SD 47.75) to 88.54
risk of child maltreatment		community resources	(SD 53.09)
risk of child mattreatment		G2: Usual care	G2: 103.50 (SD 43.26) to 92.44
Contra Costa County,		<b>32. 3344 34. 3</b>	(SD 51.44) ( $P \ge 0.05$ between
California			groups)
			<b>3</b>
N: 65			
Poor Poor		0.11	
Barth et al., 1991 <sup>74</sup>	High	G1: Home visits	Increase in total child maltreatment-
Families referred for high		G2: Usual care	related reports and court actions: G1: +40 families to +65 total reports
risk of child maltreatment		G2. Osual care	G2: +41 families to +74 total reports
nsk of child matteatment			(no significance testing reported)
Contra Costa County,			(ne eigninearies teeting reported)
California			
N: 240			
_			
Poor 128		0.111	All .
Duggan et al., 1999; <sup>128</sup> Duggan et al., 2000 <sup>78</sup>	High	G1: Home visiting with	All outcome measures at 2 years
Duggan et al., 2000		individualized service plans, child developmental screenings, and	postintervention
Families at high risk for		mother-child interaction	Reported frequent use of nonviolent
child maltreatment		assessments; family support plan	discipline strategies:
		within 45 days of initial visit,	G1: 39%
Oahu, Hawaii		reviewed every 6 months, revised	G2: 34% (P = 0.03)
		annually; periodic screening for	,
N: 730		developmental delays,	Reported parenting-related stress:
		observational assessment of	G1: 77.7%
Poor		parent-child interaction and home	G2: 80.7% ( <i>P</i> = 0.08)
		environment; ensure existence of	Deposition office on /Deposition Co
		medical home, links to other	Parenting efficacy (Parenting Sense
		needed resources	of Confidence Scale): G1: 76.1
		G2: Control (details NR)	G2: 74.1 ( <i>P</i> = 0.03)
		CZ. Control (dotalls 1414)	Maternal life skills (Community Life
			Skills Scale):
			G1: 23.9
			G2: 23.9 ( <i>P</i> = 0.84)
			Maternal social support (Maternal
			Social Support Index):
			G1: 21.4
			G2: 21.7 ( <i>P</i> = 0.48)
			Maternal substance use:
			G1: 18%
			G2: 20% (P = 0.55)

Table 17. CHW maternal and child interventions and environment conducive to child health (continued)

Author, Year Study Design **Population** Setting Intensity of **CHW** Sample Size Quality **Intervention Study Groups** Results Duggan et al., 1999;<sup>128</sup> Maternal depressive symptoms: Duggan et al., 2000<sup>78</sup> G1: 23% G2: 26% (P = 0.49) (continued) Poor, general maternal mental health: G1: 36% G2: 39% (P = 0.43) Home learning environment (Total Home Observation for Measurement of the Environment Scale): G1: 34.6 G2: 34.1 (P = 0.47) Mother-child interaction (Nursing Child Assessment Satellite Training scales): G1: Caregiver total 15.0, child total G2: Caregiver total 14.6 (P = 0.28), child total 7.2 (P = 0.83) Partner-related violence in household resulting in injury: G1: 16% G2: 24% (P = 0.03) Confirmed Child Protective Services reports: G1: 2% G2: 3% (P = 0.40) Presence of primary care provider: G2: 86% (P = 0.09) Adequate number of well-child visits: G1: 60% G2: 55% (P = 0.95) Immunizations up to date: G1: 87% G2: 85% (P = 0.45)

The Maryland study found infant warmth (on a 5-point scale) to be equal for those receiving CHW interventions and controls (2.5, SD 0.4 for both groups). 84

Home Environment 2000 demonstrated more improvement over controls in mother-infant interaction and in home environment for nurse home visits (least squares mean 1.32,  $P \le 0.05$ )

than for CHW visits (least squares mean 1.16, P < 0.1). <sup>80-82</sup> Among participating families with mothers who smoked, maternal urine cotinine was reduced in all groups; those receiving nurse home visits had a significantly greater degree of reduction than those receiving CHW visits (nurse versus control -246.68 ng/dL; 95 percent CI, -466.19 to -27.16); CHW versus control -76.19 ng/dL; 95 percent CI, -302.21 to -149.82;  $P \le 0.05$ ).

The studies from Contra Costa, California, found no significant difference between groups on the Child Abuse Potential Inventory postintervention (Table 17); both groups showed improvement and no difference in reported cases of child maltreatment.<sup>73,74</sup>

The Hawaii study<sup>78,128</sup> demonstrated no difference between groups for maternal life skills (Table 17), maternal social support, maternal substance use, maternal depressive symptoms, or incidence of poor general mental health among mothers at 2 years postintervention. Neither home learning environment nor parent-child interactions differed between groups at 2 years. The investigators did not report how each of these measures compared with baseline values. The study did show lower incidence of injuries attributable to partner-related violence among families receiving CHW intervention (P = 0.03), but no differences in reported or confirmed cases of child maltreatment.

Health care utilization. Children receiving CHW intervention in the Hawaii study were no more likely than those receiving usual care to have a primary care provider (P = 0.09) (Table 17), to have received the recommended number of well-child visits (P = 0.95), or to be current on immunization status (P = 0.45). <sup>78,128</sup>

## **Outcomes for Cancer Screening**

**Cancer screening.** *Study Characteristics.* A total of 15 studies (24 citations) examined outcomes of CHW interventions for improving breast, cervical, or colorectal cancer screening. <sup>15,17-22,59-63,103,104,106-113,116,125</sup> Information on these studies is spread across multiple tables, depending on the specific focus: improving knowledge, changing behavior, breast self-examination, Pap smears, mammography, clinical breast examination, and colorectal cancer screening.

Of these studies, 10 are RCTs<sup>15,17-22,61-63,103,104,106-113</sup> and 5 are observational studies. <sup>59,60,108,113,116,125</sup> The RCTs include three randomized by communities <sup>103</sup> or churches. <sup>19-22,104,107</sup> Of the five observational studies, one was a quasi-experimental controlled cohort, <sup>125</sup> two were prospective cohorts, <sup>108,113</sup> one used retrospective records, <sup>59,60</sup> and one used repeated cross-sectional survey of women attending beauty salons randomly assigned to experimental and control groups. <sup>116</sup> The studies spanned the quality range as well: two were of good quality, <sup>17,18,103</sup> seven of fair quality, <sup>59-63,106,108,109,125</sup> and six of poor quality. <sup>15,19-22,104,107,110-113,116</sup>

As noted in our section on KQ 1, seven studies used low-intensity CHW models, 6 used moderate-intensity interventions, and two used high-intensity interventions. Six studies included more than two arms. Studies compared the CHW arm with a variety of alternatives, including no intervention or usual care (6 studies), mail (3 studies), community interventions (4 studies), CHWs in a lesser capacity (2 studies), and CHWs in combination with other interventions (2 studies).

With the exception of two studies on colorectal cancer screening, 106,107 all other studies focus on women. All studies focused mainly on minority or underserved communities.

Studies used varied definitions of outcomes. The greatest commonality was reporting on utilization of cancer screening tests such as mammography, clinical breast examination, Pap smears, and colorectal cancer screening. Of the 15 studies, 13 reported on changes in rates of

utilization, but they varied in their specific definitions (ever use, use in the past 3 months, 1 year, 2 years, and so on). <sup>15,17-22,59-63,104,106-113,125</sup> With the exception of 3 studies examining Medicaid or medical records for mammography use, <sup>17,18,59,60,63</sup> all relied solely on self-report.

*Overview of results.* Together, the 15 studies suggest limited evidence of improvement in knowledge in the CHW arm compared with alternative approaches; they present conflicting findings on the effect of CHWs on planned and actual health behaviors, specifically breast self-examination. The volume of evidence on these outcomes is limited; the quality and design of the studies limits the interpretation of available evidence.

Unlike most of the other subsections dealing with other purposes for CHW strategies, cancer screening studies used high-, moderate-, and low-intensity interventions. Enough studies and evidence are available to permit some analysis by the intensity variable as it relates to Pap smears and mammography. Summary tables for these two outcomes are therefore presented by intensity (low, then moderate, then high), followed by quality, and then alphabetical order, by last name of first author(s); for all other sections, we present studies by quality, and then alphabetical order, by last name of first author(s).

Regarding health care utilization, our findings from this limited evidence do not support the conclusion that CHW interventions are more effective in comparison with other alternatives in raising the rates of clinical breast examination or colorectal cancer screening. More substantial evidence exists on Pap smears and mammography. The CHW approach is at least as effective as the alternative in improving Pap smear rates, but it is more effective than the alternative only in limited circumstances of low- and moderate-intensity interventions. With respect to mammography rates, studies demonstrated significantly greater improvements in the CHW arm compared with the alternative (no intervention, mail, print, or minimal CHW) in either the entire sample or in subsamples.

Knowledge. Two studies (three articles; Table 18) examined changes in knowledge and found limited evidence of improvement for the CHW arm. <sup>17,18,109</sup> A good-quality, high-intensity study in North Carolina measured knowledge for 12 individual measures on breast cancer and a composite score. <sup>17,18</sup> The studies together suggest improvements in the CHW arm, although the results are not consistent on the relative benefit of the CHW arm versus the alternative. Although differences between the CHW and the comparison arm (mail intervention) were not statistically significant for the composite measure of knowledge, the study reported significant different improvements favoring the CHW arm on two individual items measuring knowledge. Both arms demonstrated improvements in other measures, but these improvements were not statistically significantly different. A second study, of fair quality and moderate intensity in California, found significantly different improvements on two measures of knowledge, favoring the CHW arm compared with the media intervention arm. <sup>109</sup>

Table 18. CHW cancer screening: improving knowledge

Author, Year Study Design Population			
Setting	Intensity of		
Sample Size	CHW		
Quality	Intervention	Study Groups	Results
Paskett et al., 2006; <sup>17</sup>	High	G1: Letter and NCI brochure sent about	Composite knowledge score:
Katz et al., 2007 <sup>18</sup>	· ·	the need for regular cervical cancer	not statistically significantly higher in
DOT		screening 6 months after random	CHW group
RCT		assignment, followed by letter and NCI brochure about the need for	
Community health		mammography 3 months after followup	
centers, Robeson		assessment (control)	
County, North		assessment (control)	
Carolina		G2: Individualized health education	
		program that was culturally acceptable and	
820		tailored to meet the needs of each woman,	
		intensive face-to-face interactive	
Good		educational program administered over a	
		9- to 12-month period, consisting of 3 in-	
		person visits, with educational materials	
		provided at each visit and followup telephone calls and mailings thereafter	
Mock et al., 2007 <sup>109</sup>	Moderate	G1: CHW small group meetings; direct	Reported awareness of need for
Wook of al., 2007	Moderate	contact with subjects; Vietnamese	Pap test by women 18+ years old
RCT		language ads for TV, radio, newspaper;	(baseline/followup):
		booklets and printed materials in various	(
Vietnamese-American	1	community locations	G1: 68.4%/93.9% ( <i>P</i> < 0.001)
women, Santa Clara			G2: 68.5%/70.2% ( <i>P</i> = 0.55)
County, California		G2: Vietnamese-language ads for TV,	Z-test <i>P</i> < 0.001
		radio, newspaper; booklets and printed	
968		materials in various community locations;	Heard of Pap test:
Fair		delayed educational session	G1: 81.8%/99.6% (P < 0.001)
rall			G2: 87.2%/95.2% ( <i>P</i> < 0.001) Z-test <i>P</i> < 0.001
			Z-163( 1 < 0.00 l

CHW, community health workers; G, group; NCI, National Cancer Institute; RCT, randomized controlled trial; TV, television.

Behavior: planned testing. Two studies, one of fair quality and low intensity<sup>63</sup> and the other of poor quality and moderate intensity,<sup>116</sup> provide contradictory findings on the effect of CHWs on planned behavior Table 19). The fair-quality study compared a CHW arm with direct and usual care; differences in the rate of planned Pap smear tests favoring the CHW arm were statistically significant compared with either direct mail or usual care.<sup>63</sup> The poor-quality study reported no differences among study arms. However, the design of the study, which involved repeated cross-sections in salons randomly assigned to experimental and control status in which experimental salons offered barrier-specific counseling, was not measuring changes in intent over time; rather, it was concerned with differences in a cross-sectional sample. Low penetration combined with contamination across the samples (as suggested by the 37 percent and 10 percent of the sample reporting breast health messages at control sites and experimental sites, respectively) could have diluted the effects of the intervention.<sup>116</sup>

Table 19. CHW cancer screening: changing planned behaviors

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Taylor, et al., 2002 <sup>63</sup> RCT Chinese-American women, Seattle,	Low	G1: Introductory mailing, CHW visit with multimedia and tailored counseling, telephone followup and tailored counseling, logistic assistance as needed	Pap testing planned within 2 years: G1: 72% G2: 59% G3: 48%
Washington, and Vancouver, British Columbia 402 (181 Seattle, 221 Vancouver)		G2: Direct mail multimedia materials G3: Usual care at local clinics and doctors' offices (control)	(G1 vs. G3 <i>P</i> < 0.001, G2 vs. G3 <i>P</i> = 0.05, G1 vs. G2 <i>P</i> = 0.03)
Fair			
Wilson et al., 2008 <sup>116</sup> Repeated cross- sectional survey of women attending salons randomly assigned to experimental and control groups Neighborhood hair salons, Brooklyn, New York 40 salons/1,210 respondents	Moderate	G1: Control, before intervention G2: Stylist group, before intervention G3: Control, after intervention G4: Stylist group, after intervention Intervention consisted of education, counseling, and information on location of screening services during salon appointment	Intention to receive clinical breast examination in next year: G3: 90% G4: 89% AOR, 0.9; adjusted 95% CI, 0.6-1.2 Intention to receive mammogram in next year: G3: 70% G4: 74% AOR, 1.3; adjusted 95% CI, 0.9-1.2
Poor			

CHW, community health worker; CI, confidence interval; G, group; AOR, adjusted odds ratio.

*Behavior: breast self-examination.* Five studies (eight citations; Table 20) reported on changes in self-breast examination as outcomes of CHW interventions.  $^{61,62,108,110-112,116,125}$  Of these five studies, three were of fair quality and two of poor quality.  $^{110-112,116}$  They included one high-intensity,  $^{61,62}$  three moderate-intensity,  $^{110-112,116,125}$  and one low-intensity study.  $^{108}$ 

These studies provide conflicting evidence of the effectiveness of the CHW approach, either in comparison with an alternative or over time independent of a comparison. Two studies reported significant differences between the CHW arm and an alternative (low-intensity CHW, mailed intervention, delayed intervention, or no intervention). The same two studies also provided evidence of significant differences between baseline and followup for the CHW arm. A third study employed repeated cross-sectional measurements and reported higher rates in the followup assessment but these were not statistically significant. The fourth study

Table 20. CHW cancer screening: changing breast self-examination behavior

Erwin et al., 1997 <sup>108</sup> 1997 <sup>108</sup> Prospective cohort  Prospective cohort  Prospective cohort  Church or community groups, rural Mississippi River Delta region, Arkansas  Hiatt et al., 2008 <sup>125</sup> Pair  Hiatt et al., 2008 <sup>125</sup> Prospective cohort  Based organizations to community-prospective cohort  Fair  Hiatt et al., 2008 <sup>125</sup> Prospective cohort  Fair  Hiatt et al., 2008 <sup>125</sup> Forspective cohort  Forsp	Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Fair  Hiatt et al., 2008 $^{125}$	Prospective cohort  Church or community groups, rural Mississippi River Delta region, Arkansas		Project team, composed of 7 local African-American women who had survived breast or cervical cancer, spoke in groups of 2 to 5 at local churches and community organization meetings  G2: Delayed intervention	G1: 69.8% to 82% ( $P$ < 0.005 compared with baseline) G2: 82% to 82% ( $P$ = NS compared with baseline) BSE in the past month (self-report): G1: 49% to 65.4% ( $P$ < 0.001 compared with baseline) G2: 65% to 72% ( $P$ = NS compared with
2008 $^{125}$ events and locations; presentations to community- based organizations (agencies); $X^2 = NR$ , $P = 0.031$ and Women's Health Days, offering free mammograms, Pap clinics and the low-income neighborhoods in San Francisco and Contra Costa County, California events and locations; presentations to community- based organizations (agencies); $X^2 = NR$ , $P = 0.031$ G2: 793 (83)/ 802(81) $X^2 = NR$ , not significant tests, and breast self-examination monthly in the past year (Total N [%] posttest): G1: 800 (24)/808 (26) $X^2 = NR$ , not significant G2: 793 (18)/ 801(23)				
Fair	Prospective cohort Public health clinics and the low-income neighborhoods in San Francisco and Contra Costa County, California 1,616		events and locations; presentations to community- based organizations (agencies); and Women's Health Days, offering free mammograms, Pap tests, and breast self- examination instruction	(Total N [%] pretest/Total N [%] posttest): G1: 800 (89)/810 (92) $X^2 = NR$ , $P=0.031$ G2: 793 (83)/ 802(81) $X^2 = NR$ , not significant Completed breast self-examination monthly in the past year (Total N [%] pretest/Total N [%] posttest): G1: 800 (24)/808 (26) $X^2 = NR$ , not significant

AOR, adjusted odds ratio; BSE, breast self examination; CHW, community health worker; CI, confidence interval; G, group; NR, not reported; NS, not significant; OR, odds ratio; RCT, randomized controlled trial.

Table 20. CHW cancer screening: changing breast self-examination behavior (continued)

Author, Year Study Design			
Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Sung et al., 1997 <sup>61</sup> ; Sung et al., 1992 <sup>62</sup>	High	G1: CHW home visits, education on breast and cervical cancer, BSE educational materials on screening, facilitation to address	Pretest/posttest change in self-report of BSE for entire sample: G1: 52.1%/51.0% G2: 41.1%/41.0%, difference in change:
RCT		logistical barriers to screening	-1.0 (95% CI, -6.1 to 4.1)
Inner-city African Americans, state unspecified		G2: Mailed educational materials on cancer screening	Pretest/posttest change in self-report of BSE, postintervention respondents only: G1: 57.0%/53.8% G2: 40.2%/40.2%, difference in change:
195			-3.2 (95% CI, -17.5 to 11.1)
Fair			Posttest report of BSE, women not previously on recommended screening schedules, whole sample: G1: 24.4% G2: 17.2%, difference in change: 7.2% (95% CI, -5.0-19.3)
			Posttest report of BSE, women not previously on recommended screening schedules, postintervention respondents only: G1: 47.5% G2: 26.2%, difference in change: 21.3% (95% CI, 2.3-40.3)
Navarro et al., 1998, <sup>111</sup> Navarro et al., 1995, <sup>110</sup>	Moderate	G1: CHW delivering community living skills sessions, details NR	Pretest-posttest changes in percentage of women performing monthly BSEs:
Navarro et al., 2000 <sup>112</sup>		G2: CHW delivering cancer education sessions, 12 weekly group sessions conducted over	Participant unit of analysis (n = 361) G1: 18.5 G2: 33.2
RCT		3 months plus 2 additional sessions offered within a year of	<i>P</i> < 0.001
Low-income Latinas, Southeast San Diego County, California		beginning of group meetings	CHW unit of analysis (n = 35) G1: 18.6 G2: 31.8 P = 0.021 t = 2.43
Poor			Odds of monthly BSE at 1-year and 2-year followup for cancer screening group ( <i>P</i> value): Year 1: 2.03 (0.016) Year 2: 0.96 (0.877)

Table 20. CHW cancer screening: changing breast self-examination behavior (continued)

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Wilson et al., 2008 <sup>116</sup> Repeated cross-sectional survey of women attending salons randomly assigned to experimental and control groups  Neighborhood hair salons, Brooklyn,		G1: Control, before intervention G2: Stylist group, before intervention G3: Control, after intervention G4: Stylist group, after intervention  Intervention: provide messages promoting breast health during salon visit	Engaging in BSE in past 3 months: G1: 25% G2: 28%, $P = 0.26$ for differences between G1 and G2 G3: 37% G4: 40% AOR for differences between G3 and G4 1.3; adjusted 95% CI, 0.9-1.7
New York 40 salons/1,210 respondents Poor			

failed to find any improvements over time.  $^{61,62}$  The fifth study found reported conflicting results for the two selected measures.

Of the three fair-quality studies, the high-intensity study compared the CHW arm with a mailed intervention, <sup>61,62</sup> the moderate-intensity study compared the CHW arm (outreach) to no-intervention arm, and the low-intensity CHW arm compared the CHW arm to a delayed intervention. <sup>108</sup> The high-intensity study found no significant improvements over time in either arm, or between arms, except when the sample was restricted to a much reduced subsample who were available at followup and were not on the recommended screening schedule. <sup>61,62</sup> The moderate-intensity study found improvements in the intervention arm over time for ever use of breast self-examination, but no significant differences in the control arm, but also found opposite effects for another measure: monthly breast self-examinations, with significant differences in the control arm over time, but not the intervention arm The low-intensity study found that the CHW arm resulted in significant improvements over time compared with the delayed-intervention arm. <sup>108</sup> However, baseline differences between the two arms were large; significant differences between the two arms could have resulted from ceiling effects.

Of the two poor-quality studies, one moderate-intensity intervention compared a more intense CHW arm with a less intense CHW arm; <sup>110-112</sup> the other moderate-intensity intervention compared the CHW arm with a no-intervention control. <sup>116</sup> In the former study, the two arms differed significantly through 1-year followup but not at the 2-year followup. <sup>110-112</sup> In the latter study, rates of breast self-examination were higher in followup interviews than in baseline interviews, but the differences between the arms was not statistically significant. <sup>116</sup>

Satisfaction. No study reported outcomes for satisfaction.

Health outcomes: No study reported on health outcomes.

Health care utilization: Pap smears. The evidence on the effectiveness of CHW interventions draws upon six studies (nine articles; Table 21). 17,18,61-63,110-112 Most studies demonstrate that the CHW arm is as effective as the alternative in improving Pap smear rates. CHWs were not more effective than mailed interventions in high-intensity interventions. They were more effective than the alternative in limited circumstances involving low- or moderate-intensity intervention in three of four studies. Because intensity may, thus, actually be an important policy variable for analyzing use of Pap smears, we present information on Pap smear use ordered first by intensity and then by the quality of the studies.

Table 21. CHW cancer screening: Pap smears

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Taylor, et al., 2002 <sup>63</sup> RCT	Low	G1: Introductory mailing, CHW visit with multimedia and tailored counseling, telephone followup and tailored counseling, logistic assistance as needed	Self-reported Pap testing completed since intervention: G1: 39%, G2: 25%, G3: 15% (G1 vs. G3, P < 0.001; G2 vs. G3, P = 0.03; G1 vs. G2, P = 0.02)
Chinese- American women, Seattle, Washington, and Vancouver, British Columbia 402 (181 Seattle, 221 Vancouver) Fair		G2: Direct mail multimedia materials G3: Usual care at local clinics and doctors' offices (control)	Medical records for Pap screening received between randomization and followup, using intention-to-treat:  Results not provided, significant differences between outreach worker versus control ( $P$ < .001), direct mail versus control ( $P$ = .07), and outreach worker versus direct mail ( $P$ = .04)  Medical records for Pap screening received in the past 2 years, using intention-to-treat:  Results not provided, significant differences between outreach worker versus control ( $P$ < .001) and direct mail versus control ( $P$ = .03)

CHW, community health worker; CI, confidence interval; G, group; N, number; NCI, National Cancer Institute; NR, not reported; RCT, randomized controlled trial; TV, television.

Table 21. CHW cancer screening: Pap smears (continued)

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Hiatt et al., 2008 <sup>125</sup>	Moderate	G1: One-on-one visits at various events and locations; presentations to community-based organizations	Ever completed Pap smear (logistic regression, 95% CI) Residence in outreach area over time: 1.5
Prospective cohort		(agencies); and Women's Health Days, offering free mammograms, Pap tests,	(0.6-4.2)
Public health clinics and the low-income neighborhoods in San Francisco and Contra Costa County, California		and breast self-examination instruction G2: No intervention (control)	Completed Pap smear in the past 3 years (logistic regression, 95% CI) Residence in outreach area over time: 0.9 (0.6-1.3)
1,616			
Fair			
Mock et al., 2007 <sup>109</sup>	Moderate	G1: CHW small group meetings, direct contact with subjects, Vietnamese language ads for TV/radio/newspaper,	Self-report of having ever had Pap (baseline/followup): G1: 65.8%/81.8% (P < 0.001);
RCT		booklets and printed materials in various community locations	G2: 70.1%/75.5% ( <i>P</i> < 0.001); Z test P = 0.001
Vietnamese-		00.15	0.16
American women, Santa Clara		G2: Vietnamese-language ads for TV/radio/newspaper, booklets and	Self-report of Pap in past year: G1: 45.7%/67.3% ( <i>P</i> < 0.001);
County, California		printed materials in various community locations, delayed educational session	G2: 50.9%/55.7% ( <i>P</i> = 0.035); Z test <i>P</i> < 0.001
968			Ever had Den teet (emeng these what
Fair			Ever had Pap test (among those who had not had Pap test pre-outreach): G1: 46.0 (N = 144); G2: 27.1 (N = 161) P < 0.001

Table 21. CHW cancer screening: Pap smears (continued)

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Navarro et al., 1998; <sup>111</sup> Navarro et al., 1995; <sup>110</sup> Navarro et al., 2000 <sup>112</sup> RCT	Moderate	G1: CHW delivering community living skills sessions, details NR  G2: CHW delivering cancer education sessions, 12 weekly group sessions conducted over 3 months plus 2 additional sessions offered within a year of beginning of group meetings	Pretest-posttest changes in percentages of women who had a Pap test within past year:  Participant unit of analysis (n = 360) G1: 16.2 G2: 23.1 P = 0.096 t = 1.67
Low-income Latinas, southeast San Diego County, California	:		CHW unit of analysis (n = 35) G1: 18.4 G2: 23.4 P = 0.369 t = 0.91
Poor			Odds of Pap smear 1-year and 2-year followup for cancer screening group ( <i>P</i> value): Year 1: 2.10 (0.017) Year 2: 1.70 (0.082)
Paskett et al., 2006; <sup>17</sup> Katz et al., 2007 <sup>18</sup>	High	G1: Control sent letter and NCI brochure about the need for regular cervical cancer screening 6 months	Cervical cancer screening rates within risk-appropriate guidelines:
RCT Community health		after random assignment, followed by letter and NCI brochure about the need for mammography 3 months after followup assessment	Significant differences between baseline and followup for both groups, no significant differences between intervention and control groups
centers, Robeson County, North Carolina		G2: Individualized health education program that was culturally acceptable and tailored to meet the	
820		needs of each woman, intensive face- to-face interactive educational	
Good		program administered over a 9- to 12- month period, consisting of 3 in- person visits, with educational materials provided each visit and followup telephone calls and mailings after	

Table 21. CHW cancer screening: Pap smears (continued)

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Sung et al., 1997; <sup>61</sup> Sung et al., 1992 <sup>62</sup> RCT Inner-city African Americans, state unspecified 195 Fair	High	G1: CHW home visits, education on breast and cervical cancer, breast self-exam, educational materials on screening, facilitation to address logistical barriers to screening  G2: Mailed educational materials on cancer screening	Pretest/posttest change in self-report of receiving Pap smears for entire sample: G1: 50.3%/58.7% G2: 51.9%/62.1%, difference in change: -1.8 (95% CI, -8.0-4.4)  Pretest/posttest change in self-report of receiving Pap smears, postintervention respondents only: G1: 52.7%/63.4% G2: 50.0%/62.7%, difference in change: -2.0 (95% CI, -11.0-7.0)  Posttest rate of self-report of receiving Pap smears, women not previously on recommended screening schedules, whole sample: G1: 33.3% G2: 34.2%, difference in change: -0.9 (95% CI, -15.7-13.9)  Posttest rate of self-report of receiving Pap smears, women not previously on recommended screening schedules, postintervention respondents only: G1: 61.4% G2: 51.0%, difference in change: 10.4 (95% CI, -9.5-30.0)

One low-intensity trial, of fair quality, compared CHWs with direct mail and with usual care in cities in Washington and British Columbia. 63 CHWs were more effective than either alternative in increasing Pap smear rates, using both self-report and medical records.

Of the three moderate-intensity interventions, one in Santa Clara County, California, was of fair quality <sup>109</sup>, a second in San Francisco and Contra Costa was also fair quality, <sup>125</sup> and the third in San Diego County, California, was rated poor quality. <sup>110-112</sup> The fair-quality study in Santa Clara compared CHWs with a media intervention; CHWs were effective in increasing rates of Pap smears. <sup>109</sup> The fair-quality study in San Francisco and Contra Costa found no statistically significant difference in changes in self-reported Pap smears between residents of intervention and control communities. <sup>125</sup> The poor-quality study compared a higher-intensity CHW arm focusing on cancer control with a lower-intensity CHW arm. <sup>110-112</sup> Although both arms demonstrated effectiveness compared with baseline values, participation in the more intense arm did not affect use of Pap smears compared with the less intense arm in the short term, but it did demonstrate effectiveness in the longer term (at 1- and 2-year followups). Followups were

marked by high dropout rates, however, so the effectiveness in the longer term could be explained by selection bias.

Two high-intensity trials, one good-quality study in North Carolina, <sup>17,18</sup> and one fair-quality study among inner-city African Americans (location unspecified), <sup>61,62</sup> compared CHWs to mailed interventions. These two studies reported consistent results failing to demonstrate effectiveness of CHWs in improving Pap smear use compared with mailed interventions, but both studies showed that both arms demonstrated improvement compared with baseline values.

Health care utilization: mammography. Eleven studies (21 articles; Table 22), provide evidence on the effectiveness of CHW intervention with respect to breast cancer screening by mammography. 15,17-22,59-62,103,104,108,110-113,116 Eight of these studies demonstrated significantly greater improvements in the CHW arm compared with the alternative (no intervention, mail, print, or minimal CHW) in either the entire sample or in subsamples. 17-22,59-62,103,104,108,110-113 Two of three studies reporting nonsignificant differences between the CHW arm and the alternative were moderate-intensity, poor-quality studies comparing CHWs with no intervention; 15,116 one of these studies reported nonsignificant differences between the CHW arm and the control, favoring the CHW arm. The third was a moderate-intensity fair-quality study comparing the effect of CHW interventions with controls at the community level. 215 As with use of Pap smears, intensity may be a relevant analytic variable, so we report findings below first by intensity, then by study quality.

Four studies did not report changes over time; <sup>15,17-22,103,104</sup> one study failed to show improvement in the intervention area, <sup>125</sup> and the remaining six studies all demonstrated some improvement in the control arm (no intervention, delayed intervention, mail, print, or minimal CHW), although the improvement was not statistically significant.

Studies conducting subgroup analyses demonstrated that CHW interventions can provide benefits for subpopulations. Four studies provide evidence that CHW interventions are likely to be more beneficial than alternative interventions in low-income, minority populations with some health care barriers. 19-22,60,103,104,113

Low-intensity interventions generally compared CHW with minimal to no intervention, We identified five such studies, one good-quality, <sup>103</sup> two fair, <sup>59,60,108</sup> and two poor. <sup>19-22,104,113</sup> Collectively CHWs were generally effective in raising mammography rates, but with potentially greater effects in subpopulations.

The good study from Washington State, comparing a no-intervention control group with CHW groups receiving community activities, individual counseling, or a combination of community activities and individual counseling found that all the CHW intervention arms had higher rates of new users than the no-intervention control, but the study did not find significantly greater effectiveness of CHW arms in comparison with a no-intervention control. The community activities arm appeared to be more effective than a no-intervention control in preventing relapse (that is, in ensuring that regular users or women who were adherent to recommended screening guidelines at baseline continued to be adherent at followup) than in enrolling new users.

Table 22. CHW cancer screening: mammography

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Andersen, 2000 <sup>103</sup>	Low	G1: Control—no intervention reported	Proportion of mammography rates among regular users
RCT of communities		G2: Community activities—developing social norms	(regular user is more than 1 mammogram, last mammogram within 2 years, and the previous
Rural		G3: Individual counseling—telephone	mammogram within 2 years of the last mammogram) (self-
communities, Washington		G4: Community activities and individual counseling	reported): G1: 0.922 G2: 0.951, difference from G1 =
6,685			0.029, <i>P</i> = 0.01 (95% CI, 0.008-0.052)
Good			G3: 0.918, difference from G1 = 0.004, <i>P</i> = 0.81 (95% CI, -0.043-0.032) G4: 0.936, difference from G1 = 0.014, <i>P</i> = 0.27 (95% CI, -0.013-0.039)
			Proportion for G2+G3+G4: 0.935, difference from G1 = 0.013, P = 0.40 (95% CI, -0.012- 0.038)
			In subgroup analysis, the intervention was more effective than the control in preventing relapse among women who needed >2 hours to get a medical appointment G1: 88.1%, difference in proportions for G2: 7.1% $(P \le 0.01)$ G2: 6.0% $(P \le 0.01)$ G3: 5.6% $(P \le 0.05)$
			Proportion of mammography rates among new users (underusers at baseline) (self-reported): G1: 0.578 G2: 0.599, difference from G1 = 0.021, P = 0.63 (95% CI, -0.080-0.117) G3: 0.606, difference from G1 = 0.028, P = 0.47 (95% CI, -0.064-0.113) G4: 0.604, difference from G1 = 0.026, P = 0.55 (95% CI, -0.062-0.122)

CHW, community health worker; CI, confidence interval; G, group; GEE, generalized estimating equation; ICD, International Classification of Diseases; N, number; NCI, National Cancer Institute; NR, not reported; NS, not significant; OR, odds ratio; RCT, randomized controlled trial; RR, relative risk; t, t-test.

Table 22. CHW cancer screening: mammography (continued)

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Interventi on	Study Groups	Results
Andersen, 2000 <sup>103</sup>			Proportion for G2+G3+G4: 0.603, difference from G1 = 0.025, P = 0.40 (95% CI, -0.035-0.085)
(continued)			In subgroup analysis, among under- users/intervention more effective than control in increasing mammography rates among women within communities without a female physician (G2: 12.4%, G3: 10.5%, G4: 16.5%; $P < 0.05$ ) and among women with no health insurance (G2: 23.2%, G3: 9.9%, G4: 22.1%; $P \le 0.05$ )
Erwin et al., 1997 <sup>108</sup> Prospective cohort  Church or community groups, rural Mississippi River Delta region, Arkansas	Low	G1: Members of a Witness Project team, composed of 7 local African-American women who had survived breast or cervical cancer, spoke in groups of 2 to 5 at local churches and community organization meetings  G2: Delayed intervention (control)	Ever had mammography (self-report): G1: 52.4% to 64.4% ( <i>P</i> < 0.05 compared with baseline) G2: 60.4% to 63.3% ( <i>P</i> = NS compared with baseline)
Fair			
Sauaia et al., 2007; <sup>59</sup> Welsh et al., 2005 <sup>60</sup> Retrospective cohort Church communities, Colorado	Low	G1: Trained peer counselors (Promotoras) delivered health promotion message personally, through meetings held at least bimonthly immediately after mass and through other church events, conducted health groups that met at the home of one of the participants, same newsletter used in the printed intervention  G2: Printed intervention incorporated into church display, bulletin, and/or pulpit announcements	Pretest/posttest mammography rates via ICD codes on Medicaid claims (baseline/followup): Latina-only analysis: G1: 59%/61% G2: 58%/58%, unadjusted rates not significant in either group, GEE model adjusting for insurance group, age, income, rural vs. urban, and disability found increased biennial mammograms in intervention group ( <i>P</i> = 0.03) <sup>59</sup>
Latina-only analysis: 4,739 <sup>59</sup> ; Latina vs. white analysis: 6,696 <sup>60</sup>			Latina vs. white analysis: G1: Latina 25%/30% (unadjusted GEE $P = 0.3$ ); non-Latina 32%/38% (unadjusted GEE $P = 0.4$ )
Fair			G2: Latina 45%/43% (unadjusted GEE $P = 0.27$ ); non-Latina 41%/44% (unadjusted GEE $P = 0.02$ ) <sup>60</sup>

Table 22. CHW cancer screening: mammography (continued)

		,	
Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Sauaia et al., 2007; <sup>59</sup> Welsh et al., 2005 <sup>60</sup> (continued)			Comparison of mammography rates by intervention and ethnicity, via ICD codes on Medicaid claims (pretest-posttest time-intervention interaction term by GEE) Latina: G1 vs. G2 adjusted GEE $P = 0.07$ Non-Latina: G1 vs. G2 adjusted GEE $P = 0.10$
Derose et al., 2000; 19 Dean et al., 2000; 20 Derose et al., 2000; 21 Stockdale et al., 2000; 22 Fox et al., 1998 104  RCT  Church communities, Louisiana 813 Poor	Low	G1: Control churches provided minimal intervention: a library of resource materials on cancer and cancer prevention; assistance with starting a health committee or working with an existing health committee; computer hardware, software, and a printer, as well as computer training for at least 1 church member  G2: 1 session of telephone counseling annually, for 2 years, by peer counselor; counseling individualized to address barriers; churches also received computer support offered to control churches	Nonadherence rate (among baseline adherent): G1: 23.3% G2: 15.8% ( $P = 0.029$ )  Nonadherence rate (among baseline nonadherent): G1: 37.4% G2: 34.8% ( $P = 0.324$ )
Earp et al., 2002 <sup>113</sup> Prospective cohort Black women, eastern North Carolina 801 Poor	Low	G1: Counties receiving CHW and other targeted activity—presentations to community groups and events, one-on-one conversations, use of informational/motivational materials  G2: Comparison counties—no intervention reported	Self-report of mammogram in past 2 years (baseline/followup): G1: 41%/58% G2: 56%/67% (adjusted $P = 0.05$ )  Self-report of mammogram in past 2 years, stratified by income (baseline/followup): < \$12k annually—G1: 37%/59% G2: 49%/60% (adjusted $P = 0.02$ ) \$12k or greater annually—G1: 56%/59% G2: 73%/82% (adjusted $P = 0.92$ )

Table 22. CHW cancer screening: mammography (continued)

Dignan et al., M 2005 <sup>15</sup>		Study Groups	Results
Urban American- Indian women, Denver, Colorado  157 (for intervention groups, N for control NR)  Poor	Moderate	G1: Control interventions NR data from Colorado Mammography Program  G2: Tailored education brochure using data from baseline interview. Face-to-face planned for delivery at participant's home (1 session lasting 20-90 minutes), presenting information on breast cancer and value of early detection, review of brochure  G3: Telephone intervention, as above	Mammograms over past 12 months, self-report (baseline/followup): G1: 51.9%/50.0% G2: 29%/41.8% G3: 34.4%/45.2% Chi-square: G1 vs. G2+G3: 2.68, <i>P</i> = 0.10; <i>P</i> for G2 vs. G3: 0.83; <i>P</i> for G2, pre-changes: 0.029; <i>P</i> for G3, pre-changes: 0.197
	Moderate	G1: One-on-one visits at various events and locations; presentations to community-based organizations (agencies); and Women's Health Days, offering free mammograms, Pap tests, and breast self-examination instruction  G2: No intervention (control)	Ever completed mammography (logistic regression, 95% CI) Residence in outreach area over time: 0.7 (0.5-1.0)  Completed mammography in past 2 years (logistic regression, 95% CI) Residence in outreach area over time: 0.7 (0.5-1.0)  Completed 3 mammographies in past 5 years (logistic regression, 95% CI) Residence in outreach area over time: 0.8 (0.5-1.1)

Table 22. CHW cancer screening: mammography (continued)

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Navarro et al., 1998; 111 Navarro et al., 1995; 110 Navarro et al., 2000 112 RCT Low-income Latinas, southeast San Diego County, California 365 Poor	Moderate	G1: CHW delivering community living skills sessions, details NR  G2: CHW delivering cancer education sessions, 12 weekly group sessions conducted over 3 months plus 2 additional sessions offered within a year of beginning of group meetings	Pretest-posttest changes in percentage of women ≥40 years who had mammogram within past year:  Participant unit of analysis (n = 113) G1: 7 G2: 21.4 P = 0.029 t = 2.22  CHW unit of analysis (n = 33) G1: 6.8 G2: 24.3 P = 0.063 t = 1.96  Odds of mammogram 1-year and 2-year followup for cancer screening group (P value): Year 1: 1.50 (0.484)
Wilson et al., 2008 <sup>116</sup> Repeated cross-sectional survey of women attending salons randomly assigned to experimental and control groups Neighborhood hair salons, Brooklyn, New York 40 salons/1,210	Moderate	Intervention consisted of education, counseling, and information on location of screening services during salon appointment  G1: Control, before intervention  G2: Stylist group, before intervention  G3: Control, after intervention  G4: Stylist group, after intervention	Year 2: 3.88 (0.018)  Mammogram in past 3 months: G1: 13% G2: 14% AOR, 1.1 (95% CI, 0.8-1.7)
respondents			

Table 22. CHW cancer screening: mammography (continued)

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Paskett et al., 2006; <sup>17</sup> Katz et al., 2007 <sup>18</sup> RCT Community health centers, Robeson County, North Carolina 820 Good	High	G1: Sent control letter and NCI brochure about the need for regular cervical cancer screening 6 months after random assignment, followed by letter and NCI brochure about the need for mammography 3 months after followup assessment  G2: Individualized health education program that was culturally acceptable and tailored to meet the needs of each woman, intensive face-to-face interactive educational program administered over a 9- to 12-month period, consisting of 3 in-person visits, with educational materials provided each visit and followup telephone calls and mailings after	Mammogram receipt from medical record data: G1: 27.3% G2: 42.5%, RR, 1.56; 95% CI, 1.29-1.87, P < .001  Significant differences within racial groups as well
Sung et al., 1997; <sup>61</sup> Sung et al., 1992 <sup>62</sup> RCT Inner-city African Americans, state unspecified 195 Fair	High	G1: CHW home visits, education on breast and cervical cancer, breast self-exam, educational materials on screening, facilitation to address logistical barriers to screening  G2: Mailed educational materials on cancer screening	Pretest/posttest change in self-report of receiving mammography for entire sample: G1: 35.5%/50.4% G2: 34.3%/39.4%, difference in change: 9.8% (95% CI, 2.9-16.7)  Pretest/posttest change in self-report of receiving mammography, postintervention respondents only: G1: 32.5%/58.7% G2: 34.0%/47.9%, difference in change: 12.4% (95% CI, 1.0-24.3)  Posttest rate of self-report of receiving mammography, women not previously on recommended screening schedules, whole sample: G1: 29.7% G2: 24.4%, difference in change: 5.8% (95% CI, -7.0-18.6)  Posttest rate of self-report of receiving mammography, women not previously on recommended screening schedules, postintervention respondents only: G1: 50.0% G2: 35.5%, difference in change: 14.5% (95% CI, 4.5-23.6)

One fair-quality study involved Latinas in Colorado enrolled in Medicare or Medicaid fee-for-service, or three other health maintenance organizations (Kaiser Permanente of Colorado, Access, and Anthem Blue Cross and Blue Shield). <sup>59</sup> It found nonsignificant and modest differences in mammography screening rates in unadjusted analyses that compared a CHW intervention with a printed intervention. In adjusted analysis, the difference between the two arms was statistically significant, favoring the CHW arm. The other fair-quality study, in Arkansas, also reported significantly greater improvements in self-reported use of mammography in the CHW arm compared with a delayed intervention arm. However, the two groups differed significantly at baseline, with higher rates of ever-use of mammography reported in the control group; thus a ceiling effect limiting improvements in the control group cannot be ruled out. <sup>108</sup>

The two poor-quality, low-intensity studies also suggested favorable results for the CHW arm compared with a minimal <sup>19-22,104</sup> or no-intervention arm <sup>113</sup> for the entire sample or for subpopulations.

Four moderate-intensity interventions, one of fair quality <sup>125</sup> and three of poor quality, <sup>15,110-112,116</sup> reported outcomes for self-reported mammography use. The fair-quality study in San Francisco and Contra Costa found no statistically significant difference in changes in self-reported mammography between intervention communities and control communities. <sup>125</sup> One study in New York, which compared CHW with no-intervention controls, found no significant differences between intervention and control arms after the intervention in use of mammography during the prior 3 months. <sup>116</sup> Both studies described measure effects at the community level rather than at the individual level. Low penetration of the intervention and potential contamination between experimental and control samples limit the interpretation of the results.

Two other studies, both assessed as moderate intensity overall, compared higher-intensity CHW to lower-intensity CHW intervention; <sup>15,110-112</sup> they both reported improvements in both arms. Only the study in San Diego County, California, found significant differences; it demonstrated that the relatively more intense arm was more effective in the 3- to 6-month period following the intervention. <sup>110-112</sup> These improvements were not consistently significantly different between the two arms over the long run (1- and 2-year followups) for a reduced and potentially self-selected subsample.

Two high-intensity trials, one good-quality<sup>17,18</sup> and one fair-quality,<sup>61,62</sup> both compared CHWs to mailed interventions and reported improvements in the CHW arms of their studies. Only the good-quality study (using Medicaid records from North Carolina) found significant differences in mammography rates between the CHW arm and the mailed intervention arm.<sup>17,18</sup> The fair-quality study, using self-reported mammography among inner-city African Americans (location unspecified), did not find any significant differences for the overall sample using intention-to-treat analysis, but it did report significant differences when analysis was limited to a potentially biased subsample of respondents available at followup.<sup>62,129</sup>

Four studies found evidence of effect modification in subgroup analysis. <sup>19-22,60,103,104,113</sup> The evidence is derived from low-intensity studies of varying quality. The good-quality study from Washington found that CHW intervention arms were more effective than a control arm in subgroups: among regular users (women adherent at baseline), the CHW intervention arms showed significantly greater rates of mammography use among women who needed less than 2 hours to schedule a medical appointment. <sup>103</sup> In the same study, subgroup analysis for under-users (women who were not adherent at baseline) found that the CHW interventions were significantly more effective than the no-intervention control among women without female doctors or

insurance. These subgroup findings suggest that the CHW approach is effective in addressing some, but not all, access barriers to the use of mammography.

The fair-quality study from Colorado<sup>59,60</sup> reported weak but slightly more powerful effects of the CHW approach compared with a printed intervention approach in increasing mammography rates among Medicaid-enrolled Latinas compared with non-Latina whites (P = 0.07 for Latinas, and P = 0.10 for non-Latina whites).<sup>60</sup> Similarly, the poor-quality studies also suggested subgroup effects. One study found CHWs to be more effective than a no-intervention control group in increasing rates of self-reported mammography for the overall sample and in groups with incomes below \$12,000, but not in groups with incomes equal to or exceeding \$12,000. Another found that the CHW approach was more effective than with a minimal intervention approach in ensuring conversion to adherence among under-users rather than in maintaining adherence among regular or adherent users.

Health care utilization: clinical breast examination. Four studies reporting on clinical breast examination (seven articles; Table 23)<sup>61,62,110-112,116</sup> included a high-intensity and three moderate-intensity interventions. Two of these studies were of fair quality;<sup>61,62,125</sup> the other two were rated poor. Together the studies suggest that CHW interventions are not effective in comparison with other alternatives, although two studies that provide information on changes between baseline and followup found that the CHW arm results in improvements over time.

The fair-quality high-intensity trial found no differences between the CHW arm and a mailed intervention, with the exception of a reduced and possibly selective sample of respondents only at followup. The fair-quality moderate-intensity study found no difference over time in most measures of self-reported clinical breast examination in intervention communities or control communities. Of the two poor-quality moderate-intensity studies, one trial compared a more intense CHW arm with a less intense CHW arm and the cross-sectional study compared it with a no-intervention arm. Neither study reported significant differences, although the women in the more intense CHW arm of the trial did report higher rates of clinical breast examination after the intervention.

Health care utilization: colorectal cancer screening. Two studies, one of moderate intensity and fair quality, and another of low intensity and poor quality compared three groups on outcomes for fecal occult blood tests (FOBT) and other colorectal cancer screening tests (Table 24). <sup>107</sup> In the fair-quality moderate-intensity intervention, patients who received navigation services had higher rates of FOBT after three months of services than patients who received usual care, but these differences were not statistically significant. Patients receiving navigation services were significantly more likely than controls to have set an endoscopy appointment at three months and kept it by six months after the intervention. <sup>106</sup> The low-intensity poor-quality study reported that rates of FOBT were higher in the CHW arm over time; however, the CHW arm and the comparison arms of a no-intervention control or of tailored print and videotapes did not differ significantly. The study reported no benefit of the intervention for other colorectal screening tests.

Table 23. CHW cancer screening: clinical breast examination

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Sung et al., 1997 <sup>61</sup> ; Sung et al., 1992 <sup>62</sup> RCT	High	G1: CHW home visits, education on breast and cervical cancer, breast self-exam, educational materials on screening, facilitation to address logistical barriers to screening	Pretest/posttest change in self-report of receiving CBE for entire sample: G1: 55.2%/64.5% G2: 55.7%/59.5%, difference in change: 4.9 (95% CI, -6.1-4.1)
Inner-city African Americans, state unspecified 195 Fair		G2: Mailed educational materials on cancer screening	Pretest/posttest change in self-report of receiving CBE, postintervention respondents only: G1: 59.1%/72.0% G2: 57.8%/61.8%, difference in change: 8.9% (95% CI, 1.1-16.7)  Posttest rate of self-report of receiving CBE,
			women not previously on recommended screening schedules, whole sample: G1: 37.0% G2: 28.6%, difference in change: 8.4% (95% CI, -6.9-23.7)
			Posttest rate of self-report of receiving CBE, women not previously on recommended screening schedules, postintervention respondents only: G1: 71.1% G2: 46.5%, difference in change: 24.6% (95% CI, 3.9-45.3)
Hiatt et al., 2008 <sup>125</sup> Prospective cohort Public health	Moderate	G1: One-on-one visits at various events and locations; presentations to community-based organizations (agencies); and Women's Health Days, offering free mammograms, Pap tests, and breast self-examination instruction	Ever completed clinical breast examination (Total N [%] pretest/Total N [%] posttest): G1: 801 (94)/812 (95) $X^2 = NR$ , not significant G2: 798 (82)/ 803 (87) $X^2 = NR$ , $P = 0.006$
clinics and the low-income neighborhoods in San Francisco and Contra Costa County, California		G2: No intervention (control)	Completed clinical breast examination in past year (Total N [%] pretest/Total N [%] posttest): G1: 800 (75)/809 (74) $X^2 = NR$ , not significant G2: 796 (56)/ 803 (60) $X^2 = NR$ , not significant
1,616 Fair			Completed 3 or more clinical breast examinations in past 5 years (Total N [%] pretest/Total N [%] posttest): G1: 793 (73)/809 (73) $X^2 = NR$ , not significant G2: 792 (54)/ 800 (54) $X^2 = NR$ , not significant

Adj, adjusted; CBE, clinical breast examination; CHW, community health worker; CI, confidence interval; NR, not reported; OR, odds ratio; RCT, randomized controlled trial; t, t-test.

Table 23. CHW cancer screening: clinical breast examination (continued)

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Navarro et al., 1998; <sup>111</sup> Navarro et al., 1995; <sup>110</sup> Navarro et al., 2000 <sup>112</sup> RCT  Low-income Latinas, southeast San Diego County, California 365  Poor	Moderate	G1: CHW delivering community living skills sessions, details NR  G2: CHW delivering cancer education sessions, 12 weekly group sessions conducted over 3 months plus 2 additional sessions offered within a year of beginning of group meetings	Pretest-posttest changes in percentage of women who had CBE within past year:  Participant unit of analysis (n = 359) G1: 15.5 G2: 17.7 P = 0.589 t = 0.54  CHW unit of analysis (n = 35) G1: 19.3 G2: 19.5 P = 0.967 t = 0.04  Odds of CBE 1-year and 2-year followup for cancer screening group (P value): Year 1: 1.21 (0.556) Year 2: 1.93 (0.038)
Wilson et al., 2008 <sup>116</sup> Repeated cross-sectional survey of women attending salons randomly assigned to experimental and control groups  Neighborhood hair salons, Brooklyn, New York  40 salons/1,210 respondents	Moderate	Intervention consisted of education, counseling, and information on location of screening services during salon appointment  G1: Control, before intervention G2: Stylist group, before intervention G3: Control, after intervention G4: Stylist group, after intervention	CBE in past 3 months: G1: 27% G2: 27%, <i>P</i> = 0.85 for differences between G1 and G2 G3: 27% G4: 29% AOR, 1.2; adjusted 95% CI, 0.9-1.7
Poor			

Table 24. CHW cancer screening: colorectal cancer screening

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Jandorf et al., 2005 RCT East Harlem, New York City 78 Fair	Moderate	G1: Patient navigator (education and assistance with screening and navigation process)  G2: Usual care	Completed FOBT after 3 months (%): G1: 42.1 G2: 25.0 $P = 0.086$ Had endoscopy appointment at 3 months (%): G1: 18.4 G2: 0 $P = 0.005$ Completed endoscopy at 3 months (%): G1: 15.8 G2: 5.0 $P = 0.115$ Completed endoscopy at 6 months (%): G1: 23.7 G2: 5.0 $P = 0.019$
Campbell, 2004 <sup>107</sup> RCT  African-American rural churches, North Carolina  NR (12 churches; completers/dropouts of individual participants from each church NR)  Poor	Low	G1: Control churches were offered health education sessions and speakers on topics of their choice not directly related to study objectives  G2: Organized and conducted at least 3 church-wide activities on spreading information and enhancing support for healthy lifestyle and CRC screening (LHA)  G3: 4 personalized computer-tailored newsletters and 4 targeted videotapes corresponding to the same behaviors mailed to participants' homes bimonthly for first 6 months after baseline data collection; 4th targeted videotape mailing was 9 months after baseline G4: LHA and targeted videotapes	FOBT test in past year (% baseline/% followup): G1: $30.4\%/21.7\%$ G2: $23.5\%/33.3\%$ G3: $19.7\%/36.8\%$ G4: $19.5\%/31.0\%$ $P = 0.08$ Other CRC test in past year (% baseline/% followup): G1: $20.3\%/27.5\%$ G2: $19.6\%/25.5\%$ G3: $23.7\%/21.1\%$ G4: $26.4\%/14.9\%$ $P = ns$

CRC, colorectal cancer; FOBT, fecal occult blood test; LHA, lay health advisor; NR, not reported; ns, not significant; RCT, randomized controlled trial.

## **Outcomes for Chronic Disease Management**

**Chronic disease management: diabetes mellitus.** *Study characteristics.* Four studies (eight articles; Table 25), three RCTs, <sup>27,88-92,124</sup> and one prospective cohort study <sup>93</sup> examined outcomes of CHW interventions for diabetes care among underserved minority populations with type 2

diabetes mellitus. All studies were rated fair quality. Three studies<sup>27,88-93</sup> used a high-intensity intervention; one study<sup>124</sup> used a moderate-intensity intervention.

Table 25. CHW chronic disease management: diabetes mellitus

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Beckham, 2008 <sup>93</sup>	High	G1: Diabetes case management by CHW, including home visits, based on needs of patients; CHWs collaborate with	HgbA1c, mean change from baseline (SD): G1: -2.2 (1.8)
Cohort		multidisciplinary team to determine high- priority learning areas and develop an intervention plan to implement during	G2: -0.2 (1.5) P < 0.0001*
Health center for underserved with type 2 diabetes		subsequent visits, plan included a blood regimen and target levels, diet plan, exercise plan, medication schedule, insulin injection plan, and preventive health/health maintenance plan	*Note on <i>P</i> value: the investigators did not report a value comparing the groups; RTI researchers calculated the value using the data in the article
Hawaii		·	
N: 116		G2: Usual care with multidisciplinary team approach, minus CHW; glucose self-monitoring	
Fair		5	
Corkery, 1997 <sup>124</sup>	Moderate	G1: Intervention—CHW acted as liaison, attended clinic sessions, interpreted, reinforced self-care instructions and	Diabetes education program completion: G1: 80%
RCT		appointment reminders	G2: 47% (P = 0.01)
Hispanic and African- American populations in East Harlem, New York City, New York		G2: Encounters occurred between nurse and patient only (control)	No difference in mean change in HgbA1c between groups
N: 64 Fair			

Approx, approximately; CHW, Community Health Worker; DKQ, Diabetes Knowledge Questionnaire; HgbA1c, Hemoglobin A1c; LDL, low-density lipoprotein; NCM, nurse case manager; RCT, randomized controlled trial; RN, Registered nurse; SBP, systolic blood pressure.

Table 25. CHW chronic disease management: diabetes mellitus (continued)

n	
Intensity of CHW Intervention Study Groups	Results
High  G1: Usual care—continued on-going care from their own health professionals plus quarterly newsletter containing information on diabetes-related health topics  G2: NCM intervention—RN + certified diabetes educator, 45-minute face-to-face clinic visits and/or telephone contacts, direct patient care, management, education, counseling, followup, referral, physician feedback—goal was 3 visits per year  e,  G3: CHW intervention—45 to 60-minute face-to-face home visits and/or telephone contacts, no direct implementation of therapeutic strategies but facilitated preventive care by offering to schedule appointments and provide education, 3 visits per year  G4: Combined NCM plus CHW—3 visits per year with each	HgbA1c, mean change from baseline at 2 years: G1: ref G2: -0.31 ± 0.49% G3: -0.30 ± 0.48% G4: 0.8 ± 0.52% ( <i>P</i> < 0.05 for withingroup change from baseline for G4 only)  LDL, mean change from baseline at 2 years: G1: -16.7± 5.5 mg/dl G2: +6 (approximate) ( <i>P</i> < 0.05 for within-group change from baseline) G3: +6 (approximate) G4: +4 (approximate) ( <i>P</i> < 0.05 for within-group change from baseline) SBP, mean change from baseline at 2 years: G1: ref G2: +6 (approximate) ( <i>P</i> < 0.05 for within-group change from baseline) G3: -4 (approximate) G3: -4 (approximate) Dietary risk scores—validated, mean change from baseline at 2 years:
	change from baseline at 2 years: G1: ref G2: -2.4 ± 1.99 G3: -3.45 ± 1.87 G4: -2.13 ± 1.92
High  G1: A team of 2 promotoras delivered 8 weekly, 2-hour participative group classes and followup to intervention group, using multiple audiovisual teaching aids and handouts, contacted class participants by telephone biweekly to answer questions, reinforce education, promoted behavior change, sent postcards biweekly  G2: Usual care by clinic staff—verbal information and 1 or 2 pamphlets on diabetes self-management	HgbA1c at baseline (SD)/ 6 months (SD): G1: 8.21 (2.2)/7.76 (1.87) G2: 7.71 (1.49)/8.01 (1.8) Mean change between groups: P < 0.001
	information and 1 or 2 pamphlets on

The 6-month RCT conducted in Texas used a high-intensity intervention for Mexican Americans that compared eight weekly, 2-hour group classes with promotoras to usual care plus educational pamphlets.<sup>27</sup> The RCT in New York City used a moderate-intensity intervention for inner-city Hispanics and African Americans that evaluated the use of CHWs as clinic liaisons compared with nurse-patient encounters.<sup>124</sup> The Project Sugar trial RCT in Baltimore, Maryland, compared several high-intensity interventions in inner-city African Americans with type 2 diabetes: (1) CHW face-to-face home visits and telephone contact, (2) nurse care manager intervention, (3) a combined nurse care manager and CHW, and (4) standard clinical care with an additional quarterly diabetes newsletter.<sup>88-92</sup> The prospective cohort study in Hawaii examined a high-intensity intervention comparing CHW diabetes case management, including home visits, in addition to a multidisciplinary team, with usual clinical care involving a multidisciplinary team approach.<sup>93</sup> Heterogeneity of population, study designs, interventions, and outcomes preclude quantitative synthesis of results.

Overview of results. Of these four studies on diabetes management, two studies found the CHW intervention to be beneficial in decreasing hemoglobin A1c (HgbA1c) as compared with usual care; 27,93 conversely, two studies found no difference between groups in mean change from baseline in HgbA1c. 88-92,124 The Texas study also evaluated outcomes of knowledge and found that the CHW intervention was effective compared with usual clinical care in increasing diabetes knowledge. The Hawaii study found that diabetes case management by a CHW in conjunction with a multidisciplinary team was more effective at decreasing HgbA1c than a multidisciplinary team alone. The New York study demonstrated that a CHW liaison was more effective than usual clinical care in behavioral changes leading to program completion rates. Project Sugar, a high-intensity study, found significant changes from baseline within, but not between, groups for various health outcomes.

*Knowledge*. The Texas study evaluated outcomes for improved knowledge at 6 months in diabetic patients following eight weekly CHW-led group classes in Mexican Americans. A validated tool, the bilingual Diabetes Knowledge Questionnaire (DKQ), showed a difference between arms, with an improved score in the CHW group compared with the group receiving usual care plus educational pamphlets (P < 0.002).

*Behavior*. Project Sugar evaluated dietary risk scores (which identifies positive as well as problematic dietary behaviors and measures potential barriers to dietary change). Scores improved across all CHW arms as compared with the usual clinical care group following a high-intensity CHW intervention (all CHW arms versus usual clinical care [score  $\pm$  standard deviation]: -2.4  $\pm$  1.99 versus -3.45  $\pm$  1.87 versus -2.13  $\pm$  1.92; *P* not reported). <sup>88-92</sup> The New York study demonstrated an increased proportion of completion of a diabetes education program after a low-intensity CHW intervention compared with usual clinical care (80 percent versus 47 percent, P = 0.01). <sup>124</sup>

Satisfaction. No study reported outcomes about satisfaction with diabetes care.

*Health outcomes*. The Texas trial demonstrated better improvement in diabetes control (measured by mean change in HgbA1c) in the high-intensity CHW intervention group than in the usual care group after 6 months (P < 0.001). The Hawaii study found that a high-intensity CHW intervention in conjunction with a multidisciplinary team was more effective in decreasing mean HgbA1c when compared with usual care with a multidisciplinary team (-2.2 versus 0.2). The Hawaii study investigators did not report P value comparing the groups; we were able to calculate it using the data provided in the article and found the difference to be statistically significant (P < 0.0001). Project Sugar reported no significant change between the four study

groups for the primary outcome, HgbA1c. The only group with a significant improvement from baseline to 2 years was the CHW plus nurse care manager arm (improvement of 0.8 percent  $\pm$  0.52 percent, P < 0.05). Res-92 Postintervention, a power calculation showed the study was powered to detect a difference of only 1.2 percent change in HgbA1c. Secondary outcomes from Project Sugar included low density lipoprotein (LDL) cholesterol, systolic blood pressure, and diastolic blood pressure; none differed significantly between study groups in change from baseline measures. LDL cholesterol changed for the worse within the CHW plus nurse care manager arm (+4 mg/dl, P < 0.05). Res-92

Health care utilization. No study evaluated diabetes care utilization.

**Chronic disease management: hypertension.** *Study characteristics.* Four studies (five articles; Table 26), two RCTs<sup>23,98,99</sup> and two prospective cohorts, <sup>94,95,123</sup> examined outcomes of moderate-intensity CHW interventions for blood pressure management among adult patients with hypertension. We rated one study as fair quality and three as poor quality. All four studies evaluated a CHW intervention compared with an intervention that involved a CHW in a lesser capacity. <sup>23,94,95,98,99,123</sup> The two RCTs, one fair <sup>98</sup> and one poor <sup>99</sup> quality, evaluated CHW interventions in inner-city minority populations. <sup>23,98,99</sup>

Table 26. CHW chronic disease management: hypertension

Author, Year Study Design			
Population			
Setting	Intensity of		
Sample Size	CHW		
Quality		Study Groups	Results
Levine, 2003 <sup>98</sup>	High	G1: G2 care plus 5 CHW visits with blood	Pre/postintervention blood
		pressure measurement, addressing issues of	pressure (systolic/diastolic):
RCT		blood pressure management and access to	G1: 147.7/89.2 (95% CI, 145.5-
		medical care	149.9/87.8-90.6) → 145/86.2
African Americans in			(95% CI, 142.3-147.7/84.2-88.2)
inner-city Baltimore,		G2: CHW home visit for education, counseling,	G2: 148.6/89.3 (95% CI, 146.4-
Maryland		and referral	$150.7/87.8-90.8) \rightarrow 142.1/84.7$
			(95% CI, 138.8-145.4/82.7-86.7)
N: 789			P < 0.05 for differences between
			baseline and followup for each
Fair			group, $P > 0.1$ between groups
			Percentage with adequate
			hypertension control (< 140/90):
			G1: 16% → 36%
			G2: 18% → 34%
			pre/post <i>P</i> < 0.01
			group difference NS
Ward, 2000; <sup>99;</sup>	Moderate	G1: CHW post-clinic appointment counseling	Percentage with blood pressure
Morisky, 2002 <sup>23</sup>		session	control (< 140/90)—baseline/
Menory, 2002		00001011	6 months/12 months:
RCT		G2: Appointment reminder cards and telephone	
1.01		calls	G1: 35.2%/46%/46% (P < 0.01)
Inner-city African		CallS	G2: 40.2%/42%/48% ( <i>P</i> < 0.01)
Americans and Hispanics		G3: Home visits by CHW	G3: 29.7%/NR but "improved"
•		Go. Home visits by Crivv	G4: 36.9%/NR but "improved"
in a large West Coast city		G4: Standard clinic care	G4. 36.9%/NR but improved
N: 1 267		G4. Standard Cliffic Care	All groups improved: differences
N: 1,367			All groups improved; differences
Door			between groups NR
Poor			

CHW, community health worker; NS, not significant; RCT, randomized controlled trial.

Table 26. CHW chronic disease management: hypertension (continued)

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Frate, 1983 <sup>95</sup> Frate,1985 <sup>94</sup>	High	G1: Hypertension health counselors—monthly visits that encouraged compliance to both	Proportion of hypertensives controlled (< 160/95):
Prospective cohort		pharmacological and nonpharmacological therapy that had been prescribed	G1: 80.6% G2: 90.0% G3: 79.9%
Rural central Mississippi		G2: Family-based self-help	(P < 0.0001)
N: 667		G3: Church-based self-help	
Poor			
Bone, 1989 <sup>123</sup>	Moderate	G1: Control (not able to be contacted by CHW)	Returned to emergency department for followup
Prospective cohort		G2: Contacted by CHW; initially, all patients contacted by CHWs in emergency department;	appointment:
Low-income African Americans in emergency department in Baltimore, Maryland N: 722		CHWs measured pulse and blood pressure, provided educational counseling, identified barriers related to referrals, assisted with appointment-keeping and adherence to treatment plan; session lasted about 20 minutes	G2: 60% ( <i>P</i> < 0.001)
Poor			

The fair-quality trial from Baltimore, Maryland, evaluated a CHW home visit for patient education, counseling, and referral compared with a CHW home visit plus five additional visits for blood pressure measurement and management, and access to medical care. The poor-quality RCT from the West Coast, rated as such because of a high attrition rate, use of a completers analysis, and high potential for bias, evaluated CHW postclinic appointment counseling sessions, CHW home visits, appointment reminder cards and calls, and standard clinical care. 23,99

The prospective cohort study from rural central Mississippi, which we rated as poor quality because of a high potential for confounding and inappropriate statistical methods, evaluated a moderate-intensity CHW intervention using CHWs as "hypertension health counselors" in providing monthly visits encouraging compliance with previously prescribed pharmacological and nonpharmacological therapies. <sup>94,95</sup> The other prospective cohort study from Baltimore, Maryland, which we rated poor because of a lack of methods describing an analysis plan a priori, a high potential for confounding, and lack of comparison of participant characteristics at baseline, evaluated a moderate-intensity CHW intervention.. <sup>123</sup> It examined the impact on appointment followup of a CHW followup telephone call after an emergency department visit during which patients had their blood pressure measured, were provided education counseling, and were assisted with appointment keeping and adherence to a treatment plan. The comparison group included patients who had received a single CHW visit in the emergency department but who could not be reached later for assistance in appointment keeping. <sup>123</sup> Heterogeneity of study designs, interventions, and outcomes preclude quantitative synthesis of results.

Overview of results. We did not find any fair- or good-quality studies that compared the impact of a CHW intervention with usual care on blood pressure control. Of the three studies that evaluated blood pressure control, only the Mississippi prospective cohort demonstrated a significant difference between study groups in terms of proportion of hypertensive subjects controlled (defined in this study as blood pressure less than 160/95). Neither RCT demonstrated between-group differences in blood pressure control. Above However, these studies did note improvement from baseline to study completion within all groups, some of which were statistically significant. Baltimore prospective cohort did not evaluate blood pressure control but instead examined health care utilization. This study demonstrated that CHW worker followup was more effective than no followup in increasing return visit appointment rates.

*Knowledge*. No study reported improved knowledge.

Behavior. No study reported improved behaviors.

Satisfaction. No study reported satisfaction outcomes.

Health outcomes. We did not find any fair- or good-quality studies that compared the impact of a CHW intervention with usual care on blood pressure control. Three of the four studies did report on blood pressure control. Both RCTs found an improvement within most groups but no difference between groups in terms of blood pressure control. <sup>23,98,99</sup> The fair-quality RCT demonstrated that the low-intensity CHW arm (1 home visit) and the high-intensity CHW arm (6 home visits) both improved blood pressure control. However, the difference between the groups was not statistically significant. <sup>98</sup> The poor-quality RCT also demonstrated an improvement in blood pressure within all groups, including the usual care arm, but no significant difference between groups. <sup>23,99</sup> The Mississippi prospective cohort study did not report statistical tests for either between- or within-group comparisons. <sup>94</sup>

Health care utilization. The poor-quality prospective cohort in a Baltimore emergency department demonstrated that patients in the low-intensity CHW intervention were more likely to return for a followup appointment than were patients in the comparison group (60 percent versus 40 percent, P < 0.001). However, the comparison patients were not able to be contacted for followup by the CHW, thus biasing the results for this outcome in favor of the intervention arm.  $^{123}$ 

Chronic disease management: infectious diseases. *Study characteristics*. One RCT of fair quality examined outcomes of a CHW intervention to facilitate access to health care for tuberculosis (TB) in a homeless population with positive purified protein derivative (PPD) test results in San Francisco, California (Table 27). This study used a moderate-intensity model. CHWs who were familiar with homelessness were assigned to TB-infected individuals and responsible for accompanying them to their clinic appointments. Outcomes were compared with outcomes for a group receiving a monetary incentive to attend the TB clinic in addition to an appointment and bus tokens and with a control group who were given clinic appointments and bus tokens.

*Overview of results.* This RCT demonstrated that a CHW intervention was less effective than the monetary incentive but more effective than usual care in leading to adherence to a first followup appointment.<sup>122</sup>

*Knowledge*. This RCT did not report outcomes for improved knowledge.

*Behavior*. This RCT did not report outcomes for improved behaviors.

Satisfaction. This RCT did not report outcomes of satisfaction.

*Health outcomes.* This RCT did not report outcomes of health.

Table 27. CHW chronic disease management: infectious diseases

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Pilote, 1996 <sup>122</sup>	Moderate	G1: Peer health advisor—met with patient and took them to clinic	Adherence to first followup appointment (95% CI):
RCT		appointment, facilitated paperwork, reviewed physician recommendations	P calculated vs. G3
Homeless people			G1: 75% (70-80); ( <i>P</i> = 0.004)
with positive purified protein deriviative for		G2: Monetary incentive—\$5 at clinic, appointment, and bus tokens	G2: 84% (76-92); ( <i>P</i> < 0.001) G3: 53% (47-59)
tuberculosis in San Francisco, California		G3: Usual care—appointment and bus tokens	
N = 244			
Fair			

CI, confidence interval; RCT, randomized controlled trial.

*Health care utilization*. A moderate-intensity CHW intervention was less effective than a monetary incentive (\$5) in increasing adherence to a first followup clinic appointment (75 percent [95% CI, 70-80] versus 84 percent [95% CI, 76-92], P = not reported). However, the CHW intervention was more effective than a control group who received an appointment and bus tokens (75 percent [95% CI, 70-80] versus 53 percent [95% CI, 47-59], P = 0.004). 122

**Chronic disease management: back pain.** *Study characteristics.* One RCT of fair quality evaluated a moderate-intensity intervention of four 2-hour weekly group classes led by CHWs compared with usual care supplemented by a book on back pain (Table 28). The classes focused on applying problem-solving techniques for back pain self-management and included educational materials (book and videos) supporting active management of back pain. 114

*Overview of results.* This fair-quality RCT found that a moderate-intensity CHW intervention was significantly effective in reducing back pain when compared with a control group at 6 months; the groups did not differ significantly at 12 months.<sup>114</sup>

Knowledge. This RCT did not report outcomes for improved knowledge.

Behavior. This RCT did not report changes in participant behavior.

Satisfaction. This RCT did not report outcomes of satisfaction.

Health outcomes. The moderate-intensity CHW intervention was more effective in decreasing participant back pain than usual care supplemented by a book on back pain at 6 months. Hore participants in the intervention arm achieved a 50 percent or greater reduction in Roland Disability Score from baseline than in the control group at 6 months (47.9 percent versus 33 percent, P = 0.02). However, Roland Disability Scores at 12 months did not differ between arms  $(5.75 \pm 6.31 \text{ versus } 6.75 \pm 6.39, P = 0.092)$ . The authors attributed this lack of difference to the fact that the intervention was intended not to reduce pain intensity but rather to lower patient worries about back pain. Additionally, participants receiving a CHW intervention had a lower worry rating (unvalidated tool) than those in the control group at 12 months  $(2.63 \pm 2.58 \text{ versus } 3.83 \pm 3.08, P = 0.013)$ .

Table 28. CHW chronic disease management: back pain

Author, Year Study Design Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Von Korff, 1998 <sup>114</sup>	Moderate	G1: 4, 2-hour classes held once a	"The next time I have back or leg pain, I
RCT		week, with 10 to 15 participants, led by 2 CHWs	will try to manage the problem without seeing a health professional" (not
People with chronic		G2: Usual care includes back pain	validated): G1: 77% agreed
back pain in		book	G2: 60% agreed ( <i>P</i> = 0.008)
Washington state		book	32. 00% agroba (r = 0.000)
rraeimigien etate			50% or greater reduction in Roland
N = 255			Disability Questionnaire Score from baseline at 6 months (validated):
Fair			G1: 47.9%
i dii			G2: 33% ( <i>P</i> = 0.02)
			Roland Disability at 12 months
			(validated):
			G1: 5.75 (6.31)
			G2: 6.75 (6.39) ( <i>P</i> = 0.092)
			Worry rating (0-10) at 12 months (not
			validated):
			G1: 2.63 (2.58)
			G2: 3.83 (3.08) (P = 0.013)

CHW, community health worker; RCT, randomized controlled trial.

*Health care utilization.* This RCT did not report on health care utilization.

Other. Participants in the CHW arm reported being more likely to self-manage back or leg pain than those in the control arm, a measure of self-efficacy (77 percent versus 60 percent, P = 0.008). <sup>114</sup>

Chronic disease management: mental health. *Study characteristics*. One RCT of poor quality with three trial arms evaluated an assertive community treatment with a CHW intervention compared with an assertive community treatment alone and with a brokered case management intervention (Table 29). The study population included people in St. Louis, Missouri, who were homeless or at risk for being homeless and were diagnosed with serious psychiatric diagnoses. The CHWs' role was to assist with daily living and be available for leisure activities. This intervention was rated as high-intensity as defined in KQ 1. A high rate of attrition (only 85 of 165 provided followup) contributed to the poor-quality rating of this study. 120,121

Overview of results. Clients in the assertive community treatment arm plus a CHW did not differ in results when compared with the assertive community treatment group alone, although for many outcomes both of these arms were superior to the brokered case management arm. The assertive community treatment arms (both with and without a CHW) had more contact with their case managers and were more satisfied than those in the brokered case management arm. Clients in the assertive community treatment also had fewer psychiatric symptoms at 18 months than clients in the brokered condition. Days in stable housing did not differ among groups. 120,121

Table 29. CHW chronic disease management: mental health

Author, Year Study Design			
Population Setting Sample Size	Intensity of CHW		
Quality	Intervention	Study Groups	Results
Wolff, 1997 <sup>121</sup> Morse, 1997 <sup>120</sup>	High	G1: Assertive community treatment— intensive individualized treatment, responsibility for providing or coordinating all	Number of days in stable housing in past month—baseline (SD)/18 months (SD):
RCT		services needed by client, persistent followup and in-person service delivery, performed by	G1: 6.36 (11.71)/21.75 (12.76)
Homeless with serious psychiatric conditions in		staff with backgrounds in psychology, social work, and counseling	G3: 7.18 (12.38)/16.00 (14.86) (P < 0.31)
St. Louis, Missouri		G2: G1 plus CHW, whose role was to assist with activities of daily living and be available	Client satisfaction (validated): G1: 3.27 (0.42)
N = 165		for leisure activities	G2: 3.12 (0.57) G3: 2.74 (0.68) <i>P</i> < 0.01
Poor		G3: Brokered case management	,
			Brief Psychiatric Rating Scale Total Symptom Score (validated): G1: 53.54 (15.54)/39.96 (12.25) G2: 57.97 (20.29)/38.77 (12.23) G3: 50.6 (14/31)/51.6 (16.7) P = 0.001
			Program contact (days/month): G1: 8.29 (7.51)
			G2: 6.95 (4.91) G3: 0.3 (0.49) P < 0.001

CHW: community health worker; RCT, randomized controlled trial; SD: standard deviation.

Knowledge. This RCT did not report outcomes for improved knowledge.

Behavior. This RCT did not report outcomes for improved behaviors.

*Satisfaction*. Clients in the assertive community treatment arms (both with and without a CHW) were more satisfied with their treatment program than clients in the brokered case management arm (satisfaction score  $\pm$  standard deviation:  $3.12 \pm 0.57$  versus  $3.27 \pm 0.42$  versus  $2.74 \pm 0.68$ , P < 0.05).  $^{120,121}$ 

*Health outcomes*. Clients in the assertive community treatment arm plus a CHW did not differ in health outcome results as compared with the assertive community treatment group alone. Clients in the assertive community treatment arms (both with and without a CHW) had fewer psychiatric symptoms as rated by the Brief Psychiatric Rating Scale (BPRS) at 18 months compared to baseline than did those in the brokered case management arm (baseline (SD)/18-month followup (SD): 57.97 (20.29)/38.77 (12.23) versus 53.54 (15.54)/39.96 (12.25) versus 50.60 (14.31)/51.60 (16.70), P = 0.001 for any difference among the three groups; P for comparison of either assertive community treatment arm not reported). Days in stable housing between groups did not differ across the groups.

Health care utilization. Use of health services did not differ between the assertive community treatment plus a CHW arm and the assertive community treatment group alone. Clients in the assertive community treatment arms (both with and without a CHW) had more days in contact with the program than did clients in the brokered case management arm (6.95 (4.91) versus 8.29 (7.51) versus 0.3 (0.49), <math>P < 0.05).

**Chronic disease management: asthma.** Study characteristics. Two RCTs (three articles), one good-quality, 96,97 and one fair-quality, 100 examined outcomes of CHW interventions for asthma care among pediatric patients with persistent asthma. Both studies used a highly resource-intensive CHW model. Both studies provided comprehensive multifaceted interventions that included an environmental assessment, asthma action plan, education, referrals, allergy control mattress covers and pillows, vacuums, and cleaning supplies, pest management, and smoking cessation assistance to the high-intensity intervention arm, delivered over a year in several home visits. The Seattle King County Healthy Homes (SKCHH) project (Washington State) compared outcomes for children receiving a high-intensity multivisit home intervention with those for children receiving a low-intensity single home visit that included an environmental assessment, some education, and bedding encasements, followed by the full intervention after a year. 96,97 The Community Action Against Asthma (CAAA) project adapted the SKCHH project to Detroit, Michigan, comparing a group receiving the high-intensity multivisit home intervention with a control group receiving an asthma information booklet and the full intervention after a year. 100 Variations in measures of health behavior, outcomes, and health care utilization preclude quantitative synthesis of the results.

Overview of results. Two trials demonstrated that high-intensity CHW interventions are more effective than either low-intensity interventions or a control group in reducing unscheduled use of health care services and improving psychological outcomes for caregivers. Both studies demonstrated changes in behavior, such as increased use of bed encasements and vacuuming, associated with the materials distributed by the CHW, but not for other behaviors that may have required external or additional resources or change, such as removal of mold or reduced exposure to environmental tobacco smoke. Both studies demonstrated significant improvements within but not across trial arms for some measures of symptoms, <sup>96,97,100</sup> reduced days with activity limitations, and reduced use of beta-agonists. Authors postulated that these results could be explained either because a minimal intervention may be effective for some outcomes or because of regression to the mean, temporal trends, or the Hawthorne effect (improvement in performance attributable to being observed) among the less intensive or control group participants. Nevertheless, for health outcomes demonstrating a difference between trial arms such as symptom days, the more intense arm was more effective than the less intense or control arm.

*Knowledge*. Neither study reported outcomes for improved knowledge of asthma triggers. *Behavior*. Both studies examined a variety of behavioral changes (Table 30). Both studies reported increased use of materials provided—that is, mattress covers, pillows, and vacuums, suggesting reduced exposure to dust mites— in the more intense arm. Both studies failed to find differences between the two arms for behavioral changes associated with smoking cessation. Other behaviors that did not differ between arms included removal of pets and use of exhaust fans in the bathroom <sup>96,97</sup> and removal of mold. <sup>100</sup>

Table 30. CHW asthma interventions and behavior

Author, Year Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Krieger et al., 2005; 96 Krieger et al., 2002 97 RCT Children ages 4-12 years with persistent asthma Low-income households in King County, Washington N: 274	High	G1: Environmental assessment; asthma action plan; education and social support; mattress covers, pillows, vacuum, cleaning supplies; smoking	Behavior, summary score of trigger reduction behaviors Across groups comparison: GEE coefficient (95% CI, 0.41 (-0.13-0.95); $P = 0.141$ )  Frequencies of actions to reduce dust exposure and the use of bedding encasements increased more in the high-intensity group; kitchen ventilation improved more in the lowintensity group. Neither group increased the frequency of washing sheets or dusting, nor reduced exposure to pets (although pet ownership was uncommon among participants) and smoking in the home; behavior summary score improved in both groups, and the acrossgroup difference was not significant
Parker et al., 2008 <sup>100</sup> RCT  Children ages 7-11 years with persistent asthma  Southwest and eastside Detroit, Michigan  N: 298  Fair	High	G1: Environmental assessment; asthma action plan based on allergy tests; education and social support; mattress covers, pillows, vacuum, cleaning supplies; counseling on environmental tobacco smoke; integrated pest management services; minimum 9 planned home visits over 12 months  G2: Asthma information booklet, full intervention after 12 months	Intervention effect (or-intervention/or-control)  Vacuum cleaner used: 29.5 (6.90, 126); $P < 0.0001$ Allergen cover on child's pillow: 19.7 (4.12, 94.2); $P = 0.0006$ Allergen cover on child's mattress: 9.70 (4.33, 21.7); $P < 0.0001$ Visible mold growth removed: 0.74 (0.33, 1.66); $P = 0.47$ Child is around people who smoke: 0.60 (0.28, 1.32); $P = 0.20$ Statistically significant intervention effect in the reduction of concentration of dog allergen per gram of bedroom dust ( $P < 0.001$ ) but not for cockroach, dust mite, or cat allergen concentration

CI, confidence interval; GEE, generalized estimating equation; RCT, randomized controlled trial.

Satisfaction. Neither study reported outcomes for satisfaction.

*Health outcomes*. The SKCHH project reported on the number of symptom days in the past 2 weeks. The CAAA project looked at the occurrence of more than 2 symptom days per week for children not on any controller medication or corticosteroids (Table 31).

Table 31. CHW asthma interventions and health outcomes

Author, Year Study Design Population Setting Sample Size	Intensity of CHW	Study Groups	Pasults
Sample Size Quality  Krieger et al., 2005; 96 Krieger et al., 2002 97  RCT  Children ages 4-12 years with persistent asthma  Low-income households in King County, Washington  N: 274  Good	High	G1: Environmental assessment; asthma action plan; education and social support; mattress covers, pillows, vacuum, cleaning supplies; smoking cessation referral; 4-8 visits over 12 months  G2: Environmental home assessment action plan; limited education; bedding encasements; full intervention after 12 months	ITT analysis yielded similar results: improvements in QoL were greater in G1 (data NR, $P = 0.009$ )  Asthma symptom days (self-reported number of 24-hour periods during 2 weeks before interview with asthma symptoms: wheezing, tightness in chest, cough, shortness of breath, slowing down activities due to asthma, nighttime awakenings): G1 vs. G2 at exit: 3.2 vs. 3.9 GEE coefficient -1.24 (95% CI, -2.9 to 0.4), $P = 0.138$ Days with activity limitation over 2-week period Score at exit (G1 vs. G2): 1.5 vs. 1.7 GEE coefficient -1.5 (95% CI, -2.84 to -0.15), OR, 0.22 (0.06, 0.86), $P = 0.29$ Missed school in past 2 weeks: G1 vs. G2 at exit: 12.2% vs. 20.3% GEE coefficient -0.77 (95% CI, -1.70 to 0.16), OR, 0.46 (0.18, 1.18), $P = 0.105$ Days used controller medication over 2-week period: G1 vs. G2 at exit: 3.5 vs. 3.6 GEE coefficient -1.03 (95% CI, -2.79 to 0.73), $P = 0.250$ Days used beta2-agonist over 2-week period: G1 vs. G2 at exit: 4.0 vs. 4.0 GEE coefficient -0.23 (95% CI, -1.88 to 1.42), $P = 0.781$ Caregiver missed work in past 2 weeks:
			G1 vs. G2 at exit: 11.2% vs. 13.0% GEE coefficient 0.07 (95% CI, -0.91 to 1.0.5), OR, 1.07 (0.40, 2.85), P = 0.890

CI, confidence interval; GEE, generalized estimating equation; ITT, intention to treat; NNT, number needed to treated; NR, not reported; OR, odds ratio; QoL, quality of life; vs., versus.

Table 31. CHW asthma interventions and health outcomes (continued)

Author, Year Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Parker et al., 2008 <sup>100</sup>	High	G1: Environmental assessment; asthma action plan based on allergy tests; education and	Caregiver depressive symptoms measured by Center for Epidemiologic Studies Depression Scale (CES-D) mean at baseline/endpoint:
RCT		social support; mattress covers, pillows, vacuum, cleaning	G1: 1.62/1.54 G2: 1.58/1.64
Children ages 7- 11 years with		supplies; counseling on environmental tobacco smoke;	P = 0.0218
persistent asthma		integrated pest management	Improvements in both instrumental and emotional social support combined and
Southwest and eastside Detroit,		home visits over 12 months	instrumental support alone were not statistically significant (data NR)
Michigan		G2: Asthma information booklet, full intervention after 12 months	Child's self-reported average asthma symptom
N: 298			frequency: G1: symptoms occurred less frequently at
Fair			baseline for all 8 symptoms assessed G2: symptoms occurred less frequently for 6 of 8 symptoms
			Persistent cough at baseline, postintervention (on a 6-point scale, higher is worse): G1: 3.81, 3.36 G2: 3.48, 3.44 P = 0.034
			Cough with exercise at baseline, postintervention (on a 6-point scale, higher is worse): G1: 4.27, 3.69 G2: 3.80, 3.66 $P = 0.017$
			Has any symptom more than 2 days per week and not on a corticosteroid G1 (pre/post) vs. G2 (pre/post) intervention effect (95% CI): 60/42 vs. 51/46; 0.56 (0.29 to 1.06); $P = 0.073$
			Has any symptom more than 2 days per week and not on any controller G1 (pre/post) vs. G2 (pre/post) intervention effect (95% CI): 53/32 vs. 38/37; 0.39 (0.20 to 0.73); $P = 0.004$

Results from these two trials were mixed. The Seattle (SKCHH) project reported nonsignificant differences between the arms in the reduction in symptoms days, whereas the Detroit (CAAA) project found significant differences between the trial arms for children not on any controller medication (OR, 0.39 [95 percent CI, 0.20-0.73]). The differences between trial arms in reduction of symptom days was not statistically significant in the subset of children not on corticosteroids. <sup>100</sup>

The Seattle (SKCHH) project also examined differences in trial arms in days with activity limitation, use of beta-agonists, use of controller medications, missed school days for the child,

and missed caregiver workdays. With the exception of days with activity limitations, the study found no differences between the intervention arms. 96,97 It also found a significantly higher increase in caregiver quality of life (measured by the Center for Epidemiologic Studies Depression Scale in the more intense arm (coefficient for difference between groups in mean change from exit to baseline: 0.58 [95 percent CI, 0.18-0.99]).

The Detroit (CAAA) project found significant improvements in symptoms for both intervention and control arms, but differences were statistically significant only for coughing with exercise and persistent cough. It also found significant differences between trial arms in some but not all measures of lung function; these results could potentially be explained by seasonal influences, changes in instrumentation, and inadequate power. Finally, it reported a statistically significant reduction (P = 0.0218) in caregiver depressive symptoms (measured by the Center for Epidemiologic Studies Depression Scale) in the intervention arm (mean value at baseline and followup: 1.62 and 1.54) compared to a rise in depressive symptoms in the control arm (mean value at baseline and followup: 1.58 to 1.64). The study found no statistically significant differences between the two groups in changes in social support between baseline and the endpoint.  $^{100}$ 

*Health care utilization*. Both studies (Table 32). found a significant difference in the reduction in unscheduled medical care—emergency room visits, hospitalizations, and unscheduled doctor visits—favoring the more intense intervention at three points: 2 months (OR: 0.38; 95% CI, 0.16-0.89), <sup>96,97</sup> 3onths (OR: 0.43; 95% CI, 0.23-0.80), <sup>100</sup> and 12 months (OR: 0.40; 95% CI, 0.22-0.74).

Table 32. CHW asthma interventions and health care utilization

Author, Year Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Krieger et al., 2005; <sup>96</sup> Krieger et al., 2002 <sup>97</sup>	High	G1: Environmental assessment; asthma action plan; education and social support; mattress	Urgent health services used over 2 months G1 vs. G2 at exit: 8.4% vs. 16.4%
Children ages 4-12 years with persistent asthma		covers, pillows, vacuum, cleaning supplies; smoking cessation referral; 4 to 8 visits	GEE coefficient -0.97 (95% CI, -1.8 to -0.12), OR 0.38 (0.16, 0.89), $P = 0.026$ ; NNT = 12.9
Low-income		over 12 months	ITT analysis yielded similar results: improvements in urgent health services were
households in King		G2: Environmental home	greater in G1 (data NR, $P = 0.062$ )
County, Washington		assessment action plan, limited education, bedding	,
N: 274		encasements; full intervention after 12 months	
Good			

CI; confidence interval; GEE, generalized estimating equation; ITT, intention to treat; NNT, number not treated; NR, not reported; OR, odds ratio; RCT, randomized controlled trial.

Table 32. CHW asthma interventions and health care utilization (continued)

Author, Year Population Setting Sample Size Quality	Intensity of CHW Intervention	Study Groups	Results
Parker et al., 2008	High	G1: Environmental assessment; asthma action plan based on allergy tests; education and	Reduction in unscheduled health care utilization for asthma
Children ages 7-11 years with persistent asthma		social support; mattress covers, pillows, vacuum, cleaning supplies; counseling on environmental tobacco smoke;	Percentage needed unscheduled medical care—G1 (pre/post) vs. G2 (pre/post); intervention effect (95% CI):
Southwest and eastside Detroit, Michigan		integrated pest management services; minimum 9 planned home visits over 12 months	In past 3 months: $50/45$ vs. $42/56$ ; 0.43 (0.23 to 0.80); $P = 0.007$
N: 298		G2: Asthma information booklet, full intervention after 12 months	In past 12 months: 65/59 vs. 58/73; 0.40 (0.22 to 0.74);
Fair		Tall Intervention after 12 months	P = 0.004

## KQ 3: Cost-Effectiveness of Community Health Worker Interventions

## **Overview of Economic Analyses**

A total of nine studies that met inclusion criteria for this review contained information about intervention costs, cost-effectiveness, or cost-benefits. We focused here on the six studies that also demonstrated effectiveness of the CHW intervention, either as compared with the alternatives that were analyzed or as compared with baseline, or usual, care. <sup>17-22,75,80,96,104,121</sup> The studies on CHWs that included economic information varied a great deal in terms of the populations targeted for intervention, the types of interventions implemented and the settings for those interventions, the alternatives that were analyzed, and the outcomes the interventions sought to impact.

Targeted populations, for example, ranged from Latina women to low-income infants and children. The types of interventions using CHWs as a study arm included early childhood and child health interventions, cancer screening interventions, and chronic disease management interventions. Some studies evaluated alternatives that varied intensity levels for the CHW intervention; others compared the CHW intervention without nurse-delivered interventions; and others compared the CHW intervention with lower intensity alternatives that did not involve direct interaction with targeted patients (e.g., providing written materials only). Study outcomes also varied a great deal across studies, reflecting the diversity of types of interventions and targeted populations (e.g., outcomes related to use of health care, child health and development, and impacts on usual activities such as work or school). Intervention settings also varied; some CHW interventions focused on working with participants in their homes, one focused on working with homeless individuals, and another took place in urban churches.

The three studies with economic information that we eventually excluded involved (1) a diet change intervention that targeted Hispanic women, <sup>64</sup> (2) an environmental tobacco smoke intervention that targeted young Latino children, <sup>67</sup> and (3) a children's immunization intervention that compared CHW interventions with mail or telephone interventions for raising

children's immunization rates.<sup>69,70</sup> These three studies produced no statistically significant impact on CHW intervention groups as compared with outcomes in the control groups.

In the discussion below, we cite only the articles with data specific to the cost-analysis; studies spanned several other citations specific to outcomes not relevant to the discussion below.

**Economics: cancer screening.** *Study characteristics.* Two studies (one trial and one prospective cohort) evaluated program costs or cost-effectiveness for CHW interventions that sought to improve women's mammography rates. <sup>17,22</sup> The ROSE study targeted low-income, rural white, African-American, and Native-American women in North Carolina ages 40 years and older, all of whom had not had a mammogram in the previous 12 months. <sup>17,18</sup> These women were randomly assigned to a high-intensity CHW intervention, which involved three home visits with followup telephone calls and mailings, or to a comparison group. The CHW intervention was delivered for a period of 12 to 14 months. The LAMP CHW study collected data on program costs and cost-effectiveness for a low-intensity cancer screening CHW intervention. <sup>19-22,104</sup> The intervention was a church-based telephone counseling program that targeted female church members ages 50 to 80 years to promote mammography. Some of these women had obtained mammograms 1 to 2 years before the initial survey and within the 2-year window before that ("adherent" group), whereas others had not ("nonadherent" group). Church volunteers made one telephone call per 12-month period to encourage and address barriers to mammography.

Overview of economic analysis results. Both studies report program costs and the costs per additional mammography screening. Both studies estimated program costs using a program or funder perspective (i.e., including only those costs that would be incurred by a prevention program to deliver the intervention); that is, they did not employ a societal perspective. Because the LAMP study used volunteer labor, the costs of the intervention from the program perspective are necessarily low compared with the costs of the ROSE intervention, which paid their CHWs. To better understand what costs would be if CHWs had to be hired to deliver the LAMP intervention, Stockdale et al. 22 also report two alternative program cost estimates—one that values volunteer time at the minimum wage and another that values volunteer time at the average wage rate.

Measures of effectiveness for economic analysis. The main effectiveness outcome that both studies used for their economic analyses was mammogram receipt in the 12 months before a followup survey. The ROSE study outcomes were based on review of a woman's medical record. The LAMP study outcomes were based on participants' self-reports via a telephone interview; it also estimated life-years saved based on a model of screening, diagnosis, and treatment for breast cancer. 22

Economic outcomes. The total cost of the ROSE intervention was estimated to be \$329,054,<sup>17</sup> which translates to approximately \$404 per participant, based on the 815 participants who fully participated in the intervention and data collection. The year of costs was not reported for the ROSE study. Program costs for the LAMP intervention were estimated to be \$11 per participant in 1997 dollars when the opportunity cost of CHW volunteers' time was excluded from the cost calculation. Costs were estimated at \$28 per person when CHW volunteers' time was valued at the minimum wage and \$52 per person when an average wage rate for each type of volunteer was used (1997 dollars).<sup>22</sup> To compare ROSE and LAMP costs, we assumed that the ROSE costs are in 2000 dollars (the midpoint of the study time period, 1998 through 2002). Using the consumer price index for all urban consumers (CPI-U) to adjust the LAMP intervention cost of \$52 per participant in 1997 dollars to 2000 dollars yields an estimate of \$56 per LAMP

participant, as contrasted with the high-intensity ROSE intervention cost of about \$404 per participant.

Both studies also reported costs per additional screening. <sup>17,22</sup> Paskett et al. estimated the impact of the ROSE intervention to be 66 additional mammograms in the CHW intervention group, resulting in a cost-effectiveness ratio of \$4,986 per additional mammogram (assumed 2000 dollars). The Stockdale et al. estimated the impact of the LAMP intervention to be 3.24 additional mammography screenings for each of the 45 churches that participated in the study, resulting in an estimated cost per additional screening of \$903 (1997 dollars) when CHW volunteers' time was valued at the average wage rate. <sup>22</sup> Although these findings appear to suggest that the LAMP intervention had a much lower cost per additional mammogram received than did the ROSE intervention, the effectiveness and cost-effectiveness results are not comparable between these two studies because the LAMP intervention targeted women who were both adherent and nonadherent with screening guidelines, whereas the ROSE intervention targeted only nonadherent women. Focusing on results for the nonadherent LAMP participants only, the estimated intervention effectiveness is 1.46 additional screenings per church per year (not statistically significant), which we estimate to produce a cost-effectiveness ratio of \$2,005 per additional mammography screening in 1997 dollars, or \$2,151 in 2000 dollars, when the time of CHWs is valued using expected wage rates.

Stockdale et al. also estimated the cost per life-year saved by the LAMP intervention and subsequent mammography screening as \$46,308 (1997 dollars),<sup>22</sup> when CHW time was valued using expected wage rates (\$33,632 plus the estimated cost per life-year saved for mammography screening of \$12,676).

**Economics: chronic disease management.** *Study characteristics*. Two studies provided economic information on the management of chronic diseases; both studies are described in more detail in the last section of KQ 2. One study evaluated an asthma control intervention for children; <sup>96</sup>the other evaluated an intervention to prevent homelessness in patients with mental illness. <sup>121</sup>

The asthma intervention, known as the Seattle King County Healthy Homes (SKCHH) project, evaluated a 1-year high-intensity CHW intervention approach, involving five to nine CHW home visits. <sup>96</sup> The investigators compared this high-intensity intervention with a low-intensity version that involved only one CHW home visit and evaluated health care utilization and costs for participants, intervention program costs, and other measures related to asthma control, quality of life, and productivity.

The homelessness prevention intervention compared three alternative case management approaches for people with mental illness at high risk of homelessness:

- brokered case management—a low-intensity intervention that can be viewed as the baseline, or usual care, approach;
- assertive community treatment—a high-intensity intervention that involves frequent interaction with the client and assistance with a host of activities and social service acquisition; and
- assertive community treatment with CHWs—a high-intensity CHW intervention that consists of assertive community treatment, adding a CHW to interact with and assist clients. <sup>121</sup>

Each intervention was provided over 18 months. Key outcomes were health care and social services utilization, program costs, and pre- and postintervention measures of 6 months of costs for health care and social services among study participants.

Overview of economic analysis results. Both studies report program costs per participant from the program perspective. For the Seattle study, Krieger et al. <sup>96</sup> estimated the cost of the 12-month intervention by summing payments for salary and fringe benefits, supplies, rent, travel, and office expenses and adding indirect costs of 13 percent. For the homelessness prevention study, Wolff et al. <sup>121</sup> estimated the additional intervention program costs of assertive community treatment, with and without CHWs, as the costs above those for brokered case management; their estimates values CHW time at the minimum wage.

Both studies estimated the impact of the intervention on health care and/or social services costs for program participants. For example, Krieger et al. assessed the pre- and postintervention costs of urgent care services for both CHW intervention arms (high and low intensity). Wolff et al. also assessed the pre- and postintervention costs of the following services for program participants in all three intervention arms: mental and physical health, vocational and educational, residential, and supportive social. 121

Measures of effectiveness for economic analysis. Neither study created a measure of the costs per unit of program effectiveness (e.g., cost per additional day in stable housing or cost per additional day of school attendance). Instead, both studies estimated program cost savings or potential cost savings by comparing health care or social services costs in the preintervention time period with costs in the postintervention time period.

For example, the Seattle study estimated urgent care costs for the targeted children in the 2 months before the start of the intervention and compared these values without analogous costs in the 2-month period before the exit interview. For this work, Krieger et al. defined urgent care costs as the costs of hospital admissions, emergency department visits, and unscheduled clinic visits. Because this intervention sought to reduce use of urgent health care services among participants with asthma, a reduction in urgent care costs for participants may be viewed as cost savings attributable to the intervention.

The homelessness prevention intervention also compared preintervention and postintervention costs for participants in each of the study arms. For this work, Wolff et al. calculated costs for the following services, by study arm:

- mental health inpatient,
- mental health outpatient,
- physical health inpatient,
- physical health outpatient,
- vocational and educational,
- residential,
- cash social support, and
- in-kind social support. 121

Wolff et al. also provided a total cost amount that summed the per-patient costs for all of the above services and included the intervention cost for assertive community treatment (with or without CHWs). However, reductions in these total or specific services costs should not be viewed as cost savings attributable to the intervention because utilization and costs of some services might be expected to rise, rather than fall, as the result of a successful intervention. For example, successful assertive community treatment interventions might lead to larger

pre/postintervention increases in vocational and educational service costs than a brokered case management approach.

*Economic outcomes*. In the Seattle program, costs for the high-intensity CHW intervention were \$1,124 per child higher in 2001 dollars than costs for the low-intensity CHW intervention. <sup>96</sup> Estimated costs for the low-intensity asthma intervention were not provided. <sup>96</sup>

For the homelessness prevention intervention, annual program costs were \$6,200 per participant for the assertive community treatment intervention with CHWs and \$6,440 per participant for assertive community treatment only. These cost estimates are in 1992 dollars and are in addition to costs for brokered case management—costs that were not reported in the article. Adjusting these cost estimates to 2001 dollars using the CPI-U, we estimate the costs of assertive community treatment with CHWs to be \$7,826 per patient and the costs of assertive community treatment only to be \$8,129 per patient, in addition to costs for brokered case management.

For the Seattle study of children with asthma, Krieger et al. also provided estimates of pre/postintervention health care cost reductions attributable to the CHW asthma intervention. <sup>96</sup>Comparing urgent care costs in the 2 months before the intervention with costs in the 2 months at the end of the intervention, they estimated cost reductions of \$201 to \$334 per child in 2001 dollars. <sup>96</sup> For the low-intensity CHW group, analogous cost reductions were \$185 to \$315 per child. Assuming these cost reductions persist for 1 year, estimated annual cost reductions are \$1,200 to \$2,000 per child for the high-intensity CHW intervention in 2001 dollars. Krieger et al. also discussed the cost-effectiveness of the high-intensity intervention relative to the low-intensity approach.<sup>96</sup> They found savings in urgent care costs for the high intervention group relative to the low intervention group of \$57 to \$80 per child over a 2-month period. 96 The authors reported that if these cost reductions were to last for 3 to 4 years, the highintensity intervention would be cost saving relative to the low-intensity intervention. Whether assuming the same level of reduced urgent care utilization and costs for several years postintervention is reasonable, however, remains unclear. The authors did find that urgent care utilization remained low in the high-intensity group for at least 6 months following the intervention.<sup>96</sup>

For the study of homeless mentally ill participants, Wolff et al. conducted regression analyses to explore whether study arms differed in their measures of total costs over the 18month study period. 121 They found no difference in total costs across study arms after controlling for patients' costs in the preintervention period. 121 They also compared 6-month costs in the preintervention period to 6-month costs for three separate postintervention periods (1 to 6 months, 7 to 12 months, and 13 to 18 months). At least in part because the number of participants in each intervention arm was relatively small (N = 35, 28, and 22, respectively), postintervention costs varied a great deal across time periods. The authors point out that, when comparing the preintervention period with the first 6 months' postintervention period, inpatient mental health services costs fell \$1,315 for assertive community treatment with CHWs, rose almost \$4,500 for assertive community treatment only, and rose more than \$8,000 for brokered case management. 121 Considering the second 6-month period of the intervention, inpatient mental health services costs fell by more (\$4,400 per participant) in the assertive community treatment only group than in the assertive community treatment with CHWs group (\$2,651 per participant). Inpatient mental health services costs also declined in that time period for the brokered case management group (\$1,252 per participant). All of these cost estimates are in 1992 dollars.

The cost estimates for health and social services that Wolff et al.<sup>121</sup> report are difficult to interpret using the currently recommended framework for performing and evaluating costeffectiveness analyses. <sup>130,131</sup> The recommended approach for performing cost-effectiveness analysis is to specify the perspective of the study a priori and to calculate net costs for use in cost-effectiveness evaluation as intervention costs less any costs for health care or other relevant variables (including productivity losses) averted by the intervention. The societal perspective is recommended for economic evaluation, which implies that all costs should be included, regardless of who bears them. Although the Wolff et al. 121 article implies that the intent was to estimate costs from the societal perspective, their measure of total costs excludes criminal justice and family burden costs (mentioned as a limitation), it excludes productivity costs, and it includes societal transfers (cash and in-kind support) that are not recommended for inclusion in economic analyses from the societal perspective. The presentation of costs in three different intervention time periods also makes it difficult to interpret the Wolff et al. estimates, because costs differed a great deal over time for each intervention arm. <sup>121</sup> Finally, the total cost measures they presented cannot readily be used in economic evaluations without some adjustments. Their total cost estimates represent the sum of intervention costs and specific health care and social services costs. These total cost estimates vary a great deal across intervention arms (including for the preintervention period) and across time within each intervention arm. In contrast, the recommended estimates for use in economic evaluations are measures of net costs that provide a single measure of costs for each intervention arm that subtract from intervention costs the health care, productivity, and other related cost reductions attributable to the intervention. <sup>131</sup>

Economics: child health. *Study characteristics*. Two studies evaluated program costs for CHW interventions that sought to improve child health. <sup>75,80</sup> One study, set in Maryland, evaluated the impact of a high-intensity CHW intervention for children with nonorganic failure to thrive in a low-income urban setting. As reported by Black et al., children diagnosed with failure to thrive were randomized to receive either the CHW intervention, which involved the delivery of clinical services plus weekly home visits from a trained CHW, or the clinical intervention only. <sup>75</sup> The Home Visitation 2000 RCT targeted low-income, pregnant women for a home visiting intervention that involved prenatal home visits, followed by home visits every 1 to 2 months until the target child was 2 years of age. <sup>80</sup> In this study, Olds et al. compared the impact of using CHWs to deliver the home visiting intervention with the impact of using nurses. <sup>80</sup> In addition to program costs, it evaluated several child health and developmental outcomes (e.g., mother-child interaction, quality of the home environment, child developmental outcomes).

Overview of economic analysis results. Both studies reported intervention program costs. Cost components for the failure-to-thrive trial included salaries for the CHW or nurse, materials costs, transportation costs, costs of police service, and a 10 percent overhead fee. <sup>75</sup> Olds et al. provided a per-family total cost of the 2.5 year Home Visitation 2000 trial, <sup>80</sup> but they did not specify details on what was included in the cost estimate.

Measures of effectiveness for economic analysis. Because both of these studies reported only the intervention costs, they did not examine intervention costs in relationship to outcomes. Thus we had no measures of intervention effectiveness for these economic analyses.

*Economic outcomes*. Annual program costs for the failure-to-thrive CHW intervention were \$2,828 per child in 1993 dollars. Although the article did not explicitly state this, we assumed that this cost estimate reflects the additional costs of the CHW intervention relative to the clinical intervention (usual care). When adjusted to 2002 dollars using the CPI-U, the CHW intervention for these children has an estimated annual cost of \$3,520 per child. For the Home Visitation 2000

RCT, program costs were \$9,140 per family in 2002 dollars for the nurse home visitation arm and \$6,162 per family for the CHW intervention arm. <sup>80</sup> These costs are for the full 2.5 years of the program. Dividing these estimates by 2.5, we estimate annual costs of \$3,656 per family for the nurse home visitation intervention and \$2,465 for the CHW home visitation intervention—both in 2002 dollars.

**Economics: summary of findings.** Table 33 summarizes findings from the six CHW intervention articles that provided information on program costs and other economic outcomes (presented in the order of discussion above, by clinical context). Cost estimates are shown as presented in each article, but we also report each cost estimate adjusted to 2008 dollars using the CPI-U. Although adjusting some of the cost estimates using the medical care component of the CPI might have been more appropriate, because that component accounts for faster growth in prices in the health care sector than in other parts of the US economy, we used the CPI-U because all studies relied on nonmedical labor to provide the CHW intervention.

Table 33. Summary of economic analyses of CHW interventions

Author, Year	Intervention Description	Annual Intervention Program Costs Per Participant, Year of Dollars Specified or Assumed	Annual Intervention Program Costs, 2008 Dollars	Results of Other Economic Analyses
Stockdale et al., 2000 <sup>22</sup>	Mammography screening intervention	\$52 (1997)	\$70	\$903 per additional mammography screening, 1997\$
				\$46,308 per life-year saved for intervention plus mammogram, 1997\$
Paskett et al., 2006 <sup>17</sup>	Mammography screening intervention	\$404 (2000 assumed)	\$505	\$4,986 per additional mammography screening, (2000\$ assumed)
Krieger et al., 2005 <sup>96</sup>	Asthma management intervention	\$1,124 (2001)	\$1,366	\$201-\$334 reduced urgent care costs per child, high-intensity CHW intervention, 2001\$
Wolff et al., 1997 <sup>121</sup>	Homelessness prevention intervention	\$6,200 (1992) (CHW intervention)	\$9,514	Reductions in inpatient mental health services costs for CHW intervention relative to usual care in all intervention time periods
Olds et al., 2002 <sup>80</sup>	Child health and development intervention	\$2,565 (2002) (CHW intervention)	\$3,070	None
Black et al., 1995 <sup>75</sup>	Child health intervention	\$2,828 (1993)	\$4,214	None

CHW, community health worker.

# **KQ 4: Training of Community Health Workers**

## **Characteristics of Training for Community Health Workers**

**Overview.** *Study characteristics*. As noted in Chapter 2, an inclusion criterion specific to KQ 4 was that all studies reported on changes in knowledge or skills among CHWs after training. Although we identified 46 citations that were potential includes, <sup>111,132-176</sup> only 9 studies (10 citations) provided evidence of changes in knowledge or skills among CHWs after training. <sup>137,141,143,147-150,155,169,176</sup>

All included studies were set in minority or underserved communities. Three focused on cancer prevention, <sup>137,141,143,176</sup> two on cardiovascular disease, <sup>147,149</sup> and one each on health promotion, <sup>169</sup> tobacco cessation, <sup>150</sup> salmonella prevention in the manufacture of queso fresco, <sup>155</sup> and on health insurance enrollment, immunizations, and asthma prevention. <sup>148</sup>

The studies included in this section spanned a variety of models of CHW interventions. Five studies relied on volunteers; <sup>137,141,149,155,169,176</sup> other studies either paid CHWs or did not report on payment status. The size of the intervention effort also varied: the number of CHWs trained through these programs ranged from 4<sup>147</sup> to 1,504. <sup>148</sup> The educational background and prior training of the CHWs undergoing training were rarely reported: one study reported that 98 percent (of 79 CHWs) had either a college bachelor's or graduate degree, <sup>137</sup> whereas another study reported that all trainees (4 CHWs) had 10 years of prior experience as CHWs. <sup>147</sup> Studies also varied in their degree of specificity in reporting eligibility criteria for CHWs. The contribution of CHWs to developing training materials varied, ranging from intensive involvement in pretesting to no involvement. Studies also varied in their reporting on training components; in the following sections, we describe reported data on components of training.

*Training on cultural competence*. Two studies reported training for cultural competence, but they provided no details on the content, method, and number of sessions. <sup>148,149</sup>

*Training on recruitment and retention process skills.* Two studies reported training on recruitment and retention. One study noted that client recruitment was addressed, but the content, method, and number of sessions was not reported. The other recorded five 2-hour sessions covering recruitment strategies and role-playing practice. The other recorded five 2-hour sessions covering recruitment strategies and role-playing practice.

*Training on intake and assessment.* One study reported training for intake and assessment, specifically on community mobilization, communication skills, and outreach strategies, but it provided no details on the content, method, and number of sessions. A second study noted two training sessions for assessment and role-play. 147

*Training on protocol delivery.* Two studies reported on training on protocol delivery. <sup>147,148</sup> One provided no further details, <sup>148</sup> and the second listed health education counseling as part of the curriculum, and included role play for cancer screening counseling sessions and cardiovascular disease counseling sessions that was followed by external feedback from a clinical psychologist. <sup>147</sup>

*Training on health topic*. The purpose of training CHWs on health topics was to prepare them to educate participants. Seven studies described the health content of their training in some detail; <sup>137,141,143,147,150,155,169,176</sup> all provided evidence of change in knowledge of skills after training (Table 34). Only two reported significance tests.

Table 34. CHW training and evaluation results

Author, Year Study Name Setting: Geography Setting: Organizational, Social, Cultural	Objective or Aim of Training	Training on Content/Health Topic	Evaluation and Testing Results of the Curriculum (Improvements in CHW Knowledge)
Balcazar et al., 2006 <sup>149</sup> Salud Para Su Corazon-National Council of La Raza Escondido, California; Chicago, Illinois;	To promote heart-healthy behaviors among Latinos	Not described	The closed-format pre/posttest scores reported a score of 74% correct for the pretest and 100% for the posttest (n = 11). Differences in pre-post promotora knowledge score changes (N = 29) were statistically significant ( $P < 0.05$ ) but data reported in bar graph only
Ojo Caliente, New Mexico Latino communities			
Beck et al., 2007 <sup>143</sup> Center for Health	To train the trainer in cancer education	2 90-minute train-the- trainer workshops	Pre/post percentage correct— Ability to define cancer: General: 89/93; breast: 79/86; colon: 15/57; prostate: 80/75
Communities' cancer education program			Ability to identify signs and symptoms of cancer: General: NA; breast: 71/88; colon: 81/93; prostate: 40/75
Milwaukee County, Wisconsin			Ability to identify screening recommendations: General: NA; breast 67/67; colon: NA; prostate: 80/75
African- American churches			Ability to identify risk factors: General: 59/85; breast: 54/92; colon: 19/89; prostate: 40/75
			Ability to identify strategies to reduce cancer risk: General: 70/78; breast: 8/33; colon: 92/96; prostate: 20/75
Bell et al.,1999 <sup>155</sup>	To train Hispanic women to make queso fresco that	make new queso	Pretraining/posttraining: Recognized health risks associated with eating
Abuela Project Yakima County, Washington Hispanic communities	was authentic in taste and texture but did not use raw milk in an effort to reduce the incidence of Salmonella serotype Typhimurium infections resulting from eating queso fresco made from raw milk	fresco recipe (i.e., without raw milk)	unpasteurized milk and cheese (N): 10/14; 14/15  Make queso fresco with fresh unpasteurized milk: 6/12; 1/15.

BSE, breast self examination; CHW, community health workers; CVD, cardiovascular disease; NA, not applicable; SD, standard deviation.

Table 34. CHW training and evaluation results (continued)

Author, Year Study Name	anning and evaluation re		
Setting: Geography Setting: Organizational, Social, Cultural	Objective or Aim of Training	Training on Content/Health Topic	Evaluation and Testing Results of the Curriculum (Improvements in CHW Knowledge)
Kuhajda et al., 2006 <sup>147</sup> Pine Apple Heart Disease and Stroke Project  Pine Apple, Alabama  African-American women in rural southern community	To train CHWs for heart disease and stroke and in skills for counseling and assessing high-risk women in the Pine Apple clinic	training included cardiovascular disease;	Counseling CHWs' responses on pre/post training questionnaires showed increases in knowledge and self-reported behaviors in each of the following areas: heart disease and stroke prevention strategies, cancer prevention strategies, heart attack or stroke signs and symptoms, cancer signs and symptoms, current heart disease and stroke prevention activities, current cancer prevention activities. Data reported in bar graph only
Martinez-Bristow et al., 2006 <sup>150</sup> Tobacco Free El Paso El Paso, Texas Neighborhood clinics	To train Spanish- speaking counselors to deliver tobacco cessation interventions	5 days of training for each level of certification for nicotine addiction	Results from pre/posttest measuring self-confidence suggest that participants understood training material; data NR  Mean satisfaction scores (1 = definitely not confident to 5 = definitely confident) high for recipients of each certification: Beginner: 4.8, intermediate: 4.7, advanced: 4.6
Navarro et al., 2007 <sup>141,176</sup> Por La Vida Cuidandome  San Diego, California  Latino communities	To train community health advisors to conduct interactive educational group sessions and train-the-trainer and their "learning partners"	Manual had sessions for understanding female body, breast cancer, Pap test, breast health, risks	Changes in knowledge and behavior, pre/post test for primary participants; and learning partners (percentage naming the following test for breast/cervical cancer early detection): BSE 58.6/74.7; 46.4/56.3 Clinical breast exam: 29.1/28.8; 28.8/20.7 Mammography: 49.8/71.2; 45.0/63.1 Pap test: 84.6/91.9; 79.3/85.1 Knows BSE: 90.5/99.3; 82.4/93.2 Knows mammography recommendations: 32.3/55.8; 27.4/38.1 Names ≥1 breast cancer symptom: 75.1/96.8; 70.3/94.1 Names ≥1 treatment for breast cancer: 40.0/65.6; 27.9/45.0 Names ≥1 risk factor: 8.1/16.5; 6.8/7.2 Names ≥1 factor for cervical cancer: 30.9/59.6; 24.3/35.1 BSE in past month: 62.3/87.4; 55.9/71.5 Mammography ever: 63.3/70.0; 66.7/68.3 Pap test ever: 92.3/97.9; 88.3/92.8

Table 34. CHW training and evaluation results (continued)

Author, Year Study Name Setting: Geography Setting: Organizational, Social, Cultural	Objective or Aim of Training	Training on Content/Health Topic	Evaluation and Testing Results of the Curriculum (Improvements in CHW Knowledge)
Perez et al., 2006 <sup>148</sup> Northern Manhattan Community Voices Collaborative  Northern Manhattan, New York, neighborhoods	To train community health workers, focusing on facilitating insurance enrollment, child immunization, and asthma management	Yes, but not described	Pre/post scores in competency and knowledge (gains, percentage change): Insurance enrollment: 24%/72% (gain = 48%; percentage change = 200; n tested = 61)  Immunization promotion: 83%/96% (gain = 48%; percentage change = 16; n tested = 472)  Asthma management: 63%/83% (gain = 20%; percentage change = 32; n tested = 499)
Williams et al., 1996 <sup>169</sup> No study name Atlanta and Fort Valley, Georgia Older African Americans	To raise awareness of and increase participation of older African Americans in health promotion activities	Training divided into 3 categories: G1: chronic disease education and self-care G2: lifestyle education G3: consumer education Topics for these categories developed into 12 training modules	Obtained score ≥80 on pre/posttest for hypertension and diabetes training sessions: Urban, low to middle income: 32%/60% Inner-city, low income: 11%/72% Rural, mixed income: 28%/93%
Yu et al., 2007 <sup>137</sup> No study name Southeast Michigan Chinese communities	To increase the self- efficacy of CHWs in conducting breast cancer screening promotion	Training manual had 9 chapters and 5 appendices (1 was a bilingual glossary of medical terms); content includes socieodemographic characteristics and special health concerns, outreach strategies, effective communication skills for promoting screening. Also a web site, PowerPoint slides, and audio recordings available	Change in trainees' knowledge and self-efficacy Knowledge—mean number of correct answers pre (SD)/post (SD): 6 (1.4)/8 (1.1), <i>P</i> < 0.001  Self-efficacy—mean score pre (SD)/post (SD): 61.0 (11.5)/65.0 (9.2), <i>P</i> = 0.016

Training on evaluation. A single study reported evaluation as one of the seven core modules in their curriculum but provided no further details. 148

Other training. Four studies reported training on communication skills, <sup>137,148,149,176</sup> and a single study reported on making referrals. <sup>176</sup> Training curricula may well have included additional elements that were not reported.

# **Patient Outcomes of Community Health Worker Training**

We did not identify any studies that reported on patient health outcomes of CHW interventions that were linked to characteristics of training.

# **Chapter 4. Discussion**

This chapter discusses our findings for four key questions (KQs) relating to the interaction between community health workers (CHWs) and clients (KQ 1), outcomes of CHW interventions (KQ 2), costs of CHW interventions (KQ 3), and training of CHWs (KQ 4). As noted in earlier chapters, KQs 1 and 4 are largely descriptive. KQs 2 and 3 are more analytic; they focus on health and cost-effectiveness outcomes. We specify in this discussion the strength of the evidence for the KQs related to outcomes (KQ 2) and cost-effectiveness (KQ 3); we also evaluate the applicability of studies included for outcomes (KQ 2). We refer readers to Chapter 2 for methods for evaluating the strength of evidence and quality of studies.

The strength of evidence for each outcome incorporates grades for risk of bias, consistency, directness, precision, and the presence of other modifying factors. Our approach is based on one developed by the Evidence-based Practice Center program for its comparative effectiveness review activities.<sup>57</sup> In the outcome-specific tables that follow, our overall grade of the strength of evidence appears in the far right column; grades for key domains are in the intermediate columns.

In this review, we ultimately had grades of only moderate or low. To recapitulate, moderate means that we have moderate confidence that the evidence reflects the true effect; further research may change our confidence in the estimate of effect and in fact may change the estimate. Low means that we have only low confidence that the evidence reflects the true effect; further research is likely to change the confidence in the estimate of effect and is likely to change the estimate.<sup>57</sup>

# Interactions between Community Health Workers and Clients (KQ 1)

KQ 1 asks for descriptions of the interaction between CHWs and participants; specifically, we examined place of service, type of service, type of educational materials used, duration of interaction with participants, and length of followup. We identified 53 studies with 79 citations in all, addressing KQ 1. 15-23,27,59-105,107-114,116-124,126-128

CHWs interacted with participants in a broad array of locations, using a spectrum of materials at varying levels of intensity. Studies usually described the place of service and type of intervention in some detail. Across the studies, one-on-one interventions generally occurred in the home, on the telephone, or in a medical setting; by contrast, group interventions tended to take place in a community setting. Studies described types of educational materials poorly or not at all. Studies inconsistently reported duration of interaction with participants and length of followup (the number and length of sessions), and they did not always clarify whether their reporting was based on protocol or on actual experience. The frequent failure to distinguish between protocol and actual experience represents a missed opportunity to explore the balance between planned and actual resource allocation and to identify strategies to translate effective CHW interventions into a variety of community settings.

We synthesized the variety of ways that CHWs can interact with participants into a single measure of intensity that serves as a proxy of resource allocation. Interactions that reported at least four of six elements suggesting a higher intensity (one-on-one, face-to-face, 1 hour per session or more, 3 or more months' duration, three or more interactions, and tailored materials) were classified as high intensity. Interventions with two or three elements were classified as

moderate intensity. Interventions with only one or none of the elements of high intensity were classified as low intensity.

Of the total of 53 studies, we classified 27 as high intensity,  $^{16-18,27,61,62,64,65,67,68,71-98,100,120,121,127,128}$  18 as moderate intensity,  $^{15,23,63,66,69,70,99,101,102,105,106,109-112,114,116,118,119,122-125}$  and 8 as low intensity.  $^{19-22,59,60,103,104,107,108,113,117,126}$ 

The intensity of CHW interventions varied by clinical context (Table 35). Maternal and child health and chronic disease management interventions were all moderate or high intensity, whereas prevention and screening studies were more likely to involve low-intensity interventions.

Table 35. Number of studies, by clinical focus and intensity of interventions

Primary Clinical Context	Low Intensity (percentage)	Moderate Intensity (percentage)	High Intensity (percentage)	Total Number of Studies (percentage)
Health promotion and disease prevention	2 <sup>107,117</sup> (18.2)	4 <sup>66,69,70,105,118,119</sup> (36.4)	5 <sup>16,64,65,67,68,71,127</sup> (45.5)	11 (100)
Injury prevention	1 <sup>126</sup> (33.3)	2 <sup>101,102</sup> (66.7)	None	3 (100)
Maternal and child health	None	None	15 <sup>71-87</sup> (100)	15 (100)
Cancer screening	6 <sup>19-</sup> 22,59,60,103,104,107,108,113 (40.0)	7 <sup>15,63,106,109-112,116,125</sup> (46.7)	2 <sup>17,18,61,62</sup> (13.3)	15 (100)
Chronic disease management	None	5 <sup>23,99,114,122-124</sup> (38.5)	8 <sup>27,88-98,100,120</sup> (61.5)	13 (100)
Total (may be less than sum of rows because of overlapping studies)	8	18	27	53

# **Outcomes of Community Health Worker Interventions (KQ 2)**

KQ 2 asks about the impact of CHWs on outcomes, with specific attention to the following five domains: knowledge, behavior and behavior change, satisfaction, health outcomes, and health care utilization. A key source of heterogeneity is the clinical context of the CHW intervention. The applicability of our findings is related to the clinical context of intervention. Studies targeted one or more of five primary contextual categories and a wide array of specific topic areas (number of subdomains in parentheses): health promotion and disease prevention (3), injury prevention (2), maternal and child health (3), cancer screening (6), and chronic disease management (6); collectively the focus of the studies in this review covered 20 distinct clinical or public health activities. Four studies overlapped primary clinical categories. <sup>67,68,71,107</sup>

As Table 36 demonstrates, we found numerous research gaps in the key clinical areas and domains. Satisfaction and knowledge are virtually ignored by studies in this evidence base. By contrast, health outcomes and health care utilization are better represented by studies we included; more than one-half of the studies included one or both of these outcomes.

Table 36. Summary of studies reporting on outcomes by primary clinical context and subtopic

	Number of Studies by Outcomes							
Primary Clinical Context and Subdomain	Knowledge	Behavior	Satisfaction	Health Outcomes	Health care utilization	Total*		
Health promotion and disease	prevention							
Health promotion and disease prevention: pediatric immunizations	None	None	None	3	None	3		
Health promotion and disease prevention: health promotion – Latina health	None	1	None	None	1	2		
Health promotion and disease prevention: disease prevention	2	5	None	1	1	6		
Injury prevention								
Injury prevention: home safety	None	2	None	None	None	2		
Injury prevention: workplace safety	None	1	None	None	None	1		
Maternal and child health								
Maternal and child health: prenatal care and perinatal outcomes	None	None	None	5	1	6		
Maternal and child health: child development	None	None	None	4	None	4		
Maternal and child health: environment conducive to child well-being	None	3	None	7	None	10		
Cancer screening								
Cancer screening (overall)	2	2	None	None	None	2		
Cancer screening: breast self-examination	None	5	None	None	None	5		
Cancer screening: Pap smears	None	None	None	None	6	6		
Cancer screening: mammography	None	None	None	None	11	11		
Cancer screening: clinical breast examination	None	None	None	None	4	4		
Cancer screening: colorectal cancer screening	None	None	None	None	2	2		
Chronic disease management								
Chronic disease management: diabetes mellitus	1	2	None	4	None	4		
Chronic disease management: hypertension	None	None	None	3	1	4		
Chronic disease management: infectious diseases	None	None	None	None	1	1		
Chronic disease management: back pain	None	None	None	1	None	1		
Chronic disease management: mental health	None	None	1	1	1	1		
Chronic disease management: asthma	None	2	None	2	2	2		
Total*	5	22	1	27	30	53		

<sup>\*</sup>Total may be less than sum of cells because of overlapping studies.

In the section below, we discuss the strength of evidence for these five primary outcome domains and specific subdomains, reflecting the clinical context of the intervention. We follow the examination of outcomes with a summary of results for each clinical context and subdomain and then consider applicability.

We identified 53 studies comprising 79 citations addressing KQ 2. Thirty-eight were randomized controlled trials (RCTs) $^{16-18,27,61,62,64,65,67,68,71-98,100,106,120,121,127,128}$  and 15 were observational studies.  $^{59,60,71,72,83,86,87,93-95,102,108,113,116,117,123,125,126}$  Of the 53 studies, we rated 4 as good quality,  $^{17,18,69,70,96,97,103}$  29 as fair,  $^{16,27,59-63,66-68,72,75,76,79-85,88-93,98,100,101,105,106,108,109,114,117,122,124,125,127}$  and 20 as poor.  $^{15,19-23,64,65,71,73,74,77,78,86,87,94,95,99,102,104,107,110-113,116,118-121,123,126,128}$ 

### Knowledge

As noted in Chapter 1, studies examining the effectiveness of CHW interventions are based in part on theories of individual behavior change. Studies relying on social cognitive theory as a model of individual behavior change anticipate that participants in CHW interventions will change their behavior based on knowledge they gain by observing and learning from CHWs.

Very few studies presented evidence on the effect of CHW interventions on the knowledge of participants (Table 37). The five studies reporting information on knowledge together provide (a) moderate strength of evidence that CHW interventions improve the knowledge of participants on disease prevention <sup>16,117,127</sup> and cancer screening <sup>17,18,109</sup> compared with other alternatives, (b) low strength of evidence that CHW interventions improve knowledge of label reading compared with usual care, but (c) insufficient evidence for knowledge of other issues related to the clinical or self-management of diabetes, such as dietary knowledge, appropriate diet, frequency of checking blood sugar, understanding the need for eye doctor visits, knowledge of how diabetes affects the body (eye, kidney, nerve, cardiovascular problems), or understanding insulin or other medication. <sup>27</sup>

This literature did not compare CHWs with a comprehensive range of usual care providers. Therefore, we cannot conclude that CHWs outperform all alternatives in improving participant knowledge. Nevertheless, for the much smaller subset of comparators and outcomes included in this literature, the studies together suggest that CHW interventions can improve participant knowledge when compared with alternative approaches such as no intervention, media, mail, or usual care plus pamphlets.

We found no evidence on knowledge for all other clinical topics and subdomains, as documented above in Table 36. The absence of data on the vast majority of clinical concerns that investigators in this field sought to study (as listed in Table 36) suggests that researchers may have elected to give priority to collecting and publishing data on health outcomes and health care utilization data rather than intermediate outcomes such as knowledge.

Table 37. Effect of CHW interventions on knowledge: strength of evidence

Number of	Risk of Bias				Other Modifying Factors		Overall
Studies; # of Subjects	Design/ Quality	Consistency	Directness	Precision	(Intensity, Confounding)	Results	Strength of Evidence
		Health promot	ion and dise	ase preven	tion: disease prev	vention	
2; 6,841 <sup>16,117,127</sup>	Medium	Consistent	Indirect	Precise	Absent	Favors CHW intervention vs. print	Moderate
	1 RCT, 1 prospective cohort/fair					or no intervention (for improved knowledge of label reading, knowledge of fat in diet, and knowledge of where to obtain free condoms)	
			Can	cer screenii	ng		
2; 1,788 <sup>17,18,109</sup>	Low	Consistent	Indirect	Imprecise	Absent	Favors CHW vs. media or mail	Moderate
,	2 RCTs/1 good, 1 fair						
		Chronic	c disease ma	ınagement:	diabetes mellitus		
1; 150 <sup>27</sup>	Medium 1 RCT/fair	Consistency unknown (single study)	Direct	Not reported	Absent	Favors CHW intervention vs. usual care plus pamphlets (for knowledge of label reading)	Low

CHW, community health worker; RCT, randomized controlled trial.

#### **Behavior**

Twenty-two studies reported on the effect of CHW interventions on participant behavior. The evidence for workplace safety, diabetes mellitus, and the use of bedding encasements for asthma, from five studies, suggests that CHW interventions can change participant behavior in the desired direction when compared with alternatives such as a community intervention, a lower-intensity CHW intervention, and usual care combined with a pamphlet (Table 38). <sup>17,18,88-92,96,97,100,109,124,126</sup> The strength of evidence is moderate for the use of bedding encasements for asthma and low for workplace safety and diabetes mellitus.

The evidence for disease prevention, improving the environment for child well-being, planned use of cancer screening tests, and breast self-examination, from 14 studies, is mixed. Some studies demonstrate a statistically significant benefit from the CHW arm, but others show no significant differences. 16,61-63,67,75,76,78,84,105,107,108,110-112,116,118,119,125,127,128 The strength of evidence for these outcomes is low.

The evidence for health promotion among Latinas, injury prevention at home, and smoking cessation to reduce asthma, from five studies, failed to demonstrate that CHW interventions resulted in statistically significant different outcomes than alternatives; the strength of evidence for these outcomes is low. <sup>64,65,96,97,100-102</sup> We found no evidence to evaluate the effectiveness of CHW interventions for all other clinical concerns described in Table 36.

Table 38. Effect of CHW interventions on behavior: strength of evidence

Number of Studies; # of Subjects	Risk of Bias  Design/ Quality	Consistency	Directness	Precision	Other Modifying Factors (Intensity, Confounding)	Results	Overall Strength of Evidence
			disease prev	ention: health	promotion – Latin	a health	
1; 357 <sup>64,65</sup>	High 1 RCT/poor	Consistency unknown (single study)	Indirect	Not reported	Present	No difference between CHW intervention and tailored or off- the-shelf interventions	Low
		Health promotion	on and diseas	se prevention:	disease preventio	n	
5; 1,125+12 churches <sup>16,67,</sup> 105,107,118,119,12 7	Medium 5 RCTs/3 fair, 2 poor	Inconsistent	Indirect	Imprecise	Present	Mixed results: 3of 5 studies favor CHW intervention vs. control (no intervention, combination of interventions, media/print)	Low
			Injury prever	ntion: home sa	fety	1 /	
2; 2,909 <sup>101,102</sup>	Medium 2 RCTs/1 fair, 1 poor	Inconsistent	Indirect	Precise	Present	No difference between CHW and health professional or no intervention	Low
126				on: workplace			
1;786 <sup>126</sup>	High  1 prospective cohort/poor	Consistency unknown (single study)	Direct	Imprecise	Present	Favors CHW over community intervention	Low
	Ma	aternal and child	health: envir	onment condu	cive to child well-l	being	
3; 1,052 <sup>75,76,78,84</sup>	Medium 3 RCTs/2 fair, 1 poor	Inconsistent	Direct	Imprecise	Present	Mixed results: Most with no difference between CHW & control; some benefit to CHW over no intervention	Low
		Cancer se	creening: pla	nned use of sc	reening tests		
2; 1,612 <sup>63,116</sup>	Medium 1 RCT, 1 cohort/1 fair, 1 poor	Inconsistent	Indirect	Imprecise	Present	Mixed results: 1 study shows benefit in CHW arm vs. usual, other shows no difference vs. no intervention	Low

CHW, community health worker; RCT, randomized controlled trial.

Table 38. Effect of CHW interventions on behavior: strength of evidence (continued)

Number of	Risk of Bias				Other Modifying Factors		Overall
Studies; # of	Design/				(Intensity,		Strength of
Subjects	Quality	Consistency	Directness	Precision	Confounding)	Results	Evidence
		Cano	er screening:	breast self-ex	amination		
5; 3,798 <sup>61,62,108,1</sup>	Medium	Inconsistent	Direct	Imprecise	Present	Mixed results: 2 of 5 studies	Low
10-112,116,125	2 RCTs, 3 cohorts/3 fair,					show benefit of CHW vs.	
	2 poor					alternative (mail	
	_ poo.					or minimal	
						CHW), 3 of 5	
						show no	
						difference vs.	
						delayed or no	
						intervention	
		Chronic	disease mana	agement: diab	etes mellitus		
2; 213 <sup>88-92,124</sup>	Medium	Consistent	Indirect	Precise	Absent	Favors CHW	Low
						intervention vs.	
	2 RCTs/fair					usual care plus	
						newsletter	
	CI	hronic disease n	nanagement: a	asthma, use of	bedding encasem		
2; 572 <sup>96,97,100</sup>	Low	Consistent	Indirect	Precise	Absent	Favors CHW vs.	Moderate
						less intense	
	2 RCTs/1					CHW arm or	
	good, 1 fair					delayed CHW	
·						arm	
0007400	Chronic diseas				moking cessation,		)
2; 572 <sup>96,97,100</sup>	Low	Inconsistent	Indirect	Imprecise	Absent	No difference	Low
						between CHW	
	2 RCTs/1					vs. less intense	
	good, 1 fair					CHW arm or	
						delayed CHW	
						arm	

Together these studies suggest that CHW interventions can, in some instances, yield greater positive changes in participant behavior than a range of alternatives (including no intervention, community intervention, usual care plus a newsletter, media/print, a less intense or delayed CHW arm, or a combination of interventions). In other instances, CHWs interventions provided no statistically different benefit when compared with a range of alternatives, in the context of improvements in all arms. When the alternative requires greater resource allocation, as with the use of health professionals, the absence of a statistically significant difference may support the use of CHWs.<sup>101</sup>

The absence of consistent evidence showing that CHW interventions provide greater benefit when compared with alternatives may be explained in part by either the inadequacy of the CHW approach in changing some behaviors or other factors such as limitations of study design and the Hawthorne effect. Regarding the effectiveness of the CHW approach, CHWs may be more effective at changing behaviors that are relatively easy to adopt (such as the use of bedding encasements provided through the intervention) and less effective in changing behaviors that may require additional support (such as smoking cessation) or more resources (such as the removal of mold or changing home environments). Study design considerations such as the choice of lower-intensity CHW interventions or the use of other fairly intensive alternatives (or

both situations) may not produce statistically significant differences between the CHW arm and the alternative; the absence of differences may be further compounded by inadequate power in many of these studies. As for the Hawthorne effect, when CHWs collect or report on outcomes in all study arms (as was often the case in these studies), this lack of blinding of outcomes assessors can induce an observation-related improvement in performance.

#### Satisfaction

CHW interventions are often expected to prompt individual and social change and thereby reduce health disparities in either access to care or outcomes of care (or both). An indirect measure of improved access to the health care system is the participant's satisfaction with care. A single study, focusing on mental health among the homeless, found no differences between study arms in participant satisfaction; the strength of evidence for this outcome is low (Table 39).

Table 39. Effect of CHW interventions on participant satisfaction: strength of evidence

	Risk of Bias				Other Modifying		
Number of Studies; #	Design/	Canalatanav	Directness	Dracicion	Factors (Intensity,	Dogulto	Overall Strength of
of Subjects	Quality	Consistency	Directness c disease man	Precision	Confounding)	Results	Evidence
1;165 <sup>120,121</sup>	High	Consistency unknown	Direct	Not reported	Present	No difference	Low
	1 RCT/poor	(single study)		.,		between CHW intervention and control	

CHW, community health worker; RCT, randomized controlled trial.

We found no evidence to evaluate the effectiveness of CHW interventions for the other 19 other clinical concerns described in Table 36. We note that our exclusion of studies without comparison arms may have excluded program evaluations that examined participant satisfaction in greater detail.

#### **Health Outcomes**

The literature examined CHW effectiveness on a range of outcomes. Of the 53 studies, 27 reported specifically on health outcomes (Table 40).

The evidence for back pain and for improving psychosocial outcomes among caregivers of children with asthma, from three studies, provides moderate strength of evidence that CHW interventions improve health outcomes when compared with either a lower-intensity CHW intervention or a delayed-intervention control group. 96,97,100,114

The evidence for seven clinical areas and subdomains—pediatric immunizations, prenatal care and perinatal outcomes, child development, environment conducive to child well-being, diabetes, mental health, and asthma symptoms—from 22 studies, is mixed. Some studies suggested that CHW interventions are more effective than alternatives (including no intervention, usual care, and nurses), but others produced no differences between CHW interventions and alternatives. <sup>27,67-93,96,97,100,124,128</sup>

Table 40. Effect of CHW interventions on health outcomes: strength of evidence

Number of Studies; # of Subjects  3; 5,406 <sup>68-72</sup>	Medium 2 RCTs, 1 cohort/1	Consistency ealth promotion Inconsistent	Directness and disease Direct	Precision prevention: p Imprecise	Other Modifying Factors (Intensity, Confounding) Decliatric immuniz	Results zations Mixed results: 2 of 3 studies favor CHW intervention vs. control; 1 shows	Overall Strength of Evidence
	good, 1 fair, 1 poor	Health promot	ion and disease	co provention	n: disease prever	no difference between CHW interventions and no intervention	
1; 294 <sup>16,127</sup>	Medium 1 RCT/fair	Consistency unknown (single study)	Direct	Not reported	Absent	No difference between CHW intervention and print intervention	Low
						(for change in body mass index)	
					nd perinatal outc		
5; 3,389 <sup>71,77,79</sup> , 83,86,87	High 2 RCTs, 3 cohorts/2 fair, 3 poor	Inconsistent	Some direct, some indirect	Imprecise	Present	Mixed results, between CHW and professionals or no intervention or usual care	Low
		Materi	nal and child h	ealth: child	development		
4; 1,664 <sup>75,76,78</sup> , 80-83,128	Medium 3 RCTs, 1 cohorts/3 fair, 1 poor	Inconsistent	Direct	Imprecise	Present	Mixed results: 2 studies show some benefit for CHW vs. no intervention or health professional, 2 show no difference between CHW and health professional	Low
					lucive to child we		
7; 2,299 <sup>67,68,73,</sup> 74,78,84,85,128	Medium 7 RCTs/4 fair, 3 poor	Inconsistent	Mostly indirect	Imprecise	Present	Mixed results: 5 studies show no benefit for CHW over alternatives, 2 show benefit of CHW arm vs. usual care or health professional	Low

CHW, community health worker; RCT, randomized controlled trial.

Table 40. Effect of CHW interventions on health outcomes: strength of evidence (continued)

Number of Studies; #	Risk of Bias Design/	_			Other Modifying Factors (Intensity,		Overall Strength of
of Subjects	Quality	Chronic	Directness	Precision	Confounding)	Results	Evidence
<b>4</b> ; <b>479</b> <sup>27,88</sup> -93,124	Low 4 RCTs/fair	Inconsistent	Direct	Imprecise	betes mellitus Absent	Mixed results: 2 of 4 studies found CHW more effective than usual care in decreasing mean HgbA1c, 2 found	Low
		Chron	ic disease ma	nagement: h	vnertension	no difference	
3; 2,823 <sup>23,94,95,9</sup> 8,99	Medium  2 RCTs, 1 cohort/1 fair, 2 poor	Consistent	Direct	Precise	Present	No difference between CHW intervention and CHW in a lesser capacity	Low
	, ,	Chro	nic disease m	nanagement:	back pain	,	
1; 255 <sup>114</sup> 1; 165 <sup>120,121</sup>	Medium  1 RCT/fair  High  1 RCT/poor	Consistency unknown (single study)	Direct ic disease ma Direct	Not reported	Absent	Favors CHW intervention vs. usual care plus a book for Roland score at 6 months and worry score at 12 months; no difference in Roland score at 12 months  No difference between CHW intervention and usual care	Moderate
2; 572 <sup>96,97,100</sup>	Low 2 RCTs/1 good, 1 fair	Inconsistent	Direct	Imprecise	Absent	(health professionals)  Mixed results: 1 favors CHW vs. delayed intervention; no difference between CHW and less intense intervention	Low
2; 572 <sup>96,97,100</sup>	Low 2 RCTs/1 good, 1 fair	Consistent	Direct	Precise	Absent	Favors CHW vs. less intense CHW arm or delayed intervention	Moderate

For disease prevention, hypertension, and mental health, the evidence from five studies suggests no difference between CHW interventions and alternative approaches, including the use

of CHWs in a lesser capacity, nurses, and print materials; the strength of evidence for these outcomes is low. <sup>16,23,94,95,98,99,120,121,127</sup> We found no evidence to evaluate the effectiveness of CHW interventions for other clinical concerns described in Table 36.

Our overall assessment for the effect of CHWs on health outcomes is similar to our assessment of their effect on behavior change. Together these studies show that CHW interventions can have a greater effect on health outcomes than certain alternative options such as no intervention, usual care, and nurses, but these findings are not consistent across all studies; several studies find no statistically significant benefit to the CHW arm when compared with alternative approaches. The strength of evidence for the reported absence of differences is therefore low. As with our summary assessment of the effect of CHW interventions on change in participant behavior, we believe that in the context of comparable gains in study arms and the absence of statistically significant differences among study arms, the choice of CHW interventions may be reasonable when the comparator is a high-resource alternative.

#### **Health Care Utilization**

More than half of the 53 identified studies (30 studies) reported on health care utilization (Table 41).

Table 41. Effect of CHW intervention on health care utilization: strength of evidence

	Risk of Bias				Other Modifying		Overall			
Number of Studies; #	Design/				Factors (Intensity,		Strength of			
of Subjects	Quality	Consistency	Directness	Precision	Confounding)	Results	Evidence			
EE			•		oromotion - Latin					
1; 103 <sup>66</sup>	Medium	Consistency unknown	Direct	Imprecise	Present	No difference between	Low			
	1 RCT/fair	(single study)				CHW and mail				
	ŀ	Health promotion	and disease	prevention: o	disease prevention	n				
1; 421 <sup>105</sup>	Medium	Consistency unknown	Direct	Precise	Absent	Favors CHW intervention	Moderate			
	1 RCT/fair	(single study)				vs. no intervention				
	М	aternal and child	l health: prena	ital care and	perinatal outcom	nes				
1; 145 <sup>79</sup>	Medium	Consistency unknown	Indirect	Imprecise	Absent	Favors CHW vs. health	Low			
	1 RCT/fair	(single study)				professional				
	Maternal and child health: Environment conducive to child well-being									
1; 730 <sup>78,128</sup>	High	Consistency unknown	Indirect	Imprecise	Present	No difference between	Low			
	1 RCT/poor	(single study)				CHW intervention and routine clinical care				

CHW, community health worker; RCT, randomized controlled trial.

Table 41. Effect of CHW intervention on health care utilization: strength of evidence (continued)

Number of Studies; # of Subjects	Risk of Bias Design/ Quality	Consistency	Directness	Precision	Other Modifying Factors (Intensity, Confounding)	Results	Overall Strength of Evidence
or Subjects	Quanty	Consistency	Cancer scree			Nesuits	LVIGETICE
6; 4,366 <sup>17,18,61</sup> -63,110-112,125	Low 5 RCTs, 1 observatio nal/1 good, 4 fair, 1 poor	Inconsistent	Direct	Imprecise (when reported)	Present	Mixed results: 3 of 6 studies show some difference between CHW and minimal CHW, media, direct mail, and usual care, 3 show no difference between CHW and mail or no intervention	Low
			Cancer screer	ing: mammo	graphy		
11; 17,401 <sup>15,17-</sup> 22,59- 62,103,104,108,1 10- 113,116,125,177	Medium 6 RCTs, 5 observational studies/2 good, 4 fair, 5 poor	Consistent	Direct	Precise (when reported)	Present	8 of 11 studies favor CHW vs. no intervention, mail, print, or minimal CHW; 3 show no difference CHW and no- intervention control	Moderate
			r screening: c	linical breast	t examination		
4; 3,386 <sup>61,62,11</sup> 0-112,116,125	High 2 RCTs, 2 observa- tional/2 fair, 2 poor	Consistent	Direct	Imprecise	Present	No difference between CHW intervention and mail, CHW in lesser capacity and no intervention	Low
0. ND 107	1.0.1				cer screening	B.4' 1 14 4	
2; NR <sup>107</sup> , 78 <sup>106</sup>	High 2 RCT/1 fair, 1 poor	Inconsistent	Direct	NR	Present	Mixed results, 1 study favors CHW versus usual care, the other shows no difference between CHW intervention and controls (no-intervention control, tailored print and video)	Low
1; 722 <sup>123</sup>	High	Consistency	nic disease ma Direct	anagement: r Not	Present	Favors CHW	Low
1, 122	1 cohort/ poor	unknown (single study)	Direct	reported	i resent	intervention vs.	LOW

Table 41. Effect of CHW intervention on health care utilization: strength of evidence (continued)

Number of Studies; # of Subjects	Risk of Bias Design/ Quality	Consistency	Directness	Precision	Other Modifying Factors (Intensity, Confounding)	Results	Overall Strength of Evidence
			sease manager				
1; 244 <sup>122</sup>	Medium  1 RCT/fair	Consistency unknown (single study)	Direct	Precise	Absent	Favors CHW intervention vs. control group given bus tokens, but monetary incentive was more effective than CHW or control given	Moderate
		Chronic	disease mana	gement: mer	ntal health	bus tokens	
1; 165 <sup>120,121</sup>	High	Consistency unknown	Indirect	Not reported	Present	No difference between	Low
	1 RCT/poor	(single study)		. Sportod		CHW intervention and usual care (health professionals)	
		Chro	nic disease ma	anagement: a	asthma	,	
2; 572 <sup>96,97,100</sup>	Low 2 RCTs/1 good, 1 fair	Consistent	Direct	Precise	Absent	Favors CHW vs. less intense CHW arm or delayed intervention	Moderate

Fifteen studies provide moderate strength of evidence that CHW interventions increase appropriate health care utilization for disease prevention, mammography, infectious diseases, and asthma when compared with a range of alternatives such as no intervention, mail, print, or a less intense CHW arm. <sup>15,17-22,59-62,96,97,100,103-105,108,110-113,116,122,177</sup> Two studies provide low strength of evidence that CHW interventions provide benefits in health care utilization when compared with nurses for prenatal and perinatal care and usual care for hypertension. <sup>79,123</sup>

For Pap smears, six studies provide mixed evidence. Some studies report statistically significant benefit for the CHW arm but others find no significant differences; the strength of evidence for this outcome is low. <sup>17,18,61-63,110-112,125</sup> For health promotion among Latinas, child well-being, clinical breast examination, colorectal cancer screening, and mental health, evidence from nine studies suggests that the CHW intervention and alternatives do not differ; the strength of evidence for these outcomes is low. <sup>61,62,66,78,106,107,110-112,116,120,121,125,128</sup> We found no evidence to evaluate the effectiveness of CHW interventions for all other clinical concerns described in Table 36.

Together, these studies provide either low or moderate evidence that CHW interventions increase some appropriate health care utilization (e.g., more use of cancer screening tests, less use of emergency services) when compared with a range of alternatives for disease prevention, mammography, infectious diseases, and asthma. For other reported outcomes, however, the evidence is mixed or does not show a statistically significant benefit of the CHW arm. As with our discussion of results for participant behavior and health outcomes, we note that for some

outcomes that had no statistically significant benefit of the CHW arm, the strength of evidence is low; the reasons are similar to those discussed above and include study design, choice of comparators, and the Hawthorne effect.

## **Applicability of Findings about Outcomes**

Our analysis of applicability reviewed studies by clinical context along five dimensions: population, intensity of treatment, choice of comparator, outcomes, and timing of followup. We summarize these findings across all studies below.

**Population.** CHW interventions were generally conducted in underserved populations and were not overly restrictive in their inclusion criteria. We note, however, that individual studies tended to focus on a specific subset, such as low-income Latinas or inner-city African-Americans, of the larger and diverse group of the underserved. As a result, the intervention effects are likely to be applicable to the population studied, but the findings cannot be extrapolated as being relevant to all underserved populations. In particular, the applicability of these studies to low-income populations that would not qualify for Medicaid, but could not afford health insurance, is unclear.

Intensity of the treatment. As noted in earlier chapters, the studies in this review were predominantly high intensity (51 percent) or moderate intensity (34 percent) rather than low intensity (15 percent). We found CHW interventions for Pap smears to be more effective than comparison efforts (such as no intervention, media, print, community interventions, and usual care) only in the relatively limited circumstances of low- and moderate-intensity interventions rather than high-intensity interventions. We found no clear evidence of variation in the effectiveness of CHW interventions by intensity of the intervention for any other outcomes. The absence of consistent evidence supporting the use of high-intensity interventions and the limited applicability of these more costly approaches to a larger population suggests that future interventions may be well served if they re-examine assumptions that high-intensity interventions work better than moderate- or low-intensity interventions.

Choice of comparator. The wide variation in the choice of comparators across all included studies reflects the immense array of options for health care in the United States. Although investigators often did justify or explain their choices of comparator, the selections often reflected a reasonable range of usual care options for the appropriate subpopulations, such as a health professional alternative for children with chronic diseases or no intervention for home safety. The diversity of these comparators does, however, limit the generalizability of our findings significantly. Our assessment of effectiveness of the CHW arm (or lack thereof) can be interpreted only in the context of the specific comparators in the literature; these findings cannot be said to be meaningful for a comprehensive range of comparators or even for usual care.

**Outcomes.** Forty-two percent of the 53 studies reported on behaviors, 51 percent on health outcomes, and 57 percent on health care utilization. The focus on these outcomes was appropriate and applicable to settings other than those selected for the study. The choice of outcome measures was rarely comparable across studies. The variations in outcome measures and choice of comparators precluded quantitative syntheses.

**Timing of followup.** Included studies by and large had an appropriate length of followup for examining the effect of the CHW intervention. Some outcomes, such as developmental outcomes for children in the relatively short term (12 months to 4 years), may not always have a high

correlation with long-term health outcomes, but we regard them as appropriate for the intervention.

## **Summary Findings by Clinical Context**

**Health promotion and disease prevention.** Eleven studies addressed health promotion and disease prevention, including pediatric immunizations, <sup>68-72</sup> cardiovascular disease, <sup>105,118,119</sup> diabetes prevention, <sup>16,127</sup> HIV prevention, <sup>117</sup> second-hand smoke exposure, <sup>67</sup> colorectal cancer prevention, <sup>107</sup> and general preventive care. <sup>64-66</sup> Two studies on disease prevention found that CHW interventions were more effective in changing knowledge than print or no intervention. <sup>16,117,127</sup> Results for CHW interventions on behavior outcomes were mixed, with half of the studies favoring CHW intervention versus control groups consisting of no intervention, media/print, or a combination of interventions. <sup>16,105,118,119,127</sup> None of the studies evaluated satisfaction outcomes. Results for CHW interventions on health outcomes, available from four studies, <sup>16,68-72,127</sup> were also mixed.

The results suggest that CHW interventions can serve as an effective means of improving knowledge outcomes and possibly other outcomes related to preventing disease in underserved, minority populations.

**Injury prevention.** Three studies assessed injury prevention measures: two focused on home injury prevention <sup>101,102</sup> and one considered workplace injury prevention. <sup>126</sup> The workplace study found improvements in behavior associated with CHW interventions when compared with a minimal community intervention. <sup>126</sup> One home injury prevention study found mixed results with CHW interventions showing statistically significant benefit in some measures but controls (with no intervention) showing statistically significant benefit over CHW interventions for other measures. <sup>102</sup> The other home injury prevention study showed no significant difference in behavior between CHW interventions and health care professional. <sup>101</sup> None of the studies assessed direct health outcomes. The mixed results preclude any firm conclusions regarding the benefit of CHW interventions for injury prevention.

**Maternal and child health.** Fifteen studies meeting our inclusion criteria involved primarily maternal and/or child health. <sup>67,71-87,128</sup> Of these, 12 focused exclusively on potentially vulnerable populations (e.g., racial or ethnic minorities, recent immigrants, low-income families, inner-city residents). <sup>67,68,71,72,75-77,79-82,84-87</sup> Another three targeted families identified as high risk for child maltreatment. <sup>73,74,78,128</sup> Pregnant women were part of the target population for eight studies. <sup>71,72,77,79-83,86,87</sup> One study each addressed pregnant women with phenylketonuria (PKU), <sup>83</sup> children with failure to thrive, <sup>75,76</sup> and children with "chronic disease" (not otherwise characterized). <sup>85</sup>

Statistically significant benefit of CHWs over standard care was shown most prominently in the rapidity of metabolic control for mothers with PKU and in the mental development of infants of mothers with PKU. 83 CHW interventions were associated with a greater likelihood of initiating breastfeeding among African Americans, more frequent use of nonviolent discipline methods by parents, and higher parenting efficacy scores than either video intervention or no intervention. The study of infants with failure to thrive found a decline in cognitive and motor development among infants and an increase in depressive symptoms among mothers over time in both arms of the study; however, CHWs were significantly associated with attenuation in the decline in cognitive and motor development of infants with failure to thrive and in the increase in depressive symptoms among mothers when compared with no intervention. 75,76 No significant advantage to CHW intervention was seen for improvements in incidence of low birth weight,

presence of neonatal or infant health problems, language development, maternal stress or self-esteem, continuation of breastfeeding beyond 1 week, tobacco exposure for children of smokers, continued drug use among mothers with known prior drug use, growth of children with failure to thrive, or incidence of child maltreatment when compared with nurse interventions, multidisciplinary specialty clinical care, video or print intervention, routine health care, or no intervention.

Most studies involving CHWs for maternal and child health were concerned with high-risk populations. For maternal and child health, CHWs appear to be most beneficial when addressing existing health conditions instead of potential conditions, i.e., primary prevention. Eight of the 15 studies evaluated reported statistically significant benefit to CHWs compared with nurse interventions, multidisciplinary specialty clinical care, video or print intervention, routine health care, or no intervention. CHWs have not yet been shown to improve key health outcomes relating to maternal and child health such as prematurity, low birth weight, sustained breastfeeding, or child maltreatment relative to other alternatives such as video or print intervention, routine health care, or no intervention. The lack of such findings suggests either that further research is needed to demonstrate benefits or that the use of CHWs in this domain actually does not produce greater benefits than the use of existing approaches.

**Cancer screening.** Fifteen studies that examined outcomes of CHW interventions for improving breast, cervical, or colorectal cancer screening met inclusion criteria for this systematic review. <sup>15,17-22,59-63,103,104,106-113,116,125</sup> All studies focused on minority or underserved communities. With the exception of two studies on colorectal cancer screening that included both men and women, all studies focus on increasing the rates of breast and cervical cancer screening among women.

Together, the 15 studies suggest limited evidence of improvement in knowledge in the CHW arm compared with groups receiving alternative approaches such as media or mail. Findings were conflicting about the effect of CHWs on planned or actual behavior changes, specifically breast self-examination, when compared with no intervention, delayed intervention, mail, minimal CHW, or usual care. The volume of evidence on health outcomes is limited; the quality and design of the studies limits the interpretation of available evidence.

Regarding health care utilization, our findings from limited evidence suggest that CHW interventions are not effective in comparison with other alternatives (such as no intervention, mail, tailored print and video, and minimal CHW) in raising the rates of clinical breast examination or colorectal cancer screening. More substantial evidence exists on Pap smears and mammography. It suggests that CHWs are at least as effective as alternative steps (such as mail or lower-intensity CHW interventions) in improving Pap smear rates; they are more effective than alternatives (such as no intervention, media, print, community interventions, and usual care) only in limited circumstances of low- and moderate-intensity interventions rather than high-intensity interventions. Studies demonstrated significantly greater improvements in the CHW groups than in comparison groups (no intervention, mail, print, or minimal CHW) in either the entire sample or in low-income, minority, or other underserved subsamples.

CHW interventions were more effective than alternatives (ranging from usual care to a less intense CHW arm) for increasing the appropriate use of Pap smears and mammograms, for specific subpopulations and subtypes of interventions. They were not, however, more effective than alternatives for increasing the utilization of breast self-examination, clinical breast examination, or colorectal cancer screening. CHWs can serve as a means of improving

utilization of Pap smear tests and mammograms for underserved populations; the effectiveness of CHWs for other outcomes requires further research.

**Chronic disease management.** Thirteen studies addressed disease management for several diagnoses: diabetes mellitus, <sup>27,88-93,124</sup> hypertension, <sup>23,94,98,99,123</sup> asthma, <sup>96,97,100</sup> back pain, <sup>114</sup> mental health, <sup>120,121</sup> and tuberculosis. <sup>122</sup> Only one of these studies addressed knowledge of diabetes and found an improved score in the CHW group compared with the group receiving usual care plus educational pamphlets. <sup>27</sup>

Two CHW interventions on diabetes <sup>88-92,124</sup> and both asthma studies <sup>96,97,100</sup> addressed behavior changes; for diabetes, they favored CHW interventions over usual care and a less intense CHW arm, and for asthma, they favored CHWs with respect to improving use of bedding encasements but not smoking cessation. Only the study in mental health addressed satisfaction outcomes; it did not demonstrate a difference between the CHW and the control groups. <sup>120,121</sup>

Several studies investigated various health outcomes. In diabetes management, two of four studies found that a CHW intervention was more effective than usual care in decreasing HgbA1c. <sup>27,93</sup> None of the four studies addressing hypertension management showed a significant difference in blood pressure control between groups. <sup>23,94,98,99,123</sup> Both asthma studies demonstrated that CHW interventions were effective in reducing unscheduled health care services, psychological outcomes, and behavior changes between groups; <sup>96,97,100</sup> however, symptom measures improved within the CHW and comparison groups but did not differ significantly between the groups.

In four of five studies on chronic disease management, a CHW intervention was more effective than either usual care or a less intense CHW arm in improving health care utilization for hypertension, mental health, and asthma. 96,97,100,122,123 The fifth study found that CHWs were less effective than a monetary incentive in increasing adherence to clinic appointments among tuberculosis-infected patients.

For chronic disease management, the majority of CHW interventions failed to show greater improvement in health outcomes than were observed for usual care. The exception is asthma care, for which CHWs were effective for many outcomes. Further research is necessary to determine the role of CHWs in chronic disease management.

# Cost-Effectiveness of Community Health Worker Interventions (KQ 3)

Only six studies that we identified in the literature provided economic analyses of CHW interventions. <sup>17,22,75,80,96,121</sup> Our analysis does not include three other studies of CHW interventions that reported information on intervention program costs but found that CHW interventions were ineffective or less effective than the baseline care approach. <sup>64,67,69,70</sup>

All six studies included for this KQ estimated intervention program costs, but not all reported the specific components of those costs or the year for which costs were estimated. Four of the studies performed economic analyses beyond program cost estimation to examine program costs in relationship to effectiveness. The two cancer screening studies both reported estimates of the cost per additional mammography screening. Although the common measures reported across these two studies suggest that comparisons might be straightforward, differences in the targeted populations nonetheless hinder comparisons of cost-effectiveness ratios across the studies. In particular, the low-intensity intervention targeted women regardless of their adherence to screening guidelines; however, the high-intensity intervention targeted only nonadherent women.

The other two studies that performed additional economic analyses focused on estimating potential reductions in costs of both health care and social services attributable to the CHW intervention.

None of the CHW intervention evaluations that included an economic analysis reported a standard measure of costs per quality-adjusted life year saved as recommended in recent guides for performing economic evaluations. 130,131,2003 One study did report on the costs per life-year saved of the CHW intervention, which is useful for comparing the intervention costs with those for other life-saving interventions, but that study provided the intervention both to women who had previously obtained mammography in line with mammogram screening guidelines and to women who had not; this approach biases the cost-effectiveness results in favor of the intervention, even when CHW time was valued using average wage rates. The lack of reporting on intervention costs and cost-effectiveness according to standardized and commonly accepted measures makes it challenging to compare economic outcomes across CHW intervention studies; it also makes it even more complicated to compare cost-effectiveness between CHW interventions and non-CHW health care interventions currently being reported in the literature.

In sum, limited evidence is currently available on the cost-effectiveness of CHW interventions for 7 of the 20 clinical contexts and subdomains we have examined in this systematic review (Table 42). For all the other clinical concerns described in Table 36, we found no evidence. Until better information is made available, assessing whether CHW interventions are a cost-effective alternative to clinical interventions to promote health and prevent disease is difficult, if not impossible.

Table 42. Cost and cost-effectiveness of CHW interventions: strength of evidence

Number of Studies; # of Subjects	Risk of Bias Design/ Quality	Consistency	Directness	Precision	Other Modifying Factors (Intensity, Confounding) pediatric immu	Results	Overall Strength of Evidence
1; NA <sup>69,70</sup>						Not evaluated because of lack of evidence of intervention effectiveness	
	Hea	alth promotion a	nd disease prev	ention: hea	Ith promotion -	Latina health	
1; NA <sup>64</sup>						Not evaluated because of lack of evidence of intervention effectiveness	
		Mate	rnal and child	health: child	development		
2;130 <sup>75</sup> 630 <sup>80</sup>	Low 2 RCTs	Consistent	Direct	Imprecise	Absent	Cost for CHW home visitation program was lower than for nurse home visitation program; no comparison of costs to program effectiveness	Low

CHW, community health worker; RCT, randomized controlled trial.

Table 42. Cost and cost-effectiveness of CHW interventions: strength of evidence (continued)

Number of Studies; # of Subjects	Risk of Bias Design/ Quality	Consistency	Directness	Precision	Other Modifying Factors (Intensity, Confounding)	Results	Overall Strength of Evidence			
	Maternal and child health: environment conducive to child well-being									
1; NA <sup>67</sup>						Not evaluated because of lack of evidence of intervention effectiveness				
		Can	cer screening:	mammograp	hy promotion					
2; 851 <sup>17</sup> 1,443 <sup>22</sup> 1; 165 <sup>121</sup>	Moderate 2 RCTs High	Chro-Consistency	Direct  Direct  Direct	Imprecise  anagement: Imprecise	Absent  mental health Absent	Cost per additional mammogram is not a standardized measure that can be compared to the cost-effectiveness of other interventions	Low			
., 100	1 RCT	unknown (single study)		·		slightly lower for CHW arm than for traditional assertive community treatment; inconclusive results on impact of CHW on net program costs				
Chronic disease management: asthma										
1;170 <sup>96</sup>	Low 1 RCT	Consistency unknown (single study)	Direct	Imprecise	Absent	Larger urgent care cost reductions for high-intensity CHW group as compared to low-intensity CHW group.	Moderate			

# **Training of Community Health Workers (KQ 4)**

We found only nine studies meeting our inclusion criteria that described the training of CHWs. 137,141,143,147,150,155,169 148,149,176 Our inclusion criterion required the evaluation of skills before and after training; all included studies reported evidence of improvement in knowledge or skills. Few studies reported on training for cultural competence, recruitment and retention process skills, intake and assessment, and protocol delivery; studies generally focused on aspects of training relevant to the health concern.

Such data are useful for future studies on the same clinical topic, but the failure to report on common elements such as cultural competence, recruitment and retention process skills, intake and assessment, and protocol delivery presents a roadblock to identifying critical elements of a standardized curriculum applicable to all CHWs. Whether studies routinely conduct such training and do not report on them is unclear from the studies that we identified.

No study reported on the effects of CHW training on health outcomes. Practitioners and policy makers seeking to institutionalize CHWs may seek to understand what measures of CHW activities best assess the effectiveness of their contributions to improved health outcomes and further, how to incorporate those elements into training curricula. As seen from the limited evidence available to answer KQ 4b, studies do not presently report sufficient information to answer this question. The question of how to tailor CHW training to improve health outcomes is a significant gap for future studies to address.

Two studies reported certification associated with their curricula. One study, focusing on tobacco cessation, offered three levels of certification: introductory ("Basic Skills to Stop Using Tobacco"), intermediate ("Treatment Specialist"), and advanced ("Leave the Addiction"). <sup>150</sup> A second study, on cancer education, provided a certificate of completion at the end of the training, but it gave no further details. <sup>143</sup>

Several studies reported on the availability of their curricula for future projects. These included topics related to safe manufacture of queso fresco, <sup>155</sup> tobacco cessation, <sup>150</sup> breast cancer education, <sup>137</sup> heart disease and stroke, <sup>147</sup> and heart healthy behaviors among Latinos. <sup>149</sup>

We note that the nine studies identified as eligible for this KQ represent a small fraction of all studies reporting on training. Other ineligible studies did not evaluate pre- and posttraining skills or knowledge: many were purely descriptive of training programs. 

Among the ineligible studies that provided a critical appraisal or evaluation of the training program without pre- and posttraining results, several limited the assessment of the knowledge or skills of the CHW to the posttraining period only, without a pretest. 

139,142,145,156,160,167,173,176 A substantial number of other ineligible studies evaluated the training or curriculum based on feedback from designers, trainers, or other stakeholders.

<sup>174,176</sup> These studies could not inform our key question on training; thus, we excluded them from the systematic review proper, but we note them here to be helpful to readers who may wish to pursue these topics further.

## **Limitations of this Review**

#### **Limitations of the Evidence Base**

**Reporting.** Our ability to draw conclusions on the effectiveness of CHW interventions is limited by the relative paucity of detail on specific elements of the interventions. Studies inconsistently adhered to reporting standards such as STROBE<sup>178</sup> and CONSORT, <sup>179</sup> making critical appraisal of internal validity and assessment of applicability challenging. In particular, many studies did not report on the intensity of the intervention (the number and length of sessions and the time period of interaction with clients), the existence of protocols governing the intensity of intervention, or fidelity to such protocols. CHW interventions represent an opportunity to translate effective interventions into a variety of community settings; the absence of information on fidelity limits their translation. The limited available information on protocol also results in little usable data on training of CHWs.

Choice of appropriate comparators. The evidence base is marked by great heterogeneity in comparators in addition to appreciable diversity in the CHW model itself. Although appropriate comparators can and should differ by the specific outcomes being addressed, studies often did not justify the choice of comparator(s), either on its own merits or in relation to usual care. For that reason, our conclusions regarding the effectiveness of CHWs are necessarily limited. We

also note that a potential Hawthorne effect may exist for studies comparing variants of CHW interventions rather than CHW interventions with usual care: the effect of the more intense arm may have been diluted by a Hawthorne effect in the less intense arm, whereby observation by CHWs could improve outcomes (at least in the short term) in the latter case.

**Study design.** Many studies did not report *a priori* hypotheses about their primary outcomes or give details about their power calculations (if any were done). Limited sample sizes may have resulted in studies that were not powered to find a difference between "experimental" and "control" or "comparison" groups where one may in fact exist.

A further design limitation is the frequent reliance on CHWs for data collection of outcomes in all study arms. This practice can lead to potential bias on the part of the outcome assessor; when subjects are providing responses directly to the CHWs gathering data about outcomes, their information may be colored by social desirability on their part. Moreover, a potential Hawthorne effect in this situation cannot be ruled out, as noted above.

Appropriate adjustment for confounding. The evidence base is also limited by variations in the specific confounders and effect modifiers that investigators included or controlled for in their analyses. Omitting important confounders and effect modifiers, especially co-interventions in comparison arms, limits the interpretability and utility of the evidence from such investigations. Furthermore, using the studies that did account for confounders and effect modifiers is hampered by the lack of consistent definition and inclusion of key variables.

These deficiencies together appreciably limit the consistency and validity of the evidence. As a result, we found very few outcomes for which we were able to attribute at least a moderate strength of association, despite the relatively large body of evidence that we examined.

#### Limitations of the Review

We limited our search to articles published in English, primarily for reasons of time and resources. We excluded studies with samples sizes less than 40. We also limited our review to the United States, so our review does not address the nature, outcomes, or cost-effectiveness of CHW interventions, or the training of CHWs, elsewhere, particularly in developing countries. However, whether CHWs in the United States have the same professional and sociodemographic characteristics as CHWs elsewhere is not well understood, so for purposes of this review, constraining the included studies to those done in the United States may not have influenced our findings much.

Our decision to include studies with comparison arms for KQs 1 and 2 likely reduced our yield of studies for knowledge, behavior, and satisfaction. We note, however, that studies reporting on knowledge, behavior, and satisfaction alone, without additional data on health outcomes, do not add to the evidence on the critical question of whether CHW interventions improve health outcomes.

For similar time and resource reasons, we did not conduct dual independent, blinded review of articles for abstraction of information into evidence tables. Instead, one reviewer performed the initial review, and a second reviewer examined that input and recommended changes or corrections when needed. These two reviewers reconciled any differences by consensus discussion. These procedures are generally in accord with the usual procedures for the RTI-UNC Evidence-based Practice Center. To enable us to address any systematic bias in our work that the above approach may have introduced, however, we did apply dual independent review for assessing the quality of individual articles and grading the strength of evidence.

The paucity of "similar" articles, for populations, patient characteristics, settings, and outcomes measured, precluded any efforts to pool findings statistically.

### **Future Research Directions**

The evidence on CHW interventions, although extensive, could benefit from future research. We discuss methodological improvements, design considerations, and substantive gaps below.

**Methodological improvements.** Future studies should consistently adopt four important steps: (1) give clear conceptual models that explain the expected mechanism of change initiated by the CHW intervention, (2) justify the choices of alternative or comparison steps; (3) specify *a priori* the primary outcomes to be measured; and (4) state hypotheses that build upon the conceptual framework and the choice of comparator. In addition, studies of CHW interventions should calculate required sample size to ensure that they are adequately powered and report on those power calculations.

Studies will also benefit from external evaluation of outcomes by investigators or data collection personnel blinded to the experimental and comparison groups rather than measurement of outcomes by CHWs. Such results would be less likely to be influenced by social desirability bias or other problems of internal validity of results. These benefits must be weighed against the practical difficulties of obtaining outcome data through external observers who (unlike CHWs) may not have a relationship with the community and may be viewed with a greater degree of suspicion.

A significant gap that future studies can address is adequate reporting of design, exposures, and outcomes. Adherence to standards such as STROBE<sup>178</sup> and CONSORT<sup>179</sup> will help to improve the strength of evidence provided by this literature. More generally, studies infrequently reported the gap between planned and actual protocol delivery; reporting the changes to protocol delivery is critical to a better understanding of how to scale up effective interventions.

**Design considerations.** CHW interventions will also benefit from the use of practical clinical trials. CHW interventions are examples of community-based research, which is vital for successful Type 2 translation – the adaption of evidence-based interventions to real-world settings. Representative participants, multiple and diverse settings, clinically relevant alternative interventions, and a focus on measures relevant to decision makers, which include cost, quality of life, reach, and adoption) can enhance the utility of CHW studies for translational research. Representative participants and adoption can enhance the utility of CHW studies for translational research.

The RE-AIM framework<sup>††</sup>-reach, effectiveness, adoption, implementation, and maintenance-provides practical guidance for the development of measures of public health impact for CHW interventions. <sup>186</sup> Studies in our review focused on effectiveness, but they rarely provided quantitative assessments of these elements as measures of public health impact, despite their underlying reliance on models of community change in addition to individual change.

 $^{\dagger\dagger}$  According to the RE-AIM framework 186 (reach is defined as the absolute number, proportion, and representativeness of

program or policy becomes institutionalized or part of the routine organizational practices and policies. Within the RE-AIM framework, maintenance also applies at the individual level. At the individual level, maintenance has been defined as the long-term effects of a program on outcomes after 6 or more months after the most recent intervention contact.

individuals who are willing to participate in a given initiative, intervention, or program. Efficacy or effectiveness is the impact of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes. Adoption is the absolute number, proportion, and representativeness of settings and intervention agents (people who deliver the program) who are willing to initiate a program. At the setting level, implementation refers to the intervention agents' fidelity to the various elements of an intervention's protocol, including consistency of delivery as intended and the time and cost of the intervention. At the individual level, implementation refers to clients' use of the intervention strategies. Maintenance is the extent to which a

Investigators may find the RE-AIM formulation helpful in providing an analytic or logic model by which to design and conduct their studies.

**Substantive gaps.** We identified several substantive gaps in the field that warrant further attention. They fall into several groups: (1) outcomes themselves, specifically knowledge and satisfaction; (2) clinical areas, including obesity prevention and colorectal cancer screening; (3) populations addressed, and specifically interventions for certain underserved populations; and (4) costs and cost-effectiveness analysis. We discuss these points in greater detail below.

Theoretical models underpinning CHW interventions postulate changes in knowledge as precursors to changes in behavior, health outcomes, or health care utilization. Our review uncovered surprisingly few studies that examined changes in knowledge. Although the focus on health outcomes and health care utilization is appropriate, additional evaluation of changes in knowledge would help to clarify the processes of change initiated by CHWs; such information would then aid investigators in refining aspects of their interventions that are not as effective as expected.

CHW interventions serve as a bridge to the health care system for the underserved and are expected to serve as a tool to reduce disparities in access to and quality of care. Improved satisfaction of participants with CHW interventions is a necessary first step to successful implementation of the intervention and eventual reduction in disparities. As with the literature on knowledge and evaluation of public health impact, single-arm studies may well report satisfaction in greater depth; more rigorous comparative studies almost uniformly do not report on satisfaction. Further investigation of satisfaction, in addition to the existing and appropriate focus on behaviors, health outcomes, and health care utilization, can help illuminate the effects of CHW interventions on health disparities.

Despite evidence of effectiveness and recommendations from a number of organizations including the US Preventive Services Task Force and the American Cancer Society, colorectal cancer screening uptake has been suboptimal. Roughly 60 percent of adults older than 50 report having been screened for colorectal cancer. <sup>187,188</sup> In addition, even lower rates of screening have been reported in populations with high poverty rates <sup>189</sup> and in racial and ethnic minorities, including Hispanic and nonwhite populations. <sup>190</sup> We uncovered a single study focusing on CHW interventions for colorectal cancer; <sup>107</sup> future research in this area may be fruitful in identifying successful strategies for increasing screening rates for this deadly condition.

Existing CHW interventions often focus on underserved populations defined by race, ethnicity, or geographic location. Underserved groups such as low-income populations who are ineligible for Medicaid (such as low-income undocumented immigrants) and therefore at higher risk of being uninsured or the elderly may also potentially benefit from studies of CHW interventions. Important conditions for such investigators include mental health problems, dementia including Alzheimer's disease, and disabilities.

Future research on CHW interventions should focus on designing studies that prospectively collect data on program costs and effectiveness. Such work should aim to ensure that all necessary data are collected to perform and report on the cost-effectiveness or net costs of the CHW intervention as compared with baseline and alternative approaches. Program managers and local evaluators may benefit from checklists <sup>130,131</sup> and step-by-step instructions for designing and performing economic evaluations of health care and community prevention interventions. <sup>191</sup> The first step in collecting program cost data is to list the key program activities. The next steps are to determine the perspective of the cost analysis (e.g., program, patient, or societal perspective) and to list all the resources required to support each activity (e.g., labor, contracted services,

materials and supplies, building space, donated resources). The final steps are to create a system and forms for the ongoing collection of program cost data. Many resources are available to guide program managers through each step of the cost data collection process, including checklists published in Gold et al., 1996<sup>130</sup> and Haddix et al., 2003<sup>131</sup> and forms available online in Honeycutt et al., 2006. 191 These lists and forms can readily be adapted to capture all of the resources used or lost in providing CHW program activities. For example, to collect and analyze the costs of multiple arms of a CHW intervention program, a list of activities and resources to support the activities should be created for each arm. Based on these lists, worksheets should be developed specific to each intervention arm for use in prospective program data collection. After all data have been collected, costs for each intervention arm should be estimated and reported alongside other study outcomes. Economic evaluations of CHW interventions should also include sensitivity analyses to examine how uncertainty or variability in assumed costs or effectiveness affects program cost-effectiveness. For example, time spent by CHWs in delivering the intervention should be given a positive value in all economic evaluations of CHW interventions, but it may also be useful to explore the extent to which valuing time at the minimum wage makes the intervention look favorable as compared with valuing time at average wage rates for paid health care workers (e.g., licensed practical nurses or medical assistants).

In summary, future economic evaluations of CHW interventions should (1) evaluate the cost-effectiveness of the interventions as compared with baseline or alternative interventions, (2) model program outcomes to estimate the program's full impact on life years or quality-adjusted life years saved to improve comparability of results, and (3) include sensitivity analyses to examine the impact of variability in economic inputs on the cost-effectiveness of CHW interventions. Using such standard approaches to evaluate CHW interventions will improve the utility and comparability of study results; thus, such approaches will also aid decision makers in determining which health promotion and disease prevention activities to support.

In the absence of consistent data on intervention costs, we created a pragmatic measure in this report to approximate the intensity of resources used for CHW interventions. Consistent data on costs in future studies will ideally provide the best information to evaluate intervention intensity. In the interim, further development and validation of pragmatic measures of resource intensity can help policy makers shape the specifics of CHW interventions to provide the most meaningful benefit for improved health outcomes.

## Conclusion

CHW interventions have the potential to address two fundamental imperatives in improving health care in the United States: the need to address substantial and persistent health care disparities and the need to translate more research into practice. CHWs, by virtue of their role as a bridge to the health care system, can help to disseminate widely efficacious interventions to populations that rarely benefit from health care advances.

Evidence about the effectiveness of CHWs relative to other choices for providing these types of health care and public health services is at best mixed. Some studies that we assessed demonstrated statistically significant benefits of the CHW approach compared with other choices; other studies showed conflicting results or no statistically significant differences between study arms. For the latter studies, one explanation is a lack of true benefit of the CHW arm relative to other choices. In addition, the choice of controls, including health professionals

and CHWs in a lesser capacity, inadequate study power, and the Hawthorne effect may explain the lack of significant differences between CHWs and alternatives.

We found limited evidence that suggests that CHW interventions can improve participant knowledge when compared with alternative approaches such as no intervention, media, mail, or usual care plus pamphlets. We found mixed evidence for CHW effectiveness on participant behavior change and health outcomes: some studies suggested that CHW interventions can result in greater improvements in participant behavior and health outcomes when compared with various alternatives, but other studies suggested that CHW interventions provide no statistically different benefits. Low or moderate strength of evidence suggests that CHWs can increase appropriate utilization for some conditions or preventive services.

The literature showed mixed results of effectiveness when analyzed by clinical context. CHW interventions had the greatest effectiveness relative to alternatives for some disease prevention, asthma management, cervical cancer screening, and mammography screening outcomes. CHW interventions were not significantly different from alternatives for clinical breast examination, self-breast examination, colorectal cancer screening, chronic disease management, or most maternal and child health interventions. We found insufficient evidence to evaluate the cost-effectiveness of CHW interventions relative to other public health interventions.

Our review suggests that CHWs may serve as a means of improving outcomes for underserved populations for some health conditions, as described above. Other health concerns require further research that addresses methodological limitations of prior studies to evaluate fully the effectiveness of CHW interventions.

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**Appendix A: Exact Search Strings** 

# **Appendix A: Exact Search Strings**

Medline Focused Search: April 2008	
#2 Search "Community Health Aides" [Mesh] OR "health advisor" OR "health worker" OR "health advocate" OR "health paraprofessional" OR "community health representative" OR "outreach worker" OR dumas OR promotoras OR embajadores OR consejeras	6051
#3 Search "Community Health Aides" [Mesh] OR "health advisor" OR "health worker" OR "health advocate" OR "health paraprofessional" OR "community health representative" OR "outreach worker" OR dumas OR promotoras OR embajadores OR consejeras Limits: Humans, English	3031
#6 Search (("Outcome Assessment (Health Care)"[Mesh] OR "Pregnancy Outcome"[Mesh])) OR ("Treatment Outcome"[Mesh] OR "Outcome and Process Assessment (Health Care)"[Mesh] OR "Fatal Outcome"[Mesh])  Limits: Humans, English	369350
#7 Search #3 AND #6 Limits: Humans, English	175
#17 Search ((("Patient Education as Topic"[Mesh] OR "Patient Education Handout "[Publication Type])) OR "Professional-Patient Relations"[Mesh]) OR "Office Visits"[Mesh] Limits: Humans, English	109582
#18 Search #3 AND #17 Limits: Humans, English	90
#26 Search ("Costs and Cost Analysis" [Mesh] OR "Economics" [Mesh] OR "economics" [Subheading] OR "Cost-Benefit Analysis" [Mesh] OR "Cost Allocation" [Mesh] OR "Cost of Illness" [Mesh] OR "Cost Control [Mesh] OR "Cost Sharing" [Mesh] OR "Cost Savings" [Mesh] OR "Health Care Costs" [Mesh] OR "Direct Service Costs" [Mesh] OR "Hospital Costs" [Mesh] OR "Employer Health Costs" [Mesh] OR "Drug Costs" [Mesh] Limits: Humans, English	257114
#27 Search #3 AND #26 Limits: Humans, English	254
#28 Search United States Limits: Humans, English	606881
#29 Search #27 AND #28 Limits: Humans, English	71
#33 Search (("Education"[Mesh] OR "education "[Subheading])) OR "Education, Professional"[Mesh] OR training Limits: Humans, English	370579
#34 Search #3 AND #33 Limits: Humans, English	1013
#35 Search #34 AND #28 Limits: Humans, English	241
#41 Search (((("Randomized Controlled Trials as Topic"[Mesh] OR "Randomized Controlled Trial "[Publication Type])) OR "Single-Blind Method"[Mesh]) OR "Double-Blind Method"[Mesh]) OR "Random Allocation"[Mesh] Limits: Humans, English	303728
#42 Search #3 AND #41 Limits: Humans, English	165
#44 Search control OR controlled Limits: Humans, English	1368901
#45 Search #3 AND #44 Limits: Humans, English	908

154

Medline unduplicated records = 640

```
Cochrane April 2008
Analogous terms
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= 11\*

Cochrane Clinical Trials Registry April 2008

Analogous terms

= 41\*

Unduplicated in Medline search

CINAHL April 2008

Analogous terms

KQ1 = 61\*

KQ2 = 45\*

KQ3 = 21\*

KO4 = 21\*

Total unduplicated across all searches = 815

Update search November 2008

Medline = 38\*

Cochrane = 0

Cochrane Clinical Trials Registry = 9\*

CINAHL = 13\*

\*Unduplicated in previous searches

Supplemental search: "Patient Navigator"

Medline = 21

CINAHL = 26

Cochrane – 8

Total new (unduplicated across all new and prior searches) = 25

<sup>\*</sup>Unduplicated in Medline search

<sup>\*</sup>Unduplicated in Medline search

**Appendix B: Abstract Forms** 

#### **Appendix B. Abstraction Forms**

#### **Abstract Review Form** (Originally in Excel)

Column	Question
A	Refid
В	Author, Year
С	Original research (Exclude editorials, commentaries, letters to the editor, reviews etc)
D	Includes community health worker component
E	Study published in English?
F	Is this study located in the US?
G	If not in US, where?
Н	RCT and
	n ≥ 40
I	Cohorts with comparison and
	n <u>&gt;</u> 40
J	Cost or cost-benefit analysis
К	Exclude ("No" on one or more questions in Columns C - I)?
L	Name of intervention (if provided)
M	Retain for - Background or
	discussion or review of references
	other
N	Comments
0	Reviewer initials

# Full-text review form (Originally in EXCEL)

Column	Question
Α	Refid
В	Author, year
С	Reviewer Initials
D	Abstract only
E	Wrong population (non-US)
F	Wrong Outcomes (no patient related health
	or economic outcomes)
G	Study not about CHW
Н	Wrong publication type (review or letter to
	the editor)
1	Sample size too small (<40)
J	No comparison arm/data
K	Comparison arm/data not about CHW or
	CHW alone
L	CHW component insufficiently described to
	distinguish between CHW and other peer
	led models
M	Other?
N	Exclude but save for background, cost,
	training or setting, pick one! (only if yes for
	at least one column D-M)
0	Should be included for KQ 4a
	(What are characteristics of training for
	community health workers in the outpatient
	setting?)
Р	Should be included!
Q	Need more information
R	Related citations
S	Left blank
Т	How do community health workers interact
	with clients? Specifically, what is the place
	of service, type of service, type of
	educational materials used, duration of
	interaction with clients, and length of
	followup?
U	What is the impact of community health
	workers on outcomes, particularly
	knowledge, behavior, satisfaction, health
	outcomes, and health care utilization?
V	What is known about the cost-effectiveness
	of community health workers for improving

	health outcomes?
W	Are particular training characteristics
	associated with improved outcomes for
	patients?
X	Study design
Υ	Comparisons (identify arms) i
Z	Health condition of interest
AA	Name of intervention
AB	Notes- including additional citations

# **Abstraction Form for Evidence Tables** (Originally in EXCEL)

Column	Category	Question
Α	Identifying information	Reviewer Initials
В		Author Year {#RefID}
С	_	Trial Name
D	_	Objective or aim
E	Setting	Setting: Geography
F		Setting: Organizational, Social, Cultural
G		What is the community? (neighborhood, disease etc.)
Н	_	Study design: RCT/Prospective cohort/Retropective cohort/Prospective cohort with historic control/case-control/case series/other
1		Start date- year
J	1	Duration - length
K	N	Eligible
L		Enrolled
M	_	Randomized
N		Completers
0		Withdrawals or dropouts
Р		Health condition of interest
Q	Inclusion/Exclusion	Inclusion criteria (include run-in details)
R		Exclusion criteria
S	Groups	Groups (please use-G1: G2: G3: etc.)
Т		Describe interventions (if necessary)
U		n of each group
V	Community Health	CHW definition:
W	Worker	CHW training:
Х		Place of service
Υ		Title of CHW (specify: lay health advisor, community health worker, etc)
Z		Paid or volunteer
AA		Relationship with the community (rshared race, ethnicity, disease condition, etc)
AB	Community Health	N of CHW
AC	Worker (continued)	Supervision of CHW (who supervises [clinician vs non clinician] and frequency of supervision)  Prior training of CHW
ad		
AE	_	Type of advectional materials utilized
AF		Type of educational materials utilized
AG	_	Duration of interaction with clients
AH		Length of followup

Column	Category	Question
Al	Baseline	Age (mean)
	characteristics of patients	
	patients	
AJ		Sex (% female)
AK		Race (%)
AL		Other?
AM	Recruiting and	Role of CHW in recruiting and retention
AN	retention	Recruitment: Need rates for each group
AO		Retention: Need rates for each group
AP	Knowledge and	Measure (Is it valdidated?)
AQ	attitude	Results
AR		Measure (Is it valdidated?)
AS		Results
AT		Measure (Is it valdidated?)
AU	7	Results
AV	Quality of Life	Measure (Is it valdidated?)
AW		Results
AX	7	Measure (Is it valdidated?)
AY	7	Results
AZ	7	Measure (Is it valdidated?)
BA		Results
BB	Health Outcomes	Measure (Is it valdidated?)
ВС		Results
BD		Measure (Is it valdidated?)
BE		Results
BF		Measure (Is it valdidated?)
BG		Results
ВН	Healthcare utilization	Measure (Is it valdidated?)
BI		Results
BJ		Measure (Is it valdidated?)
BK		Results
BL		Measure (Is it valdidated?)
BM		Results
BN	Costs (Economics)	Measure (Is it valdidated?)
ВО		Results
BP		Measure (Is it valdidated?)
BQ		Results
BR		Explanation of overall outcomes.
BS		Quality rating: Good / fair / poor
ВТ	Applicable key	KQ 1 - How do community health workers interact with
	questions	clients? Specifically, what is the place of service, type
		of service, type of educational materials used, duration of interaction with clients, and length of
		followup?
BU		KQ 2 - What is the impact of community health
		workers on outcomes, particularly knowledge,

Column	Category	Question
	, , , , , , , , , , , , , , , , , , ,	behavior, satisfaction, health outcomes, and health
		care utilization?
BV		KQ 3 - What is known about the cost-effectiveness of
		community health workers for improving health
		outcomes?
BW		KQ 4a - What are characteristics of training for
51/	4	community health workers in the outpatient setting?
BX		KQ 4b - Are particular training characteristics associated with improved outcomes for patients?
BY	Additional outcomes	Measure (Is it validated?)
	(please add more	Results
BZ	here at the end if	
CA	you must!)	Measure (Is it validated?)
СВ		Results
CC		Measure (Is it validated?)
CD		Results
CE		Measure (Is it validated?)
CF		Results
CG		The gulf between the rest and KQ4a
СН		(Blank)
CI	Training	Eligibility for CHW training (inclusion criteria for CHW)
CJ	Characteristics	Input of CHW in curriculum development
CK	7	Training on cultural competency (describe content;
O.K		instructional method; number of sessions; testing)
CL	Training	Training on recruitment and retention process skills,
	Characteristics	e.g., motivational interviewing (describe content;
	(continued)	instructional method; number of sessions; testing)
CM		Training on intake/assessment, (describe content;
	4	instructional method; number of sessions; testing)
CN		Training on protocol delivery, i.e., recruitment, followup, fidelity to the intervention, referrals (describe
		content; instructional method; number of sessions;
		testing)
СО		Training on health topic (describe content;
		instructional method; number of sessions; testing)
СР		Training on evaluation (describe content; instructional
		method; number of sessions; testing)
CQ		Other training (describe type)
CR		Other training content; instructional method; number
	_	of sessions; testing
CS		Other training (describe type)
СТ		Other training content; instructional method; number of sessions; testing
CU		Name of curriculum
CV		Availability
CW	=	Evaluation and testing results of the curriculum
CVV		(improvements in CHW knowledge)
CX		Certification (any certication [yes/no/nr]; if yes, name
		of certifying body

# Quality Review for randomized controlled trials (Originally in EXCEL)

Column	Category	Question
Α		REFID
В		Reviewer initial
С	Background/context	Is the hypothesis/aim/objective of the study described?
		Yes No
D	Sample Definition and Selection	Are the inclusion/exclusion criteria clearly stated (does not require the reader to infer)? [Abstractor: use "Partially" if only some criteria are stated clearly.]
		Yes Partially No
Е		Did the authors report conducting a power analysis or some other basis for determining the adequacy of study group sizes for the primary outcome(s) being abstracted?
		Yes No
F	Randomization	Was the assignment to the treatment groups adequately randomized?
		Yes (Adequate approaches to sequence generation, i.e., computer-generated random numbers, random numbers tables) No (Inadequate approaches to sequence generation, i.e., use of alternation, case record numbers, birth dates or week days)  NR
G		Was allocation of randomization adequately concealed?
		Yes (Adequate approaches to concealment of randomisation, i.e., centralised or pharmacy-controlled randomisation, serially-numbered identical containers, on-site computer based system with a randomisation sequence that is not readable until allocation, other approaches with robust methods to prevent foreknowledge of the allocation sequence to clinicians and patients)
		No (Inadequate approaches to concealment of randomisation, i.e., use of alternation, case record numbers, birth dates or week days, open random numbers lists, serially numbered envelopes (even sealed opaque envelopes can be subject to manipulation)
		NA (study not adequately randomized)
		NR
Н	Interventions/Expos ure	What is the level of detail in describing the intervention or exposure?
		Low (unclear, many details missing) Medium (pretty clear, most details provided) High (very clear, all required details provided)

Column	Category	Question
1		Is usual clinical care (sometimes called standard care)
		described?
		Yes
		No
		NA (not an intervention study)
J	Contamination	Did researchers rule out any impact from an unintended
		intervention/exposure that might bias results, e.g., through
		multivariate analysis, stratification, or subgroup analysis?
		Yes
		No
		NA (no unintended interventions reported)
K		Could variation from the protocol have compromised the findings
		of study?
		Yes (variation from protocol exists and could have compromised findings)
		No (variation from protocol exists, but unlikely to have
		compromised findings)
		Cannot determine (no variation from protocol reported)
		NA (study does not require protocol, or no variation from protocol
		exists)
		,
L	Blinding	Outcome assessors masked?
		V
		Yes
		No Yes, but method not described
		Not reported
M		Care provider masked?
IVI		Care provider masked:
		Yes
		No
		Yes, but method not described
		Not reported
		NA NA
N		Patient masked?
		Yes
		No
		Yes, but method not described
0	Soundness of	Not reported  Are interventions/exposures measured in a valid and reliable
0	information	manner?
	inionnation	manner:
		Objective (clinical reports, lab findings, previously validated
		measures)
		Objective measure, not validated
		Prospective documentation (including self-report in daily diaries)
		Retrospective self-report (patient/participant response)
		Not reported
Р		Are outcomes measured in a valid and reliable manner?

Column	Category	Question
		Objective (clinical reports, lab findings, previously validated measures)
		Objective measure, not validated Prospective documentation (including self-report in daily diaries) Retrospective self-report (patient/participant response) Not reported
Q	Follow-up	Is the length of time following the intervention/exposure sufficient to support the conclusions of the study regarding outcomes?
		Yes No
R		Did attrition from any group exceed 20 percent (after randomization)?
		Yes - how much? No Cannot determine
S		Did attrition differ between groups by more than 15 percentage points (after randomization)?
		Yes - how much?
		Cannot determine
Т	Analysis Comparability	Are baseline characteristics similar in exposed and comparison cohorts?
		Yes No Cannot determine
U		Does the analysis control for baseline differences?
		Yes No Cannot determine
		NA (no baseline differences reported)
V	Analysis Outcome	Is the analysis conducted on an intention-to-treat (ITT) basis, that is, the intervention allocation status rather than the actual intervention received?
		Yes No
W		Were there any post-randomization exclusions?
		Yes (how many?) No
V	Interpretation	Cannot tell  Are conclusions supported by results with possible bias and
X	Interpretation	limitations taken into consideration?
		Yes Partially
		railially

Column	Category	Question
		No
Υ	Quality	Good
		Fair
		Poor

# **Quality Review for observational trials** (Originally in EXCEL)

Column	Category	Question
Α		REFID
В		Reviewer initial
С	Background/ Context	Is the hypothesis/aim/objective of the study described?
	Comexe	Yes No
D	Sample Definition and Selection	Are the inclusion/exclusion criteria clearly stated (does not require the reader to infer)? [Abstractor: use "Partially" if only some criteria are stated clearly.]
		Yes Partially No
Е		Did the authors report conducting a power analysis or some other basis for determining the adequacy of study group sizes for the primary outcome(s) being abstracted?
		Yes No
F	Interventions/ Exposure	What is the level of detail in describing the intervention or exposure?
		Intensity, duration, frequency, setting and timing  Low (unclear, many details missing)  Medium (pretty clear, most details provided)  High (very clear, all required details provided)
G		Is usual clinical care (sometimes called standard care) described?
		Yes
		No NA (not an intervention study)
Н	Contamination	Did researchers rule out any impact from an unintended intervention/exposure that might bias results, e.g., through multivariate analysis, stratification, or subgroup analysis?
		Yes No
I		NA (no unintended interventions reported)  Could variation from the protocol have compromised the findings of study?
		Yes (variation from protocol exists and could have compromised findings)  No (variation from protocol exists, but unlikely to have compromised findings)  Cannot determine (no variation from protocol reported)  NA (study does not require protocol, or no variation from protocol exists)
J	Blinding	Were the outcome assessors blinded to the intervention or

Column	Category	Question
		exposure status of participants?
		Vac
		Yes No
		NA (not an intervention study)
K	Soundness of	Are interventions/exposures measured in a valid and reliable
	information	manner?
		Objective (clinical reports, lab findings, previously validated measures)
		Objective measure, not validated
		Prospective documentation (including self-report in daily diaries) Retrospective self-report (patient/participant response)
1	_	Not reported  Are outcomes measured in a valid and reliable manner?
L		Are outcomes measured in a valid and reliable mariner?
		Objective (clinical reports, lab findings, previously validated measures)
		Objective measure, not validated
		Prospective documentation (including self-report in daily diaries)
		Retrospective self-report (patient/participant response)  Not reported
M	Follow-up	In cohort studies, do the analyses adjust for different lengths of
IVI	Follow-up	follow-up of patients, or in case-control studies, is the time period
		between the intervention/exposure and outcome the same for
		cases and controls? [Abstractor: Where follow-up was the same for
		all study patients the answer is yes. If different lengths of follow-up
		were adjusted by, for example, survival analysis, the answer is yes.  Studies where differences in follow-up are ignored should be answered NA.]
		anowored tv.t.j
		Yes
		No
		Cannot determine
		NA (cross-sectional)
N		Is the length of time following the intervention/exposure sufficient to support the conclusions of the study regarding outcomes?
		, , ,
		Yes
		No NA (areas a satisasal)
		NA (cross-sectional)
0	$\dashv$	Did attrition from any group exceed 20 percent (after allocation of
		treatment)?
		Yes - how much?
		No
		Cannot determine
		NA (cross sectional)
P	$\dashv$	Did attrition differ between groups by more than 15 percentage
		points (after allocation of treatment)?

Column	Category	Question
		Yes - how much?
		No
		Cannot determine
		NA (cross sectional)
Q	Analysis comparability	Are baseline characteristics similar in exposed and comparison cohorts?
		Yes
		No
		Cannot determine
		NA (case series)
R		Does the analysis control for baseline differences?
		Yes No
		Cannot determine
S	-	NA (no baseline differences reported)  Were the important confounding and modifying variables taken into
3		account in the design and analysis (e.g., through matching, stratification, or statistical adjustment)?
		Yes
		Partially
		No
		Cannot determine
Т	Analysis Outcome	Is the analysis conducted on an intention-to-treat (ITT) basis, that is, the intervention allocation status rather than the actual intervention received?
		V
		Yes No
		INO
U		Is the impact of loss to follow-up (or differential loss to followup) assessed (e.g. through sensitivity analysis or other intention-to-treat adjustment methods?
		Vaa
		Yes No
		Cannot determine
		NA (cross-sectional or case-control selected on outcome)
V		Are the statistical methods used to assess the primary outcomes appropriate to the data? [Abstractor: The statistical techniques used must be appropriate to the data. For example, non-parametric methods should be used for small sample sizes (N<30). If studies have not accounted for differences between the unit of allocation and the unit of analysis, (e.g., through mixed models or generalized estimating equations for analysis of individual covariates or through t-tests or weighted t-tests for cluster-level analysis) then the answer is no. If outcomes are rare and little or no statistical
		analysis has been conducted, answer yes if studies have accounted for alternative causes other than the

Column	Category	Question
		intervention/exposure. For details on whether specific statistical
		tests are appropriate, go to
		http://bama.ua.edu/~jleeper/627/choosestat.html.4]
		Yes
		Partially
		No
		NA (not reported)
W		For cohort studies only, if the outcome has a greater than 10 percent prevalence, is the risk ratio and relative risk calculated directly (not using logistic regression)?
		Yes
		No
		NA (not a cohort study)
Х		Does the study report appropriate estimates of the random variability in the data for the main outcomes?4 [Abstractors: In nonnormally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported.]
		Yes No
Υ	Interpretation	Are conclusions supported by results with possible bias and limitations taken into consideration?
		Yes
		Partially
		No
Z	Quality	Good
_	Quality	Fair
		Poor

**Appendix B: Abstract Forms** 

#### **Appendix B. Abstraction Forms**

#### **Abstract Review Form** (Originally in Excel)

Column	Question
A	Refid
В	Author, Year
С	Original research (Exclude editorials, commentaries, letters to the editor, reviews etc)
D	Includes community health worker component
E	Study published in English?
F	Is this study located in the US?
G	If not in US, where?
Н	RCT and
	n ≥ 40
I	Cohorts with comparison and
	n <u>&gt;</u> 40
J	Cost or cost-benefit analysis
К	Exclude ("No" on one or more questions in Columns C - I)?
L	Name of intervention (if provided)
M	Retain for - Background or
	discussion or review of references
	other
N	Comments
0	Reviewer initials

# Full-text review form (Originally in EXCEL)

Column	Question
Α	Refid
В	Author, year
С	Reviewer Initials
D	Abstract only
E	Wrong population (non-US)
F	Wrong Outcomes (no patient related health
	or economic outcomes)
G	Study not about CHW
Н	Wrong publication type (review or letter to
	the editor)
1	Sample size too small (<40)
J	No comparison arm/data
K	Comparison arm/data not about CHW or
	CHW alone
L	CHW component insufficiently described to
	distinguish between CHW and other peer
	led models
M	Other?
N	Exclude but save for background, cost,
	training or setting, pick one! (only if yes for
	at least one column D-M)
0	Should be included for KQ 4a
	(What are characteristics of training for
	community health workers in the outpatient
	setting?)
Р	Should be included!
Q	Need more information
R	Related citations
S	Left blank
Т	How do community health workers interact
	with clients? Specifically, what is the place
	of service, type of service, type of
	educational materials used, duration of
	interaction with clients, and length of
	followup?
U	What is the impact of community health
	workers on outcomes, particularly
	knowledge, behavior, satisfaction, health
	outcomes, and health care utilization?
V	What is known about the cost-effectiveness
	of community health workers for improving

	health outcomes?
W	Are particular training characteristics
	associated with improved outcomes for
	patients?
X	Study design
Υ	Comparisons (identify arms) i
Z	Health condition of interest
AA	Name of intervention
AB	Notes- including additional citations

# **Abstraction Form for Evidence Tables** (Originally in EXCEL)

Column	Category	Question
Α	Identifying information	Reviewer Initials
В		Author Year {#RefID}
С	_	Trial Name
D	_	Objective or aim
E	Setting	Setting: Geography
F		Setting: Organizational, Social, Cultural
G		What is the community? (neighborhood, disease etc.)
Н	_	Study design: RCT/Prospective cohort/Retropective cohort/Prospective cohort with historic control/case-control/case series/other
1		Start date- year
J	1	Duration - length
K	N	Eligible
L		Enrolled
M	_	Randomized
N		Completers
0		Withdrawals or dropouts
Р		Health condition of interest
Q	Inclusion/Exclusion	Inclusion criteria (include run-in details)
R		Exclusion criteria
S	Groups	Groups (please use-G1: G2: G3: etc.)
Т		Describe interventions (if necessary)
U		n of each group
V	Community Health	CHW definition:
W	Worker	CHW training:
Х		Place of service
Υ		Title of CHW (specify: lay health advisor, community health worker, etc)
Z		Paid or volunteer
AA		Relationship with the community (rshared race, ethnicity, disease condition, etc)
AB	Community Health	N of CHW
AC	Worker (continued)	Supervision of CHW (who supervises [clinician vs non clinician] and frequency of supervision)  Prior training of CHW
ad		
AE	_	Type of advectional materials utilized
AF		Type of educational materials utilized
AG	_	Duration of interaction with clients
AH		Length of followup

Column	Category	Question
Al	Baseline	Age (mean)
	characteristics of patients	
	patients	
AJ		Sex (% female)
AK		Race (%)
AL		Other?
AM	Recruiting and	Role of CHW in recruiting and retention
AN	retention	Recruitment: Need rates for each group
AO		Retention: Need rates for each group
AP	Knowledge and	Measure (Is it valdidated?)
AQ	attitude	Results
AR		Measure (Is it valdidated?)
AS		Results
AT		Measure (Is it valdidated?)
AU	7	Results
AV	Quality of Life	Measure (Is it valdidated?)
AW		Results
AX	7	Measure (Is it valdidated?)
AY	7	Results
AZ	7	Measure (Is it valdidated?)
BA		Results
BB	Health Outcomes	Measure (Is it valdidated?)
ВС		Results
BD		Measure (Is it valdidated?)
BE		Results
BF		Measure (Is it valdidated?)
BG		Results
ВН	Healthcare utilization	Measure (Is it valdidated?)
BI		Results
BJ		Measure (Is it valdidated?)
BK		Results
BL		Measure (Is it valdidated?)
BM		Results
BN	Costs (Economics)	Measure (Is it valdidated?)
ВО		Results
BP		Measure (Is it valdidated?)
BQ		Results
BR		Explanation of overall outcomes.
BS		Quality rating: Good / fair / poor
ВТ	Applicable key	KQ 1 - How do community health workers interact with
	questions	clients? Specifically, what is the place of service, type
		of service, type of educational materials used, duration of interaction with clients, and length of
		followup?
BU		KQ 2 - What is the impact of community health
		workers on outcomes, particularly knowledge,

Column	Category	Question
	, , , , , , , , , , , , , , , , , , ,	behavior, satisfaction, health outcomes, and health
		care utilization?
BV		KQ 3 - What is known about the cost-effectiveness of
		community health workers for improving health
		outcomes?
BW		KQ 4a - What are characteristics of training for
51/	4	community health workers in the outpatient setting?
BX		KQ 4b - Are particular training characteristics associated with improved outcomes for patients?
BY	Additional outcomes	Measure (Is it validated?)
	(please add more	Results
BZ	here at the end if	
CA	you must!)	Measure (Is it validated?)
СВ		Results
CC		Measure (Is it validated?)
CD		Results
CE		Measure (Is it validated?)
CF		Results
CG		The gulf between the rest and KQ4a
СН		(Blank)
CI	Training	Eligibility for CHW training (inclusion criteria for CHW)
CJ	Characteristics	Input of CHW in curriculum development
CK	7	Training on cultural competency (describe content;
O.K		instructional method; number of sessions; testing)
CL	Training	Training on recruitment and retention process skills,
	Characteristics	e.g., motivational interviewing (describe content;
	(continued)	instructional method; number of sessions; testing)
CM		Training on intake/assessment, (describe content;
	4	instructional method; number of sessions; testing)
CN		Training on protocol delivery, i.e., recruitment, followup, fidelity to the intervention, referrals (describe
		content; instructional method; number of sessions;
		testing)
СО		Training on health topic (describe content;
		instructional method; number of sessions; testing)
СР		Training on evaluation (describe content; instructional
		method; number of sessions; testing)
CQ		Other training (describe type)
CR		Other training content; instructional method; number
	_	of sessions; testing
CS		Other training (describe type)
СТ		Other training content; instructional method; number of sessions; testing
CU		Name of curriculum
CV		Availability
CW	=	Evaluation and testing results of the curriculum
CVV		(improvements in CHW knowledge)
CX		Certification (any certication [yes/no/nr]; if yes, name
		of certifying body

# Quality Review for randomized controlled trials (Originally in EXCEL)

Column	Category	Question
Α		REFID
В		Reviewer initial
С	Background/context	Is the hypothesis/aim/objective of the study described?
		Yes No
D	Sample Definition and Selection	Are the inclusion/exclusion criteria clearly stated (does not require the reader to infer)? [Abstractor: use "Partially" if only some criteria are stated clearly.]
		Yes Partially No
Е		Did the authors report conducting a power analysis or some other basis for determining the adequacy of study group sizes for the primary outcome(s) being abstracted?
		Yes No
F	Randomization	Was the assignment to the treatment groups adequately randomized?
		Yes (Adequate approaches to sequence generation, i.e., computer-generated random numbers, random numbers tables) No (Inadequate approaches to sequence generation, i.e., use of alternation, case record numbers, birth dates or week days)  NR
G		Was allocation of randomization adequately concealed?
		Yes (Adequate approaches to concealment of randomisation, i.e., centralised or pharmacy-controlled randomisation, serially-numbered identical containers, on-site computer based system with a randomisation sequence that is not readable until allocation, other approaches with robust methods to prevent foreknowledge of the allocation sequence to clinicians and patients)
		No (Inadequate approaches to concealment of randomisation, i.e., use of alternation, case record numbers, birth dates or week days, open random numbers lists, serially numbered envelopes (even sealed opaque envelopes can be subject to manipulation)
		NA (study not adequately randomized)
		NR
Н	Interventions/Expos ure	What is the level of detail in describing the intervention or exposure?
		Low (unclear, many details missing) Medium (pretty clear, most details provided) High (very clear, all required details provided)

Column	Category	Question
1		Is usual clinical care (sometimes called standard care)
		described?
		Yes
		No
		NA (not an intervention study)
J	Contamination	Did researchers rule out any impact from an unintended
		intervention/exposure that might bias results, e.g., through
		multivariate analysis, stratification, or subgroup analysis?
		Yes
		No
		NA (no unintended interventions reported)
K		Could variation from the protocol have compromised the findings
		of study?
		Yes (variation from protocol exists and could have compromised findings)
		No (variation from protocol exists, but unlikely to have
		compromised findings)
		Cannot determine (no variation from protocol reported)
		NA (study does not require protocol, or no variation from protocol
		exists)
		,
L	Blinding	Outcome assessors masked?
		V
		Yes
		No Yes, but method not described
		Not reported
M		Care provider masked?
IVI		Care provider masked:
		Yes
		No
		Yes, but method not described
		Not reported
		NA NA
N		Patient masked?
		Yes
		No
		Yes, but method not described
0	Soundness of	Not reported  Are interventions/exposures measured in a valid and reliable
0	information	manner?
	inionnation	manner:
		Objective (clinical reports, lab findings, previously validated
		measures)
		Objective measure, not validated
		Prospective documentation (including self-report in daily diaries)
		Retrospective self-report (patient/participant response)
		Not reported
Р		Are outcomes measured in a valid and reliable manner?

Column	Category	Question
		Objective (clinical reports, lab findings, previously validated measures)
		Objective measure, not validated Prospective documentation (including self-report in daily diaries) Retrospective self-report (patient/participant response) Not reported
Q	Follow-up	Is the length of time following the intervention/exposure sufficient to support the conclusions of the study regarding outcomes?
		Yes No
R		Did attrition from any group exceed 20 percent (after randomization)?
		Yes - how much? No Cannot determine
S		Did attrition differ between groups by more than 15 percentage points (after randomization)?
		Yes - how much?
		Cannot determine
Т	Analysis Comparability	Are baseline characteristics similar in exposed and comparison cohorts?
		Yes No Cannot determine
U		Does the analysis control for baseline differences?
		Yes No Cannot determine
		NA (no baseline differences reported)
V	Analysis Outcome	Is the analysis conducted on an intention-to-treat (ITT) basis, that is, the intervention allocation status rather than the actual intervention received?
		Yes No
W		Were there any post-randomization exclusions?
		Yes (how many?) No
V	Interpretation	Cannot tell  Are conclusions supported by results with possible bias and
X	Interpretation	limitations taken into consideration?
		Yes Partially
		railially

Column	Category	Question
		No
Υ	Quality	Good
		Fair
		Poor

## **Quality Review for observational trials** (Originally in EXCEL)

Column	Category	Question	
Α		REFID	
В		Reviewer initial	
С	Background/ Context	Is the hypothesis/aim/objective of the study described?	
	Comexe	Yes No	
D	Sample Definition and Selection	Are the inclusion/exclusion criteria clearly stated (does not require the reader to infer)? [Abstractor: use "Partially" if only some criteria are stated clearly.]	
		Yes Partially No	
Е		Did the authors report conducting a power analysis or some other basis for determining the adequacy of study group sizes for the primary outcome(s) being abstracted?	
		Yes No	
F	Interventions/ Exposure	What is the level of detail in describing the intervention or exposure?	
		Intensity, duration, frequency, setting and timing  Low (unclear, many details missing)  Medium (pretty clear, most details provided)  High (very clear, all required details provided)	
G		Is usual clinical care (sometimes called standard care) described?	
		Yes	
		No NA (not an intervention study)	
Н	Contamination	Did researchers rule out any impact from an unintended intervention/exposure that might bias results, e.g., through multivariate analysis, stratification, or subgroup analysis?	
		Yes No	
I		NA (no unintended interventions reported)  Could variation from the protocol have compromised the findings of study?	
		Yes (variation from protocol exists and could have compromised findings)  No (variation from protocol exists, but unlikely to have compromised findings)  Cannot determine (no variation from protocol reported)  NA (study does not require protocol, or no variation from protocol exists)	
J	Blinding	Were the outcome assessors blinded to the intervention or	

Column	Category	Question
		exposure status of participants?
		Vac
		Yes No
		NA (not an intervention study)
K	Soundness of	Are interventions/exposures measured in a valid and reliable
	information	manner?
		Objective (clinical reports, lab findings, previously validated measures)
		Objective measure, not validated
		Prospective documentation (including self-report in daily diaries) Retrospective self-report (patient/participant response)
1	_	Not reported  Are outcomes measured in a valid and reliable manner?
L		Are outcomes measured in a valid and reliable mariner?
		Objective (clinical reports, lab findings, previously validated measures)
		Objective measure, not validated
		Prospective documentation (including self-report in daily diaries)
		Retrospective self-report (patient/participant response)  Not reported
M	Follow-up	In cohort studies, do the analyses adjust for different lengths of
IVI	Follow-up	follow-up of patients, or in case-control studies, is the time period
		between the intervention/exposure and outcome the same for
		cases and controls? [Abstractor: Where follow-up was the same for
		all study patients the answer is yes. If different lengths of follow-up
		were adjusted by, for example, survival analysis, the answer is yes.  Studies where differences in follow-up are ignored should be answered NA.]
		anowored tv.t.j
		Yes
		No
		Cannot determine
		NA (cross-sectional)
N		Is the length of time following the intervention/exposure sufficient to support the conclusions of the study regarding outcomes?
		, , ,
		Yes
		No NA (areas a satisasal)
		NA (cross-sectional)
0	$\dashv$	Did attrition from any group exceed 20 percent (after allocation of
		treatment)?
		Yes - how much?
		No
		Cannot determine
		NA (cross sectional)
P	$\dashv$	Did attrition differ between groups by more than 15 percentage
		points (after allocation of treatment)?

Column	Category	Question
		Yes - how much?
		No
		Cannot determine
		NA (cross sectional)
Q	Analysis comparability	Are baseline characteristics similar in exposed and comparison cohorts?
		Yes
		No
		Cannot determine
		NA (case series)
R		Does the analysis control for baseline differences?
		Yes No
		Cannot determine
<u> </u>	_	NA (no baseline differences reported)
S		Were the important confounding and modifying variables taken into account in the design and analysis (e.g., through matching, stratification, or statistical adjustment)?
		Yes
		Partially
		No
		Cannot determine
Т	Analysis Outcome	Is the analysis conducted on an intention-to-treat (ITT) basis, that is, the intervention allocation status rather than the actual intervention received?
		V.
		Yes
		No
U		Is the impact of loss to follow-up (or differential loss to followup) assessed (e.g. through sensitivity analysis or other intention-to-treat adjustment methods?
		Voo
		Yes No
		Cannot determine
		NA (cross-sectional or case-control selected on outcome)
V		Are the statistical methods used to assess the primary outcomes appropriate to the data? [Abstractor: The statistical techniques used must be appropriate to the data. For example, non-parametric methods should be used for small sample sizes (N<30). If studies have not accounted for differences between the unit of allocation and the unit of analysis, (e.g., through mixed models or generalized estimating equations for analysis of individual covariates or through
		t-tests or weighted t-tests for cluster-level analysis) then the answer is no. If outcomes are rare and little or no statistical analysis has been conducted, answer yes if studies have accounted for alternative causes other than the

Column	Category	Question
		intervention/exposure. For details on whether specific statistical
		tests are appropriate, go to
		http://bama.ua.edu/~jleeper/627/choosestat.html.4]
		Yes
		Partially
		No
		NA (not reported)
W		For cohort studies only, if the outcome has a greater than 10 percent prevalence, is the risk ratio and relative risk calculated directly (not using logistic regression)?
		Yes
		No
		NA (not a cohort study)
Х		Does the study report appropriate estimates of the random variability in the data for the main outcomes?4 [Abstractors: In nonnormally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported.]
		Yes No
Υ	Interpretation	Are conclusions supported by results with possible bias and limitations taken into consideration?
		Yes
		Partially
		No
Z	Quality	Good
_	Quality	Fair
		Poor

**Appendix C:** Evidence Tables

## **List of Abbreviations**

AA African American

AIDS Acquired immune deficiency syndrome

b/c because
BF breastfeeding
BMI body mass index
BP blood pressure

BSN bachelor of science - Nursing

BW body weight

CAD Coronary artery disease
CBC community based care
CD cannot determine

CES Community environmental specialists

CES-D Center for Epidemiologic Studies Depression Scale

CG control group

CHD coronary heart disease

CHO Carbohydrates

CHW(s) community health worker(s)
CPEP Child Parent Enrichment Program

DR Doctor

DSM-III-R Diagnostic and Statistical Manual of Mental Disorders, 3<sup>rd</sup> edition, revised

EAG Enhanced Anticipatory Guidance

EG experimental group

EPC evidence-based practice center EPC "enhanced" primary care

ER emergency room

ETS Environmental tobacco smoke

FPL federal poverty level FTT Failure to thrive

g gram

GED general education degree

GHC Group Health Cooperative of Puget Sound

gm gram h hour

HbA1c Glycosylated (or glycated) hemoglobin

HBP high blood pressure

HIV Human immunodeficiency virus
HMO Health Maintenance Organization

HS high school

HSP Hawaii's Health Start Program

ht height hypertension hx history

ICD International Classification of Diseases
IHDP Infant Health and Development Program

IL Illinois ITT intent to treat

JNC-VI Sixth Report of Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High

Blood Pressure

kcal kilocalorie
LBW low birth weight
LDL Low-density lipoprotein
LHA Lay Health Advisor
MD medical doctor; Maryland
mg/dl milligrams/deciliter

MI Michigan
min minute
mmol/L millimoles/liter
mo month

mo month N number

NA not applicable NCM nurse case manager Nutrition Data System NDS NNT number needed to treat NP nurse practitioner not reported NR not significant NS northwest NWNew York NY NYC New York City PCP primary care physician

principal investigator Ы phenylketonuria PKU

Psychiatric Symptom Index randomized controlled trials Resources, Education and Care in Home PSI **RCT** 

**REACH** 

RIA radioimmunoassay registered nurse RN SBP systolic blood pressure standard deviation SD SE standard error SLE stressful life events TPV tailored print and video

UC usual care

**VLBW** very low birth weight

Wellness for African Americans Through Churches Project WATCH

Women, Infants, and Children WIC

wk week у year y/o years old

YMCA Young Men's Christian Association

year

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Andersen et al., 2000	Eligible (N) 10,967 at baseline 8,907 at followup	<b>Title of CHW</b> Volunteer	<b>Age (mean)</b> NR
Trial Name Community Trial of	Enrolled (N)	Paid or Volunteer Volunteer Relationship with	Sex (% female) 100 Race (%)
Mammography Promotion	Randomized (N) 14,080	Community Shared community	97% white
Objective or Aim To learn how best	Completers (N) 6,685	CHW (N) NR	<b>Other</b> NR
to increase use of screening among women aged 50 to	Withdrawals or Dropouts (N) 2,222 of N eligible at followup	Supervision of CHW Non-clinician- field research	Role of CHW in Recruiting and Retention None
80  Geography 40 communities in	Health Condition of Interest Mammography	Prior Training N	Recruitment Rates NA
predominantly rural Washington state, selected by zipcodes corresponding to towns or clusters of	Inclusion Criteria Women age 50 to 80 living in one of 40 communities	Type of Service  Barrier-specific telephone	Retention Rates NA
	Exclusion Criteria History of breast cancer	counseling to promote screening	
towns  Organization	Groups G1: Control	Type of Educational Materials Used NR	
Community or telephone	G1: Control, no intervention reported G2: Community activities - developing social norms	Duration of Interaction with Clients One interaction (time of interaction NR) Length of Follow-up 2 years	
Type of Community			
Rural neighborhoods			
Study Design RCT of communities	G3: Individual counseling - telephone G4: Community activities and individual couseling		
Start Date NR	Group (N)		
<b>Duration</b> 2 years	G1: 1,688 G2: 1,630 G3: 1,650 G4: 1,717		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)
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Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR <b>Quality of Life:</b> NR	Healthcare Utilization: Measure 1 Increase in mammography rates (self-reported)	Explanation of Overall Outcomes NR
	<b>Results</b> No significant differences between intervention groups and control; no significant differences for individual counseling or combined individual couseling and communitities activities, but increased mammography use by regular users between baseline and followup for community activities arm by $2.9\%$ ( $P = 0.01$ ).	Quality Rating Good
	Measure 2 Increase in mammography rates (self-reported)	
	Results  Among under-users at baseline, intervention more effective than control in increasing mammography rates amon women with in communities without a female physician (10% to 16%; <i>P</i> < 0.05), and among women with no health insurance (10% to 23%; <i>P</i> ≤ 0.05); NS effect for community attitudes on mammography, age, time taken to get a medical appointment, financial comfort, mammography facility in community, income, education, proportion of Hispanic population, urban/rural, size of community, and employment status among regular users, intervention was more effective than control in preventing relapse among women who needed > 2 hours to get a medical appointment. NS effect for community attitudes on mammography, age, use of mammography in community, female MD, financial comfort, mammography facility in community, income, education, proportion of Hispanic population, urban/rural, size of community, and employment status	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Auslander et al., 2002; Williams et al.,	Eligible (N) NR Enrolled (N) NR	Title of CHW Peer educators  Paid or Volunteer NR	Age (mean) G1: 41.2 G2: 40.2 Sex (% female)
Trial Name Eat Well Live Well Nutrition Program  Objective or Aim A culturally specific, peer-led dietary change program designed to reduce risk of type 2 diabetes in low-income African-American women.  Geography Large Midwestern city in Missouri  Organization Targeted neighborhoods  Type of Community Race, Neighborhood  Study Design RCT  Start Date NR	Randomized (N) NR  Completers (N) 294  Withdrawals or Dropouts (N) 104  Health Condition of Interest Diabetes Prevention  Inclusion Criteria African-American women ages 25– 55 years and living in neighborhoods  Exclusion Criteria Pregnancy, diabetes, BMI < 27  Groups G1: Treatment G2: Control  Interventions G1: Six group sessions	Relationship with Community African-American women from target community with no background in nutrition or education, were recruited by lead agency to deliver intervention.  CHW (N) 3  Supervision of CHW Weekly supervision during implementation phases, including meeting with educators, research dietitian, project coordinator and research assistants  Prior Training No background in nutrition or education  Type of Service Counseling  Type of Educational Materials Used Program Manual  Duration of Interaction with Clients 3 months	Race (%) African-American Other NR Role of CHW in Recruiting and Retention NR Recruitment Rates NR Retention Rates NR
<b>Duration</b> 3 months	Group (N) G1: Treatment 138 G2: Control 156	Length of Follow-up 3 months	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: Measure 1	Health Outcomes: Measure 1 Weight, BMI	Costs (Economics): NR
Knowledge of Label Reading Questionnaire (Unvalidated) –baseline/6 months	Results No significant group differences	Explanation of Overall Outcomes NR
Results G2: 5.4/5.7,	<b>Measure 2</b> FFQ - Validated	<b>Quality Rating</b> Fair
<b>G1:</b> 5.5/6.3 ( <i>P</i> > 0.0001)	Results	
<b>Measure 2</b> Readiness to change dietary patterns - no	Intervention was effective in reducing fat intake, as measured by percent of calories from total fat (baseline/6 months): G2: 36.0/34.5,	
<b>Results</b> Overall, participants in	G1: 35.9/32.3, P < 0.05	
treatment group reported a greater readiness to change their dietary patterns than those in control group at posttest assessment.	Healthcare Utilization: NR	
Quality of Life: NR		

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Barnes et al., 1999	Eligible (N) 434	Title of CHW Community volunteers	Age (mean) G1: 9.5 months
<b>Trial Name</b> NR	Enrolled (N) 163	<b>Paid or Volunteer</b> Volunteer	G2: 9.4 months  Sex (% female)
Objective or Aim To assess effectiveness of a volunteer driven outreach program on immunization rates in children younger than 2 years.  Geography NW Manhatten, NY  Organization Organizational: Patients of 1 of 2 ambulatory pediatric clinics of a major medical center  Type of Community Low-income children who are part of a large, highly mobile immigrant community originating from DR  Study Design RCT  Start Date 1993  Duration 6 months	Randomized (N) 434  Completers (N) 140  Withdrawals or Dropouts (N) 23  Health Condition of Interest Immunizations Inclusion Criteria • Younger than 2 years residing in NW Manhattan • No-shows for a scheduled appointment in pediatric clinic, and • Overdue for a vaccine.  Exclusion Criteria NR  Groups G1: Intervention G2: Control Interventions G1: Basic immunization education and referral. During subsequent contacts (home visits or telephone calls) throughout remainder of follow-up , families were reminded of upcoming vaccinations and were recontacted to ensure that requisite vaccines were received. If a family required support or assistance to obtain immunization services G2: Informed of their child's immunization status at enrollment visit by control group interviewer and were instructed to reschedule missed appointment.  Group (N) G1: 71	Relationship with Community NR- community volunteers CHW (N) NR Supervision of CHW Organized by coordinator from local branch of larger international charitable organization Prior Training NR Type of Service Unspecified # of home visits and phone calls Type of Educational Materials Used NR Duration of Interaction with Clients Unspecified # of calls and visits over 6 months (time per session NR) Length of Follow-up Maximum of 6 months	Sex (% female) G1: 50 G2: 40  Race (%) G1: 87% Hispanic G2: 85% Hispanic  Other Primary language of caregiver -spanish G1: 66 G2: 75%  Role of CHW in Recruiting and Retention NR  Recruitment Rates NR  Retention Rates NR
	G2: 84		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR	Healthcare Utilization:	Explanation of Overall
Quality of Life: NR	Measure 1 Late for immunization	Outcomes NR
	Results G1: 18% G2: 38% P < 0.05	<b>Quality Rating</b> Fair
	<b>Measure 2</b> Up to date on immunizations	
	Results G1: 75% G2: 54% P = 0.03	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Barnes-Boyd et al., 2001	Eligible (N) 1,922 Enrolled (N)	Title of CHW Maternal-Child Health Advocate	<b>Age (mean)</b> G1: 51% < 20 y/o G2: 36% < 20 y/o
Trial Name REACH-Futures	1,922 Randomized (N)	<b>Paid or Volunteer</b> Paid	<b>Sex (% female)</b> 100
<b>Objective or Aim</b> NR	NA Completers (N)	Relationship with Community	Race (%) G1: 85% African-American
<b>Geography</b> Chicago	NA Withdrawals or Dropouts (N)	Within community CHW (N)	G2: 80% African-American Other
Organization Inner city	0 Health Condition of Interest	10 Supervision of CHW	G1: 56% primiparous G2: 41%
community clinic  Type of	Infant health Inclusion Criteria	Teamed with nurses (at least BSN)	G1: 53% < HS education G2: 36%
Community Mostly African- American;	All recipients:  • below 150% of poverty line  • lived in inner-city communities  Exclusion Criteria  NA  Groups	<ul> <li>Prior Training</li> <li>Minimum HS or GED</li> <li>Experience in community service</li> </ul>	G1: 94% BW > 2500gm G2: 93%
impoverished; low employment and			Role of CHW in Recruiting and Retention NR
literacy, high infant and child morbidity and mortality, poor		Type of Service home visits	Recruitment Rates
maternal outcomes, high incidence early	G1: REACH-Futures CHW+nurse G2: REACH nurse-only historic control	Type of Educational Materials Used Direct instruction	Retention Rates G1: 2 mo 86%, 11 mo 56%
unplanned pregnancies and childhood injuries	Interventions  Home visits-family focused care plan	Duration of Interaction with Clients 12 monthly visits by CHW	G2: 2 mo 75%, 11 mo 58%
Study Design Cohort with historic control	<ul> <li>Support model problem-solving skills</li> <li>Promote self-development of</li> </ul>	alone, teamed with nurses for one prenatal visit and at 1, 6 and 12 months; duration per visit NR	
Start Date 1986	<ul><li>mother</li><li>Provide instruction in infant care</li><li>Transportation</li></ul>	Length of Follow-up 12 months	
<b>Duration</b> 8 years	<ul> <li>Find community resources for childhood immunizations</li> </ul>		
	<b>Group (N)</b> G1: 666 G2: 1256		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1  Future elected infant mortality rate (a too amell)	Costs (Economics): NR
NR Quality of Life: NR	Extrapolated infant mortality rate (n too small)  Results G1: 3.0 G2: 4.7 (not significant)	Explanation of Overall Outcomes CHW+nurse home visits resulted in higher
Measure 2 Presence of health proble Results Neonatal G1: 27% G2: 25%	<b>Measure 2</b> Presence of health problems	immunization status than nurse-only visits; no difference in health problems or mortality  Quality Rating Poor
	Neonatal	
	Postneonatal G1: 27% G2: 25% (neither significant)	
	Measure 3 % fully immunized at 12 months	
	<b>Results</b> G1: 77% G2: 63% ( <i>P</i> < 0.001)	
	Healthcare Utilization: NR	

Organization Social Social G1: 5 G2: 10  Type of Community At rick Child abuse  Withdrawals or Dropouts (N) G1: 5 Prior Training 100 hours  Type of Service  Type of Service  Group Supervision South East Asian refugees) 4% Native American Other	Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Objective or Aim Preventing child abuse  Completers (N)  Geography California / Contra Costa County  Organization Social  Type of  Community  Relationship with Community Members of community Members of community  CHW (N)  8  CHW (N)  8  CHW (N)  8  Supervision of CHW Group Supervision  Frior Training 100 hours  Type of Community  At rick  At rick  Race (%)  43% white  27% were Latino (primarily Chicano)  20% black  66% were Asian (primarily South East Asian refugees)  4% Native American  Other	Barth et al., 1988  Trial Name	95 referred Enrolled (N)	Parenting Consultants  Paid or Volunteer	G1: 21.75 G2: 23.04
Task centered approach RCT Referred to CPEP, by public health, education, or social service professionals    Duration 6 months	Preventing child abuse  Geography California / Contra Costa County  Organization Social  Type of Community At risk  Study Design RCT  Start Date NR  Duration	Completers (N) 50 G1: 24 G2: 26 Withdrawals or Dropouts (N) G1: 5 G2: 10 Health Condition of Interest Child abuse Inclusion Criteria Referred to CPEP, by public health, education, or social service professionals Exclusion Criteria NA Groups G1: Intervention G2: Control Interventions G1: CPEP services involved six months of home visiting by paraprofessional women and linkage to other formal and informal community resources. Group (N) G1: 24	Community Members of community  CHW (N)  8  Supervision of CHW Group Supervision  Prior Training 100 hours  Type of Service Task centered approach  Type of Educational Materials Used NR  Duration of Interaction with Clients ≈2 visits per month, ≈ 4 hours per session, over 6 months  Length of Follow-up	Race (%)  43% white  27% were Latino (primarily Chicano)  20% black  6% were Asian (primarily South East Asian refugees)  4% Native American  Other  Role of CHW in Recruiting and Retention  NR  Recruitment Rates  NR  Retention Rates

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR Quality of Life: Measure 1 Child Abuse Potential Inventory Results	Healthcare Utilization: NR	Explanation of Overall Outcomes Overall no differences in outcomes, though clients appreciated services
G1: pre/post means 116.33/88.54 G2: pre/post means 103.50/92.44 No significant difference between posttests		<b>Quality Rating</b> Poor

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Barth, 1991 Trial Name CPEP	Eligible (N) 313 referred Enrolled (N) 240	Title of CHW Parenting Consultants Paid or Volunteer NR	Age (mean) G1: 23.25 G2: 23.75 Sex (% female)
Objective or Aim Prevent child abuse  Geography Contra Costa County, California  Organization Organizational/ Community  Type of Community At risk for chid abuse  Study Design RCT  Start Date NR  Duration 6 months	Randomized (N) 240  Completers (N) 61% (191)  Withdrawals or Dropouts (N) 39% (49)  Health Condition of Interest Child abuse  Inclusion Criteria Referred to CPEP by public health, education, or social service professionals  Exclusion Criteria NA  Groups G1: Intervention G2: Control  Interventions G1: Intervention G2: Control  Group (N) G1: 97 G2: 94 (Completers - article indicates 240	Relationship with Community Members of community CHW (N) 8 Supervision of CHW Group supervision Prior Training NR Type of Service • Task centered approach • Home visits • Links to community resources Type of Educational Materials Used NR Duration of Interaction with Clients On average 11 visits (range 5-20) over 6 months (time per session not reported but ≈ 4 hours implied) Length of Follow-up	Race (%)  White: 45%  Latin (primarily Chicano): 31%  Black: 17%  Other: 7%  Other Role of CHW in Recruiting and Retention NR  Recruitment Rates NR  Retention Rates NR
	were initially randomized but only 191 completed posttest)	Mean 3 years (range 2-5)	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1 Reported child abuse	Costs (Economics): NR
Quality of Life: NR	Results No differences in increase between groups	Explanation of Overal Outcomes Overall no differences
	Healthcare Utilization: NR	in outcomes, though clients appreciated services
		Quality Rating Poor

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Batts et al., 2001; Garyet al., 2003; Vetter, et al., 2004; Gary et al., 2005; Gary et al., 2000	Eligible (N) 822 Enrolled (N) 332 Randomized (N)	Title of CHW  Members of community of interest trained to perform non-medical case management tasks	Age (mean) 59 Sex (% female) 75 Race (%)
Trial Name Project Sugar  Objective or Aim To determine diabetes care priorities and needs in a group of urban African-American adults with type 2 diabetes; To determine prevalence of depressive symptoms and re I a t i o n s h i p between depressive symptoms and metabolic control.	Completers (N) 183 Withdrawals or Dropouts (N) 3 Health Condition of Interest • Diabetes Mellitus, type 2 • Depression Inclusion Criteria Eligibility criteria included following: • Age 35–75 years • African-American ancestry • Residence in East Baltimore • Presence of type 2 diabetes • Absence of comorbid conditions limiting probable life span to 4 years (e.g., cancer, AIDS)	Paid or Volunteer NR  Relationship with Community  Local hs graduate enrolled in college part- time  No formal training in health care prior to study  CHW (N)  Supervision of CHW NR  Prior Training None  Type of Service  Home visits to provide education	100% AA  Other  50% had an income of \$7,500  Participants had diabetes an average of 9 years  91% on medication (46% used insulin, 45% used an oral agent)  Role of CHW in Recruiting and Retention NR  Recruitment Rates NR  Retention Rates
Geography East Baltimore, MD  Organization 2 primary care clinics  Type of Community African-American adults with type 2 diabetes  Study Design RCT	Attendance at either of 2 Johns Hopkins–affiliated primary care clinics No indication of end-stage complications of diabetes (e.g., kidney dialysis or transplant, blindness, or lower- extremity amputation)  xclusion Criteria Comorbid conditions limiting probable life span < 4 years Indication of end-stage complications of diabetes (dialysis or t+R2ransplant, blindness or lower extremity amputation)	Mobilize social support for adults with diabetes mellitus      Type of Educational Materials Used NR      Duration of Interaction with Clients     3 visits (45-60 minutes each) per year over 2 years (+ additional contacts as needed)	NR
Start Date 1994 Duration 2 years	Groups G1: usual care G2: nurse care manager G3: CHW G4: NCM + CHW	Length of Follow-up 2 years	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 LDL	Costs (Economics): NR
Quality of Life: NR	<b>Results</b> G1: -16.7± 5.5 mg/dl	Explanation of Overall Outcomes NR
	<ul> <li>G2: +6 (approx) (P&lt;0.05 for within-group change from baseline)</li> <li>G3: +6 (approx.)</li> <li>G4: +4 (approx.) (P&lt;0.05 for within-group change from baseline)</li> </ul>	Quality Rating Good
	Measure 2 SBP	
	Results G1: ref G2: +6 (approx.) ( <i>P</i> <0.05 for within-group change from baseline) G3: -4 (approx) G4: -2 (approx).	
	Measure 3 hga1c	
	Results G1: ref G2: -0.31 ± 0.49% G3: -0.30 ± 0.48% G4: 0.8 ± 0.52%	
	Measure 4 Dietary risk scores	
	Results G1: ref G2: -2.4± 1.99 G3: -3.45 ± 1.87 G4: -2.13 ± 1.92	
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Batts et al., 2001; Garyet al., 2003; Vetter, et al., 2005; Gary et al., 2000 (continued)	Interventions G1: continued on-going care from their own health professionals + quarterly newsletter containing info on diabetes-related health topics and trial communication G2: NCM intervention: NCM was RN + certified diabetes educator, interventions were 45 min face-to-face clinic visits and/or phone contacts, direct patient care, management, education, counseling, follow-up, referral and physician feedback - goal was 3 visits/yr G3: CHW interventions were 45-60 min face-to-face home visits and/or phone contacts, no direct implementation of therapeutic strategieis but facilitated preventibe care by offering to schedule appointments + provide education, 3 visits/yr G4: combined NCM + CHW - three visits/year with each  Group (N) G1: 34 G2: 38 G3: 41 G4: 36		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude,		Costs (Economics)
and Behavior	Health Outcomes	Additional
Quality of Life	Healthcare Utilization	Outcomes

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Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Becker et al., 2005; Cene et al., 2008  Trial Name NR  Objective or Aim Determine relative effectiveness of alternative model of community-based care provided in black community compared with "enhanced" primary care  Geography Baltimore, MD  Organization Identified from Baltimore Hospitals  Type of Community Blacks  Study Design RCT  Start Date NR  Duration 1 year	Eligible (N) NR  Enrolled (N) NR  Randomized (N) 364 siblings (194 families)  Completers (N) 267  Withdrawals or Dropouts (N) 97  Health Condition of Interest Cardiovascular disease prevention Inclusion Criteria  Sibling of black < 60 years hospitalized for a CHD event at one of 10 Baltimore hospitals  Aged 30-59  No known history of CAD  No chronic glucocorticosteroid therapy  No autoimmune disease  No cancer  No immediate life-threatening comorbidity  Exclusion Criteria See prior  Groups G1: EPC G2: CBC Interventions G1: EPC- received risk-specific materials (same as intervention group), PCP received results and recommendations, sent info on YMCA program, etc. G2: CBC - received care in 1 nonclinical site in community from a NP and CHW. CHW provided dietary counseling, smoking cessation, and exercise counseling lasting 30 minutes.  Group (N) G1: 168 G2: 196	Prior Training NR  Type of Service Counseling for adults with risk factors for cardiovascular disease, face-to-face, phone calls  Type of Educational Materials Used Written, culturally sensitive  Duration of Interaction with Clients Multiple (# unspecified) 30 minute sessions over 1 year  Length of Follow-up 1 year	Age (mean) G1: 47.9 G2: 47.6 Sex (% female) G1: 66 G2: 61 Race (%) African American:100% Other Role of CHW in Recruiting and Retention NA Recruitment Rates NA Retention Rates NA

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 Smoking Cessation (self-report)	Costs (Economics): NR Explanation of Overall
Quality of Life: NR	Results         Outcomes           G1: 7% reduction         NR           G2: 16.2% reduction (P < 0.001)	Outcomes
	<b>Measure 2</b> BP	Fair
	Results	
	Measure 3 LDL (mmol/L)	
G2: 3.06+	<b>Results</b> G1: 3.38+-1 G2: 3.06+-1 ( <i>P</i> < 0.0001)	
	<b>Healthcare Utilization:</b> NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
		Title of CHW Community health worker  Paid or Volunteer Paid  Relationship with Community Ethnicity and language  CHW (N)  3  Supervision of CHW CHWs met with Medical Director and Preventive Health Department Director once every 2 weeks for inservice training and case conferences for duration of project.  Prior Training 6 months of study at community college  Type of Service Based on needs of patient - CHWs would collaborate with rest of multidisciplinary team to determine high-priority learning areas and to develop an intervention plan to implement during subsequent visits. Each plan included a blood glucose self-monitoring regimen and target levels, diet plan, exercise plan, medication schedule, insulin injection plan, and preventive health/health maintenance plan.  Type of Educational Materials Used NR  Duration of Interaction with Clients Up to a year - number of CHW visits per participant averaged 4.24 (range 5 1–15 visits), with each visit averaging 1 to 1.5 hours.  Length of Follow-up	
		1 year	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 Post intervention	Costs (Economics): NR Explanation of Overall
Quality of Life: NR	period HbA1c  Results G1: 8.8 6 (1.7) G2: 10.4 (6 1.3) P < 0.0001 (Note on P value: investigators did not report one comparing groups, RTI researchers	Explanation of Overal Outcomes NR Quality Rating Fair
	calculated it using data in article  Measure 2  Decrease in HbA1C	
	<b>Results</b> G1: 2.2 (SD 1.8) G2: 0.2 (SD 1.5); <i>P</i> < 0.01 compared to baseline	
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Blacket al., 1995;	Eligible (N) approx 163	Title of CHW Lay home visitor	Age (mean) G1: younger 7.8 mo (SD 2.8);
Hutcheson, et al., 1997	Enrolled (N) 130	<b>Paid or Volunteer</b> Paid	older 17.1 mo (3.7) G2: younger 6.6 (3.6); older 17.9 (4.3)
<b>Trial Name</b> NR	Randomized (N) 130	Relationship with Community	Sex (% female) G1: younger 50%, older 44%
Objective or Aim Evaluate efficacy of family-focused,	Completers (N) 706: 116 ( to end of intervention)	Knowledge of community Familiarity with culture	G2: younger 45%, older 38%  Race (%)
home-based intervention on	1445: 74 (to 4 y/o) Withdrawals or Dropouts (N)	CHW (N) 3 part-time	African American – G1: younger 84%, older 91%
growth and development of	706: 14 1445: 56	Supervision of CHW Community health nurse,	G2: younger 85%, older 97% Other
children with nonorganic FTT	Health Condition of Interest Nonorganic failure to thrive	frequency NR  Prior Training	Mean BW G1: younger 2881 gm (400),
<b>Geography</b> Baltimore, MD	Inclusion Criteria • < 25 mo	Experience with children and families	older 2868 (385) G2: younger 3010 (524),
Organization Recruited from urban pediatric clinics serving low	<ul> <li>Wt for age &lt; 5th percentile</li> <li>EGA 36+ wk</li> <li>Birth weight appropriate for gestational age</li> </ul>	<ul> <li>Type of Service</li> <li>Home visits to develop individualized family service plan with specific</li> </ul>	older 2881 (432) Prior FTT hospitalization G1: younger 6%, older 0 G2: younger 10%, older 3%
income families  Type of	Wt for ht < 10th percentile  Exclusion Criteria	<ul><li>goals</li><li>Support mother's needs</li></ul>	Role of CHW in Recruiting and Retention NR
Community Low-income, urban	No congenital disorders     No chronic illness	<ul> <li>Promote maternal-child relationship</li> </ul>	Recruitment Rates
Study Design RCT	<ul> <li>No developmental disabilities</li> </ul>	Type of Educational Materials Used	80% overall Retention Rates
Start Date NR	Groups G1: home intervention G2: clinic-only	Hawaii Early Learning Program was used as curriculum guide; handouts,	706: G1: 89% G2: 89%
<b>Duration</b> 1 year	Interventions G1: CHW home visit weekly x 1 year w/ community health nurse	developmental assessment toys, personalized notebooks	1,445: G1: 65%
	supervision G2: clinic-based multidisciplinary services	Duration of Interaction with Clients Weekly visits (≈ 1 hour per visit) for 1 year	G2: 68%
	<b>Group (N)</b> G1: 64 G2: 66	Length of Follow-up 18 months	

## Knowledge, Attitude, and Behavior **Quality of Life**

## **Health Outcomes Healthcare Utilization**

## Knowledge, Attitude, and Behavior:

NR

## Quality of Life: Measure 1

Home environment (validated: Home Observation for Measurement of **Environment Scales**)

#### **Results**

G1 higher post-intervention scores than G2 (no significance testing reported)

#### Measure 2

Competence pre vs. post intervention

#### Results

Negative affect (below median on Brief Symptom Inventory)

G1: 3.1 (SD 0.9)  $\rightarrow$  3.4 (0.6) G2:  $2.9(0.9) \rightarrow 3.6(0.7)$ 

#### Non-negative

G1:  $3.1(0.6) \rightarrow 3.6(0.6)$ G2:  $3.1 (0.9) \rightarrow 3.5 (0.6)$ 

## Measure 3

Growth (wt for age, wt for ht, ht for age) (validated with Natl Center for Health Statistics charts)

#### Results

Significant improvement in each, no difference in improvement btw groups

#### Measure 4

Parent-child behavior during feeding (validated: modified Parent Child Early Relational Assessment)

#### Results

No significant differences between groups

#### **Health Outcomes:** Measure 1

Cognitive and motor development (validated: Bayley Scales of Infant Development @ postintervention; Battelle Developmental Inventory @ 4 y/o)

#### Results

Younger (1-12 mo at recruitment): G1: less decline pre/post vs. G2 (P = 0.02)

Older (12.1-24.9 mo at recruitment): no significant difference in decline between groups

Negative affect - cognitive

G1: 96.6 (SD 17.0)  $\rightarrow$  86.2 (15.8)  $\rightarrow$  77.4 (18.3) G2: 91.8 (13.0)

#### Measure 2

Language development (validated: Bayley Scales and Receptive/Expressive Emergent Language Scale)

#### **Results**

Receptive-younger G1: 92.7→88.5 G2: 98.7→88.0

#### Older

G1: 92.3→83.2

G2: 98.3 $\rightarrow$ 82.7 (overall P = 0.05)

Expressive - no differences in declines reported between groups

#### **Healthcare Utilization:**

NR

## Costs (Economics) **Additional Outcomes**

### Costs (Economics):

#### Measure 1

Annual per-child cost of home visits (ingredients method)

#### Results

\$2,828/child/year

#### **Explanation of Overall Outcomes**

CHW home visit + multidisciplinary clinic management were significantly better than MDC alone in attenuating cognitive and motor decline among infants (but not older children) and attenuating receptive language decline; no significant difference observed in growth, expressive language, or parent-child interaction

#### Quality Rating

Fair

## **Health Outcomes:**

#### Measure 1

Negative affect @ baseline, postintervention, 4 y/o

#### Results

Negative affect group

G1: 4.2 (SD 1.0)  $\rightarrow$  4.4 (0.7)  $\rightarrow$  3.5 (0.5) G2:  $4.3(0.7) \rightarrow 4.4(0.6) \rightarrow 3.6(0.3)$ 

Non-negative group

G1:  $4.2(0.7) \rightarrow 4.3(0.6) \rightarrow 3.7(0.2)$ G2:  $4.5 (0.5) \rightarrow 4.4 (0.7) \rightarrow 3.4 (0.6)$ 

# Measure 2

Warmth @ 4 y/o

#### Results

Negative affect group G1: 2.8 (SD 0.5) G2: 2.9 (0.5)

Non-negative group G1: 2.9 (0.5) G2: 2.5 (0.5)

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Bone et al., 1989	Eligible (N) 722	Title of CHW CHW	<b>Age (mean)</b> NR
<b>Trial Name</b> NA	Enrolled (N) 722	Paid or Volunteer NR	Sex (% female) NR
	scheduled follow-up. Telephone encounters lasted 5-10 minutes, conducted at night. <b>Group (N)</b> G1: 278 G2: 444	1 face-to-face session (≈20 minutes) and at least 1 pre- followup appointment reminder telephone call (5- 10 minutes) (time period over which this occurred NR)	
		Length of Follow-up NR	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR  Quality of Life: NR	Healthcare Utilization: Measure 1 Returned to ED for follow-up appt	Explanation of Overall Outcomes NR
	<b>Results</b> G1: 41% G2: 60% ( <i>P</i> < 0.001)	<b>Quality Rating</b> Poor

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Campbell, 2004	Eligible (N) 26 churches	Title of CHW Lay health advisor	Age (mean) 52
<b>Trial Name</b> WATCH	Enrolled (N) 12 churches	<b>Paid or Volunteer</b> Volunteer	Sex (% female) 74
Objective or Aim Compare	Randomized (N) 12 churches	Relationship with Community	Race (%) African American: 99%
effectiveness of 2 strategies to promote colorectal	Completers (N) NR (presumably 12 churches;	Church membership CHW (N)	<b>Other</b> BMI ≥30: 40%
cancer preventive behaviors among African American	completers/dropouts of individual participants from each church not reported)	62 Supervision of CHW NR	Role of CHW in Recruiting and Retention Organize church activities,
members of 12 rural North Carolina churches.	Withdrawals or Dropouts (N) NR (presumably 12 churches;	Prior Training NR	but recruitment is really NA in this case
Geography Rural NC	completers/dropouts of individual participants from each church not reported)	Type of Service Provide information through	Recruitment Rates NR
Organization Churches in rural	Health Condition of Interest Colorectal cancer	existing networks; organize and conduct at least three church-wide activities	Retention Rates Participated in WATCH church activities (%):
counties	Inclusion Criteria	focused on spreading	G1: 22.5
Type of Community	<ul> <li>Church in one of five rural eastern NC counties with at least 80 active</li> </ul>	information for colorectal cancer prevention	G2: 32.5 G3: 23.3
African American rural churches	<ul><li>members and expressed interest in participation</li><li>All active members (i.e., attending</li></ul>	Type of Educational Materials Used	G4: 16.5
Study Design RCT	study church at least once/month) aged 18 or older were eligible to	TPV and combined groups (G2 and G4): videos, computer-tailored	
Start Date 1999	participate  Exclusion Criteria	newsletters	
Duration	NR	Duration of Interaction with Clients	
1 yr	Groups G1: Control G2: LHA only	Three church- based activities during 12 months (time per session NR)	
	G3: TPV only G4: Combined LHA and TPV	Length of Follow-up 12 months	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1	Costs (Economics): NR
NR <b>Quality of Life:</b> NR	Dietary changedaily fruit and vegetable servings (Baseline/Followup)	Explanation of Overall Outcomes NR
NK	Results G1: 3.3/3.4 G2: 3.5/3.5 G3: 3.3/3.9	Quality Rating Poor
	G4: 3.4/3.7 P = 0.02 for G3 vs. G1 P = ns for G2 vs. G1	Health Outcomes: NR
	Measure 2 Physical Activity: recreational (moderate-vigorous) activity MET hours/week, M (SE) (baseline/followup)	
	Results G1: 9.3 (0.88)/8.4 (0.69) G2: 10.5 (0.90)/10.6 (0.70) G3: 9.5 (0.80)/10.9 (0.61) G4: 9.7 (0.76)/9.7 (0.60) P = 0.07 for G2	
	Healthcare Utilization: Measure 1 Other CRC test in past year (% Baseline/% Followup)	
	Results G1: 20.3/27.5 G2: 19.6/25.5 G3: 23.7/21.1 G4: 26.4/14.9 P = ns	
	<b>Measure 2</b> FOBT test in past year (% Baseline/% Followup)	
	Results G1: 30.4/21.7 G2: 23.5/33.3 G3: 19.7/36.8 G4: 19.5/31.0 P = 0.08	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Campbell, 2004 (continued)	Interventions G1: Control churches offered health education sessions and speakers on topics of their choice not directly related to study objectives G2: Organize and conduct at least 3 church-wide activities on spreading info and enhancing support for healthy lifestyle and CRC screening (LHA) G3: 4 personalized computertailored newsletters and 4 targeted videotapes (TPV) corresponding to same behaviors mailed to participants' homes bimonthly for first 6 months after baseline data collection; 4th mailing was 9 months post baseline G4: LHA + TPV		
	Group (N) G1: 129 G2: 123 G3: 159 G4: 176		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude,		Costs (Economics)
and Behavior	Health Outcomes	Additional
Quality of Life	Healthcare Utilization	Outcomes

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	Community Health	Baseline Characteristics Recruiting and Retention
Author Year Caulfield et al., 1998 Enrolled (N) Trial Name NR  Objective or Aim To promote breast feeding among African-American women Withdrawals or Dropouts (N) Geography Baltimore, MD Organization Organization Organizational WIC  Type of Community Neighborhood-socioeconomic Study Design RCT Start Date 1992 Enrolled (N) Fa Conpleters (N) Completers (N) Completer	ritle of CHW Peer counselor Paid or Volunteer IR Relationship with Community Chared condition - WIC Pecipient that successfully reast fed in past CHW (N) IR Compervision of CHW Condom quality assurance isit to one clinic each week Prior Training Weeks of training Type of Service One-on-one counselling Type of Educational Platerials Used Paration of Interaction Point Clients Or more meetings during Tregnancy (from 24 weeks To gestation) and then Preekly up to 16 weeks Ostpartum if they Continued breast feeding Type of Follow-up Type of Service One-on-one counselling Type of Educational Type of Educat	Retention         Age (mean)         G1: < 18 37%,

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1 Still broads fooding at 7,10 days	Costs (Economics): NR
NR Quality of Life: NR	Still breast feeding at 7-10 days  Results G1: 14% OR 1.00 G2: 30% OR 0.79 95% CI, (0.25, 2.52) G3: 38% OR 1.11 95% CI, (0.34, 3.61) G4: 38% OR 1.52 95% CI, (0.50, 4.59) P < 0.05	Explanation of Overall Outcomes CHW were effective at increasing initiation of BF, but no difference in continuation at 7-10 days
	Measure 2 Odds of intitiating and continuing BF (@7-10 d) relative to control group	<b>Quality Rating</b> Poor
	Results G1: 1 (control) G2: 1.36 (0.52, 3.54) / 0.79 (0.25, 2.52) G3: 3.84 (1.44, 10.21) / 1.11 (0.34, 3.61) G4: 1.92 (0.78, 4.76) / 1.52 (0.50, 4.59)	
	Measure 3 Intiation of breast feeding	
	Results G1: 26% (OR, 1.00) G2: 50% (OR, 1.36; 95% CI, 0.52-3.54) G3: 62% (OR, 3.84; 95% CI, 1.44-10.21)G4: 52% (OR, 1.92; 95% CI, 0.78-4.76)	
	Healthcare Utilization:	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Conway et al.,	Eligible (N) NR	Title of CHW Promotora	Age (mean) 33 y (adults), 4 y (children)
2004 Trial Name	Enrolled (N) 143	Paid or Volunteer NR (text implies volunteer)	Sex (% female)  • Adult: Nearly 100%
NR  Objective or Aim  Evaluate a	Randomized (N) 143	Relationship with Community Bicultural, bilingual, Latina	Children: 55%  Race (%) 100% Latino
culturally tailored behavioral problem	Completers (N) 127	CHW (N) NR	Other
solving intervention to reduce environmental	16	Supervision of CHW	<ul><li>Income: \$700-1099/mo</li><li>Mexican-born: 85%</li><li>Acculturation: 2.0/5</li></ul>
tobacco smoke exposure amongst	Health Condition of Interest Environmental tobacco smoke exposure	Prior Training NR	<ul><li>Mexican-educated: 71%</li><li>Median education: 9-11 y</li></ul>
young Latino children  Geography	Inclusion Criteria  Latino	Type of Service Home and telephone visits on problem-solving	Role of CHW in Recruiting and Retention NR
Organization		techniques to reduce ETS exposure to children	Recruitment Rates NR
Areas with large Latino population  Type of Community  Community organizations and	Exclusion Criteria NR Groups G1: CHW G2: control	Type of Educational Materials Used Contracting, shaping, positive reinforcement, problem solving, social support	Retention Rates 81% overall
venues  Study Design RCT  Start Date NR  Duration 12 months	Interventions G1: Home and telephone visits on problem-solving techniques to reduce environmental tobacco smoke exposure; 6 visits over 4 months G2: Participated in surveys but received no other intervention	Duration of Interaction with Clients 6 home and telephone visits over 4 months (time per session NR) Length of Follow-up 12 mo	
	Group (N) 1 adult + 1 child dyad G1: 71 G2: 72		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 RIA of child's hair for nicotine and cotinine	Costs (Economics): Measure 1 CHW intervention cost
Quality of Life: NR	Results No significant differences between groups	(estimated)  Results \$29000
	<b>Measure 2</b> Parent report of child's past month ETS exposure	Explanation of Overall
	Results No significant differences between groups	Outcomes  No difference observed in subjective or
	Healthcare Utilization: NR	objective measures of ETS exposure with CHW visits vs. control
		<b>Quality Rating</b> Fair

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Corkery et al.,	Eligible (N) 64	Title of CHW CHW	Age (mean) 52.8 years
1997 Trial Name	Enrolled (N) 64	Paid or Volunteer NR	Sex (% female) 74
NR  Objective or Aim  Determine effect of	Randomized (N) 64	Relationship with Community Bicultural, bilingual	Race (%) 100% Hispanic
bicultural CHW on completion of	Completers (N)	Hispanic-American of Puerto Rican heritage who	Other 46% literate
diabetes education in inner-city Hispanic patient	Withdrawals or Dropouts (N) 24 (37%)	lived in East Harlem  CHW (N) 1	Role of CHW in Recruiting and Retention NR
population and evaluate impact of completion of	Health Condition of Interest Diabetes Inclusion Criteria	Supervision of CHW	Recruitment Rates NR
education program on patient knowledge, self- care behaviors,	<ul><li>Newly referred to clinic for patient education</li><li>Hispanic</li></ul>	Prior Training Previously volunteered in a diabetes clinic	Retention Rates NR
and glycemic control.	• > 20 yrs old  Exclusion Criteria	Type of Service Attended clinic visits	
<b>Geography</b> NYC - East Harlem	G1: Intervention G2: Control Interventions	Type of Educational Materials Used	
Organization Cultural: Hispanic- Americans, primarily PR origin, and African- Americans		NR  Duration of Interaction with Clients Varied (mean = 3.4 months, range: 0.9-5.4), time per session equal to	
Type of Community Disease: diabetes, neighborhood, socio-economic, cultural	reminders G2: Control - encounters occurred between nurse and patient only  Group (N) G1: 30	clinic visit duration  Length of Follow-up  Mean - 7.7 months (range 6-16.2)	
Study Design RCT	G2: 34		
Start Date NR			
<b>Duration</b> Mean 3.4 months (range 0.9 to 5.4)			

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 HgbA1c	Costs (Economics): NR
Quality of Life: NR	Results No difference in mean change between groups	Explanation of Overall Outcomes NR
	Measure 2 Diabetes Education Program Completion	<b>Quality Rating</b> Fair
	<b>Results</b> G1: 80% G2: 47% ( <i>P</i> = 0.01)	
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Derose et al.,	Eligible (N) 1,969 on first screening	Title of CHW Peer counselor	<b>Age (mean)</b> NR
2000; Dean et al., 2000; Derose et al.,	1,777 on second screening Enrolled (N)	Paid or Volunteer Some full-time staff,	<b>Sex (% female)</b> 100
2000; Stockdale et al.,	1443 Randomized (N)	telephone counselors paid \$150 stipend per year	Race (%) NR
2000; Fox et al., 1998	1113	Relationship with Community	Other
<b>Trial Name</b> Los Angeles Mammography	Completers (N) 813 Withdrawals or Dropouts (N)	Hired from participating churches assigned to telephone counseling	Role of CHW in Recruiting and Retention NA
Promotion  Objective or Aim	300 Health Condition of Interest	<b>CHW (N)</b> 26	Recruitment Rates
Assess effectiveness of	Breast cancer screening Inclusion Criteria	Supervision of CHW NR	Retention Rates NA
telephone counseling in a church-based	Women ages 50-80, living in private residencies, not being too ill or impaired to be interviewed, being	Prior Training NA	
mammography promotion intervention trial	able to be interveiwed in English or Spanish, living in a sample area, and being reachable by telephone	Type of Service Barrier-specific telephone counseling to promote	
<b>Geography</b> LA county	Exclusion Criteria NR	screening, discussion of resources for free- and	
<b>Organization</b> Telephone counseling	Groups G1: Control G2: CHW	reduced-cost mammograms, translation services, transportation, and childcare assistance	
Type of Community Church	Interventions G1: Control churches provided minimal intervention: a library of	Type of Educational Materials Used Verbal	
communities  Study Design  RCT	resource materials on cancer and cancer prevention, assistance with starting a health committee or	Duration of Interaction with Clients	
Start Date 1996	working with an existing health committee, computer hardware, software, and a printer, as well as	2 telephone calls (one per year over 2 years), time per session 7-11 minutes on	
Duration	computer training for at least one church member	average  Length of Follow-up	
2 years	G2: One session of telephone counseling annually, for 2 years, by peer counselor; counseling individualized to address barriers, churches also received computer support offered to control churches	2 years	
	<b>Group (N)</b> G1: 397 G2: 416		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: NR	Costs (Economics): Measure 1 Sensitivity Analysis
Quality of Life: NR	Healthcare Utilization: Measure 1 Nonadherence to mammogram, by self-report  Results Nonadherence rates among adherent users at baseline: G1: 23.3% G2: 15.8% ( <i>P</i> = 0 .029)  Nonadherence rate among nonadherent users at baseline G1: 37.4% G2: 34.8 ( <i>P</i> = 0.324)	Results Assuming that all labor is voluntary and that churches provide materials and resources:  • Cost per additional screening for a LAMP study participant = \$188;  • Cost if all participants are adherent at baseline = \$145;  • Cost if all participants nonadherent at baseline = \$419 (using LAMP effectiveness rates for adherent (7.5%) and nonadherent (2.6%) participants  Explanation of Overall Outcomes NR  Quality Rating Fair

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Dignan et al., 2005	Eligible (N) 929	Title of CHW Native sister/Navigators	Age (mean) 54.2 years
Trial Name	Enrolled (N) 157 (for intervention groups, N for	Paid or Volunteer NR	<b>Sex (% female)</b> 100
Objective or Aim Determine relative effectiveness of	control NR) Randomized (N)	Relationship with Community	Race (%) Native Americans
face-to-face and telephone delivery	157 (for intervention groups, N for Re	Recruited from Denver metro area	Other Role of CHW in Recruiting
of culturally sensitive Navigator intervention to	Completers (N) 157 (for intervention groups, N for	CHW (N) N	and Retention NR
increase adherence to guidelines for	control NR)  Withdrawals or Dropouts (N)	Supervision of CHW NR	Recruitment Rates NR
mammography screening among	157 (for intervention groups, N for control NR)	<b>Prior Training</b> NR	Retention Rates NR
American Indian women	Health Condition of Interest Breast cancer screening	Type of Service Barrier-specific counseling	
<b>Geography</b> Denver	Inclusion Criteria Urban American Indian women 40 years and older living in greater	to promote screening, face-to-face vs. telephone	
metropolitan area  Organization  Urban American  Indian Women	Denver Metropolitan area and had not had a mammogram within previous 18 months	Type of Educational Materials Used Tailored educational brochure	
Type of Community	Exclusion Criteria  Groups G1: control	Duration of Interaction with Clients One time session 20-90	
Study Design RCT	G2: face-to-face G3: telephone intervention	Length of Follow-up	
Start Date August 2001	Interventions G1: Control, interventions not reported, data from Colorado	6 months	
<b>Duration</b> One year	Mammography Program data G2: Tailored education brochure using data from baseline interview. face-to-face planned for delivery at participant's home (1 session lasting 20-90 minutes), presenting information on breast cancer and value of early detection, review of brochure G3: Telephone intervention, as above		
	Group (N) G1: G2: 77 G3:133		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR Quality of Life:	Healthcare Utilization: Measure 1	Explanation of Overall Outcomes
NR	Mammograms over past 12 months (self-report)	NR
	Results G1: 51.9 > 50.0 G2: 29 > 41.8 G3: 34.4 > 45.2 Chi-square G1 vs G2+G3:2.68, P = 0.10; P for G2 vs G3: 0.83; P for G2, pre-post changes: 0.029; P for G3, pre-post changes: 0.197	<b>Quality Rating</b> Poor

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Duggan et al., 1999; Duggan et al., 2000 Trial Name Hawaii's Healthy Start Program (HSP)	Eligible (N) 901 families Enrolled (N) 730 families Randomized (N) 730 families Completers (N)	Title of CHW Home visitors Paid or Volunteer NR Relationship with Community from community	Age (mean) Mother's average age G1: 24 years G2: 24 years Sex (% female) 100 Race (%) G1: Hawaiian: 21%
Objective or Aim Prevent child abuse and neglect and promote child health and development in newborns of families at risk for poor child outcomes  Geography Hawaii Oahu  Organization Organizational  Type of Community At risk for chid abuse  Study Design RCT  Start Date 1994  Duration 2 years	Withdrawals or Dropouts (N) 164 families  Health Condition of Interest Child abuse Inclusion Criteria Lived in target community, and not known to child protective services  Exclusion Criteria Non-English speaking  Groups G1: Healthy Start Program G2: Control G3: Test Control Interventions G1: Home visiting with individualized service plans, child developmental screenings, and mother-child interaction assessments; family support plan within 45 days of initial visit, reviewed q 6 mo, revised annually; periodic screening for DD, observational assessment of parent-child interaction and home environment; ensure existence of medical home, links to other needed resources G2: Control G3: Test Control was only interviewed at end  Group (N) G1: HSP: 373 G2: Control: 270 G3: Test Control: 41	CHW (N) NR  Supervision of CHW Non-clinician- met weekly w/home visitors  Prior Training NR  Type of Service Counsellingbuilding relationship with families; active assistance to address existing crises; model problem-solving skills and effective parent-child interaction; link families with needed resources; provide parenting education; ensuring presence of medical home for children  Type of Educational Materials Used NR  Duration of Interaction with Clients  ≈22 visits (1 hour each) over 2 years [Protocol called for weekly visits]  Length of Follow-up 2 years	Pacific Islander: 13% Asian: 10% Filipino: 18%

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1	Costs (Economics): NR
NR Quality of Life:	Bayley Scales of Infant Development, Mental Development Index at 2 years post-intervention	Explanation of Overall Outcomes
NR	<b>Results</b> G1: 90.0 G2: 89.2 P = 0.60	NR <b>Quality Rating</b> Poor
	<b>Measure 2</b> Bayley Scales of Infant Development, Psychomotor Development Index at 2 years post-interventino	
	<b>Results</b> G1: 92.1 G2: 90.4 P = 0.12	
	Measure 3 Has primary care provider?	
	Results G1: 91% G2: 86% P = 0.09	
	Healthcare Utilization: Measure 1 Adequate # of well-child visits	
	<b>Results</b> G1: 89% G2: 84% P = 0.09	
	Measure 2 Immunizations up to date	
	<b>Results</b> G1: 87% G2: 85% P = 0.45	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Earp et al., 2002	Eligible (N) 10 counties, 2441 women	Title of CHW Lay health advisor	Age (mean) G1: 46% < 65, 23% > 74
Author Year Earp et al., 2002 Trial Name North Carolina Breast Cancer Screening Program Objective or Aim Determine effectiveness of lay health advisor intervention, supplemented by limited number of other activities, aimed at increasing self-reported mammography use among African American women 50 years and older in eastern North Carolina; correcting beliefs about causes of breast cancer; increasing acceptance of need for regular mammography Geography Eastern NC Organization Black women Type of Community Mostly rural, 37% minority, 12% below FPL; low likelihood of having had mammogram	Eligible (N)	Title of CHW Lay health advisor  Paid or Volunteer Volunteer  Relationship with Community Members of community; same county  CHW (N) 170  Supervision of CHW Main analysis: - described in Earp JA, Viadro CI, Vincus AA, et al. Lay health advisors: a strategy for getting word out about breast cancer. Health Educ Behav. 1997;24:432–451. 412 - by "community outreach specialists" monthly (meetings and assistance  Prior Training NR  Type of Service Presentations to community groups and events, one-on-one conversations, use of informational/motivational materials  Type of Educational Materials Used Brochures, posters, church fans, holiday cards  Duration of Interaction with Clients 2 community activities per month; one-on-one	Age (mean)
Study Design Prospective cohort for main analysis Start Date 1993	<b>Group (N)</b> G1: 390 G2: 411	conversations once a week over a 24- month period, time per session NR Length of Follow-up	
Duration 4 years		32 months	

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR Quality of Life: NR	Health Outcomes: Measure 1 Pre/post percentage point difference in reported mammogram, adjusted for change in mammography attitude  Results • No recent mammogram at baseline: CHW advice: +9 diffused discussion: +10 project awareness: +15 • Recent mammogram at baseline: CHW advice: +8 diffused discussion: 0 project awareness: +5  Healthcare Utilization: Measure 1 Self-report of mammogram in past 2 years, stratified by	Costs (Economics): NR  Explanation of Overall Outcomes CHW community intervention is associated with significantly higher proportions of African- American women reporting having received mammograms, especially among lower income strata  Quality Rating Poor  Health Outcomes: NR
	income  Results < \$12k annually G1: pre 37%, post 59% G2: pre 49%, post 60% (adjusted $P = 0.02$ ); \$12k or greater annually G1: pre 56%, post 59% G2: pre 73%, post 82% (adjusted $P = 0.92$ )  Measure 2 Self-report of mammogram in past 2 years  Results G1: pre 41%, post 58% G2: pre 56%, post 67% (adjusted $P = 0.05$ )	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Elder et al., 2006; Elder et al., 2005	Eligible (N) 510 Enrolled (N)	Title of CHW Promotora Paid or Volunteer	Age (mean) G1: 38.6 (SD 10.1) G2: 40.4 (9.9) G3: 40.1 (9.8)
Trial Name Secretos de la Buena Vida  Objective or Aim Determine whether CHW + tailored print materials vs. tailored print materials vs. off- the-shelf print materials was more effective to maintain diet change at 1 y f/u  Geography San Diego County	Randomized (N) 357  Completers (N) 281  Withdrawals or Dropouts (N) 76  Health Condition of Interest Dietary behavior  Inclusion Criteria • Female • 18-65 y/o • Hispanic surname • Spanish-dominant	Relationship with Community Indigenous to community, Spanish language dominant, perceived as a community role model CHW (N) 4 Supervision of CHW NR Prior Training NR Type of Service G1: weekly home visits or	G3: 40.1 (9.8)  Sex (% female) 100  Race (%) Hispanic  Other Married G1: 94% G2: 93% G3: 93%;  BMI G1: 28.9 (SD 5.7) G2: 30.4 (5.6) G3: > 29.6 (5.4)  Role of CHW in Recruiting
Organization Spanish-dominant Latina Type of Community Central and southern regions Study Design RCT Start Date 2001 Duration 2 years	<ul> <li>Valid telephone number</li> <li>Exclusion Criteria</li> <li>Pregnant</li> <li>Medically prescribed diet</li> <li>Not remaining in San Diego</li> <li>Groups</li> <li>G1: CHW + tailored print</li> <li>G2: tailored print</li> <li>G3: control</li> <li>Interventions</li> <li>G1: CHW home visits and/or phone calls + tailored print materials</li> <li>G2: 12 weekly tailored newsletters and homework</li> <li>G3: 12 weekly off-the-shelf dietary printed material</li> <li>Group (N)</li> <li>G1: 120</li> <li>G2: 118</li> <li>G3: 119</li> </ul>	telephone calls + tailored health info newsletters G2: tailored health info newsletters G3: population-targeted print materials  Type of Educational Materials Used G1: negotiated behavioral change goals G1 and G2: tailored newsletters and activity inserts based on baseline participant data; magnets w/ healthy lifestyle messages; recipes G3: language-appropriate materials w/ dietary information developed for Latino popul  Duration of Interaction	and Retention NR Recruitment Rates NR Retention Rates G1: 93/120 = 78% G2: 90/118 = 76% G3: 98/119 = 82%
		with Clients 12 home visits or telephone calls over a 12-week period, 12 weekly tailored newsletters (duration per session NR) Length of Follow-up 1 year	

•	,	
Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1 % calories from fat (Nutrition Data System 24-h dietary recall interview)	Measure 1 Cost per unit of change Results
Quality of Life: NR	Results No significant difference between groups at 6 and 12 months post-intervention	Per reduced fat gm G1: \$8.28 G2: \$5.11 G3: \$1.30
	<b>Measure 2</b> Total gm fiber (Nutrition Data System 24-h dietary recall interview)	Per reduced saturated fat gm G1: \$21.09 G2: \$17.31 G3: \$3.21
	<b>Results</b> No significant difference between groups at 6 and 12 months post-intervention	Per reduced calorie G1: \$0.36
	<b>Measure 3</b> Total fat gm (Nutrition Data System 24-h dietary recall interview)	G2: \$3.21 G3: \$0.07 <b>Measure 2</b>
	Results	Per-participant cost
	No significant difference between groups at 6 and 12 months post-intervention	Results G1: \$135 G2: \$45
	<b>Measure 4</b> Post-intervention calorie/fat intake (using Nutrition Data System)	G3: 9  Explanation of Overall  Outcomes
	Results kcal (P < .01) G1: 1,286.9 G2: 1,419.2 G3: 1,436.2 (G1-G3 P < .05 G1-G2 P < .1)	NR  Quality Rating  Poor
	Fat gm (P < .05) G1: 43.1 G2: 49.8 G3: 49.3 (G1-G3 p < .1 G1-G2 P < .05)	
	% fat cal G1: 29.3 G2: 30.4 G3: 30 (NS)	
	Saturated fat gm ( <i>P</i> < .05) G1: 14.4 G2: 16.9 G3: 16.6 (G1-G3 <i>P</i> < .1 G1-G2	
	Healthcare Utilization: NR	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

			Baseline
Study	Number (N)		Characteristics
Characteristics	Inclusion/Exclusion	Community Health	Recruiting and
Setting	Groups	Worker	Retention

Author Year Elder et al., 2006; Elder et al., 2005

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
		Measure 2 Dietary fiber intake (gm) (using Nutrition Data System)
		Results Total fiber gm G1: 16.1 G2: 17.2 G3: 15.6 (NS)
		Soluble fiber gm G1: 4.7 G2: 5.1 G3: 4.8 (NS)
		Insoluble fiber gm G1: 11.1 G2: 11.8 G3: 10.5 (NS)
		<b>Measure 3</b> Other dietary intake (via NDS)
		Results CHO gm (P < .05) G1: 171.2 G2: 187.3 G3: 187.1 (G1-G3 P < .05 G1-G2 P < .1)
		Glucose gm ( P < .01) G1: 16 G2: 21.1 G3: 18.4 (G1-G3 NS) G1-G2 P < .05)
		Fructose gm ( P < .001) G1: 16.9 G2: 22.7 G3: 19.1 G1-G3 NS G1-G2 P < .05 G2-G3 P < .1)
		Sucrose gm G1: 30.5 G2: 31.2 G3

6 months

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Erwin et al., 1997	Eligible (N) NA	Title of CHW Witness role model	Age (mean) G1: 52.5
<b>Trial Name</b> Witness project	Enrolled (N) 433	Paid or Volunteer NR	G2: 49.3 Sex (% female)
Objective or Aim Examine effectiveness of	Randomized (N) NA	Relationship with Community Shared race, cancer	100 Race (%) 100% African-American
Witness Project, a culturally competent cancer	Completers (N) 412	survivors CHW (N)	Other Role of CHW in Recruiting
education program that trains cancer	Withdrawals or Dropouts (N) 21  Health Condition of Interest	7 Supervision of CHW	and Retention NA
survivors to promote early detection and	BSE and mammography Inclusion Criteria	NR Prior Training	Recruitment Rates NA Retention Rates
increased breast self-examination and mammography	Inclusion criteria for women NR, churches selected from convenience sample	NR  Type of Service  Motivational speeches	NA NA
in population of rural, underserved, African American women	Exclusion Criteria NA	based on cancer survivor, experience of CHWs, breast self-exam lessons	
<b>Geography</b> Rural Mississippi	Groups G1: Intervention G2: Control	using a breast model, discussion of resources for free- and reduced-cost	
River Delta region of Arkansas  Organization	Interventions G1: Members of a Witness Project team, composed of 7 local African	mammograms  Type of Educational  Materials Used	
Church or community group	American women who had survived breast or cervical cancer, speak in groups of 2 to 5 at local	Duration of interaction	
Type of Community Neighborhood	churches and community organization meetings G2: Control group offered delayed	With Clients One presentation, time NR	
Study Design Prospective cohort	intervention  Group (N)	<b>Length of Follow-up</b> 6 months	
Start Date 1994	G1: 204 (152 aged ≥40) G2: 206 (140 aged ≥40)		
Duration			

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 Breast self exam in past month (self-report)	Costs (Economics): NR
Quality of Life: NR	Results G1: 49% to 65.4% ( <i>P</i> < 0.001 compared to baseline) G2: 65% to 72% ( <i>P</i> = NS compared to baseline)	Explanation of Overall Outcomes Through use of community churches and cancer survivors, breast cancer screening activities can be improved in this population
	Measure 2 Regular practice of breast self-exam (self-report)	
	Results Baseline	
	G1: 69.8% to 82% ( <i>P</i> = NS compared to baseline) G2: 82% to 82% ( <i>P</i> < 0.005 compared to baseline)	<b>Quality Rating</b> Fair
	Measure 3 Ever had mammography (self-report)	
	<b>Results</b> G1: 52.4% to 64.4% ( $P < 0.05$ compared to baseline) G2: 60.4% to 63.3% ( $P = NS$ compared to baseline)	
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Forst et al., 2004 Trial Name	Eligible (N) 36 farms, total workers NR Enrolled (N)	Title of CHW Promotor de salud Paid or Volunteer	Age (mean) G1: 33.5 G2: 32.4 G3: 32.8
NR  Objective or Aim Evaluate CHW model to reduce eye injuries and illnesses in Latino migrant and seasonal farmworkers  Geography SE Michigan,	34 farms, 1,000 workers  Randomized (N) 786  Completers (N) 703  Withdrawals or Dropouts (N) 83  Health Condition of Interest Eye injury Inclusion Criteria	NR  Relationship with Community Actively employed farm workers; Spanish fluency CHW (N) 16  Supervision of CHW Weekly with promotor- coordinators from study team	Sex (% female) G1: 24 G2: 19 G3: 15 Race (%) 90% Mexican 10% Mexican-American Other • Read Spanish: 77% • < 8 y school: 75%
northern Illinois  Organization Latino migrant and seasonal farm workers  Type of Community Farm workers; high incidence of eye injury	Farm owners' consent  Exclusion Criteria NR  Groups G1: CHW + protective eyewear + training + information sheet G2: CHW + eyewear + information sheet G3: Eyewear + information sheet	Prior Training Demonstrated leadership and communication skills; demonstrated respect for farm workers and owners  Type of Service G1: CHW worked w/ subjects, trained subjects on eye health and safety	<ul> <li>&lt; 4 y school: 25%</li> <li>Read English: 16%</li> <li>Role of CHW in Recruiting and Retention</li> <li>G1: Recruited and worked alongside subjects, collected data</li> <li>G2: Recruited, collected data</li> <li>Recruitment Rates</li> </ul>
Study Design Prospective cohort Start Date 2001 Duration 16 wk	Interventions G1: CHW worked w/ subjects, trained subjects on eye health and safety (minimum of 2 training sessions = 1 individual + 1 group) G2: CHW distributed eyewear w/o additional training G3: Research team distributed eyewear w/o additional training  Group (N) G1: 256 (141 IL, 115 MI) G2: 298 (179 IL, 119 MI) G3: 149 (78 IL, 71 MI)	G2: CHW distributed eyewear w/o additional training  Type of Educational Materials Used G1: Trainer training; reference manual on agricultural eye illness and injury; photos and fotonovelas; tool kit to demonstrate eye injuries and hazards  Duration of Interaction with Clients G1: At least 1 individual and at least 1 group session during farming season (duration per session NR)  Length of Follow-up 16 wk	786/1000 = 78.6%  Retention Rates G1: 67/186 = 36% G2: 172/198 = 87% G3: 76/107 = 71%

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: Measure 1	Health Outcomes: Measure 1 Cumulative number of eye injuries for season	Costs (Economics): NR Explanation of Overall
Pre/post change in % wearing safety glasses	Results IL 11 cases pterygium; MI 4 (both likely underreported)	Outcomes CHW intervention
Results Self-report: G1: 1.48 ( <i>P</i> < .0001) G2: 0.71 ( <i>P</i> < .0001) G3: 0.96 ( <i>P</i> < .0001)	Healthcare Utilization: NR	increased reported and observed use of protective eyewear, more so with associated training
G1-G2 $P < .0001$ G1-G3 $P = .03$ G1and 2-G3 $P = .0004$		<b>Quality Rating</b> Poor
Observed: G1: 1.1→36% G2: 0→5.2% G3: 0→14%)		
<b>Measure 2</b> Pre/post subject risk perception of eye injury		
Results Results not interpretable		
Quality of Life: NR		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Frate et al., 1985;	Eligible (N) NR	Title of CHW Hypertension Health	<b>Age (mean)</b> NR
Frate et al., 1983  Trial Name	Enrolled (N) NR	Counselors  Paid or Volunteer	Sex (% female) NR
NR Objective or Aim	Randomized (N) NA	Volunteer  Relationship with	Race (%) NR
Evaluation of different	Completers (N)	Community Native	Other
interventions to contol hypertension in a rural setting	667 Withdrawals or Dropouts (N) NR	<b>CHW (N)</b> 5	Role of CHW in Recruiting and Retention NR
<b>Geography</b> Central Mississippi	Health Condition of Interest Hypertension	Supervision of CHW NR	Recruitment Rates
<b>Organization</b> Cultural	Inclusion Criteria Patients with physician confirmed	Prior Training Certified and equipped to measure blood pressure	Retention Rates NR
Type of Community Hypertension and	hpertension  Exclusion Criteria  NA	Type of Service Monitoring BP, education and support	
rural community  Study Design Observational- quasi-experimental	Groups G1: Hypertension Health Counselors G2: Family based self help G3: Church based self help	Type of Educational Materials Used NR	
Start Date Early 1980's	Interventions	Duration of Interaction with Clients	
Duration 18 months	<b>Group (N)</b> G1: 207 G2: 131	Monthly visits over 18 months (time per session NR)	
	G3: 229	<b>Length of Follow-up</b> 18 months	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1 Proportion controlled	Costs (Economics): NR
Quality of Life:	Results G1: 80.6%	Explanation of Overall Outcomes NR
	G2: 90.0% G3: 79.9%	Quality Rating Extra Poor!
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Gielen et al., 2002 Trial Name NA  Objective or Aim Present results of an intervention trial to enhance parents' home- safety practices through pediatric safety counseling, home visits and an on-site children's safety center where paretns receive personalized education and can purchase reduced- cost products  Geography NR (probably Baltimore, MD)  Organization Pediatric resident continuity clinic in large, urban teaching hospital  Type of Community Same  Study Design RCT  Start Date NR  Duration 18 months	Eligible (N) 43 first- and second-year residents; 305 patients' parents  Enrolled (N) 39 residents; 187 families  Randomized (N) 39 residents; 187 families  Completers (N) 122 families  Withdrawals or Dropouts (N) 11 became ineligible, 15 refused further contact, 39 unable to contact  Health Condition of Interest Pediatric safety  Inclusion Criteria • Residents: all first- and second- year resdients • Parent-patient dyads of participating residents were then approached in clinic waiting room - elgibiliy criteria included infants 6 mos or younger, free of serious medical problems, caretakers were english-speaking and lived with child  Exclusion Criteria See prior  Groups G1: Standard intervention G2: Enhanced intervention Interventions Both groups of pediatric residents invited to attend 1-hour seminar on problme of injuries; both groups received 5-hr EAG training program G1: received safety counseling and referral to children's safety center from their pediatrician G2: received standard services plus "offer of" a home-safety visit from a CHW  Group (N) G1: 20 residents, 93 parents G2: 19 residents, 94 parents	Title of CHW CHW Paid or Volunteer NR Relationship with Community NR CHW (N) NR Supervision of CHW NR Prior Training NR Type of Service Home visits between 6 and 9 mo well child checks: assessed injury hazards; made recommendations about appropriate safety products and practices; referred families to CSC Type of Educational Materials Used NR Duration of Interaction with Clients 1 home-safety visit sometime between patient's 6- and 9-month well-infant visits (duration of session NR) Length of Follow-up NA	Age (mean) Mean age of mother = 24 years Sex (% female) Parents 98% female Race (%) 94% AA Other NR Role of CHW in Recruiting and Retention NA Recruitment Rates NA Retention Rates NA

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

P-value NR

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
<b>Measure 1</b> Poisons kept latched or locked	Healthcare Utilization: NR	Explanation of Overall Outcomes NR
Results G1: 12% G2: 10% P-value not reported		<b>Quality Rating</b> Fair
<b>Measure 2</b> Presence of ipecac		
Results G1: 27% G2: 31% <i>P</i> -value NR		
Quality of Life: Measure 1 Hot water ≤ 48.9 C		
Results G1: 47% G2: 47% <i>P</i> -value NR		
<b>Measure 2</b> Working smoke alarm		
Results G1: 84% G2: 81% <i>P</i> -value NR		
<b>Measure 3</b> Stairs protected by gate or door,		
Results G1: 23% G2: 27%		

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Graham et al.,	Eligible (N) 190 145 (190 total used to validate	Title of CHW Home visitors	Age (mean) 24 y
1992 Trial Name	instrument, but some were ineligible at > 28 wk)	Paid or Volunteer NR	<b>Sex (% female)</b> 100
NR Objective or Aim	Enrolled (N) 145	Relationship with Community	Race (%) Black 100%
Prevention of low birth weight using	Randomized (N) 87 in experimental group,	Shared race and gender having children of their own	Other
home intervention  Geography	145 overall  Completers (N)	<b>CHW (N)</b> 2	<ul><li> 38% primiparous</li><li> 11% married</li><li> 84% receiving Medicaid</li></ul>
Cleveland	52 in experimental group 110 total	Supervision of CHW	Role of CHW in Recruiting
Organization Organizational clinic-derived	Withdrawals or Dropouts (N) 35 out of 87 in experimental group	NR Prior Training	and Retention NR
sample  Type of	Health Condition of Interest Low birth weight	motherhood  Type of Service	Recruitment Rates  1326 screened
Community Inner city black	Inclusion Criteria  Black	Home visits: psychosocial support to patient and	<ul><li>190 high-risk</li><li>145 randomized</li></ul>
Study Design RCT	<ul> <li>Between 17th and 28th week of gestation</li> <li>Low family functioning score</li> </ul>	encouragement to family to be supportive of pregnancy, accomplished through	O1. 32/01 completed all 4
Start Date 1987	<ul><li>At least 1 stressful life event prior to registration</li><li>Registering at study clinic during</li></ul>	education about pregnancy and encouragement of significant others to attend	visits (60%) G2: 100% (only birth information needed for this group)
<b>Duration</b> NR	specified period  Exclusion Criteria	home visits, clinic visits, clinic	
	<ul> <li>Living &gt; 5 mi from clinic</li> <li>Limited reading ability</li> </ul>	Type of Educational Materials Used NR	
	Groups G1: Experimental G2: Control	Duration of Interaction with Clients 4 visits (1 hour each) at 2-4	
	Interventions G1: Experimental - 4 home visits	week intervals for 2 to 5 months (until birth of child)	
	G2: Control  Group (N) G1: Experimental- 87 G2: Control - 58	<b>Length of Follow-up</b> Birth of child	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 LBW rate	Costs (Economics): NR
Quality of Life: NR	Results G1: (All): 12.9% ( <i>P</i> = 0.51) G1: (Completers): 7.7% ( <i>P</i> = 0.98) G2: 7.5%	Explanation of Overall Outcomes CHW home visits increased utilization of prenatal clinic care, but
	Healthcare Utilization: Measure 1	had no effect on LBW incidence
	Ratio of actual:expected prenatal clinic visits	Quality Rating
	Results G1 (All): 1.12 (SD 0.48, <i>P</i> = 0.029) G1 (Completers): 1.17 (SD 0.46, <i>P</i> = 0.007) G2: 0.93 (SD 0.44)	Fair

4 years

	Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
	Author Year Hiatt et al., 2008	<b>Eligible (N)</b> 25,000	Title of CHW Lay health workers	<b>Age (mean)</b> ~60% > 50 yrs
	Trial Name Breast and	Enrolled (N) NA	<b>Paid or Volunteer</b> Paid	<b>Sex (% female)</b> 100
	Cervical cancer Intervention Study (BACCIS)	Randomized (N) NA	Relationship with Community	Race (%) White: 31
	Objective or Aim Effect of Breast and Cervical	Completers (N) 1,616	Locally recruited  CHW (N)  NR	Black: 30 Latina: 14% Latina Chinese: 17% Other: 7%
	Cancer Intervention Study	Withdrawals or Dropouts (N) NR Health Condition of Interest	Supervision of CHW NR	Other NR
	(BACCIS), a multi- component	Cancer	Prior Training	Role of CHW in Recruiting
	intervention conducted in San Francisco Bay	Inclusion Criteria Women living in area of interest	Intensively trained in basic breast and cervical cancer biology, screening and	and Retention NR
	Francisco Bay Area between 1992 and 1997.	Exclusion Criteria NR	treatment, and availability of health care and	Recruitment Rates NR
	<b>Geography</b> San Francisco, CA	G1: Intervention	Type of Service Support and information	Retention Rates NR
	Organization	G2: Control Interventions	Support and information  Type of Educational	
	Hospital  Type of	G1: one-on-one visits at various events and locations; presentations	Materials Used NR	
	Community Income, Neighborhood	to community-based organizations (agencies); and Women's Health	Duration of Interaction with Clients	
	Study Design Modified 2x2 design in 8 neighborhoods	Days, offering free mammograms, Pap tests, and breast self- examination instruction.	Unspecified # of interactions (length per session NR) over 2 years	
		G2: Control	Length of Follow-up	
	Start Date 1993	<b>Group (N)</b> G1: 801 G2: 798	4 years	
	Duration			

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
Measure 1	Healthcare Utilization:	Explanation of Overall
Ever completed breast self- examination (Total N [%] pretest/Total N [%] posttest)	Measure 1 Ever completed mammography (Total N [%] pretest/Total N [%] posttest)	Outcomes NR
<b>Results</b> G1: 800 (89)/810 (92) $X^2 = NR, P = 0.031$ G2: 793 (83)/ 802(81) $X^2 = NR, \text{ not significant}$	<b>Results</b> G1: 798 (83)/812 (86) $X^2 = NR$ , not significant G2: 798 (68)/ 803 (77) $X^2 = NR$ , $P = 0.001$	<b>Quality Rating</b> Fair
Measure 2 Completed breast self- examination monthly in past year (Total N [%]	Measure 2 Ever completed mammography (logistic regression, 95% CI)	
pretest/Total N [%] posttest)  Results	Results Residence in outreach area over time: 0.7 (0.5, 1.0)	
G1: 800 (24)/808 (26) $X^2$ = NR, not significant G2: 793 (18)/ 801(23) $X^2$ = NR, $P$ =0.018 <b>Quality of Life:</b> NR	Measure 3 Completed mammography in the past 2 years (Total N [%] pretest/Total N [%] posttest)	
	<b>Results</b> G1: 798 (73)/812 (71) $X^2 = NR$ , not significant G2: 798 (57)/ 803 (62) $X^2 = NR$ , $P = 0.022$	
	Measure 4 Completed mammography in past 2 years (logistic regression, 95% CI)	
	Results Residence in outreach area over time: 0.7 (0.5, 1.0)	
	Measure 5 Completed 3 or more mammographies in past 5 years (Total N [%] pretest/Total N [%] posttest)	
	<b>Results</b> G1: 794 (50)/812 (51) $X^2 = NR$ , not significant G2: 794 (35)/ 803 (41) $X^2 = NR$ , $P = 0.008$	
	<b>Measure 6</b> Completed 3 mammographies in past 5 years (logistic regression, 95% CI)	
	Results Residence in outreach area over time: 0.8 (0.5, 1.1)	
	Measure 7 Ever completed clinical breast examination (Total N [%] pretest/Total N [%] posttest)	

## Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

			Baseline
Study	Number (N)		Characteristics
Characteristics	Inclusion/Exclusion	Community Health	Recruiting and
Setting	Groups	Worker	Retention

Author Year Hiatt et al., 2008 (continued)

Evidence Table C-1.	Key Questions 1, 2, and 3 (continued)	
Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
	<b>Results</b> G1: 801 (94)/812 (95) $X^2 = NR$ , not significant G2: 798 (82)/ 803 (87) $X^2 = NR$ , $P = 0.006$	
	Measure 8 Completed clinical breast examination in past year (Total N [%] pretest/Total N [%] posttest)	
	<b>Results</b> G1: 800 (75)/809 (74) $X^2 = NR$ , not significant G2: 796 (56)/ 803 (60) $X^2 = NR$ , not significant	
	Measure 9 Completed 3 or more clinical breast examinations in past 5 years (Total N [%] pretest/Total N [%] posttest)	
	<b>Results</b> G1: 793 (73)/809 (73) $X^2 = NR$ , not significant G2: 792 (54)/ 800 (54) $X^2 = NR$ , not significant	
	Measure 10 Ever completed pap smear (Total N [%] pretest/Total N [%] posttest)	
	<b>Results</b> G1: 801 (95)/812 (96) $X^2 = NR$ , not significant G2: 798 (83)/ 801 (87) $X^2 = NR$ , $P = 0.021$	
	<b>Measure 11</b> Ever completed Pap smear (logistic regression, 95% CI)	
	Results Residence in outreach area over time: 1.5 (0.6, 4.2)	
	Measure 12 Completed pap smear in past 3 years (Total N [%] pretest/Total N [%] posttest)	
	<b>Results</b> G1: 799 (84)/811 (87) $X^2 = NR$ , not significant G2: 798 (69)/ 801 (75) $X^2 = NR$ , $P = 0.009$	
	<b>Measure 13</b> Completed Pap smear in the past 3 years (logistic regression, 95% CI)	

Residence in outreach area over time: 0.9 (0.6, 1.3)

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Hunter et al., 2004	Eligible (N) 151	Title of CHW Promotora	<b>Age (mean)</b> 50.3 years
<b>Trial Name</b> NR	Enrolled (N) 103	Paid or Volunteer NR	Sex (% female) 100
Objective or Aim Test effectiveness of a CHW (promotora) program to increase compliance with annual preventive exams among uninsured Hispanic women, aged 40 and older, living at US-Mexico border Geography US-Mexico border communities:	Randomized (N) 101  Completers (N) 98  Withdrawals or Dropouts (N) 3  Health Condition of Interest Preventive care - Women's health Inclusion Criteria • Aged 40 or older • Residents of household • Not pregnant • At least 2 months postpartum • US women who participated in an	Relationship with Community NR CHW (N) NR Supervision of CHW NR Prior Training NR Type of Service Home visits; telephone calls to facilitate appt scheduling for annual preventive exams	Race (%) 96% Hispanic  Other  • Born in Mexico: 86%  • Blow federal poverty line: 76%  • Less than hs education: 77%  Role of CHW in Recruiting and Retention NA  Recruitment Rates NA  Retention Rates NA
Douglas, Arizona - 16,500 residents  Organization cultural/community  Type of Community Latina women  Study Design RCT  Start Date 1999  Duration 1 year	initial comprehensive clinical exam  Exclusion Criteria  Groups G1: Postcard G2: Promotora  Interventions G1: received postcards in mail 2 weeks before month their annual exams were due, printed in language used to complete original questionnaire G2: Received postcard reminders and were visited by promotora 2 weeks after postcard had been mailed. Promotora facilitated appointment scheduling, contacted them to facilitate	Type of Educational Materials Used None  Duration of Interaction with Clients One initial home visit and one final follow-up visit 8 weeks after postcard mailing to begin intervention(time per session NR)  Length of Follow-up NA	
	rescheduling if appt was missed. <b>Group (N)</b> G1: 50 G2: 51		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR	Measure 3	<b>Explanation of Overall</b>
Quality of Life: NR	Healthcare Utilization: Measure 1	<b>Outcomes</b> NR
	Returned to clinic for a second comprehensive annual exam	<b>Quality Rating</b> Fair
	Results G1: 48% (n = 24) G2: 65% (n = 33) RR, 1.35, 95% CI, 0.95-1.92	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Jandorf et al., 2005	Eligible (N) 125	<b>Title of CHW</b> Patient Navigator	<b>Age (mean)</b> G1: 61.1
<b>Trial Name</b> NR	Enrolled (N) NR	<b>Paid or Volunteer</b> Paid	G2: 61.2 Sex (% female) G1: 76.3
Objective or Aim To determine whether a patient navigator (PN) would enhance CRC screening	Randomized (N) 78  Completers (N) 78  Withdrawals or Dropouts (N)	Relationship with Community Shared community & ethnic background CHW (N)	G2: 72.5 <b>Race (% Hispanic)</b> G1: 78.9 G2: 85.0
participation beyond physician recommendation alone in a neighborhood healthcare setting.	Health Condition of Interest Colorectal cancer Inclusion Criteria	1 Supervision of CHW NR Prior Training NR	Other G1: Income ≤\$10,000: 72.2% ≥ HS education: 13.2% Had family history of cancer: 36.8%
Geography East Harlem, NYC Organization Inner city primary care practice Type of Community NR Study Design RCT	Men and women ≥ 50 yrs of age  Exclusion Criteria  FOBT within past yr; FS or barium enema within past 3-5 yrs; colonoscopy within past 10 yrs  Groups G1: Patient navigator G2: Usual care  Interventions G1: Navigated G2: Not navigated  Group (N)	Type of Service Assistance with completing screening process including written and telephone reminders, scheduling & assistance; education; support and advocacy Type of Educational Materials Used NR Duration of Interaction with Clients	G2:     Income ≤\$10,000: 64.1%     ≥ HS education:10.0%     Had family history of cancer: 38.5%  Role of CHW in Recruiting and Retention PN approached prospective participants  Recruitment Rates NR  Retention Rates
Start Date 2002 Duration 6 months	G1: 38 G2: 40	Telephone calls (unspecified #, unspecified length) over 6 month period  Length of Follow-up 6 months	NR

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR <b>Quality of Life:</b> NR	Healthcare Utilization: Measure 1 Completed FOBT after 3 months (% yes)	Explanation of Overall Outcomes NR
	Results G1: 42.1 G2: 25.0 P = 0.086	<b>Quality Rating</b> Fair
	Measure 2 Had endoscopy appointment at 3 months (%)	
	Results G1: 18.4 G2: 0 P = 0.005	
	Measure 3 Completed endoscopy at 3 months (%)	
	<b>Results</b> G1: 15.8 G2: 5.0 P = 0.115	
	Measure 4 Completed endoscopy at 6 months (%)	
	Results G1: 23.7 G2: 5.0 P = 0.019	

Author Year Korfmacher et al., 178   Filipible (N)   Title of CHW   Paraprofessional   G1: 19.44   G2: 20.24   G3: 19.70   G	Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
	Korfmacher et al., 1999; Olds et al., 2002; Olds et al., 2004;  Trial Name Home Visitation 2000  Objective or Aim Examine differences between CHWs and nurses in using home visitation to reduce incidence of child maltreatment; to examine distal effects of prenatal and infancy home visiting by CHWs or nurses, at 2-4 y/o  Geography Denver  Organization Recruited from prenatal clinics  Type of Community Low-income  Study Design RCT  Start Date 1994  Duration	Enrolled (N) 735  Randomized (N) 735  Completers (N) 560  Withdrawals or Dropouts (N) 175 (n at 24 month assessment), 130 (n at 4 year assessment)  Health Condition of Interest Child maltreatment; maternal and child health  Inclusion Criteria Pregnant; Medicaid-qualified or no private insurance  Exclusion Criteria Previous live birth  Groups G1: CHW visitation G2: nurse visitation G3: control  Interventions G1: Incremental developmental screening and referral + CHW home visitations G2: Developmental screening and referral + nurse home visitations G3: Developmental screening and referral Group (N) G1: 244 G2: 236	Paid or Volunteer Paid  Relationship with Community "Shared social characteristics"  CHW (N) 10  Supervision of CHW 2 LCSWs (2 supervisors to 10 visitors)  Prior Training HS education, no degree in "helping professions"; preferentially prior work experience in human services agencies  Type of Service Intensive home visitation: promoting healthy behaviors, competent child care, pregnancy planning, education, employment; linking to social and health services; promoting healthy family/friend relationships  Type of Educational Materials Used Visit-specific protocol, adapted to individual needs of mother  Duration of Interaction with Clients Every other week (except for weekly visits during first 4 weeks after enrollment and first 6 weeks after delivery) through child's 21st month, followed by monthly visits during final 3 months, ≈ 75 min per session	G1: 19.44 G2: 20.24 G3: 19.70  Sex (% female) 100  Race (%) G1: Hispanic: 45%,

# Knowledge, Attitude, and Behavior Quality of Life

#### Health Outcomes Healthcare Utilization

### Costs (Economics) Additional Outcomes

### Knowledge, Attitude, and Behavior:

Measure 1

Content of home visit, pregnancy

Results

Personal health G1 27%

G2: 38% (P < 0.001)

Environmental health

G1 15%

G2: 7% (*P* < 0.001)

Life course development

G1: 15%

G2: 14% (P < 0.05)

Parental caregiving

G1: 24% G2: 25%

Friends/family

G1: 19%

G2: 15% (P < 0.001)

#### **Health Outcomes:**

Measure 1

Language @ 21 mo (Preschool Lanaguge Scale)

Results

Least squares mean

G1: 99.89 G2: 101.22 G3: 99.49

Mean difference

G1-G3: 0.4 (-1.94 - 2.74) G2-G3: 1.73 (-0.64 - 4.11)

Least squares mean (low resource group)

G1: 97.83 G2: 101.52 G3: 96.85

Mean difference

G1-G3: 0.98 (-2.65 - 4.62) G2-G3: 4.67 (0.85-8.49,

Measure 2

Mental development delay @ 24 mo (Mental Development Index)

Results

Least squares mean

G1: 89.45 G2: 90.13 G3: 89.38 Difference

G1-G3: 0.07 (-2.39 - 2.53) G2-G3: 0.75 (-1.77 - 3.28)

Low resource group: least squares mean

G1: 88.54 G2: 90.18 G3: 86.2

Difference

G1-G3: 2.33 (-1.46 - 6.12) G2-G3: 3.98 (-0.07 - 8.02)

G1-G2 1.26

Measure 1

Subsequent fertility @ 24 mo

Results

Pregnancy G1: 33% G2: 29% G3: 41%

G1-G3: 0.7 (0.46-1.06, P < 0.1) G2-G3: 0.6 (0.39-0.93,  $P \le 0.05$ )

G1-G2: 0.88 (0.57-1.36)

G1-G2 (adjusted) = 0.82 (0.51-1.31)

### Costs (Economics): Measure 1

Per-family cost over 2.5 years (inflation adjusted, 2002 dollars)

**Results** G2: \$6,162 G3: \$9,140

Measure 3

Average cost (including salary + benefits, supplies, travel, rent, equipment, training) over approx 2.5 y

Results

G1: \$5,178/family G2: \$7,681/family

### Explanation of Overall Outcomes

CHWs were more likely than nurses to discuss environmental health and friends/family, life course development (after pregnancy), and less likely to discuss personal health (during pregnancy) and parental caregiving (after pregnancy): CHWs home visits have little significant effect on maternal & infant health outcomes, except for improved mother-child interactions among low psychological resource subpopulation; CHW visits showed improvement over control in maternal health but not in child health: nurse visit outcomes generally favored child health but not maternal

**Quality Rating** 

Fair

**Health Outcomes:** 

NR

**Key Questions 1, 2, and 3 (continued)** Evidence Table C-1.

			Baseline	
Study	Number (N)		Characteristics	
Characteristics	Inclusion/Exclusion	Community Health	Recruiting and	
Setting	Groups	Worker	Retention	

**Author Year** 

Korfmacher et al., 1999; Olds et al., 2002; Olds et al., 2004

(continued)

Evidence Table C-1. Key	Questions 1, 2, and 3 (continued)	
Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Measure 3 Mother-infant interaction  Results Least squares mean G1: 100.15 G2: 100.31	Birth G1: 13% G2: 12% G3: 19% G1-G3: 0.63 (0.37-1.07, <i>P</i> < 0.1) G2-G3: 0.58 (0.33-1.01, <i>P</i> ≤ 0.05) G1-G2: 0.9	
G3: 98.99 G1 vs. G3: 1.16 (-0.11 - 2.42, P < 0.1) G2 vs. G3: 1.32 (0.03-2.60, P ≤ 0.05) Least squares mean difference G1 vs. G2 (low resource group) = 0.06 (01.87 - 1.98), adjusted 0.08 (-1.99 - 2.16)	Healthcare Utilization: NR  Measure 2 Maternal life course  Results Married G1: 32% G3: 44% (P = 0.02)	
Quality of Life: Measure 1 Home environment	Living w/ bio father G1: 33% G3: 43% ( <i>P</i> = 0.03)	
Results Least squares mean G1: 37.4 G2: 37.79 G3: 37.1; Mean difference G1-G3: 0.3 (-0.49 - 1.1) G2-G3: 0.69 (-0.12 - 1.5, P < 0.1) Least squares mean difference (low resource group) G1-G2: 0.26 (-0.95 - 1.47), adjusted -0.05 (-1.35 - 1.24)	Working at child 2-4 y/o G1: 15 mo G3: 13 mo $(P = 0.04)$ Sense of mastery G1: 101 G3: 99 $(P = 0.03)$ Mental health score G1: 101 G2: 99 $(P = 0.03)$ No G1-G3 difference on education, welfare <b>Measure 3</b> Mother-child interaction	
Measure 3 Post-intervention reductino in urine cotinine levels among smokers (ng/mL)	Results Sensitive responsive interactions during free play G1: 101	
Results G1: 89 G2: 259 G3: 12 (NS) Least squares mean difference G1 vs G2: 189.16 (-51.38 - 429.69), adjusted 266.75 (-3.34 - 536.84) Mean difference G1 vs. G3 -76.19 ng/dL (95% CI, -302.21,-149.82) G2 vs. G3 -246.68 ng/dL (95% CI, -466.19,-27.16) P≤0.05	G3: 99 ( <i>P</i> = 0.03); no difference G2 vs G3  Measure 4  Home environment (Home Observation for Measurement of Environment inventory)  Results  For low psychologic resource group: environment supportive of early learning G1: 24.63  G2: 24.61  G3: 23.35 (G1-G3 <i>P</i> = 0.03  G2-G3: <i>P</i> = 0.03)	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Krieger et al., 1999	Eligible (N) 759	Title of CHW Community health worker	<b>Age (mean)</b> 24.9% < 40 y/o
<b>Trial Name</b> Seattle Hypertension	Enrolled (N) 421	Paid or Volunteer NR	18.3% > 64 y/o Sex (% female) 27.8
Intervention Project  Objective or Aim  Determine whether tracking and	Randomized (N) 421  Completers (N) 397	Relationship with Community Similar income community, predominantly black (12/14) CHW (N)	Race (%) 79.1% Black Other 40% uninsured
outreach intervention delivered by community health workers improved medical follow-up of persons whose elevated blood pressure detected during blood pressure measurement at community sites  Geography Seattle  Organization Various community	Withdrawals or Dropouts (N) 110  Health Condition of Interest Hypertension  Inclusion Criteria  • BP at least 140/90  • 18+ y/o  • Black or White race  • Income no more than 200% FPL (1995)  Exclusion Criteria See inclusion criteria  Groups G1: Intervention G2: Usual care	Supervision of CHW NR Prior Training NR Type of Service Medical referral, telephone appt scheduling, appt reminder letter, post-appt f/u, rescheduling missed appt, assistance with other barriers to care (e.g. transportation) Type of Educational Materials Used	Role of CHW in Recruiting and Retention Providing initial BP measurement Recruitment Rates 55.5% (421 enrolled of 759 eligible) Retention Rates G1: 95% G2: 93%
sites: social services agencies, food banks, shelters/missions, public libraries, grocery stores, community centers, etc.  Type of Community Low-income neighborhoods  Study Design RCT  Start Date 1994  Duration 28 months	Interventions G1: CHW assistance with medical follow-up G2: advice to see medical provider, list of public and community clinics Group (N) G1: 209 G2: 212	Duration of Interaction with Clients Various, brief interactions over 3 months (time per session NR) Length of Follow-up 3 months	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR  Quality of Life: NR	Healthcare Utilization: Self-report of completed f/u appt (validated by medical provider report)	Explanation of Overall Outcomes CHW intervention was
	<b>Results</b> G1: 65.1% completed f/u within 90 days G2: 46.7% ( <i>P</i> = 0.001)	associated with significantly higher proportion of subjects completing HTN follow- up exam within 90 days
		<b>Quality Rating</b> Fair

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Krieger et al., 2002; Krieger et al., 2005 <sup>47,48</sup>	Eligible (N) 447 Enrolled (N) 274	Title of CHW Community Home Environmental Specialists (CHES)	Age (mean) G1: 7.4 G2: 7.3 Sex (% female)
Trial Name Seattle-King County Health	Randomized (N) 274	Paid or Volunteer Paid	G1: 44.2 G2: 38.2
Homes Project (SKCHH)	Completers (N) 214	Relationship with Community Connection to and	Race (%) Non-Hispanic White G1: 12.3
Objective or Aim Assess effectiveness of a	Withdrawals or Dropouts (N) 60	understanding of community; shared ethnic, linguistic, and	G2: 21.3 Non-Hispanic AA G1: 31.9
CHW intervention focused on reducing	Health Condition of Interest pediatric asthma	cultural background with project participants;	G2: 27.9 Vietnamese G1: 25.4
exposure to indoor asthma triggers	<ul> <li>Inclusion Criteria</li> <li>A household was eligibile if:</li> <li>home to a child 4-12 years with diagnosed persistent asthma</li> </ul>	recognition as a person who can be respected and trusted	G1: 25.4 G2: 22.1 Other Asian G1: 9.4 G2: 5.2
<b>Geography</b> King Co, Washington	<ul> <li>income &lt; 200% of 1996 federal poverty threshold</li> <li>child enrolled in Medicaid</li> </ul>	CHW (N) 6 Supervision of CHW	G2: 5.2 Hispanic G1: 17.4 G2: 17.7
Organization Low income urban households	<ul> <li>caregiver verbally proficient in English, Spanish or Vietnamese</li> <li>child spent ≥ 50% of nights in house</li> <li>house was in King County.</li> </ul>	NR Prior Training NR	Other G1: 3.6 G2: 5.9
Type of Community Low income urban households with	Exclusion Criteria A child with another chronic illness requiring daily medications; household participation in other asthma case management or care coordination	Type of Service	Other Household had at least 1 asthma trigger: 75%
child diagnosed with asthma	programs in past 2 years; plans to leave King County during next 6 months		Urgent health use in past 2 months (%) G1: 25.9
Study Design RCT	Groups G1: high intensity G2: low intensity		G2: 21.3 Smoker in home (%)
Start Date 1999 Duration	Interventions G1: Initial home environmental assessment and		G1: 39.9 G2: 41.9
1 year	individualized action plans specifying participant and CHES actions to reduce household exposures. CHES made additional visits over 12-month period to provide		Severe persist asthma G1: 32.6 G2: 23.5
	education and social support, materials to reduce exposures (e.g., bedding covers, vacuums); free allergy testing; advocacy for improved housing conditions.  G2: Single CHES visit which consisted of initial		Role of CHW in Recruiting and Retention Cannot determine
	environmental assessment, home action plan, limited education, and bedding encasements		Recruitment Rates NR
	<b>Group (N)</b> G1: 138 G2: 136		Retention Rates G1: 80% G2: 76%

### Knowledge, Attitude, and Behavior Quality of Life

### **Knowledge, Attitude, and Behavior: Measure 1**

Behavior summary score of trigger reduction behaviors (vacuum and dust child's bedroom at least twice/2 weeks, vacuum cloth-covered furniture at least twice/2 weeks or remove it, use doormat or remove shoes, use allergy control covers on mattress and pillow

#### Results

Across groups comparison: GEE coefficient (95% CI): 0.41 (-0.13, 0.95); P = 0.141 frequencies of actions to reduce dust exposure and use of bedding encasements increased more in high-intensity group. Kitchen ventilation improved more in low-intensity group. Neither group increased frequency of washing sheets or dusting nor reduced exposure to pets (although pet ownership was uncommon among participants) and smoking in home. behavior summary score improved in both groups, and across-group difference was not significant

### Quality of Life: Measure 1

Pediatric Asthma Caregiver Quality of Life Scale (score range 1-7 with higher scores indicating better QoL)

#### Results

Score at exit (G1 vs. G2): 5.6 vs. 5.4 GEE coefficient 0.58 (95% CI, 0.18, 0.99), P = 0.005; NNT = 4.8 ITT analysis yielded simalr results: improvements in QoL were greater in G1 (data NR, P = 0.009)

#### Measure 2

Asthma symptom days (self-reported # of 24-hour periods during 2 weeks before interview with asthma symptoms: wheeze, tightness in chest, cough, shortness of breath, slowing down activities due to asthma, nighttime awakenings)

#### Results

G1 vs. G2 at exit: 3.2 vs. 3.9 GEE coefficient -1.24 (95% CI, -2.9, 0.4), P = 0.138

### Health Outcomes Healthcare Utilization

### Health Outcomes: Measure 1

Days with activity limitation/2 weeks

#### Results

Score at exit (G1 vs. G2): 1.5 vs. 1.7 GEE coefficient -1.5 (95% CI, -2.84, -0.15), OR 0.22 (0.06, 0.86), P = 0.29

#### Measure 2

Missed school in past 2 weeks (%)

#### Results

G1 vs. G2 at exit: 12.2 vs. 20.3 GEE coefficient -0.77 (95% CI, -1.70, 0.16), OR 0.46 (0.18, 1.18), P = 0.105

#### Measure 3

Urgent health services use/2 months (%)

#### Results

G1 vs. G2 at exit: 8.4 vs. 16.4 GEE coefficient -0.97 (95% CI, -1.8, -0.12), OR 0.38 (0.16, 0.89), P = 0.026; NNT = 12.9

ITT analysis yielded simalr results: improvements in urgent health services were greater in G1 (data NR, *P* = 0.062)

#### Measure 4

Days used controller medication/2 weeks

#### Results

G1 vs. G2 at exit: 3.5 vs. 3.6 GEE coefficient -1.03 (95% CI, -2.79, 0.73), P = 0.250

#### Measure 5

Days used beta2-agonist/2 weeks

#### Results

G1 vs. G2 at exit: 4.0 vs. 4.0 GEE coefficient -0.23 (95% CI, -1.88, 1.42), P = 0.781

#### Measure 6

Missed work in past 2 weeks (%)

#### Results

G1 vs. G2 at exit: 11.2 vs. 13.0 GEE coefficient 0.07 (95% CI, -0.91, 1.0.5), OR 1.07 (0.40, 2.85), P = 0.890

#### **Healthcare Utilization:**

NR

### Costs (Economics) Additional Outcomes

### Costs (Economics): Measure 1

Urgent care costs (hospital admissions, ER visits, unscheduled clinic visits)

#### Results

Two months before exit interview G1 \$6301-\$8856 (\$57-\$80/child) less than G2. Estimated decrease in 2 month costs between baseline and exit:

G1: \$22084-\$36700 (\$201-\$344/child) vs. G2: \$19246-\$32756 (\$185-\$315/child)

## Explanation of Overall Outcomes NR

Quality Rating

Good

**Health Outcomes:** 

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Levine et al., 2003	Eligible (N) 817	<b>Title of CHW</b> Community health worker	<b>Age (mean)</b> G1: 53.8
<b>Trial Name</b> NR	Enrolled (N) 789	Paid or Volunteer NR	G2: 54.6  Sex (% female)
Objective or Aim Compare program effectiveness and intervention efficacy of more and less intensive education/behavior interventions on control of SBP  Geography Sandtown- Winchester Community, Baltimore  Organization inner city  Type of Community Urban African- American  Study Design RCT  Start Date NR  Duration	Randomized (N) 789  Completers (N) 471  Withdrawals or Dropouts (N) 318  Health Condition of Interest Hypertensive heart disease Inclusion Criteria African-American adults w/ HTN (140+/90+)  Exclusion Criteria • Terminal conditions • Mental impairment • Acute conditions precluding participation  Groups G1: More intense intervention G2: Less intense intervention Interventions G1: G2 care + 5 CHW visits with BP measurement, addressing issues of BP management and access to medical care	Relationship with Community Indigenous to community CHW (N) NR Supervision of CHW Nurse-supervised Prior Training NR Type of Service Home visits; BP measurement; education; assistance with access to care Type of Educational Materials Used Counseling; BP tracking card; educational pamphlet Duration of Interaction with Clients 6 visits over 2.5 years (length per visit NR) Length of Follow-up 40 mo	G1: 61.2 G2: 62.5  Race (%) 100'% African-American  Other  • HS-level education: 42% • < HS: 45% • Unemployed: 32% • Income < \$10k: 65% • With usual source of care: 79% • Uninsured: 20%  Role of CHW in Recruiting and Retention • Initial neighborhood surveillance • Recruiting for individual RCT  Recruitment Rates 0.97  Retention Rates G1: 240/387 = 62% G2: 231/402 = 57%
30 months	G2: CHW home visit for education, counseling, and referral  Group (N) G1: 387 G2: 402		

Evidence Table C-1.	Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1	Costs (Economics): NR
NR Quality of Life:	BP change (unadjusted systolic/diastolic ± SE; adjusted systolic/diastolic ± SE)	Explanation of Overall Outcomes
Quality of Life: NR	<b>Results</b> G1: $-5.5\pm1.5/-4.1\pm0.9$ ; $5.6\pm1.5/-3.8\pm1.0$ ) G2: $-3.2\pm1.5/-2.9\pm1.0$ ; $-3.3\pm1.5/-2.6\pm1.0$ ) $P < .005$ for differences between baseline and followup for each group, no differences between groups	CHW intervention produced significant pre/post change in proportion of HTN under control in both
	Measure 2 % with adequate HTN control ( < 140/90)	arms, but no difference between arms; no significant pre vs post
	Results G1: $16\% \rightarrow 36\%$ G2: $18\% \rightarrow 34\%$ pre/post $P < .01$ group difference NS	change in BP classification within or between arms; more intensive group had less favorable results
	Measure 3 Pre/post BP (systolic/diastolic)	than less intensive group
	Results	<b>Quality Rating</b> Fair
	G1: 147.7/89.2 (95% CI, 145.5, 149.9 / 87.8, 90.6) → 145/86.2 (95% CI, 142.3, 147.7 / 84.2, 88.2) G2: 148.6/89.3 (95% CI, 146.4, 150.7 / 87.8, 90.8) → 142.1/84.7 (95% CI, 138.8, 145.4 / 82.7, 86.7)	Health Outcomes: NR
	P < 0.05 for differences between baseline and followup for eachHealthcare	
	Measure 4 JNC-VI classification pre/post	
	Results No significant differences	
	Utilization: NR	

Study Number (N) Characteristics Inclusion/Exclusion Setting Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Characteristics Inclusion/Exclusion	Title of CHW Community lay workers (promotoras)  Paid or Volunteer paid  Relationship with Community bilingual clinic employees CHW (N) NR  Supervision of CHW PI attended every class Prior Training NR  Type of Service Classroom: 8 weekly 2-hour group classes; Biweekly Telephone calls Type of Educational Materials Used Developed by certified health educator with promotoras, based on ADA Guidelines  Duration of Interaction with Clients 8 weekly 2-hour classes + biweekly telephone calls for 8 weeks followed by biweekly postcards for 16 weeks 24 weeks total duration of interaction with	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: Measure 1	Health Outcomes: Measure 1 HgbA1c	Costs (Economics): NR
Bilingual DKQ - validated: 24 itms designed for Mexican Americans and elicits	Results Baseline(SD)/6 months(SD): G1: 8.21(2.2)/7.76(1.87)	Explanation of Overall Outcomes NR
information about respondent's understanding of cause of diabetes, types	G2: 7.71(1.47)/8.01(1.8)  Mean change between groups: <i>P</i> < 0.001	<b>Quality Rating</b> Good
of diabetes, self- management skills, and complications of diabetes	Measure 3 HgbA1c - validated Results	
Results Baseline/ 6 months (SD): G1: 69.1 (13.6)/77.2 (14.4) G2: 66.9 (15.2)/65.1 (21.0)	At 6 months: G1: 7.76 G2: 8.01 ( <i>P</i> < .001)	
( <i>P</i> < .002 for mean change between groups)	Healthcare Utilization: NR	
Measure 2		
Diabetes Health Belief Measure (DHBM)		
Results Baseline(SD)/6 months(SD):		
G1: 56.4(12.2)/54.6(8.4) G2: 57.0(10.6)/50.8(13.6) Mean change between groups: <i>P</i> < 0.01		
Quality of Life: NR		

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Mock et al., 2007	Eligible (N) NR	Title of CHW Lay health worker	<b>Age (mean)</b> G1: 45.7
<b>Trial Name</b> Vietnamese REACH for Health	Enrolled (N) 1005	Paid or Volunteer Paid, \$1500	G2: 46.0 Sex (% female) G1: 100
Initiative  Objective or Aim	Randomized (N) NR Completers (N)	Relationship with Community Shared race/ethnicity,	G2: 100  Race (%)
Increase cervical cancer screening rates	968 Withdrawals or Dropouts (N)	physical community  CHW (N) 50	Vietnamese 100  Other  Mean years in US
Geography Santa Clara County, CA	37  Health Condition of Interest Pap screening	Supervision of CHW Non clinician	G1: 8.92 G2: 9.23
Organization Commnity	Inclusion Criteria  • Vietnamese American	Prior Training NR	Self-rated speaking English poorly/not at all G1: 56.3% G2: 57.7%
Type of Community Vietnamese American women	<ul> <li>Female</li> <li>≥18 years</li> <li>Living in Santa Clara County</li> </ul>	Type of Service Small group gatherings, direct contacts to help access medical services	> HS education G1: 57.5% G2: 54.8%
Study Design RCT	Exclusion Criteria NR Groups	and schedule appts  Type of Educational  Materials Used	Married G1: 61.3% G2: 64.3%
Start Date 2001	G1: CHW + media G2: media only	Prepared presentation with flip chart, QandA	Employed G1: 26%
<b>Duration</b> 3 years	Interventions G1: CHW small group meetings, direct contact with subjects,	Duration of Interaction with Clients 2 sessions of 90 or 120	G2: 27.1% Role of CHW in Recruiting
	Vietnamese language ads for TV/radio/newspaper, booklets and printed materials in various	minutes each plus	and Retention CHW recruited subjects from within her own social
	community locations G2: Vietnamese language ads for TV/radio/newspaper, booklets and printed materials in various	Length of Follow-up 3-4 months	network  Recruitment Rates G1: 100%
	community locations, delayed educational session		G2: 100% Retention Rates
	<b>Group (N)</b> G1: 491 G2: 477		G1: 97.8% G2: 94.8%

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
Measure 1 Reported awareness of need for Pap by women 18+ y/o	Healthcare Utilization: Measure 1 Self-report of Pap in past year	Explanation of Overall Outcomes CHW + media
Results G1: 68.4→93.9% ( <i>P</i> < 0.001) G2: 68.5→70.2% ( <i>P</i> = 0.55);	Results G1: 45.7→67.3% ( <i>P</i> < 0.001) G2: 50.9→55.7% ( <i>P</i> = 0.035); Z test <i>P</i> < 0.001	intervention significantly increases understanding of and utilization of Pap compared to media intervention alone
Z-test P < 0.001)	<b>Measure 2</b> Ever had Pap test (among those who had not had Pap test preoutreach)	
Measure 2 Reported awareness of need		Quality Rating
for pap test by women 18+ years old	<b>Results</b> G1: 46.0 (N = 144)	Fair
Results	G2: 27.1 P < .001 (N = 161)	
G1: 81.8%/99.6% ( <i>P</i> < 0.001) G2: 87.2%/95.2% ( <i>P</i> <	Measure 3 Self-report of having ever had Pap	
0.001) Z-test <i>P</i> < 0.001	Results G1: 65.8→81.8% (P < 0.001) G0: 70.4 → 75.5 (P → 0.004): 7 to at P → 0.004	
Quality of Life: NR	G2: $70.1 \rightarrow 75.5 \ (P < 0.001)$ ; Z test $P = 0.001$	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Morisky et al.,	Eligible (N) NR	Title of CHW Community health worker	<b>Age (mean)</b> 53.5 (SD 12.0)
2002; Ward et al., 2000	Enrolled (N) 1367	Paid or Volunteer NR	<b>Sex (% female)</b> 59.2
Trial Name Community Hypertension	Randomized (N) 1367	Relationship with Community Same ethnic group as	Race (%) Black: 77% Hispanic: 21%
Intervention Project (CHIP)	Completers (N) NR	patient, language concordant	Other
Objective or Aim Develop effective	<b>Withdrawals or Dropouts (N)</b> NR	CHW (N) NR	<ul><li>&lt; HS education: 49%</li><li>Married: 33%</li><li>Income &lt; \$14k/y: &gt; 87%</li></ul>
strategies for enhancing treatment	Health Condition of Interest Hypertension	Supervision of CHW NR	<ul><li>Public insurance: 54%</li><li>Uninsured: 30%</li></ul>
adherence for hypertensive minority populations	Inclusion Criteria Adult w/ diagnosis of HTN attending county hospital clinic or private health clinic	Prior Training 1 month interview training program	Role of CHW in Recruiting and Retention Interviews with new enrollees
Geography Large West Coast city	Exclusion Criteria NR	Type of Service Counselling after clinic visits, or home visits	Recruitment Rates > 98% overall
Organization County medical center	Groups G1: Individualized CHW pt counseling G2: Appt tracking	Type of Educational Materials Used Education on treatment, lifestyle modification info,	Retention Rates NR
Type of Community Low-income, inner-	G3: CHW home visits + voluntary discussion group attendance G4: Usual care	info on community resources	
city Blacks and Hispanics	Interventions G1: CHW post-clinic appt counseling session	Duration of Interaction with Clients G1: 5-10 min after each	
<b>Study Design</b> RCT	G2: Appt reminder cards and phone calls	clinic visit G3: variable	
<b>Start Date</b> NR	G3: Home visits by CHW G4: Standard clinic care	Number of visits, duration per session,	
<b>Duration</b> 4 years	<b>Group (N)</b> G1: 330 G2: 328	time period over which interactions occurred NR	
	G3: 333 G4: 328	<b>Length of Follow-up</b> 12 mo	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1 BP Control	Costs (Economics): NR Explanation of Overall
Quality of Life: NR	Results G1: 35.2% @ baseline,     46% @ 6 and 12 mo (P < 0.01) G2: 40.2% @ baseline     42% @ 6 mo     48% @ 12 mo (P < 0.01) G3: 29.7% @ baseline %NR but "improved" @ 6 & 12 mo G4: 36.9% @ baseline % NR but "improved"	Explanation of Overall Outcomes NR Quality Rating Poor
	No significant differences vs. control - all groups improved	
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Nacion et al., 2000	Eligible (N) 218	Title of CHW Maternal-Child Health	<b>Age (mean)</b> 58% 20+ y/o
<b>Trial Name</b> REACH-Futures	Enrolled (N) 213	Advocate  Paid or Volunteer	<b>Sex (% female)</b> 100
Objective or Aim Can maternal-child	Randomized (N) 213	Paid Relationship with	Race (%) • African-American: 90%
health advocates, working with	Completers (N) 213	Community Within community, minority	• Latina: 9% Other
professional nurses, provdie health screening,	Withdrawals or Dropouts (N)	<b>CHW (N)</b> 11	<ul><li> &lt; HS education: 51%</li><li> Gravida-1: 53%</li></ul>
problem identification, self and infant care	Health Condition of Interest Maternal and child health	Supervision of CHW Validation by nurse after each visit	Role of CHW in Recruiting and Retention NA - CHW visits were unit of
information, and referrals in a safe manner?	Inclusion Criteria Home visit accomplished by CHW with validating follow-up by nurse	Prior Training Minimum HS or GED; experience in community	analysis  Recruitment Rates  NA - CHW visits were unit of
<b>Geography</b> Chicago	Exclusion Criteria Visit conducted by CHW + nurse	service	analysis
Organization	together	Type of Service Intensive home visits for	Retention Rates NA - CHW visits were unit of
inner city  Type of  Community	Groups G1: CHW visit G2: nurse visit	assessment, problem solving, emotional support, and information	analysis
Predominantly African-American and Latino	Interventions NR	Type of Educational Materials Used NR	
Study Design Retrospective cohort	<b>Group (N)</b> G1: 213 G2: 213	Duration of Interaction with Clients	
Start Date 1992		Length of Follow-up NR	
<b>Duration</b> 32 mo			

Evidence Table C-1.	Key Questions 1, 2, and 3 (continued)
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Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: NR	Costs (Economics): NR
Quality of Life: NR	Healthcare Utilization: Measure 1 Agreement in identifying problems	Explanation of Overall Outcomes  CHW and nurse home visits were comparable in most regards CHW more likely to identify problems and provide problem solving Nurse more likely to provide referrals and emotional support  Quality Rating Fair
	<b>Results</b> CHW more likely to identify problems in woman's health $(P=0.01)$ , well child health care deficits $(P=0.02)$ , parenting $(P=0.02)$ , socioeconomic $(P<0.01)$ ; most visits identified no problems	
	Measure 2 Agreement in placing referrals	
	<b>Results</b> Nurse more likely to make referrals for woman's health $(P = 0.01)$ , well woman $(P = 0.02)$ , emotional/interpersonal, parental support, and socioeconomic $(P < 0.01)$ ; most visits involved no referrals	
	Measure 3 Services provided (per completed Maternal-Child Activity form)	
	Results Problem solving G1: 16% G2: 7% (P < 0.01)	
	Emotional support G1: 4% G2: 14% ( <i>P</i> < 0.01)	
	Assessment, information: No difference between groups	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Characteristics Recruiting and Retention
Author Year Navarro et al.,	Eligible (N) NR	Title of CHW Consejeras	Age (mean) • Average: 34
1998; Navarro et al., 1995;	Enrolled (N) 512	Paid or Volunteer NR	• Range: 18-72 Sex (% female)
Navarro et al., 2000	Randomized (N) 512	Relationship with Community	100 Race (%)
<b>Trial Name</b> Por La Vida Damos	Completers (N) 365	Member of Latino community perceived, as "natural helpers" by	Latina: 100 Other
Cuenta Program  Objective or Aim	Withdrawals or Dropouts (N) 147	community	<ul> <li>Median gross family income: \$12,000</li> </ul>
To describe impact of intervention	Health Condition of Interest	<b>CHW (N)</b> 36	Median years of formal education: 7
known as Por La Vida (PLV) on cancer screening	Breast and cervical cancer Inclusion Criteria	Supervision of CHW Yes"unobtrusive	<ul><li>Born in Mexico: 92%</li><li>Avg acculturation: 2</li></ul>
for Latinas in San Diego, California	Part of social network of consejeras recruiting participants. No other inclusion criteria reported.	observations" of ongoing sessions and debriefing sessions with consejeras	Role of CHW in Recruiting and Retention CHW recruited all
Geography Southeast area of	Exclusion Criteria NR	each month by PLV "staff" but no reporting of who these staff members are	participants through social networks
San Diego County, CA	Groups G1: Lower intensity CHW	Prior Training NR	Recruitment Rates
Organization Low-income Latino communites	intervention G2: Higher intensity CHW intervention	Type of Service Small group educational	Retention Rates G1: 68.1 G2: 72.6
Type of Community Low-income Latino women	Interventions G1: CHW delivering Community Living Skills sessions, details NR G2: CHW delivering Cancer	Type of Educational Materials Used Pamphlets, work sheets,	
Study Design RCT	education sessions, 12 weekly group sessions conducted over 3-	posters, plastic models of female body, pelvic models	
Start Date NR	months plus 2 additional sessions offered within a year of beginning of group meetings	Duration of Interaction with Clients 12 sessions of 90 minutes	
<b>Duration</b> NR	Group (N)	each over 3 months	
	G1: 18 consejeras, 238 women G2: 18 consejeras, 274 women	Length of Follow-up 3 months 1 and 2 year followup	

Baseline

Evidence Table C-1. Kev Que	stions 1, 2, and 3 (continued)
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Lviderice rable 0-1.	ney Questions 1, 2, and 3 (continued)	
Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1	Costs (Economics): NR
NR Quality of Life: NR	Pretest-posttest changes in % of women performing monthly BSEs	Explanation of Overall Outcomes
	Results Participant unit of analysis (n = 361) G1: 18.5 G2: 33.2 $P < 0.001$ $t = 3.23$	Increase in use of cancer screening tests higher in PLV cancer intervention group compared to community living skills (control) group
	Consejera unit of analysis (n = 35) G1: 18.6 G2: 31.8 P = 0.021 t = 2.43	Results from 1 and 2 yr followup suggest that cancer screening rates
	Measure 3 Pretest-posttest changes in % of women ≥40 yrs who had mammogram within past year	in Latinas of low socio- economic level with limited a
	Results Participant unit of analysis (n = 113)	<b>Quality Rating</b> Poor
	G1: 7 G2: 21.4 P = 0.029 t = 2.22	Health Outcomes: Measure 1 Odds of montly BSE 1 yr and 2 yr followup for cancer screening group
	Consejera unit of analysis (n = 33) G1: 6.8	(P value)
	G2: 24.3 P = 0.063 t = 1.96	<b>Results</b> Year 1: 2.03 (.016) Year 2: 0.96 (.877)
	Healthcare Utilization: Measure 1 Pretest-posttest changes in % of women who had physical breast exam within past year	Measure 2 Odds of CBE 1 yr and 2 yr followup for cancer screening group (P value)
	Results Participant unit of analysis (n = 359) G1: 15.5 G2: 17.7	Results Year 1: 1.21 (.556) Year 2: 1.93 (.038)
	P = 0.589 t = 0.54 Consejera unit of analysis (n = 35) G1: 19.3 G2: 19.5	Measure 3 Odds of mammogram 1 yr and 2 yr followup for cancer screening group (P value)
	P = 0.967 t = 0.04	Results Year 1: 1.50 (.484) Year 2: 3.88 (.018)

Evidence Table C-1. **Key Questions 1, 2, and 3 (continued)** 

			Baseline
Study	Number (N)		Characteristics
Characteristics	Inclusion/Exclusion	Community Health	Recruiting and
Setting	Groups	Worker	Retention

**Author Year** 

Navarro et al.,

1998; Navarro et al., 1995; Navarro et al., 2000

(continued)

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
	Measure 2 Pretest-posttest changes in percentages of women who had a Pap test within past year	<b>Measure 4</b> Odds of pap smear 1 yr and 2 yr followup for
	Results Participant unit of analysis (n = 360) G1: 16.2 G2: 23.1 $P = 0.096$ t = 1.67	cancer screening group (P value)  Results Year 1: 2.10 (.017) Year 2: 1.70 (.082)
	Consejera unit of analysis (n = 35) G1: 18.4 G2: 23.4 P = 0.369 t = 0.91	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Parker et al., 2008	Eligible (N) 510	Title of CHW CES	<b>Age (mean)</b> G1: 9.01
Trial Name Community Action Against Asthma (CAAA)	Enrolled (N) 328 Randomized (N)	Paid or Volunteer NR Relationship with	G2: 8.8  Sex (% female) G1: 43 G2: 41
Objective or Aim Evaluate a CHW intervention to improve children's asthma-related	328  Completers (N) 227  Withdrawals or Dropouts (N) 101	Community Detroit residents; 2 were bilingual (Spanish and English) CHW (N)	Race (%) African American G1: 83 G2: 79
health by reducing household environmental	Health Condition of Interest pediatric asthma	Supervision of CHW NR; however, there was	Hispanic G1: 11 G2: 10
triggers for asthma  Geography Eastside and southwest Detroit, MI	Inclusion Criteria Child 7-11 years with persistent asthma (defined as any of following being true: one or more daytime symptoms reported as being present "more than two times per week,"; sleep	a steering committee of community members, health agencies, etc. involved in project; also CHWs had continued training throughout	Caucasian G1: 4 G2: 5 Other G1: 3 G2: 6
Organization Urban households with children attending neighborhood	disturbance reported "more than two times per week"; and daily use of doctor-prescribed medicine for respiratory symptoms) living in southwest or eastside Detroit	intervention period  Prior Training NR  Type of Service	G2: 6  Other  Caregiver smokers (%) G1: 40 G2: 35
elementary schools  Type of Community Urban neighborhoods with	Exclusion Criteria Children who lived outside of defined geographic area or were monolingual in a language other than Spanish or English were excluded from study.	Type of Educational Materials Used Written materials on on dangers of ETS exposure	Moderate-severe persistent asthma G1: 51 G2: 44
child with asthma  Study Design  RCT	Groups G1: CHW G2: Control	for children with asthma Global Initiative for Asthma booklet	Household income < \$10000 G1: 37 G2: 46
Start Date 2000 Duration 1 year	Interventions G1: Environmental assessment; asthma action plan based on allergy tests; education and social support; social support; mattress covers, pillows, vacuum, cleaning supplies; counseling on environmental tobacco smoke; integrated pest management services; minimum 9 planned home visits over 12 months G2: Asthma information booklet, full	Duration of Interaction with Clients At least 9 visits over 12 months (time per session NR Length of Follow-up 1 year	Role of CHW in Recruiting and Retention No role; CES was assigned cases Recruitment Rates NA Retention Rates G1: 77% G2: 75% (Does not include 30 postrandomization
	intervention after 12 months  Group (N) G1: 150 G2: 148		exclusions)

Results Intervention Effect (OR-  Results  G1: Symptoms occurring less frequently at baseline for all eight symptoms assessed  G2: Symptoms occurring less frequently for 6 of 8  Results  Outcomes  NR  Quality Rating	Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
intervention/OR-control) Vacuum cleaner used: 29.5 (6.90, 126); P < 0.0001  Allergen cover on child's pillow: 19.7 (4.12, 94.2); P = 0.0006  Allergen cover on child's mattress: 9.70 (4.33, 21.7); P < 0.0001  Visible mold growth remo  Measure 3  Caregiver depressive symptoms measured by CES-D  Results  Mean @ Baseline/Endpoint G1: 1.62/1.54 G2: 1.58/1.64 P = 0.0218  Improvements in both instrumental and emotional social support combined and instrumental support alone were not statistically significant (data NR)  Quality of Life:  NR  Persistent cough baseline, post-intervention: G1: 3.81, 3.36 G2: 3.48, 3.44 P = 0.034  Cough w/ exercise baseline, post: G1: 4.27, 3.69 G2: 3.80, 3.66 P = 0.017  Healthcare Utilization: Measure 1 Has any symptom more than 2 days/week and not on a corticosteroid  Results G1 (pre/post) vs. G2 (pre/post) Intervention Effect (95% CI): 60/42 vs. 51/46; 0.56 (0.29, 1.06); P = 0.073  Measure 2 Has any symptom more than 2 days/week and not on any controller  Results G1 (pre/post) vs. G2 (pre/post) Intervention Effect (95% CI: 53/32 vs. 38/37; 0.39 (0.20, 0.73); P = 0.004  Measure 3 Reduction in unscheduled health care utilization for asthma  Results Needed unscheduled medical care G1 (pre/post) vs. G2 (pre/post) Intervention Effect (95% CI): In last 12 months: 65/59 vs. 58/73; 0.40 (0.22, 0.74); P =	and Behavior Quality of Life  Knowledge, Attitude, and Behavior: Measure 1 Behavior to reduce asthma triggers in house  Results Intervention Effect (OR- intervention/OR-control) Vacuum cleaner used: 29.5 (6.90, 126); P < 0.0001 Allergen cover on child's pillow: 19.7 (4.12, 94.2); P = 0.0006 Allergen cover on child's mattress: 9.70 (4.33, 21.7); P < 0.0001 Visible mold growth remo  Measure 3 Caregiver depressive symptoms measured by CES-D  Results Mean @ Baseline/Endpoint G1: 1.62/1.54 G2: 1.58/1.64 P = 0.0218 Improvements in both instrumental and emotional social support combined and instrumental support alone were not statistically significant (data NR)  Quality of Life:	Health Outcomes: Measure 1 Child's average asthma symptom frequency  Results G1: Symptoms occurring less frequently at baseline for all eight symptoms assessed G2: Symptoms occurring less frequently for 6 of 8  Persistent cough baseline, post-intervention: G1: 3.81, 3.36 G2: 3.48, 3.44 P = 0.034  Cough w/ exercise baseline, post: G1: 4.27, 3.69 G2: 3.80, 3.66 P = 0.017  Healthcare Utilization: Measure 1 Has any symptom more than 2 days/week and not on a corticosteroid  Results G1 (pre/post) vs. G2 (pre/post) Intervention Effect (95% CI): 60/42 vs. 51/46; 0.56 (0.29, 1.06); P = 0.073  Measure 2  Has any symptom more than 2 days/week and not on any controller  Results G1 (pre/post) vs. G2 (pre/post) Intervention Effect (95% CI: 53/32 vs. 38/37; 0.39 (0.20, 0.73); P = 0.004  Measure 3  Reduction in unscheduled health care utilization for asthma  Results Needed unscheduled medical care G1 (pre/post) vs. G2 (pre/post) Intervention Effect (95% CI):	Additional Outcomes  Costs (Economics): NR  Explanation of Overall Outcomes NR

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Paskett et al., 2006; Katz et al., 2007	Eligible (N) 1,503 Enrolled (N)	Title of CHW Lay health advisor Paid or Volunteer	Age (mean) 55.1 Sex (% female)
Trial Name ROSE (Robeson County Outreach Screening and Education)	901 Randomized (N) 897 Completers (N) 820	Relationship with Community Ethnicity: 2 native American and 1 African-American	<ul><li>Race (%)</li><li>African-American: 33%</li><li>Native American: 42%</li><li>White: 25%</li></ul>
Objective or Aim To use LHAs to deliver individualized health education to improve rates of mammography screening	Withdrawals or Dropouts (N) 77  Health Condition of Interest Breast cancer screening Inclusion Criteria Women withdrawals	CHW (N) 3 Supervision of CHW LHA supervisor checked in weekly by phone or inperson to discuss cases and problems; periodic attendance of LHA	Other NR Role of CHW in Recruiting and Retention NA Recruitment Rates NA
Geography Robeson County, NC Organization Community health centers - Robeson Health Care	past 12 months  Exclusion Criteria  Mentally or physically unable to participate, unreachable, language/hearing barrier  Groups G1: Control	supervisor during patient visits  Prior Training 1 nurse, 1 social worker, 1 research study interviewer  Type of Service home visits, phone calls	Retention Rates NA
Corporation (federally funded, four centers)  Type of Community County  Study Design RCT  Start Date February 1998  Duration 4 years	Interventions G1: Control sent letter and NCI brochure about need for regular cervical cancer screening 6 months after random assignment, followed by letter and NCI brochure about need for mammography 3 months after follow-up assssment G2: Individualized health education program that was culturally acceptable and tailored to meet needs of each woman, intensive face-to-face interactive educational program administered over a 9- to 12 month period, consisting of 3 in-person visits, with educational materials provided each visit and follow-up phone calls and mailings after  Group (N) G1: 444	Type of Educational Materials Used written, culturally sensitive Duration of Interaction with Clients Two visits, 45-60 minutes, and 30-45 minutes, two intervening telephone calls, and a final visit (duration of final visit NR) over 9 to 12 months Length of Follow-up 14 months	
	G1: 444 G2: 453		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
Measure 1 Composite belief scores (higher is better)	Healthcare Utilization: Measure 1 Cervical cancer screening rates within risk-appropriate	Explanation of Overall Outcomes NR
Results	guidelines	Quality Rating
G1: 6.95 G2: 7.55 ( <i>P</i> = 0.004)	Results Significant differences between baseline and followup	Good
<b>Measure 2</b> Composite knowledge	for both groups, no significant differences between intervention and control groups	
scores Results	Measure 2 Mammogram receipt from medical record data	
Specific scores NR, <i>P</i> value for G1 = 0.002, G1 < 0.001, no statistically significant differences	<b>Results</b> G1: 27.3% G2: 42.5%, RR = 1.56, 95% CI, 1.29 to 1.87, <i>P</i> < .001; significant differences within racial groups as well	
Quality of Life: NR	Measure 3 Intervention cost divided by additional mammograms in LHA group compared with usual care	
	Results \$4,986 per additional mammogram in LHA group	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Pilote et al., 1996	Eligible (N) 297	<b>Title of CHW</b> Peer health adviser	Age (mean) Median
<b>Trial Name</b> NR	Enrolled (N) 244	<b>Paid or Volunteer</b> Paid	G1: 40 G2: 39 G3: 40
Objective or Aim Peer health advisers familiar with homelessness and ways of street could facilitate access to health care for TB in a homeless population.  Geography San Francisco, CA  Organization Homeless population  Type of Community Lack of neighborhood (homeless)  Study Design RCT  Start Date June 1992	Randomized (N) 244  Completers (N) 173  Withdrawals or Dropouts (N) 71  Health Condition of Interest TB  Inclusion Criteria Homeless men and women, PPD positive  Exclusion Criteria recent follow-up  Groups G1: Peer health advisor G2: Monetary incentive G3: Usual care  Interventions G1: Peer health advisor- met with patient and took them to clinic appointment, facilitated paperwork, reviewed physician recommendations	Relationship with Community Also homeless CHW (N) 7 Supervision of CHW NR Prior Training NR Type of Service Took client to clinic and helped with proccess Type of Educational Materials Used None Duration of Interaction with Clients NR - met client and went to clinic within a 3 week period (duration of session NR) Length of Follow-up 3 weeks	G3: 40  Sex (% female) G1: 13 G2:19 G3:16  Race (%) G1: African American: 48 White: 33 Hispanic: 16 G2: African American: 57 White: 27 Hispanic: 11 G3: African American: 54 White: 27 Hispanic: 13  Other  Role of CHW in Recruiting and Retention NR  Recruitment Rates NR  Retention Rates NR
<b>Duration</b> 23 months	G2: Monetary incentive - \$5 at clinic, appointment and bus tokens G3: Usual care - appointment and bus tokens		
	<b>Group (N)</b> G1: 83 G2: 82 G3: 79		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR  Quality of Life:	Healthcare Utilization: Measure 1	Explanation of Overall Outcomes
NR	Adherence to first follow-up appointment % (95% CI) P versus usual care - unclear how obtained	<b>Quality Rating</b> Fair
	<b>Results</b> G1: Peer health advisor 75 (70-80) $P = 0.004$ G2: Monetary incentive 84 (76-92) $P < 0.001$ G3: Usual care 53 (47-59)	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Rask et al., 2001;	Eligible (N) 3050	Title of CHW Outreach worker	<b>Age (mean)</b> 9 months
LeBaron et al., 2004 <sup>63</sup>	Enrolled (N) 3050	Paid or Volunteer NR	Sex (% female) 51
Trial Name NA	Randomized (N) 3050	Relationship with Community	Race (%) 93% minority (black or
Objective or Aim (1) Prospectively measure costs of 3	Completers (N) NR	African American woman raised in inner-city Atlanta	Hispanic) Other
different registry- based interventions implemented in an urban indigent	Withdrawals or Dropouts (N) 304 not exposed to intervention (within intervention arms)	<ul> <li>Bilingual Hispanic worker</li> <li>CHW (N)</li> </ul>	NR Role of CHW in Recruiting and Retention NR
population and (2) evaluate how size of	Health Condition of Interest Pediatric immunizations	Supervision of CHW Doctorate in community	Recruitment Rates
targeted population affects cost estimates	Inclusion Criteria Children aged < 12 months seen in a county public health clinic	psychology and extensive experience in conducting inner-city studies	NR Retention Rates NR
<b>Geography</b> Fulton County, GA	Exclusion Criteria NR	Prior Training College-educated	
Organization MATCH (Metro Atlanta Team for Child Health) immunization registry: community- based partnership between two county health agencies, local nonprofit, federally qualified community health centers  Type of Community See prior  Study Design RCT  Start Date 1996  Duration 22 months (35 mo for follow-up contact; 53 months for electronic acquisition of vaccine information)	Groups G1: AUTODIAL G2: OUTREACH worker G3: combination of 1 and 2 G4: CONTROL  Interventions G1: Autodial -received an automated telephone call or postcard to remind families 7 calendar days before child was due to be immunized. Patient received postcard if no number or nonworking. Delivered recorded message from head medical staff. G2: Outreach - contacted by outreach worker following a standardized protocol initated by a phone call wihtin 1 week. outreach worker made reminder call before appt if time known. if child remained behind next monht, a home visit was attempted monthly until contact was made.  Group (N) G1: 763 G2: 760 G3: 764	Type of Service Phone calls, home visit for appointment reminder, assistance in overcoming barriers to appointment for pediatric immunizations if needed Phone calls, home visits  Type of Educational Materials Used NR  Duration of Interaction with Clients At least one telephone call, followed by repeat calls and home visit if no telephone contact, over 15 months or less (time per interaction NR)  Length of Follow-up 15 months	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 Vaccine Series complete from immunization registry	Costs (Economics): Measure 1 Average monthly costs
Quality of Life: NR	<b>Results</b> No statistical difference between CHW and control groups	to dleiver immunization interventions per child
	Healthcare Utilization: NR	Results G1: \$1.34 G2: \$1.87 G3: \$2.76
		Explanation of Overall Outcomes NR
		Quality Rating Good

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Welsh et al., 2005 <b>Trial Name</b> Tepeyac Project	Eligible (N)  • Latina only analysis: 4,739; <sup>64</sup> • Latina vs. white analysis: 6,696 <sup>65</sup> Enrolled (N)  NA	Title of CHW Promotora (peer counselors)  Paid or Volunteer Paid	Age (mean) Latina only analysis: Not specified; <sup>64</sup> Latina vs. white analysis G1: Latina 59 (SD 4.1); non-Latina 57.5 (4.3) G2: Latina 58 4 (4.4):
Objective or Aim To increase breast cancer screening rates among Latinas in Colorado; 64 To compare effect of promotora vs printed statewide interventions on mammogram rates of Latinas and non-Latina whites (NLWs) enrolled in Medicaid fee-forservice program 65 Geography Colorado Organization Catholic Churches, Latina Women Type of Community Church communities Study Design Retrospective cohort Start Date 2000 Duration 5 yrs	Randomized (N) NA  Completers (N) Latina only analysis: 4739 <sup>64</sup> ; Latina vs. white analysis: 6696 <sup>65</sup> Withdrawals or Dropouts (N) NA  Health Condition of Interest Breast cancer screening Inclusion Criteria Latina only analysis:  Latinas (identified through race and ethnicity data combined with surnames)  Aged 50 to 69 years  Continuously enrolled in insurance plan (Medicaid or Medicare) for longer than 23 months with no gap in coverage longer than 30 days  Survived entire baseline or follow-up period <sup>64</sup> Latina vs. white comparison:  White or Latina women (identified through race and ethnicity data)  Aged 50-64 years  Enrolled in CO Medicaid at least 18 mo during baseline and follow-up periods <sup>65</sup> Exclusion Criteria NR  Groups G1: Promotora Intervention - study	Relationship with Community Shared community and ethnicity CHW (N) NR Supervision of CHW NR Prior Training NR Type of Service Peer "approach" after Sunday mass and during church-related activities; facilitation of home discussion groups Type of Educational Materials Used Letter describing project Bilingual printed materials from NCI that promote breast ca screening and reflect a sense of family Display unit Short bilingual messages suitable for delivery from pulpit and publication in church bulletins Duration of Interaction with Clients At least bimonthly meetings(length NR) over 5	G2: Latina 58.4 (4.4); non-Latina 57.9 (4.5) <sup>65</sup> Sex (% female) 100  Race (%) Latina only analysis: 100% Latina; <sup>64</sup> Latina vs. white analysis G1: 52% Latina, 48% non-Latina white G2: 26% Latina, 74% non-Latina white G3: 40% Latina T4% non-Latina white C5: 40% Latina T4% non-Latina white C6: 40% Latina T4% non-Latina white C7: 40% Latina T4% non-Latina white C7: 40% Latina T4% non-Latina white C8: 40% Latina T4% non-Latina white C9: 40% Latina T4% non-Latina T4% non-Latina T4% non-Latina T4% non-Latina T5% Latina
	subjects living in zip codes of churches visited by promotoras during 2000 and 2001 G2: Printed intervention - Subjects living in remaining zip codes	years  Length of Follow-up  NA	

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: NR Healthcare Utilization:	Costs (Economics): NR
Quality of Life: NR	Measure 1 comparison of mammography rates by intervention and ethnicity, via ICD codes on Medicaid claims (pre/post time-intervention interaction term by GEE)	Explanation of Overall Outcomes CHW intervention in churches resulted in slight improvement in
	<b>Results</b> Latina, G1 vs. G2 adjusted GEE $P = 0.07$ Non-Latina, G1 vs. G2 adjusted GEE $P = 0.10$	mammography rates among Medicaid- eligible Latinas, no
	<b>Measure 2</b> Pre/post mammography rates via ICD codes on Medicaid claims	statistically significant difference in ethnic disparities within promotora group,
	Results Latina only analysis G1: 59 to 61% G2: 58% at baseline and followup, unadjusted rates not significant in either group, GEE model adjusting for insurance group, age, income, rural vs. urban, and disability found increased biennial mammograms in	increased disparities in non promotora group (because non Latina had greater improvement than Latinas) Quality Rating
	Intervention group $(P=0.03)$ ; 64  Latina vs. white analysis G1: Latina 25 $\rightarrow$ 30% (unadjusted GEE $P=0.3$ ); non-Latina 32 $\rightarrow$ 38% (unadjusted GEE $P=0.4$ ) G2: Latina 45 $\rightarrow$ 43% (unadjusted GEE $P=0.27$ ); non-Latina 41 $\rightarrow$ 44% (unadjusted GEE $P=0.02$ ) 65	Fair

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Sauaia et al., 2007; Welsh et al., 2005 (continued)	Interventions G1: Trained peer counselors (Promotoras) delived health promotion message personally, through meetings held at least bimonthly immediately after mass and through other church events, conducted health groups that met at home of one of participants, same newsletter used in printed Intervention G2: Printed intervention incorporated into church display, bulletin and/or pulpit announcements		
	Group (N) Latina only analysis G1: 4 churches, N at baseline: 536, N at followup: 590 G2: 209 churches, N at baseline: 5130, N at followup: 5708; <sup>64</sup>		
	Latina vs. white analysis G1: 4 churches, N at baseline: 197, N at followup: 211 G2: 209 churches, N at baseline		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude,		Costs (Economics)
and Behavior	Health Outcomes	Additional
Quality of Life	Healthcare Utilization	Outcomes

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Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Schuler et al.,	Eligible (N) NR	<b>Title of CHW</b> Lay Visitors	Age (mean) 27 years
2000 Trial Name	Enrolled (N) 192 families	<b>Paid or Volunteer</b> NR	<b>Sex (% female)</b> 100
Objective or Aim Effects of home- based intervention on mother-infant interaction among drug using women and their infants to compare mother-infant interaction among drug-using mothers who did and did not receive home- based intervention	Randomized (N) 192	Relationship with Community Shared ethnicity African American women who "knew community"	Race (%) African American: 96%
	Completers (N) 171		Other NR
	Withdrawals or Dropouts (N) 21 families Not at all clear from article: "study included 171 families (87 control,	CHW (N) 3- 2 for intervention, one for control group	Role of CHW in Recruiting and Retention
	84 intervention). 31 dyads were lost before 2-week baseline visit, and 32 additional families lost after 2-week visit (see Table 1). Thus, 192 (97 control, 95 intervention) families seen for 6-month evaluation visit. Observation data dropped from 13 families because interaction involved caretaker other than	Supervision of CHW Visitors met with a psychologist and a pediatrician weekly to track progress of families and to	NR Recruitment Rates NR
		discuss concerns about families  Prior Training  Past experience making home	Retention Rates NR
<b>Geography</b> Maryland NR	mother, and data from 8 families were lost because of mechanical difficulties"	visits, no additional details provided	
Organization Organizational recruited from large university hospital  Type of Community Drug abuse Inner city, African- American  Study Design RCT  Start Date NR  Duration 6 months	Health Condition of Interest Infant health Maternal drug use; motherchild interaction  Inclusion Criteria Women were eligible if they or their infants had a positive urine toxicology screen at birth or history of recent drug use was noted in medical charts.  Exclusion Criteria Infants who were not discharged into care of their mothers or had serious developmental or congenital problems that required special services (e.g., spina bifida)  Groups G1: CHW G2: Control Interventions G1: Visits to enhance mothers' ability to manage self-identified problems by using existing services and family and social supports; modeling infant development behavior/activities	Type of Service G1: home intervention was developmentally oriented and was based on program used by IHDP- visitors went once a week enhancing mothers' ability to manage self- identified problems by using existing services and family and social supports; modelling infant development behavior/activities G2: brief monthly home tracking visits to reduce attrition  Type of Educational Materials Used HELP at Home: Hawaii Early Learning Profile  Duration of Interaction with Clients G1: 9 visits, about 30 minutes per visit G2: 3 visits, about 17 minutes each	
	G2: Meetings for tracking purposes only  Group (N) G1: 84 G2: 87	<b>Length of Follow-up</b> 6 months	

Evidence Table C-1.	Key Questions 1, 2, and 3 (continued)
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responsiveness.

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 3 Self-reported maternal drug use	Costs (Economics): NR
Quality of Life:	Results	Explanation of Overall Outcomes No direct effects of intervention, in control group, mothers who continued to use drugs
Measure 1 Infant warmth measured by assessment of videotaped mother-infant interaction using previously validated scale	At 6 months, there were no significant group differences in cocaine and/or heroin use, alcohol use, or marijuana use during last 6 months	
	Healthcare Utilization:	were less responsive to their babies than
Results  No difference between groups. In control group, mothers who continued to use drugs were less responsive to their babies		mothers who were drug free. In intervention group, drug use was not associated with maternal responsiveness.
than were mothers who were drug free. In intervention group, drug use was not associated with maternal		<b>Quality Rating</b> Fair

Author Year Schwarz et al., 1993  Trial Name Safe Block Project  Objective or Aim Improve injury prevention knowledge and reduce number of hazards in home and reduce rates of injury occurring to residents of an inner city community.  Eligible (N) 34 203 (17,058 intervention = approx 5,890 homes; 17,145 control)  Enrolled (N) 2722 4476 (3004 received intervention, 1472 control homes randomly selected)  Relationship of Community Shared community	### 5-17 ### 18-6 ###	5 yrs: 9.3%, 7 yrs: 17.6%, 64 yrs: 53.7%, 4 yrs: 19.5% 5 yrs: 9.9%, 7 yrs: 18.9%, 64 yrs: 58.1%, 4 yrs: 13.1%
Trial Name Safe Block Project  Objective or Aim Improve injury prevention knowledge and reduce number of hazards in home and reduce rates of injury occurring to residents of an inner city  Enrolled (N)  2722 4476 (3004 received intervention, 1472 control homes randomly selected)  Relationship of Community Shared community Share	with Sex (%) safety liaisons an Or volunteer ors and 10 ors.  of CHW Sex (%)  Sex (%)  Sex (%)  Sex (%)  Race (%)  G1: Af  Other  Sex (%)  G2: Af	4 yrs: 19.5% 5 yrs: 9.9%, 7 yrs: 18.9%, 64 yrs: 58.1%, 4 yrs: 13.1% 6 female) (%) rican-American: 96.8%,
Geography Philadelphia  28% not inspected in each group (348 intervention, 412 control)  Granization  28% not inspected in each group (348 intervention, 412 control)  From Injury Cor of Philadelphia of Public Health	ntrol Section a Department th.  Other Injuries reside	rican-American: 95.7%, er: 4.3% s in 1987- rate per 1000 nts
Social Home Safety Prior Training NR  Type of Community Neighborhood High injury rate  NR  Type of Servic Consus tracks with highest injury rates in community  NR  Type of Servic Safety inspection modifications, i	ce Role co and Role inspections, Block	5.7 of CHW in Recruiting etention Representatives were
Study Design Prospective case- control observational Quasi- experimental; non-  Study Design Prospective case- control Observational Quasi- experimental; non-  Exclusion Criteria NA inability to contact household residents  Groups  and education; safety devices detectors, ipecate emergency phonumbers, light batteries, bathway thermometer)	(e.g. smoke participate cac, one NR	to urge neighbors to pate in project.  itment Rates  tion Rates
random controlled trial  Interventions  Home modification for simple prevention measures  Home inspection to inform residents about hazards and ways of alleviating them  Type of Educa Materials User NR direct teach safety inspector	ational ed hing from ors	
Education about selected injury prevention practices.      Group (N)     G1: 17 085     G2: 17 145  For postintervention assessments, 1250 of 3004 homes were randomly selected. assessments were conducted in 902 of1250 homes  1 home visit an block meetings month-period (session NR)  Length of Foll  12 months	s over 18 (duration per	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Evidence Tuble 6 1.	y wacstions 1, 2, and 5 (continued)	
Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
Measure 1  No syrup of ipecac for children < 5 yrs	Healthcare Utilization: NR	Explanation of Overall Outcomes Principal positive
Results G1: 29% G2: 90.2% P < 0.001 Adjusted OR, 0.04 95% CI, 0.02-0.07		finding of this study is a distinct difference between control and intervention homes with respect to safety
Measure 2 Inadequate light on stairs		knowledge and home hazards that required minimal to moderate
Results G1: 17.9% G2: 19.9% P = 0.41 Adjusted OR, .41 95% CI, 0.69-1.16		effort to correct. Intervention homes were found to be safer than control homes, particularly with respect
<b>Measure 3</b> Hot water ≥125°F		to hazards related to fires and poisonings.
Results G1: 36.8% G2: 26.8% P < 0.001 Adjusted OR, 1.73 95% CI, 1.39, 2.15		<b>Quality Rating</b> Poor
<b>Measure 1</b> No bedside light for > 64 yrs adults		
Results G1: 13.3% G2: 15.1% P = 0.90 Adjusted OR, 1.03 95% CI, 0.68- 1.57		
Measure 2 No smoke detectors		
Results G1: 4% G2: 23% P < 0.001 Adjusted OR, 0.14 95% CI, 0.09- 0.20		
Quality of Life: NR		

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Silver et al., 1997	Eligible (N) 512	Title of CHW Lay Intervenor	Age (mean) Mother's age
Author Year Silver et al., 1997 Trial Name Parent to Parent Network  Objective or Aim Evaluate psychological outcomes of Parent-To-Parent Network (PTPN), a community-based support program for mothers of five- to eight-year-old children with a variety of ongoing health conditions  Geography NYC - Bronx; or Lower Westchester  Organization Organizational Large urban medical centers; community-based delivery of intervention  Type of Community Mothers that have children with chronic disease	Eligible (N) 512  Enrolled (N) 365 mothers  Randomized (N) 365  Completers (N) 94% completed 12 month interview (343)  Withdrawals or Dropouts (N) 6% LTF  Health Condition of Interest Maternal health Mothers' psychiatric well-being  Inclusion Criteria • Five-to-eight-year-old children who had ongoing health conditions (defined as one that had lasted or was expected to last for at least three months or had required hospitalization for 30 days or more in previous year) • Mother could speak conversational english and live with her child in catchment area • Have easy access to a phone  Exclusion Criteria A family was excluded if child was moderately or severely mentally retarded or had a life expectancy under 18 months.	Title of CHW Lay Intervenor  Paid or Volunteer NR (guessing paid) Paid ("accepted jobs")  Relationship with Community Shared experience Same neighborhoods (recruited via community newspapers); raised children with ongoing healht conditions  CHW (N) 3  Supervision of CHW Supervised by a clinical psychologist and a social worker - frequency NR  Prior Training 40 hours plus intensive training  Type of Service Counselling, face-to-face meetings; telephone calls; group activities with others in program  Type of Educational Materials Used NR  Duration of Interaction	Retention  Age (mean) Mother's age G1: 34.7 G2: 34.0  Children's age G1: 7.2 G2: 7.0  Sex (% female) 100% female (mothers) Children G1: (45%) G2: (47%)  Race (%) Mother's ethnicity % Hispanic G1:43 G2: 46  Black G1: 41 G2:32  White, not Hispanic G1:11 G2: 17  Mixed/Other G1: 5 G2: 6  Other  Asthma 35%, sickle cell anemia, epilepsy, and congenital heart disease (8% each), and cleft lip or palate, cancer, and
Inner-city, low- income, minority  Study Design RCT  Start Date 1990	Groups G1: Experimental G2: Control  Interventions G1: 6 one-hour meetings and 3 group activities 6 face-to-face interventions at home or in	with Clients 6 meetings (1 hour each) with at least biweekly telephone calls + 3 group social activities over 12 months  Length of Follow-up 12 months 6, 12, and 18	endocrine disorders (5% each). Spina bifida and other congenital anomalies each occurred in 2%; 15% had multiple health conditions, mostly asthma G1: 35% fair to poor health; G2: 31%
<b>Duration</b> 1-2 years	hospital + telephone calls + group activities G2: Usual care <b>Group (N)</b> G1: 183 G2: 182	mo	Role of CHW in Recruiting and Retention NR Recruitment Rates NR
			Retention Rates G1: 95% G2: 93%

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1	Costs (Economics): NR
NR Quality of Life:	PSI Results	Explanation of Overall Outcomes
NR	Pre- intervention G1: 24.1 G2: 20.3 ( <i>P</i> < 0.05)	Posttest scores of EG and CG mothers did not differ significantly. Although intervention effects were not related to participation level or illness-related and sociodemographic factors, a significant interaction with stressful life events (SLE) was found.
	Post intervention G1: 22.1 G2: 20.1 (no significant difference between groups)	
	Measure 2 PSI subsets	
	Results All adjusted posttest scores other than Depression were directionally lower in EG than CG	
	Healthcare Utilization:	<b>Quality Rating</b> Fair

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year St. James et al.,	Eligible (N) NR	Title of CHW Resource Mother	Age (mean) Maternal age
1999 Trial Name	Enrolled (N) 83 pregnancies from 69 mothers	<b>Paid or Volunteer</b> Paid	G1: 26.5 G2: 24.1
Resource Mothers Program for Maternal PKU	Randomized (N) NA	Relationship with Community	<b>Sex (% female)</b> 100
Objective or Aim	Completers (N) NA	Resource mothers had children with PKU	Race (%) NR
Increase number of well-treated pregnancies and	Withdrawals or Dropouts (N)	CHW (N) NR	Other Role of CHW in Recruiting
thus reduce number of adverely affected offspring	Health Candition of Interest	Supervision of CHW NR	and Retention
Geography New England	Inclusion Criteria Mothers with PKU	Prior Training Lived with disease	Recruitment Rates NR
Organization Maternal PKU	Exclusion Criteria NA	Type of Service Face-to-face meetings	Retention Rates NR
Collaborative Study enrollees	G1: control (no resource mother) -	Type of Educational Materials Used NR	
Type of Community PKU	women with PKU G2: PKU women with resource mother	Duration of Interaction with Clients	
Study Design Retrospective cohort	Interventions G1: NR G2: resource mothers met with pregnant women for approx 20 sessions of 2 hours each, weekly in beginning and less frequently	≈20 sessions of 2 hours each (weekly in beginning then less frequently) throughout pregnancy	
<b>Start Date</b> NR		Length of Follow-up 12 months after birth	
<b>Duration</b> NR	as pregnancy proceeded. Activities included cooking, shopping, meal planning, preparing for baby, discussing pregnancy, discussing medical recommendations.		
	Group (N) G1: 64 offspring from 55 mothers G2: 19 offspring from 14 mothers		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes	
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1 Birth head-circumference z score	Costs (Economics): NR Explanation of Overall Outcomes NR	
NR Quality of Life: NR	<b>Results</b> G1: -1.4 (95% CI, -1.561.2)		
	G2:-0.56 (95% CI, -0.880.24); <i>P</i> = 0.08 <b>Measure 2</b> Baylely developmental quotient	<b>Quality Rating</b> Fair	
	<b>Results</b> G1: 95 (95% CI, 92-98) G2: 108 (95% CI, 104-112); <i>P</i> < 0.05		
	Measure 3 maternal metabolic control		
	<b>Results</b> G1: 16.1 weeks(95% CI, 14.4-17.8) G2: 8.5 weeks (95% CI, 6.3-10.7); <i>P</i> < 0.05		
	Healthcare Utilization:		

**Duration** 17 months

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Sung et al., 1997; Sung et al., 1992	Eligible (N) NR	Title of CHW Lay health worker	<b>Age (mean)</b> G1: 18-34: 13.5% 35-44: 46%
Trial Name	Enrolled (N) 321	Paid or Volunteer NR	45-59: 22.1% 60-97: 18.4%
National Black Women's Health Project	Randomized (N) 321	Relationship with Community	G2: 18-34: 13.3% 35-44: 44.3% 45-59: 24.7%
Objective or Aim Test effectiveness	Completers (N) 195	Recruited from National Black Women's Health Project	60-97: 17.7%
of in-home, culturally sensitive	Withdrawals or Dropouts (N) 126	CHW (N) NR	<b>Sex (% female)</b> 100
educational program conducted by lay health	Health Condition of Interest breast cancer, cervical cancer	Supervision of CHW NR	Race (%) NR (presumed 100% African American)
workers by measuring improvement in	Inclusion Criteria NR	Prior Training Self-help support group	Other G1:
frequency of breast and cervical cancer		leaders within NBWHP  Type of Service	Income ≤\$15,000: 45.4% Married: 33.7% > HS education: 40.5%
screening  Geography Unclear, possibly	Groups G1: intervention G2: control	Home visits  Type of Educational	Employed: 55.2% G2: Income ≤\$15,000: 48%
Atlanta  Organization Inner city	Interventions G1: CHW home visits, education on breast and cervical cancer, breast	Materials Used Home visits, video of Pap and breast exam, printed materials	Married: 30.4% > HS education: 38.4% Employed: 46.8%
community health center	self-exam, educational materials on screening, facilitation to	on screening, facilitation to with Clients	Role of CHW in Recruiting and Retention NR
Type of Community Inner city African- American	screening G2: mailed educational materials on cancer screening	3 visits (months 1, 2, 4) over four month period, visits 1 and 2 1.5 hours each, time for visit 3 NR	Recruitment Rates 1st attempt: 20% (55/275) 2nd attempt: 44% (266/600)
Study Design RCT	<b>Group (N)</b> G1: 163 G2: 158	Length of Follow-up 11 months	Retention Rates G1: 57% (93/163) G2: 65% (102/158)
Start Date NR			G2. 6576 (102/156)

# Knowledge, Attitude, and Behavior **Quality of Life**

## Knowledge, Attitude, and Behavior:

### Measure 1

Pretest-posttest change in self-report of BSE for entire sample

### Results

G1: 52.1%/51.0%; G2: 41.1%/41.0%, diff in change: -1.0 (95% CI, -6.1-4.1)

### Measure 2

Pretest-posttest change in self-report of BSE, postintervention respondents only

### Results

G1: 57.0%/53.8%; G2: 40.2%/40.2%, diff in change: -3.2 (95% CI, -17.5, 11.1)

### Measure 3

Posttest report of BSE, women not previously on recommended screening schedules, whole sample

### Results

G1: 24.4%; G2: 17.2%, diff in change: 7.2% (95% CI, -5.0-19.3)

### Measure 4

Posttest report of BSE, women not previously on recommended screening schedules, post-intervention respondents only

### Results

G1: 47.5%; G2: 26.2%, diff in change: 21.3% (95% CI, 2.3-40.3)

### **Quality of Life:**

NR

# **Health Outcomes Healthcare Utilization**

# **Health Outcomes:**

### Measure 1

Pre/post change in self-report of receiving screening exams, women not previously on recommended screening schedules, whole sample

No significant difference between groups for any screening modality

### **Healthcare Utilization:**

### Measure 1

Pretest-posttest change in self-report of receiving Pap smears for entire sample

### Results

G1: 50.3%/58.7%; G2: 51.9%/62.1%, diff in change: -1.8 (95% CI, -8.0-4.4)

Pretest-posttest change in self-report of receiving Pap smears, postintervention respondents only

G1: 52.7%/63.4%; G2: 50.0%/62.7%, diff in change: -2.0 (95% CI, -11.0-7.0)

### Measure 3

Posttest rate of self-report of receiving Pap smears, women not previously on recommended screening schedules, whole sample

# **Results**

G1: 33.3% G2: 34.2%

diff in change: -0.9 (95% CI, -15.7-13.9)

### Measure 4

Posttest rate of self-report of receiving Pap smears, women not previously on recommended screening schedules, postintervention respondents only

### Results

G1: 61.4% G2: 51.0%

diff in change: 10.4 (95% CI, -9.5-30.0)

# Costs (Economics) Additional **Outcomes**

# Costs (Economics):

### **Explanation of Overall Outcomes**

CHW intervention effective in increasing receipt of clinical breast exam and mammogram, only when including women already on some recommended screening schedule, and only when nonrespondents are assumed to be similar to respondents. Using intention-to-treat, no differences in any screening modality

# **Quality Rating**

Study	Number (N)		
Characteristics	Inclusion/Exclusion	Community Health	<b>Baseline Characteristics</b>
Setting	Groups	Worker	Recruiting and Retention

Author Year Sung et al., 1997; Sung et al., 1992

Evidence Table C-1.	Key Questions 1, 2, and 3 (continued)	
Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
	<b>Measure 5</b> Pretest-posttest change in self-report of receiving mammography for entire sample	
	Results G1: 35.5%/50.4% G2: 34.3%/39.4% diff in change: 9.8% (95% CI, 2.9-16.7)	
	<b>Measure 6</b> Pretest-posttest change in self-report of receiving mammography, postintervention respondents only	
	Results G1: 32.5%/58.7%; G2: 34.0%/47.9%, diff in change: 12.4% difference (95% CI, 1.0-24.3)	
	<b>Measure 7</b> Posttest rate of self-report of receiving mammography, women not previously on recommended screening schedules, whole sample	
	<b>Results</b> G1: 29.7% G2: 24.4% diff in change: 5.8% (95% CI, -7.0-18.6)	
	Measure 8 Posttest rate of self-report of receiving mammography, women not previously on recommended screening schedules, postintervention respondents only	
	Results G1: 50.0% G2: 35.5% diff in change: 14.5% (95% CI, 4.5-23.6)	
	<b>Measure 9</b> Pretest-posttest change in self-report of receiving CBE for entire sample	
	Results G1: 55.2%/64.5% G2: 55.7%/59.5% diff in change: 4.9 (95% CI, -6.1-4.1)	

**Measure 10**Pretest-posttest change in self-report of receiving CBE, postintervention respondents only

Results

G1: 59.1%/72.0% G2: 57.8%/61.8%

diff in change: 8.9% (95% CI, 1.1-16.7)

Study	Number (N)		
Characteristics	Inclusion/Exclusion	Community Health	Baseline Characteristics
Setting	Groups	Worker	Recruiting and Retention

**Author Year** Sung et al., 1997; Sung et al., 1992<sup>71</sup>

Evidence Table C-1. Key Questions 1, 2, and 3 (continue	Evidence Table C-1.
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Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
	<b>Measure 11</b> Posttest rate of self-report of receiving CBE, women not previously on recommended screening schedules, whole sample	
	Results G1: 37.0% G2: 28.6% diff in change: 8.4% (95% CI, -6.9-23.7)	
	<b>Measure 12</b> Posttest rate of self-report of receiving CBE, women not previously on recommended screening schedules, postintervention respondents only:	
	Results G1: 71.1% G2: 46.5% diff in change: 24.6% (95% CI, 3.9-45.3)	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Taylor et al., 2002 Trial Name	Eligible (N) 2312 (986 Seattle, 1326 Vancouver) (numbers deduced from text)	Title of CHW Outreach worker Paid or Volunteer	<b>Age (mean)</b> 58% 45-69 y/o: G1: 53% G2: 63%
NR Objective or Aim Evaluate impact of 2 culturally and linguistically appropriate	Enrolled (N) 1532 (710 Seattle, 822 Vancouver) Randomized (N) 482 (199 Seattle, 283 Vancouver) Completers (N)	Relationship with Community Shared culture, ethnicity CHW (N)	G3: 58%  Sex (% female) 100  Race (%) Chinese 100%
cervical cancer control educational interventions: a "high intensity" outreach worker-	402 (181 Seattle, 221 Vancouver)  Withdrawals or Dropouts (N) 80 (18 Seattle, 62 Vancouver)  Health Condition of Interest	NR Supervision of CHW NR Prior Training	Other • 12 or more years education: 44% • Married: 81%
based intervention and a "low intensity" direct mail intervention  Geography Seattle and Vancouver BC  Organization Recruited from respondents to community-based	Pap testing  Inclusion Criteria  Chinese women  No history of Pap or intention of Pap within 2 years of survey  20-69 years old  Speak Cantonese, English, or Mandarin  Exclusion Criteria  Hysterectomy  Invasive cervical cancer	NR  Type of Service Trained to act as role models, to provide social support, to serve as cultural mediators between women and health care facilities, to use visual aids and provide tailored responses to each woman's individual barriers to cervical cancer	Role of CHW in Recruiting and Retention NR  Recruitment Rates 66% (proportions not available for each group)  Retention Rates 402/432 = 83% G1: 129/161 = 80% G2: 139/161 = 86%
survey  Type of Community Chinese-American women  Study Design RCT  Start Date 1999  Duration 18 months	Groups G1: CHW G2: direct mail G3: control Interventions G1: Introductory mailing, CHW visit with multimedia and tailored counseling, phone followup and tailored counseling, logistic assistance as needed G2: Direct mail multimedia materials G3: Control: usual care at local clinics and doctors' offices  Group (N) G1: 161 G2: 161 G3: 160	Type of Educational Materials Used Video, motivational pamphlet, educational brochure, fact sheet, tailored counseling  Duration of Interaction with Clients One time visit with follow up telephone call (time per interaction NR)  Length of Follow-up 6 months	G3: 134/160 = 84%

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
Measure 1 Report Pap testing planned within 2 years Results	Healthcare Utilization: Measure 1 Medical records for pap screening received between randomization and followup, using intent-to-treat	Explanation of Overall Outcomes Women who received CHW home visits were
G1: 72% G2: 59% G3: 48% (G1 vs G3 P < 0.001 G2 vs G3: P = 0.05 G1 vs G2 P = 0.03)	<b>Results</b> Results not provided, significant differences between outreach worker versus control ( $P < .001$ ), direct mail versus control ( $P = .07$ ), and outreach worker versus direct mail ( $P = .04$ )	significantly more likely to report having Pap testing after intervention compared to women receiving direct mail or no
Quality of Life:	Measure 2 Medical records for pap screening received in past 2 years, using intent-to-treat	intervention <b>Quality Rating</b> Fair
	Results Results not provided, significant differences between outreach worker versus control ( $P < .001$ ) and direct mail versus control ( $P = .03$ )	T CAIT
	<b>Measure 3</b> Self-reported Pap testing completed since intervention	
	Results G1: 39% G2: 25% G3: 15% (G1 vs G3, P < 0.001 G2 vs G3, P = 0.03 G1 vs G2, P = 0.02)	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Tessaro et al., 1997; Navaie- Waliser et al., 2000 Trial Name Maternal Outreach	Eligible (N) 14,977 Enrolled (N) 705 Randomized (N) NA	Title of CHW Maternal Outreach Worker (MOW) Paid or Volunteer NR Relationship with	Age (mean) < 18 y G1: 31% G2: 15.6% Sex (% female) 100
Worker (MOW) Program  Objective or Aim Reduce infant morbidity and mortality via early	Completers (N) 447 Withdrawals or Dropouts (N) 258 Health Condition of Interest	Community NR CHW (N) NR Supervision of CHW	Race (%) G1:     African-American: 61.8%     Caucasian: 38.2% G2:     African-American, 59.4%     Caucasian (limited to
prenatal care, consistence of care, health behavior and parenting skills, infant preventive	Infant health Inclusion Criteria Medicaid-eligible, < 28 wk EGA, singleton livebirth; Caucasian or African-American (this study)	NR Prior Training NR Type of Service Home visits, assistance in	Caucasian (limited to African-American and Caucasian): 40.6%  Other  Often receive aid from
care and social services, increased pregnancy spacing, decreasing unplanned	Exclusion Criteria Moved away, lost to follow-up, declined services, interview not completed	applying for govt benefits, housing, employment, education; general advocacy for families	friends/family G1: 41.4% G2: 58.1% ( <i>P</i> < 0.001) Reported good health G1: 78.4%
pregnancies; to determine whether particip Geography North Carolina	Groups G1: CHW G2: matched controls Interventions G1: CHW home visits	Type of Educational Materials Used Reinforcing positive health behavior; modeling parent- infant interactions; reinforce need for prenatal care,	G2: 85.5% ( <i>P</i> < 0.05)  Social supportiveness of pregnancy G1: 52.6% G2: 62.9% ( <i>P</i> < 0.05)
Organization Medicaid-eligible population, via social worker or nurse referral	Group (N) G1: 373 (yr 2) > 221 (yr 3) G2: 332 (yr 2) > 198 (yr 3)	immunizations, family planning  Duration of Interaction with Clients One visit/month (more if	Prior physical abuse by partner G1: 14.9% G2: 10% ( <i>P</i> < 0.1)
Type of Community High infant mortality with disproportionately		needed) for approximately 14 months (duration per visit NR) Length of Follow-up	No difference in education, gravidity, smoking  Role of CHW in Recruiting and Retention  Active recruitment of very
higher in African- Americans vs. Caucasians Study Design		1 year	high risk population  Recruitment Rates  NR  Retention Rates
prospective cohort  Start Date 1992  Duration			G1: 249/373 = 67% G2: 198/332 = 60%
3 years			

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Von Korff et al.,	Eligible (N) 364	Title of CHW Lay leaders	<b>Age (mean)</b> G1: 49.4
1998 Trial Name	Enrolled (N) 255	Paid or Volunteer Volunteer	G2: 50.3  Sex (% female)
NR Objective or Aim	Randomized (N) 255	Relationship with Community Shared disease	G1: 68.2 G2: 56.4
Evaluate a4- session self- management group	Completers (N) 0.85	CHW (N)	Race (%) G1: White: 91.4%
intervention for patients with pain in primary care, led	Withdrawals or Dropouts (N) 0.145	Supervision of CHW	Non-white: 8.6% G2: White: 79.7%
by trained lay persons with back	<b>Health Condition of Interest</b> Back pain	Prior Training NR	Non-white: 20.3%  Other
pain. intervention was designed to reduce patient	Inclusion Criteria Patients diagnosed with back pain ages 25-70, at least one prior back	Type of Service classes	Role of CHW in Recruiting and Retention NR
worries, encourage self-care, and reduce activity limitations.	pain visit, interested in learning more about caring for back pain,enrolled for at least a year Group Health Cooperative of Puget Sound	Type of Educational Materials Used Book, pamphlets, videotapes	Recruitment Rates NR Retention Rates
<b>Geography</b> Western Washington State	Exclusion Criteria Surgery or disenrollment from GHC	Duration of Interaction with Clients	NR
Organization HMO	Groups G1: Self management group G2: Usual care	Four 2-hour classes held once a week for 1 month	
Type of Community Condition - back pain	Interventions G1: Four 2-hour classes held once a week, with 10 to 15 participants, led by two trained volunteers.	Length of Follow-up 12 months	
Study Design RCT	G2: Usual care includes back pain book		
Start Date 1996	Group (N) G1: 129 G2: 126		
<b>Duration</b> NR	OZ. 120		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1	Costs (Economics): NR
Measure 1 "Next time I have back or leg pain, I will try to manage	Roland Disability at 12 months - validated  Results G1: 5.75 (6.31)	Explanation of Overall Outcomes NR
problem without seeing a health professional" - Not validated	G2: 6.75 (6.39) P = 0.092	<b>Quality Rating</b> Fair
Results G1: 77% agreed G2: 60%	Measure 2 Worry rating (0-10) at 12 months - not validated	
(P = 0.008)  Quality of Life: NR	Results G1: 2.63 (2.58) G2: 3.83 (3.08) P = 0.013	
	Measure 3 50% or greater reduction in Roland Disability Questionnaire Score from baseline at 6 months - validated	
	<b>Results</b> G1: 47.9% G2: 33% (X2 = 5.2; df = 1; P = 0.02)	
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Characteristics	Inclusion/Exclusion		Recruiting and
			Retention Rates NA

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1	Costs (Economics): NR
Measure 1	Survey - not validated	Explanation of Overall
Survey - not validated	Results	Outcomes
Results	Condom use Intervention vs. comparison [odds ratio	NR
Know where to get free condoms G1: 90 G2: 74 OR	1.37 (95% confidence Interval 1.20, 1.56; <i>P</i> <0.001)].	Quality Rating Fair
95% CI, 3.2 (2.75, 3.73) <i>P</i> = 0.001	Healthcare Utilization:	r dii
Quality of Life: NR		

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Wilson et al., 2008	Eligible (N) 257 salons	Title of CHW Lay health advisor	Age (mean) G1: 38
<b>Trial Name</b> NR	Enrolled (N) Paid or Volunteer NR Volunteer (with \$30	G2: 39 G3+G4: 38	
Objective or Aim Assess effectiveness of breast health promoting	Randomized (N) 40 salons	compensation for training time)	<b>Sex (% female)</b> 100
	Completers (N) 40 salons/1210 respondents	Relationship with Community Hair stylist working in	Race (%) African G1: 91
messages administered by	eages Withdrawals or Dropouts (N) neighborhood/community	G2: 93 Hispanic	
salon stylists to clients in salon setting	Health Condition of Interest breast cancer	CHW (N) 29 Supervision of CHW	G1: 7 G2: 6 Other G1: 2 G2: 1
<b>Geography</b> Brooklyn, NY	Inclusion Criteria Salons providing services in target NYC neighborhoods; clients receiving services at experimental and control salons were eligible to participate	Program staff made frequent visits to salons to support stylists in their promotion of message delivery throughout time during which program was administered.	
<b>Organization</b> Neighborhood hair salons			Other Born in US (%) G1: 56 G2: 52
Type of Community Neighborhoods	Exclusion Criteria Salons were excluded if owner was a member of Health and Beauty	Prior Training NR	Family hx of breast cancer (%)
Study Design Repeated cross- sectional survey of women attending salons randomly assigned to experimental and control groups Start Date 2002 Duration 3 months for each salon	Groups G1: Control salon, at baseline G2: Experimental salon, at baseline G3: Control salon, at followup G4: Experimental salon, at followup Interventions G1: Control, before intervention G2: Stylists group, before intervention G3: Control, after intervention G4: Stylists group, after intervention	Type of Service One-on-one counseling during salon visit to provide education, counseling, and information on location of	G1: 10 G2: 9
			Role of CHW in Recruiting and Retention NA
		Type of Educational Materials Used Written materials (not described)	Recruitment Rates
			Retention Rates NA
		Duration of Interaction with Clients	
	Intervention consisted of education, counseling, and information on location of screening services during salon appointment	One visit - (time of session NR)	
		Length of Follow-up 3 months	
	Group (N) G1: 369 (12 salons) G2: 816 (28 salons) G3+G4: 1210 (N of salons NR, individual N NR)		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
Measure 1 Engaging in BSE in past 3 months	Healthcare Utilization: Measure 1 Clinical breast exam (CBE) in past 3 months	Explanation of Overall Outcomes NR
Results G1: 25% G2: 28%, P = 0.26 for differences between G1 and G2 G3: 37% G4: 40%	Results G1: 27% G2: 27%, P = 0.85 for differences between G1 and G2 G3: 27% G4: 29% AOR 1.2 (95% CI, 0.9-1.7)	Quality Rating Poor
Adjusted OR, for differences between G3: and G4 1.3; Adj 95% CI, 0.9-1.7	Measure 2 Mammogram in past 3 months	
Measure 2 Intention to receive mammogram in next year	Results G1: 13% G2: 14% Adj OR 1.1; Adj 95% CI, 0.8-1.7	
Results G3: 70% G4: 74% Adj OR 1.3; Adj 95% CI, 0.9-1.2		
Quality of Life: NR		

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
		Title of CHW Community worker  Paid or Volunteer Some paid and some volunteer  Relationship with Community NR  CHW (N) NR  Supervision of CHW NR  Prior Training	Retention  Age (mean) 33.6 years  Sex (% female) 41.2  Race (%)  • African-American: 55.3 %  • Aglo-American: 44.7%  Other Role of CHW in Recruiting and Retention NR  Recruitment Rates NR
homeless or at risk of homeless or at risk of homelessness. and costeffectiveness of three approaches to case management for individuals with severe mental illness who were at risk for homelessness  Geography St. Louis, Missouri  Organization Organizational  Type of Community Mental Illness and homelessness  Study Design RCT  Start Date 1990  Duration 18 months	Current homelessness or risk for homelessness; serious DSM-III-R axis I diagnosis; no recent convictions for rape, homicide, or serious assault; and willingness to receive services and participate in a longitudinal study  Exclusion Criteria  See Inclusion criteria  Groups  G1: Assertive community treatment with community workers, G3: Receiving brokered case management (purchase of services).  Interventions  G1: Assertive community treatment responsibility for providing or coordingating all services needed by client, persistent follow-up and in vivo service delivery, performed by staff with backgounds in psychology, social work, and counseling  G2: G1 + Community Health Worker, whose role was to assist with activities of daily living and be available for leisure activities  Group (N)  NR for primary intervention study G1: 28 in assertive community treatment G2: 35 in assertive community treatment with community workers, G3: 22 receiving brokered case management (purchase of services).	NR  Type of Service Included participation in individual and community leisure activities. Some also supplemented work of assertive community treatment staff by assisting clients with activities of daily living, although this usually occurred only on a limited basis.  Type of Educational Materials Used NR  Duration of Interaction with Clients Face-to-face meetings (length of each and number NR) over 18 months  Length of Follow-up 18 months	Retention Rates NR

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 BPRS (Brief Psychiatric Rating Scale score) Total	Costs (Economics): Measure 1 Total costs over 18-
Quality of Life: Measure 1 Client Satisfaction	Symptom Score  Results G1:53.54(15.54)/39.96(12.25)	month study period for average client in each treatment condition
Results	G2: 57.97(20.29)/38.77(12.23)	Results
G1: 3.27(0.42) G2: 3.12(0.57) G3: 2.74(0.68) P < 0.01	G3: 50.6(14/31)/51.6(16.7) $P = 0.001$ Healthcare Utilization:  Measure 1  Program contact (days/mo)	Assertive community treatment only, \$49,510; No significant difference
N of days in stable housing in past month	Results G1:8.29(7.51) G2: 6.95(4.91) G3: 0.3(0.49) <i>P</i> < 0.001	Assertive community treatment with community workers,
Results Basline(SD)/18 months(SD) G1: 6.36(11.71)/21.75(12.76)		\$39,913; brokered case management, \$45,076
G2: 4.94(11.08)/17.54(14.45) G3: 7.18(12.38)/16.00(14.86) (P < 0.31)		Explanation of Overall Outcomes NR
		Quality Rating Poor

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Andersen et al., 2000

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended

Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Care Provider Masked?

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

Retrospective self-report

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Cannot tell

**Conclusions Supported by Results?** 

**Quality Rating** 

Good

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Auslander, et al., 2002; Williams et al., 2001

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

No

**Could Variation from Protocol have Compromised Study** 

Findings?

No

**Outcome Assessors Masked?** 

NR

Care Provider Masked?

Nο

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Retrospective self-report (patient/participant response)

Outcomes Measured in Valid and Reliable

Retrospective self-report (patient/participant response)

Length of Time Following
Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20% After Randomization?

Cannot determine

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

Cannot determine

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Yes

Does Analysis Control for Baseline Differences?

NA

Analysis Conducted on ITT Basis?

No

**Any Post-Randomization Exclusions?** 

Cannot tell

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Barnes et al., 1999

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Not reported

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Prospective documentation

**Outcomes Measured in Valid and Reliable** 

Manner Objective

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes: 24% in G1

Did Attrition Differ by More Than 15

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Yes many as they were randomized before

enrollment

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** Barth, 1991

Hypothesis/Aim/ Objective of Study Described?

YES- kind of

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

No

Allocation of Randomization Adequately Concealed?

Can't tell so No

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended

Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Objective in some

**Outcomes Measured in Valid and Reliable** 

Manner

Objective in some

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

Yes

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Yes at least 3

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Barth et al., 1988

Hypothesis/Aim/ Objective of Study Described?

YES- kind of

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

No

Allocation of Randomization Adequately Concealed?

Can't tell so No

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended

Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Not reported

**Care Provider Masked?** 

**Patient Masked?** 

Not reported

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Objective in some

**Outcomes Measured in Valid and Reliable** 

Manner

Objective in some

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

Yes

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Yes at least 3

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Batts et al., 2001;

Gary et al., 2005; Gary et al., 2003;

Gary et al., 2000;

Vetter et al., 2004

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No (and primary outcome not clearly identified)

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

Yes

**Outcome Assessors Masked?** 

Yes

**Care Provider Masked?** 

**Patient Masked?** 

Nο

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable** 

Manner Objective

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Did Attrition Differ by More Than 15 **Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

No (completers analysis)

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

**Quality Rating** 

Good

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Becker et al., 2005; Cene et al., 2008

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

**Allocation of Randomization Adequately Concealed?** 

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Yes

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

Retrospective self-report (patient/participant

response)

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization? Yes - G1:26% G2:27%

**Did Attrition Differ by More Than 15** 

Percentage Points After Randomization?

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

NA

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

**Quality Rating** 

Key Questions 1, 2, and 3: Quality RCTs (continued) Evidence Table C-2.

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Black et al., 1995; Hutcheson et al., 1997

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

**Allocation of Randomization Adequately Concealed?** 

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Yes

Care Provider Masked?

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

Objective, validated; and retrospective self-report

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Did Attrition Differ by More Than 15

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

Yes, for characteristics in table 1, but trend toward lower baseline receptive language in intervention group at baseline (table 2): no reporting of maternal baseline psychiatric

measures

**Does Analysis Control for Baseline** Differences?

NA

**Analysis Conducted on ITT Basis?** 

**Any Post-Randomization Exclusions?** 

Cannot tell

**Conclusions Supported by Results?** 

Partially (difficult to tell since there is no sample size calculation, no definition of primary outcome, numerous comparisons/outcomes evaluated, no clarity of what represents a clinically important difference for outcomes rather than just a statistically important difference, and there were baseline differences in receptive language

socres...)

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Campbell et al., 2004

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

No

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

Nο

Allocation of Randomization Adequately Concealed?

Nο

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

NA

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Vο

**Could Variation from Protocol have Compromised Study** 

Findings?

No

**Outcome Assessors Masked?** 

Nο

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

**Manner** NR

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Ye

Did Attrition from Any Group Exceed 20%

After Randomization?

Cannot determine

Did Attrition Differ by More Than 15

Percentage Points After Randomization?

Cannot determine

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

poseurcomp

**Does Analysis Control for Baseline** 

Differences?

Yes

**Analysis Conducted on ITT Basis?** 

Nο

Any Post-Randomization Exclusions?

Cannot tell

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Caulfield et al., 1998

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

Nο

Allocation of Randomization Adequately Concealed?

NA

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

Yes

**Outcome Assessors Masked?** 

Nο

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Retrospective self-report (patient/participant

response)

Outcomes Measured in Valid and Reliable

Manner

Retrospective self-report (patient/participant

response)

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization?

56% overall drop out

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

NR

Baseline Characteristics Similar in

**Exposed/Comparison Cohorts?** 

Nο

**Does Analysis Control for Baseline** 

Differences?

Yes (via logistic regression)

**Analysis Conducted on ITT Basis?** 

No

**Any Post-Randomization Exclusions?** 

Yes

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Conway et al., 2004

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

Yes

**Assignment Randomized** 

NR (randomization method NR)

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

Low, broad concepts provided without detailed description of promotoras intervetion techniques

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

NΑ

**Could Variation from Protocol have Compromised Study** 

Findings?

NA

**Outcome Assessors Masked?** 

Yes

**Care Provider Masked?** 

No

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective, not validated

**Outcomes Measured in Valid and Reliable** 

Manner

Objective, validated

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Ye

Did Attrition from Any Group Exceed 20%

After Randomization?

No

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

NR, no table 1, inadequate description of

comparability of groups

**Does Analysis Control for Baseline** 

Differences?

NA

Analysis Conducted on ITT Basis?

No, completers analysis

**Any Post-Randomization Exclusions?** 

Yes

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

Good

Key Questions 1, 2, and 3: Quality RCTs (continued) Evidence Table C-2.

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Corkery et al., 1997

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Not reported

**Care Provider Masked?** 

Not reported

**Patient Masked?** 

Not reported

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Objective (some validated, some not) and

retrospective self-report

**Outcomes Measured in Valid and Reliable** 

Manner

Objective (some validated, some not) and

retrospective self-report

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes - 37%

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

Yes

Baseline Characteristics Similar in **Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

**Any Post-Randomization Exclusions?** 

Cannot tell

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Dean et al., 2000;

Derose et al., 2000;

Derose et al., 2000:

Fox et al., 1998;

Stockdale et al., 2000

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended

Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

Nο

**Outcome Assessors Masked?** 

Nο

**Care Provider Masked?** 

**Patient Masked?** 

Nο

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Prospective documentation

**Outcomes Measured in Valid and Reliable** 

Manner

Retrospective self-report

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes - 73%

Did Attrition Differ by More Than 15 **Percentage Points After Randomization?** 

CD

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

Yes

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Dignan et al., 2005

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

No

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Νo

**Could Variation from Protocol have Compromised Study** 

Findings?

Yes

**Outcome Assessors Masked?** 

Nο

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Prospective documentation

**Outcomes Measured in Valid and Reliable** 

Manner

Retrospective self-report

Length of Time Following Intervention/Exposure Sufficient to Support

Conclusions?

No (outcome asks about past 12 months, followup data obtained within 6 months)

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes - 29%

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

Cannot determine

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Greater number of patients age 65+ in telephone

aroun

Does Analysis Control for Baseline

Differences?

Cannot determine

**Analysis Conducted on ITT Basis?** 

Yes

**Any Post-Randomization Exclusions?** 

Cannot tell

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Duggan et al., 1999; Duggan et al., 2000

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Yes

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Retrospective self-report (patient/participant response)

**Outcomes Measured in Valid and Reliable** 

Retrospective self-report (patient/participant response)

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in **Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

**Any Post-Randomization Exclusions?** 

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Elder et al., 2006; Elder et al., 2005

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary

Outcome(s)?

No

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

Low, many details about tailored print materials not provided (just general topics covered are identified); minimal description of what promotoras acually did

**Usual Clinical Care Described?** 

NΑ

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

No

**Could Variation from Protocol have Compromised Study Findings?** 

Cannot determine, possible there could be contamination if subjects in various groups had interactions w/ each other

**Outcome Assessors Masked?** 

No

Care Provider Masked?

No

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable Manner** 

Retrospective self-report (24-hour dietary recall) for primary outcomes; accuracy of measure is debatable given recall issues, social desirability/those working with promotoras may have greater desire to report lower intake of fat/etc. to please promotoras with which they've established a relationship. Of not, BMI changes from baseline were similar in all groups but decreased least in promotoras group—suggesting that intermediate measures used (dietary intake of fat, etc.) were not in line with BMI changes that would be expected.

Length of Time Following Intervention/Exposure Sufficient to Support Conclusions?

Ye

Did Attrition from Any Group Exceed 20% After Randomization?

No for 12 week outcomes; Yes for 1 year outcomes (G1 22%, G2 24%)

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

No, important differences in perceived barriers to fat, stages of change for fat, ...More participants in tailored condition (than promotoras group) were in earlier stages of change. Also, tailored group had worse overall health (per self-report)

**Does Analysis Control for Baseline Differences?** 

NO

Analysis Conducted on ITT Basis?

No

Any Post-Randomization Exclusions?

No

**Conclusions Supported by Results?** 

**Partially** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Gielen et al., 2002

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

Yes

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Yes

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

CD

**Outcome Assessors Masked?** 

NR

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable** 

Manner

Objective meansure, not validated

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Ye

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes - 27% in standard; 15% in enhanced

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Yes

**Does Analysis Control for Baseline** 

Differences?

Yes

**Analysis Conducted on ITT Basis?** 

CD

Any Post-Randomization Exclusions?

No

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Graham et al., 1992

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

Yes

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Yes

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Yes

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner Objective

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Ye

Did Attrition from Any Group Exceed 20%

After Randomization?

G1: 60% completers; 72% overall received some

visits

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

Yes (control group 100% of sample available)

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Cannot determine

**Does Analysis Control for Baseline** 

Differences?

NA

**Analysis Conducted on ITT Basis?** 

Yes

Any Post-Randomization Exclusions?

Yes (24)

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Hiatt et al., 2008

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

2x2

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended

Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Yes

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner? Retrospective self-report

**Outcomes Measured in Valid and Reliable** 

Manner

Objective, previously validated

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

No

Baseline Characteristics Similar in **Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

Yes - some

Analysis Conducted on ITT Basis?

Any Post-Randomization Exclusions?

Cannot tell

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Hunter et al., 2004

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

No

**Outcome Assessors Masked?** 

NR

**Care Provider Masked?** 

NR

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable** 

Manner Objective

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Ye

Did Attrition from Any Group Exceed 20%

After Randomization?

No

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in

**Exposed/Comparison Cohorts?** 

Yes

**Does Analysis Control for Baseline** 

Differences?

NA

**Analysis Conducted on ITT Basis?** 

Yes

Any Post-Randomization Exclusions?

No

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Jandorf et al., 2005

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

Yes

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Objective

**Outcomes Measured in Valid and Reliable** 

Manner Objective

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Korfmacher et al., 1999;

Olds et al., 2002; Olds et al., 2004

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

Yes

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Yes

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Yes

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Prospective documentation

Prospective documentation

**Outcomes Measured in Valid and Reliable** 

Manner

Objective, some validated; Prospective

documentation

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes - G1 48%, G2 38%

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

Yes - G1 48%, G2 38%, G3 20%

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Yes

**Does Analysis Control for Baseline** 

Differences?

NA

**Analysis Conducted on ITT Basis?** 

Vac

Any Post-Randomization Exclusions?

Yes (G1 = 11, G2 = 12, G3 = 17 in one study); Yes (G1 = 34, G2 = 35, G3 = 34 in another

study)

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Krieger et al., 1999

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

Yes

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Yes

Level of Detail in Describing Intervention/Exposure

High

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

NR

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Prospective documentation

Outcomes Measured in Valid and Reliable Manner

For main outcome (completing follow-up visit): retrospective self-report of patient

For blood pressure: Objective, previously

validated

Length of Time Following Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20% After Randomization?

Yes (30% vs. 22% attrition)

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

Nο

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Yes (by report)

**Does Analysis Control for Baseline** 

Differences?

NA

**Analysis Conducted on ITT Basis?** 

No, completers analysis

**Any Post-Randomization Exclusions?** 

Yes

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Krieger et al., 2002; Krieger et al., 2005

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended

Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

No

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Yes and no

Any Post-Randomization Exclusions?

Yes

**Conclusions Supported by Results?** 

**Quality Rating** 

Good

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Levine et al., 2003

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

Nο

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

High

**Usual Clinical Care Described?** 

NA

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

NΑ

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

NR

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?
Prospective documentation

Prospective documentation

**Outcomes Measured in Valid and Reliable** 

Manner

Objective, validated

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Ye

Did Attrition from Any Group Exceed 20%

After Randomization? Yes - G1 38%, G2 43%

Did Attrition Differ by More Than 15

Percentage Points After Randomization?

No

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Exposed/Comparison Cohorts?

res

**Does Analysis Control for Baseline** 

Differences?

NA

Analysis Conducted on ITT Basis?

Yes

Any Post-Randomization Exclusions?

Yes (G1 = 145, G2 = 173)

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

Author Year Lujanet al., 2007

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

Yes

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

NA

Could Variation from Protocol have Compromised Study Findings?

Yes (but only 1 subject crossed over from control to intervention, so minimal impact on results)

**Outcome Assessors Masked?** 

Yes

Care Provider Masked?

NR

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable** 

Manner Objective

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Ye

Did Attrition from Any Group Exceed 20%

After Randomization?

No

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Cannot determine (for most characteristics because no table 1; most characteristics reported for entire sample rather than for each group; of note, mean Hgb A1c levels were different at

baseline---8.71 vs. 7.71)

Does Analysis Control for Baseline Differences?

CD

**Analysis Conducted on ITT Basis?** 

No

Any Post-Randomization Exclusions?

Yes (1)

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

Good

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** Mock et al., 2007

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

NR (but subjects from same household were kept in same arm)

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

Retrospective self-report

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Did Attrition Differ by More Than 15

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Cannot tell

**Conclusions Supported by Results?** 

**Quality Rating** 

Key Questions 1, 2, and 3: Quality RCTs (continued) Evidence Table C-2.

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Morisky et al., 2002; Ward et al., 2000

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

No

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

NR

**Allocation of Randomization Adequately Concealed?** 

Level of Detail in Describing Intervention/Exposure

High

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

NR

Care Provider Masked?

Patient Masked?

NR

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

Blood pressure measurement technique not

reported

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes (flow diagram/attrition not clearly reported, but Table 2 "BP in control" section indicates that

was quite high)

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

Cannot determine

Baseline Characteristics Similar in

**Exposed/Comparison Cohorts?** 

Cannot determine (they suggest that they are,

but there is no Table 1 and baseline

characteristics are not adequately reported)

**Does Analysis Control for Baseline** Differences?

NA

Analysis Conducted on ITT Basis?

No, completers analysis

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

Partially (no discussion of effect of CHWs)

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Navarro et al., 1998; Navarro et al., 1995; Navarro et al., 2000

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

High

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

**Outcome Assessors Masked?** 

NR

**Care Provider Masked?** 

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner? Retrospective self-report

**Outcomes Measured in Valid and Reliable** 

Manner

Retrospective self-report

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15 Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

Yes

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Cannot tell

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Parker et al., 2008

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

High

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective (some validated, some not) and

retrospective self-report

**Outcomes Measured in Valid and Reliable** 

Manner

Objective (some validated, some not) and

retrospective self-report Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20% After Randomization?

Yes (23% and 25%)

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in

**Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

**Any Post-Randomization Exclusions?** 

Yes (30)

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Paskett et al., 2006; Katz et al., 2007

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

**Allocation of Randomization Adequately Concealed?** 

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

No

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Prospective documentation

**Outcomes Measured in Valid and Reliable** 

Manner Objective

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15 Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Yes: 17 refused

**Conclusions Supported by Results?** 

**Quality Rating** 

Good

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Pilote et al., 1996

**Blinding** 

**Author Year** 

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended

Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15 Percentage Points After Randomization?** 

CD

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Cannot tell

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Rask t al., 2001; LeBaron et al., 2004

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

**Partially** 

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

High

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

CD

**Outcome Assessors Masked?** 

NR

**Care Provider Masked?** 

Patient Masked?

NR

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Prospective documentation

**Outcomes Measured in Valid and Reliable** 

Manner Objective

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

CD

Baseline Characteristics Similar in **Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

CD

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

**Quality Rating** 

Good

Key Questions 1, 2, and 3: Quality RCTs (continued) Evidence Table C-2.

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Schuler et al., 2000

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

No Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

No NR

Allocation of Randomization Adequately Concealed?

No NR

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

No Yes: exclusion of families with a different home visiting component; multivariate analyses

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Yes, but method not described

Care Provider Masked?

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Retrospective self-report (patient/participant

response)

**Outcomes Measured in Valid and Reliable** 

Manner

Some objective; others Retrospective self-report

(patient/participant response)

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization?

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in **Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Kind of Yes

**Any Post-Randomization Exclusions?** 

Yes

**Conclusions Supported by Results?** 

**Partially** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Silver et al., 1997

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

NR

**Allocation of Randomization Adequately Concealed?** 

Yes (randomizer unaware of baseline responses & not involved

with intervention)

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Nο

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Yes, but method not described Not reported

**Care Provider Masked?** 

No

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Retrospective self-report (patient/participant

response)

Outcomes Measured in Valid and Reliable

Manner Objective

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization?

No

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

Νo

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

No: experimental group had significantly higher

baseline PSI score

Does Analysis Control for Baseline Differences?

NA Yes

**Analysis Conducted on ITT Basis?** 

Yes

**Any Post-Randomization Exclusions?** 

Cannot tell Yes (22)

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Sung et al., 1997; Sung et al., 1992

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

No

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

na

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

No

Care Provider Masked?

No

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

Retrospective self-report

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization? Yes (G1 43%, G2 35%)

Did Attrition Differ by More Than 15

Percentage Points After Randomization?

No

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Voc

res

**Does Analysis Control for Baseline** 

Differences?

NA

**Analysis Conducted on ITT Basis?** 

Yes

Any Post-Randomization Exclusions?

No

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Taylor et al., 2002

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

High

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

**Outcome Assessors Masked?** 

Care Provider Masked?

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner? Retrospective self-report

**Outcomes Measured in Valid and Reliable** 

Manner

Objective, previously validated

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15 Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Cannot tell

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Von Korff et al., 1998

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended

Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Yes, but method not described

Care Provider Masked?

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner Objective

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Wolff et al., 1997 Morse et al., 1997

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

No

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

Yes

**Outcome Assessors Masked?** 

NR

Care Provider Masked?

Nο

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Retrospective self-report (patient/participant response)

Outcomes Measured in Valid and Reliable

Manner

Retrospective self-report (patient/participant response)

гоороноо

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20% After Randomization?

Yes 85/165

Did Attrition Differ by More Than 15
Percentage Points After Randomization?

Yes - 30+%

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Cannot determine

Does Analysis Control for Baseline Differences?

Cannot determine

**Analysis Conducted on ITT Basis?** 

No

**Any Post-Randomization Exclusions?** 

Cannot tell

**Conclusions Supported by Results?** 

No

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination Blinding

**Soundness of Information** 

Follow-Up

**Analysis Comparability/Outcome** 

**Author Year** 

Barnes-Boyd et al., 2001

Hypothesis/Aim/ Objective of Study Described?

No

**Criteria Clearly Stated?** 

No

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

No

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

No

Could Variation from Protocol have Compromised Study Findings?

Cannot determine

Outcome Assessors Blinded to Intervention/Exposure Status of Participants?

No

Interventions/Exposures Measured in Valid and Reliable Manner?

Prospective documentation

Outcomes Measured in Valid and Reliable Manner? NR

Same Length of Follow-up or Adjustment for Different Length of Follow-up?

Cannot determine

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Yes

Did Attrition for Any Group Exceed 20% After Allocation of Treatment?

Yes (14% at 2 months and 44% at 11 months for REACH-Futures and 25% and 42% for REACH, respectively)

Did Attrition Differ by More Than 15 Percentage Points After Allocation of Treatment?

Nο

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

No

**Does Analysis Control for Baseline Differences?** 

No

Confounding and Modifying Variables Accounted for?

No (no assessment of secular trend; this is a historical comparison)

**Analysis Conducted on ITT Basis?** 

Yes

Impact of Loss to Follow-up (or Differential Loss to Follow-up) Assessed?

Cannot determine

Statistical Methods Used to Assess Primary Outcomes Appropriate to Data?

Yes

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

No (no RR reported)

Does Study Report Appropriate Estimates of Random Variability in Data for Main Outcomes?

No

**Conclusions Supported by Results?** 

Nο

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination **Blinding** 

**Soundness of Information** 

Follow-Up

**Author Year** 

Beckham et al., 2008

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

NA

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** 

Study Findings?

**Outcome Assessors Blinded to Intervention/Exposure Status of Participants?** 

No

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective (clinical reports, lab findings, previously validated measures)

**Outcomes Measured in Valid and Reliable Manner?** 

Objective (clinical reports, lab findings, previously validated measures)

**Analysis Comparability/Outcome** 

Same Length of Follow-up or Adjustment for

Different Length of Follow-up?

No

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

Did Attrition Differ by More Than 15 Percentage

**Points After Allocation of Treatment?** 

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

Yes

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for?

No

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

NA

**Statistical Methods Used to Assess Primary** 

Outcomes Appropriate to Data?

Partially

For Cohort Studies Only, If Outcome has Greater

than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

Does Study Report Appropriate Estimates of Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Soundness of Information** 

Follow-Up

**Analysis Comparability/Outcome** 

**Author Year** 

Bone et al., 1989

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

Nο

Level of Detail in Describing Intervention/Exposure? Medium (odd that it is described in results rather than

methods section)

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

NA

**Could Variation from Protocol have Compromised** Study Findings?

**Outcome Assessors Blinded to Intervention/Exposure Status of Participants?** 

Interventions/Exposures Measured in Valid and **Reliable Manner?** 

prospective documentation

**Outcomes Measured in Valid and Reliable Manner?** 

Prospective documentation (return to ED for follow up visit)

Same Length of Follow-up or Adjustment for Different Length of Follow-up?

CD

Is Length of Time Following Intervention/Exposure **Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After Allocation of Treatment?

Did Attrition Differ by More Than 15 Percentage **Points After Allocation of Treatment?** 

Cannot determine (this is really just one prospective cohort, they did not a priori define analysis plan and only in results define those that CHWs were unable to reach as comparison group)

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

No or cannot determine, not reported

**Does Analysis Control for Baseline Differences?** 

Cannot determine, no description of analysis

**Confounding and Modifying Variables Accounted** for?

CD

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to Follow-up) Assessed?

Statistical Methods Used to Assess Primary **Outcomes Appropriate to Data?** 

NA, methods not reported

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

**Does Study Report Appropriate Estimates of** Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding Soundness of Information**  Follow-Up

**Analysis Comparability/Outcome** 

Different Length of Follow-up?

**Author Year** 

Caulfield et al., 1998

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** 

Study Findings?

**Outcome Assessors Blinded to Intervention/Exposure Status of Participants?** 

No

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable Manner?** 

Retrospective self-report (patient/participant response)

Same Length of Follow-up or Adjustment for

No

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

Yes

Did Attrition Differ by More Than 15 Percentage **Points After Allocation of Treatment?** 

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

No

Does Analysis Control for Baseline Differences?

**Confounding and Modifying Variables Accounted** 

for?

Yes

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

Yes a bit

**Statistical Methods Used to Assess Primary** 

**Outcomes Appropriate to Data?** 

Partially

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

Does Study Report Appropriate Estimates of Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination **Blinding** 

**Soundness of Information** 

Follow-Up

**Analysis Comparability/Outcome** 

**Author Year** 

Earp et al., 2002

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

Partially

Level of Detail in Describing Intervention/Exposure?

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** 

Study Findings?

**Outcome Assessors Blinded to Intervention/Exposure** 

**Status of Participants?** 

Interventions/Exposures Measured in Valid and

Reliable Manner?

**Outcomes Measured in Valid and Reliable Manner?** 

Retrospective self-report

Same Length of Follow-up or Adjustment for

Different Length of Follow-up?

Yes

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

Did Attrition Differ by More Than 15 Percentage

**Points After Allocation of Treatment?** 

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

No (for income, lack of medical visits, perceived barriers to screening, knowledge about breast cancer)

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for? Yes

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

Statistical Methods Used to Assess Primary

Outcomes Appropriate to Data?

Partially

For Cohort Studies Only, If Outcome has Greater

than 10% Prevalence, is Risk Ratio and Relative

Risk Calculated Directly?

**Does Study Report Appropriate Estimates of** 

Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding Soundness of Information**  Follow-Up

No

**Analysis Comparability/Outcome** 

**Sufficient to Support Conclusions?** 

**Points After Allocation of Treatment?** 

**Baseline Characteristics Similar in** 

**Analysis Conducted on ITT Basis?** 

**Exposed/Comparison Cohorts?** 

Different Length of Follow-up?

Allocation of Treatment?

Same Length of Follow-up or Adjustment for

Did Attrition for Any Group Exceed 20% After

Did Attrition Differ by More Than 15 Percentage

Does Analysis Control for Baseline Differences?

**Confounding and Modifying Variables Accounted** 

Is Length of Time Following Intervention/Exposure

**Author Year** 

Erwin et al., 1997

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

No

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** Study Findings?

Cannot determine

**Outcome Assessors Blinded to Intervention/Exposure Status of Participants?** 

No

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable Manner?** Retrospective self-report (patient/participant response)

Impact of Loss to Follow-up (or Differential Loss to Follow-up) Assessed?

No

No

for?

Partially

**Statistical Methods Used to Assess Primary Outcomes Appropriate to Data?** 

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative **Risk Calculated Directly?** 

NA

**Does Study Report Appropriate Estimates of** Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Soundness of Information** 

Follow-Up

**Analysis Comparability/Outcome** 

Different Length of Follow-up?

**Author Year** 

Forst et al., 2004

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** 

Study Findings?

No (authors do not describe any variation, or lack of variation, from protocol; however, there is fair potential for

contamination)

Outcome Assessors Blinded to Intervention/Exposure **Status of Participants?** 

No

Interventions/Exposures Measured in Valid and **Reliable Manner?** 

Objective, not validated

**Outcomes Measured in Valid and Reliable Manner?** 

Retrospective self-report

Same Length of Follow-up or Adjustment for

Yes

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After Allocation of Treatment?

Yes - about 30% overall (note: 83 subjects were excluded at end b/c one CHW admitted to completing questionnaires herself)

Did Attrition Differ by More Than 15 Percentage Points After Allocation of Treatment?

Cannot determine

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

Cannot determine

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for?

No

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

No

Statistical Methods Used to Assess Primary

**Outcomes Appropriate to Data?** 

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

Does Study Report Appropriate Estimates of Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination **Blinding** 

**Soundness of Information** 

Follow-Up

**Analysis Comparability/Outcome** 

**Author Year** 

Frate et al., 1985

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

No

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** 

Study Findings?

**Outcome Assessors Blinded to Intervention/Exposure** 

**Status of Participants?** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective

**Outcomes Measured in Valid and Reliable Manner?** 

Objective

Same Length of Follow-up or Adjustment for

Different Length of Follow-up?

NA

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After Allocation of Treatment?

Cannot determine

Did Attrition Differ by More Than 15 Percentage **Points After Allocation of Treatment?** 

Cannot determine

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

Cannot determine

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for?

No

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

No

**Statistical Methods Used to Assess Primary** 

**Outcomes Appropriate to Data?** 

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

**Does Study Report Appropriate Estimates of** Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

**Quality Rating** 

Extra Poor

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding Soundness of Information**  Follow-Up

**Analysis Comparability/Outcome** 

**Author Year** 

Nacion et al., 2000

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** 

Study Findings?

Outcome Assessors Blinded to Intervention/Exposure **Status of Participants?** 

No

Interventions/Exposures Measured in Valid and Reliable Manner?

Prospective documentation

**Outcomes Measured in Valid and Reliable Manner?** NR

Same Length of Follow-up or Adjustment for Different Length of Follow-up?

NA

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After Allocation of Treatment?

Did Attrition Differ by More Than 15 Percentage **Points After Allocation of Treatment?** 

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

No

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for?

Cannot determine

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

NA

**Statistical Methods Used to Assess Primary** 

**Outcomes Appropriate to Data?** 

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

Does Study Report Appropriate Estimates of Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

**Quality Rating** 

Fair

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

**Author Year** 

Sauaia et al., 2007; Welsh et al., 2005

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

No

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

No

**Could Variation from Protocol have Compromised** 

Study Findings?

NΑ

Outcome Assessors Blinded to Intervention/Exposure Status of Participants?

No

Interventions/Exposures Measured in Valid and Reliable Manner?

Prospective documentation

Outcomes Measured in Valid and Reliable Manner?

objective measure

Same Length of Follow-up or Adjustment for

Different Length of Follow-up?

NA

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Yes

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

NA

Did Attrition Differ by More Than 15 Percentage

Points After Allocation of Treatment?

NA

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

CD

**Does Analysis Control for Baseline Differences?** 

NA

**Confounding and Modifying Variables Accounted** 

for?

Partially

Analysis Conducted on ITT Basis?

Yes

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

NΑ

Statistical Methods Used to Assess Primary

**Outcomes Appropriate to Data?** 

Yes

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

Risk Calculated Directly?

NA

Does Study Report Appropriate Estimates of

Random Variability in Data for Main Outcomes?

Nο

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

Fair

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination **Blinding** 

**Soundness of Information** 

Follow-Up

**Analysis Comparability/Outcome** 

**Author Year** 

Schwarz et al., 1993

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Not really

**Could Variation from Protocol have Compromised** 

Study Findings?

Outcome Assessors Blinded to Intervention/Exposure Status of Participants?

No: "health department personnel were not blinded to intervention or control status of each household"

Interventions/Exposures Measured in Valid and **Reliable Manner?** 

Objective measure, not validated

**Outcomes Measured in Valid and Reliable Manner?** 

Objective measure, not validated

Same Length of Follow-up or Adjustment for Different Length of Follow-up?

NA

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

Did Attrition Differ by More Than 15 Percentage

Points After Allocation of Treatment?

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

No

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for?

No

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

No

**Statistical Methods Used to Assess Primary** 

**Outcomes Appropriate to Data?** 

Partially

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

Does Study Report Appropriate Estimates of Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

Poor

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding Soundness of Information** 

**Analysis Comparability/Outcome** 

**Author Year** 

St. James et al., 1999

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** 

Study Findings?

**Outcome Assessors Blinded to Intervention/Exposure Status of Participants?** 

Yes

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable Manner?** Objective

Follow-Up

Same Length of Follow-up or Adjustment for

Different Length of Follow-up?

NA

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

Did Attrition Differ by More Than 15 Percentage

**Points After Allocation of Treatment?** 

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

CD

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for?

CD

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

NA

**Statistical Methods Used to Assess Primary** 

**Outcomes Appropriate to Data?** 

For Cohort Studies Only, If Outcome has Greater

than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

No

**Does Study Report Appropriate Estimates of** Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

**Quality Rating** 

Fair

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination **Blinding** 

**Soundness of Information Analysis Comparability/Outcome** 

**Author Year** 

Tessaro et al., 1997; Navaie-Waliser, et al., 2000

Hypothesis/Aim/ Objective of Study

Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for **Determining Adequacy of Study Group Sizes** 

for Primary Outcome(s)?

Level of Detail in Describing Intervention/Exposure?

Low

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might

**Bias Results?** 

Yes

**Could Variation from Protocol have Compromised Study Findings?** 

Cannot determine

**Outcome Assessors Blinded to** Intervention/Exposure Status of

Participants?

Interventions/Exposures Measured in Valid and Reliable Manner?

**Outcomes Measured in Valid and Reliable** Manner?

Combination of validated scales/questionnaires and responses to interview questions

Follow-Up

Same Length of Follow-up or Adjustment for Different Length of Follow-up?

Yes

Is Length of Time Following Intervention/Exposure Sufficient

to Support Conclusions?

Did Attrition for Any Group Exceed 20% After Allocation of Treatment?

Yes - G1 34%; G2 40%

Did Attrition Differ by More Than 15 Percentage Points After

Allocation of Treatment?

**Baseline Characteristics Similar in Exposed/Comparison** 

No, differences in age, race, marital status, education, annual family income. (Baseline data for a number of other important

factors NR) **Does Analysis Control for Baseline Differences?** 

Confounding and Modifying Variables Accounted for?

Partially

Cohorts?

Analysis Conducted on ITT Basis?

Impact of Loss to Follow-up (or Differential Loss to Follow-

up) Assessed?

No

Statistical Methods Used to Assess Primary Outcomes Appropriate to Data?

Partially (a great number of analyses conducted w/ multiple comparisons and several regressions; no description of primary outcomes; no sample size calculations; no adjustment for multiple comparisons; potential data mining)

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative Risk Calculated Directly?

No

**Does Study Report Appropriate Estimates of Random** 

Variability in Data for Main Outcomes?

Yes

**Conclusions Supported by Results?** 

No (conclusions do not reflect potential biases in results)

Quality Rating

Poor

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Soundness of Information** 

Follow-Up

**Analysis Comparability/Outcome** 

**Author Year** 

Wendell et al., 2003

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

NA

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** Study Findings?

Cannot determine

**Outcome Assessors Blinded to Intervention/Exposure Status of Participants?** 

No

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable Manner?** 

Objective measure, not validated

Same Length of Follow-up or Adjustment for Different Length of Follow-up?

NA

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

Did Attrition Differ by More Than 15 Percentage **Points After Allocation of Treatment?** 

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

Yes

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for?

Yes

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

NA

**Statistical Methods Used to Assess Primary** 

**Outcomes Appropriate to Data?** 

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

**Does Study Report Appropriate Estimates of** Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

**Quality Rating** 

Fair

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

**Author Year** 

Wilson et al., 2008

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

No

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary

Outcome(s)?

Yes

Level of Detail in Describing Intervention/Exposure?

Low

Is Usual Clinical Care Described?

NA

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

No

**Could Variation from Protocol have Compromised** 

Study Findings?

NΑ

Outcome Assessors Blinded to Intervention/Exposure Status of Participants?

Nο

Interventions/Exposures Measured in Valid and Reliable Manner?

NR

Outcomes Measured in Valid and Reliable Manner?

retrospective self-report

Same Length of Follow-up or Adjustment for Different Length of Follow-up?

NA

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

NΑ

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

NA

Did Attrition Differ by More Than 15 Percentage

**Points After Allocation of Treatment?** 

NA

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

NR

Does Analysis Control for Baseline Differences?

NΑ

**Confounding and Modifying Variables Accounted** 

for?

No

Analysis Conducted on ITT Basis?

NΑ

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

NA

**Statistical Methods Used to Assess Primary** 

**Outcomes Appropriate to Data?** 

Partially

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

Does Study Report Appropriate Estimates of Random Variability in Data for Main Outcomes?

Yes

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

Poor

# Evidence Table C-4. Key Questions 4 and 4a

Study Characteristics Setting	Community Health Worker
Author Year Balcazar et al., 2006	Title of CHW Promotora
<b>Trial Name</b> Salud Para Su Corazon-NCLR	Relationship with Community NR
Objective or Aim To promote heart-healthy behaviors	<b>CHW (N)</b> 29
among Latinos	Supervision of CHW
Geography Escondido CA, Chicago IL, Ojo Caliente	NR
NM	Prior Training NR
Organization Latino communities	Type of Service Education sessions
Type of Community Latino communities	Type of Educational Materials Used Handouts, recipes, videos, actor scripts, games
Start Date 2000	Duration of Interaction with Clients 7 2-hour sessions over 6 months
Health Condition of Interest Cardiovascular disease	Length of Follow-up 1 year

### **Eligibility for CHW Training**

NR

### Input of CHW in Curriculum Development

None

### **Training on Cultural Competency**

NR (curriculum does offer "cultural and language appropriate instructional methods" but details NR)

### **Training on Recruitment/Retention Process**

NR

### Training on Intake/Assessment

NR

### **Training on Protocol Delivery**

NR

### **Training on Health Topic**

NK

### **Training on Evaluation**

NR

## **Other Training**

NR

### Other Training Content; Instructional Method; Number of Sessions; Testing

NR

### Name of Curriculum

Your Heart, Your life

## **Availability of Curriculum**

Available online

### **Evaluation and Testing Results of Curriculum**

closed-format pre-post test scores reported a score of 74% for pretest and 100% correct for posttest (n = 11). Differences in pre-post promotora knowledge scores changes (N = 29) were statistically (P < 0.05) but data reported in bar graph only.

### Certification

NR

### **Other Pertinent Information**

NΑ

### Are Particular Training Characteristics Associate with Improved Outcomes?

**Health Condition of Interest** 

Cancer prevention

Study Characteristics Setting	Community Health Worker
Author Year Beck et al., 2007	Title of CHW Church Health Action Team (CHAT) member
Trial Name Center for Health Communities' cancer	Relationship with Community Respected member of church congregation
education program  Objective or Aim	CHW (N) 6 (2 from each of 3 participating churches)
Train trainer in cancer education  Geography	Supervision of CHW NR
Milwaukee County	Prior Training NR
Organization African- American churches	Type of Service
Type of Community African- American churches	Small group educational presentations
Start Date	Type of Educational Materials Used PowerPoint slides, handouts, brochures
2002	Duration of Interaction with Clients

4 60-minute presentations

Length of Follow-up NR

## **Eligibility for CHW Training**

Member of congregation, well-respected, formal or informal leader, expressed enthusiasm for project

### Input of CHW in Curriculum Development

None

### **Training on Cultural Competency**

NR

### **Training on Recruitment/Retention Process**

NR

### Training on Intake/Assessment

NR

### **Training on Protocol Delivery**

NR

### **Training on Health Topic**

NR

### **Training on Evaluation**

NR

### **Other Training**

2 90-minute train-the-trainer workshops

### Other Training Content; Instructional Method; Number of Sessions; Testing

NR

### Name of Curriculum

NR

### **Availability of Curriculum**

NR

### **Evaluation and Testing Results of Curriculum**

Pre-post % correct

Ability to define cancer:

(1)General 89/93 (2)Breast 79/86

(3)Colon 15/57 (4)Prostate 80/75

Ability to identify signs/symptoms of cancer:

(1) NA/NA (2) 71/88

(3) 81/93 (4) 40/75

Ability to identify screening recommendations:

(1) NA/NA (2) 67/67

(3) NA/NA (4) 80/75

Ability to identify risk factors:

(1) 59/85 (2) 54/92

(3) 19/89 (4) 40/75

Ability to identify strategies to reduce cancer risk:

(1) 70/78 (2) 8/33

(3) 92/96 (4) 20/75

### Certification

"Certificate of completion" at 2nd training session

### **Other Pertinent Information**

Results reported for 1 church only; CHWs presented 3 of modules while pastor presented 4th

## Are Particular Training Characteristics Associate with Improved Outcomes?

Study	Chara	cteristics	
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Setting

**Community Health Worker** 

Author Year Bell, et al., 1999

Trial Name
Abuela Project

Objective or Aim

To train Hispanic women to make queso fresco that was authentic in taste and texture but did not use raw milk in an effort to reduce incidence of Salmonella serotype Typhimurium infections resulting from eating queso fresco made from raw milk.

Geography

Yakima County, Washington

Organization

Hispanic communities

**Type of Community** 

Hispanics

Start Date 1997

**Health Condition of Interest** 

Salmonella

**Title of CHW**Abuela educators

**Relationship with Community** 

Shared ethnicity

CHW (N)

15

Supervision of CHW

NR

**Prior Training** 

NR

Type of Service

Workshop, After training, each CHW singed contract indicating willingness to teach at least 15 members of community

Type of Educational Materials Used

Pamphlet,

**Duration of Interaction with Clients** 

1 workshop

Length of Follow-up

## **Eligibility for CHW Training**

Older Hispanic women from Yakima County

### Input of CHW in Curriculum Development

None; however, curriculum was developed with input from respected Hispanic woman from Yakima community

### **Training on Cultural Competency**

NR

### **Training on Recruitment/Retention Process**

NR

### Training on Intake/Assessment

NR

### **Training on Protocol Delivery**

NR

### **Training on Health Topic**

NR

### **Training on Evaluation**

NR

### **Other Training**

Workshops on how to make new queso fresco recipe (i.e., w/o raw milk)

### Other Training Content; Instructional Method; Number of Sessions; Testing

Training sessions were hands-on and interactive; participants encouraged to ask questions & make comments

### Other Training Content; Instructional Method; Number of Sessions; Testing

NR

### Name of Curriculum

Abuela Project

## **Availability of Curriculum**

Pamphlet available

### **Evaluation and Testing Results of Curriculum**

Pretraining/ post-training: recognized health risks associated with eating unpasteurized milk and cheese: 10/14; 14/15

Make gueso fresco with fresh unpasteurized milk: 6/12; 1/15.

### Certification

Nο

### **Other Pertinent Information**

NA

### Are Particular Training Characteristics Associate with Improved Outcomes?

Cardiovascular disease

Evidence Table C-4. Key Questions 4 and 4a (continued)		
Study Characteristics Setting	Community Health Worker	
Author Year Kuhajda et al., 2006	Title of CHW Counseling CHW; Assessment CHW	
<b>Trial Name</b> Pine Apple Heart Disease and Stroke Project	Relationship with Community African American women with experience as community health volunteers in county	
Objective or Aim To train CHWs for heart disease and	CHW (N) 4	
stroke and in skills for counseling and assessing high-risk women in Pine Apple clinic.	Supervision of CHW NR	
<b>Geography</b> Pine Apple, Alabama	<b>Prior Training</b> Trained as community health advisors through U of Alabama-Birmingham; all had 10 yrs experience as community health volunteers	
Organization African American women in rural southern community	Type of Service Counseling CHWs counseled clinic patients using project manual; Assessment CHWs assessed future patients before and after	
Type of Community	counseling sessions	
African American women in rural southern community	Type of Educational Materials Used NR	
Start Date NR	Duration of Interaction with Clients NR	
Health Condition of Interest	Length of Follow-up	

Length of Follow-up NR

### **Eligibility for CHW Training**

Chosen from a pool of CHWs trained as community health advisers through U of Alabama; expert advisory panel member assisted in selection

### Input of CHW in Curriculum Development

CHWs shared ideas and concerns about training content and implementation of training sessions at a preliminary planning meeting

### **Training on Cultural Competency**

NR

### **Training on Recruitment/Retention Process**

NR

### Training on Intake/Assessment

NR

### **Training on Protocol Delivery**

Health education counseling; role-played cancer screening counseling sessions and CVD counseling sessions

### **Training on Health Topic**

NR

### Training on Evaluation

Topics addressed in training included CVD; Developing action plans (heart attack, congestive heart failure, stroke); High blood pressure; tobacco control; Cancer (lung, colorectal, breast, cervical)

### Other Training

NR

### Name of Curriculum

Training used revised Women's Wellness Sourcebook Module III: Heart and Stroke

### **Availability of Curriculum**

Yes--revised manuals on cancer & stroke served as guide for training

### **Evaluation and Testing Results of Curriculum**

Counseling CHWs' responses on pre-post training questionnaires showed increases in knowledge and self-reported behaviors in each of following areas: heart disease and stroke prevention strategies, cancer prevention strategies, heart attack or stroke signs and symptoms, cancer signs and symptoms, current heart disease and stroke prevention activities, current cancer prevention activities. Data reported in bar graph only.

### Certification

NR

### **Other Pertinent Information**

4 week training period; counseling CHWs required to be present for entire 4-wk period (except 2 half days devoted to training assessment CHWs). A variety of media and text materials usd to simulate active participation

### Are Particular Training Characteristics Associate with Improved Outcomes?

Study Characteristics Setting	Community Health Worker
Author Year Martinez-Bristow et al., 2006	Title of CHW Promotores
<b>Trial Name</b> Tobacco Free El Paso	Relationship with Community Spanish speaking members of community
Objective or Aim To train Spanish speaking counselors to deliver tobacco cessation interventions.	CHW (N) NR (89 participants in total, but 5% were healthcare professionals; baseline data collected for 74)
<b>Geography</b> El Paso	Supervision of CHW NR
Organization Neighborhood clinics	<b>Prior Training</b> NR
Type of Community Spanish-speaking populations	Type of Service Counseling
Start Date 2003	Type of Educational Materials Used NR
Health Condition of Interest Tobacco cessation	<b>Duration of Interaction with Clients</b> NR
	Length of Follow-up NR

### **Eligibility for CHW Training**

NR (training was open to employees of certain clinics, healthcare professionals as well as promotores)

### Input of CHW in Curriculum Development

Curriculum taken from University of Arizona's Healthcare Partnership which was developed in 1996

### **Training on Cultural Competency**

NR

### **Training on Recruitment/Retention Process**

Client recruitment was addressed in level 2 (Treatment Specialist) training; content, method, # of sessions NR

### **Training on Intake/Assessment**

NR

### **Training on Protocol Delivery**

NR

### **Training on Health Topic**

Nicotine addiction

### **Training on Evaluation**

NR

### **Other Training**

5 days of training for each level of certification

### Other Training Content; Instructional Method; Number of Sessions; Testing

NR

### Name of Curriculum

NR

### **Availability of Curriculum**

Available through U of Arizona developed website; no separate curriculum developed for Tobacco Free El Paso-curriculum "borrowed" directly from U of A

### **Evaluation and Testing Results of Curriculum**

Results from pre-posttest measuring self-confidence suggest that participants understood training material; however data NR.

Mean satisfaction scores (1 = definitely not confident to 5 = definitely confident) high for recipients of each certification: beginner: 4.8, intermediate: 4.7, advanced: 4.6

### Certification

3 certifications offered: introductory (Basic Skills to Stop Using Tobacco); intermediate (Treatment Specialist); advanced (Leave Addiction)

### **Other Pertinent Information**

NA

### Are Particular Training Characteristics Associate with Improved Outcomes?

Study Characteristics Setting	Community Health Worker	
Author Year Navarro et al., 2007	Title of CHW Consejeras	
<b>Trial Name</b> Por La Vida Cuidandome	Relationship with Community Part of local Latino community	
Objective or Aim Train community health advisors to	CHW (N) 17 consejeras, 285 primary participants, 222 learning partners	
conduct interactive educational group sessions and train-the-trainer (through "learning partners"	Supervision of CHW NR	
Geography San Diego, CA	Prior Training NR	
Organization Latino communities	Type of Service Interactive educational group sessions, recruiting women from local community to be primary participants in these sessions	
Type of Community Women with low level of acculturation in low socioeconomic Latino communities	Type of Educational Materials Used Manual to guide sessions	
Start Date 1996	Duration of Interaction with Clients 12 weekly sessions	
Health Condition of Interest Breast & cervical cancer	Length of Follow-up 6 months after pretest	

## **Eligibility for CHW Training**

NR

### Input of CHW in Curriculum Development

Developed over time & preveiously implement, so no

### **Training on Cultural Competency**

NR

### **Training on Recruitment/Retention Process**

There were 5 2-hour sessions covering recruitment strategies and role playing practice to lead sessions

### Training on Intake/Assessment

NR

### **Training on Protocol Delivery**

NR

### **Training on Health Topic**

Manual had sessions for understanding female body, breast cancer, Pap test, breast health, risks

### **Training on Evaluation**

NR

### **Other Training**

Referral, communication skills

### Other Training Content; Instructional Method; Number of Sessions; Testing

NR

### Name of Curriculum

Por La Vida Cuidandomje, Taking Care of Myself: Women and Cancer

### **Availability of Curriculum**

NR

### **Evaluation and Testing Results of Curriculum**

Changes in knowledge & behavior pre/post test for primary participants; & learning partners

Names following test for breast/cervical cancer early detection:

BSE 58.6/74.7; 46.4/56.3

Clinical breast exam: 29.1/28.8; 28.8/20.7 Mammography: 49.8/71.2; 45.0/63.1 Pap test 84.6/91.9/79.3/85.1 Knows BSE: 90.5/99.3; 82.4/93.2

Knows mammography recs: 32.3/55.8; 27.4/38.1 Names ≥1 breast cancer symptom: 75.1/96.8; 70.3/94.1 Names ≥1 txt for breast cancer: 40.0/65.6; 27.9/45.0

Names ≥1 risk factor: 8.1/16.5; 6.8/7.2

Names ≥1 factor for cervical cancer: 30.9/59.6; 24.3/35.1

BSE in pasat month: 62.3/87.4; 55.9/71.5 Mammography ever: 63.3/70.0; 66.7/68.3 Pap test ever: 92.3/97.9; 88.3/92.8

### Certification

No

### **Other Pertinent Information**

14 program sessions (12 weekly sessions + 2 monthly session) plus 5 additional 2-hour sessions covering recruitment strategies and role playing practice to lead sessions

### Are Particular Training Characteristics Associate with Improved Outcomes?

Evidence Table C-4. Rey Questions 4 and 4a (continued)		
Study Characteristics Setting	Community Health Worker	
Author Year Perez, 2006	Title of CHW CHW	
<b>Trial Name</b> Northern Manhattan Community Voices Collaborative	Relationship with Community Live in community or a nearby neighborhood; share cultural & ethnic traditions with program participants	
Objective or Aim To train community health workers, focusing on facilitating insurance enrollment, child immunization, and asthma management	<b>CHW (N)</b> # trained between 2000 & 2005: (1) 88 (2) 792 (3 624	
<b>Geography</b> Northern Manhattan	Supervision of CHW NR	
<b>Organization</b> Neighborhoods	Prior Training NR	
Type of Community Northern Manhattan - Washington Heights, Inwood, and Harlem, comprising	Type of Service Community-wide health promotion activities; serve as bridge to primary health care provider	
low income communities and/or racial and ethnic minorities (Dominican, African-American)	Type of Educational Materials Used NR	
Start Date 2000	Duration of Interaction with Clients NR	
Health Condition of Interest (1) health insurance	Length of Follow-up varied	

## **Health Condition of Interest**

- (1) health insurance
- (2) child immunizaations
- (3) asthma management

### **Eligibility for CHW Training**

Reside in community; shared culturual & enthic traditions with those they'll be serving; experience with programs offered by organization; good people skills; committed to community development

### Input of CHW in Curriculum Development

NR

### **Training on Cultural Competency**

Yes but not described

### **Training on Recruitment/Retention Process**

NR

### Training on Intake/Assessment

Yes but not described

### **Training on Protocol Delivery**

Yes but not described

### **Training on Health Topic**

Yes but not described

### **Training on Evaluation**

Yes but not described (one of 7 core modules)

### Other Training Content; Instructional Method; Number of Sessions; Testing

NR

### Name of Curriculum

NR

## **Availability of Curriculum**

NR

### **Evaluation and Testing Results of Curriculum**

Gains in competency and knowledge (pre/post):

- (1) 24%/72% (gain = 48%; % change = 200; n tested = 61)
- (2) 83%/96% (gain-48%; %change = 16; n tested = 472)
- (3) 63%/83% (gain = 20%; %change = 32; n tested = 499)

## Certification

NR

### **Other Pertinent Information**

NΑ

### Are Particular Training Characteristics Associate with Improved Outcomes?

Study Characteristics	
Setting	Community Health Worker
<b>Author Year</b> Williams, 1996	Title of CHW Lay health educator
<b>Trial Name</b> NR	Relationship with Community Older adult community members
Objective or Aim To raise awareness of & increase	<b>CHW (N)</b> 47
participation of older African-Americans in health promotion activities	Supervision of CHW Program outreach coordinators
Geography Atlanta & Fort Valley Georgia	Prior Training NR
<b>Organization</b> Older African-Americans	Type of Service Conduct or facilitate at least 1 health promotion session/month &
Type of Community large urban & small township	disseminate health ed materials through at least 1 of grassroots channels
Start Date 1992	Type of Educational Materials Used Leaflets, brochures, pamphlets
Health Condition of Interest Health promotion & education	Duration of Interaction with Clients 1 group session/month
	Length of Follow-up NR

### **Eligibility for CHW Training**

Older ( > 55) living in target communities; expected to be knowledgeable about community, have history of volunteering, demonstrate good communication skills & ability to establish rapport with target population; nonsmokers of moderate weight, have at least 8th grade education

### Input of CHW in Curriculum Development

None

### **Training on Cultural Competency**

NIR

### **Training on Recruitment/Retention Process**

NR

### Training on Intake/Assessment

NR

## **Training on Protocol Delivery**

NR

### **Training on Health Topic**

1111

### **Training on Evaluation**

NR

### Other Training

Training divided into 3 categories: chronic disease education & self-care, lifestyle education, and consumer education. Topics for these categories developed into 12 training modules

## Other Training Content; Instructional Method; Number of Sessions; Testing

NR

### Name of Curriculum

NR

## **Availability of Curriculum**

NR

## **Evaluation and Testing Results of Curriculum**

Obtained score ≥80 on pre and posttest for hypertension & diabetes training sessions:

G1: 32%/60% G2: 11%/72% G3: 28%/93%

### Certification

No

## **Other Pertinent Information**

NA

### Are Particular Training Characteristics Associate with Improved Outcomes?

,,			
Study Characteristics Setting	Community Health Worker		
Author Year Yu et al., 2007	Title of CHW Lay health advisor (LHA)		
<b>Trial Name</b> NR	Relationship with Community Shared language		
Objective or Aim To inrease self-efficacy of HLAs in conducting breast cancer screening	CHW (N) 79 (10 others were eligible but unable to complete training program)		
geography Southeast Michigan	Supervision of CHW NR		
Organization Chinese communities	Prior Training NR with respect to breast cancer screening; however Graduate degree: 67.4%		
Type of Community Chinese American women	College degree: 30.3% High school education: 2.2%		
Start Date	Type of Service NR		
Health Condition of Interest Breast cancer	Type of Educational Materials Used NR		
	<b>Duration of Interaction with Clients</b> NR (Phase I only)		
	Length of Follow-up NR		

### **Eligibility for CHW Training**

Adults bilingual in English & Chinese; at least a high school diploma; demonstrated enthusiasm for helping others

### Input of CHW in Curriculum Development

Community leaders gave input to training materials; first-tier LHAs pretested training manual & Web site and provided comments for final version

### **Training on Cultural Competency**

NR (but point out critical imporantance of a culturally competent program for this population)

### **Training on Recruitment/Retention Process**

NR

### **Training on Intake/Assessment**

NR

### **Training on Protocol Delivery**

NR

### **Training on Health Topic**

NR

## **Training on Evaluation**

NR

### Other Training

Training manual had 9 chapters + 5 appendices (1 was a bilingual glossary of medical terms); content includes socieodemographi characteristics & special health concerns, outreach strategies, effective communication skills for promoting screening. Also a web site, PowerPointslides and audio recordings available

### Other Training Content; Instructional Method; Number of Sessions; Testing

3-month self-study of training materials. program included both on-site instruction and materials on paper as well as on Web sites or CDs for self-paced study.

Name of Curriculum

### Name of Curriculum

Training manual: Helping Women Fight Breast Cancer

## **Availability of Curriculum**

Through U of Michigan HAAP

### **Evaluation and Testing Results of Curriculum**

Change in trainees' knowledge & self-efficacy

Knowledge-Mean # of correct answers pre (SD)/post (SD): 6 (1.4)/8 (1.1), P < 0.001

Self-efficacy-mean score pre (SD)/post (SD): 61.0 (11.5)/65.0 (9.2), P = 0.016

### Certification

No

### **Other Pertinent Information**

NA

### Are Particular Training Characteristics Associate with Improved Outcomes?

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**Appendix C:** Evidence Tables

# **List of Abbreviations**

AA African American

AIDS Acquired immune deficiency syndrome

b/c because
BF breastfeeding
BMI body mass index
BP blood pressure

BSN bachelor of science - Nursing

BW body weight

CAD Coronary artery disease
CBC community based care
CD cannot determine

CES Community environmental specialists

CES-D Center for Epidemiologic Studies Depression Scale

CG control group

CHD coronary heart disease

CHO Carbohydrates

CHW(s) community health worker(s)
CPEP Child Parent Enrichment Program

DR Doctor

DSM-III-R Diagnostic and Statistical Manual of Mental Disorders, 3<sup>rd</sup> edition, revised

EAG Enhanced Anticipatory Guidance

EG experimental group

EPC evidence-based practice center EPC "enhanced" primary care

ER emergency room

ETS Environmental tobacco smoke

FPL federal poverty level FTT Failure to thrive

g gram

GED general education degree

GHC Group Health Cooperative of Puget Sound

gm gram h hour

HbA1c Glycosylated (or glycated) hemoglobin

HBP high blood pressure

HIV Human immunodeficiency virus
HMO Health Maintenance Organization

HS high school

HSP Hawaii's Health Start Program

ht height hypertension hx history

ICD International Classification of Diseases
IHDP Infant Health and Development Program

IL Illinois
ITT intent to treat

JNC-VI Sixth Report of Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High

Blood Pressure

kcal kilocalorie
LBW low birth weight
LDL Low-density lipoprotein
LHA Lay Health Advisor
MD medical doctor; Maryland
mg/dl milligrams/deciliter

MI Michigan
min minute
mmol/L millimoles/liter
mo month

mo month N number NA not applicable NCM nurse case manager Nutrition Data System NDS NNT number needed to treat NP nurse practitioner not reported NR not significant NS northwest NWNew York NY NYC New York City PCP primary care physician

principal investigator Ы phenylketonuria PKU

Psychiatric Symptom Index randomized controlled trials Resources, Education and Care in Home PSI **RCT** 

**REACH** 

RIA radioimmunoassay registered nurse RN SBP systolic blood pressure standard deviation SD SE standard error SLE stressful life events TPV tailored print and video

UC usual care

**VLBW** very low birth weight

Wellness for African Americans Through Churches Project WATCH

Women, Infants, and Children WIC

wk week у year y/o years old

YMCA Young Men's Christian Association

year

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Andersen et al., 2000	Eligible (N) 10,967 at baseline 8,907 at followup	<b>Title of CHW</b> Volunteer	<b>Age (mean)</b> NR
Trial Name Community Trial of	Enrolled (N)	Paid or Volunteer Volunteer Relationship with	Sex (% female) 100 Race (%)
Mammography Promotion	Randomized (N) 14,080	Community Shared community	97% white
Objective or Aim To learn how best	Completers (N) 6,685	CHW (N) NR	<b>Other</b> NR
to increase use of screening among women aged 50 to	Withdrawals or Dropouts (N) 2,222 of N eligible at followup	Supervision of CHW Non-clinician- field research	Role of CHW in Recruiting and Retention None
80  Geography 40 communities in	Health Condition of Interest Mammography	coordinators  Prior Training	Recruitment Rates NA
predominantly rural Washington state, selected by	Inclusion Criteria Women age 50 to 80 living in one of 40 communities	NR <b>Type of Service</b> Barrier-specific telephone	Retention Rates NA
zipcodes corresponding to towns or clusters of	Exclusion Criteria History of breast cancer	counseling to promote screening	
towns  Organization	Groups G1: Control	Type of Educational Materials Used NR	
Community or telephone	G2: Community activities G3: Individual counseling G4: Both	Duration of Interaction with Clients	
Type of Community	Interventions G1: Control, no intervention reported	One interaction (time of interaction NR)	
Rural neighborhoods	G2: Community activities - developing social norms	Length of Follow-up 2 years	
Study Design RCT of communities	G3: Individual counseling - telephone G4: Community activities and individual couseling		
Start Date NR	Group (N)		
<b>Duration</b> 2 years	G1: 1,688 G2: 1,630 G3: 1,650 G4: 1,717		

Evidence rable of it. Ittly adequations it at and o tooritinaed	Evidence Table C-1.	Key Questions 1, 2, and 3 (continued)
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Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR <b>Quality of Life:</b> NR	Healthcare Utilization: Measure 1 Increase in mammography rates (self-reported)	Explanation of Overall Outcomes NR
	<b>Results</b> No significant differences between intervention groups and control; no significant differences for individual counseling or combined individual couseling and communitities activities, but increased mammography use by regular users between baseline and followup for community activities arm by $2.9\%$ ( $P = 0.01$ ).	Quality Rating Good
	Measure 2 Increase in mammography rates (self-reported)	
	Results  Among under-users at baseline, intervention more effective than control in increasing mammography rates amon women with in communities without a female physician (10% to 16%; <i>P</i> < 0.05), and among women with no health insurance (10% to 23%; <i>P</i> ≤ 0.05); NS effect for community attitudes on mammography, age, time taken to get a medical appointment, financial comfort, mammography facility in community, income, education, proportion of Hispanic population, urban/rural, size of community, and employment status among regular users, intervention was more effective than control in preventing relapse among women who needed > 2 hours to get a medical appointment. NS effect for community attitudes on mammography, age, use of mammography in community, female MD, financial comfort, mammography facility in community, income, education, proportion of Hispanic population, urban/rural, size of community, and employment status	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Auslander et al., 2002; Williams et al.,	Eligible (N) NR Enrolled (N) NR	Title of CHW Peer educators  Paid or Volunteer NR	Age (mean) G1: 41.2 G2: 40.2 Sex (% female)
Trial Name Eat Well Live Well Nutrition Program  Objective or Aim A culturally specific, peer-led dietary change program designed to reduce risk of type 2 diabetes in low-income African-American women.  Geography Large Midwestern city in Missouri  Organization Targeted neighborhoods  Type of Community Race, Neighborhood  Study Design RCT  Start Date NR	Randomized (N) NR  Completers (N) 294  Withdrawals or Dropouts (N) 104  Health Condition of Interest Diabetes Prevention  Inclusion Criteria African-American women ages 25– 55 years and living in neighborhoods  Exclusion Criteria Pregnancy, diabetes, BMI < 27  Groups G1: Treatment G2: Control  Interventions G1: Six group sessions (approximately six to eight participants per group) and six individual sessions targeting stages of change to tailor dietary pattern with a peer educator, meeting weekly over a 3-month period; duration of each session 45-90 minutes G2: Control - a book	Relationship with Community African-American women from target community with no background in nutrition or education, were recruited by lead agency to deliver intervention.  CHW (N) 3  Supervision of CHW Weekly supervision during implementation phases, including meeting with educators, research dietitian, project coordinator and research assistants  Prior Training No background in nutrition or education  Type of Service Counseling  Type of Educational Materials Used Program Manual  Duration of Interaction with Clients 3 months	Race (%) African-American Other NR Role of CHW in Recruiting and Retention NR Recruitment Rates NR Retention Rates NR
<b>Duration</b> 3 months	Group (N) G1: Treatment 138 G2: Control 156	Length of Follow-up 3 months	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: Measure 1	Health Outcomes: Measure 1 Weight, BMI	Costs (Economics): NR
Knowledge of Label Reading Questionnaire (Unvalidated) –baseline/6 months	Results No significant group differences	Explanation of Overall Outcomes NR
Results G2: 5.4/5.7,	<b>Measure 2</b> FFQ - Validated	<b>Quality Rating</b> Fair
<b>G1:</b> 5.5/6.3 ( <i>P</i> > 0.0001)	Results	
<b>Measure 2</b> Readiness to change dietary patterns - no	Intervention was effective in reducing fat intake, as measured by percent of calories from total fat (baseline/6 months): G2: 36.0/34.5,	
<b>Results</b> Overall, participants in	G1: 35.9/32.3, P < 0.05	
treatment group reported a greater readiness to change their dietary patterns than those in control group at posttest assessment.	Healthcare Utilization: NR	
Quality of Life: NR		

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Barnes et al., 1999	Eligible (N) 434	Title of CHW Community volunteers	Age (mean) G1: 9.5 months
<b>Trial Name</b> NR	Enrolled (N) 163	<b>Paid or Volunteer</b> Volunteer	G2: 9.4 months  Sex (% female)
Objective or Aim To assess effectiveness of a volunteer driven outreach program on immunization rates in children younger than 2 years.  Geography NW Manhatten, NY  Organization Organizational: Patients of 1 of 2 ambulatory pediatric clinics of a major medical center  Type of Community Low-income children who are part of a large, highly mobile immigrant community originating from DR  Study Design RCT  Start Date 1993  Duration 6 months	Randomized (N) 434  Completers (N) 140  Withdrawals or Dropouts (N) 23  Health Condition of Interest Immunizations Inclusion Criteria • Younger than 2 years residing in NW Manhattan • No-shows for a scheduled appointment in pediatric clinic, and • Overdue for a vaccine.  Exclusion Criteria NR  Groups G1: Intervention G2: Control Interventions G1: Basic immunization education and referral. During subsequent contacts (home visits or telephone calls) throughout remainder of follow-up , families were reminded of upcoming vaccinations and were recontacted to ensure that requisite vaccines were received. If a family required support or assistance to obtain immunization services G2: Informed of their child's immunization status at enrollment visit by control group interviewer and were instructed to reschedule missed appointment.  Group (N) G1: 71	Relationship with Community NR- community volunteers CHW (N) NR Supervision of CHW Organized by coordinator from local branch of larger international charitable organization Prior Training NR Type of Service Unspecified # of home visits and phone calls Type of Educational Materials Used NR Duration of Interaction with Clients Unspecified # of calls and visits over 6 months (time per session NR) Length of Follow-up Maximum of 6 months	Sex (% female) G1: 50 G2: 40  Race (%) G1: 87% Hispanic G2: 85% Hispanic  Other Primary language of caregiver -spanish G1: 66 G2: 75%  Role of CHW in Recruiting and Retention NR  Recruitment Rates NR  Retention Rates NR
	G2: 84		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR	Healthcare Utilization:	Explanation of Overall
Quality of Life: NR	Measure 1 Late for immunization	Outcomes NR
	Results G1: 18% G2: 38% P < 0.05	<b>Quality Rating</b> Fair
	<b>Measure 2</b> Up to date on immunizations	
	Results G1: 75% G2: 54% P = 0.03	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Barnes-Boyd et al., 2001	Eligible (N) 1,922 Enrolled (N)	Title of CHW Maternal-Child Health Advocate	<b>Age (mean)</b> G1: 51% < 20 y/o G2: 36% < 20 y/o
Trial Name REACH-Futures	1,922 Randomized (N)	<b>Paid or Volunteer</b> Paid	<b>Sex (% female)</b> 100
<b>Objective or Aim</b> NR	NA Completers (N)	Relationship with Community	Race (%) G1: 85% African-American
<b>Geography</b> Chicago	NA Withdrawals or Dropouts (N)	Within community CHW (N)	G2: 80% African-American Other
Organization Inner city	0 Health Condition of Interest	Supervision of CHW	G1: 56% primiparous G2: 41%
community clinic  Type of	Infant health Inclusion Criteria	Teamed with nurses (at least BSN)	G1: 53% < HS education G2: 36%
Community Mostly African- American; impoverished; low employment and literacy, high infant and child morbidity and mortality, poor maternal outcomes, high	All recipients:  • below 150% of poverty line  • lived in inner-city communities  Exclusion Criteria	<ul> <li>Prior Training</li> <li>Minimum HS or GED</li> <li>Experience in community service</li> <li>Type of Service</li> </ul>	G1: 94% BW > 2500gm G2: 93%
			Role of CHW in Recruiting and Retention NR
	NA Groups	home visits	Recruitment Rates
	G1: REACH-Futures CHW+nurse G2: REACH nurse-only historic control	Materials Used	Retention Rates G1: 2 mo 86%, 11 mo 56%
incidence early unplanned pregnancies and childhood injuries	Interventions  Home visits-family focused care plan	Duration of Interaction with Clients 12 monthly visits by CHW	G2: 2 mo 75%, 11 mo 58%
Study Design Cohort with historic control	<ul> <li>Support model problem-solving skills</li> <li>Promote self-development of</li> </ul>	alone, teamed with nurses for one prenatal visit and at 1, 6 and 12 months; duration per visit NR	
Start Date 1986	<ul><li>mother</li><li>Provide instruction in infant care</li><li>Transportation</li></ul>	Length of Follow-up 12 months	
<b>Duration</b> 8 years	<ul> <li>Find community resources for childhood immunizations</li> </ul>		
	<b>Group (N)</b> G1: 666 G2: 1256		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1  Future elected infant mortality rate (a too amell)	Costs (Economics): NR
NR Quality of Life: NR	Extrapolated infant mortality rate (n too small)  Results G1: 3.0 G2: 4.7 (not significant)	Explanation of Overall Outcomes CHW+nurse home visits resulted in higher immunization status than nurse-only visits; no difference in health problems or mortality Quality Rating
Measure 2 Presence of health problems  Results Neonatal G1: 27% G2: 25%		
	Neonatal	
		Poor
	Postneonatal G1: 27% G2: 25% (neither significant)	
	Measure 3 % fully immunized at 12 months	
	<b>Results</b> G1: 77% G2: 63% ( <i>P</i> < 0.001)	
	Healthcare Utilization: NR	

Organization Social Social G1: 5 G2: 10  Type of Community At rick Child abuse  Withdrawals or Dropouts (N) G1: 5 Prior Training 100 hours  Type of Service  Type of Service  Group Supervision South East Asian refugees) 4% Native American Other	Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Objective or Aim Preventing child abuse  Completers (N)  Geography California / Contra Costa County  Organization Social  Type of  Community  Relationship with Community Members of community Members of community  CHW (N)  8  CHW (N)  8  CHW (N)  8  Supervision of CHW Group Supervision  Prior Training 100 hours  Type of Community  At rick  At rick  Race (%)  43% white  27% were Latino (primarily Chicano)  20% black  66% were Asian (primarily South East Asian refugees)  4% Native American  Other	Barth et al., 1988  Trial Name	95 referred Enrolled (N)	Parenting Consultants  Paid or Volunteer	G1: 21.75 G2: 23.04
Task centered approach RCT Referred to CPEP, by public health, education, or social service professionals    Duration 6 months	Preventing child abuse  Geography California / Contra Costa County  Organization Social  Type of Community At risk  Study Design RCT  Start Date NR  Duration	Completers (N) 50 G1: 24 G2: 26 Withdrawals or Dropouts (N) G1: 5 G2: 10 Health Condition of Interest Child abuse Inclusion Criteria Referred to CPEP, by public health, education, or social service professionals Exclusion Criteria NA Groups G1: Intervention G2: Control Interventions G1: CPEP services involved six months of home visiting by paraprofessional women and linkage to other formal and informal community resources. Group (N) G1: 24	Community Members of community  CHW (N)  8  Supervision of CHW Group Supervision  Prior Training 100 hours  Type of Service Task centered approach  Type of Educational Materials Used NR  Duration of Interaction with Clients ≈2 visits per month, ≈ 4 hours per session, over 6 months  Length of Follow-up	Race (%)  43% white  27% were Latino (primarily Chicano)  20% black  6% were Asian (primarily South East Asian refugees)  4% Native American  Other  Role of CHW in Recruiting and Retention  NR  Recruitment Rates  NR  Retention Rates

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR Quality of Life: Measure 1 Child Abuse Potential Inventory Results	Healthcare Utilization: NR	Explanation of Overall Outcomes Overall no differences in outcomes, though clients appreciated services
G1: pre/post means 116.33/88.54 G2: pre/post means 103.50/92.44 No significant difference between posttests		<b>Quality Rating</b> Poor

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Barth, 1991 Trial Name CPEP	Eligible (N) 313 referred Enrolled (N) 240	Title of CHW Parenting Consultants Paid or Volunteer NR	Age (mean) G1: 23.25 G2: 23.75 Sex (% female)
Objective or Aim Prevent child abuse  Geography Contra Costa County, California  Organization Organizational/ Community  Type of Community At risk for chid abuse  Study Design RCT  Start Date NR  Duration 6 months	Randomized (N) 240  Completers (N) 61% (191)  Withdrawals or Dropouts (N) 39% (49)  Health Condition of Interest Child abuse  Inclusion Criteria Referred to CPEP by public health, education, or social service professionals  Exclusion Criteria NA  Groups G1: Intervention G2: Control  Interventions G1: Intervention G2: Control  Group (N) G1: 97 G2: 94 (Completers - article indicates 240	Relationship with Community Members of community CHW (N) 8 Supervision of CHW Group supervision Prior Training NR Type of Service • Task centered approach • Home visits • Links to community resources Type of Educational Materials Used NR Duration of Interaction with Clients On average 11 visits (range 5-20) over 6 months (time per session not reported but ≈ 4 hours implied) Length of Follow-up	Race (%)  White: 45%  Latin (primarily Chicano): 31%  Black: 17%  Other: 7%  Other Role of CHW in Recruiting and Retention NR  Recruitment Rates NR  Retention Rates NR
	were initially randomized but only 191 completed posttest)	Mean 3 years (range 2-5)	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1	Costs (Economics): NR
NR	Reported child abuse	Explanation of Overall
Quality of Life: NR	Results No differences in increase between groups	Outcomes Overall no differences in outcomes, though clients appreciated services
	Healthcare Utilization:	
		Quality Rating Poor

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Batts et al., 2001; Garyet al., 2003; Vetter, et al., 2004; Gary et al., 2005; Gary et al., 2000	Eligible (N) 822 Enrolled (N) 332 Randomized (N)	Title of CHW  Members of community of interest trained to perform non-medical case management tasks	Age (mean) 59 Sex (% female) 75 Race (%)
Trial Name Project Sugar  Objective or Aim To determine diabetes care priorities and needs in a group of urban African-American adults with type 2 diabetes; To determine prevalence of depressive symptoms and re I a t i o n s h i p between depressive symptoms and metabolic control.	Completers (N) 183 Withdrawals or Dropouts (N) 3 Health Condition of Interest • Diabetes Mellitus, type 2 • Depression Inclusion Criteria Eligibility criteria included following: • Age 35–75 years • African-American ancestry • Residence in East Baltimore • Presence of type 2 diabetes • Absence of comorbid conditions limiting probable life span to 4 years (e.g., cancer, AIDS)	Paid or Volunteer NR  Relationship with Community  Local hs graduate enrolled in college part- time  No formal training in health care prior to study  CHW (N)  Supervision of CHW NR  Prior Training None  Type of Service  Home visits to provide education	100% AA  Other  50% had an income of \$7,500  Participants had diabetes an average of 9 years  91% on medication (46% used insulin, 45% used an oral agent)  Role of CHW in Recruiting and Retention NR  Recruitment Rates NR  Retention Rates
Geography East Baltimore, MD  Organization 2 primary care clinics  Type of Community African-American adults with type 2 diabetes  Study Design RCT	Attendance at either of 2 Johns Hopkins—affiliated primary care clinics No indication of end-stage complications of diabetes (e.g., kidney dialysis or transplant, blindness, or lower- extremity amputation)  Exclusion Criteria Comorbid conditions limiting probable life span < 4 years Indication of end-stage complications of diabetes (dialysis or t+R2ransplant, blindness or lower extremity amputation)	Mobilize social support for adults with diabetes mellitus      Type of Educational Materials Used NR      Duration of Interaction with Clients     3 visits (45-60 minutes each) per year over 2 years (+ additional contacts as needed)	NR
Start Date 1994 Duration 2 years	Groups G1: usual care G2: nurse care manager G3: CHW G4: NCM + CHW	Length of Follow-up 2 years	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 LDL	Costs (Economics): NR
Quality of Life: NR	<b>Results</b> G1: -16.7± 5.5 mg/dl	Explanation of Overall Outcomes NR
	<ul> <li>G2: +6 (approx) (P&lt;0.05 for within-group change from baseline)</li> <li>G3: +6 (approx.)</li> <li>G4: +4 (approx.) (P&lt;0.05 for within-group change from baseline)</li> </ul>	Quality Rating Good
	Measure 2 SBP	
	Results G1: ref G2: +6 (approx.) ( <i>P</i> <0.05 for within-group change from baseline) G3: -4 (approx) G4: -2 (approx).	
	Measure 3 hga1c	
	Results G1: ref G2: -0.31 ± 0.49% G3: -0.30 ± 0.48% G4: 0.8 ± 0.52%	
	Measure 4 Dietary risk scores	
	Results G1: ref G2: -2.4± 1.99 G3: -3.45 ± 1.87 G4: -2.13 ± 1.92	
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Batts et al., 2001; Garyet al., 2003; Vetter, et al., 2005; Gary et al., 2000 (continued)	Interventions G1: continued on-going care from their own health professionals + quarterly newsletter containing info on diabetes-related health topics and trial communication G2: NCM intervention: NCM was RN + certified diabetes educator, interventions were 45 min face-to-face clinic visits and/or phone contacts, direct patient care, management, education, counseling, follow-up, referral and physician feedback - goal was 3 visits/yr G3: CHW interventions were 45-60 min face-to-face home visits and/or phone contacts, no direct implementation of therapeutic strategieis but facilitated preventibe care by offering to schedule appointments + provide education, 3 visits/yr G4: combined NCM + CHW - three visits/year with each  Group (N) G1: 34 G2: 38 G3: 41 G4: 36		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude,		Costs (Economics)
and Behavior	Health Outcomes	Additional
Quality of Life	Healthcare Utilization	Outcomes

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Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Becker et al., 2005; Cene et al., 2008  Trial Name NR  Objective or Aim Determine relative effectiveness of alternative model of community-based care provided in black community compared with "enhanced" primary care  Geography Baltimore, MD  Organization Identified from Baltimore Hospitals  Type of Community Blacks  Study Design RCT  Start Date NR  Duration 1 year	Eligible (N) NR  Enrolled (N) NR  Randomized (N) 364 siblings (194 families)  Completers (N) 267  Withdrawals or Dropouts (N) 97  Health Condition of Interest Cardiovascular disease prevention Inclusion Criteria  Sibling of black < 60 years hospitalized for a CHD event at one of 10 Baltimore hospitals  Aged 30-59  No known history of CAD  No chronic glucocorticosteroid therapy  No autoimmune disease  No cancer  No immediate life-threatening comorbidity  Exclusion Criteria See prior  Groups G1: EPC G2: CBC Interventions G1: EPC- received risk-specific materials (same as intervention group), PCP received results and recommendations, sent info on YMCA program, etc. G2: CBC - received care in 1 nonclinical site in community from a NP and CHW. CHW provided dietary counseling, smoking cessation, and exercise counseling lasting 30 minutes.  Group (N) G1: 168 G2: 196	Prior Training NR  Type of Service Counseling for adults with risk factors for cardiovascular disease, face-to-face, phone calls  Type of Educational Materials Used Written, culturally sensitive  Duration of Interaction with Clients Multiple (# unspecified) 30 minute sessions over 1 year  Length of Follow-up 1 year	Age (mean) G1: 47.9 G2: 47.6 Sex (% female) G1: 66 G2: 61 Race (%) African American:100% Other Role of CHW in Recruiting and Retention NA Recruitment Rates NA Retention Rates NA

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 Smoking Cessation (self-report)	Costs (Economics): NR  Explanation of Overall
Quality of Life: NR	<b>Results</b> G1: 7% reduction G2: 16.2% reduction ( <i>P</i> < 0.001)	Outcomes  NR  Quality Rating
	<b>Measure 2</b> BP	Fair
	Results	
	Measure 3 LDL (mmol/L)	
	<b>Results</b> G1: 3.38+-1 G2: 3.06+-1 ( <i>P</i> < 0.0001)	
	<b>Healthcare Utilization:</b> NR	

Beckham et al., 175  Trial Name NR  Randomized (N) NB  Completers (N) Bobjective or Aim Effectiveness of CHWs on diabetes management among a withdrawals or Dropouts (N) NN  A Completers (N) Bob Mithdrawals or Dropouts (N) NA  Supervision of CHW  Chilw (N) Supervision of CHW Community Underserved with Medical Director and Preventive Health Department Director once every 2 weeks for in- once every 2 weeks f	Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
	Author Year Beckham et al., 2008 Trial Name NR Objective or Aim Effectiveness of CHWs on diabetes management among a population with primarily Native Hawaiian and Samoan ethnic minority participants with HbA1c greater than 10% Geography Hawaii Organization Organizational Type of Community Underserved diabetics Study Design Prospective cohort Start Date 2002 Duration	Eligible (N) 175  Enrolled (N) 116  Randomized (N) NA  Completers (N) 80  Withdrawals or Dropouts (N) NA  Health Condition of Interest Diabetes  Inclusion Criteria Patients with HBa1C > 10  Exclusion Criteria Refusal to participate (these became control group)  Groups G1: Intervention G2: UC  Interventions G1: diabetes case management by CHW, including home visits; based on needs of patients, CHWs collaborate with rest of multidisciplinary team to determine high-priority learning areas and to develop an intervention plan to implement during subsequent visits, plan included a blood regimen and target levels, diet plan, exercise plan, medication schedule, insulin injetion plan, and preventive health/health mainteance plan G2: UC  Group (N) G1: 80	Title of CHW Community health worker  Paid or Volunteer Paid  Relationship with Community Ethnicity and language  CHW (N)  3  Supervision of CHW CHWs met with Medical Director and Preventive Health Department Director once every 2 weeks for inservice training and case conferences for duration of project.  Prior Training 6 months of study at community college  Type of Service Based on needs of patient - CHWs would collaborate with rest of multidisciplinary team to determine high-priority learning areas and to develop an intervention plan to implement during subsequent visits. Each plan included a blood glucose self-monitoring regimen and target levels, diet plan, exercise plan, medication schedule, insulin injection plan, and preventive health/health maintenance plan.  Type of Educational Materials Used NR  Duration of Interaction with Clients Up to a year - number of CHW visits per participant averaged 4.24 (range 5 1–15 visits), with each visit averaging 1 to 1.5 hours.  Length of Follow-up	Age (mean) G1: 51.8 G2: 46.6 Sex (% female) G1: 55 G2: 50 Race (%) G1: Hawaiian 51.3% Samoan 12.5% Filipino10% Caucasian 16.2% Tongan 2.5% Other 7.5% G2: Hawaiian 55.6% Samoan 11.1% Filipino 8.3% Caucasian 11.1% Tongan 2.8% Other 11.1% Other Baseline HbA1c (%) G1: 11.0 (6.8) G2: 10.8 (6 (%) Role of CHW in Recruiting and Retention NR Recruitment Rates NR Retention Rates

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR Quality of Life: NR	Health Outcomes: Measure 1 Post intervention period HbA1c  Results G1: 8.8 6 (1.7) G2: 10.4 (6 1.3) P < 0.0001 (Note on P value: investigators did not report one comparing groups, RTI researchers calculated it using data in article	Costs (Economics): NR Explanation of Overall Outcomes NR Quality Rating Fair
	Measure 2 Decrease in HbA1C  Results G1: 2.2 (SD 1.8) G2: 0.2 (SD 1.5); P < 0.01 compared to baseline  Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Blacket al., 1995;	Eligible (N) approx 163	Title of CHW Lay home visitor	Age (mean) G1: younger 7.8 mo (SD 2.8);
Hutcheson, et al., 1997	Enrolled (N) 130	<b>Paid or Volunteer</b> Paid	older 17.1 mo (3.7) G2: younger 6.6 (3.6); older 17.9 (4.3)
<b>Trial Name</b> NR	Randomized (N) 130	Relationship with Community	Sex (% female) G1: younger 50%, older 44%
Objective or Aim Evaluate efficacy of	Completers (N) 706: 116 ( to end of intervention)	Knowledge of community Familiarity with culture	G2: younger 45%, older 38%
family-focused, home-based intervention on	1445: 74 (to 4 y/o) Withdrawals or Dropouts (N)	CHW (N) 3 part-time	Race (%) African American – G1: younger 84%, older 91%
growth and development of	706: 14 1445: 56	Supervision of CHW Community health nurse,	G2: younger 85%, older 97% Other
children with nonorganic FTT	Health Condition of Interest Nonorganic failure to thrive	frequency NR  Prior Training	Mean BW G1: younger 2881 gm (400),
<b>Geography</b> Baltimore, MD	Inclusion Criteria • < 25 mo	Experience with children and families	older 2868 (385) G2: younger 3010 (524),
Organization Recruited from urban pediatric clinics serving low	<ul> <li>Wt for age &lt; 5th percentile</li> <li>EGA 36+ wk</li> <li>Birth weight appropriate for gestational age</li> </ul>	<ul> <li>Type of Service</li> <li>Home visits to develop individualized family service plan with specific</li> </ul>	older 2881 (432) Prior FTT hospitalization G1: younger 6%, older 0 G2: younger 10%, older 3%
income families  Type of	Wt for ht < 10th percentile  Exclusion Criteria	<ul><li>goals</li><li>Support mother's needs</li></ul>	Role of CHW in Recruiting and Retention NR
Community Low-income, urban	No congenital disorders     No chronic illness	<ul> <li>Promote maternal-child relationship</li> </ul>	Recruitment Rates
<b>Study Design</b> RCT	<ul> <li>No developmental disabilities</li> <li>Groups</li> </ul>	Type of Educational Materials Used	80% overall Retention Rates
Start Date NR	G1: home intervention G2: clinic-only	Hawaii Early Learning Program was used as curriculum guide; handouts,	706: G1: 89% G2: 89%
<b>Duration</b> 1 year	Interventions G1: CHW home visit weekly x 1 year w/ community health nurse	developmental assessment toys, personalized notebooks	1,445: G1: 65%
	supervision G2: clinic-based multidisciplinary services	Duration of Interaction with Clients Weekly visits (≈ 1 hour per visit) for 1 year	G2: 68%
	<b>Group (N)</b> G1: 64 G2: 66	Length of Follow-up 18 months	

# Knowledge, Attitude, and Behavior **Quality of Life**

# **Health Outcomes Healthcare Utilization**

# Knowledge, Attitude, and Behavior:

NR

# Quality of Life: Measure 1

Home environment (validated: Home Observation for Measurement of **Environment Scales**)

#### **Results**

G1 higher post-intervention scores than G2 (no significance testing reported)

#### Measure 2

Competence pre vs. post intervention

#### Results

Negative affect (below median on Brief Symptom Inventory)

G1: 3.1 (SD 0.9)  $\rightarrow$  3.4 (0.6) G2:  $2.9(0.9) \rightarrow 3.6(0.7)$ 

#### Non-negative

G1:  $3.1(0.6) \rightarrow 3.6(0.6)$ G2:  $3.1(0.9) \rightarrow 3.5(0.6)$ 

# Measure 3

Growth (wt for age, wt for ht, ht for age) (validated with Natl Center for Health Statistics charts)

#### Results

Significant improvement in each, no difference in improvement btw groups

#### Measure 4

Parent-child behavior during feeding (validated: modified Parent Child Early Relational Assessment)

#### Results

No significant differences between groups

### **Health Outcomes:** Measure 1

Cognitive and motor development (validated: Bayley Scales of Infant Development @ postintervention; Battelle Developmental Inventory @ 4 y/o)

### Results

Younger (1-12 mo at recruitment): G1: less decline pre/post vs. G2 (P = 0.02)

Older (12.1-24.9 mo at recruitment): no significant difference in decline between groups

Negative affect - cognitive

G1: 96.6 (SD 17.0)  $\rightarrow$  86.2 (15.8)  $\rightarrow$  77.4 (18.3) G2: 91.8 (13.0)

#### Measure 2

Language development (validated: Bayley Scales and Receptive/Expressive Emergent Language Scale)

### Results

Receptive-younger G1: 92.7→88.5 G2: 98.7→88.0

#### Older

G1: 92.3→83.2

G2: 98.3 $\rightarrow$ 82.7 (overall P = 0.05)

Expressive - no differences in declines reported between groups

#### **Healthcare Utilization:**

NR

# Costs (Economics) **Additional Outcomes**

# Costs (Economics):

#### Measure 1

Annual per-child cost of home visits (ingredients method)

#### Results

\$2,828/child/year

#### **Explanation of Overall Outcomes**

CHW home visit + multidisciplinary clinic management were significantly better than MDC alone in attenuating cognitive and motor decline among infants (but not older children) and attenuating receptive language decline; no significant difference observed in growth, expressive language, or parent-child interaction

#### Quality Rating

Fair

# **Health Outcomes:**

#### Measure 1

Negative affect @ baseline, postintervention, 4 y/o

# Results

Negative affect group

G1: 4.2 (SD 1.0)  $\rightarrow$  4.4 (0.7)  $\rightarrow$  3.5 (0.5) G2:  $4.3(0.7) \rightarrow 4.4(0.6) \rightarrow 3.6(0.3)$ 

#### Non-negative group

G1:  $4.2(0.7) \rightarrow 4.3(0.6) \rightarrow 3.7(0.2)$ G2:  $4.5 (0.5) \rightarrow 4.4 (0.7) \rightarrow 3.4 (0.6)$ 

# Measure 2

Warmth @ 4 y/o

#### Results

Negative affect group G1: 2.8 (SD 0.5) G2: 2.9 (0.5)

Non-negative group G1: 2.9 (0.5) G2: 2.5 (0.5)

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Bone et al., 1989	Eligible (N) 722	Title of CHW CHW	<b>Age (mean)</b> NR
<b>Trial Name</b> NA	Enrolled (N) 722	Paid or Volunteer NR	Sex (% female) NR
	scheduled follow-up. Telephone encounters lasted 5-10 minutes, conducted at night. <b>Group (N)</b> G1: 278 G2: 444	1 face-to-face session (≈20 minutes) and at least 1 pre- followup appointment reminder telephone call (5- 10 minutes) (time period over which this occurred NR)	
		Length of Follow-up NR	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR  Quality of Life: NR	Healthcare Utilization: Measure 1 Returned to ED for follow-up appt	Explanation of Overall Outcomes NR
	<b>Results</b> G1: 41% G2: 60% ( <i>P</i> < 0.001)	<b>Quality Rating</b> Poor

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Campbell, 2004	Eligible (N) 26 churches	Title of CHW Lay health advisor	Age (mean) 52
<b>Trial Name</b> WATCH	Enrolled (N) 12 churches	<b>Paid or Volunteer</b> Volunteer	Sex (% female) 74
Objective or Aim Compare	Randomized (N) 12 churches	Relationship with Community	Race (%) African American: 99%
effectiveness of 2 strategies to promote colorectal	Completers (N) NR (presumably 12 churches;	Church membership CHW (N)	<b>Other</b> BMI ≥30: 40%
cancer preventive behaviors among African American	completers/dropouts of individual participants from each church not reported)	62 Supervision of CHW NR	Role of CHW in Recruiting and Retention Organize church activities,
members of 12 rural North Carolina churches.	Withdrawals or Dropouts (N) NR (presumably 12 churches;	Prior Training NR	but recruitment is really NA in this case
Geography Rural NC	completers/dropouts of individual participants from each church not reported)	Type of Service Provide information through	Recruitment Rates NR
Organization Churches in rural	Health Condition of Interest Colorectal cancer	existing networks; organize and conduct at least three church-wide activities	Retention Rates Participated in WATCH church activities (%):
counties	Inclusion Criteria	focused on spreading	G1: 22.5
Type of Community	<ul> <li>Church in one of five rural eastern NC counties with at least 80 active</li> </ul>	information for colorectal cancer prevention	G2: 32.5 G3: 23.3
African American rural churches	<ul><li>members and expressed interest in participation</li><li>All active members (i.e., attending</li></ul>	Type of Educational Materials Used	G4: 16.5
Study Design RCT	study church at least once/month) aged 18 or older were eligible to	TPV and combined groups (G2 and G4): videos, computer-tailored	
Start Date 1999	participate  Exclusion Criteria	newsletters	
Duration	NR	Duration of Interaction with Clients	
1 yr	Groups G1: Control G2: LHA only	Three church- based activities during 12 months (time per session NR)	
	G3: TPV only G4: Combined LHA and TPV	Length of Follow-up 12 months	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1	Costs (Economics): NR
NR <b>Quality of Life:</b> NR	Dietary changedaily fruit and vegetable servings (Baseline/Followup)  Results	Explanation of Overall Outcomes NR
NK	G1: 3.3/3.4 G2: 3.5/3.5 G3: 3.3/3.9	Quality Rating Poor
	G4: 3.4/3.7 P = 0.02 for G3 vs. G1 P = ns for G2 vs. G1	Health Outcomes: NR
	Measure 2 Physical Activity: recreational (moderate-vigorous) activity MET hours/week, M (SE) (baseline/followup)	
	Results G1: 9.3 (0.88)/8.4 (0.69) G2: 10.5 (0.90)/10.6 (0.70) G3: 9.5 (0.80)/10.9 (0.61) G4: 9.7 (0.76)/9.7 (0.60) P = 0.07 for G2	
	Healthcare Utilization: Measure 1 Other CRC test in past year (% Baseline/% Followup)	
	Results G1: 20.3/27.5 G2: 19.6/25.5 G3: 23.7/21.1 G4: 26.4/14.9 P = ns	
	<b>Measure 2</b> FOBT test in past year (% Baseline/% Followup)	
	Results G1: 30.4/21.7 G2: 23.5/33.3 G3: 19.7/36.8 G4: 19.5/31.0 P = 0.08	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Campbell, 2004 (continued)	Interventions G1: Control churches offered health education sessions and speakers on topics of their choice not directly related to study objectives G2: Organize and conduct at least 3 church-wide activities on spreading info and enhancing support for healthy lifestyle and CRC screening (LHA) G3: 4 personalized computertailored newsletters and 4 targeted videotapes (TPV) corresponding to same behaviors mailed to participants' homes bimonthly for first 6 months after baseline data collection; 4th mailing was 9 months post baseline G4: LHA + TPV		
	Group (N) G1: 129 G2: 123 G3: 159 G4: 176		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude,		Costs (Economics)
and Behavior	Health Outcomes	Additional
Quality of Life	Healthcare Utilization	Outcomes

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	Community Health	Baseline Characteristics Recruiting and Retention
Author Year Caulfield et al., 1998 Enrolled (N) Trial Name NR  Objective or Aim To promote breast feeding among African-American women Withdrawals or Dropouts (N) Geography Baltimore, MD Organization Organization Organizational WIC  Type of Community Neighborhood-socioeconomic Study Design RCT Start Date 1992 Enrolled (N) Fa Conpleters (N) Completers (N) Completer	itle of CHW leer counselor laid or Volunteer lR lelationship with community chared condition - WIC lecipient that successfully reast fed in past lR landom quality assurance list to one clinic each week landom quality assurance list to one clinic each week landom quality assurance list to one clinic each week landom quality assurance list to one clinic each week landom quality assurance list to one clinic each week landom quality assurance list to one clinic each week landom quality assurance list to one clinic each week landom quality assurance list to one clinic each week landom quality assurance list to one clinic each week landom quality assurance list to one clinic each week landom quality assurance list to one clinic each week laterials used	Retention         Age (mean)         G1: < 18 37%,

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1 Still broads fooding at 7,10 days	Costs (Economics): NR
NR  Quality of Life:  NR	Still breast feeding at 7-10 days  Results G1: 14% OR 1.00 G2: 30% OR 0.79 95% CI, (0.25, 2.52) G3: 38% OR 1.11 95% CI, (0.34, 3.61) G4: 38% OR 1.52 95% CI, (0.50, 4.59) P < 0.05	Explanation of Overall Outcomes CHW were effective at increasing initiation of BF, but no difference in continuation at 7-10 days
	Measure 2 Odds of intitiating and continuing BF (@7-10 d) relative to control group	<b>Quality Rating</b> Poor
	Results G1: 1 (control) G2: 1.36 (0.52, 3.54) / 0.79 (0.25, 2.52) G3: 3.84 (1.44, 10.21) / 1.11 (0.34, 3.61) G4: 1.92 (0.78, 4.76) / 1.52 (0.50, 4.59)	
	Measure 3 Intiation of breast feeding	
	Results G1: 26% (OR, 1.00) G2: 50% (OR, 1.36; 95% CI, 0.52-3.54) G3: 62% (OR, 3.84; 95% CI, 1.44-10.21)G4: 52% (OR, 1.92; 95% CI, 0.78-4.76)	
	Healthcare Utilization:	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Conway et al.,	Eligible (N) NR	Title of CHW Promotora	Age (mean) 33 y (adults), 4 y (children)
2004 Trial Name	Enrolled (N) 143	Paid or Volunteer NR (text implies volunteer)	Sex (% female) • Adult: Nearly 100%
NR  Objective or Aim  Evaluate a	Randomized (N) 143	Relationship with Community Bicultural, bilingual, Latina	<ul> <li>Children: 55%</li> <li>Race (%)</li> <li>100% Latino</li> </ul>
culturally tailored behavioral problem	Completers (N) 127	CHW (N) NR	Other
solving intervention to reduce environmental	16	Supervision of CHW	<ul><li>Income: \$700-1099/mo</li><li>Mexican-born: 85%</li><li>Acculturation: 2.0/5</li></ul>
tobacco smoke exposure amongst	Health Condition of Interest Environmental tobacco smoke exposure	Prior Training NR	<ul><li>Mexican-educated: 71%</li><li>Median education: 9-11 y</li></ul>
young Latino children  Geography	Inclusion Criteria  Latino	Type of Service Home and telephone visits on problem-solving	Role of CHW in Recruiting and Retention NR
San Diego County  Organization	<ul> <li>Have child 1-9 y/o</li> <li>Exposure of child to 6+ cigarettes/week</li> </ul>	techniques to reduce ETS exposure to children	Recruitment Rates NR
Areas with large Latino population  Type of Community Community organizations and	Exclusion Criteria NR Groups G1: CHW G2: control	Type of Educational Materials Used Contracting, shaping, positive reinforcement, problem solving, social support	Retention Rates 81% overall
venues  Study Design RCT  Start Date NR  Duration 12 months	Interventions G1: Home and telephone visits on problem-solving techniques to reduce environmental tobacco smoke exposure; 6 visits over 4 months G2: Participated in surveys but received no other intervention	Duration of Interaction with Clients 6 home and telephone visits over 4 months (time per session NR) Length of Follow-up 12 mo	
	Group (N) 1 adult + 1 child dyad G1: 71 G2: 72		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 RIA of child's hair for nicotine and cotinine	Costs (Economics): Measure 1 CHW intervention cost
Quality of Life: NR	Results No significant differences between groups	(estimated)  Results \$29000
	<b>Measure 2</b> Parent report of child's past month ETS exposure	Explanation of Overall
	Results No significant differences between groups	Outcomes  No difference observed in subjective or
	Healthcare Utilization: NR	objective measures of ETS exposure with CHW visits vs. control
		<b>Quality Rating</b> Fair

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Corkery et al.,	Eligible (N) 64	Title of CHW CHW	Age (mean) 52.8 years
1997 Trial Name	Enrolled (N) 64	Paid or Volunteer NR	Sex (% female) 74
NR  Objective or Aim  Determine effect of	Randomized (N) 64	Relationship with Community Bicultural, bilingual	Race (%) 100% Hispanic
bicultural CHW on completion of	Completers (N) 40 (63%)	Hispanic-American of Puerto Rican heritage who	Other 46% literate
diabetes education in inner-city Hispanic patient	Withdrawals or Dropouts (N) 24 (37%)	lived in East Harlem  CHW (N)	Role of CHW in Recruiting and Retention NR
population and evaluate impact of completion of	Health Condition of Interest Diabetes	1 Supervision of CHW NR	Recruitment Rates NR
education program on patient knowledge, self- care behaviors,	<ul> <li>Inclusion Criteria</li> <li>Newly referred to clinic for patient education</li> <li>Hispanic</li> </ul>	Prior Training Previously volunteered in a diabetes clinic	Retention Rates NR
and glycemic control.	• > 20 yrs old  Exclusion Criteria	Type of Service Attended clinic visits	
	NYC - East Harlem  Organization Cultural: Hispanic- Americans, primarily PR origin, and African- Americans  Type of  G1: Intervention G2: Control Interventions G1: Intervention- CHW acted as liason, attended clinic sessions, interpreter, reinforced self are instructions and appointment	Type of Educational Materials Used	
Cultural: Hispanic- Americans, primarily PR origin, and African-		Duration of Interaction with Clients Varied (mean = 3.4 months, range: 0.9-5.4),	
Type of		time per session equal to clinic visit duration	
Community Disease: diabetes, neighborhood, socio-economic, cultural	G2: Control - encounters occurred between nurse and patient only  Group (N) G1: 30	Length of Follow-up Mean - 7.7 months (range 6-16.2)	
Study Design RCT	G2: 34		
Start Date NR			
<b>Duration</b> Mean 3.4 months (range 0.9 to 5.4)			

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 HgbA1c	Costs (Economics): NR
Quality of Life: NR	Results No difference in mean change between groups	Explanation of Overall Outcomes NR
	Measure 2 Diabetes Education Program Completion	<b>Quality Rating</b> Fair
	<b>Results</b> G1: 80% G2: 47% ( <i>P</i> = 0.01)	
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Derose et al.,	Eligible (N) 1,969 on first screening	Title of CHW Peer counselor	<b>Age (mean)</b> NR
2000; Dean et al., 2000; Derose et al.,	1,777 on second screening  Enrolled (N)	Paid or Volunteer Some full-time staff,	<b>Sex (% female)</b> 100
2000; Stockdale et al.,	1443 Randomized (N)	telephone counselors paid \$150 stipend per year	Race (%) NR
2000; Fox et al., 1998	1113	Relationship with Community	Other
<b>Trial Name</b> Los Angeles Mammography	Completers (N) 813 Withdrawals or Dropouts (N)	Hired from participating churches assigned to telephone counseling	Role of CHW in Recruiting and Retention NA
Promotion  Objective or Aim	300 Health Condition of Interest	<b>CHW (N)</b> 26	Recruitment Rates
Assess effectiveness of	Breast cancer screening Inclusion Criteria	Supervision of CHW NR	Retention Rates NA
telephone counseling in a church-based	Women ages 50-80, living in private residencies, not being too ill or impaired to be interviewed, being	Prior Training NA	
mammography promotion intervention trial	able to be interveiwed in English or Spanish, living in a sample area, and being reachable by telephone	Type of Service Barrier-specific telephone counseling to promote	
<b>Geography</b> LA county	Exclusion Criteria NR	screening, discussion of resources for free- and	
<b>Organization</b> Telephone counseling	Groups G1: Control G2: CHW	reduced-cost mammograms, translation services, transportation, and childcare assistance	
Type of Community Church	Interventions G1: Control churches provided minimal intervention: a library of	Type of Educational Materials Used Verbal	
communities  Study Design  RCT	resource materials on cancer and cancer prevention, assistance with starting a health committee or	Duration of Interaction with Clients	
Start Date 1996	working with an existing health committee, computer hardware, software, and a printer, as well as	2 telephone calls (one per year over 2 years), time per session 7-11 minutes on	
Duration	computer training for at least one church member	average  Length of Follow-up	
2 years	G2: One session of telephone counseling annually, for 2 years, by peer counselor; counseling individualized to address barriers, churches also received computer support offered to control churches	2 years	
	<b>Group (N)</b> G1: 397 G2: 416		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: NR	Costs (Economics): Measure 1 Sensitivity Analysis
Quality of Life: NR	Healthcare Utilization: Measure 1 Nonadherence to mammogram, by self-report  Results Nonadherence rates among adherent users at baseline: G1: 23.3% G2: 15.8% ( <i>P</i> = 0 .029)  Nonadherence rate among nonadherent users at baseline G1: 37.4% G2: 34.8 ( <i>P</i> = 0.324)	Results Assuming that all labor is voluntary and that churches provide materials and resources:  • Cost per additional screening for a LAMP study participant = \$188;  • Cost if all participants are adherent at baseline = \$145;  • Cost if all participants nonadherent at baseline = \$419 (using LAMP effectiveness rates for adherent (7.5%) and nonadherent (2.6%) participants  Explanation of Overall Outcomes  NR  Quality Rating  Fair

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Dignan et al., 2005	Eligible (N) 929	Title of CHW Native sister/Navigators	Age (mean) 54.2 years
Trial Name	Enrolled (N) 157 (for intervention groups, N for	Paid or Volunteer NR	<b>Sex (% female)</b> 100
Objective or Aim Determine relative effectiveness of	control NR) Randomized (N)	Relationship with Community	Race (%) Native Americans
face-to-face and telephone delivery	157 (for intervention groups, N for control NR)	Recruited from Denver metro area	Other Role of CHW in Recruiting
of culturally sensitive Navigator intervention to	Completers (N) 157 (for intervention groups, N for	CHW (N) N	and Retention NR
increase adherence to guidelines for	control NR)  Withdrawals or Dropouts (N)	Supervision of CHW NR	Recruitment Rates NR
mammography screening among	157 (for intervention groups, N for control NR)	<b>Prior Training</b> NR	Retention Rates NR
American Indian women	Health Condition of Interest Breast cancer screening	Type of Service Barrier-specific counseling	
<b>Geography</b> Denver	Denver Metropolitan area and had not had a mammogram within previous 18 months  Urban American Indian women 40 years and older living in greater Denver Metropolitan area and had not had a mammogram within previous 18 months	to promote screening, face- to-face vs. telephone	
Organization		Type of Educational Materials Used Tailored educational brochure	
Type of Community	Exclusion Criteria  Groups G1: control	Duration of Interaction with Clients One time session 20-90	
Study Design RCT	G2: face-to-face G3: telephone intervention	Length of Follow-up	
Start Date August 2001	Interventions G1: Control, interventions not reported, data from Colorado	6 months	
<b>Duration</b> One year	Mammography Program data G2: Tailored education brochure using data from baseline interview. face-to-face planned for delivery at participant's home (1 session lasting 20-90 minutes), presenting information on breast cancer and value of early detection, review of brochure G3: Telephone intervention, as above		
	Group (N) G1: G2: 77 G3:133		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR Quality of Life:	Healthcare Utilization: Measure 1	Explanation of Overall Outcomes
NR	Mammograms over past 12 months (self-report)	NR
	Results G1: 51.9 > 50.0 G2: 29 > 41.8 G3: 34.4 > 45.2 Chi-square G1 vs G2+G3:2.68, P = 0.10; P for G2 vs G3: 0.83; P for G2, pre-post changes: 0.029; P for G3, pre-post changes: 0.197	<b>Quality Rating</b> Poor

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Duggan et al., 1999; Duggan et al., 2000 Trial Name Hawaii's Healthy Start Program (HSP)	Eligible (N) 901 families Enrolled (N) 730 families Randomized (N) 730 families Completers (N)	Title of CHW Home visitors  Paid or Volunteer NR  Relationship with Community from community	Age (mean) Mother's average age G1: 24 years G2: 24 years Sex (% female) 100 Race (%) G1: Hawaiian: 21%
Objective or Aim Prevent child abuse and neglect and promote child health and development in newborns of families at risk for poor child outcomes  Geography Hawaii Oahu  Organization Organizational  Type of Community At risk for chid abuse  Study Design RCT  Start Date 1994  Duration 2 years	Withdrawals or Dropouts (N) 164 families  Health Condition of Interest Child abuse Inclusion Criteria Lived in target community, and not known to child protective services  Exclusion Criteria Non-English speaking  Groups G1: Healthy Start Program G2: Control G3: Test Control Interventions G1: Home visiting with individualized service plans, child developmental screenings, and mother-child interaction assessments; family support plan within 45 days of initial visit, reviewed q 6 mo, revised annually; periodic screening for DD, observational assessment of parent-child interaction and home environment; ensure existence of medical home, links to other needed resources G2: Control G3: Test Control was only interviewed at end  Group (N) G1: HSP: 373 G2: Control: 270 G3: Test Control: 41	CHW (N) NR  Supervision of CHW Non-clinician- met weekly w/home visitors  Prior Training NR  Type of Service Counsellingbuilding relationship with families; active assistance to address existing crises; model problem-solving skills and effective parent-child interaction; link families with needed resources; provide parenting education; ensuring presence of medical home for children  Type of Educational Materials Used NR  Duration of Interaction with Clients ≈22 visits (1 hour each) over 2 years [Protocol called for weekly visits] Length of Follow-up 2 years	Pacific Islander: 13% Asian: 10% Filipino: 18%

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1	Costs (Economics): NR
NR Quality of Life:	Bayley Scales of Infant Development, Mental Development Index at 2 years post-intervention	Explanation of Overall Outcomes
NR	<b>Results</b> G1: 90.0 G2: 89.2 P = 0.60	NR <b>Quality Rating</b> Poor
	<b>Measure 2</b> Bayley Scales of Infant Development, Psychomotor Development Index at 2 years post-interventino	
	<b>Results</b> G1: 92.1 G2: 90.4 P = 0.12	
	Measure 3 Has primary care provider?	
	Results G1: 91% G2: 86% P = 0.09	
	Healthcare Utilization: Measure 1 Adequate # of well-child visits	
	<b>Results</b> G1: 89% G2: 84% P = 0.09	
	Measure 2 Immunizations up to date	
	<b>Results</b> G1: 87% G2: 85% P = 0.45	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Earp et al., 2002	Eligible (N) 10 counties, 2441 women	Title of CHW Lay health advisor	Age (mean) G1: 46% < 65, 23% > 74
Author Year Earp et al., 2002 Trial Name North Carolina Breast Cancer Screening Program Objective or Aim Determine effectiveness of lay health advisor intervention, supplemented by limited number of other activities, aimed at increasing self-reported mammography use among African American women 50 years and older in eastern North Carolina; correcting beliefs about causes of breast cancer; increasing acceptance of need for regular mammography Geography Eastern NC Organization Black women Type of Community Mostly rural, 37% minority, 12% below FPL; low likelihood of having had mammogram	Eligible (N)	Title of CHW Lay health advisor  Paid or Volunteer Volunteer  Relationship with Community Members of community; same county  CHW (N) 170  Supervision of CHW Main analysis: - described in Earp JA, Viadro CI, Vincus AA, et al. Lay health advisors: a strategy for getting word out about breast cancer. Health Educ Behav. 1997;24:432–451. 412 - by "community outreach specialists" monthly (meetings and assistance  Prior Training NR  Type of Service Presentations to community groups and events, one-on-one conversations, use of informational/motivational materials  Type of Educational Materials Used Brochures, posters, church fans, holiday cards  Duration of Interaction with Clients 2 community activities per month; one-on-one	Age (mean)
Study Design Prospective cohort for main analysis Start Date 1993	<b>Group (N)</b> G1: 390 G2: 411	conversations once a week over a 24- month period, time per session NR Length of Follow-up	
Duration 4 years		32 months	

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR Quality of Life: NR	Health Outcomes: Measure 1 Pre/post percentage point difference in reported mammogram, adjusted for change in mammography attitude  Results • No recent mammogram at baseline: CHW advice: +9 diffused discussion: +10 project awareness: +15 • Recent mammogram at baseline: CHW advice: +8 diffused discussion: 0 project awareness: +5  Healthcare Utilization: Measure 1 Self-report of mammogram in past 2 years, stratified by	Costs (Economics): NR  Explanation of Overall Outcomes CHW community intervention is associated with significantly higher proportions of African- American women reporting having received mammograms, especially among lower income strata  Quality Rating Poor  Health Outcomes: NR
	income  Results < \$12k annually G1: pre 37%, post 59% G2: pre 49%, post 60% (adjusted $P = 0.02$ ); \$12k or greater annually G1: pre 56%, post 59% G2: pre 73%, post 82% (adjusted $P = 0.92$ )  Measure 2 Self-report of mammogram in past 2 years  Results G1: pre 41%, post 58% G2: pre 56%, post 67% (adjusted $P = 0.05$ )	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Elder et al., 2006; Elder et al., 2005	Eligible (N) 510 Enrolled (N)	Title of CHW Promotora Paid or Volunteer	Age (mean) G1: 38.6 (SD 10.1) G2: 40.4 (9.9) G3: 40.1 (9.8)
Trial Name Secretos de la Buena Vida  Objective or Aim Determine whether CHW + tailored print materials vs. tailored print materials vs. off- the-shelf print materials was more effective to maintain diet change at 1 y f/u  Geography San Diego County	Randomized (N) 357  Completers (N) 281  Withdrawals or Dropouts (N) 76  Health Condition of Interest Dietary behavior  Inclusion Criteria • Female • 18-65 y/o • Hispanic surname • Spanish-dominant	Relationship with Community Indigenous to community, Spanish language dominant, perceived as a community role model CHW (N) 4 Supervision of CHW NR Prior Training NR Type of Service G1: weekly home visits or	G3: 40.1 (9.8)  Sex (% female) 100  Race (%) Hispanic  Other Married G1: 94% G2: 93% G3: 93%;  BMI G1: 28.9 (SD 5.7) G2: 30.4 (5.6) G3: > 29.6 (5.4)  Role of CHW in Recruiting
Organization Spanish-dominant Latina Type of Community Central and southern regions Study Design RCT Start Date 2001 Duration 2 years	<ul> <li>Valid telephone number</li> <li>Exclusion Criteria</li> <li>Pregnant</li> <li>Medically prescribed diet</li> <li>Not remaining in San Diego</li> <li>Groups</li> <li>G1: CHW + tailored print</li> <li>G2: tailored print</li> <li>G3: control</li> <li>Interventions</li> <li>G1: CHW home visits and/or phone calls + tailored print materials</li> <li>G2: 12 weekly tailored newsletters and homework</li> <li>G3: 12 weekly off-the-shelf dietary printed material</li> <li>Group (N)</li> <li>G1: 120</li> <li>G2: 118</li> <li>G3: 119</li> </ul>	telephone calls + tailored health info newsletters G2: tailored health info newsletters G3: population-targeted print materials  Type of Educational Materials Used G1: negotiated behavioral change goals G1 and G2: tailored newsletters and activity inserts based on baseline participant data; magnets w/ healthy lifestyle messages; recipes G3: language-appropriate materials w/ dietary information developed for Latino popul  Duration of Interaction	and Retention NR Recruitment Rates NR Retention Rates G1: 93/120 = 78% G2: 90/118 = 76% G3: 98/119 = 82%
		with Clients 12 home visits or telephone calls over a 12-week period, 12 weekly tailored newsletters (duration per session NR) Length of Follow-up 1 year	

•	,	
Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1 % calories from fat (Nutrition Data System 24-h dietary recall interview)	Measure 1 Cost per unit of change Results
Quality of Life: NR	Results No significant difference between groups at 6 and 12 months post-intervention	Per reduced fat gm G1: \$8.28 G2: \$5.11 G3: \$1.30
	<b>Measure 2</b> Total gm fiber (Nutrition Data System 24-h dietary recall interview)	Per reduced saturated fat gm G1: \$21.09 G2: \$17.31 G3: \$3.21
	<b>Results</b> No significant difference between groups at 6 and 12 months post-intervention	Per reduced calorie G1: \$0.36
	<b>Measure 3</b> Total fat gm (Nutrition Data System 24-h dietary recall interview)	G2: \$3.21 G3: \$0.07 <b>Measure 2</b>
	Results	Per-participant cost
	No significant difference between groups at 6 and 12 months post-intervention	Results G1: \$135 G2: \$45
	<b>Measure 4</b> Post-intervention calorie/fat intake (using Nutrition Data System)	G3: 9  Explanation of Overall Outcomes
	Results kcal (P < .01) G1: 1,286.9 G2: 1,419.2 G3: 1,436.2 (G1-G3 P < .05 G1-G2 P < .1)	NR  Quality Rating  Poor
	Fat gm (P < .05) G1: 43.1 G2: 49.8 G3: 49.3 (G1-G3 p < .1 G1-G2 P < .05)	
	% fat cal G1: 29.3 G2: 30.4 G3: 30 (NS)	
	Saturated fat gm ( <i>P</i> < .05) G1: 14.4 G2: 16.9 G3: 16.6 (G1-G3 <i>P</i> < .1 G1-G2	
	Healthcare Utilization: NR	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

			Baseline
Study	Number (N)		Characteristics
Characteristics	Inclusion/Exclusion	Community Health	Recruiting and
Setting	Groups	Worker	Retention

Author Year Elder et al., 2006; Elder et al., 2005

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
		Measure 2 Dietary fiber intake (gm) (using Nutrition Data System)
		Results Total fiber gm G1: 16.1 G2: 17.2 G3: 15.6 (NS)
		Soluble fiber gm G1: 4.7 G2: 5.1 G3: 4.8 (NS)
		Insoluble fiber gm G1: 11.1 G2: 11.8 G3: 10.5 (NS)
		<b>Measure 3</b> Other dietary intake (via NDS)
		Results CHO gm (P < .05) G1: 171.2 G2: 187.3 G3: 187.1 (G1-G3 P < .05 G1-G2 P < .1)
		Glucose gm ( P < .01) G1: 16 G2: 21.1 G3: 18.4 (G1-G3 NS) G1-G2 P < .05)
		Fructose gm ( P < .001) G1: 16.9 G2: 22.7 G3: 19.1 G1-G3 NS G1-G2 P < .05 G2-G3 P < .1)
		Sucrose gm G1: 30.5 G2: 31.2 G3

6 months

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Erwin et al., 1997	Eligible (N) NA	Title of CHW Witness role model	Age (mean) G1: 52.5
<b>Trial Name</b> Witness project	Enrolled (N) 433	Paid or Volunteer NR	G2: 49.3 Sex (% female)
Objective or Aim Examine effectiveness of	Randomized (N) NA	Relationship with Community Shared race, cancer	100 Race (%) 100% African-American
Witness Project, a culturally competent cancer	Completers (N) 412	survivors CHW (N)	Other Role of CHW in Recruiting
education program that trains cancer	Withdrawals or Dropouts (N) 21  Health Condition of Interest	7 Supervision of CHW	and Retention NA
survivors to promote early detection and	BSE and mammography Inclusion Criteria	NR Prior Training	Recruitment Rates NA Retention Rates
increased breast self-examination and mammography	Inclusion criteria for women NR, churches selected from convenience sample	NR  Type of Service  Motivational speeches	NA NA
in population of rural, underserved, African American women	Exclusion Criteria NA	based on cancer survivor, experience of CHWs, breast self-exam lessons	
<b>Geography</b> Rural Mississippi	Groups G1: Intervention G2: Control	using a breast model, discussion of resources for free- and reduced-cost	
River Delta region of Arkansas  Organization	Interventions G1: Members of a Witness Project team, composed of 7 local African	mammograms  Type of Educational  Materials Used	
Church or community group	American women who had survived breast or cervical cancer, speak in groups of 2 to 5 at local	Duration of interaction	
Type of Community Neighborhood	churches and community organization meetings G2: Control group offered delayed	With Clients One presentation, time NR	
Study Design Prospective cohort	intervention  Group (N)	<b>Length of Follow-up</b> 6 months	
Start Date 1994	G1: 204 (152 aged ≥40) G2: 206 (140 aged ≥40)		
Duration			

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 Breast self exam in past month (self-report)	Costs (Economics): NR
Quality of Life: NR	Results G1: 49% to 65.4% ( <i>P</i> < 0.001 compared to baseline) G2: 65% to 72% ( <i>P</i> = NS compared to baseline)	Explanation of Overall Outcomes Through use of community churches and cancer survivors, breast cancer screening activities can be improved in this population
	Measure 2 Regular practice of breast self-exam (self-report)	
	Results Baseline	
	G1: 69.8% to 82% ( <i>P</i> = NS compared to baseline) G2: 82% to 82% ( <i>P</i> < 0.005 compared to baseline)	<b>Quality Rating</b> Fair
	Measure 3 Ever had mammography (self-report)	
	<b>Results</b> G1: 52.4% to 64.4% ( $P < 0.05$ compared to baseline) G2: 60.4% to 63.3% ( $P = NS$ compared to baseline)	
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Forst et al., 2004 Trial Name	Eligible (N) 36 farms, total workers NR Enrolled (N)	Title of CHW Promotor de salud Paid or Volunteer	Age (mean) G1: 33.5 G2: 32.4 G3: 32.8
NR  Objective or Aim Evaluate CHW model to reduce eye injuries and illnesses in Latino migrant and seasonal farmworkers  Geography SE Michigan,	34 farms, 1,000 workers  Randomized (N) 786  Completers (N) 703  Withdrawals or Dropouts (N) 83  Health Condition of Interest Eye injury Inclusion Criteria	NR  Relationship with Community Actively employed farm workers; Spanish fluency CHW (N) 16  Supervision of CHW Weekly with promotor- coordinators from study team	Sex (% female) G1: 24 G2: 19 G3: 15 Race (%) 90% Mexican 10% Mexican-American Other • Read Spanish: 77% • < 8 y school: 75%
northern Illinois  Organization Latino migrant and seasonal farm workers  Type of Community Farm workers; high incidence of eye injury	Farm owners' consent  Exclusion Criteria NR  Groups G1: CHW + protective eyewear + training + information sheet G2: CHW + eyewear + information sheet G3: Eyewear + information sheet	Prior Training Demonstrated leadership and communication skills; demonstrated respect for farm workers and owners  Type of Service G1: CHW worked w/ subjects, trained subjects on eye health and safety	<ul> <li>&lt; 4 y school: 25%</li> <li>Read English: 16%</li> <li>Role of CHW in Recruiting and Retention</li> <li>G1: Recruited and worked alongside subjects, collected data</li> <li>G2: Recruited, collected data</li> <li>Recruitment Rates</li> </ul>
Study Design Prospective cohort Start Date 2001 Duration 16 wk	Interventions G1: CHW worked w/ subjects, trained subjects on eye health and safety (minimum of 2 training sessions = 1 individual + 1 group) G2: CHW distributed eyewear w/o additional training G3: Research team distributed eyewear w/o additional training  Group (N) G1: 256 (141 IL, 115 MI) G2: 298 (179 IL, 119 MI) G3: 149 (78 IL, 71 MI)	G2: CHW distributed eyewear w/o additional training  Type of Educational Materials Used G1: Trainer training; reference manual on agricultural eye illness and injury; photos and fotonovelas; tool kit to demonstrate eye injuries and hazards  Duration of Interaction with Clients G1: At least 1 individual and at least 1 group session during farming season (duration per session NR)  Length of Follow-up 16 wk	786/1000 = 78.6%  Retention Rates G1: 67/186 = 36% G2: 172/198 = 87% G3: 76/107 = 71%

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: Measure 1	Health Outcomes: Measure 1 Cumulative number of eye injuries for season	Costs (Economics): NR Explanation of Overall
Pre/post change in % wearing safety glasses	Results IL 11 cases pterygium; MI 4 (both likely underreported)	Outcomes CHW intervention
Results Self-report: G1: 1.48 ( <i>P</i> < .0001) G2: 0.71 ( <i>P</i> < .0001) G3: 0.96 ( <i>P</i> < .0001)	Healthcare Utilization: NR	increased reported and observed use of protective eyewear, more so with associated training
G1-G2 $P < .0001$ G1-G3 $P = .03$ G1and 2-G3 $P = .0004$		<b>Quality Rating</b> Poor
Observed: G1: 1.1→36% G2: 0→5.2% G3: 0→14%)		
<b>Measure 2</b> Pre/post subject risk perception of eye injury		
Results Results not interpretable		
Quality of Life: NR		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Frate et al., 1985;	Eligible (N) NR	Title of CHW Hypertension Health	<b>Age (mean)</b> NR
Frate et al., 1983  Trial Name	Enrolled (N) NR	Counselors  Paid or Volunteer	Sex (% female) NR
NR Objective or Aim	Randomized (N) NA	Volunteer  Relationship with	Race (%) NR
Evaluation of different	Completers (N)	Community Native	Other
interventions to contol hypertension in a rural setting	667 Withdrawals or Dropouts (N) NR	<b>CHW (N)</b> 5	Role of CHW in Recruiting and Retention NR
Geography Central Mississippi	Health Condition of Interest Hypertension	Supervision of CHW NR	Recruitment Rates
<b>Organization</b> Cultural	Inclusion Criteria Patients with physician confirmed	Prior Training Certified and equipped to measure blood pressure	Retention Rates NR
Type of Community Hypertension and	hpertension  Exclusion Criteria  NA	Type of Service Monitoring BP, education and support	
rural community  Study Design Observational- quasi-experimental	Groups G1: Hypertension Health Counselors G2: Family based self help G3: Church based self help	Type of Educational Materials Used NR	
Start Date Early 1980's	Interventions	Duration of Interaction with Clients	
Duration 18 months	<b>Group (N)</b> G1: 207 G2: 131	Monthly visits over 18 months (time per session NR)	
	G3: 229	<b>Length of Follow-up</b> 18 months	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1 Proportion controlled	Costs (Economics): NR
Quality of Life:	Results G1: 80.6%	Explanation of Overall Outcomes NR
	G2: 90.0% G3: 79.9%	Quality Rating Extra Poor!
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Gielen et al., 2002 Trial Name NA  Objective or Aim Present results of an intervention trial to enhance parents' home- safety practices through pediatric safety counseling, home visits and an on-site children's safety center where paretns receive personalized education and can purchase reduced- cost products  Geography NR (probably Baltimore, MD)  Organization Pediatric resident continuity clinic in large, urban teaching hospital  Type of Community Same  Study Design RCT  Start Date NR  Duration 18 months	Eligible (N) 43 first- and second-year residents; 305 patients' parents  Enrolled (N) 39 residents; 187 families  Randomized (N) 39 residents; 187 families  Completers (N) 122 families  Withdrawals or Dropouts (N) 11 became ineligible, 15 refused further contact, 39 unable to contact  Health Condition of Interest Pediatric safety  Inclusion Criteria • Residents: all first- and second- year resdients • Parent-patient dyads of participating residents were then approached in clinic waiting room - elgibiliy criteria included infants 6 mos or younger, free of serious medical problems, caretakers were english-speaking and lived with child  Exclusion Criteria See prior  Groups G1: Standard intervention G2: Enhanced intervention Interventions Both groups of pediatric residents invited to attend 1-hour seminar on problme of injuries; both groups received 5-hr EAG training program G1: received safety counseling and referral to children's safety center from their pediatrician G2: received standard services plus "offer of" a home-safety visit from a CHW  Group (N) G1: 20 residents, 93 parents G2: 19 residents, 94 parents	Title of CHW CHW Paid or Volunteer NR Relationship with Community NR CHW (N) NR Supervision of CHW NR Prior Training NR Type of Service Home visits between 6 and 9 mo well child checks: assessed injury hazards; made recommendations about appropriate safety products and practices; referred families to CSC Type of Educational Materials Used NR Duration of Interaction with Clients 1 home-safety visit sometime between patient's 6- and 9-month well-infant visits (duration of session NR) Length of Follow-up NA	Age (mean) Mean age of mother = 24 years Sex (% female) Parents 98% female Race (%) 94% AA Other NR Role of CHW in Recruiting and Retention NA Recruitment Rates NA Retention Rates NA

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

P-value NR

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
<b>Measure 1</b> Poisons kept latched or locked	Healthcare Utilization: NR	Explanation of Overall Outcomes NR
Results G1: 12% G2: 10% P-value not reported		<b>Quality Rating</b> Fair
<b>Measure 2</b> Presence of ipecac		
Results G1: 27% G2: 31% <i>P</i> -value NR		
Quality of Life: Measure 1 Hot water ≤ 48.9 C		
Results G1: 47% G2: 47% <i>P</i> -value NR		
<b>Measure 2</b> Working smoke alarm		
Results G1: 84% G2: 81% <i>P</i> -value NR		
<b>Measure 3</b> Stairs protected by gate or door,		
Results G1: 23% G2: 27%		

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Graham et al.,	Eligible (N) 190 145 (190 total used to validate	Title of CHW Home visitors	Age (mean) 24 y
1992 Trial Name	instrument, but some were ineligible at > 28 wk)	Paid or Volunteer NR	<b>Sex (% female)</b> 100
NR Objective or Aim	Enrolled (N) 145	Relationship with Community	Race (%) Black 100%
Prevention of low birth weight using	Randomized (N) 87 in experimental group,	Shared race and gender having children of their own	Other
home intervention  Geography	145 overall  Completers (N)	<b>CHW (N)</b> 2	<ul><li> 38% primiparous</li><li> 11% married</li><li> 84% receiving Medicaid</li></ul>
Cleveland	52 in experimental group 110 total	Supervision of CHW	Role of CHW in Recruiting
Organization Organizational clinic-derived	Withdrawals or Dropouts (N) 35 out of 87 in experimental group	NR Prior Training	and Retention NR
sample  Type of	Health Condition of Interest Low birth weight	motherhood  Type of Service	Recruitment Rates  1326 screened
Community Inner city black	Inclusion Criteria  Black	Home visits: psychosocial support to patient and	<ul><li>190 high-risk</li><li>145 randomized</li></ul>
Study Design RCT	<ul> <li>Between 17th and 28th week of gestation</li> <li>Low family functioning score</li> </ul>	encouragement to family to be supportive of pregnancy, accomplished through	O1. 32/01 completed all +
Start Date 1987	<ul><li>At least 1 stressful life event prior to registration</li><li>Registering at study clinic during</li></ul>	education about pregnancy and encouragement of significant others to attend	visits (60%) G2: 100% (only birth information needed for this group)
<b>Duration</b> NR	specified period  Exclusion Criteria	home visits, clinic visits, clinic	
	<ul> <li>Living &gt; 5 mi from clinic</li> <li>Limited reading ability</li> </ul>	Type of Educational Materials Used NR	
	Groups G1: Experimental G2: Control	Duration of Interaction with Clients 4 visits (1 hour each) at 2-4	
	Interventions G1: Experimental - 4 home visits	week intervals for 2 to 5 months (until birth of child)	
	G2: Control  Group (N) G1: Experimental- 87 G2: Control - 58	<b>Length of Follow-up</b> Birth of child	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 LBW rate	Costs (Economics): NR
Quality of Life: NR	Results G1: (All): 12.9% ( <i>P</i> = 0.51) G1: (Completers): 7.7% ( <i>P</i> = 0.98) G2: 7.5%	Explanation of Overall Outcomes CHW home visits increased utilization of prenatal clinic care, but
	Healthcare Utilization: Measure 1	had no effect on LBW incidence
	Ratio of actual:expected prenatal clinic visits	Quality Rating
	Results G1 (All): 1.12 (SD 0.48, <i>P</i> = 0.029) G1 (Completers): 1.17 (SD 0.46, <i>P</i> = 0.007) G2: 0.93 (SD 0.44)	Fair

4 years

	Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
	Author Year Hiatt et al., 2008	<b>Eligible (N)</b> 25,000	Title of CHW Lay health workers	<b>Age (mean)</b> ~60% > 50 yrs
	Trial Name Breast and	Enrolled (N) NA	<b>Paid or Volunteer</b> Paid	<b>Sex (% female)</b> 100
	Cervical cancer Intervention Study (BACCIS)	Randomized (N) NA	Relationship with Community	Race (%) White: 31
	Objective or Aim Effect of Breast and Cervical	Completers (N) 1,616	Locally recruited  CHW (N)  NR	Black: 30 Latina: 14% Latina Chinese: 17% Other: 7%
	Cancer Intervention Study	Withdrawals or Dropouts (N) NR Health Condition of Interest	Supervision of CHW NR	Other NR
	(BACCIS), a multi- component	Cancer	Prior Training	Role of CHW in Recruiting
	intervention conducted in San Francisco Bay	Inclusion Criteria Women living in area of interest	Intensively trained in basic breast and cervical cancer biology, screening and	and Retention NR
	Francisco Bay Area between 1992 and 1997.	Exclusion Criteria NR	treatment, and availability of health care and	Recruitment Rates NR
	<b>Geography</b> San Francisco, CA	G1: Intervention	Type of Service Support and information	Retention Rates NR
	Organization	G2: Control Interventions	Support and information  Type of Educational	
	Hospital  Type of	G1: one-on-one visits at various events and locations; presentations	Materials Used NR	
	Community Income, Neighborhood	to community-based organizations (agencies); and Women's Health	Duration of Interaction with Clients	
	Study Design Modified 2x2 design in 8 neighborhoods	Days, offering free mammograms, Pap tests, and breast self- examination instruction.	Unspecified # of interactions (length per session NR) over 2 years	
		G2: Control	Length of Follow-up	
	Start Date 1993	<b>Group (N)</b> G1: 801 G2: 798	4 years	
	Duration			

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
Measure 1	Healthcare Utilization:	Explanation of Overall
Ever completed breast self- examination (Total N [%] pretest/Total N [%] posttest)	Measure 1 Ever completed mammography (Total N [%] pretest/Total N [%] posttest)	Outcomes NR
Results G1: 800 (89)/810 (92) $X^2 = NR, P=0.031$ G2: 793 (83)/ 802(81) $X^2 = NR, \text{ not significant}$	<b>Results</b> G1: 798 (83)/812 (86) $X^2 = NR$ , not significant G2: 798 (68)/ 803 (77) $X^2 = NR$ , $P = 0.001$	<b>Quality Rating</b> Fair
Measure 2 Completed breast self- examination monthly in past year (Total N [%]	Measure 2 Ever completed mammography (logistic regression, 95% CI)	
pretest/Total N [%] posttest)  Results	Results Residence in outreach area over time: 0.7 (0.5, 1.0)	
G1: 800 (24)/808 (26) $X^2$ = NR, not significant G2: 793 (18)/ 801(23) $X^2$ = NR, $P$ =0.018 <b>Quality of Life:</b> NR	Measure 3 Completed mammography in the past 2 years (Total N [%] pretest/Total N [%] posttest)	
	<b>Results</b> G1: 798 (73)/812 (71) $X^2 = NR$ , not significant G2: 798 (57)/ 803 (62) $X^2 = NR$ , $P = 0.022$	
	Measure 4 Completed mammography in past 2 years (logistic regression, 95% CI)	
	Results Residence in outreach area over time: 0.7 (0.5, 1.0)	
	Measure 5 Completed 3 or more mammographies in past 5 years (Total N [%] pretest/Total N [%] posttest)	
	<b>Results</b> G1: 794 (50)/812 (51) $X^2 = NR$ , not significant G2: 794 (35)/ 803 (41) $X^2 = NR$ , $P = 0.008$	
	<b>Measure 6</b> Completed 3 mammographies in past 5 years (logistic regression, 95% CI)	
	Results Residence in outreach area over time: 0.8 (0.5, 1.1)	
	Measure 7 Ever completed clinical breast examination (Total N [%] pretest/Total N [%] posttest)	

#### Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

			Baseline
Study	Number (N)		Characteristics
Characteristics	Inclusion/Exclusion	Community Health	Recruiting and
Setting	Groups	Worker	Retention

Author Year Hiatt et al., 2008 (continued)

Evidence Table C-1.	Key Questions 1, 2, and 3 (continued)	
Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
	<b>Results</b> G1: 801 (94)/812 (95) $X^2 = NR$ , not significant G2: 798 (82)/ 803 (87) $X^2 = NR$ , $P = 0.006$	
	Measure 8 Completed clinical breast examination in past year (Total N [%] pretest/Total N [%] posttest)	
	<b>Results</b> G1: 800 (75)/809 (74) $X^2 = NR$ , not significant G2: 796 (56)/ 803 (60) $X^2 = NR$ , not significant	
	Measure 9 Completed 3 or more clinical breast examinations in past 5 years (Total N [%] pretest/Total N [%] posttest)	
	<b>Results</b> G1: 793 (73)/809 (73) $X^2 = NR$ , not significant G2: 792 (54)/ 800 (54) $X^2 = NR$ , not significant	
	Measure 10 Ever completed pap smear (Total N [%] pretest/Total N [%] posttest)	
	<b>Results</b> G1: 801 (95)/812 (96) $X^2 = NR$ , not significant G2: 798 (83)/ 801 (87) $X^2 = NR$ , $P = 0.021$	
	<b>Measure 11</b> Ever completed Pap smear (logistic regression, 95% CI)	
	Results Residence in outreach area over time: 1.5 (0.6, 4.2)	
	Measure 12 Completed pap smear in past 3 years (Total N [%] pretest/Total N [%] posttest)	
	<b>Results</b> G1: 799 (84)/811 (87) $X^2 = NR$ , not significant G2: 798 (69)/ 801 (75) $X^2 = NR$ , $P = 0.009$	
	<b>Measure 13</b> Completed Pap smear in the past 3 years (logistic regression, 95% CI)	

Residence in outreach area over time: 0.9 (0.6, 1.3)

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Hunter et al., 2004	Eligible (N) 151	Title of CHW Promotora	<b>Age (mean)</b> 50.3 years
<b>Trial Name</b> NR	Enrolled (N) 103	Paid or Volunteer NR	Sex (% female) 100
Objective or Aim Test effectiveness of a CHW (promotora) program to increase compliance with annual preventive exams among uninsured Hispanic women, aged 40 and older, living at US-Mexico border Geography US-Mexico border communities:	Randomized (N) 101  Completers (N) 98  Withdrawals or Dropouts (N) 3  Health Condition of Interest Preventive care - Women's health Inclusion Criteria • Aged 40 or older • Residents of household • Not pregnant • At least 2 months postpartum • US women who participated in an	Relationship with Community NR CHW (N) NR Supervision of CHW NR Prior Training NR Type of Service Home visits; telephone calls to facilitate appt scheduling for annual preventive exams	Race (%) 96% Hispanic  Other  • Born in Mexico: 86%  • Blow federal poverty line: 76%  • Less than hs education: 77%  Role of CHW in Recruiting and Retention NA  Recruitment Rates NA  Retention Rates NA
Douglas, Arizona - 16,500 residents  Organization cultural/community  Type of Community Latina women  Study Design RCT  Start Date 1999  Duration 1 year	initial comprehensive clinical exam  Exclusion Criteria  Groups G1: Postcard G2: Promotora  Interventions G1: received postcards in mail 2 weeks before month their annual exams were due, printed in language used to complete original questionnaire G2: Received postcard reminders and were visited by promotora 2 weeks after postcard had been mailed. Promotora facilitated appointment scheduling, contacted them to facilitate	Type of Educational Materials Used None  Duration of Interaction with Clients One initial home visit and one final follow-up visit 8 weeks after postcard mailing to begin intervention(time per session NR)  Length of Follow-up NA	
	rescheduling if appt was missed. <b>Group (N)</b> G1: 50 G2: 51		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR	Measure 3	<b>Explanation of Overall</b>
Quality of Life: NR	Healthcare Utilization: Measure 1	<b>Outcomes</b> NR
	Returned to clinic for a second comprehensive annual exam	<b>Quality Rating</b> Fair
	Results G1: 48% (n = 24) G2: 65% (n = 33) RR, 1.35, 95% CI, 0.95-1.92	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Jandorf et al., 2005	Eligible (N) 125	<b>Title of CHW</b> Patient Navigator	<b>Age (mean)</b> G1: 61.1
<b>Trial Name</b> NR	Enrolled (N) NR	<b>Paid or Volunteer</b> Paid	G2: 61.2 Sex (% female) G1: 76.3
Objective or Aim To determine whether a patient navigator (PN) would enhance CRC screening	Randomized (N) 78  Completers (N) 78  Withdrawals or Dropouts (N)	Relationship with Community Shared community & ethnic background CHW (N)	G2: 72.5 <b>Race (% Hispanic)</b> G1: 78.9 G2: 85.0
participation beyond physician recommendation alone in a neighborhood healthcare setting.	Health Condition of Interest Colorectal cancer Inclusion Criteria	1 Supervision of CHW NR Prior Training NR	Other G1: Income ≤\$10,000: 72.2% ≥ HS education: 13.2% Had family history of cancer: 36.8%
Geography East Harlem, NYC Organization Inner city primary care practice Type of Community NR Study Design RCT	Men and women ≥ 50 yrs of age  Exclusion Criteria  FOBT within past yr; FS or barium enema within past 3-5 yrs; colonoscopy within past 10 yrs  Groups G1: Patient navigator G2: Usual care  Interventions G1: Navigated G2: Not navigated  Group (N)	Type of Service Assistance with completing screening process including written and telephone reminders, scheduling & assistance; education; support and advocacy Type of Educational Materials Used NR Duration of Interaction with Clients	G2:     Income ≤\$10,000: 64.1%     ≥ HS education:10.0%     Had family history of cancer: 38.5%  Role of CHW in Recruiting and Retention PN approached prospective participants  Recruitment Rates NR  Retention Rates
Start Date 2002 Duration 6 months	G1: 38 G2: 40	Telephone calls (unspecified #, unspecified length) over 6 month period  Length of Follow-up 6 months	NR

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR <b>Quality of Life:</b> NR	Healthcare Utilization: Measure 1 Completed FOBT after 3 months (% yes)	Explanation of Overall Outcomes NR
	Results G1: 42.1 G2: 25.0 P = 0.086	<b>Quality Rating</b> Fair
	Measure 2 Had endoscopy appointment at 3 months (%)	
	Results G1: 18.4 G2: 0 P = 0.005	
	Measure 3 Completed endoscopy at 3 months (%)	
	<b>Results</b> G1: 15.8 G2: 5.0 P = 0.115	
	Measure 4 Completed endoscopy at 6 months (%)	
	Results G1: 23.7 G2: 5.0 P = 0.019	

Author Year Korfmacher et al., 178   Filipible (N)   Title of CHW   Paraprofessional   G1: 19.44   G2: 20.24   G3: 19.70   G	Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
	Korfmacher et al., 1999; Olds et al., 2002; Olds et al., 2004;  Trial Name Home Visitation 2000  Objective or Aim Examine differences between CHWs and nurses in using home visitation to reduce incidence of child maltreatment; to examine distal effects of prenatal and infancy home visiting by CHWs or nurses, at 2-4 y/o  Geography Denver  Organization Recruited from prenatal clinics  Type of Community Low-income  Study Design RCT  Start Date 1994  Duration	Enrolled (N) 735  Randomized (N) 735  Completers (N) 560  Withdrawals or Dropouts (N) 175 (n at 24 month assessment), 130 (n at 4 year assessment)  Health Condition of Interest Child maltreatment; maternal and child health  Inclusion Criteria Pregnant; Medicaid-qualified or no private insurance  Exclusion Criteria Previous live birth  Groups G1: CHW visitation G2: nurse visitation G3: control  Interventions G1: Incremental developmental screening and referral + CHW home visitations G2: Developmental screening and referral + nurse home visitations G3: Developmental screening and referral Group (N) G1: 244 G2: 236	Paid or Volunteer Paid  Relationship with Community "Shared social characteristics"  CHW (N) 10  Supervision of CHW 2 LCSWs (2 supervisors to 10 visitors)  Prior Training HS education, no degree in "helping professions"; preferentially prior work experience in human services agencies  Type of Service Intensive home visitation: promoting healthy behaviors, competent child care, pregnancy planning, education, employment; linking to social and health services; promoting healthy family/friend relationships  Type of Educational Materials Used Visit-specific protocol, adapted to individual needs of mother  Duration of Interaction with Clients Every other week (except for weekly visits during first 4 weeks after enrollment and first 6 weeks after delivery) through child's 21st month, followed by monthly visits during final 3 months, ≈ 75 min per session	G1: 19.44 G2: 20.24 G3: 19.70  Sex (% female) 100  Race (%) G1: Hispanic: 45%,

# Knowledge, Attitude, and Behavior Quality of Life

#### Health Outcomes Healthcare Utilization

### Costs (Economics) Additional Outcomes

### Knowledge, Attitude, and Behavior:

Measure 1

Content of home visit, pregnancy

Results

Personal health G1 27%

G2: 38% (P < 0.001)

Environmental health

G1 15%

G2: 7% (*P* < 0.001)

Life course development

G1: 15%

G2: 14% (P < 0.05)

Parental caregiving

G1: 24% G2: 25%

Friends/family

G1: 19%

G2: 15% (P < 0.001)

#### **Health Outcomes:**

Measure 1

Language @ 21 mo (Preschool Lanaguge Scale)

Results

Least squares mean

G1: 99.89 G2: 101.22 G3: 99.49

Mean difference

G1-G3: 0.4 (-1.94 - 2.74) G2-G3: 1.73 (-0.64 - 4.11)

Least squares mean (low resource group)

G1: 97.83 G2: 101.52 G3: 96.85

Mean difference

G1-G3: 0.98 (-2.65 - 4.62) G2-G3: 4.67 (0.85-8.49,

Measure 2

Mental development delay @ 24 mo (Mental Development Index)

Results

Least squares mean

G1: 89.45 G2: 90.13 G3: 89.38 Difference

G1-G3: 0.07 (-2.39 - 2.53) G2-G3: 0.75 (-1.77 - 3.28)

Low resource group: least squares mean

G1: 88.54 G2: 90.18 G3: 86.2

Difference

G1-G3: 2.33 (-1.46 - 6.12) G2-G3: 3.98 (-0.07 - 8.02)

G1-G2 1.26

Measure 1

Subsequent fertility @ 24 mo

Results

Pregnancy G1: 33% G2: 29% G3: 41%

G1-G3: 0.7 (0.46-1.06, P < 0.1) G2-G3: 0.6 (0.39-0.93,  $P \le 0.05$ )

G1-G2: 0.88 (0.57-1.36)

G1-G2 (adjusted) = 0.82 (0.51-1.31)

### Costs (Economics): Measure 1

Per-family cost over 2.5 years (inflation adjusted, 2002 dollars)

**Results**G2: \$6,162
G3: \$9,140

Measure 3

Average cost (including salary + benefits, supplies, travel, rent, equipment, training) over approx 2.5 y

Results

G1: \$5,178/family G2: \$7,681/family

### Explanation of Overall Outcomes

CHWs were more likely than nurses to discuss environmental health and friends/family, life course development (after pregnancy), and less likely to discuss personal health (during pregnancy) and parental caregiving (after pregnancy): CHWs home visits have little significant effect on maternal & infant health outcomes, except for improved mother-child interactions among low psychological resource subpopulation; CHW visits showed improvement over control in maternal health but not in child health: nurse visit outcomes generally favored child health but not maternal

**Quality Rating** 

Fair

**Health Outcomes:** 

NR

**Key Questions 1, 2, and 3 (continued)** Evidence Table C-1.

			Baseline	
Study	Number (N)		Characteristics	
Characteristics	Inclusion/Exclusion	Community Health	Recruiting and	
Setting	Groups	Worker	Retention	

**Author Year** 

Korfmacher et al., 1999; Olds et al., 2002; Olds et al., 2004

(continued)

Evidence Table C-1. Key	y Questions 1, 2, and 3 (continued)	
Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Measure 3 Mother-infant interaction  Results Least squares mean G1: 100.15 G2: 100.31	Birth G1: 13% G2: 12% G3: 19% G1-G3: 0.63 (0.37-1.07, <i>P</i> < 0.1) G2-G3: 0.58 (0.33-1.01, <i>P</i> ≤ 0.05) G1-G2: 0.9	
G3: 98.99 G1 vs. G3: 1.16 (-0.11 - 2.42, P < 0.1) G2 vs. G3: 1.32 (0.03-2.60, P ≤ 0.05) Least squares mean difference G1 vs. G2 (low resource group) = 0.06 (01.87 - 1.98), adjusted 0.08 (-1.99 - 2.16)	Healthcare Utilization: NR  Measure 2 Maternal life course  Results Married G1: 32% G3: 44% (P = 0.02)	
Quality of Life: Measure 1 Home environment	Living w/ bio father G1: 33% G3: 43% ( <i>P</i> = 0.03)	
Results Least squares mean G1: 37.4 G2: 37.79 G3: 37.1; Mean difference G1-G3: 0.3 (-0.49 - 1.1) G2-G3: 0.69 (-0.12 - 1.5, P < 0.1) Least squares mean difference (low resource group) G1-G2: 0.26 (-0.95 - 1.47), adjusted -0.05 (-1.35 - 1.24)	Working at child 2-4 y/o G1: 15 mo G3: 13 mo $(P = 0.04)$ Sense of mastery G1: 101 G3: 99 $(P = 0.03)$ Mental health score G1: 101 G2: 99 $(P = 0.03)$ No G1-G3 difference on education, welfare <b>Measure 3</b> Mother-child interaction	
Measure 3 Post-intervention reductino in urine cotinine levels among smokers (ng/mL)	Results Sensitive responsive interactions during free play G1: 101	
Results G1: 89 G2: 259 G3: 12 (NS) Least squares mean difference G1 vs G2: 189.16 (-51.38 - 429.69), adjusted 266.75 (-3.34 - 536.84) Mean difference G1 vs. G3 -76.19 ng/dL (95% CI, -302.21,-149.82) G2 vs. G3 -246.68 ng/dL (95% CI, -466.19,-27.16) P≤0.05	G3: 99 ( <i>P</i> = 0.03); no difference G2 vs G3  Measure 4  Home environment (Home Observation for Measurement of Environment inventory)  Results  For low psychologic resource group: environment supportive of early learning G1: 24.63  G2: 24.61  G3: 23.35 (G1-G3 <i>P</i> = 0.03  G2-G3: <i>P</i> = 0.03)	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Krieger et al., 1999	Eligible (N) 759	Title of CHW Community health worker	<b>Age (mean)</b> 24.9% < 40 y/o
Trial Name Seattle Hypertension	Enrolled (N) 421	Paid or Volunteer NR	18.3% > 64 y/o Sex (% female) 27.8
Intervention Project  Objective or Aim  Determine whether tracking and	Randomized (N) 421  Completers (N) 397	Relationship with Community Similar income community, predominantly black (12/14) CHW (N)	Race (%) 79.1% Black Other 40% uninsured
outreach intervention delivered by community health workers improved medical follow-up of persons whose elevated blood pressure detected during blood pressure measurement at community sites  Geography Seattle  Organization Various community	Withdrawals or Dropouts (N) 110  Health Condition of Interest Hypertension  Inclusion Criteria  • BP at least 140/90  • 18+ y/o  • Black or White race  • Income no more than 200% FPL (1995)  Exclusion Criteria See inclusion criteria  Groups G1: Intervention G2: Usual care	Supervision of CHW NR Prior Training NR Type of Service Medical referral, telephone appt scheduling, appt reminder letter, post-appt f/u, rescheduling missed appt, assistance with other barriers to care (e.g. transportation) Type of Educational Materials Used	Role of CHW in Recruiting and Retention Providing initial BP measurement Recruitment Rates 55.5% (421 enrolled of 759 eligible) Retention Rates G1: 95% G2: 93%
sites: social services agencies, food banks, shelters/missions, public libraries, grocery stores, community centers, etc.  Type of Community Low-income neighborhoods  Study Design RCT  Start Date 1994  Duration 28 months	Interventions G1: CHW assistance with medical follow-up G2: advice to see medical provider, list of public and community clinics Group (N) G1: 209 G2: 212	Duration of Interaction with Clients Various, brief interactions over 3 months (time per session NR) Length of Follow-up 3 months	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR  Quality of Life: NR	Healthcare Utilization: Self-report of completed f/u appt (validated by medical provider report)	Explanation of Overall Outcomes CHW intervention was
	<b>Results</b> G1: 65.1% completed f/u within 90 days G2: 46.7% ( <i>P</i> = 0.001)	associated with significantly higher proportion of subjects completing HTN follow- up exam within 90 days
		<b>Quality Rating</b> Fair

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Krieger et al., 2002; Krieger et al., 2005 <sup>47,48</sup>	Eligible (N) 447 Enrolled (N) 274	Title of CHW Community Home Environmental Specialists (CHES)	Age (mean) G1: 7.4 G2: 7.3 Sex (% female)
Trial Name Seattle-King County Health	Randomized (N) 274	Paid or Volunteer Paid	G1: 44.2 G2: 38.2
Homes Project (SKCHH)	Completers (N) 214	Relationship with Community Connection to and	Race (%) Non-Hispanic White G1: 12.3
Objective or Aim Assess effectiveness of a	Withdrawals or Dropouts (N) 60	understanding of community; shared ethnic, linguistic, and	G2: 21.3 Non-Hispanic AA G1: 31.9
CHW intervention focused on reducing	Health Condition of Interest pediatric asthma	cultural background with project participants;	G2: 27.9 Vietnamese G1: 25.4
exposure to indoor asthma triggers	<ul> <li>Inclusion Criteria</li> <li>A household was eligibile if:</li> <li>home to a child 4-12 years with diagnosed persistent asthma</li> </ul>	recognition as a person who can be respected and trusted	G1: 25.4 G2: 22.1 Other Asian G1: 9.4 G2: 5.2
<b>Geography</b> King Co, Washington	<ul> <li>income &lt; 200% of 1996 federal poverty threshold</li> <li>child enrolled in Medicaid</li> </ul>	CHW (N) 6 Supervision of CHW	Hispanic G1: 17.4 G2: 17.7
Organization Low income urban households	<ul> <li>caregiver verbally proficient in English, Spanish or Vietnamese</li> <li>child spent ≥ 50% of nights in house</li> <li>house was in King County.</li> </ul>	NR Prior Training NR	Other G1: 3.6 G2: 5.9
Type of Community Low income urban households with	Exclusion Criteria A child with another chronic illness requiring daily medications; household participation in other asthma case management or care coordination	Type of Service home visits  Type of Educational	Other Household had at least 1 asthma trigger: 75%
child diagnosed with asthma	programs in past 2 years; plans to leave King County during next 6 months	Materials Used NR	Urgent health use in past 2 months (%) G1: 25.9
Study Design RCT	Groups G1: high intensity G2: low intensity	Duration of Interaction with Clients	G2: 21.3 Smoker in home (%)
Start Date 1999 Duration	Interventions G1: Initial home environmental assessment and	4 to 9 visits over 12 months (time per session NR)	G1: 39.9 G2: 41.9
1 year	individualized action plans specifying participant and CHES actions to reduce household exposures. CHES made additional visits over 12-month period to provide	Length of Follow-up 1 year	Severe persist asthma G1: 32.6 G2: 23.5
	education and social support, materials to reduce exposures (e.g., bedding covers, vacuums); free allergy testing; advocacy for improved housing conditions.  G2: Single CHES visit which consisted of initial		Role of CHW in Recruiting and Retention Cannot determine
	environmental assessment, home action plan, limited education, and bedding encasements		Recruitment Rates NR
	<b>Group (N)</b> G1: 138 G2: 136		Retention Rates G1: 80% G2: 76%

### Knowledge, Attitude, and Behavior Quality of Life

### **Knowledge, Attitude, and Behavior: Measure 1**

Behavior summary score of trigger reduction behaviors (vacuum and dust child's bedroom at least twice/2 weeks, vacuum cloth-covered furniture at least twice/2 weeks or remove it, use doormat or remove shoes, use allergy control covers on mattress and pillow

#### Results

Across groups comparison: GEE coefficient (95% CI): 0.41 (-0.13, 0.95); P = 0.141 frequencies of actions to reduce dust exposure and use of bedding encasements increased more in high-intensity group. Kitchen ventilation improved more in low-intensity group. Neither group increased frequency of washing sheets or dusting nor reduced exposure to pets (although pet ownership was uncommon among participants) and smoking in home. behavior summary score improved in both groups, and across-group difference was not significant

### Quality of Life: Measure 1

Pediatric Asthma Caregiver Quality of Life Scale (score range 1-7 with higher scores indicating better QoL)

#### Results

Score at exit (G1 vs. G2): 5.6 vs. 5.4 GEE coefficient 0.58 (95% CI, 0.18, 0.99), P = 0.005; NNT = 4.8 ITT analysis yielded simalr results: improvements in QoL were greater in G1 (data NR, P = 0.009)

#### Measure 2

Asthma symptom days (self-reported # of 24-hour periods during 2 weeks before interview with asthma symptoms: wheeze, tightness in chest, cough, shortness of breath, slowing down activities due to asthma, nighttime awakenings)

#### Results

G1 vs. G2 at exit: 3.2 vs. 3.9 GEE coefficient -1.24 (95% CI, -2.9, 0.4), P = 0.138

### Health Outcomes Healthcare Utilization

### Health Outcomes: Measure 1

Days with activity limitation/2 weeks

#### Results

Score at exit (G1 vs. G2): 1.5 vs. 1.7 GEE coefficient -1.5 (95% CI, -2.84, -0.15), OR 0.22 (0.06, 0.86), P = 0.29

#### Measure 2

Missed school in past 2 weeks (%)

#### Results

G1 vs. G2 at exit: 12.2 vs. 20.3 GEE coefficient -0.77 (95% CI, -1.70, 0.16), OR 0.46 (0.18, 1.18), P = 0.105

#### Measure 3

Urgent health services use/2 months (%)

#### Results

G1 vs. G2 at exit: 8.4 vs. 16.4 GEE coefficient -0.97 (95% CI, -1.8, -0.12), OR 0.38 (0.16, 0.89), P = 0.026; NNT = 12.9

ITT analysis yielded simalr results: improvements in urgent health services were greater in G1 (data NR, *P* = 0.062)

#### Measure 4

Days used controller medication/2 weeks

#### Results

G1 vs. G2 at exit: 3.5 vs. 3.6 GEE coefficient -1.03 (95% CI, -2.79, 0.73), P = 0.250

#### Measure 5

Days used beta2-agonist/2 weeks

#### Results

G1 vs. G2 at exit: 4.0 vs. 4.0 GEE coefficient -0.23 (95% CI, -1.88, 1.42), P = 0.781

#### Measure 6

Missed work in past 2 weeks (%)

#### Results

G1 vs. G2 at exit: 11.2 vs. 13.0 GEE coefficient 0.07 (95% CI, -0.91, 1.0.5), OR 1.07 (0.40, 2.85), P = 0.890

#### **Healthcare Utilization:**

NR

### Costs (Economics) Additional Outcomes

### Costs (Economics): Measure 1

Urgent care costs (hospital admissions, ER visits, unscheduled clinic visits)

#### Results

Two months before exit interview G1 \$6301-\$8856 (\$57-\$80/child) less than G2. Estimated decrease in 2 month costs between baseline and exit:

G1: \$22084-\$36700 (\$201-\$344/child) vs. G2: \$19246-\$32756 (\$185-\$315/child)

## Explanation of Overall Outcomes NR

Quality Rating

Good

**Health Outcomes:** 

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Levine et al., 2003	Eligible (N) 817	<b>Title of CHW</b> Community health worker	<b>Age (mean)</b> G1: 53.8
<b>Trial Name</b> NR	Enrolled (N) 789	Paid or Volunteer NR	G2: 54.6  Sex (% female)
Objective or Aim Compare program effectiveness and intervention efficacy of more and less intensive education/behavior interventions on control of SBP  Geography Sandtown- Winchester Community, Baltimore  Organization inner city  Type of Community Urban African- American Study Design RCT  Start Date NR  Duration	Randomized (N) 789  Completers (N) 471  Withdrawals or Dropouts (N) 318  Health Condition of Interest Hypertensive heart disease Inclusion Criteria African-American adults w/ HTN (140+/90+)  Exclusion Criteria • Terminal conditions • Mental impairment • Acute conditions precluding participation  Groups G1: More intense intervention G2: Less intense intervention Interventions G1: G2 care + 5 CHW visits with BP measurement, addressing issues of BP management and access to medical care	Relationship with Community Indigenous to community CHW (N) NR Supervision of CHW Nurse-supervised Prior Training NR Type of Service Home visits; BP measurement; education; assistance with access to care Type of Educational Materials Used Counseling; BP tracking card; educational pamphlet Duration of Interaction with Clients 6 visits over 2.5 years (length per visit NR) Length of Follow-up 40 mo	G1: 61.2 G2: 62.5  Race (%) 100'% African-American  Other  • HS-level education: 42% • < HS: 45% • Unemployed: 32% • Income < \$10k: 65% • With usual source of care: 79% • Uninsured: 20%  Role of CHW in Recruiting and Retention • Initial neighborhood surveillance • Recruiting for individual RCT  Recruitment Rates 0.97  Retention Rates G1: 240/387 = 62% G2: 231/402 = 57%
30 months	G2: CHW home visit for education, counseling, and referral  Group (N) G1: 387 G2: 402		

Evidence Table C-1.	Key Questions 1, 2, and 3 (continued)
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Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1	Costs (Economics): NR
NR	BP change (unadjusted systolic/diastolic ± SE; adjusted systolic/diastolic ± SE)	Explanation of Overall
Quality of Life: NR	Results G1: -5.5±1.5/-4.1±0.9; 5.6±1.5/-3.8±1.0) G2: -3.2±1.5/-2.9±1.0; -3.3±1.5/-2.6±1.0) P < .005 for differences between baseline and followup for each group, no differences between groups	Outcomes CHW intervention produced significant pre/post change in proportion of HTN under control in both
	Measure 2 % with adequate HTN control ( < 140/90)	arms, but no difference between arms; no significant pre vs post
	Results G1: $16\% \rightarrow 36\%$ G2: $18\% \rightarrow 34\%$ pre/post $P < .01$ group difference NS	change in BP classification within or between arms; more intensive group had less favorable results
	Measure 3 Pre/post BP (systolic/diastolic)	than less intensive group
	Results	<b>Quality Rating</b> Fair
	G1: 147.7/89.2 (95% CI, 145.5, 149.9 / 87.8, 90.6) → 145/86.2 (95% CI, 142.3, 147.7 / 84.2, 88.2) G2: 148.6/89.3 (95% CI, 146.4, 150.7 / 87.8, 90.8) → 142.1/84.7 (95% CI, 138.8, 145.4 / 82.7, 86.7)	<b>Health Outcomes:</b> NR
	P < 0.05 for differences between baseline and followup for eachHealthcare	
	Measure 4 JNC-VI classification pre/post	
	Results No significant differences	
	Utilization: NR	

Characteristics Inclusion/Exclusion	Community Health	Baseline Characteristics
Setting Groups	Worker	Recruiting and Retention
	Title of CHW Community lay workers (promotoras)  Paid or Volunteer paid  Relationship with Community bilingual clinic employees CHW (N) NR  Supervision of CHW PI attended every class  Prior Training NR  Type of Service Classroom: 8 weekly 2-hour group classes; Biweekly Telephone calls  Type of Educational Materials Used Developed by certified health educator with promotoras, based on ADA Guidelines  Duration of Interaction with Clients 8 weekly 2-hour classes + biweekly telephone calls for 8 weeks followed by biweekly postcards for 16 weeks 24 weeks total duration of interaction with participants  Length of Follow-up 6 months	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: Measure 1	Health Outcomes: Measure 1 HgbA1c	Costs (Economics): NR
Bilingual DKQ - validated: 24 itms designed for Mexican Americans and elicits	Results Baseline(SD)/6 months(SD): G1: 8.21(2.2)/7.76(1.87)	Explanation of Overall Outcomes NR
information about respondent's understanding of cause of diabetes, types	G2: 7.71(1.47)/8.01(1.8)  Mean change between groups: <i>P</i> < 0.001	<b>Quality Rating</b> Good
of diabetes, self- management skills, and complications of diabetes	Measure 3 HgbA1c - validated Results	
Results Baseline/ 6 months (SD): G1: 69.1 (13.6)/77.2 (14.4) G2: 66.9 (15.2)/65.1 (21.0) (P < .002 for mean change between groups)	At 6 months: G1: 7.76 G2: 8.01 ( <i>P</i> < .001)	
	Healthcare Utilization: NR	
Measure 2		
Diabetes Health Belief Measure (DHBM)		
Results Baseline(SD)/6 months(SD):		
G1: 56.4(12.2)/54.6(8.4) G2: 57.0(10.6)/50.8(13.6) Mean change between groups: <i>P</i> < 0.01		
Quality of Life: NR		

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Mock et al., 2007	Eligible (N) NR	Title of CHW Lay health worker	<b>Age (mean)</b> G1: 45.7
<b>Trial Name</b> Vietnamese REACH for Health	Enrolled (N) 1005	Paid or Volunteer Paid, \$1500	G2: 46.0 Sex (% female) G1: 100
Initiative  Objective or Aim	Randomized (N) NR Completers (N)	Relationship with Community Shared race/ethnicity,	G2: 100  Race (%)
Increase cervical cancer screening rates	968 Withdrawals or Dropouts (N)	physical community  CHW (N) 50	Vietnamese 100  Other  Mean years in US
Geography Santa Clara County, CA	37  Health Condition of Interest Pap screening	Supervision of CHW Non clinician	G1: 8.92 G2: 9.23
Organization Commnity	Inclusion Criteria  • Vietnamese American	Prior Training NR	Self-rated speaking English poorly/not at all G1: 56.3% G2: 57.7%
Type of Community Vietnamese American women	<ul> <li>Female</li> <li>≥18 years</li> <li>Living in Santa Clara County</li> </ul>	Type of Service Small group gatherings, direct contacts to help access medical services	> HS education G1: 57.5% G2: 54.8%
Study Design RCT	Exclusion Criteria NR Groups	and schedule appts  Type of Educational  Materials Used	Married G1: 61.3% G2: 64.3%
Start Date 2001	G1: CHW + media G2: media only	Prepared presentation with flip chart, QandA	Employed G1: 26%
<b>Duration</b> 3 years	Interventions G1: CHW small group meetings, direct contact with subjects,	Duration of Interaction with Clients 2 sessions of 90 or 120	G2: 27.1% Role of CHW in Recruiting
	Vietnamese language ads for TV/radio/newspaper, booklets and printed materials in various community locations G2: Vietnamese language ads for TV/radio/newspaper, booklets and	minutes each plus	and Retention CHW recruited subjects from within her own social
		Length of Follow-up 3-4 months	network  Recruitment Rates G1: 100%
	printed materials in various community locations, delayed educational session		G2: 100% Retention Rates
	<b>Group (N)</b> G1: 491 G2: 477		G1: 97.8% G2: 94.8%

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
Measure 1 Reported awareness of need for Pap by women 18+ y/o	Healthcare Utilization: Measure 1 Self-report of Pap in past year	Explanation of Overall Outcomes CHW + media
Results G1: 68.4→93.9% ( <i>P</i> < 0.001) G2: 68.5→70.2% ( <i>P</i> = 0.55);	Results G1: 45.7→67.3% ( <i>P</i> < 0.001) G2: 50.9→55.7% ( <i>P</i> = 0.035); Z test <i>P</i> < 0.001	intervention significantly increases understanding of and utilization of Pap
Z-test P < 0.001)	Measure 2 Ever had Pap test (among those who had not had Pap	compared to media intervention alone
Measure 2 Reported awareness of need	test preoutreach)	Quality Rating
for pap test by women 18+ years old	<b>Results</b> G1: 46.0 (N = 144)	Fair
Results	G2: 27.1 P < .001 (N = 161)	
G1: 81.8%/99.6% ( <i>P</i> < 0.001) G2: 87.2%/95.2% ( <i>P</i> <	Measure 3 Self-report of having ever had Pap	
0.001) Z-test <i>P</i> < 0.001	Results G1: 65.8→81.8% (P < 0.001) G0: 70.4 → 75.5 (P → 0.004): 7 to at P → 0.004	
Quality of Life: NR	G2: $70.1 \rightarrow 75.5 \ (P < 0.001)$ ; Z test $P = 0.001$	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Morisky et al.,	Eligible (N) NR	Title of CHW Community health worker	<b>Age (mean)</b> 53.5 (SD 12.0)
2002; Ward et al., 2000	Enrolled (N) 1367	Paid or Volunteer NR	<b>Sex (% female)</b> 59.2
Trial Name Community Hypertension	Randomized (N) 1367	Relationship with Community Same ethnic group as	Race (%) Black: 77% Hispanic: 21%
Intervention Project (CHIP)	Completers (N) NR	patient, language concordant	Other
Objective or Aim Develop effective	<b>Withdrawals or Dropouts (N)</b> NR	CHW (N) NR	<ul><li>&lt; HS education: 49%</li><li>Married: 33%</li><li>Income &lt; \$14k/y: &gt; 87%</li></ul>
strategies for enhancing treatment	Health Condition of Interest Hypertension	Supervision of CHW NR	<ul><li>Public insurance: 54%</li><li>Uninsured: 30%</li></ul>
adherence for hypertensive minority populations	Inclusion Criteria Adult w/ diagnosis of HTN attending county hospital clinic or private health clinic	Prior Training 1 month interview training program	Role of CHW in Recruiting and Retention Interviews with new enrollees
Geography Large West Coast city	Exclusion Criteria NR	Type of Service Counselling after clinic visits, or home visits	Recruitment Rates > 98% overall
Organization County medical center	Groups G1: Individualized CHW pt counseling G2: Appt tracking	Type of Educational Materials Used Education on treatment, lifestyle modification info,	Retention Rates NR
Type of Community Low-income, inner-	G3: CHW home visits + voluntary discussion group attendance G4: Usual care	info on community resources	
city Blacks and Hispanics	Interventions G1: CHW post-clinic appt counseling session	Duration of Interaction with Clients G1: 5-10 min after each	
<b>Study Design</b> RCT	G2: Appt reminder cards and phone calls	clinic visit G3: variable	
<b>Start Date</b> NR	G3: Home visits by CHW G4: Standard clinic care	Number of visits, duration per session,	
<b>Duration</b> 4 years	<b>Group (N)</b> G1: 330 G2: 328	time period over which interactions occurred NR	
	G3: 333 G4: 328	<b>Length of Follow-up</b> 12 mo	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1 BP Control	Costs (Economics): NR Explanation of Overall
Quality of Life: NR	Results G1: 35.2% @ baseline,     46% @ 6 and 12 mo (P < 0.01) G2: 40.2% @ baseline     42% @ 6 mo     48% @ 12 mo (P < 0.01) G3: 29.7% @ baseline %NR but "improved" @ 6 & 12 mo G4: 36.9% @ baseline % NR but "improved"	Explanation of Overall Outcomes NR Quality Rating Poor
	No significant differences vs. control - all groups improved	
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Nacion et al., 2000	Eligible (N) 218	Title of CHW Maternal-Child Health	<b>Age (mean)</b> 58% 20+ y/o
<b>Trial Name</b> REACH-Futures	Enrolled (N) 213	Advocate  Paid or Volunteer	<b>Sex (% female)</b> 100
Objective or Aim Can maternal-child	Randomized (N) 213	Paid Relationship with	Race (%) • African-American: 90%
health advocates, working with	Completers (N) 213	Community Within community, minority	• Latina: 9% Other
professional nurses, provdie health screening,	Withdrawals or Dropouts (N)	<b>CHW (N)</b> 11	<ul><li> &lt; HS education: 51%</li><li> Gravida-1: 53%</li></ul>
problem identification, self and infant care	Health Condition of Interest Maternal and child health	Supervision of CHW Validation by nurse after each visit	Role of CHW in Recruiting and Retention NA - CHW visits were unit of
information, and referrals in a safe manner?	Inclusion Criteria Home visit accomplished by CHW with validating follow-up by nurse	Prior Training Minimum HS or GED; experience in community	analysis  Recruitment Rates  NA - CHW visits were unit of
<b>Geography</b> Chicago	Exclusion Criteria Visit conducted by CHW + nurse	service	analysis
Organization	together	Type of Service Intensive home visits for	Retention Rates NA - CHW visits were unit of
inner city  Type of  Community	Groups G1: CHW visit G2: nurse visit	assessment, problem solving, emotional support, and information	analysis
Predominantly African-American and Latino	Interventions NR	Type of Educational Materials Used NR	
Study Design Retrospective cohort	<b>Group (N)</b> G1: 213 G2: 213	Duration of Interaction with Clients	
Start Date 1992		Length of Follow-up NR	
<b>Duration</b> 32 mo			

Evidence Table C-1.	Key Questions 1, 2, and 3 (continued)
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Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: NR	Costs (Economics): NR
Quality of Life: NR	Healthcare Utilization: Measure 1 Agreement in identifying problems	Explanation of Overall Outcomes  CHW and nurse home visits were comparable in most regards  CHW more likely to identify problems and provide problem solving  Nurse more likely to provide referrals and emotional support  Quality Rating Fair
	<b>Results</b> CHW more likely to identify problems in woman's health $(P=0.01)$ , well child health care deficits $(P=0.02)$ , parenting $(P=0.02)$ , socioeconomic $(P<0.01)$ ; most visits identified no problems	
	Measure 2 Agreement in placing referrals	
	<b>Results</b> Nurse more likely to make referrals for woman's health $(P = 0.01)$ , well woman $(P = 0.02)$ , emotional/interpersonal, parental support, and socioeconomic $(P < 0.01)$ ; most visits involved no referrals	
	Measure 3 Services provided (per completed Maternal-Child Activity form)	
	Results Problem solving G1: 16% G2: 7% (P < 0.01)	
	Emotional support G1: 4% G2: 14% ( <i>P</i> < 0.01)	
	Assessment, information: No difference between groups	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Characteristics Recruiting and Retention
Author Year Navarro et al.,	Eligible (N) NR	Title of CHW Consejeras	Age (mean) • Average: 34
1998; Navarro et al., 1995;	Enrolled (N) 512	Paid or Volunteer NR	• Range: 18-72 Sex (% female)
Navarro et al., 2000	Randomized (N) 512	Relationship with Community	100 Race (%)
<b>Trial Name</b> Por La Vida Damos	Completers (N) 365	Member of Latino community perceived, as "natural helpers" by	Latina: 100 Other
Cuenta Program  Objective or Aim	Withdrawals or Dropouts (N) 147	community	<ul> <li>Median gross family income: \$12,000</li> </ul>
To describe impact of intervention	Health Condition of Interest	<b>CHW (N)</b> 36	Median years of formal education: 7
known as Por La Vida (PLV) on cancer screening	Breast and cervical cancer Inclusion Criteria	Supervision of CHW Yes"unobtrusive	<ul><li>Born in Mexico: 92%</li><li>Avg acculturation: 2</li></ul>
for Latinas in San Diego, California	Part of social network of consejeras recruiting participants. No other inclusion criteria reported.	observations" of ongoing sessions and debriefing sessions with consejeras	Role of CHW in Recruiting and Retention CHW recruited all
Geography Southeast area of	Exclusion Criteria NR	each month by PLV "staff" but no reporting of who these staff members are	participants through social networks
San Diego County, CA	Groups G1: Lower intensity CHW	Prior Training NR	Recruitment Rates
Organization Low-income Latino communites	intervention G2: Higher intensity CHW intervention	Type of Service Small group educational	Retention Rates G1: 68.1 G2: 72.6
Type of Community Low-income Latino women	Interventions G1: CHW delivering Community Living Skills sessions, details NR G2: CHW delivering Cancer	Type of Educational Materials Used Pamphlets, work sheets,	
Study Design RCT	education sessions, 12 weekly group sessions conducted over 3-	posters, plastic models of female body, pelvic models	
Start Date NR	months plus 2 additional sessions offered within a year of beginning of group meetings	Duration of Interaction with Clients 12 sessions of 90 minutes	
<b>Duration</b> NR	Group (N)	each over 3 months	
	G1: 18 consejeras, 238 women G2: 18 consejeras, 274 women	Length of Follow-up 3 months 1 and 2 year followup	

Baseline

Evidence Table C-1. Key Questions 1, 2, and 3 (co
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Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1	Costs (Economics): NR
NR  Quality of Life:  NR	Pretest-posttest changes in % of women performing monthly BSEs  Results  Participant unit of analysis (n = 361) G1: 18.5 G2: 33.2 P < 0.001 t = 3.23  Consejera unit of analysis (n = 35)	Explanation of Overall Outcomes Increase in use of cancer screening tests higher in PLV cancer intervention group compared to community living skills (control) group
	G1: 18.6 G2: 31.8 P = 0.021 t = 2.43 Measure 3 Pretest-posttest changes in % of women ≥40 yrs who had	Results from 1 and 2 yr followup suggest that cancer screening rates in Latinas of low socioeconomic level with limited a
	mammogram within past year  Results	Quality Rating Poor
	Participant unit of analysis (n = 113) G1: 7 G2: 21.4 P = 0.029 t = 2.22 Consejera unit of analysis (n = 33) G1: 6.8	Health Outcomes: Measure 1 Odds of montly BSE 1 yr and 2 yr followup for cancer screening group (P value)
	G1: 0.0 G2: 24.3 P = 0.063 t = 1.96	<b>Results</b> Year 1: 2.03 (.016) Year 2: 0.96 (.877)
	Healthcare Utilization: Measure 1 Pretest-posttest changes in % of women who had physical breast exam within past year	Measure 2 Odds of CBE 1 yr and 2 yr followup for cancer screening group (P value)
	Results Participant unit of analysis (n = 359) G1: 15.5 G2: 17.7	Results Year 1: 1.21 (.556) Year 2: 1.93 (.038)
	P = 0.589 t = 0.54 Consejera unit of analysis (n = 35) G1: 19.3 G2: 19.5	Measure 3 Odds of mammogram 1 yr and 2 yr followup for cancer screening group (P value)
	P = 0.967 t = 0.04	Results Year 1: 1.50 (.484) Year 2: 3.88 (.018)

Evidence Table C-1. **Key Questions 1, 2, and 3 (continued)** 

			Baseline
Study	Number (N)		Characteristics
Characteristics	Inclusion/Exclusion	Community Health	Recruiting and
Setting	Groups	Worker	Retention

**Author Year** 

Navarro et al.,

1998; Navarro et al., 1995; Navarro et al., 2000

(continued)

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
	Measure 2 Pretest-posttest changes in percentages of women who had a Pap test within past year	<b>Measure 4</b> Odds of pap smear 1 yr and 2 yr followup for
	Results Participant unit of analysis (n = 360) G1: 16.2 G2: 23.1 $P = 0.096$ t = 1.67	cancer screening group (P value)  Results Year 1: 2.10 (.017) Year 2: 1.70 (.082)
	Consejera unit of analysis (n = 35) G1: 18.4 G2: 23.4 P = 0.369 t = 0.91	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Parker et al., 2008	Eligible (N) 510	Title of CHW CES	<b>Age (mean)</b> G1: 9.01
Trial Name Community Action Against Asthma (CAAA)	Enrolled (N) 328 Randomized (N)	Paid or Volunteer NR Relationship with	G2: 8.8  Sex (% female) G1: 43 G2: 41
Objective or Aim Evaluate a CHW intervention to improve children's asthma-related	328  Completers (N) 227  Withdrawals or Dropouts (N) 101	Community Detroit residents; 2 were bilingual (Spanish and English) CHW (N)	Race (%) African American G1: 83 G2: 79
health by reducing household environmental	Health Condition of Interest pediatric asthma	Supervision of CHW NR; however, there was	Hispanic G1: 11 G2: 10
triggers for asthma  Geography Eastside and southwest Detroit, MI	Inclusion Criteria Child 7-11 years with persistent asthma (defined as any of following being true: one or more daytime symptoms reported as being present "more than two times per week,"; sleep	a steering committee of community members, health agencies, etc. involved in project; also CHWs had continued training throughout	Caucasian G1: 4 G2: 5 Other G1: 3 G2: 6
Organization Urban households with children attending neighborhood	disturbance reported "more than two times per week"; and daily use of doctor-prescribed medicine for respiratory symptoms) living in southwest or eastside Detroit	intervention period  Prior Training NR  Type of Service	G2: 6  Other  Caregiver smokers (%) G1: 40 G2: 35
elementary schools  Type of Community Urban neighborhoods with	Exclusion Criteria Children who lived outside of defined geographic area or were monolingual in a language other than Spanish or English were excluded from study.	Type of Educational Materials Used Written materials on on dangers of ETS exposure	Moderate-severe persistent asthma G1: 51 G2: 44
child with asthma  Study Design  RCT	Groups G1: CHW G2: Control	for children with asthma Global Initiative for Asthma booklet	Household income < \$10000 G1: 37 G2: 46
Start Date 2000 Duration 1 year	Interventions G1: Environmental assessment; asthma action plan based on allergy tests; education and social support; social support; mattress covers, pillows, vacuum, cleaning supplies; counseling on environmental tobacco smoke; integrated pest management services; minimum 9 planned home visits over 12 months G2: Asthma information booklet, full	Duration of Interaction with Clients At least 9 visits over 12 months (time per session NR Length of Follow-up 1 year	Role of CHW in Recruiting and Retention No role; CES was assigned cases Recruitment Rates NA Retention Rates G1: 77% G2: 75% (Does not include 30 postrandomization
	intervention after 12 months  Group (N) G1: 150 G2: 148		exclusions)

Results Intervention Effect (OR-  Results  G1: Symptoms occurring less frequently at baseline for all eight symptoms assessed  G2: Symptoms occurring less frequently for 6 of 8  Results  Outcomes  NR  Quality Rating	Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
intervention/OR-control) Vacuum cleaner used: 29.5 (6.90, 126); P < 0.0001  Allergen cover on child's pillow: 19.7 (4.12, 94.2); P = 0.0006  Allergen cover on child's mattress: 9.70 (4.33, 21.7); P < 0.0001  Visible mold growth remo  Measure 3  Caregiver depressive symptoms measured by CES-D  Results  Mean @ Baseline/Endpoint G1: 1.62/1.54 G2: 1.58/1.64 P = 0.0218  Improvements in both instrumental and emotional social support combined and instrumental support alone were not statistically significant (data NR)  Quality of Life:  NR  Persistent cough baseline, post-intervention: G1: 3.81, 3.36 G2: 3.48, 3.44 P = 0.034  Cough w/ exercise baseline, post: G1: 4.27, 3.69 G2: 3.80, 3.66 P = 0.017  Healthcare Utilization: Measure 1 Has any symptom more than 2 days/week and not on a corticosteroid  Results G1 (pre/post) vs. G2 (pre/post) Intervention Effect (95% CI): 60/42 vs. 51/46; 0.56 (0.29, 1.06); P = 0.073  Measure 2 Has any symptom more than 2 days/week and not on any controller  Results G1 (pre/post) vs. G2 (pre/post) Intervention Effect (95% CI: 53/32 vs. 38/37; 0.39 (0.20, 0.73); P = 0.004  Measure 3 Reduction in unscheduled health care utilization for asthma  Results Needed unscheduled medical care G1 (pre/post) vs. G2 (pre/post) Intervention Effect (95% CI): In last 12 months: 65/59 vs. 58/73; 0.40 (0.22, 0.74); P =	and Behavior Quality of Life  Knowledge, Attitude, and Behavior: Measure 1 Behavior to reduce asthma triggers in house  Results Intervention Effect (OR- intervention/OR-control) Vacuum cleaner used: 29.5 (6.90, 126); P < 0.0001 Allergen cover on child's pillow: 19.7 (4.12, 94.2); P = 0.0006 Allergen cover on child's mattress: 9.70 (4.33, 21.7); P < 0.0001 Visible mold growth remo  Measure 3 Caregiver depressive symptoms measured by CES-D  Results Mean @ Baseline/Endpoint G1: 1.62/1.54 G2: 1.58/1.64 P = 0.0218 Improvements in both instrumental and emotional social support combined and instrumental support alone were not statistically significant (data NR)  Quality of Life:	Health Outcomes: Measure 1 Child's average asthma symptom frequency  Results G1: Symptoms occurring less frequently at baseline for all eight symptoms assessed G2: Symptoms occurring less frequently for 6 of 8  Persistent cough baseline, post-intervention: G1: 3.81, 3.36 G2: 3.48, 3.44 P = 0.034  Cough w/ exercise baseline, post: G1: 4.27, 3.69 G2: 3.80, 3.66 P = 0.017  Healthcare Utilization: Measure 1 Has any symptom more than 2 days/week and not on a corticosteroid  Results G1 (pre/post) vs. G2 (pre/post) Intervention Effect (95% CI): 60/42 vs. 51/46; 0.56 (0.29, 1.06); P = 0.073  Measure 2  Has any symptom more than 2 days/week and not on any controller  Results G1 (pre/post) vs. G2 (pre/post) Intervention Effect (95% CI: 53/32 vs. 38/37; 0.39 (0.20, 0.73); P = 0.004  Measure 3  Reduction in unscheduled health care utilization for asthma  Results Needed unscheduled medical care G1 (pre/post) vs. G2 (pre/post) Intervention Effect (95% CI):	Additional Outcomes  Costs (Economics): NR  Explanation of Overall Outcomes NR

	Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
	Author Year Paskett et al., 2006; Katz et al., 2007	Eligible (N) 1,503 Enrolled (N)	Title of CHW Lay health advisor Paid or Volunteer	Age (mean) 55.1 Sex (% female)
	Trial Name ROSE (Robeson County Outreach Screening and Education)	901 Randomized (N) 897 Completers (N) 820	Relationship with Community Ethnicity: 2 native American and 1 African-American	<ul><li>Race (%)</li><li>African-American: 33%</li><li>Native American: 42%</li><li>White: 25%</li></ul>
	Objective or Aim To use LHAs to deliver individualized health education to improve rates of mammography screening	Withdrawals or Dropouts (N) 77  Health Condition of Interest Breast cancer screening Inclusion Criteria Women withdrawals	CHW (N) 3 Supervision of CHW LHA supervisor checked in weekly by phone or inperson to discuss cases and problems; periodic attendance of LHA	Other NR Role of CHW in Recruiting and Retention NA Recruitment Rates NA
	Geography Robeson County, NC Organization Community health centers - Robeson	past 12 months  Exclusion Criteria  Mentally or physically unable to participate, unreachable, language/hearing barrier  Groups G1: Control	supervisor during patient visits  Prior Training 1 nurse, 1 social worker, 1 research study interviewer  Type of Service home visits, phone calls	Retention Rates NA
Health Care Corporation (federally funded, four centers)  Type of Community County  Study Design RCT  Start Date February 1998  Duration 4 years	Interventions G1: Control sent letter and NCI brochure about need for regular cervical cancer screening 6 months after random assignment, followed by letter and NCI brochure about need for mammography 3 months after follow-up assssment G2: Individualized health education program that was culturally acceptable and tailored to meet needs of each woman, intensive face-to-face interactive educational program administered over a 9- to 12 month period, consisting of 3 in-person visits, with educational materials provided each visit and follow-up phone calls and mailings after  Group (N) G1: 444	Type of Educational Materials Used written, culturally sensitive Duration of Interaction with Clients Two visits, 45-60 minutes, and 30-45 minutes, two intervening telephone calls, and a final visit (duration of final visit NR) over 9 to 12 months Length of Follow-up 14 months		
		G1: 444 G2: 453		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
Measure 1 Composite belief scores (higher is better)	Healthcare Utilization: Measure 1 Cervical cancer screening rates within risk-appropriate	Explanation of Overall Outcomes NR
Results	guidelines	Quality Rating
G1: 6.95 G2: 7.55 ( <i>P</i> = 0.004)	Results Significant differences between baseline and followup	Good
<b>Measure 2</b> Composite knowledge	for both groups, no significant differences between intervention and control groups	
scores Results	Measure 2 Mammogram receipt from medical record data	
Specific scores NR, <i>P</i> value for G1 = 0.002, G1 < 0.001, no statistically significant differences	<b>Results</b> G1: 27.3% G2: 42.5%, RR = 1.56, 95% CI, 1.29 to 1.87, <i>P</i> < .001; significant differences within racial groups as well	
Quality of Life: NR	Measure 3 Intervention cost divided by additional mammograms in LHA group compared with usual care	
	Results \$4,986 per additional mammogram in LHA group	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Pilote et al., 1996	Eligible (N) 297	<b>Title of CHW</b> Peer health adviser	Age (mean) Median
<b>Trial Name</b> NR	Enrolled (N) 244	<b>Paid or Volunteer</b> Paid	G1: 40 G2: 39 G3: 40
Objective or Aim Peer health advisers familiar with homelessness and ways of street could facilitate access to health care for TB in a homeless population.  Geography San Francisco, CA  Organization Homeless population  Type of Community Lack of neighborhood (homeless)  Study Design RCT  Start Date June 1992	Randomized (N) 244  Completers (N) 173  Withdrawals or Dropouts (N) 71  Health Condition of Interest TB  Inclusion Criteria Homeless men and women, PPD positive  Exclusion Criteria recent follow-up  Groups G1: Peer health advisor G2: Monetary incentive G3: Usual care  Interventions G1: Peer health advisor- met with patient and took them to clinic appointment, facilitated paperwork, reviewed physician recommendations	Relationship with Community Also homeless CHW (N) 7 Supervision of CHW NR Prior Training NR Type of Service Took client to clinic and helped with proccess Type of Educational Materials Used None Duration of Interaction with Clients NR - met client and went to clinic within a 3 week period (duration of session NR) Length of Follow-up 3 weeks	G3: 40  Sex (% female) G1: 13 G2:19 G3:16  Race (%) G1: African American: 48 White: 33 Hispanic: 16 G2: African American: 57 White: 27 Hispanic: 11 G3: African American: 54 White: 27 Hispanic: 13  Other  Role of CHW in Recruiting and Retention NR  Recruitment Rates NR  Retention Rates NR
<b>Duration</b> 23 months	G2: Monetary incentive - \$5 at clinic, appointment and bus tokens G3: Usual care - appointment and bus tokens	o weeke	
	<b>Group (N)</b> G1: 83 G2: 82 G3: 79		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
NR  Quality of Life:	Healthcare Utilization: Measure 1	Explanation of Overall Outcomes
NR	Adherence to first follow-up appointment % (95% CI) P versus usual care - unclear how obtained	<b>Quality Rating</b> Fair
	<b>Results</b> G1: Peer health advisor 75 (70-80) $P = 0.004$ G2: Monetary incentive 84 (76-92) $P < 0.001$ G3: Usual care 53 (47-59)	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Rask et al., 2001;	Eligible (N) 3050	Title of CHW Outreach worker	<b>Age (mean)</b> 9 months
LeBaron et al., 2004 <sup>63</sup>	Enrolled (N) 3050	Paid or Volunteer NR	Sex (% female) 51
Trial Name NA	Randomized (N) 3050	Relationship with Community	Race (%) 93% minority (black or
Objective or Aim (1) Prospectively measure costs of 3	Completers (N) NR	African American woman raised in inner-city Atlanta	Hispanic) Other
different registry- based interventions implemented in an urban indigent	Withdrawals or Dropouts (N) 304 not exposed to intervention (within intervention arms)	<ul> <li>Bilingual Hispanic worker</li> <li>CHW (N)</li> </ul>	NR Role of CHW in Recruiting and Retention NR
population and (2) evaluate how size of	Health Condition of Interest Pediatric immunizations	Supervision of CHW Doctorate in community	Recruitment Rates
targeted population affects cost estimates	Inclusion Criteria Children aged < 12 months seen in a county public health clinic	psychology and extensive experience in conducting inner-city studies	NR Retention Rates NR
<b>Geography</b> Fulton County, GA	Exclusion Criteria NR	Prior Training College-educated	
Organization MATCH (Metro Atlanta Team for Child Health) immunization registry: community- based partnership between two county health agencies, local nonprofit, federally qualified community health centers  Type of Community See prior  Study Design RCT  Start Date 1996  Duration 22 months (35 mo for follow-up contact; 53 months for electronic acquisition of vaccine information)	Groups G1: AUTODIAL G2: OUTREACH worker G3: combination of 1 and 2 G4: CONTROL  Interventions G1: Autodial -received an automated telephone call or postcard to remind families 7 calendar days before child was due to be immunized. Patient received postcard if no number or nonworking. Delivered recorded message from head medical staff. G2: Outreach - contacted by outreach worker following a standardized protocol initated by a phone call wihtin 1 week. outreach worker made reminder call before appt if time known. if child remained behind next monht, a home visit was attempted monthly until contact was made.  Group (N) G1: 763 G2: 760 G3: 764	Type of Service Phone calls, home visit for appointment reminder, assistance in overcoming barriers to appointment for pediatric immunizations if needed Phone calls, home visits  Type of Educational Materials Used NR  Duration of Interaction with Clients At least one telephone call, followed by repeat calls and home visit if no telephone contact, over 15 months or less (time per interaction NR)  Length of Follow-up 15 months	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 1 Vaccine Series complete from immunization registry	Costs (Economics): Measure 1 Average monthly costs
Quality of Life: NR	<b>Results</b> No statistical difference between CHW and control groups	to dleiver immunization interventions per child
	Healthcare Utilization: NR	Results G1: \$1.34 G2: \$1.87 G3: \$2.76
		Explanation of Overall Outcomes NR
		Quality Rating Good

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Welsh et al., 2005 <b>Trial Name</b> Tepeyac Project	Eligible (N)  • Latina only analysis: 4,739; <sup>64</sup> • Latina vs. white analysis: 6,696 <sup>65</sup> Enrolled (N)  NA	Title of CHW Promotora (peer counselors)  Paid or Volunteer Paid	Age (mean) Latina only analysis: Not specified; <sup>64</sup> Latina vs. white analysis G1: Latina 59 (SD 4.1); non-Latina 57.5 (4.3) G2: Latina 58 4 (4.4):
Objective or Aim To increase breast cancer screening rates among Latinas in Colorado; 64 To compare effect of promotora vs printed statewide interventions on mammogram rates of Latinas and non-Latina whites (NLWs) enrolled in Medicaid fee-forservice program 65 Geography Colorado Organization Catholic Churches, Latina Women Type of Community Church communities Study Design Retrospective cohort Start Date 2000 Duration 5 yrs	Randomized (N) NA  Completers (N) Latina only analysis: 4739 <sup>64</sup> ; Latina vs. white analysis: 6696 <sup>65</sup> Withdrawals or Dropouts (N) NA  Health Condition of Interest Breast cancer screening Inclusion Criteria Latina only analysis:  Latinas (identified through race and ethnicity data combined with surnames)  Aged 50 to 69 years  Continuously enrolled in insurance plan (Medicaid or Medicare) for longer than 23 months with no gap in coverage longer than 30 days  Survived entire baseline or follow-up period <sup>64</sup> Latina vs. white comparison:  White or Latina women (identified through race and ethnicity data)  Aged 50-64 years  Enrolled in CO Medicaid at least 18 mo during baseline and follow-up periods <sup>65</sup> Exclusion Criteria NR  Groups G1: Promotora Intervention - study	Relationship with Community Shared community and ethnicity CHW (N) NR Supervision of CHW NR Prior Training NR Type of Service Peer "approach" after Sunday mass and during church-related activities; facilitation of home discussion groups Type of Educational Materials Used Letter describing project Bilingual printed materials from NCI that promote breast ca screening and reflect a sense of family Display unit Short bilingual messages suitable for delivery from pulpit and publication in church bulletins Duration of Interaction with Clients At least bimonthly meetings(length NR) over 5	G2: Latina 58.4 (4.4); non-Latina 57.9 (4.5) <sup>65</sup> Sex (% female) 100  Race (%) Latina only analysis: 100% Latina; <sup>64</sup> Latina vs. white analysis G1: 52% Latina, 48% non-Latina white G2: 26% Latina, 74% non-Latina white G3: 40% Latina T4% non-Latina white C5: 40% Latina T4% non-Latina white C6: 40% Latina T4% non-Latina white C7: 40% Latina T4% non-Latina white C7: 40% Latina T4% non-Latina white C8: 40% Latina T4% non-Latina white C9: 40% Latina T4% non-Latina T4% non-Latina T4% non-Latina T4% non-Latina T5% Latina
	subjects living in zip codes of churches visited by promotoras during 2000 and 2001 G2: Printed intervention - Subjects living in remaining zip codes	years  Length of Follow-up  NA	

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: NR Healthcare Utilization:	Costs (Economics): NR
Quality of Life: NR	Measure 1 comparison of mammography rates by intervention and ethnicity, via ICD codes on Medicaid claims (pre/post time-intervention interaction term by GEE)	Explanation of Overall Outcomes CHW intervention in churches resulted in slight improvement in
	<b>Results</b> Latina, G1 vs. G2 adjusted GEE $P = 0.07$ Non-Latina, G1 vs. G2 adjusted GEE $P = 0.10$	mammography rates among Medicaideligible Latinas, no statistically significant difference in ethnic disparities within promotora group, increased disparities in non promotora group (because non Latina
	<b>Measure 2</b> Pre/post mammography rates via ICD codes on Medicaid claims	
	Results Latina only analysis G1: 59 to 61% G2: 58% at baseline and followup, unadjusted rates not significant in either group, GEE model adjusting for insurance group, age, income, rural vs. urban, and disability found increased biennial mammograms in	
	Intervention group $(P=0.03)$ ; 64  Latina vs. white analysis G1: Latina 25 $\rightarrow$ 30% (unadjusted GEE $P=0.3$ ); non-Latina 32 $\rightarrow$ 38% (unadjusted GEE $P=0.4$ ) G2: Latina 45 $\rightarrow$ 43% (unadjusted GEE $P=0.27$ ); non-Latina 41 $\rightarrow$ 44% (unadjusted GEE $P=0.02$ ) 65	Fair

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Sauaia et al., 2007; Welsh et al., 2005 (continued)	Interventions G1: Trained peer counselors (Promotoras) delived health promotion message personally, through meetings held at least bimonthly immediately after mass and through other church events, conducted health groups that met at home of one of participants, same newsletter used in printed Intervention G2: Printed intervention incorporated into church display, bulletin and/or pulpit announcements		
	Group (N) Latina only analysis G1: 4 churches, N at baseline: 536, N at followup: 590 G2: 209 churches, N at baseline: 5130, N at followup: 5708; <sup>64</sup>		
	Latina vs. white analysis G1: 4 churches, N at baseline: 197, N at followup: 211 G2: 209 churches, N at baseline		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude,		Costs (Economics)
and Behavior	Health Outcomes	Additional
Quality of Life	Healthcare Utilization	Outcomes

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Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Schuler et al.,	Eligible (N) NR	Title of CHW Lay Visitors	Age (mean) 27 years
2000 Trial Name	Enrolled (N) 192 families	Paid or Volunteer NR	<b>Sex (% female)</b> 100
NR  Objective or Aim  Effects of home-	Randomized (N) 192	Relationship with Community Shared ethnicity African American women who "knew	Race (%) African American: 96%
based intervention on mother-infant	Completers (N) 171	community"	<b>Other</b> NR
interaction among drug using women and their infants	Withdrawals or Dropouts (N) 21 families Not at all clear from article: "study included 171 families (87 control,	CHW (N) 3- 2 for intervention, one for control group	Role of CHW in Recruiting and Retention
to compare mother–infant	84 intervention). 31 dyads were lost before 2-week baseline visit, and 32	Supervision of CHW Visitors met with a psychologist	NR
interaction among drug-using	additional families lost after 2-week visit (see Table 1). Thus, 192 (97 control, 95	and a pediatrician weekly to track progress of families and to	Recruitment Rates NR
mothers who did and did not	intervention) families seen for 6-month evaluation visit. Observation data	discuss concerns about families	Retention Rates NR
receive home- based intervention	dropped from 13 families because interaction involved caretaker other than	Prior Training Past experience making home	
<b>Geography</b> Maryland NR	mother, and data from 8 families were lost because of mechanical difficulties"	visits, no additional details provided	
Organization Organizational recruited from	Health Condition of Interest Infant health Maternal drug use; mother- child interaction	Type of Service G1: home intervention was developmentally oriented and was based on program used	
large university hospital	Inclusion Criteria Women were eligible if they or their	by IHDP- visitors went once a week enhancing mothers'	
Type of Community Drug abuse Inner	infants had a positive urine toxicology screen at birth or history of recent drug use was noted in medical charts.	ability to manage self- identified problems by using existing services and family	
city, African- American	Exclusion Criteria Infants who were not discharged into	and social supports; modelling infant development behavior/activities	
<b>Study Design</b> RCT	care of their mothers or had serious developmental or congenital problems that required special services (e.g.,	G2: brief monthly home tracking visits to reduce attrition	
Start Date NR	spina bifida)	Type of Educational Materials Used	
<b>Duration</b> 6 months	Groups G1: CHW G2: Control	HELP at Home: Hawaii Early Learning Profile	
o monuis	Interventions	Duration of Interaction with	
	G1: Visits to enhance mothers' ability to manage self-identified problems by using existing services and family and social supports; modeling infant	Clients G1: 9 visits, about 30 minutes per visit G2: 3 visits, about 17 minutes each	
	development behavior/activities G2: Meetings for tracking purposes only	Length of Follow-up	
	<b>Group (N)</b> G1: 84 G2: 87	6 months	

Evidence Table C-1.	Key Questions 1, 2, and 3 (continued)
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Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR	Health Outcomes: Measure 3 Self-reported maternal drug use	Costs (Economics): NR
Quality of Life:	Results	Explanation of Overall Outcomes
Measure 1 Infant warmth measured by assessment of videotaped mother-infant interaction using previously validated scale	At 6 months, there were no significant group differences in cocaine and/or heroin use, alcohol use, or marijuana use during last 6 months	No direct effects of intervention, in control group, mothers who continued to use drugs
	Healthcare Utilization:	were less responsive to their babies than
Results  No difference between groups. In control group, mothers who continued to use drugs were less responsive to their babies		mothers who were drug free. In intervention group, drug use was not associated with maternal responsiveness.
than were mothers who were drug free. In intervention group, drug use was not associated with maternal		<b>Quality Rating</b> Fair

Author Year Schwarz et al., 1993  Trial Name Safe Block Project  Objective or Aim Improve injury prevention knowledge and reduce number of hazards in home and reduce rates of injury occurring to residents of an inner city community.  Eligible (N) 34 203 (17,058 intervention = approx 5,890 homes; 17,145 control)  Enrolled (N) 2722 4476 (3004 received intervention, 1472 control homes randomly selected)  Relationship of Community Shared community	### 5-17 ### 18-6 ###	5 yrs: 9.3%, 7 yrs: 17.6%, 64 yrs: 53.7%, 4 yrs: 19.5% 5 yrs: 9.9%, 7 yrs: 18.9%, 64 yrs: 58.1%, 4 yrs: 13.1%
Trial Name Safe Block Project  Objective or Aim Improve injury prevention knowledge and reduce number of hazards in home and reduce rates of injury occurring to residents of an inner city  Enrolled (N)  2722 4476 (3004 received intervention, 1472 control homes randomly selected)  Relationship of Community Shared community Share	with Sex (%) safety liaisons an Or volunteer ors and 10 ors.  of CHW Sex (%)  Sex (%)  Sex (%)  Race (%)  Control or	4 yrs: 19.5% 5 yrs: 9.9%, 7 yrs: 18.9%, 64 yrs: 58.1%, 4 yrs: 13.1% 6 female) (%) rican-American: 96.8%,
Geography Philadelphia  28% not inspected in each group (348 intervention, 412 control)  Granization  28% not inspected in each group (348 intervention, 412 control)  From Injury Cor of Philadelphia of Public Health	ntrol Section a Department th.  Other Injuries reside	rican-American: 95.7%, er: 4.3% s in 1987- rate per 1000 nts
Social Home Safety Prior Training NR  Type of Community Neighborhood High injury rate  NR  Type of Servic Consus tracks with highest injury rates in community  NR  Type of Servic Safety inspection modifications, i	ce Role co and Role inspections, Block	5.7 of CHW in Recruiting etention Representatives were
Study Design Prospective case- control observational Quasi- experimental; non-  Study Design Prospective case- control Observational Quasi- experimental; non-  Exclusion Criteria NA inability to contact household residents  Groups  and education; safety devices detectors, ipecate emergency phonumbers, light batteries, bathway thermometer)	(e.g. smoke participate cac, one NR	to urge neighbors to pate in project.  itment Rates  tion Rates
random controlled trial  Interventions  Home modification for simple prevention measures  Home inspection to inform residents about hazards and ways of alleviating them  Type of Educa Materials User NR direct teach safety inspector	ational ed hing from ors	
Education about selected injury prevention practices.      Group (N)     G1: 17 085     G2: 17 145  For postintervention assessments, 1250 of 3004 homes were randomly selected. assessments were conducted in 902 of1250 homes  1 home visit an block meetings month-period (session NR)  Length of Foll  12 months	s over 18 (duration per	

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Evidence Tuble 6 1.	y wacstions 1, 2, and 5 (continued)	
Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
<b>Measure 1</b> No syrup of ipecac for children < 5 yrs	Healthcare Utilization: NR	Explanation of Overall Outcomes Principal positive
Results G1: 29% G2: 90.2% P < 0.001 Adjusted OR, 0.04 95% CI, 0.02-0.07		finding of this study is a distinct difference between control and intervention homes with respect to safety
Measure 2 Inadequate light on stairs		knowledge and home hazards that required minimal to moderate
Results G1: 17.9% G2: 19.9% P = 0.41 Adjusted OR, .41 95% CI, 0.69-1.16		effort to correct. Intervention homes were found to be safer than control homes, particularly with respect
<b>Measure 3</b> Hot water ≥125°F		to hazards related to fires and poisonings.
Results G1: 36.8% G2: 26.8% P < 0.001 Adjusted OR, 1.73 95% CI, 1.39, 2.15		<b>Quality Rating</b> Poor
<b>Measure 1</b> No bedside light for > 64 yrs adults		
Results G1: 13.3% G2: 15.1% P = 0.90 Adjusted OR, 1.03 95% CI, 0.68- 1.57		
Measure 2 No smoke detectors		
Results G1: 4% G2: 23% P < 0.001 Adjusted OR, 0.14 95% CI, 0.09- 0.20		
Quality of Life: NR		

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Silver et al., 1997	Eligible (N) 512	Title of CHW Lay Intervenor	Age (mean) Mother's age
Author Year Silver et al., 1997 Trial Name Parent to Parent Network  Objective or Aim Evaluate psychological outcomes of Parent-To-Parent Network (PTPN), a community-based support program for mothers of five- to eight-year-old children with a variety of ongoing health conditions  Geography NYC - Bronx; or Lower Westchester  Organization Organizational Large urban medical centers; community-based delivery of intervention  Type of Community Mothers that have children with chronic disease	Eligible (N) 512  Enrolled (N) 365 mothers  Randomized (N) 365  Completers (N) 94% completed 12 month interview (343)  Withdrawals or Dropouts (N) 6% LTF  Health Condition of Interest Maternal health Mothers' psychiatric well-being  Inclusion Criteria • Five-to-eight-year-old children who had ongoing health conditions (defined as one that had lasted or was expected to last for at least three months or had required hospitalization for 30 days or more in previous year) • Mother could speak conversational english and live with her child in catchment area • Have easy access to a phone  Exclusion Criteria A family was excluded if child was moderately or severely mentally retarded or had a life expectancy under 18 months.	Title of CHW Lay Intervenor  Paid or Volunteer NR (guessing paid) Paid ("accepted jobs")  Relationship with Community Shared experience Same neighborhoods (recruited via community newspapers); raised children with ongoing healht conditions  CHW (N) 3  Supervision of CHW Supervised by a clinical psychologist and a social worker - frequency NR  Prior Training 40 hours plus intensive training  Type of Service Counselling, face-to-face meetings; telephone calls; group activities with others in program  Type of Educational Materials Used NR  Duration of Interaction	Retention  Age (mean) Mother's age G1: 34.7 G2: 34.0  Children's age G1: 7.2 G2: 7.0  Sex (% female) 100% female (mothers) Children G1: (45%) G2: (47%)  Race (%) Mother's ethnicity % Hispanic G1:43 G2: 46  Black G1: 41 G2:32  White, not Hispanic G1:11 G2: 17  Mixed/Other G1: 5 G2: 6  Other  Asthma 35%, sickle cell anemia, epilepsy, and congenital heart disease (8% each), and cleft lip or palate, cancer, and
Inner-city, low- income, minority  Study Design RCT  Start Date 1990	Groups G1: Experimental G2: Control  Interventions G1: 6 one-hour meetings and 3 group activities 6 face-to-face interventions at home or in	with Clients 6 meetings (1 hour each) with at least biweekly telephone calls + 3 group social activities over 12 months  Length of Follow-up 12 months 6, 12, and 18	endocrine disorders (5% each). Spina bifida and other congenital anomalies each occurred in 2%; 15% had multiple health conditions, mostly asthma G1: 35% fair to poor health; G2: 31%
<b>Duration</b> 1-2 years	hospital + telephone calls + group activities G2: Usual care <b>Group (N)</b> G1: 183 G2: 182	mo	Role of CHW in Recruiting and Retention NR Recruitment Rates NR
			Retention Rates G1: 95% G2: 93%

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1	Costs (Economics): NR  Explanation of Overall Outcomes Posttest scores of EG and CG mothers did not differ significantly. Although intervention effects were not related to participation level or illness-related and sociodemographic factors, a significant interaction with stressful life events (SLE) was found.  Quality Rating Fair
NR Quality of Life:	PSI Results	
NR	Pre- intervention G1: 24.1 G2: 20.3 ( <i>P</i> < 0.05)	
	Post intervention G1: 22.1 G2: 20.1 (no significant difference between groups)	
	Measure 2 PSI subsets	
	Results All adjusted posttest scores other than Depression were directionally lower in EG than CG	
	Healthcare Utilization:	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year St. James et al.,	Eligible (N) NR	Title of CHW Resource Mother	Age (mean) Maternal age
1999 Trial Name	Enrolled (N) 83 pregnancies from 69 mothers	<b>Paid or Volunteer</b> Paid	G1: 26.5 G2: 24.1
Resource Mothers Program for Maternal PKU	Randomized (N) NA	Relationship with Community	<b>Sex (% female)</b> 100
Objective or Aim	Completers (N) NA	Resource mothers had children with PKU	Race (%) NR
Increase number of well-treated pregnancies and	Withdrawals or Dropouts (N)	CHW (N) NR	Other Role of CHW in Recruiting
thus reduce number of adverely affected offspring	Health Candition of Interest	Supervision of CHW NR	and Retention
Geography New England	Inclusion Criteria Mothers with PKU	Prior Training Lived with disease	Recruitment Rates NR
Organization Maternal PKU	Exclusion Criteria NA	Type of Service Face-to-face meetings	Retention Rates NR
Collaborative Study enrollees	G1: control (no resource mother) -	Type of Educational Materials Used NR	
Type of Community PKU	women with PKU G2: PKU women with resource mother	Duration of Interaction with Clients	
Study Design Retrospective cohort	Interventions G1: NR G2: resource mothers met with pregnant women for approx 20	≈20 sessions of 2 hours each (weekly in beginning then less frequently) throughout pregnancy	
<b>Start Date</b> NR	sessions of 2 hours each, weekly in beginning and less frequently	Length of Follow-up 12 months after birth	
<b>Duration</b> NR	as pregnancy proceeded. Activities included cooking, shopping, meal planning, preparing for baby, discussing pregnancy, discussing medical recommendations.		
	Group (N) G1: 64 offspring from 55 mothers G2: 19 offspring from 14 mothers		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Behavior: N	Health Outcomes: Measure 1 Birth head-circumference z score	Costs (Economics): NR
NR Quality of Life: NR	<b>Results</b> G1: -1.4 (95% CI, -1.561.2)	Explanation of Overall Outcomes NR Quality Rating Fair
	G2:-0.56 (95% CI, -0.880.24); <i>P</i> = 0.08 <b>Measure 2</b> Baylely developmental quotient	
	<b>Results</b> G1: 95 (95% CI, 92-98) G2: 108 (95% CI, 104-112); <i>P</i> < 0.05	
	Measure 3 maternal metabolic control	
	<b>Results</b> G1: 16.1 weeks(95% CI, 14.4-17.8) G2: 8.5 weeks (95% CI, 6.3-10.7); <i>P</i> < 0.05	
	Healthcare Utilization: NR	

**Duration** 17 months

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Sung et al., 1997; Sung et al., 1992	Eligible (N) NR	Title of CHW Lay health worker	<b>Age (mean)</b> G1: 18-34: 13.5% 35-44: 46%
Trial Name	Enrolled (N) 321	Paid or Volunteer NR	45-59: 22.1% 60-97: 18.4%
National Black Women's Health Project	Randomized (N) 321	Relationship with Community	G2: 18-34: 13.3% 35-44: 44.3% 45-59: 24.7%
Objective or Aim Test effectiveness	Completers (N) 195	Recruited from National Black Women's Health Project	60-97: 17.7%
of in-home, culturally sensitive	Withdrawals or Dropouts (N) 126	CHW (N) NR	<b>Sex (% female)</b> 100
educational program conducted by lay health	Health Condition of Interest breast cancer, cervical cancer	Supervision of CHW NR	Race (%) NR (presumed 100% African American)
workers by measuring improvement in	Inclusion Criteria NR	Prior Training Self-help support group	Other G1:
frequency of breast and cervical cancer		leaders within NBWHP  Type of Service	Income ≤\$15,000: 45.4% Married: 33.7% > HS education: 40.5%
screening  Geography Unclear, possibly	Groups G1: intervention G2: control	Home visits  Type of Educational	Employed: 55.2% G2: Income ≤\$15,000: 48%
Atlanta Interventions Organization G1: CHW hom		Materials Used Home visits, video of Pap and breast exam, printed materials	Married: 30.4% > HS education: 38.4% Employed: 46.8%
community health center	self-exam, educational materials on screening, facilitation to address logistical barriers to	Duration of Interaction with Clients	Role of CHW in Recruiting and Retention NR
Type of Community Inner city African- American	screening G2: mailed educational materials on cancer screening	3 visits (months 1, 2, 4) over four month period, visits 1 and 2 1.5 hours each, time for visit 3 NR	Recruitment Rates 1st attempt: 20% (55/275) 2nd attempt: 44% (266/600)
Study Design RCT	<b>Group (N)</b> G1: 163 G2: 158	Length of Follow-up 11 months	Retention Rates G1: 57% (93/163) G2: 65% (102/158)
Start Date NR			G2. 6576 (102/156)

# Knowledge, Attitude, and Behavior **Quality of Life**

# Knowledge, Attitude, and Behavior:

# Measure 1

Pretest-posttest change in self-report of BSE for entire sample

# Results

G1: 52.1%/51.0%; G2: 41.1%/41.0%, diff in change: -1.0 (95% CI, -6.1-4.1)

### Measure 2

Pretest-posttest change in self-report of BSE, postintervention respondents only

# Results

G1: 57.0%/53.8%; G2: 40.2%/40.2%, diff in change: -3.2 (95% CI, -17.5, 11.1)

### Measure 3

Posttest report of BSE, women not previously on recommended screening schedules, whole sample

### Results

G1: 24.4%; G2: 17.2%, diff in change: 7.2% (95% CI, -5.0-19.3)

# Measure 4

Posttest report of BSE, women not previously on recommended screening schedules, post-intervention respondents only

# Results

G1: 47.5%; G2: 26.2%, diff in change: 21.3% (95% CI, 2.3-40.3)

### **Quality of Life:**

NR

# **Health Outcomes Healthcare Utilization**

# **Health Outcomes:**

# Measure 1

Pre/post change in self-report of receiving screening exams, women not previously on recommended screening schedules, whole sample

No significant difference between groups for any screening modality

# **Healthcare Utilization:**

#### Measure 1

Pretest-posttest change in self-report of receiving Pap smears for entire sample

#### Results

G1: 50.3%/58.7%; G2: 51.9%/62.1%, diff in change: -1.8 (95% CI, -8.0-4.4)

Pretest-posttest change in self-report of receiving Pap smears, postintervention respondents only

G1: 52.7%/63.4%; G2: 50.0%/62.7%, diff in change: -2.0 (95% CI, -11.0-7.0)

# Measure 3

Posttest rate of self-report of receiving Pap smears, women not previously on recommended screening schedules, whole sample

# **Results**

G1: 33.3% G2: 34.2%

diff in change: -0.9 (95% CI, -15.7-13.9)

# Measure 4

Posttest rate of self-report of receiving Pap smears, women not previously on recommended screening schedules, postintervention respondents only

# Results

G1: 61.4% G2: 51.0%

diff in change: 10.4 (95% CI, -9.5-30.0)

# Costs (Economics) Additional **Outcomes**

# Costs (Economics):

# **Explanation of Overall Outcomes**

CHW intervention effective in increasing receipt of clinical breast exam and mammogram, only when including women already on some recommended screening schedule, and only when nonrespondents are assumed to be similar to respondents. Using intention-to-treat, no differences in any screening modality

# **Quality Rating**

Poor

Study	Number (N)		
Characteristics	Inclusion/Exclusion	Community Health	<b>Baseline Characteristics</b>
Setting	Groups	Worker	Recruiting and Retention

Author Year Sung et al., 1997; Sung et al., 1992

Knowledge, Attitude,		Costs (Economics)
and Behavior	Health Outcomes	Additional
Quality of Life	Healthcare Utilization	Outcomes
	Measure 5	

#### Measure 5

Pretest-posttest change in self-report of receiving mammography for entire sample

# Results

G1: 35.5%/50.4% G2: 34.3%/39.4% diff in change: 9.8% (95% CI, 2.9-16.7)

### Measure 6

Pretest-posttest change in self-report of receiving mammography, postintervention respondents only

G1: 32.5%/58.7%; G2: 34.0%/47.9%,

diff in change: 12.4% difference (95% CI, 1.0-24.3)

#### Measure 7

Posttest rate of self-report of receiving mammography, women not previously on recommended screening schedules, whole sample

# **Results**

G1: 29.7% G2: 24.4%

diff in change: 5.8% (95% CI, -7.0-18.6)

# Measure 8

Posttest rate of self-report of receiving mammography, women not previously on recommended screening schedules, postintervention respondents only

### Results

G1: 50.0% G2: 35.5%

diff in change: 14.5% (95% CI, 4.5-23.6)

# Measure 9

Pretest-posttest change in self-report of receiving CBE for entire sample

# **Results**

G1: 55.2%/64.5% G2: 55.7%/59.5%

diff in change: 4.9 (95% CI, -6.1-4.1)

# Measure 10

Pretest-posttest change in self-report of receiving CBE, postintervention respondents only

# Results

G1: 59.1%/72.0% G2: 57.8%/61.8%

diff in change: 8.9% (95% CI, 1.1-16.7)

Study	Number (N)		
Characteristics	Inclusion/Exclusion	Community Health	Baseline Characteristics
Setting	Groups	Worker	Recruiting and Retention

**Author Year** Sung et al., 1997; Sung et al., 1992<sup>71</sup>

Evidence Table C-1. Key Questions 1, 2, and 3 (continue	Evidence Table C-1.
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Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
	<b>Measure 11</b> Posttest rate of self-report of receiving CBE, women not previously on recommended screening schedules, whole sample	
	Results G1: 37.0% G2: 28.6% diff in change: 8.4% (95% CI, -6.9-23.7)	
	<b>Measure 12</b> Posttest rate of self-report of receiving CBE, women not previously on recommended screening schedules, postintervention respondents only:	
	Results G1: 71.1% G2: 46.5% diff in change: 24.6% (95% CI, 3.9-45.3)	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Taylor et al., 2002	Eligible (N) 2312 (986 Seattle, 1326 Vancouver)	Title of CHW Outreach worker	<b>Age (mean)</b> 58% 45-69 y/o:
<b>Trial Name</b> NR	(numbers deduced from text)  Enrolled (N)	Paid or Volunteer NR	G1: 53% G2: 63% G3: 58%
Objective or Aim Evaluate impact of 2 culturally and	1532 (710 Seattle, 822 Vancouver)  Randomized (N) 482 (199 Seattle, 283 Vancouver)	Relationship with Community Shared culture, ethnicity	Sex (% female) 100
linguistically appropriate	Completers (N) 402 (181 Seattle, 221 Vancouver)	CHW (N) NR	Race (%) Chinese 100%
cervical cancer control educational interventions: a	Withdrawals or Dropouts (N) 80 (18 Seattle, 62 Vancouver)	Supervision of CHW NR	Other • 12 or more years education: 44%
"high intensity" outreach worker- based intervention	Health Condition of Interest Pap testing	Prior Training NR	Married: 81%
and a "low intensity" direct mail intervention	Inclusion Criteria  Chinese women	Type of Service Trained to act as role	Role of CHW in Recruiting and Retention NR
Geography Seattle and Vancouver BC	<ul> <li>No history of Pap or intention of Pap within 2 years of survey</li> <li>20-69 years old</li> <li>Speak Cantonese, English, or</li> </ul>	models, to provide social support, to serve as cultural mediators between women and health care facilities, to	Recruitment Rates 66% (proportions not available for each group)
Organization Recruited from respondents to community-based	Mandarin  Exclusion Criteria  Hysterectomy Invasive cervical cancer	use visual aids and provide tailored responses to each woman's individual barriers to cervical cancer screening	Retention Rates 402/432 = 83% G1: 129/161 = 80% G2: 139/161 = 86% G3: 134/160 = 84%
Type of Community Chinese-American	Groups G1: CHW G2: direct mail G3: control	Type of Educational Materials Used Video, motivational pamphlet, educational	
women Study Design	esign G1: Introductory mailing, CHW visit	brochure, fact sheet, tailored counseling	
RCT Start Date 1999 Duration	with multimedia and tailored counseling, phone followup and tailored counseling, logistic assistance as needed G2: Direct mail multimedia materials	Duration of Interaction with Clients One time visit with follow up telephone call (time per interaction NR)	
18 months	G3: Control: usual care at local clinics and doctors' offices	Length of Follow-up 6 months	
	Group (N) G1: 161 G2: 161 G3: 160		

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
Measure 1 Report Pap testing planned within 2 years Results	Healthcare Utilization: Measure 1 Medical records for pap screening received between randomization and followup, using intent-to-treat	Explanation of Overall Outcomes Women who received CHW home visits were
G1: 72% G2: 59% G3: 48% (G1 vs G3 P < 0.001 G2 vs G3: P = 0.05 G1 vs G2 P = 0.03)	<b>Results</b> Results not provided, significant differences between outreach worker versus control ( $P < .001$ ), direct mail versus control ( $P = .07$ ), and outreach worker versus direct mail ( $P = .04$ )	significantly more likely to report having Pap testing after intervention compared to women receiving direct mail or no
Quality of Life: NR	Measure 2 Medical records for pap screening received in past 2 years, using intent-to-treat	intervention <b>Quality Rating</b> Fair
	Results Results not provided, significant differences between outreach worker versus control ( $P < .001$ ) and direct mail versus control ( $P = .03$ )	T CAIT
	<b>Measure 3</b> Self-reported Pap testing completed since intervention	
	Results G1: 39% G2: 25% G3: 15% (G1 vs G3, P < 0.001 G2 vs G3, P = 0.03 G1 vs G2, P = 0.02)	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Tessaro et al., 1997; Navaie- Waliser et al., 2000 Trial Name Maternal Outreach	Eligible (N) 14,977 Enrolled (N) 705 Randomized (N) NA	Title of CHW Maternal Outreach Worker (MOW) Paid or Volunteer NR Relationship with	Age (mean) < 18 y G1: 31% G2: 15.6% Sex (% female) 100
Worker (MOW) Program  Objective or Aim Reduce infant morbidity and mortality via early	Completers (N) 447 Withdrawals or Dropouts (N) 258 Health Condition of Interest	Community NR CHW (N) NR Supervision of CHW	Race (%) G1:     African-American: 61.8%     Caucasian: 38.2% G2:     African-American, 59.4%     Caucasian (limited to
prenatal care, consistence of care, health behavior and parenting skills, infant preventive	Infant health Inclusion Criteria Medicaid-eligible, < 28 wk EGA, singleton livebirth; Caucasian or African-American (this study)	NR Prior Training NR Type of Service Home visits, assistance in	Caucasian (limited to African-American and Caucasian): 40.6%  Other  Often receive aid from
care and social services, increased pregnancy spacing, decreasing unplanned	Exclusion Criteria Moved away, lost to follow-up, declined services, interview not completed	applying for govt benefits, housing, employment, education; general advocacy for families	friends/family G1: 41.4% G2: 58.1% ( <i>P</i> < 0.001) Reported good health G1: 78.4%
pregnancies; to determine whether particip Geography North Carolina	Groups G1: CHW G2: matched controls Interventions G1: CHW home visits	Type of Educational Materials Used Reinforcing positive health behavior; modeling parent- infant interactions; reinforce need for prenatal care,	G2: 85.5% ( <i>P</i> < 0.05)  Social supportiveness of pregnancy G1: 52.6% G2: 62.9% ( <i>P</i> < 0.05)
Organization Medicaid-eligible population, via social worker or nurse referral	Group (N) G1: 373 (yr 2) > 221 (yr 3) G2: 332 (yr 2) > 198 (yr 3)	immunizations, family planning  Duration of Interaction with Clients One visit/month (more if	Prior physical abuse by partner G1: 14.9% G2: 10% ( <i>P</i> < 0.1)
Type of Community High infant mortality with disproportionately		needed) for approximately 14 months (duration per visit NR) Length of Follow-up	No difference in education, gravidity, smoking  Role of CHW in Recruiting and Retention  Active recruitment of very
higher in African- Americans vs. Caucasians Study Design		1 year	high risk population  Recruitment Rates  NR  Retention Rates
prospective cohort  Start Date 1992  Duration			G1: 249/373 = 67% G2: 198/332 = 60%
3 years			

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Von Korff et al.,	Eligible (N) 364	Title of CHW Lay leaders	<b>Age (mean)</b> G1: 49.4
1998 Trial Name	Enrolled (N) 255	Paid or Volunteer Volunteer	G2: 50.3  Sex (% female)
NR Objective or Aim	Randomized (N) 255	Relationship with Community Shared disease	G1: 68.2 G2: 56.4
Evaluate a4- session self- management group	Completers (N) 0.85	CHW (N)	Race (%) G1: White: 91.4%
intervention for patients with pain in primary care, led	Withdrawals or Dropouts (N) 0.145	Supervision of CHW	Non-white: 8.6% G2: White: 79.7%
by trained lay persons with back	<b>Health Condition of Interest</b> Back pain	Prior Training NR	Non-white: 20.3%  Other
pain. intervention was designed to reduce patient	Inclusion Criteria Patients diagnosed with back pain ages 25-70, at least one prior back	Type of Service classes	Role of CHW in Recruiting and Retention NR
worries, encourage self-care, and reduce activity limitations.	pain visit, interested in learning more about caring for back pain,enrolled for at least a year Group Health Cooperative of Puget Sound	Type of Educational Materials Used Book, pamphlets, videotapes	Recruitment Rates NR Retention Rates
<b>Geography</b> Western Washington State	Exclusion Criteria Surgery or disenrollment from GHC	Duration of Interaction with Clients	NR
Organization HMO	Groups G1: Self management group G2: Usual care	Four 2-hour classes held once a week for 1 month	
Type of Community Condition - back pain	Interventions G1: Four 2-hour classes held once a week, with 10 to 15 participants, led by two trained volunteers.	Length of Follow-up 12 months	
Study Design RCT	G2: Usual care includes back pain book		
Start Date 1996	Group (N) G1: 129 G2: 126		
<b>Duration</b> NR	OZ. 120		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Behavior: Measure 1 "Next time I have back or leg pain, I will try to manage	Health Outcomes: Measure 1	Costs (Economics): NR
	Roland Disability at 12 months - validated  Results G1: 5.75 (6.31)	Explanation of Overall Outcomes NR
problem without seeing a health professional" - Not validated	G2: 6.75 (6.39) P = 0.092	<b>Quality Rating</b> Fair
Results G1: 77% agreed G2: 60%	Measure 2 Worry rating (0-10) at 12 months - not validated	
( <i>P</i> = 0.008) <b>Quality of Life:</b> NR	Results G1: 2.63 (2.58) G2: 3.83 (3.08) P = 0.013	
	Measure 3 50% or greater reduction in Roland Disability Questionnaire Score from baseline at 6 months - validated	
	<b>Results</b> G1: 47.9% G2: 33% (X2 = 5.2; df = 1; P = 0.02)	
	Healthcare Utilization: NR	

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Characteristics	Inclusion/Exclusion		Recruiting and
			Retention Rates NA

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: Measure 1	Costs (Economics): NR
Measure 1	Survey - not validated	Explanation of Overall
Survey - not validated	Results	Outcomes
Results	Condom use Intervention vs. comparison [odds ratio	NR
Know where to get free condoms G1: 90 G2: 74 OR	1.37 (95% confidence Interval 1.20, 1.56; <i>P</i> <0.001)].	Quality Rating Fair
95% CI, 3.2 (2.75, 3.73) <i>P</i> = 0.001	Healthcare Utilization:	r dii
Quality of Life: NR		

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
Author Year Wilson et al., 2008	Eligible (N) 257 salons	Title of CHW Lay health advisor	Age (mean) G1: 38
<b>Trial Name</b> NR	Enrolled (N) NR	Paid or Volunteer Volunteer (with \$30	G2: 39 G3+G4: 38
Objective or Aim Assess	Randomized (N) 40 salons	compensation for training time)	<b>Sex (% female)</b> 100
effectiveness of breast health promoting	Completers (N) 40 salons/1210 respondents	Relationship with Community Hair stylist working in	Race (%) African G1: 91
messages administered by	Withdrawals or Dropouts (N)	neighborhood/community CHW (N)	G2: 93 Hispanic
salon stylists to clients in salon setting	Health Condition of Interest breast cancer	29 Supervision of CHW	G1: 7 G2: 6
<b>Geography</b> Brooklyn, NY	pgraphy oklyn, NY Salons providing services in target NYC neighborhoods; clients receiving services at experimental and control salons were eligible to participate	Program staff made frequent visits to salons to support stylists in their	Other G1: 2 G2: 1
<b>Organization</b> Neighborhood hair salons		promotion of message delivery throughout time during which program was administered.	Other Born in US (%) G1: 56 G2: 52
Type of Community Neighborhoods	Exclusion Criteria Salons were excluded if owner was a member of Health and Beauty	Prior Training NR	Family hx of breast cancer (%)
Study Design Repeated cross-	Council  Groups	<b>Type of Service</b> One-on-one counseling	G1: 10 G2: 9
sectional survey of women attending salons randomly assigned to experimental and	G1: Control salon, at baseline G2: Experimental salon, at baseline G3: Control salon, at followup G4: Experimental salon, at followup Interventions	during salon visit to provide education, counseling, and information on location of	Role of CHW in Recruiting and Retention NA
		cancer screening services  Type of Educational	Recruitment Rates
control groups  Start Date 2002	G1: Control, before intervention G2: Stylists group, before intervention	Materials Used Written materials (not described)	Retention Rates NA
Duration 3 months for each salon	G3: Control, after intervention G4: Stylists group, after intervention	Duration of Interaction with Clients	
	Intervention consisted of education, counseling, and information on	One visit - (time of session NR)	
	location of screening services during salon appointment	Length of Follow-up 3 months	
	Group (N) G1: 369 (12 salons) G2: 816 (28 salons) G3+G4: 1210 (N of salons NR, individual N NR)		

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior:	Health Outcomes: NR	Costs (Economics): NR
Measure 1 Engaging in BSE in past 3 months	Healthcare Utilization: Measure 1 Clinical breast exam (CBE) in past 3 months	Explanation of Overall Outcomes NR
Results G1: 25% G2: 28%, P = 0.26 for differences between G1 and G2 G3: 37% G4: 40%	Results G1: 27% G2: 27%, P = 0.85 for differences between G1 and G2 G3: 27% G4: 29% AOR 1.2 (95% CI, 0.9-1.7)	Quality Rating Poor
Adjusted OR, for differences between G3: and G4 1.3; Adj 95% CI, 0.9-1.7	Measure 2 Mammogram in past 3 months	
Measure 2 Intention to receive mammogram in next year	Results G1: 13% G2: 14% Adj OR 1.1; Adj 95% CI, 0.8-1.7	
Results G3: 70% G4: 74% Adj OR 1.3; Adj 95% CI, 0.9-1.2		
Quality of Life: NR		

Study Characteristics Setting	Number (N) Inclusion/Exclusion Groups	Community Health Worker	Baseline Characteristics Recruiting and Retention
			Retention  Age (mean) 33.6 years  Sex (% female) 41.2  Race (%)  • African-American: 55.3 %  • Aglo-American: 44.7%  Other  Role of CHW in Recruiting and Retention  NR  Recruitment Rates  NR
homeless or at risk of homeless or at risk of homelessness. and costeffectiveness of three approaches to case management for individuals with severe mental illness who were at risk for homelessness  Geography St. Louis, Missouri  Organization Organizational  Type of Community Mental Illness and homelessness  Study Design RCT  Start Date 1990  Duration 18 months	Current homelessness or risk for homelessness; serious DSM-III-R axis I diagnosis; no recent convictions for rape, homicide, or serious assault; and willingness to receive services and participate in a longitudinal study  Exclusion Criteria  See Inclusion criteria  Groups  G1: Assertive community treatment with community workers, G3: Receiving brokered case management (purchase of services).  Interventions  G1: Assertive community treatment responsibility for providing or coordingating all services needed by client, persistent follow-up and in vivo service delivery, performed by staff with backgounds in psychology, social work, and counseling  G2: G1 + Community Health Worker, whose role was to assist with activities of daily living and be available for leisure activities  Group (N)  NR for primary intervention study G1: 28 in assertive community treatment G2: 35 in assertive community treatment with community workers, G3: 22 receiving brokered case management (purchase of services).	NR  Type of Service Included participation in individual and community leisure activities. Some also supplemented work of assertive community treatment staff by assisting clients with activities of daily living, although this usually occurred only on a limited basis.  Type of Educational Materials Used NR  Duration of Interaction with Clients Face-to-face meetings (length of each and number NR) over 18 months  Length of Follow-up 18 months	Retention Rates NR

Evidence Table C-1. Key Questions 1, 2, and 3 (continued)

Knowledge, Attitude, and Behavior Quality of Life	Health Outcomes Healthcare Utilization	Costs (Economics) Additional Outcomes
Knowledge, Attitude, and Behavior: NR Quality of Life:	Health Outcomes: Measure 1 BPRS (Brief Psychiatric Rating Scale score) Total Symptom Score  Results G1:53.54(15.54)/39.96(12.25) G2: 57.97(20.29)/38.77(12.23) G3: 50.6(14/31)/51.6(16.7) P = 0.001  Healthcare Utilization: Measure 1 Program contact (days/mo)	Costs (Economics): Measure 1 Total costs over 18- month study period for average client in each treatment condition
Measure 1 Client Satisfaction		
Results		Results
G1: 3.27(0.42) G2: 3.12(0.57) G3: 2.74(0.68) P < 0.01		Assertive community treatment only, \$49,510; No significant difference
N of days in stable housing in past month	Results G1:8.29(7.51) G2: 6.95(4.91) G3: 0.3(0.49) P < 0.001	Assertive community treatment with community workers,
Results Basline(SD)/18 months(SD) G1: 6.36(11.71)/21.75(12.76)		\$39,913; brokered case management, \$45,076
G2: 4.94(11.08)/17.54(14.45) G3: 7.18(12.38)/16.00(14.86) (P < 0.31)		Explanation of Overall Outcomes NR
		Quality Rating Poor

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Andersen et al., 2000

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended

Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Care Provider Masked?

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

Retrospective self-report

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Cannot tell

**Conclusions Supported by Results?** 

**Quality Rating** 

Good

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Auslander, et al., 2002; Williams et al., 2001

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

No

**Could Variation from Protocol have Compromised Study** 

Findings?

No

**Outcome Assessors Masked?** 

NR

Care Provider Masked?

Nο

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Retrospective self-report (patient/participant response)

Outcomes Measured in Valid and Reliable

Retrospective self-report (patient/participant

response)

Length of Time Following Intervention/Exposure Sufficient to Support Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization?

Cannot determine

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

Cannot determine

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Yes

Does Analysis Control for Baseline Differences?

NΑ

**Analysis Conducted on ITT Basis?** 

No

**Any Post-Randomization Exclusions?** 

Cannot tell

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Barnes et al., 1999

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Not reported

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Prospective documentation

**Outcomes Measured in Valid and Reliable** 

Manner Objective

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes: 24% in G1

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Yes many as they were randomized before

enrollment

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** Barth, 1991

Hypothesis/Aim/ Objective of Study Described?

YES- kind of

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

No

Allocation of Randomization Adequately Concealed?

Can't tell so No

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended

Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Care Provider Masked?

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Objective in some

**Outcomes Measured in Valid and Reliable** 

Manner

Objective in some

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

Yes

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Yes at least 3

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Barth et al., 1988

Hypothesis/Aim/ Objective of Study Described?

YES- kind of

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

No

Allocation of Randomization Adequately Concealed?

Can't tell so No

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended

Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Not reported

**Care Provider Masked?** 

**Patient Masked?** 

Not reported

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Objective in some

**Outcomes Measured in Valid and Reliable** 

Manner

Objective in some

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

Yes

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Yes at least 3

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Batts et al., 2001;

Gary et al., 2005;

Gary et al., 2003;

Gary et al., 2000;

Vetter et al., 2004

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No (and primary outcome not clearly identified)

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

Yes

**Outcome Assessors Masked?** 

Yes

**Care Provider Masked?** 

Patient Masked?

Nο

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable** 

Manner Objective

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Did Attrition Differ by More Than 15 **Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

No (completers analysis)

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

**Quality Rating** 

Good

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Becker et al., 2005; Cene et al., 2008

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

**Allocation of Randomization Adequately Concealed?** 

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Yes

**Outcome Assessors Masked?** 

Care Provider Masked?

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

Retrospective self-report (patient/participant

response)

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization? Yes - G1:26% G2:27%

**Did Attrition Differ by More Than 15** 

Percentage Points After Randomization?

Baseline Characteristics Similar in

**Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

NA

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

**Quality Rating** 

Key Questions 1, 2, and 3: Quality RCTs (continued) Evidence Table C-2.

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Black et al., 1995; Hutcheson et al., 1997

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

**Allocation of Randomization Adequately Concealed?** 

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Yes

Care Provider Masked?

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

Objective, validated; and retrospective self-report

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Did Attrition Differ by More Than 15

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

Yes, for characteristics in table 1, but trend toward lower baseline receptive language in intervention group at baseline (table 2): no reporting of maternal baseline psychiatric

measures

**Does Analysis Control for Baseline** Differences?

NA

**Analysis Conducted on ITT Basis?** 

**Any Post-Randomization Exclusions?** 

Cannot tell

**Conclusions Supported by Results?** 

Partially (difficult to tell since there is no sample size calculation, no definition of primary outcome, numerous comparisons/outcomes evaluated, no clarity of what represents a clinically important difference for outcomes rather than just a statistically important difference, and there were baseline differences in receptive language

**Quality Rating** 

socres...)

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Campbell et al., 2004

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

No

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

Nο

Allocation of Randomization Adequately Concealed?

Nο

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

NA

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Vο

**Could Variation from Protocol have Compromised Study** 

Findings?

No

**Outcome Assessors Masked?** 

Nο

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

**Manner** NR

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Ye

Did Attrition from Any Group Exceed 20%

After Randomization?

Cannot determine

Did Attrition Differ by More Than 15

Percentage Points After Randomization?

Cannot determine

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

poseu/compani

INO

**Does Analysis Control for Baseline** 

Differences?

Yes

**Analysis Conducted on ITT Basis?** 

Nο

Any Post-Randomization Exclusions?

Cannot tell

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Caulfield et al., 1998

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

Nο

Allocation of Randomization Adequately Concealed?

NA

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

Yes

**Outcome Assessors Masked?** 

Nο

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Retrospective self-report (patient/participant response)

Outcomes Measured in Valid and Reliable

Retrospective self-report (patient/participant response)

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20% After Randomization?

56% overall drop out

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

NR

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

ا. ما

Does Analysis Control for Baseline

Differences?

Yes (via logistic regression)

**Analysis Conducted on ITT Basis?** 

No

**Any Post-Randomization Exclusions?** 

Yes

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Conway et al., 2004

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

Yes

**Assignment Randomized** 

NR (randomization method NR)

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

Low, broad concepts provided without detailed description of promotoras intervetion techniques

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

NΑ

**Could Variation from Protocol have Compromised Study** 

Findings?

NA

**Outcome Assessors Masked?** 

Yes

Care Provider Masked?

No

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective, not validated

**Outcomes Measured in Valid and Reliable** 

Manner

Objective, validated

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Ye

Did Attrition from Any Group Exceed 20%

After Randomization?

No

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

NR, no table 1, inadequate description of

comparability of groups

**Does Analysis Control for Baseline** 

Differences?

NA

Analysis Conducted on ITT Basis?

No, completers analysis

**Any Post-Randomization Exclusions?** 

Yes

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

Good

Key Questions 1, 2, and 3: Quality RCTs (continued) Evidence Table C-2.

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Corkery et al., 1997

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Not reported

**Care Provider Masked?** 

Not reported

**Patient Masked?** 

Not reported

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Objective (some validated, some not) and

retrospective self-report

**Outcomes Measured in Valid and Reliable** 

Manner

Objective (some validated, some not) and

retrospective self-report

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes - 37%

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

Yes

Baseline Characteristics Similar in **Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

**Any Post-Randomization Exclusions?** 

Cannot tell

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Dean et al., 2000; Derose et al., 2000;

Derose et al., 2000:

Fox et al., 1998;

Stockdale et al., 2000

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

Nο

**Outcome Assessors Masked?** 

Nο

**Care Provider Masked?** 

Patient Masked?

Nο

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Prospective documentation

**Outcomes Measured in Valid and Reliable** 

Manner

Retrospective self-report

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes - 73%

Did Attrition Differ by More Than 15 **Percentage Points After Randomization?** 

CD

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

Yes

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Dignan et al., 2005

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

No

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

No

**Could Variation from Protocol have Compromised Study** 

Findings?

Yes

**Outcome Assessors Masked?** 

Nο

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Prospective documentation

**Outcomes Measured in Valid and Reliable** 

Manner

Retrospective self-report

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

No (outcome asks about past 12 months, followup data obtained within 6 months)

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes - 29%

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

Cannot determine

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Greater number of patients age 65+ in telephone

aroun

Does Analysis Control for Baseline

Differences?

Cannot determine

**Analysis Conducted on ITT Basis?** 

Yes

**Any Post-Randomization Exclusions?** 

Cannot tell

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Duggan et al., 1999; Duggan et al., 2000

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Yes

**Outcome Assessors Masked?** 

Care Provider Masked?

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Retrospective self-report (patient/participant

response)

**Outcomes Measured in Valid and Reliable** 

Retrospective self-report (patient/participant

response)

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Did Attrition Differ by More Than 15

Percentage Points After Randomization?

No

Baseline Characteristics Similar in **Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

**Any Post-Randomization Exclusions?** 

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Elder et al., 2006; Elder et al., 2005

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary

Outcome(s)?

No

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

Low, many details about tailored print materials not provided (just general topics covered are identified); minimal description of what promotoras acually did

**Usual Clinical Care Described?** 

NΑ

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

No

**Could Variation from Protocol have Compromised Study Findings?** 

Cannot determine, possible there could be contamination if subjects in various groups had interactions w/ each other

**Outcome Assessors Masked?** 

No

Care Provider Masked?

No

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable Manner** 

Retrospective self-report (24-hour dietary recall) for primary outcomes; accuracy of measure is debatable given recall issues, social desirability/those working with promotoras may have greater desire to report lower intake of fat/etc. to please promotoras with which they've established a relationship. Of not, BMI changes from baseline were similar in all groups but decreased least in promotoras group—suggesting that intermediate measures used (dietary intake of fat, etc.) were not in line with BMI changes that would be expected.

Length of Time Following Intervention/Exposure Sufficient to Support Conclusions?

Ye

Did Attrition from Any Group Exceed 20% After Randomization?

No for 12 week outcomes; Yes for 1 year outcomes (G1 22%, G2 24%)

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

No, important differences in perceived barriers to fat, stages of change for fat, ...More participants in tailored condition (than promotoras group) were in earlier stages of change. Also, tailored group had worse overall health (per self-report)

**Does Analysis Control for Baseline Differences?** 

NO

Analysis Conducted on ITT Basis?

No

Any Post-Randomization Exclusions?

No

**Conclusions Supported by Results?** 

**Partially** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Gielen et al., 2002

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

Yes

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Yes

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

CD

**Outcome Assessors Masked?** 

NR

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable** 

Manner

Objective meansure, not validated

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Ye

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes - 27% in standard; 15% in enhanced

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Yes

**Does Analysis Control for Baseline** 

Differences?

Yes

**Analysis Conducted on ITT Basis?** 

CD

Any Post-Randomization Exclusions?

No

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Graham et al., 1992

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

Yes

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Yes

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Yes

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner Objective

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Ye

Did Attrition from Any Group Exceed 20%

After Randomization?

G1: 60% completers; 72% overall received some

visits

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

Yes (control group 100% of sample available)

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Cannot determine

**Does Analysis Control for Baseline** 

Differences?

NA

**Analysis Conducted on ITT Basis?** 

Yes

Any Post-Randomization Exclusions?

Yes (24)

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Hiatt et al., 2008

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

2x2

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended

Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Yes

**Outcome Assessors Masked?** 

Care Provider Masked?

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner? Retrospective self-report

**Outcomes Measured in Valid and Reliable** 

Manner

Objective, previously validated

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

No

Baseline Characteristics Similar in **Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

Yes - some

Analysis Conducted on ITT Basis?

Any Post-Randomization Exclusions?

Cannot tell

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Hunter et al., 2004

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

No

**Outcome Assessors Masked?** 

Care Provider Masked?

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable** 

Manner Objective

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Jandorf et al., 2005

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Care Provider Masked?

Yes

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Objective

**Outcomes Measured in Valid and Reliable** 

Manner Objective

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Korfmacher et al., 1999;

Olds et al., 2002; Olds et al., 2004

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

Yes

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Yes

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Yes

**Care Provider Masked?** 

No

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Prospective documentation

Prospective documentation

**Outcomes Measured in Valid and Reliable** 

Manner

Objective, some validated; Prospective

documentation

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes - G1 48%, G2 38%

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

Yes - G1 48%, G2 38%, G3 20%

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Yes

**Does Analysis Control for Baseline** 

Differences?

NA

**Analysis Conducted on ITT Basis?** 

Yes

Any Post-Randomization Exclusions?

Yes (G1 = 11, G2 = 12, G3 = 17 in one study);

Yes (G1 = 34, G2 = 35, G3 = 34 in another

study)

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Krieger et al., 1999

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

Yes

**Assignment Randomized** 

Yes

**Allocation of Randomization Adequately Concealed?** 

Yes

Level of Detail in Describing Intervention/Exposure

High

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

NR

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Prospective documentation

Outcomes Measured in Valid and Reliable

Manner

For main outcome (completing follow-up visit): retrospective self-report of patient

retrospective seir-report of patient

For blood pressure: Objective, previously validated

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20% After Randomization?

Yes (30% vs. 22% attrition)

Did Attrition Differ by More Than 15

Percentage Points After Randomization?

No

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Yes (by report)

res (by report)

**Does Analysis Control for Baseline Differences?** 

NA

**Analysis Conducted on ITT Basis?** 

No, completers analysis

**Any Post-Randomization Exclusions?** 

Yes

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Krieger et al., 2002; Krieger et al., 2005

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

No

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Yes and no

Any Post-Randomization Exclusions?

Yes

**Conclusions Supported by Results?** 

**Quality Rating** 

Good

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Levine et al., 2003

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

Nο

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

High

**Usual Clinical Care Described?** 

NA

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

NΑ

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

NR

**Care Provider Masked?** 

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?
Prospective documentation

Prospective documentation

**Outcomes Measured in Valid and Reliable** 

Manner

Objective, validated

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Ye

Did Attrition from Any Group Exceed 20%

After Randomization? Yes - G1 38%, G2 43%

Did Attrition Differ by More Than 15

Percentage Points After Randomization?

No

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Exposed/Comparison Cohorts?

res

**Does Analysis Control for Baseline** 

Differences?

NA

Analysis Conducted on ITT Basis?

Yes

Any Post-Randomization Exclusions?

Yes (G1 = 145, G2 = 173)

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Lujanet al., 2007

Yes

Criteria Clearly Stated?

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

Hypothesis/Aim/ Objective of Study Described?

Yes

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

NA

Could Variation from Protocol have Compromised Study

Findings?

Yes (but only 1 subject crossed over from control to intervention,

so minimal impact on results)

**Outcome Assessors Masked?** 

Yes

Care Provider Masked?

NR

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable** 

Manner Objective

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Ye

Did Attrition from Any Group Exceed 20%

After Randomization?

No

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Cannot determine (for most characteristics because no table 1; most characteristics reported for entire sample rather than for each group; of note, mean Hgb A1c levels were different at

baseline---8.71 vs. 7.71)

Does Analysis Control for Baseline Differences?

CD

**Analysis Conducted on ITT Basis?** 

No

Any Post-Randomization Exclusions?

Yes (1)

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

Good

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** Mock et al., 2007

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

NR (but subjects from same household were kept in same arm)

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

Retrospective self-report

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

Did Attrition Differ by More Than 15

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Cannot tell

**Conclusions Supported by Results?** 

**Quality Rating** 

Key Questions 1, 2, and 3: Quality RCTs (continued) Evidence Table C-2.

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Morisky et al., 2002; Ward et al., 2000

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

No

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

NR

**Allocation of Randomization Adequately Concealed?** 

Level of Detail in Describing Intervention/Exposure

High

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

NR

Care Provider Masked?

Patient Masked?

NR

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

Blood pressure measurement technique not

reported

Length of Time Following Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization?

Yes (flow diagram/attrition not clearly reported, but Table 2 "BP in control" section indicates that

was quite high)

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

Cannot determine

Baseline Characteristics Similar in **Exposed/Comparison Cohorts?** 

Cannot determine (they suggest that they are, but there is no Table 1 and baseline

characteristics are not adequately reported)

**Does Analysis Control for Baseline** 

Differences?

NA

Analysis Conducted on ITT Basis?

No, completers analysis

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

Partially (no discussion of effect of CHWs)

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Navarro et al., 1998; Navarro et al., 1995; Navarro et al., 2000

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

High

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

**Outcome Assessors Masked?** 

NR

**Care Provider Masked?** 

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner? Retrospective self-report

**Outcomes Measured in Valid and Reliable** 

Manner

Retrospective self-report

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15 Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

Yes

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Cannot tell

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Parker et al., 2008

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

High

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective (some validated, some not) and

retrospective self-report

**Outcomes Measured in Valid and Reliable** 

Manner

Objective (some validated, some not) and

retrospective self-report Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20% After Randomization?

Yes (23% and 25%)

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in

**Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

**Any Post-Randomization Exclusions?** 

Yes (30)

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Paskett et al., 2006; Katz et al., 2007

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

**Allocation of Randomization Adequately Concealed?** 

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

No

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Prospective documentation

**Outcomes Measured in Valid and Reliable** 

Manner Objective

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15 Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Yes: 17 refused

**Conclusions Supported by Results?** 

**Quality Rating** 

Good

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Pilote et al., 1996

**Blinding** 

**Author Year** 

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended

Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15 Percentage Points After Randomization?** 

CD

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Cannot tell

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Rask t al., 2001; LeBaron et al., 2004

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

High

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

CD

**Outcome Assessors Masked?** 

NR

**Care Provider Masked?** 

Patient Masked?

NR

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

Prospective documentation

**Outcomes Measured in Valid and Reliable** 

Manner Objective

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

CD

Baseline Characteristics Similar in **Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

CD

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

**Quality Rating** 

Good

Key Questions 1, 2, and 3: Quality RCTs (continued) Evidence Table C-2.

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Schuler et al., 2000

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

No Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

No NR

Allocation of Randomization Adequately Concealed?

No NR

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

No Yes: exclusion of families with a different home visiting component; multivariate analyses

**Could Variation from Protocol have Compromised Study** Findings?

Cannot determine

**Outcome Assessors Masked?** 

Yes, but method not described

Care Provider Masked?

No

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Retrospective self-report (patient/participant

response)

**Outcomes Measured in Valid and Reliable** 

Manner

Some objective; others Retrospective self-report

(patient/participant response)

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization?

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in **Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Kind of Yes

**Any Post-Randomization Exclusions?** 

Yes

**Conclusions Supported by Results?** 

**Partially** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Silver et al., 1997

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

NR

**Allocation of Randomization Adequately Concealed?** 

Yes (randomizer unaware of baseline responses & not involved

with intervention)

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Nο

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Yes, but method not described Not reported

**Care Provider Masked?** 

No

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Retrospective self-report (patient/participant response)

Outcomes Measured in Valid and Reliable

Manner Objective

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization?

No

Did Attrition Differ by More Than 15 Percentage Points After Randomization?

No

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

No: experimental group had significantly higher

baseline PSI score

Does Analysis Control for Baseline Differences?

NA Yes

**Analysis Conducted on ITT Basis?** 

Yes

**Any Post-Randomization Exclusions?** 

Cannot tell Yes (22)

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Sung et al., 1997; Sung et al., 1992

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

No

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

NR

**Allocation of Randomization Adequately Concealed?** 

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

Patient Masked?

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner

Retrospective self-report

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20%

After Randomization? Yes (G1 43%, G2 35%)

**Did Attrition Differ by More Than 15 Percentage Points After Randomization?** 

Baseline Characteristics Similar in **Exposed/Comparison Cohorts?** 

No

**Does Analysis Control for Baseline** 

Differences?

NA

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Taylor et al., 2002

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

Yes

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

High

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

**Outcome Assessors Masked?** 

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner? Retrospective self-report

**Outcomes Measured in Valid and Reliable** 

Manner

Objective, previously validated

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15 Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

Cannot tell

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Author Year** 

Von Korff et al., 1998

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

**Assignment Randomized** 

NR

Allocation of Randomization Adequately Concealed?

Level of Detail in Describing Intervention/Exposure

Medium

**Usual Clinical Care Described?** 

Researchers Rule out Impact from Unintended

Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised Study** 

Findings?

Cannot determine

**Outcome Assessors Masked?** 

Yes, but method not described

**Care Provider Masked?** 

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid

and Reliable Manner?

NR

**Outcomes Measured in Valid and Reliable** 

Manner Objective

**Length of Time Following** 

Intervention/Exposure Sufficient to Support

Conclusions?

Did Attrition from Any Group Exceed 20%

After Randomization?

**Did Attrition Differ by More Than 15** 

**Percentage Points After Randomization?** 

No

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

**Does Analysis Control for Baseline** 

Differences?

**Analysis Conducted on ITT Basis?** 

Any Post-Randomization Exclusions?

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding

**Author Year** 

Wolff et al., 1997 Morse et al., 1997

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary Outcome(s)?

No

**Assignment Randomized** 

No

Allocation of Randomization Adequately Concealed?

NR

Level of Detail in Describing Intervention/Exposure

Low

**Usual Clinical Care Described?** 

Yes

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Yes

**Could Variation from Protocol have Compromised Study** 

Findings?

Yes

**Outcome Assessors Masked?** 

NR

**Care Provider Masked?** 

Nο

**Patient Masked?** 

No

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

Interventions/Exposures Measured in Valid and Reliable Manner?

Retrospective self-report (patient/participant response)

Outcomes Measured in Valid and Reliable

Manner

Retrospective self-report (patient/participant response)

гоороноо

Length of Time Following

Intervention/Exposure Sufficient to Support

Conclusions?

Yes

Did Attrition from Any Group Exceed 20% After Randomization?

Yes 85/165

Did Attrition Differ by More Than 15
Percentage Points After Randomization?

Yes - 30+%

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

Cannot determine

Does Analysis Control for Baseline Differences?

Cannot determine

**Analysis Conducted on ITT Basis?** 

No

**Any Post-Randomization Exclusions?** 

Cannot tell

**Conclusions Supported by Results?** 

No

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination Blinding

**Soundness of Information** 

Follow-Up

**Analysis Comparability/Outcome** 

**Author Year** 

Barnes-Boyd et al., 2001

Hypothesis/Aim/ Objective of Study Described?

No

**Criteria Clearly Stated?** 

No

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

No

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

No

Could Variation from Protocol have Compromised Study Findings?

Cannot determine

Outcome Assessors Blinded to Intervention/Exposure Status of Participants?

No

Interventions/Exposures Measured in Valid and Reliable Manner?

Prospective documentation

Outcomes Measured in Valid and Reliable Manner? NR

Same Length of Follow-up or Adjustment for Different Length of Follow-up?

Cannot determine

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Yes

Did Attrition for Any Group Exceed 20% After Allocation of Treatment?

Yes (14% at 2 months and 44% at 11 months for REACH-Futures and 25% and 42% for REACH, respectively)

Did Attrition Differ by More Than 15 Percentage Points After Allocation of Treatment?

Nο

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

No

**Does Analysis Control for Baseline Differences?** 

No

Confounding and Modifying Variables Accounted for?

No (no assessment of secular trend; this is a historical comparison)

**Analysis Conducted on ITT Basis?** 

Yes

Impact of Loss to Follow-up (or Differential Loss to Follow-up) Assessed?

Cannot determine

Statistical Methods Used to Assess Primary Outcomes Appropriate to Data?

Yes

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

No (no RR reported)

Does Study Report Appropriate Estimates of Random Variability in Data for Main Outcomes?

No

**Conclusions Supported by Results?** 

Nο

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination **Blinding** 

**Soundness of Information** 

Follow-Up

**Author Year** 

Beckham et al., 2008

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

NA

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** 

Study Findings?

Outcome Assessors Blinded to Intervention/Exposure **Status of Participants?** 

No

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective (clinical reports, lab findings, previously validated measures)

**Outcomes Measured in Valid and Reliable Manner?** 

Objective (clinical reports, lab findings, previously validated measures)

Analysis Comparability/Outcome

Same Length of Follow-up or Adjustment for

Different Length of Follow-up?

No

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

Did Attrition Differ by More Than 15 Percentage

**Points After Allocation of Treatment?** 

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

Yes

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for?

No

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

NA

**Statistical Methods Used to Assess Primary** 

Outcomes Appropriate to Data?

Partially

For Cohort Studies Only, If Outcome has Greater

than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

Does Study Report Appropriate Estimates of Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Soundness of Information** 

Follow-Up

Analysis Comparability/Outcome

**Author Year** 

Bone et al., 1989

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

Nο

Level of Detail in Describing Intervention/Exposure? Medium (odd that it is described in results rather than

methods section)

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

NA

**Could Variation from Protocol have Compromised** Study Findings?

**Outcome Assessors Blinded to Intervention/Exposure Status of Participants?** 

Interventions/Exposures Measured in Valid and **Reliable Manner?** 

prospective documentation

**Outcomes Measured in Valid and Reliable Manner?** 

Prospective documentation (return to ED for follow up visit)

Same Length of Follow-up or Adjustment for Different Length of Follow-up?

CD

Is Length of Time Following Intervention/Exposure **Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After Allocation of Treatment?

Did Attrition Differ by More Than 15 Percentage **Points After Allocation of Treatment?** 

Cannot determine (this is really just one prospective cohort, they did not a priori define analysis plan and only in results define those that CHWs were unable to reach as comparison group)

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

No or cannot determine, not reported

**Does Analysis Control for Baseline Differences?** 

Cannot determine, no description of analysis

**Confounding and Modifying Variables Accounted** for?

CD

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to Follow-up) Assessed?

Statistical Methods Used to Assess Primary **Outcomes Appropriate to Data?** 

NA, methods not reported

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

**Does Study Report Appropriate Estimates of** Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding Soundness of Information**  Follow-Up

Analysis Comparability/Outcome

Different Length of Follow-up?

**Author Year** 

Caulfield et al., 1998

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** 

Study Findings?

**Outcome Assessors Blinded to Intervention/Exposure Status of Participants?** 

No

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable Manner?** 

Retrospective self-report (patient/participant response)

Same Length of Follow-up or Adjustment for

No

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

Yes

Did Attrition Differ by More Than 15 Percentage **Points After Allocation of Treatment?** 

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

No

Does Analysis Control for Baseline Differences?

**Confounding and Modifying Variables Accounted** 

for?

Yes

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

Yes a bit

**Statistical Methods Used to Assess Primary** 

**Outcomes Appropriate to Data?** 

Partially

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

Does Study Report Appropriate Estimates of Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination **Blinding** 

**Soundness of Information** 

Follow-Up

Analysis Comparability/Outcome

**Author Year** 

Earp et al., 2002

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

Partially

Level of Detail in Describing Intervention/Exposure?

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** 

Study Findings?

Outcome Assessors Blinded to Intervention/Exposure

**Status of Participants?** 

Interventions/Exposures Measured in Valid and

Reliable Manner?

**Outcomes Measured in Valid and Reliable Manner?** 

Retrospective self-report

Same Length of Follow-up or Adjustment for

Different Length of Follow-up?

Yes

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

Did Attrition Differ by More Than 15 Percentage

**Points After Allocation of Treatment?** 

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

No (for income, lack of medical visits, perceived barriers to screening, knowledge about breast cancer)

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for? Yes

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

Statistical Methods Used to Assess Primary

Outcomes Appropriate to Data?

Partially

For Cohort Studies Only, If Outcome has Greater

than 10% Prevalence, is Risk Ratio and Relative

Risk Calculated Directly?

**Does Study Report Appropriate Estimates of** 

Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding Soundness of Information**  Follow-Up

No

**Analysis Comparability/Outcome** 

**Sufficient to Support Conclusions?** 

**Points After Allocation of Treatment?** 

**Baseline Characteristics Similar in** 

**Analysis Conducted on ITT Basis?** 

**Exposed/Comparison Cohorts?** 

Different Length of Follow-up?

Allocation of Treatment?

Same Length of Follow-up or Adjustment for

Did Attrition for Any Group Exceed 20% After

Did Attrition Differ by More Than 15 Percentage

Does Analysis Control for Baseline Differences?

**Confounding and Modifying Variables Accounted** 

Is Length of Time Following Intervention/Exposure

**Author Year** 

Erwin et al., 1997

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

No

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** Study Findings?

Cannot determine

Outcome Assessors Blinded to Intervention/Exposure **Status of Participants?** 

No

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable Manner?** Retrospective self-report (patient/participant response)

Impact of Loss to Follow-up (or Differential Loss to Follow-up) Assessed?

No

No

for?

Partially

**Statistical Methods Used to Assess Primary Outcomes Appropriate to Data?** 

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative **Risk Calculated Directly?** 

NA

**Does Study Report Appropriate Estimates of** Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Soundness of Information** 

Follow-Up

Analysis Comparability/Outcome

**Author Year** 

Forst et al., 2004

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** 

Study Findings?

No (authors do not describe any variation, or lack of variation, from protocol; however, there is fair potential for

contamination)

Outcome Assessors Blinded to Intervention/Exposure **Status of Participants?** 

No

Interventions/Exposures Measured in Valid and **Reliable Manner?** 

Objective, not validated

**Outcomes Measured in Valid and Reliable Manner?** 

Retrospective self-report

Same Length of Follow-up or Adjustment for Different Length of Follow-up?

Yes

Is Length of Time Following Intervention/Exposure **Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After Allocation of Treatment?

Yes - about 30% overall (note: 83 subjects were excluded at end b/c one CHW admitted to completing questionnaires herself)

Did Attrition Differ by More Than 15 Percentage Points After Allocation of Treatment?

Cannot determine

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

Cannot determine

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for?

No

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

No

Statistical Methods Used to Assess Primary

**Outcomes Appropriate to Data?** 

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

Does Study Report Appropriate Estimates of Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Soundness of Information** 

Follow-Up

Analysis Comparability/Outcome

**Author Year** 

Frate et al., 1985

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

No

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** 

Study Findings?

Outcome Assessors Blinded to Intervention/Exposure

**Status of Participants?** 

Interventions/Exposures Measured in Valid and

Reliable Manner?

Objective

**Outcomes Measured in Valid and Reliable Manner?** 

Objective

Same Length of Follow-up or Adjustment for

Different Length of Follow-up?

NA

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

Cannot determine

Did Attrition Differ by More Than 15 Percentage

**Points After Allocation of Treatment?** 

Cannot determine

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

Cannot determine

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for?

No

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

No

**Statistical Methods Used to Assess Primary** 

**Outcomes Appropriate to Data?** 

For Cohort Studies Only, If Outcome has Greater

than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

**Does Study Report Appropriate Estimates of** 

Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

**Quality Rating** 

Extra Poor

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding Soundness of Information**  Follow-Up

Analysis Comparability/Outcome

**Author Year** 

Nacion et al., 2000

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** 

Study Findings?

Outcome Assessors Blinded to Intervention/Exposure **Status of Participants?** 

No

Interventions/Exposures Measured in Valid and Reliable Manner?

Prospective documentation

**Outcomes Measured in Valid and Reliable Manner?** NR

Same Length of Follow-up or Adjustment for

Different Length of Follow-up?

NA

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

Did Attrition Differ by More Than 15 Percentage

**Points After Allocation of Treatment?** 

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

No

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for?

Cannot determine

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

NA

**Statistical Methods Used to Assess Primary** 

**Outcomes Appropriate to Data?** 

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

Does Study Report Appropriate Estimates of Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

Blinding Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

**Author Year** 

Sauaia et al., 2007; Welsh et al., 2005

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

No

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

No

**Could Variation from Protocol have Compromised** 

Study Findings?

NΑ

Outcome Assessors Blinded to Intervention/Exposure Status of Participants?

No

Interventions/Exposures Measured in Valid and Reliable Manner?

Prospective documentation

Outcomes Measured in Valid and Reliable Manner?

objective measure

Same Length of Follow-up or Adjustment for

Different Length of Follow-up?

NA

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Yes

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

NA

Did Attrition Differ by More Than 15 Percentage

Points After Allocation of Treatment?

NΑ

Baseline Characteristics Similar in Exposed/Comparison Cohorts?

CD

**Does Analysis Control for Baseline Differences?** 

NA

**Confounding and Modifying Variables Accounted** 

for?

Partially

Analysis Conducted on ITT Basis?

Yes

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

NΑ

Statistical Methods Used to Assess Primary

**Outcomes Appropriate to Data?** 

Yes

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

Risk Calculated Directly?

NA

Does Study Report Appropriate Estimates of Random Variability in Data for Main Outcomes?

Nο

**Conclusions Supported by Results?** 

Yes

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Soundness of Information** 

**Author Year** 

Schwarz et al., 1993

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

Not really

**Could Variation from Protocol have Compromised** 

Study Findings?

Outcome Assessors Blinded to Intervention/Exposure Status of Participants?

No: "health department personnel were not blinded to intervention or control status of each household"

Interventions/Exposures Measured in Valid and **Reliable Manner?** 

Objective measure, not validated

**Outcomes Measured in Valid and Reliable Manner?** 

Objective measure, not validated

Follow-Up

**Analysis Comparability/Outcome** 

Same Length of Follow-up or Adjustment for

Different Length of Follow-up?

NA

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

Did Attrition Differ by More Than 15 Percentage

Points After Allocation of Treatment?

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

No

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for?

No

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

No

**Statistical Methods Used to Assess Primary** 

**Outcomes Appropriate to Data?** 

Partially

For Cohort Studies Only, If Outcome has Greater

than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

Does Study Report Appropriate Estimates of

Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

Partially

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination Blinding

Soundness of Information

Follow-Up

**Analysis Comparability/Outcome** 

**Author Year** 

St. James et al., 1999

Hypothesis/Aim/ Objective of Study Described?

Yes

**Criteria Clearly Stated?** 

Partially

Power Analysis or Some Other Basis for Determining Adequacy of Study Group Sizes for Primary

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Low

Is Usual Clinical Care Described?

No

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

No

**Could Variation from Protocol have Compromised** 

Study Findings?

Yes

Outcome Assessors Blinded to Intervention/Exposure

**Status of Participants?** 

Yes

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable Manner?** 

Objective

Analysis Comparability/Outcome

Same Length of Follow-up or Adjustment for Different Length of Follow-up?

NA

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Yes

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

NA

Did Attrition Differ by More Than 15 Percentage

**Points After Allocation of Treatment?** 

NA

Baseline Characteristics Similar in

**Exposed/Comparison Cohorts?** 

CD

**Does Analysis Control for Baseline Differences?** 

CD

**Confounding and Modifying Variables Accounted** 

for?

CD

Analysis Conducted on ITT Basis?

Yes

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

NA

Statistical Methods Used to Assess Primary

Outcomes Appropriate to Data?

Yes

For Cohort Studies Only, If Outcome has Greater

than 10% Prevalence, is Risk Ratio and Relative

Risk Calculated Directly?

No

Does Study Report Appropriate Estimates of Random Variability in Data for Main Outcomes?

andom variability in Data for Main Out

Nο

**Conclusions Supported by Results?** 

Nο

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination **Blinding** 

**Soundness of Information** Analysis Comparability/Outcome

**Author Year** 

Tessaro et al., 1997; Navaie-Waliser, et al., 2000

Hypothesis/Aim/ Objective of Study

Described?

Yes

**Criteria Clearly Stated?** 

Yes

Power Analysis or Some Other Basis for **Determining Adequacy of Study Group Sizes** 

for Primary Outcome(s)?

Level of Detail in Describing Intervention/Exposure?

Low

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might

**Bias Results?** 

Yes

**Could Variation from Protocol have Compromised Study Findings?** 

Cannot determine

**Outcome Assessors Blinded to** Intervention/Exposure Status of

Participants?

Interventions/Exposures Measured in Valid and Reliable Manner?

**Outcomes Measured in Valid and Reliable** Manner?

Combination of validated scales/questionnaires and responses to interview questions

Follow-Up

Same Length of Follow-up or Adjustment for Different Length of Follow-up?

Yes

Is Length of Time Following Intervention/Exposure Sufficient

to Support Conclusions?

Did Attrition for Any Group Exceed 20% After Allocation of Treatment?

Yes - G1 34%; G2 40%

Did Attrition Differ by More Than 15 Percentage Points After

Allocation of Treatment?

**Baseline Characteristics Similar in Exposed/Comparison** 

No, differences in age, race, marital status, education, annual family income. (Baseline data for a number of other important

factors NR) **Does Analysis Control for Baseline Differences?** 

Confounding and Modifying Variables Accounted for?

Partially

Cohorts?

Analysis Conducted on ITT Basis?

Impact of Loss to Follow-up (or Differential Loss to Follow-

up) Assessed?

No

Statistical Methods Used to Assess Primary Outcomes Appropriate to Data?

Partially (a great number of analyses conducted w/ multiple comparisons and several regressions; no description of primary outcomes; no sample size calculations; no adjustment for multiple comparisons; potential data mining)

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative Risk Calculated Directly?

No

**Does Study Report Appropriate Estimates of Random** 

Variability in Data for Main Outcomes?

Yes

**Conclusions Supported by Results?** 

No (conclusions do not reflect potential biases in results)

Quality Rating

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Soundness of Information** 

Follow-Up

**Analysis Comparability/Outcome** 

**Author Year** 

Wendell et al., 2003

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

NA

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** 

Outcome(s)?

No

Level of Detail in Describing Intervention/Exposure?

Medium

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** Study Findings?

Cannot determine

**Outcome Assessors Blinded to Intervention/Exposure Status of Participants?** 

No

Interventions/Exposures Measured in Valid and Reliable Manner?

Objective measure, not validated

**Outcomes Measured in Valid and Reliable Manner?** 

Objective measure, not validated

Same Length of Follow-up or Adjustment for Different Length of Follow-up?

NA

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

Did Attrition Differ by More Than 15 Percentage **Points After Allocation of Treatment?** 

**Baseline Characteristics Similar in Exposed/Comparison Cohorts?** 

Yes

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for?

Yes

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

NA

**Statistical Methods Used to Assess Primary** 

**Outcomes Appropriate to Data?** 

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

**Does Study Report Appropriate Estimates of** Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

**Quality Rating** 

**Study Characteristics** 

**Background** 

Inclusion/Exclusion Criteria

Randomization

Interventions/Exposure

Contamination

**Blinding** 

**Soundness of Information** 

Follow-Up

**Analysis Comparability/Outcome** 

**Author Year** 

Wilson et al., 2008

Hypothesis/Aim/ Objective of Study Described?

**Criteria Clearly Stated?** 

No

Power Analysis or Some Other Basis for Determining **Adequacy of Study Group Sizes for Primary** Outcome(s)?

Yes

Level of Detail in Describing Intervention/Exposure?

Is Usual Clinical Care Described?

Researchers Rule out Impact from Unintended Intervention/Exposure that Might Bias Results?

**Could Variation from Protocol have Compromised** 

Study Findings?

Outcome Assessors Blinded to Intervention/Exposure **Status of Participants?** 

Interventions/Exposures Measured in Valid and Reliable Manner?

**Outcomes Measured in Valid and Reliable Manner?** retrospective self-report

Same Length of Follow-up or Adjustment for

Different Length of Follow-up?

NA

Is Length of Time Following Intervention/Exposure

**Sufficient to Support Conclusions?** 

Did Attrition for Any Group Exceed 20% After

Allocation of Treatment?

Did Attrition Differ by More Than 15 Percentage

**Points After Allocation of Treatment?** 

**Baseline Characteristics Similar in** 

**Exposed/Comparison Cohorts?** 

NR

**Does Analysis Control for Baseline Differences?** 

**Confounding and Modifying Variables Accounted** 

for?

No

**Analysis Conducted on ITT Basis?** 

Impact of Loss to Follow-up (or Differential Loss to

Follow-up) Assessed?

NA

**Statistical Methods Used to Assess Primary** 

**Outcomes Appropriate to Data?** 

Partially

For Cohort Studies Only, If Outcome has Greater than 10% Prevalence, is Risk Ratio and Relative

**Risk Calculated Directly?** 

NA

**Does Study Report Appropriate Estimates of** Random Variability in Data for Main Outcomes?

**Conclusions Supported by Results?** 

**Quality Rating** 

# Evidence Table C-4. Key Questions 4 and 4a

Study Characteristics Setting	Community Health Worker
Author Year Balcazar et al., 2006	Title of CHW Promotora
<b>Trial Name</b> Salud Para Su Corazon-NCLR	Relationship with Community NR
Objective or Aim To promote heart-healthy behaviors	<b>CHW (N)</b> 29
among Latinos	Supervision of CHW
Geography Escondido CA, Chicago IL, Ojo Caliente	NR
NM	Prior Training NR
Organization Latino communities	Type of Service Education sessions
Type of Community Latino communities	Type of Educational Materials Used Handouts, recipes, videos, actor scripts, games
Start Date 2000	Duration of Interaction with Clients 7 2-hour sessions over 6 months
Health Condition of Interest Cardiovascular disease	Length of Follow-up 1 year

# **Training Characteristics**

# **Eligibility for CHW Training**

NR

### Input of CHW in Curriculum Development

None

#### **Training on Cultural Competency**

NR (curriculum does offer "cultural and language appropriate instructional methods" but details NR)

#### **Training on Recruitment/Retention Process**

NR

#### Training on Intake/Assessment

NR

### **Training on Protocol Delivery**

NR

# **Training on Health Topic**

NK

# **Training on Evaluation**

NR

### **Other Training**

NR

# Other Training Content; Instructional Method; Number of Sessions; Testing

NR

#### Name of Curriculum

Your Heart, Your life

# **Availability of Curriculum**

Available online

### **Evaluation and Testing Results of Curriculum**

closed-format pre-post test scores reported a score of 74% for pretest and 100% correct for posttest (n = 11). Differences in pre-post promotora knowledge scores changes (N = 29) were statistically (P < 0.05) but data reported in bar graph only.

## Certification

NR

#### **Other Pertinent Information**

NΑ

#### Are Particular Training Characteristics Associate with Improved Outcomes?

NR

# Evidence Table C-4. Key Questions 4 and 4a (continued)

**Health Condition of Interest** 

Cancer prevention

Study Characteristics Setting	Community Health Worker
Author Year Beck et al., 2007	Title of CHW Church Health Action Team (CHAT) member
Center for Health Communities' cancer education program  Objective or Aim Train trainer in cancer education  Geography Milwaukee County Organization African- American churches  Respected CHW (N) 6 (2 from each supervision of the content of the co	Relationship with Community Respected member of church congregation
	CHW (N) 6 (2 from each of 3 participating churches)
	Supervision of CHW NR
	Prior Training
	Type of Service
Type of Community African- American churches	Small group educational presentations
Start Date 2002	Type of Educational Materials Used PowerPoint slides, handouts, brochures
	Duration of Interaction with Clients

4 60-minute presentations

Length of Follow-up NR

# **Training Characteristics**

# **Eligibility for CHW Training**

Member of congregation, well-respected, formal or informal leader, expressed enthusiasm for project

### Input of CHW in Curriculum Development

None

#### **Training on Cultural Competency**

NR

#### **Training on Recruitment/Retention Process**

NR

### Training on Intake/Assessment

NR

### **Training on Protocol Delivery**

NR

# **Training on Health Topic**

NR

# **Training on Evaluation**

NR

#### **Other Training**

2 90-minute train-the-trainer workshops

### Other Training Content; Instructional Method; Number of Sessions; Testing

NR

#### Name of Curriculum

NR

## **Availability of Curriculum**

NR

### **Evaluation and Testing Results of Curriculum**

Pre-post % correct

Ability to define cancer:

(1)General 89/93 (2)Breast 79/86

(3)Colon 15/57 (4)Prostate 80/75

Ability to identify signs/symptoms of cancer:

(1) NA/NA (2) 71/88

(3) 81/93 (4) 40/75

Ability to identify screening recommendations:

(1) NA/NA (2) 67/67

(3) NA/NA (4) 80/75

Ability to identify risk factors:

(1) 59/85 (2) 54/92

(3) 19/89 (4) 40/75

Ability to identify strategies to reduce cancer risk:

(1) 70/78 (2) 8/33

(3) 92/96 (4) 20/75

#### Certification

"Certificate of completion" at 2nd training session

### **Other Pertinent Information**

Results reported for 1 church only; CHWs presented 3 of modules while pastor presented 4th

# Are Particular Training Characteristics Associate with Improved Outcomes?

NR

# Evidence Table C-4. Key Questions 4 and 4a (continued)

**Study Characteristics** 

Setting Con

Author Year Bell, et al., 1999

**Trial Name**Abuela Project

**Objective or Aim** 

To train Hispanic women to make queso fresco that was authentic in taste and texture but did not use raw milk in an effort to reduce incidence of Salmonella serotype Typhimurium infections resulting from eating queso fresco made from raw milk.

Geography

Yakima County, Washington

Organization

Hispanic communities

**Type of Community** 

Hispanics

Start Date

1997

**Health Condition of Interest** 

Salmonella

Community Health Worker

**Title of CHW**Abuela educators

**Relationship with Community** 

Shared ethnicity

CHW (N)

15

Supervision of CHW

NR

**Prior Training** 

NR

Type of Service

Workshop, After training, each CHW singed contract indicating willingness to teach at least 15 members of community

Type of Educational Materials Used

Pamphlet,

**Duration of Interaction with Clients** 

1 workshop

Length of Follow-up

NR

# **Eligibility for CHW Training**

Older Hispanic women from Yakima County

## Input of CHW in Curriculum Development

None; however, curriculum was developed with input from respected Hispanic woman from Yakima community

#### **Training on Cultural Competency**

NR

#### **Training on Recruitment/Retention Process**

NR

#### Training on Intake/Assessment

NR

## **Training on Protocol Delivery**

NR

## **Training on Health Topic**

NR

# **Training on Evaluation**

NR

# **Other Training**

Workshops on how to make new queso fresco recipe (i.e., w/o raw milk)

# Other Training Content; Instructional Method; Number of Sessions; Testing

Training sessions were hands-on and interactive; participants encouraged to ask questions & make comments

## Other Training Content; Instructional Method; Number of Sessions; Testing

NR

## Name of Curriculum

Abuela Project

# **Availability of Curriculum**

Pamphlet available

#### **Evaluation and Testing Results of Curriculum**

Pretraining/ post-training: recognized health risks associated with eating unpasteurized milk and cheese: 10/14; 14/15

Make gueso fresco with fresh unpasteurized milk: 6/12; 1/15.

#### Certification

Nο

#### **Other Pertinent Information**

NA

# Are Particular Training Characteristics Associate with Improved Outcomes?

# Evidence Table C-4. Key Questions 4 and 4a (continued)

Cardiovascular disease

Evidence Table C-4. Key Questions 4 and 4a (continued)	
Study Characteristics Setting	Community Health Worker
Author Year Kuhajda et al., 2006	Title of CHW Counseling CHW; Assessment CHW
<b>Trial Name</b> Pine Apple Heart Disease and Stroke Project	Relationship with Community African American women with experience as community health volunteers in county
Objective or Aim To train CHWs for heart disease and	CHW (N) 4
stroke and in skills for counseling and assessing high-risk women in Pine Apple clinic.	Supervision of CHW NR
<b>Geography</b> Pine Apple, Alabama	<b>Prior Training</b> Trained as community health advisors through U of Alabama-Birmingham; all had 10 yrs experience as community health volunteers
Organization African American women in rural southern community	Type of Service Counseling CHWs counseled clinic patients using project manual; Assessment CHWs assessed future patients before and after
Type of Community	counseling sessions
African American women in rural southern community	Type of Educational Materials Used NR
Start Date NR	Duration of Interaction with Clients NR
Health Condition of Interest	Length of Follow-up

Length of Follow-up NR

## **Eligibility for CHW Training**

Chosen from a pool of CHWs trained as community health advisers through U of Alabama; expert advisory panel member assisted in selection

#### Input of CHW in Curriculum Development

CHWs shared ideas and concerns about training content and implementation of training sessions at a preliminary planning meeting

#### **Training on Cultural Competency**

NR

#### **Training on Recruitment/Retention Process**

NR

## Training on Intake/Assessment

NR

#### **Training on Protocol Delivery**

Health education counseling; role-played cancer screening counseling sessions and CVD counseling sessions

#### **Training on Health Topic**

NR

## Training on Evaluation

Topics addressed in training included CVD; Developing action plans (heart attack, congestive heart failure, stroke); High blood pressure; tobacco control; Cancer (lung, colorectal, breast, cervical)

#### Other Training

NR

#### Name of Curriculum

Training used revised Women's Wellness Sourcebook Module III: Heart and Stroke

## **Availability of Curriculum**

Yes--revised manuals on cancer & stroke served as guide for training

# **Evaluation and Testing Results of Curriculum**

Counseling CHWs' responses on pre-post training questionnaires showed increases in knowledge and self-reported behaviors in each of following areas: heart disease and stroke prevention strategies, cancer prevention strategies, heart attack or stroke signs and symptoms, cancer signs and symptoms, current heart disease and stroke prevention activities, current cancer prevention activities. Data reported in bar graph only.

#### Certification

NR

#### **Other Pertinent Information**

4 week training period; counseling CHWs required to be present for entire 4-wk period (except 2 half days devoted to training assessment CHWs). A variety of media and text materials usd to simulate active participation

## Are Particular Training Characteristics Associate with Improved Outcomes?

# Evidence Table C-4. Key Questions 4 and 4a (continued)

Study Characteristics Setting	Community Health Worker
Author Year Martinez-Bristow et al., 2006	Title of CHW Promotores
<b>Trial Name</b> Tobacco Free El Paso	Relationship with Community Spanish speaking members of community
Objective or Aim To train Spanish speaking counselors to deliver tobacco cessation interventions.	CHW (N) NR (89 participants in total, but 5% were healthcare professionals; baseline data collected for 74)
<b>Geography</b> El Paso	Supervision of CHW NR
Organization Neighborhood clinics	<b>Prior Training</b> NR
Type of Community Spanish-speaking populations	Type of Service Counseling
Start Date 2003	Type of Educational Materials Used NR
Health Condition of Interest Tobacco cessation	<b>Duration of Interaction with Clients</b> NR
	Length of Follow-up NR

## **Eligibility for CHW Training**

NR (training was open to employees of certain clinics, healthcare professionals as well as promotores)

#### Input of CHW in Curriculum Development

Curriculum taken from University of Arizona's Healthcare Partnership which was developed in 1996

#### **Training on Cultural Competency**

NR

#### **Training on Recruitment/Retention Process**

Client recruitment was addressed in level 2 (Treatment Specialist) training; content, method, # of sessions NR

#### **Training on Intake/Assessment**

NR

## **Training on Protocol Delivery**

NR

## **Training on Health Topic**

Nicotine addiction

# **Training on Evaluation**

NR

#### **Other Training**

5 days of training for each level of certification

#### Other Training Content; Instructional Method; Number of Sessions; Testing

NR

#### Name of Curriculum

NR

## **Availability of Curriculum**

Available through U of Arizona developed website; no separate curriculum developed for Tobacco Free El Paso-curriculum "borrowed" directly from U of A

# **Evaluation and Testing Results of Curriculum**

Results from pre-posttest measuring self-confidence suggest that participants understood training material; however data NR.

Mean satisfaction scores (1 = definitely not confident to 5 = definitely confident) high for recipients of each certification: beginner: 4.8, intermediate: 4.7, advanced: 4.6

#### Certification

3 certifications offered: introductory (Basic Skills to Stop Using Tobacco); intermediate (Treatment Specialist); advanced (Leave Addiction)

## **Other Pertinent Information**

NA

## Are Particular Training Characteristics Associate with Improved Outcomes?

#### Evidence Table C-4. Key Questions 4 and 4a (continued)

Study Characteristics Setting	Community Health Worker
Author Year Navarro et al., 2007	Title of CHW Consejeras
<b>Trial Name</b> Por La Vida Cuidandome	Relationship with Community Part of local Latino community
Objective or Aim Train community health advisors to	CHW (N) 17 consejeras, 285 primary participants, 222 learning partners
conduct interactive educational group sessions and train-the-trainer (through "learning partners"	Supervision of CHW NR
Geography San Diego, CA	Prior Training NR
Organization Latino communities	Type of Service Interactive educational group sessions, recruiting women from local community to be primary participants in these sessions
Type of Community Women with low level of acculturation in low socioeconomic Latino communities	Type of Educational Materials Used Manual to guide sessions
Start Date 1996	Duration of Interaction with Clients 12 weekly sessions
Health Condition of Interest Breast & cervical cancer	Length of Follow-up 6 months after pretest

# **Eligibility for CHW Training**

NR

#### Input of CHW in Curriculum Development

Developed over time & preveiously implement, so no

#### **Training on Cultural Competency**

NR

#### **Training on Recruitment/Retention Process**

There were 5 2-hour sessions covering recruitment strategies and role playing practice to lead sessions

#### Training on Intake/Assessment

NR

## **Training on Protocol Delivery**

NR

#### **Training on Health Topic**

Manual had sessions for understanding female body, breast cancer, Pap test, breast health, risks

# **Training on Evaluation**

NR

#### **Other Training**

Referral, communication skills

#### Other Training Content; Instructional Method; Number of Sessions; Testing

NR

#### Name of Curriculum

Por La Vida Cuidandomje, Taking Care of Myself: Women and Cancer

## **Availability of Curriculum**

NR

## **Evaluation and Testing Results of Curriculum**

Changes in knowledge & behavior pre/post test for primary participants; & learning partners

Names following test for breast/cervical cancer early detection:

BSE 58.6/74.7; 46.4/56.3

Clinical breast exam: 29.1/28.8; 28.8/20.7 Mammography: 49.8/71.2; 45.0/63.1 Pap test 84.6/91.9/79.3/85.1 Knows BSE: 90.5/99.3; 82.4/93.2

Knows mammography recs: 32.3/55.8; 27.4/38.1 Names ≥1 breast cancer symptom: 75.1/96.8; 70.3/94.1 Names ≥1 txt for breast cancer: 40.0/65.6; 27.9/45.0

Names ≥1 risk factor: 8.1/16.5; 6.8/7.2

Names ≥1 factor for cervical cancer: 30.9/59.6; 24.3/35.1

BSE in pasat month: 62.3/87.4; 55.9/71.5 Mammography ever: 63.3/70.0; 66.7/68.3 Pap test ever: 92.3/97.9; 88.3/92.8

## Certification

No

## **Other Pertinent Information**

14 program sessions (12 weekly sessions + 2 monthly session) plus 5 additional 2-hour sessions covering recruitment strategies and role playing practice to lead sessions

## Are Particular Training Characteristics Associate with Improved Outcomes?

#### Evidence Table C-4. **Key Questions 4 and 4a (continued)**

Evidence Table C-4. Rey Questions 4 and 4a (continued)	
Study Characteristics Setting	Community Health Worker
Author Year Perez, 2006	Title of CHW CHW
<b>Trial Name</b> Northern Manhattan Community Voices Collaborative	Relationship with Community Live in community or a nearby neighborhood; share cultural & ethnic traditions with program participants
Objective or Aim To train community health workers, focusing on facilitating insurance enrollment, child immunization, and asthma management	<b>CHW (N)</b> # trained between 2000 & 2005: (1) 88 (2) 792 (3 624
<b>Geography</b> Northern Manhattan	Supervision of CHW NR
<b>Organization</b> Neighborhoods	Prior Training NR
Type of Community Northern Manhattan - Washington Heights, Inwood, and Harlem, comprising	Type of Service Community-wide health promotion activities; serve as bridge to primary health care provider
low income communities and/or racial and ethnic minorities (Dominican, African- American)	Type of Educational Materials Used NR
Start Date 2000	Duration of Interaction with Clients NR
Health Condition of Interest (1) health insurance	Length of Follow-up varied

# **Health Condition of Interest**

- (1) health insurance
- (2) child immunizaations
- (3) asthma management

## **Eligibility for CHW Training**

Reside in community; shared culturual & enthic traditions with those they'll be serving; experience with programs offered by organization; good people skills; committed to community development

## Input of CHW in Curriculum Development

NR

## **Training on Cultural Competency**

Yes but not described

#### **Training on Recruitment/Retention Process**

NR

## Training on Intake/Assessment

Yes but not described

## **Training on Protocol Delivery**

Yes but not described

## **Training on Health Topic**

Yes but not described

#### **Training on Evaluation**

Yes but not described (one of 7 core modules)

## Other Training Content; Instructional Method; Number of Sessions; Testing

NR

## Name of Curriculum

NR

# **Availability of Curriculum**

NR

## **Evaluation and Testing Results of Curriculum**

Gains in competency and knowledge (pre/post):

- (1) 24%/72% (gain = 48%; % change = 200; n tested = 61)
- (2) 83%/96% (gain-48%; %change = 16; n tested = 472)
- (3) 63%/83% (gain = 20%; %change = 32; n tested = 499)

# Certification

NR

#### **Other Pertinent Information**

NΑ

#### Are Particular Training Characteristics Associate with Improved Outcomes?

# Evidence Table C-4. Key Questions 4 and 4a (continued)

Study Characteristics	
Setting	Community Health Worker
Author Year Williams, 1996	Title of CHW Lay health educator
<b>Trial Name</b> NR	Relationship with Community Older adult community members
Objective or Aim To raise awareness of & increase	<b>CHW (N)</b> 47
participation of older African-Americans in health promotion activities	Supervision of CHW Program outreach coordinators
Geography Atlanta & Fort Valley Georgia	Prior Training NR
<b>Organization</b> Older African-Americans	Type of Service Conduct or facilitate at least 1 health promotion session/month & disseminate health ed materials through at least 1 of grassroots channels
Type of Community large urban & small township	
Start Date 1992	Type of Educational Materials Used Leaflets, brochures, pamphlets
Health Condition of Interest Health promotion & education	Duration of Interaction with Clients 1 group session/month
	Length of Follow-up NR

## **Eligibility for CHW Training**

Older ( > 55) living in target communities; expected to be knowledgeable about community, have history of volunteering, demonstrate good communication skills & ability to establish rapport with target population; nonsmokers of moderate weight, have at least 8th grade education

## Input of CHW in Curriculum Development

None

## **Training on Cultural Competency**

NIR

## **Training on Recruitment/Retention Process**

NR

## Training on Intake/Assessment

NR

# **Training on Protocol Delivery**

NR

#### **Training on Health Topic**

1111

## **Training on Evaluation**

NR

#### Other Training

Training divided into 3 categories: chronic disease education & self-care, lifestyle education, and consumer education. Topics for these categories developed into 12 training modules

# Other Training Content; Instructional Method; Number of Sessions; Testing

NR

#### Name of Curriculum

NR

# **Availability of Curriculum**

NR

# **Evaluation and Testing Results of Curriculum**

Obtained score ≥80 on pre and posttest for hypertension & diabetes training sessions:

G1: 32%/60% G2: 11%/72% G3: 28%/93%

## Certification

No

# **Other Pertinent Information**

NA

## Are Particular Training Characteristics Associate with Improved Outcomes?

# Evidence Table C-4. Key Questions 4 and 4a (continued)

.,,	
Study Characteristics Setting	Community Health Worker
Author Year Yu et al., 2007	Title of CHW Lay health advisor (LHA)
<b>Trial Name</b> NR	Relationship with Community Shared language
Objective or Aim To inrease self-efficacy of HLAs in conducting breast cancer screening	CHW (N) 79 (10 others were eligible but unable to complete training program)
geography Southeast Michigan	Supervision of CHW NR
Organization Chinese communities	Prior Training NR with respect to breast cancer screening; however Graduate degree: 67.4%
Type of Community Chinese American women	College degree: 30.3% High school education: 2.2%
Start Date	Type of Service NR
Health Condition of Interest Breast cancer	Type of Educational Materials Used NR
	<b>Duration of Interaction with Clients</b> NR (Phase I only)
	Length of Follow-up NR

# **Eligibility for CHW Training**

Adults bilingual in English & Chinese; at least a high school diploma; demonstrated enthusiasm for helping others

#### Input of CHW in Curriculum Development

Community leaders gave input to training materials; first-tier LHAs pretested training manual & Web site and provided comments for final version

## **Training on Cultural Competency**

NR (but point out critical imporantance of a culturally competent program for this population)

#### **Training on Recruitment/Retention Process**

NR

## **Training on Intake/Assessment**

NR

## **Training on Protocol Delivery**

NR

## **Training on Health Topic**

NR

# **Training on Evaluation**

NR

#### Other Training

Training manual had 9 chapters + 5 appendices (1 was a bilingual glossary of medical terms); content includes socieodemographi characteristics & special health concerns, outreach strategies, effective communication skills for promoting screening. Also a web site, PowerPointslides and audio recordings available

## Other Training Content; Instructional Method; Number of Sessions; Testing

3-month self-study of training materials. program included both on-site instruction and materials on paper as well as on Web sites or CDs for self-paced study.

Name of Curriculum

## Name of Curriculum

Training manual: Helping Women Fight Breast Cancer

# **Availability of Curriculum**

Through U of Michigan HAAP

## **Evaluation and Testing Results of Curriculum**

Change in trainees' knowledge & self-efficacy

Knowledge-Mean # of correct answers pre (SD)/post (SD): 6 (1.4)/8 (1.1), P < 0.001

Self-efficacy-mean score pre (SD)/post (SD): 61.0 (11.5)/65.0 (9.2), P = 0.016

#### Certification

No

## **Other Pertinent Information**

NA

## Are Particular Training Characteristics Associate with Improved Outcomes?

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**Appendix D: Excluded Studies** 

#### CHW EXCLUDED STUDIES

#### Non-US population

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- 17. McNeil JK. Effects of nonprofessional home visit programs for subclinically unhappy and unhealthy older adults. J App Gerontol 1995;14(3):333-342.
- 18. Morrow AL, Guerrero ML, Shults J, Calva JJ, Lutter C, Bravo J, et al. Efficacy of home-based peer counselling to promote exclusive breastfeeding: a randomised controlled trial. Lancet 1999;353(9160):1226-31.
- 19. Nichols DC, Berrios C, Samar H. Texas' community health workforce: from state health promotion policy to community-level practice. Prev Chronic Dis 2005;2 Spec no:A13.
- 20. Palmer J. Nurse-led train-the-trainer program breaks new ground in HIV/AIDS care. Reflect Nurs Leadersh 2004;30(2):34-8.
- 21. Raphael D. New patterns in Doula client relations. Midwife Health Visit Community Nurse 1988;24(9):376-9.
- 22. Rissel C, Salmon A, Hughes AM. Evaluation of a (pilot) stage-tailored brief smoking cessation intervention among hospital patients presenting to a hospital pre-admission clinic. Aust Health Rev 2000;23(3):83-93.
- 23. Rowe AK, Lama M, Onikpo F, Deming MS. Health worker perceptions of how being observed influences their practices during consultations with ill children. Trop Doct 2002;32(3):166-7.
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#### No health or economic outcomes

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**Appendix E: Acknowledgments** 

# Appendix E. Acknowledgments

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# **Technical Expert Panel**

We extend our appreciation to the members of our Technical Expert Panel (TEP), who provided advice and input during our research process. The RTI-UNC EPC team solicited the views of TEP members from the beginning of the project. TEP members also provided insights into and reactions to work in progress and advice on substantive issues or possibly overlooked areas of research. TEP members participated in refining the analytic framework and key questions and discussing the preliminary assessment of the literature, including inclusion/exclusion criteria, and also provided input on the information and categories, including evidence tables. The TEP was both a substantive resource and a "sounding board" throughout the study. It was also the body from which expertise was formally sought at several junctions.

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# **Peer Review**

Peer reviewers read and provided feedback on a draft version of the report. We revised the report as appropriate in response to their suggestions.

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