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Community Health Worker Interventions for Latinos With Type 2 Diabetes: a Systematic Review of Randomized Controlled Trials

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Abstract

This systematic review aimed to synthesize glucose (HbA1c) outcomes of community health worker (CHW)-delivered interventions for Latinos with type 2 diabetes that were tested in randomized controlled trials and to summarize characteristics of the targeted populations and interventions, including the background, training, and supervision of the CHWs. Searches of PubMed and Google Scholar databases and references from selected articles identified 12 studies that met the inclusion criteria. Of these, seven reported statistically significant improvements in HbA1c. Study participants were largely low-income, female, and Spanish-speaking and had uncontrolled diabetes. The CHWs led the interventions alone, in pairs, or as part of a team. Interventions varied considerably in session time, duration, and number. Most met standards for tailored, high-intensity interventions and half were theory-based. Overall, methodological quality was good but there were inconsistencies in the reporting of key information. Future research

Conflict of Interest Tariana V. Little, Monica L. Wang, Eida M. Castro, and Julio Jiménez declare that they have no conflict of interest.

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Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

Compliance with Ethics Guidelines

should report in greater detail CHW background, training, and supervision; examine factors associated with intervention effectiveness; and provide data on cost and cost-effectiveness.

Keywords

Community health worker; Randomized control trial; Type 2 diabetes; Hispanic; Culture; Literacy

Introduction

Compared to non-Latino Whites, Latinos have 1.7 times greater risk of developing type 2 diabetes (T2D) [1], a higher prevalence of diabetes (12 vs. 7 %) [2], and greater odds of diabetes-related complications and mortality [3]. In the overall US population and among US Latinos, T2D prevalence, morbidity, and mortality are inversely related to education, with those with less than a high school degree being at increased risk for poor outcomes [1, 2, 4].

Behavioral self-management is critical to prevention of diabetes complications [5], but difficult among Latinos due to patient factors, such as low literacy, limited English proficiency, and cultural differences, and healthcare system factors related to limited resources [6]. As a result, less than half of Latinos with T2D achieve ideal glycemic control, defined as hemoglobin A_{1c} (HbA1c) levels <7 % [7]. The continued growth of the Latino population in the US [8]; persistent ethnic and socioeconomic disparities in T2D outcomes [9]; and the rising economic and other costs of T2D to individuals, families [10], and society [11] underscore the need for interventions tailored to the needs of Latinos. Tailoring implies the use of approaches that are culturally-, linguistically-, and literacy-sensitive and that demonstrate feasibility in implementation and sustainability in low-resource settings.

For several decades in the US [12••] and around the world [13], community health workers (CHWs) have been used to extend health care providers' reach for implementing self-management interventions for chronic health conditions (i.e., diabetes, hypertension) [14]. Encompassing various terms including lay health workers, peer leaders, or *promotores(as) de salud* (health promoters), CHWs are defined as "individuals who serve as bridges between their ethnic, cultural, or geographic communities and health care providers, and engage their community to prevent diabetes and its complications through education, lifestyle change, self-management and social support" [15].

A growing body of evidence suggests that CHWs have a high potential to improve the health of socioeconomically disadvantaged populations [14, 16–19]. CHWs have been viewed as particularly relevant to the treatment of diabetes due to their close relationship with and knowledge of target communities [16••, 17]. However, few reviews have examined the impact of CHW-delivered interventions on Latino health [18, 20], and none to our knowledge have focused on the effectiveness of CHW-delivered interventions on glycemia among Latinos with T2D.

This systematic review aimed to synthesize randomized controlled trials (RCT) examining the impact of CHW-delivered interventions on HbA1c among Latinos with T2D and to

describe characteristics of the Latino populations targeted by the studies; characteristics of the interventions; and the background, training, and supervision of the CHWs.

Method

Data Sources

PubMed and Google Scholar databases were searched through February 25, 2014 using a combination of four key search terms: community, diabetes, intervention, and Latino (see Appendix 1 for the complete search algorithms). Reference lists of articles that met the eligibility criteria were manually screened to identify additional relevant studies.

Study Selection

Inclusion criteria were (a) original article published in a peer-reviewed journal, in English or Spanish, (b) RCT design, (c) study tested a T2D intervention led or co-led by CHWs, and (d) study reported HbA1c outcomes for Latino participants. After eliminating duplicates among the articles retrieved, three independent reviewers (TVL, EMC, and JJ) screened titles and abstracts. Full-text articles were reviewed for further assessment if the abstract information was insufficient to determine eligibility. Study lead authors were contacted as needed to obtain inaccessible articles that appeared relevant.

Data Abstraction

A data abstraction form was developed to standardize the data extraction process. One reviewer (TVL) first abstracted data of interest for each article and two additional reviewers (MLW and MCR) conducted independent validations of the data abstracted. Discrepancies were reviewed and resolved by consensus. Data abstracted included intervention effect(s) on HbA1c and other outcomes, sample characteristics (e.g., recruitment site and method, demographics, baseline HbA1c), intervention characteristics (e.g., theoretical frameworks, format, delivery, content, intensity, setting), and CHW characteristics (e.g., background, training, role, supervision). Intensity of the CHW intervention in each study was categorized based on guidelines from the RTI International-University of North Carolina Evidence-based Practice Center as low, moderate or high based on six elements: one-on-one, face-to-face, 1 h per session, 3 months duration, 3 interactions, and tailored materials [21]. Low-intensity interventions had 0–1 element or did not report them; moderate-intensity interventions had 2–3 elements; and high-intensity interventions had 4–6 elements.

Quality Assessment

Study quality was assessed using a slightly modified version of the 27-item checklist for measuring study quality [22]. Our checklist consisted of 25 questions across five sections: study reporting, external validity, internal validity (bias and confounding), and power. To our knowledge, no standard study quality cutoff scores currently exist. Thus, we used two different scoring methods. First, we obtained a median quality score out of 100 (checklist score (range 0–26) divided by the total possible score of 26 and then multiplied by 100), with higher scores corresponding to a higher study quality. Second, we summarized the percentage of studies that scored positively on each quality criterion across the five sections.

Percentages were categorized as poor (0–25 %), low (26–50 %), fair (51–75 %), or good (76–100 %) as in prior studies [23].

Results

Description of Studies

Figure 1 depicts a diagram of the search and study selection process. PubMed and Google Scholar searches yielded 1749 articles. After the elimination of duplicates (N=134), we screened 1615 articles, of which 1371 titles and 200 abstracts were excluded. The majority of these exclusions were due to article type (reviews, books, dissertations, etc.), topics unrelated to diabetes, and studies of non-Latino samples. Forty-four full-text articles were assessed and 32 were excluded. Discrepancies in title or abstract exclusion (n = 86) were reviewed and resolved. A total of 12 studies met the eligibility criteria and were abstracted [24–35]. All 12 were US-based and published between 2007 and 2014.

Overall quality scores ranged from 46 to 92, with a median of 84 out of 100. Overall, the studies we evaluated for this report were classified as being of "good" quality in terms of study reporting, external validity, internal validity regarding bias, and power and "fair" with regard to potential for confounding. Determination of internal validity was challenged by non-reporting of whether the main outcome assessors were blinded to study condition [24–26, 28, 31–33] and difficulty ascertaining whether studies adequately adjusted for confounding in the main analyses [28, 29, 32–35]. In addition, only half of the studies reported using an intention-to-treat (ITT) analysis [24–27, 30, 31]. Four did not use ITT [29, 32, 33, 35], and the other two were unclear [28, 34]. Variable rates of attrition were reported: two studies reported less than 10 % [30, 35], five reported between 10 and 20 % [25–27, 33, 34], two reported between 21 % and 25 % [24, 29], one reported 41 % [32], and two studies did not report attrition data [28, 31]. No studies reported whether randomization assignment was concealed to health care providers (in addition to study assessors). Similarly, no studies reported data on adverse events.

Intervention Impact

Intervention outcomes were measured at follow-up periods varying from 6 to 24 months (Table 1). Seven studies reported significant HbA1c change differences between the CHW intervention and controls at 1 follow-up time points (p<0.05), with effect sizes ranging from -0.37 to -0.75 [26, 27, 29–31, 33, 35]. Of the seven studies that assessed HbA1c change at 12-month follow-up, five found no differences in HbA1c between intervention and comparison conditions [24, 25, 28, 30, 31]. The three studies with the longest follow-up periods (18 to 24 months) reported statistically significant HbA1c improvements [27, 31, 33], with effect sizes at 24 months of -0.6 and -0.69 (p<0.05) [27, 31] (the third study did not report the effect size [33]). Five of the seven studies that did report significant findings also reported lower (<20 %) attrition rates [26, 27, 30, 33, 35] (including two of the three studies with the longest follow-up [27, 33]), compared to studies that did not find significant HbA1c improvements. Three of the five studies with attrition rates of 20 % or greater reported nonsignificant HbA1c change results [24, 32, 34].

Behavioral improvements associated with the CHW interventions included changes in diet [30, 32], physical activity [27, 32], diabetes self-care activities [31], and goal-setting [28]. Several studies also reported improvements in diabetes knowledge [30, 32, 34, 35], self-reported health [32], and self-efficacy [27, 30–32]. Additional clinical outcomes measured included lipids, weight, blood pressure, and symptoms of hypo- and hyperglycemia, although most studies reported no improvements in these clinical outcomes. One study reported statistically significant improvements in symptoms of hypoand hyperglycemia at 6-month follow-up (p=0.04 and p<0.01, respectively) [33], and another one reported significant improvements in weight loss (p=0.04) [27], although four reported no significant changes in body mass index (BMI) [26, 29, 31, 32]. Five studies that measured blood pressure as an outcome reported no improvements [25–29].

Participant Characteristics

Participants were recruited from low-income communities through clinics, hospitals, or community health centers (CHCs) [24–32, 35] or community sources including churches [27, 33] (Table 1). A wide variety of recruitment methods were used, such as letters from health care providers followed by recruitment calls from study staff, direct physician referral in combination with medical chart review, waiting room promotions, and other forms of clinic and community outreach [24, 26–32, 34, 35]. One study utilized Spanish-language mass media combined with word-of-mouth [33]. There was inconsistent reporting of the total pool of the population targeted, the total number of eligible individuals, and refusal rate, precluding the ascertainment of the recruitment rate in several studies [24, 27–29, 31, 33–35]. For studies reporting adequate recruitment information, recruitment rates ranged from 67.4 to 91 % [25, 26, 30, 32].

Most study participants were female, low-income, Spanish-speaking, and had less than a high school education. Participants were described as immigrants in four studies [26, 29, 33, 34]. Two studies did not report specific demographics (e.g., age, gender, origin) for Latinos [24, 28]. Seven studies included exclusively or primarily Mexican-Americans/Chicanos, of those five were based in Texas [26, 27, 31, 34, 35] and two in California [29, 33]. Three studies included unspecified Latinos, of those one was based in Texas [24], one in Massachusetts [28], and another in California [32]. Two studies included Caribbean Latinos: Dominicans in New York [25] and primarily Puerto Ricans in Massachusetts [30]. The average baseline HbA1c levels ranged from 7.3 to 10.5 % for intervention and control participants. The average baseline BMI ranged from 30.1 to 34.4 kg/m for both groups [26, 27, 29, 31, 32]. Where baseline categorical BMI was presented, 31.7 to 75 % of the intervention and control participants were classified as obese [24, 30].

Intervention Characteristics

Theoretical Framework/Curriculum Content—Half of the studies explicitly identified a theoretical framework or conceptual model as guiding the intervention. These included the social cognitive theory [26, 30], transtheoretical stages of change model [32], community empowerment theory [35], chronic care model [28], and chronic disease self-management model [31] (Table 2). Intervention topics and curricula were overall similar across studies and included self-management, diabetes knowledge or education, nutrition, physical activity,

glucose testing and/or monitoring, care seeking, medication adherence, advocacy, and self-efficacy Additional content covered in some studies included diabetes comorbidities or complications, foot care, eye care, dental care, smoking cessation, guidelines for managing sick days, psychological health (e.g., stress management), and general behavior modification.

Setting—Interventions were delivered in a variety of community-based settings, including clinics [24, 35], CHCs [26, 28, 34], participants' homes [25, 27, 31], or a combination of community organizations and participants' homes [30, 32] or unspecified community sites and telephone contact [33]. One study did not specify an intervention setting [29].

CHW Roles—CHWs were described in various terms across and within studies: community health workers [25–28, 31, 32], *promotoras* [29, 34, 35], trained lay individuals [30], trained lay people [32], lay leaders [24], peer educators [29], peer leaders [33], and experienced master trainers [24]. CHWs led the intervention either alone [25–27, 29, 32], in pairs [24, 33, 34], or as part of a team [28, 30, 35], with responsibilities including serving as educators [24–32, 34, 35], advocates (e.g., referral to medical care, encourage patient-physician communication) [25, 26, 28, 29, 32, 34], supporters (e.g., provide goal-setting assistance, resource for social and community support) [25, 29–32, 34, 35], and logistics coordinators (e.g., call participants, set up appointments, secure space and materials) [26–28, 32, 35]. In one study, CHWs co-developed the class curriculum in conjunction with a certified health educator [35]. CHWs were described as paid staff in six studies [25, 27, 28, 32, 34, 35].

Tailoring—Nine of the 12 studies [24, 25, 28] described the CHW intervention as being tailored with respect to participants' language (Spanish). Of the three that did not report linguistic tailoring, two [24, 28] did not provide Latino sub-sample demographics. By definition, CHW interventions are presumed to be culturally congruent. However, some studies additionally reported distinct cultural tailoring of their program materials or approaches through inclusion of family/friends [30, 32, 33], planning and/or preparation of ethnic foods [26, 30], prayer encouragement and receipt of CHW-signed prayer cards [35], and food bingo that included ethnic foods [30]. In addition, some studies reported addressing cultural beliefs that interfere with access to health care [25] and diabetes self-management [29, 30]. Four studies reported tailoring to participant literacy needs with narrative-based interventions such as an educational video novella [30], brief telephone-based audio vignettes [33], visual aids such as food model [35], and picture-based materials [30, 34, 35], including a colorful food guide and a color-coded chart to facilitate understanding of glucose levels [30]. Three studies reported provision of free glucose meters and testing strips [26, 29, 30] and one study offered free pedometers [30].

Intensity and Cost—All but two interventions [24, 28] were high-intensity as per the RTI classification [22]. The two studies that used moderate-intensity interventions reported nonsignificant HbA1c outcomes [24, 28]. The length of interventions ranged from 1.5 to 24 months and the number of sessions ranged from 6 to 36, mostly weekly and lasting between 1 and 2.5 h. Only two studies reported intervention-related costs. One study estimated the

"direct costs" of the intervention at approximately \$250 per participant [33]. The other reported that the "salary and benefits" of CHWs were \$85 per participant [27]. No study reported cost-benefit or cost-effectiveness of the CHW intervention.

CHW Background, Training, and Supervision

Descriptions of CHWs' background and training are critical for facilitating the implementation of evidence-based CHW interventions in real-world settings. Table 2 presents descriptive data on CHW characteristics, training, and supervision. Seven studies specified that CHWs shared characteristics with participants, including language [25–27, 29, 32, 33, 35], race/ethnicity [25–27, 29, 32, 33], community residency [25–27, 29], and diabetes history personally [29, 32, 33] or through family or friends [32]. One study described CHWs as representative of the populations they served, with no further details provided [28]. One study reported the gender of the CHWs (female) [26]. Two studies reported how CHWs were recruited. In one, three CHWs were recruited from the surrounding community, clinics, and organizations [32]. In the second study, the CHW was a diabetes patient from the CHC who was identified as having leadership skills [29]. Three studies described the educational level and/or prior training of the CHWs, including a high school education [32] and a high school education combined with CHW state certification [26, 31].

Ten of the 12 studies reported that CHWs were trained in the delivery of the intervention [24, 26–30, 32–35]. Training duration was described in eight studies, ranging from hourly units (27–100 h) [26–29, 35] to daily or weekly units (4 days [24, 33], 6 weeks [32], and 3 months [29]). Only six studies reported training content [26–29, 32, 35], which varied across studies, but often included diabetes-related content (i.e., diabetes education, medications), behavioral intervention strategies (i.e., interpersonal communication and interviewing, group instruction, behavioral self-management and change techniques, cultural and spiritual sensitivity), and role-specific duties (i.e., CHW role and responsibilities, home visiting, advocacy and service coordination, leadership, managerial skills, and clinical employee standards). Six studies indicated that a health care professional (e.g., nurse) [28, 34] or a project investigator [27, 29, 30, 35] supervised the CHWs. One study explicitly stated that the CHW was not supervised [26].

Discussion

The present study reviewed existing evidence of impact of CHW interventions as alternative or complementary models for promoting diabetes self-management among Latinos, a population that experiences considerable diabetes disparities. In addition to reviewing the effect of the interventions on glucose control and other outcomes, we described the Latino samples with which the CHW interventions were tested, characteristics of the interventions, and background and training of the CHWs. We reviewed a total of 12 RCTs and observed that overall methodological quality was good, although we found limitations across studies worth noting. In particular, study limitations included participant loss to follow-up, inconsistent reporting of the main outcomes (only half of the studies reported ITT), and unclear adjustment for confounders, which raise concerns regarding the possibility of study

biases. These concerns need to be taken into consideration in interpreting the findings from the studies reviewed herein.

Seven of the 12 studies reported significant intervention effects on glucose levels at one or more follow-up time points. Glucose levels were measured by HbA1c, a valid indicator of treatment effectiveness in patients with T2D, and strongly correlated with diabetes complications [36, 37]. A 1 % decrease in HbA1c is associated with a 37 % reduction in microvascular complications and a 21 % decrease in diabetes-related mortality, and any reduction in HbA1c is considered to be clinically significant as it is likely to reduce the risk of diabetic complications [37]. However, five studies reported nonsignificant findings. These overall study discrepancies may be due to differences in intervention characteristics (format, delivery, duration), study design quality, and inconsistent reporting of results. Whether the length of intervention and follow-up play a role in the findings is difficult to discern from current evidence; however, in contrast with prior suggestions that the impact of the lifestyle interventions for diabetes self-management may be greatest in the short term [38], we found that the three studies with the longest follow-up periods (18- and 24-month follow-up) all reported significant between-group differences in HbA1c change [27, 31, 33]. Beyond HbA1c change, reported improvements in physiological, behavioral, and/or psychosocial outcome were difficult to synthesize for a number of reasons, including differences in the outcomes measured and the assessment instruments used. However, initial evidence suggests that CHW interventions may have a promise for promoting behavioral self-management and diabetes knowledge and self-efficacy.

The CHW interventions included in this review aimed to address challenges associated with cultural, language, and literacy factors of the targeted Latino populations, primarily Mexican-Americans and to a lesser extent Puerto Ricans and Dominicans, residing in Texas, California, Massachusetts, and New York. However, cultural differences among Latino subgroups are well documented and could impact patient receptivity to CHW interventions, potentially moderating their impact. At present, conclusions cannot be drawn regarding the effectiveness of CHW interventions among Caribbean Latinos; future studies should aim to focus on Puerto Ricans and Dominicans, the most prevalent Latino groups in the northeast US.

CHWs had a variety of titles across studies but were commonly described as lay members of the community who shared similarities with the Latino population targeted, including language, ethnicity, and exposure to diabetes either personally or through a family member or friend. As CHWs gain recognition for the potential to deliver culturally sensitive and effective care for diabetes among Latino populations, further research should address the qualitative factors that may be contributing to their impact. The existing literature did not examine the types of CHW characteristics that exert an influence on intervention outcomes. Current evidence of patient satisfaction with CHW intervention is limited and mixed, with some studies reporting satisfaction with CHW-delivered diabetes interventions among Latinos [19, 22, 39] and others suggesting that some Latinos may prefer diabetes interventions led by health professionals. In fact, two RCTs (one targeting Mexican-Americans, the other Puerto Ricans) [40, 41] were excluded from this review because the CHWs did not have a leading role in delivering the intervention. These studies reported that

the researchers had to shift the CHW roles from intervention leaders to ancillary staff assisting health professionals due to participant feedback. In addition, given that Latino men have been less represented in the existing research, it also is unclear whether patient sex influences receptivity to CHW-delivered interventions.

Similarly, there was variability in the intervention delivery model, with some interventions delivered by CHWs alone or in peers, whereas other interventions involved a team where the CHW was one of several providers. Only one study provided information on how CHWs were integrated within the intervention delivery team [28]. Models for integrating CHWs within primary care teams are needed and these programs can be evaluated. A few state programs offer promising approaches to and growing legislative support for integrating CHWs into healthcare systems. Successful CHW state certification programs have been developed in Texas and Minnesota, as well as models for the integration and payment of CHWs in healthcare settings in North Carolina and Ohio [42]. Professional, team-based training and financial compensation may help build CHWs' work capacity as well as fulfill the personal practical needs required for them to continue to serve patients. Available literature suggests that the clinical care teams support the integration of CHWs in delivering health interventions [43].

Overall, most of the CHW interventions in this review were high-intensity, yet no study provided cost-effectiveness data of the CHW interventions. Cost-effectiveness evidence is critical for stakeholders and policy-makers to facilitate the dissemination and implementation of CHW interventions for T2D in Latino communities in the future and for making an economic case for policy initiatives and funding [16••, 19, 22]. A recent review that documented several advancements in CHW diabetes interventions noted a paucity of cost-effectiveness data [16••].

This systematic review identified areas for improvement in the reporting of CHW-delivered self-management interventions for Latinos with T2D. While the majority of studies reported that the CHWs received training in implementing the intervention, there was little information regarding the background of the CHWs and considerable variability in the intensity and content of the training given. These findings are consistent with previous research [16••, 19, 20, 22] and call for improved reporting of CHW competencies associated with the most optimal outcomes, including background (such as educational level), content and duration of the training provided, supervision, as well as challenges with recruitment and retention of CHWs, including attrition [44]. Such data will also help address current challenges facing CHWs, such as the development of a national definition of the CHW workforce [45].

Strengths and Limitations

The current review synthesizes findings from existing RCTs of CHW-delivered interventions aimed at improving glucose control among Latinos with T2D, an area previously underinvestigated. Evaluation of RCTs, the strongest study design for establishing causal inference, addresses a key methodological gap in the literature. However, the evidence reviewed was limited and mixed, thus findings should be interpreted with caution. Several of the studies included primarily female and Spanish-speaking Mexican-Americans in

California or Texas, which may limit the generalizability of findings to other Latino populations. It was not possible to determine key intervention or CHW-level characteristics associated with the intervention effect. As with all reviews, the conclusions drawn from assessment of only published studies may be subject to publication bias. Lastly, in the absence of standard approaches to quality cutoff scores, we used two somewhat arbitrary methods to interpret the quality ratings.

Future Research Directions

It is important to note that all of the studies included in this review were published in the USA between 2007 and 2014. Thus, although CHW interventions have been implemented for decades across many countries, RCTs of these interventions for promoting T2D self-management among Latinos are relatively recent and US-based. Additional research is needed to conclusively demonstrate the impact of CHW interventions as an effective strategy for decreasing diabetes disparities among US Latinos.

To advance the field, it is imperative that future studies address the methodological and reporting issues highlighted in this review. In addition, research on the impact of CHW interventions for Latinos with T2D should utilize theoretical frameworks that help examine how and which parts of these interventions work; what patient-, intervention-, CHW-, or context-related factors optimize their impact; and what possible adverse effects are associated with these interventions. This knowledge will facilitate the refinement of the interventions and the roles of CHWs in the future. Lastly, future studies must assess and report cost and cost-effectiveness data, both needed for facilitating the dissemination and implementation of effective CHW-delivered diabetes interventions for Latinos.

Conclusions

In conclusion, this systematic review showed mixed yet promising evidence of the impact of CHW interventions on glycemic control among Latinos with T2D and some evidence of the impact on diabetes-related behaviors, knowledge, and self-efficacy. Additional high-quality evidence is needed to understand the optimal characteristics of CHW interventions and how to best integrate these interventions within disease management health care systems, as supported by the Patient Protection and Affordable Care Act [12••, 15]. Cost-effectiveness of these interventions also should be assessed, which is critical to decision makers and impacts translation of research evidence to clinical practice.

Acknowledgments

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Appendix 1: Search Algorithms

Google Scholar community health latino OR hispanic OR "mexican american" OR minority "diabetes intervention"

PubMed community AND (management OR intervention OR prevention OR education OR pilot OR trial OR programs) AND (chronic disease OR diabetes) AND (hispanic OR latino OR mexican american OR minorit*)

Extended PubMed Search Algorithm ("residence characteristics" [MeSH Terms] OR ("residence" [All Fields] AND "characteristics" [All Fields]) OR "residence characteristics" [All Fields] OR "community" [All Fields]) AND (("organization and administration" [MeSH Terms] OR ("organization" [All Fields] AND "administration" [All Fields]) OR "organization and administration" [All Fields] OR "management" [All Fields] OR "disease management" [MeSH Terms] OR ("disease" [All Fields] AND "management" [All Fields]) OR "disease management" [All Fields]) OR ("Intervention (Amstelveen)" [Journal] OR "Interv Sch Clin" [Journal] OR "intervention" [All Fields]) OR ("prevention and control" [Subheading] OR ("prevention" [All Fields] AND "control" [All Fields]) OR "prevention and control" [All Fields] OR "prevention" [All Fields]) OR ("education" [Subheading] OR "education" [All Fields] OR "educational status" [MeSH Terms] OR ("educational" [All Fields] AND "status" [All Fields]) OR "educational status" [All Fields] OR "education" [All Fields] OR "education" [MeSH Terms]) OR ("Pilot Evanst Hosp" [Journal] OR "pilot" [All Fields]) OR ("clinical trials as topic" [MeSH Terms] OR ("clinical" [All Fields] AND "trials" [All Fields] AND "topic" [All Fields]) OR "clinical trials as topic" [All Fields] OR "trial" [All Fields]) OR programs[All Fields]) AND (("chronic disease" [MeSH Terms] OR ("chronic" [All Fields] AND "disease" [All Fields]) OR "chronic disease" [All Fields]) OR ("diabetes mellitus" [MeSH Terms] OR ("diabetes" [All Fields] AND "mellitus" [All Fields]) OR "diabetes mellitus" [All Fields] OR "diabetes" [All Fields] OR "diabetes insipidus" [MeSH Terms] OR ("diabetes" [All Fields] AND "insipidus" [All Fields]) OR "diabetes insipidus" [All Fields])) AND (("hispanic americans" [MeSH Terms] OR ("hispanic" [All Fields] AND "americans" [All Fields]) OR "hispanic americans" [All Fields] OR "hispanic" [All Fields]) OR ("hispanic americans" [MeSH Terms] OR ("hispanic" [All Fields] AND "americans" [All Fields]) OR "hispanic americans" [All Fields] OR "latino" [All Fields]) OR ("mexican americans" [MeSH Terms] OR ("mexican" [All Fields] AND "americans" [All Fields]) OR "mexican americans" [All Fields] OR ("mexican" [All Fields] AND "american" [All Fields]) OR "mexican american" [All Fields]) OR (minorita [All Fields] OR minoritaire [All Fields] OR minoritaries[All Fields] OR minoritari[All Fields] OR minoritarian[All Fields] OR minoritarilor[All Fields] OR minoritarios[All Fields] OR minoritarios[All Fields] OR minoritary[All Fields] OR minoritaten[All Fields] OR minoritatsbasen[All Fields] OR minorite[All Fields] OR minorites[All Fields] OR minoritet[All Fields] OR minoriteter[All Fields] OR minoriteternas[All Fields] OR minoritetsgrupper[All Fields] OR minoritetshelse[All Fields] OR minorities[All Fields] OR minorities/language[All Fields] OR minorities/women[All Fields] OR minorities'[All Fields] OR minoritis[All Fields] OR minoritisation[All Fields] OR minoritites[All Fields] OR minoritiy[All Fields] OR minoritization[All Fields] OR minoritize[All Fields] OR minoritized[All Fields] OR minoritizing[All Fields] OR minoritnich[All Fields] OR minority[All Fields] OR minority/ admissions[All Fields] OR minority/disadvantaged[All Fields] OR minority/ethnic[All Fields] OR minority/human[All Fields] OR minority/immigrant[All Fields] OR minority/ international[All Fields] OR minority/less[All Fields] OR minority/low[All Fields] OR minority/majority[All Fields] OR minority/minority [All Fields] OR minority/

nonminority[All Fields] OR minority/specialist[All Fields] OR minority/white[All Fields] OR minority/women's[All Fields] OR minority'[All Fields] OR minority's[All Fields] OR minoritynurse[All Fields]))

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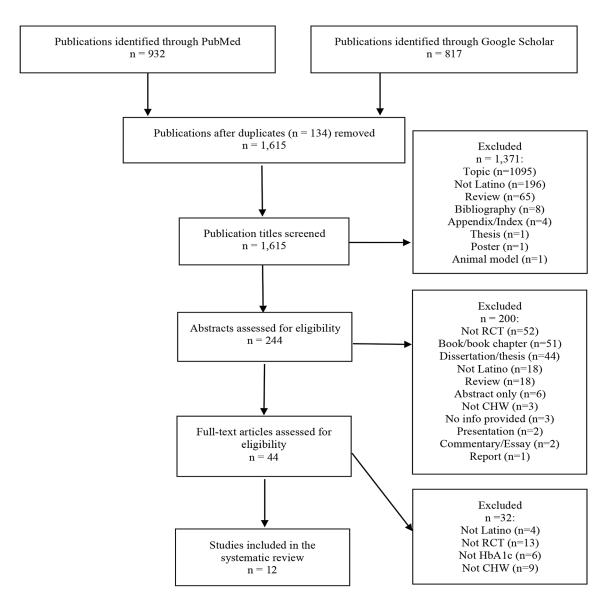


Fig. 1. Flow diagram of the article search and selection process

Table 1

Summary of Latino sample characteristics, intervention characteristics, assessment time points, intention-to-treat analysis, and mean HbA_{1c} betweengroup difference change

Citation number	Latino sample characteristics	Intervention characteristics	Assessment time points, analysis type intention-to-treat (ITT) analysis, and effect size
Forjuoh et al. [24]	Recruitment strategy: letters from physicians with telephone follow-up by project coordinators Site: clinics; TX Rate, NR A=101 CDSMP (Latino A=20) Demographics: NR Baseline HbA1c, mean (SD) ^a T1, 94 (1.7) T2, 9.3 (1.6) T3, 9.2 (1.4) C, 9.2 (1.6) Attrition, 24.4 % ^a	Theory: NR T1: chronic disease self-management program (CDSMP), N=101 (Latino N=20) T2: personal digital assistant (PDA), N=81 T3: CDSMP+PDA, N=99 C: usual care, N=95 C: usual care, N=95 C: usual care, N=95 C: usual care, in a master trainers/lay leaders Term: experienced master trainers/lay leaders Setting delivered: clinic, community-based settings Topics: diabetes knowledge, general self-management Distinct features: scripted materials (format not specified); monetary compensation (\$20 at orientation and at 12- and 24-month follow-up visits) Moderate intensity ^b : six weekly face-to-face group sessions; tailored: NR	Assessment time points: baseline and 6, 12, and 24 months Analysis type: multilevel models with group-by- Highanic-by-time interaction HTT: yes HbA _{1c} effect size: • Baseline to 12 months, -0.003 (NS)
Palmas et al. [25]	Recruitment strategy: NR Site: hospital; NY Rate, 67.4 % A=360 Dominicans Demographics: Female T, 60.8 %; C, 62.6 % Mean age T, 57.1; C, 58.1 4High school education T, 83.4 %; C, 88.8 % Employed full/part-time T, 17.1 %; C, 19 % <\$20,000 yearly income T, 84.6 %; C, 90.5 % Married T, 30.9 %; C, 33.5 % Baseline HbA _{1c} , mean (SD) T, 8.8 (1.7) C, 8.6 (1.6) Attrition T, 15.6 %; C, 18.8 %	Theory: NR T: 12-month CHWintervention, N=181 C: usual PCP care plus four sets of Spanish-language educational materials on patient-provider communication, diabetes management, mental health, and diabetes cookbook. Quarterly phone calls to ensure receipt of materials and subject retention, V=179 CHW role: program facilitator, educator, advocate, supporter; delivered intervention: alone THE: CHW Tern: CHW Tern	Assessment time points: baseline and 12 months Analysis type: longitudinal mixed effects models with group-by-time interaction ITT: yes HbA _{1c} effect size: • Baseline to 12 months, NR (NS)
Prezio et al. [26]	Recruitment strategy: clinic physician referrals Site: urban faith-based community health center; TX Rate, 86 % A=180 mainly Spanish-language dominant, Mexican-American immigrants Demographics ^{2,} Female T, 66.7 %; C, 54.4 % Mean age T, 47.9; C, 45.7 <high %="" %;="" 100="" 57.8="" 62.9="" 70.1="" 78.6="" baseline="" c,="" education="" hba<sub="" married="" medically="" school="" t,="" uninsured="">1c, mean (SD)^a</high>	Theory: social cognitive theory T: community diabetes education self-management with usual care, Λ =90 (Latino 81.1%) C: wait list with usual provider care, Λ =90 (Latino 82.2%) C: wait list with usual provider care, Λ =90 (Latino 82.2%) C: wait list with usual provider care, Λ =90 (Latino 82.2%) delivered intervention: alone delivered intervention: alone Term: CHW Setting delivered: single urban faith-based community health center Topics: care seeking (e.g., physician referral, eye exams, dentist, pharmacy refills), diabetes knowledge, glucose meter use and monitoring, medication adherence, nutrition, physical activity, self-management, sick day rules, smoking cessation, long-term diabetes complications	Assessment time points: baseline and 3, 6, 9, and 12 months Analysis type: linear mixed models with group-by-time interaction ITT: yes HbA ₁ effect size: • Baseline to 12 months, -0.7*

Citation number	Latino sample characteristics	Intervention characteristics	Assessment time points, analysis type intention-to-treat (ITT) analysis, and effect size
	T, 8.9 (2.2) C, 8.7 (2.3) Attrition, 14.4 % ²	Distinct features: private clinic office for CHW consultation, case management, individualized culturally appropriate meal planning, glucose meter and testing strips, cash incentives (\$5 at the third quarter and \$10 post-intervention) High intensity: seven 1-h face-to-face personalized individual sessions; tailored: culture, language, literacy	
Rothschild et al. [27]	Recruitment strategy: community-based via direct mailings, community events and churches, primary care clinics, CHWoutreach Site: churches and primary care clinics; TX Rate, NR A=144 Spanish-speaking Mexican—Americans Demographics: Fernale, 67.4 % Mean age, 53.7 -High school education, 74.3 % Difficulty paying for basics, very hard, 23.8 % Married, 65.3 % Baseline HbA _{1c} , mean (SD) T, 8.5 (2.2) C, 8.1 (1.6) Attrition, 16 %	Theory: NR T: CHW home visits, $\Lambda = 75$ C: bilingual newsletter <i>Diabetes Action</i> , $\Lambda = 71$ C: bilingual newsletter <i>Diabetes Action</i> , $\Lambda = 71$ C: Wrole: program facilitator, educator, logistics coordinator; delivered intervention: alone Item: CHW Setting delivered: participants' homes Topics: self-management, behavior modification techniques Distinct features: American Association of Diabetes Educators curriculum High intensity: $36 \sim 1.5$ -h face-to-face individual sessions over 2 years; tailored: culture, language	Assessment time points: baseline and 12 and 24 months Analysis type: linear mixed effects models with group-by- time interaction ITT: yes HbA ₁ effect size: • Baseline to 12 months, -0.55* • Baseline to 24 months, -0.69***
Hargraves et al. [28]	Recruitment strategy: NR Site: community health centers; MA Rate, NR (cluster RCT of health centers) A=366 Latinos Demographics: NR Baseline HbA1c, percentage (SD) <7 % ^a T, 53.2 (5.5) C, 51.0 (3.8) Attrition, NR	Theory: chronic care model T: six community health centers with CHW, N=494 (Latino N=125) C: six community health centers without CHW, N=921 (Latino N=241) C: six community health centers without CHW, N=921 (Latino N=241) C: Strong chievrention: in a team Term: CHW Setting delivered: community health centers Topics: care seeking (making and keeping appointments), diabetes education, glucose testing, nutrition, physical activity, self-management, self-efficacy Distinct features: CHWs integrated in health center medical care teams, participant—CHW encounter forms completed by CHWs to track participant goal self-efficacy Moderate intensity: 12-month face-to-face, one-on-one care; tailored: NR	Assessment time points: baseline (12 months preintervention) and 12 months Analysis type: within-group hierarchical regression models ITT: OR HbA1c effect size: HbA1c dichotomized as level of HbA1c < 7% (yes/no) • Baseline to 12 months, -2.6% of Latino participants in the CHW intervention group with HbA1c <7% vs6.4% of Latino participants in the CHW intervention group with HbA1c <7% vs6.4% of Latino participants in the comparison group (NS)
Philis-Tsimikas et al. [29]	Recruitment strategy: provider referrals, medical chart reviews, and waiting room demos Site: community health center; CA Rate, NR A–207 Spanish-language dominant, mainly Mexican–American immigrants Demographics: Fernale T, 66.3 %; C, 74.8 % Mean age T, 52.2; C, 49.2 <8h grade T, 54.8 %; C, 49.5 % <\$12.000 yearly income T, 46.2 %; C, 53.4 %	Theory: NR T: Project Dulce peer-education, N=104 C: standard diabetes care, N=103 CHW role: program facilitator, educator, advocate, supporter; delivered intervention: alone Term: peer educator/promotora Setting delivered. NR Topics: care seeking (referral to care, encouragement to communicate with physician regarding clinical target levels), diabetes knowledge, glucose monitoring, medication adherence, nutrition, physical activity, self-management, ancillary education on hypertension and dyslipidemia	Assessment time points: baseline and 4 and 10 months Analysis type: multilewel models with group-by-time interaction ITT: no HbA _{1c} effect size: • Baseline to 10 months, NR *

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Citation number	Latino sample characteristics	Intervention characteristics	Assessment time points, analysis type intention-to-treat (ITT) analysis, and effect size
	Married T, 48.1 %; C, 51.4 % Medically uninsured T, 67.3 %; C, 65 % Baseline HbA1c, mean (SD) T, 10.5 (1.7) C, 10.3 (1.7) Attrition, 25 %	Distinct features: American Diabetes Association guidelines, glucose meter; testing strips, cultural beliefs that interfere with self-management, occasional guest speakers. High intensity: eight weekly 2-h face-to-face group sessions, monthly 2-h face-to-face support group sessions, monthly telephone follow-up; tailored: culture, language	
Rosal et al. [30]	Recruitment strategy; letters from primary care providers with telephone follow-up by recruitment staff Site: community bealth centers; MA Rate, 91 % N=252 mainly Spanish-monolingual, predominantly Puerto Rican Latinos Demographics: Female, 76.6 % Aged 55-64, 32.9 % Employed full/part-time, 11.3 % - High school education, 75.2 % - \$10,000 yearly income, 55.3 % Medically uninsured, 2 % Baseline HbA1c, mean (SD) T, 8.85 (1.8) C, 9.11 (2.0) Attrition, 7 %	Theory: social cognitive theory T: Latinos en Control (Latinos in Control), N=128 C: enhanced usual care, N=124 C: enhanced usual care, N=124 C: which is the company of th	Assessment time points: baseline and 4 and 12 months Analysis type: linear mixed effects models with group-by- time interaction ITT: yes HbA _{1c} effect size: • Baseline to 4 months, -0.53*** (NS)
Ryabov [31]	Recruitment strategy: community health centers; TX Rate, NR A=30 Spanish-language dominant Mexican-Americans Demographics: Female, 80 % Mean age, 54.6 Mean age, 54.6 Mean education years, 8.5 <\$10,000 yearly income, 47 % Married, 77 % Baseline HbA1c, mean (SD) T, 7.6 (0.5) C, 7.7 (0.3) Attrition, NR	Theory: chronic disease self-management model T: CHW-led, N=15 C: no CHW, N=15 C: HW role: program facilitator, educator, supporter; delivered intervention: or specified Term: CHW Setting delivered: participants' homes Topics: diabetes knowledge, glucose monitoring, and results interpretation; nutrition; physical activity; self-management; psychological health (e.g., stress management) Distinct features: National Diabetes Education Program guidelines, individualized self-management plan drafted by CHW and participant on the first visit, short personalized behavior change tips High intensity: 2-year monthly 1-h face-to-face individual sessions; tailored: culture, language	Assessment time points: baseline and 12 and 24 months Analysis type: ANOVA with group-by-time interaction ITT: yes HbA1c effect size: • Baseline to 12 months, NR (NS)
Babamoto et al. [32]	Recruitment strategy: approaching patients at routine clinic visits Site: inner-city family health centers; CA Rate, 89.8 % A=189 Spanish-language dominant Hispanics Demographics: Female, 64 % Mean age, 50 <fi>6fb grade education, 61 % <\$25,000 yearly income, 53 % Married/cohabitating 52 % Baseline HbA1c, mean (SD) T. 8.6 (NR)</fi>	Theory: transtheoretical (stages of change) model T: Amigos en Salud (Friends in Health), N=75 CI: case management, A=60 CI: case management, A=60 CI: case program facilitator, educator, advocate, logistics CHW role: program facilitator, educator, advocate, logistics coordinator, supporter, delivered intervention: alone Term: CHW/trained laypeople Setting delivered: community organization, clinic, patient's home Topics: Glabetes knowledge, medication adherence, physical activity, self- management Distinct features: American Diabetes Association guidelines, family/friend inclusion	Assessment time points: baseline (3 months pre- intervention enrollment) and 6 months months Analysis type: between- and within-group multivariate logistic regression models ITT: no HbA _{Le} effect size: • Baseline to 6 months, -0.70 (NS)

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Citation number	Latino sample characteristics	Intervention characteristics	Assessment time points, analysis type intention-to-treat (ITT) analysis, and effect size
	C2, 9.5 (NR) Attrition, 41 %	High intensity: mean 10 weekly face-to-face individual sessions and routine telephone follow-up; tailored: culture, language, literacy	
Lorig et al. [33]	Recruitment strategy: word-of-mouth, Spanish language media, community outreach Site: community, churches, and clinics; CA Rate, NR N=567 Spanish-language dominant, predominantly Mexican-American immigrants Demographics: Female, 62 % Mean age, 52.9 Mean age, 52.9 Mean age, 52.9 Mean age, 52.9 Married T1, 66.7 %; C, 63.6 % Baseline HbA1c, mean (SD) T1, 744 (2.0) C, 7.38 (1.87) Attrition T, 18 %; C, 13 %	Theory: NR T1: peer-led Spanish Diabetes Self-Management Program (SDSMP) with monthly telephone reinforcement, N=116 T2: SDSMP without monthly telephone reinforcement, N=219 C: usual care wait list control, N=198 CHW role: program facilitator; delivered intervention: in pairs Term: peer leaders Setting delivered: community sites Topics: NR Distinct features: automated telephone reinforcement where participants were (1) greeted and asked to rate their certainty in managing their diabetes in the next month, (2) given a choice of listening or not listening to two 90-s vignettes about diabetes, each of the 15 vignettes was offered twice over 15 months, and (3) invited to leave a message (if needed, a staff member responded); family/friend inclusion High intensity: six weekly 2.5-h face-to-face group sessions, monthly automated telephone reinforcement; tailored: culture, language	Assessment time points: baseline and 6 and 18 months Analysis type: ANCOVAs and paired tests ITT: no HbA1e effect size: • Baseline to 6 months, -0.36* • Baseline to 18 months, NR *
Sixta and Ostwald [34]	Recruitment strategy; provider referral, research assistant telephone calls inviting participation Site: TX Rate, NR A=131 Spanish-language dominant, mostly immigrant Mexican-Americans Demographics: Female, 71 % Mean age, 56.3 Baseline HbA _{1c} , mean (SD) T, 7.32 (NR) C, 7.65 (NR) Attrition, 20 %	Theory: NR T: promotora-led self-management, N=63 C: wait list usual provider care, N=68 C: Wait list usual provider care, N=68 C: Wait list usual provider care, N=68 C: Wait list usual program facilitator, educator, advocate, supporter; delivered intervention: in pairs Term: promotoras Setting delivered: community health center Topics: care seeking (physician referral, certified diabetes educator, nursing director), diabetes knowledge, glucose monitoring, nutrition, physical activity, self-management Distinct features: scripted curriculum, pictures, multidisciplinary team, management skills High intensity: 10 weekly 2.5-h face-to-face group sessions; tailored: culture, language, literacy	Assessment time points: baseline and 3 and 6 months Analysis type: mixed effects models with group-by-time interaction ITT: NR HbA _{1c} effect size: • Baseline to 3 months, NR (NS) • Baseline to 6 months, NR (NS)
Lujan et al. [35]	Recruitment strategy: clinic posters, mailed invitations Site: faith-based community clinic; TX Rate, NR A-150 Spanish-language dominant Mexican-Americans Demographics: Female, 80 % Mean age, 58 - High school education, 95 % - Si 10,000 yearly income, 42 % Medically uninsured, 68 % Baseline HbAlc, mean (SD) T, 8.21 (2.2) C, 7.71 (1.49) Attrition, 6 %	Theory: adapted community-empowerment theory T: promotora-led, Λ =75 C: usual care, Λ =77 C: usual care, supporter; delivered intervention: in pairs with interdisciplinary team Term: promotors Setting delivered: Catholic, faith-based community clinic Topics: diabetes knowledge, foot care, eye care, dental care, sick day guidelines, glucose meter use and monitoring, nutrition, self-management, diabetes comorbidities and complications Distinct features: American Diabetes Association guidelines, flip charts, food models, food product label reading, handheld mirror, prayer encouraged to increase dietary self-control, promotora-signed prayer cards, inspirational faith-based health	Assessment time points: baseline and 3 and 6 months Analysis type: ANCOVAs for between and within-group comparisons ITI: no HbA _{1c} effect size: • Baseline to 3 months, -0.59 (NS)

Little	et al.
Assessment time points, analysis type intention-to-treat (ITT) analysis, and effect size	
Intervention characteristics	High intensity: eight weekly 2-h face-to-face group sessions, biweekly telephone follow-up; 16-week biweekly mailing; tailored: culture, language, literacy
itation number Latino sample characteristics	
Citation number	

NR not reported

 $\begin{tabular}{ll} * \\ Significant improvements at $p < 0.05$; \end{tabular}$

** significant improvements at p < 0.01

bntensity of CHW intervention in each study was categorized as low (0-1), moderate (2-3), or high (4-6), based on the following six elements: one-on-one, face-to-face, 1 h per session, 3 months duration, 3 interactions, and tailored materials

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Table 2

Summary of community health worker background and training characteristics

Citation	Recruitment and employment status	Background	Training characteristics	Fidelity and supervision
Forjuoh et al. [24]	Recruitment: NR Employment: NR	NR	Training: yes Duration: 4 days Content: NR Strategies: NR	Fidelity: "not monitored" Supervision: NR
Palmas et al. [25]	Recruitment: NR Employment: paid staff	Bilingual Spanish–English Mexican–American community residents	Training: NR Duration: NR Content: NR Strategies: NR	Fidelity: NR Supervision: NR
Prezio et al. [26]	Recruitment: NR Employment: NR	Bilingual Spanish–English Mexican– American female, community resident, General Educational Development diploma and CHW state-certification	Training: yes Duration: 27 h Content: CHW role and responsibilities, diabetes information, managerial skills Strategies: didactic instruction, written exam, clinical observation	Fidelity: NR Supervision: no
Rothschild et al. [27]	Recruitment: NR Employment: paid staff	Bilingual Spanish–English Mexican– American community residents	Training: yes Duration: 100 h Content: diabetes information, behavioral self- management support, home visiting Strategies: NR	Fidelity: study visits videotaped, study psychologist reviewed tapes Supervision: study psychologist
Hargraves et al. [28]	Recruitment: NR Employment: part-time paid clinical staff	Representative of the populations they served, unspecified characteristics	Training: yes Duration: 66 h Content: service coordination, interpersonal and organizational relationships, communication and interviewing, advocacy, leadership, cultural awareness, chronic care model, managing chronic disease and diabetes Strategies: on-the-job training and reinforcement	Fidelity: NR Supervision: frequent telephone communication with project director/ registered nurse
Philis-Tsimikas et al. [29]	Recruitment: community health center Employment: NR	Spanish–English bilingual Mexican– American community resident with diabetes	Training: yes Duration: 3 months Content: diabetes education, behavior modification techniques, group instruction and mediation methods, employee standards, and 40-h education on Project Dulce curriculum "Diabetes with Friends" Strategies: after meeting competencies, co-taught two series of classes with trainer, then independently taught two series with trainer observation	Fidelity: all classes audio recorded and reviewed using checklists Supervision: one trainer
Rosal et al. [30]	Recruitment: NR Employment: NR	N.	Training: yes Duration: NR Content: NR Strategies: NR	Fidelity: NR Supervision: two investigators
Ryabov [31]	Recruitment: NR Employment: NR	High school diploma and CHW state certification	Training: NR Duration: NR Content: NR	Fidelity: NR Supervision: NR

Citation	Recruitment and employment status	Background	Training characteristics	Fidelity and supervision
			Strategies: NR	
Babamoto et al. [32]	Recruitment: community, clinics, and community organizations Employment: paid clinical staff	Bilingual Spanish–English Mexican and South American origin, high school or General Educational Development diploma, diabetes diagnosis or history of diabetes among family/friends	Training: yes Duration: 6 weeks Content: CHWroles and responsibilities, cultural sensitivity, diabetes education, diabetes self- management, clinic policies and procedures, sensitivity to spiritual beliefs Strategies: NR	Fidelity: NR Supervision: NR
Lorig et al. [33]	Recruitment: NR Employment: NR	Bilingual Spanish–English Mexican– Americans with diabetes	Training: yes Duration: 4 days Content: NR Strategies: NR	Fidelity: NR Supervision: NR
Sixta and Ostwald [34]	Recruitment: NR Employment: paid clinical staff	Z Z	Training: yes Duration: NR Content: NR Strategies: NR	Fidelity: nursing director randomly attended sessions to observe promotora presentations; promotora-patient interactions; and patients' responses, participation, level of understanding, and session satisfaction. After each session, promotoras and principal investigator debriefed and planned for next session. Monthly meetings with nursing director, certified diabetes educator, and providers to discuss session and participant progress.
Lujan et al. [35]	Recruitment: NR Employment: paid clinical staff	Bilingual Spanish—English	Training: yes Duration: 60 h Content: diabetes self-management Strategies: NR	Fidelity: principal investigator attended every class to ensure consistent curriculum delivery Supervision: principal investigator

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