Community health workers assisting Latinos manage stress and diabetes (CALMS-D): rationale, intervention design, implementation, and process outcomes

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Abstract

Latinos have high rates of diabetes and mental distress, but lack appropriate services. A study was designed to compare enhanced standard diabetes care with enhanced standard care plus community health worker (CHW) delivered stress management for Latinos with type 2 diabetes. This paper reports intervention design and process outcomes. A formative process was used to develop and implement an eight-session, group stress management intervention. One hundred twenty-one participants completed baseline assessments; $n=107$ attended diabetes education and were then randomized. Recruits reported high credibility and treatment expectancies. Treatment fidelity was high. Participants reported high treatment satisfaction and therapeutic alliance and their diabetes knowledge and affect improved over the short term. Retention and attendance at group sessions was challenging but successful relative to similar trials. This comprehensive and culturally sensitive stress management intervention, delivered by a well-trained CHW, was successfully implemented.

Keywords

Diabetes, Stress management, Latinos, Community health workers

INTRODUCTION

Latinos currently comprise 12.5 % of the US population, likely rising to 25 % by the year 2050 [1]. Latinos are almost twice as likely to have diabetes compared to non-Latino Whites, with the highest prevalence among Puerto Ricans [2]. Latinos with diabetes have A1c (average glucose over 120 days) that is 0.5 % higher than non-Hispanic Whites [3], and they are twice as likely to be hospitalized for diabetes-related complications [4].

Mental stress has been shown to worsen glycemic control among persons with type 2 diabetes [5]. Stress can raise blood glucose directly through stress hormones [6] and indirectly by interfering with diabetes self-care behaviors ([7]. Latinos face stressors including immigration, separation from family, social isolation, and exposure to discrimination [8]. Financial strain and

Implications

Practitioners: Supportive services for people with diabetes—even insured, English speaking patients with transportation and no comorbidities—are lacking in most but tertiary care treatment sites and this study provides evidence that stress management skills can be provided by CHWs.

Policy: The Affordable Care Act formally recognizes the role of CHWs and offers reimbursement for CHW activities including providing culturally and linguistically appropriate health education, thus making uptake of CHW-led interventions more likely.

Researchers: By employing community research staff (rather than a research assistant based at an academic institution), engagement of this population is not only possible, but on par with similar studies not employing community research staff.

food insecurity are significant mental stressors among the Latino community in Hartford, Connecticut, which is primarily Puerto Rican [8]. National data also suggest that, whereas some minorities may not endorse higher general distress than non-Hispanic White comparators, they do endorse higher diabetes-related distress [9].

Interventions that modulate the perception and appraisal of stressors, improve stress-related coping strategies, and that promote physical relaxation have the potential to improve quality of life, mood, and diabetes self-care (e.g., [10]). Although data are mixed (e.g., [10]), such interventions may even improve glycemic control [11, 12].

Yet, those at greatest need for such interventions may be those who face the greatest barriers to treatment. Community health workers (CHWs) engage medically underserved communities to overcome barriers to health care [13]. They can also develop the skills needed to deliver health education and care when properly integrated into the health care team. In the previous Diabetes Among Latinos Best Practices

(DIALBEST) study, diabetes education delivered by CHWs improved glycemic control among Hartford Latinos [14]. DIALBEST also underscored the serious contextual stressors faced by many diabetic Latinos, very high rates of elevated depressive symptoms [15], and lack of psychosocial services for this population.

To a very limited degree, CHWs have been employed to address mental health issues among Latinos with diabetes (e.g., [16]); however, there have been no randomized controlled trials. To address this gap, we conducted a randomized controlled trial of a CHW-led stress management intervention for Latinos with type 2 diabetes, Community Health Workers Assisting Latinos Manage Stress and Diabetes (CALMS-D). Whereas CHWs have been shown to successfully improve diabetes self-management among Latinos [14], their ability to deliver effective psychosocial support is untested. CALMS-D is a single-site, randomized, controlled trial to compare the efficacy of CHW-led diabetes education (DE) vs. CHW-led DE plus CHW-led stress management (DE + SM) in Latinos with type 2 diabetes. This paper describes the development and implementation of CALMS-D. Data collection was recently completed and future analyses will investigate the effect of the intervention on biological, behavioral, and psychosocial outcomes.

METHODS

Overview

All participants completed the baseline survey and DE and were then randomized. The SM intervention consisted of eight 2-h sessions of group psychoeducation, skills training, and relaxation exercises. The same CHW delivered both DE and SM throughout the study to avoid interventionist effects. All intervention sessions were delivered at the Hispanic Health Council (hereafter “the Council”), in Hartford, CT, which is a community-based organization located in a large Latino neighborhood and trusted by the community, and that has been active with the Hartford Hispanic community for over three decades.

Intervention development

Enhanced standard care—All study participants received the standard care offered by the Hartford Hospital’s “Brownstone Clinic,” which has been described elsewhere [14]. All participants also received a 2.5-h group DE session delivered by the study CHW. The DE curriculum was condensed (by author SSP) from the DIALBEST curriculum [14]. The session covered basic information about diabetes and its management. Nutrition was emphasized using the “Choose My Plate” method [17]. Participants were also provided a glucose meter with ten strips and were instructed in their use. Finally, participants were advised to increase physical activity, and they were provided with a portable CD player and an audio CD of *Movimiento Por Su Vida* to encourage physical activity [17].

Stress management—The SM intervention was developed, tested, and refined over approximately 12 months across three phases. The bilingual intervention included a manualized curriculum, flip chart, recorded relaxation exercises, and handouts (see Table 1).

In phase 1, two clinical psychologists reviewed the literature on stress management in medical populations (e.g., patients with cancer, HIV). The resulting SM intervention was derived from the theoretical frameworks of Lazarus and Folkman [18] and the General Adaptation Syndrome [19]. The core components were group psychoeducational skills training and physiological relaxation skills training.

First, for the psychoeducation skills training, a broad overview of topics and activities by session was laid out. The orientation was drawn from traditional cognitive behavioral therapy (e.g., thought restructuring [20]), and third wave, mindfulness therapies (e.g., momentary awareness and the principles of nonjudgment and loving kindness [21]). Each session employed a culturally relevant analogy or story to introduce its learning objectives.

PI Wagner, a clinical psychologist, wrote the first detailed draft of the intervention manual. The manual was then reviewed and revised by the multi-ethnic, multidisciplinary research team. The manual was written in English and translated into Spanish by PI Pérez-Escamilla. Translations were then reviewed by Mexican, Puerto Rican, and South American research team members, and language was revised. A final translation review was conducted by a Cuban Buddhist monk who has extensive experience teaching relaxation techniques and mindfulness exercises in Spanish.

In phase 1, the relaxation exercises were also developed. The program sequenced the two relaxation techniques shown to reduce A1c in type 2 diabetes—progressive muscle relaxation [11] and thermal biofeedback [12]. The exercises were culturally tailored, written in English, edited by the research team, and then translated as described above. They were recorded both in Spanish and English to accommodate participants’ preferences and set to culturally appropriate music, including a song performed and recorded specifically for the study. Participants were given a portable CD player and a CD of the relaxation exercises to use for home practice.

Phase 2 involved a first pilot testing of the entire intervention with one cohort. PI Wagner delivered the intervention, in English, to the staff of the Council. Feedback from pilot participants was quite positive, and led to modifications including shortening exercises, adding more humor, and making teaching examples more reflective of the lived experience of community members.

Phase 3 entailed a second pilot testing of the revised intervention with a different cohort of the Council staff. This time, the CHW interventionist delivered the intervention in Spanish. Feedback from pilot participants and also from the CHW re-sequenced topics and exercises, informed transitions, and simplified the in-session data collection forms.

Table 1 | Content of CALMS-D stress management sessions

Session and Icon	Theoretical underpinnings	Metaphor	In-session group activities	In-session relaxation activity	Home relaxation exercise
#1 Pressure cooker	<ul style="list-style-type: none"> General adaptation syndrome Mindfulness-based stress reduction 	People are like pressure cookers—problems create a fire and steam builds up inside us. We must learn how to put out the fire and release the steam safely.	<ul style="list-style-type: none"> On a drawing of a human form, each participant marks the places in his/her body where stress is felt. Personal goal setting. 	<ul style="list-style-type: none"> Guided meditation on appreciation of our bodies Awareness of breathing 	<ul style="list-style-type: none"> Guided meditation on appreciation of our bodies
#2 Chain of paperclips	Cognitive behavioral theory; introduction	Our feeling of being “stressed out” is a link in the chain of what happens around us, what we think, how our bodies react, and what we do	<ul style="list-style-type: none"> Each participant links together five paperclips representing event, thought, sensation, emotion, and behavior. Guided imagery of eating a lemon to demonstrate the influence of thoughts on bodily processes. 	<ul style="list-style-type: none"> Seven muscle group progressive muscle relaxation with awareness of breathing 	<ul style="list-style-type: none"> Seven muscle group progressive muscle relaxation with awareness of breathing
#3 Softball coach	Cognitive behavioral theory; identifying thoughts	We are like kids at softball practice; we have an inner coach that says things to us that affect how we feel. We should stop and examine what is being said.	<ul style="list-style-type: none"> “Looking deeply” at an automatic activity, i.e., eating a grape. 	<ul style="list-style-type: none"> Four muscle group progressive muscle relaxation with deep breathing 	<ul style="list-style-type: none"> Four muscle group progressive muscle relaxation with deep breathing
#4 Radio	Cognitive behavioral theory; thought restructuring	Changing thoughts is like switching the station on a radio.	<ul style="list-style-type: none"> The group co-writes two versions of a 4-panel <i>fotonovela</i> in which different ways of thinking about a problem change the outcome of the story. 	<ul style="list-style-type: none"> Body scan 	<ul style="list-style-type: none"> Body scan
#5 House	Social support	We are like houses and need a strong foundation to withstand storms.	<ul style="list-style-type: none"> Participants each generate a list of people available for tangible, emotional, and instrumental support, and generate ways to seek support. 	<ul style="list-style-type: none"> Guided meditation on ancestral and cultural support Thermal biofeedback 	<ul style="list-style-type: none"> Thermal biofeedback: guided meditation of beach sunset
#6 Fisherman	Dialectical behavior therapy communication skills training	Communication is like going fishing. To catch the kind of fish you want, you have to use the right bait.	<ul style="list-style-type: none"> Participants use real-life examples to illustrate the effect of communication. 	<ul style="list-style-type: none"> Lovingkindness meditation Thermal biofeedback 	<ul style="list-style-type: none"> Thermal biofeedback: guided meditation of sitting by the fire during a traditional family pig roast <i>lechón asado</i>

Table 1 | (continued)

Session and Icon	Theoretical underpinnings	Metaphor	In-session group activities	In-session relaxation activity	Home relaxation exercise
#7 Seedling	<ul style="list-style-type: none"> • Mindfulness-based cognitive therapy. • Dialectical behavior therapy distress tolerance training 	To manage anger, we have to become aware of our emotions. To prevent anger from becoming a habit, we can water the seeds of peace in our hearts.	<ul style="list-style-type: none"> • Each participant plants flower seeds in a small flower pot to take home. 	<ul style="list-style-type: none"> • Group walking meditation • Thermal biofeedback 	<ul style="list-style-type: none"> • Thermal biofeedback: guided meditation of walking in a sunny field of flowers
#8 Walking path	Relapse prevention	Stress management is not an achievement, it is a path that we travel with bumps and turns along the way.	<ul style="list-style-type: none"> • Each participant reviews his/her progress toward personal goal. • The group plays a board game: an adaptation of “chutes and ladders” to represent the stress management path. 	<ul style="list-style-type: none"> • Music: learning a song to assist in mindfulness of breathing 	Participants are encouraged to maintain their practice of stress management and relaxation skills.

After the first cohort of RCT participants, additional modifications were made; the two DE sessions were condensed into one, the nine SM sessions were condensed into eight, and relaxation exercises were re-ordered. A decision was also made to incentivize attendance at the first intervention sessions to increase initial engagement (\$5 for the first session of both DE and SM).

Community health worker training

The same CHW provided both the DE and the SM intervention in order to minimize interventionist effects. The CHW was hired by the Council specifically for this study through a local employment advertisement. The CHW was in her 30s, Puerto Rican and bilingual. She had a high school diploma and, although not required for the CHW position, she had 2 years of experience as a Certified Nursing Assistant during which time she cared for patients with diabetes. She had led religious education groups for adults in her church for several years so was connected to and respected by the Hartford Latino church community, but had no experience in SM. Her training for the study was intensive, involving approximately 150 h spanning 5 months. Her training in diabetes was approximately 45 h, including studying the DIALBEST curriculum [14] and attending several local diabetes education classes. Regarding her training in SM, during phase 1, a detailed interventionist manual was created (separate from the manualized SM curriculum). The majority of the 40-page manual covered interventionist skills such as listening skills, managing difficult group members, and confidentiality. During phase 1, the CHW studied this manual, one chapter at a time, and PI Wagner and senior study staff met with her regularly to systematically discuss its content. During phase 2, the CHW was further trained by viewing videotapes of PI Wagner delivering the pilot SM intervention to the Council staff and discussing illustrative clinical examples. During phase 3, the CHW delivered the intervention to a pilot cohort and received supervision from both PIs and senior research staff. The CHW also participated in a 16-h mindfulness-based stress reduction program at a local hospital. Her ongoing training included reviewing and critiquing, with PI Wagner, videotapes of herself delivering DE and SM.

Participants, setting, and procedures

Participants in the randomized trial were Hartford residents, age 18 or older, Latino or Hispanic, Spanish-speaking, ambulatory, with type 2 diabetes for 6 months duration or longer and most recent past year A1c > 7.0. Participants were excluded for medical instability or intensive medical treatment (e.g., chemotherapy; active hepatitis; stroke with neurological residual); bipolar disorder or thought disorder; suicide attempt or psychiatric hospitalization in the past 2 years; enrolled in another research study; another

member of the household enrolled in CALMS-D; or positive screening for alcohol problems [22].

Participants were recruited from the “Brownstone Clinic,” an outpatient clinic at Hartford Hospital, serving low-income patients with diabetes, including approximately 80 % Latinos. Charts for next-day participants were reviewed for basic eligibility criteria (e.g., age, diabetes diagnosis, zip code). Patients who were not excluded by chart review were approached while waiting for their clinical appointment, socialized to the study, and screened face-to-face. For those eligible and interested in participating, a referral document was sent to the Council. A CHW at the Council (different from the interventionist) contacted the recruit by phone to arrange a home visit for consenting and baseline assessment. After the baseline assessment, participants were invited to attend the group DE session at the Council. Transportation was offered to all intervention sessions for those who requested it ($n=88$ [82 %] relied on study transportation solely, $n=6$ [5 %] used it at some point, and the remainder did not use it at all). Upon completing DE, participants were randomized to DE or DE + SM. We hypothesized that attrition would be higher in the DE + SM arm than DE arm given the participant burden of the intervention. Therefore, block randomization was used with greater assignment to the intervention than control group. Blocks ranged from 9 to 16 participants. ID numbers were randomly drawn and SPSS (v.19) assigned participants to study group using a binary allocation procedure. Within approximately 2 weeks of the end of the last SM session, participants completed a post-intervention assessment and approximately 3 months later, a follow-up fasting blood draw was obtained. The study was approved by the institutional review boards of all institutions involved.

Measures

Participant characteristics—Demographics were self-reported. Participants rated their literacy on a 5-point scale from 1 = “excellent” to 5 = “I cannot read at all,” and their numeracy on 5-point scale from 1 = “excellent” to 5 = “I cannot read or write numbers.” Financial strain was measured on a 5-point Likert scale from “We have enough and we can save” to 5 = “We don’t have enough and we have great difficulties.” Health status was self-reported on a scale from 1 = “excellent” to 5 = “poor.” A1c was assayed at University of Connecticut Health Center clinical laboratory with high pressure liquid chromatography (HPLC).

Recruitment, attendance, and retention—Data for recruits and participants was tracked over time and reasons for non-attendance were recorded.

Participant home skills practice—Participants completed weekly diaries, broken down into AM and PM time-slots across 7 days, thus, weekly home practice varied from 0 to 14.

Treatment fidelity—Two methods were used to assess fidelity. The first was assessment by a supervisor who

observed the delivery of the session using a 15-item checklist covering activities such as “Provide a succinct summary of the session,” and “Demonstrate the skill being taught.” Items were answered with yes/no/not applicable. A trained observer completed the checklist for every session for the first cohort of participants, after which, once the CHW’s performance reached 80 %, she was “spot checked.” In all, 14 supervisor checklists were completed (4 DE and 10 SM). The second method was a CHW self-assessment. The checklist mirrored the supervisor’s checklist. In all, CHW self-report checklists were completed for 38 sessions (12 DE and 26 SM). Paired observer and CHW checklists were collected for 11 sessions.

Treatment expectations—Immediately after socializing the recruit to the study, but before intervention, participants responded to three items that were adapted from the 6-item Credibility Expectancy Scale [23]. The items measure expectancy of treatment efficacy and rationale credibility for experimental treatments. The items were, “How much does the program make sense to you?” “How much do you think Stress Management will reduce your stress?” and, “How much do you think Diabetes Education will improve your diabetes control?” Responses were on a 5-point Likert scale from 1 = “not at all” to 5 = “totally.” Cronbach’s alpha=0.79.

Diabetes knowledge—A 10-item true/false/don’t know quiz of basic diabetes knowledge was developed based on the assessment from DIALBEST [14]. Items covered the pathology underlying diabetes, its daily management, the prevention of complications, and A1c testing. It was administered immediately before and after the DE session.

Therapeutic cohesion and alliance—The 4-item Outcome Alliance Scale was used to assess participant perception of relationship to the CHW and the group [24]. The scale was administered after the DE session, and after SM session 2. Because it was administered at SM session #2, only those present for that session completed the measure. Twenty-seven participants (44 % of those randomized to SM, 57 % of those attending at least one session of SM) completed the Therapeutic Alliance Scale for SM. Cronbach’s alpha was 0.72.

In-session affect—Participants were asked to complete affect reports after each in-session relaxation exercise. Eight affective states were assessed including nervous, sad, mad, and bored (negative affect) and happy, enthusiastic, calm, and relaxed (positive affect) [25]. Participants were asked to rate each relative to before the exercise, i.e., 0 = “the same,” 1 = “more,” or -1 = “less.” Cronbach’s alpha was 0.95 for negative affect and 0.94 for positive affect.

Treatment satisfaction—Participant satisfaction with SM sessions was measured twice, once at session 4 referencing the first four sessions, and once at session 8 referencing the second four sessions. Study staff unrelated to delivering the intervention administered the satisfaction surveys. Items were created for this study and responses were on a 3-point Likert scale from 1 = “did not like it”

to 3 = “liked it a lot.” Four items covered in-session and home practice activities. Because it was administered at SM sessions #4 and #8, only those present for one of those sessions completed the measure. Thirty-three participants (54 % of those randomized to SM, or 72 % of those attending at least one SM session) completed it. Cronbach’s alpha was 0.76.

Data analysis

Descriptive statistics were calculated to describe the sample. Chi-square was used to test for differences in categorical variables and *t* tests for continuous variables. Coefficient kappa was used to calculate interrater reliability. Logistic regressions were used to predict likelihood of attendance at DE and SM sessions from participant characteristics.

RESULTS

Recruitment and participants—One hundred thirty-eight individuals were consented and 121 completed baseline assessments (see Fig. 1 for participant flow). As can be seen in Table 2, the randomization procedure worked as groups did not differ at baseline except on education where participants assigned to the DE + SM had higher levels of education. The $n=121$ participants were 73 % women, mean age = 60.32 (SD=11.62) years old, 59 % taking insulin, with A1c mean=8.54 (SD=1.60). Most identified as Puerto Rican (71 %), had lived in the mainland USA for mean=34.30 years (SD=13.86), and preferred being interviewed in Spanish (93 %). Educational attainment was low, with 42 % reporting an eighth grade education or less. Literacy was low, with 52 % indicating their reading as “fair,” “poor,” or “I cannot read at all.” The majority (58 %) were unemployed due to disability.

Treatment expectations—Participants reported high expectancy and credibility, mean=3.94 (SD=0.76).

Attendance—One hundred seven participants (78 % of those who were consented and 88 % of those who completed baseline assessments) completed the DE session. Among those who completed the baseline assessment, logistic regression was used to predict likelihood of attending the DE session from patient characteristics (age, gender, language, years in the USA, education, literacy, A1c, health status, and treatment expectations). Higher education (OR=5.34, $p=0.01$), lower A1c (OR=0.56, $p=0.01$), higher treatment expectations (OR=2.77, $p=0.04$), and higher reading ability (OR=2.76, $p=0.04$) increased likelihood of participating in DE. Preferring Spanish, as opposed to preferring English or having no language preference, marginally increased likelihood of attending DE (OR=22.72, $p=0.07$).

The 107 participants who attended DE were then randomized—46 to DE and 61 to DE + SM. Among those randomized to DE + SM, logistic regression was used to calculate likelihood of attending at least one SM session. In logistic regression, there was a trend for male gender to decrease the likelihood of participating in SM (OR=−0.22, $p=0.09$); no other variables

predicted SM participation. Of those randomized to SM, $n=47$ (77 %) attended at least one session and $n=11$ (18 %) completed all eight sessions. Of all individuals who attended at least one session, the mean number of SM sessions was $M=5.83$ (SD=1.97). Of all individuals randomized to SM, including non-attenders with zero sessions, the mean number of SM sessions attended was $M=4.47$ (SD=3.02). Reasons given for non-attendance, in order of frequency, were illness, appointments with healthcare providers and social service agencies, family care obligations, unpredictable/incompatible work schedules, travel, and stressful events such as accident, death, or incarceration of a loved one.

Therapeutic cohesion and alliance—Therapeutic alliance was high for DE, mean=4.79 (SD=0.44) and for SM, mean=4.89 (SD=0.23).

Diabetes knowledge—Diabetes knowledge scores increased from mean=62 % (SD=17 %) correct before DE to mean=76 % (SD=14 %) correct after DE, $t(92)=-8.53$, $*p=0.000$.

Affect—In-session relaxation exercises increased positive affect, $M=0.63$ (SD=0.29), $t(40)=13.84$, $*p<0.00$, and decreased negative affect, $M=-0.27$ (SD=0.19), $t(40)=-8.98$, $*p=0.001$.

Weekly home practice—Of the 61 people randomized to SM, 46 people (75 %) attended >1 SM class and therefore would have been expected to turn in at least one home practice log. Thirty-eight participants (62 %) turned in at least one log. The 38 individuals completed 192 individual logs, or mean=5.00 (SD=2.08) logs per participant. Participants who turned in logs reported mean=6.17 (SD=3.99) home relaxation practice sessions per week. Of all participants randomized to SM, 62 % completed at least one practice log.

Treatment satisfaction—Satisfaction with SM was high. The session with the highest satisfaction was social support, mean=3.00 (SD=0.00, i.e., all participants rated this session “3”), and the lowest was for cognitive behavioral theory, mean=2.69 (SD=0.62). Mean scores for “learning,” “talking,” “practicing in session,” and “practicing at home” were also high, mean=2.93 (SD=0.15), as was satisfaction with the relaxation exercises, mean=2.93 (SD=0.15).

Treatment fidelity—Concordance was high between CHW and independent observers’ checklists for the 11 sessions with paired data (14 % of sessions). Cohen’s kappa was 1.0 for 14 of the 15 yes/no checklist items. Cohen’s kappa was 0.55 for one item, “help participants problem solve nonadherence to home practice.” The CHW assessed herself independently for 38 sessions (42 % of sessions); mean percentage of checklist items per session was 86 % (SD=5 %). An independent observer rated the CHW independently for 14 sessions; mean percentage of checklist items was 83 % (SD=5 %).

DISCUSSION

The main findings reported here are that a SM intervention tailored for culture, literacy, and numeracy, carefully designed with attention to the target

Fig. 1 | Participant flow

community's characteristics and preferences, and delivered by a well-trained and supervised CHW, was successfully implemented; however, retention of participants in the intervention over time proved difficult. Overall, participants reported high credibility and expectancy for treatment effects, suggesting that they were well socialized to the study and its goals prior to attending any intervention sessions. Participants who attended reported high therapeutic alliance and high satisfaction with the intervention. The CHW delivered the intervention with a high degree of fidelity. Moreover, DE modestly increased diabetes knowledge and relaxation exercises improved short-term affect.

These data are consistent with qualitative data from our group and others that suggest that Latinos are receptive to novel nonpharmacological approaches. Whereas many Latinos may hold negative views regarding psychotropic medications [26], Latinos as a group may view behavioral approaches as more acceptable than non-Hispanic Whites do [27].

This study confirmed extensive poverty and a poor profile on the social determinants of health in this community [8]. Despite this clear need for services, and the

potential of CHWs to deliver basic services, CHWs have delivered very few mental health interventions (c.f., [28]). The successful delivery of a culturally appropriate and affordable program targeting distress among Latinos is a significant step toward filling the service gap.

Lessons learned

The intervention was designed using a community-based participatory approach in order to make it appealing to and appropriate for the target population. Notwithstanding this approach, higher education and higher self-reported reading level were still predictors of attendance at the DE session. We suspect that the consenting procedure—which necessarily occurred after recruitment but before attendance at an intervention session—may have created apprehension about the level of literacy and numeracy needed for meaningful participation. The institutional review board's required template, even for this study that was deemed low risk, resulted in 12 single-spaced pages of consent and HIPAA documentation. Individuals who were initially interested in the study during recruitment

Table 2 | Participant characteristics by condition ($n=121$). Values are mean (SD) or % (n)

	Total	Stress management	Enhanced standard care	P value
Age (in years)	60.32 (11.62)	59.95 (11.27)	60.80 (12.19)	0.71
Sex (% female)	73 %	74 %	72 %	0.82
Marital status				
Single, no partner	68.6 (83)	62.3 (38)	76.1 (35)	0.13
Partner	31.4 (38)	37.7 (23)	23.9 (11)	
Employment status				
Employed	9.9 (12)	13.1 (8)	4.3 (2)	0.12
Not employed	90.1 (109)	86.9 (53)	96.7 (44)	
Employment				
Unemployed, and looking for work	6.5 (7)	3.8 (2)	11.6 (5)	0.17
Unemployed, not looking for work	5.6 (6)	5.7 (3)	4.7 (2)	
Homemaker	8.3 (9)	15.1 (8)	2.3 (1)	
Retired	21.3 (23)	20.8 (11)	18.6 (8)	
Disabled	58.3 (63)	54.7 (29)	62.8 (27)	
Financial strain	2.46 (0.82)	2.54 (0.81)	2.35 (0.82)	0.23
Health insurance				
Yes	95 (115)	96.7 (59)	91.3 (42)	0.23
No	5 (6)	3.3 (2)	8.7 (4)	
Education				
No formal education school	1.7 (2)	0	2.2 (1)	0.01
Eight grade or less	42.1 (51)	31.1 (19)	52.2 (24)	
Some high school	33.1 (40)	34.4 (21)	30.4 (14)	
High school or high school graduate	13.2 (16)	18.0 (11)	10.9 (5)	
Trade or technical schooling	0.8 (1)	1.6 (1)	0	
Some college	6.6 (8)	9.8 (6)	4.3 (2)	
Finished four years of college	2.5 (3)	4.9 (3)	0	
Language preference for interview				
English	4.1 (5)	4.9 (3)	0	0.09
Spanish	92.6 (112)	90.2 (55)	100 (46)	
No preference	3.3 (4)	4.9 (3)	0	
Sub-ethnicity				
Puerto Rican	70.8 (85)	65 (39)	76.1 (35)	0.47
Hispanic or Latino	14.2 (17)	16.7 (10)	10.9 (5)	
Puerto Rican-American	15.0 (18)	18.3 (11)	13.0 (6)	
Years in the USA	34.30 (13.86)	33.80 (13.97)	35.02 (13.83)	0.64
Reading ability	2.55 (0.87)	2.57 (0.87)	2.52 (0.89)	0.76
Math ability	2.67 (1.01)	2.62 (0.99)	2.74 (1.04)	0.56
A1c (NGSP %)	8.54 (1.60)	8.60 (1.86)	8.50 (1.39)	0.74
Diabetes treatment				
None	3.3 (4)	1.6 (1)	4.3 (2)	0.65
Insulin	15.7 (19)	18 (11)	13 (6)	
Pills	38.0 (46)	36.1 (22)	43.5 (20)	
Both	43 (52)	44.3 (27)	39.1 (18)	
Self-reported health status	3.45 (0.97)	3.52 (0.99)	3.35 (0.99)	0.36

NGSP National Glycohemoglobin Standardization Program. Financial strain on a scale from 1 = “we have enough and we can save” to 4 = “we don’t have enough and we have great difficulties”; reading ability on a scale from 1 = “excellent” to 5 = “I cannot read at all”; math ability on a scale from 1 = “excellent” to 5 = “I cannot read or write numbers”; health status on a scale from 1 = “excellent” to 5 = “poor”

may have lost enthusiasm or even become wary of participating during the consent procedure. We suggest that the regulatory body should consider the complexity of their required documentation relative to the target community’s literacy levels.

Because of our unique decades-long community-academic-medical partnership, we did not experience lack of trust and low recruitment that can plague otherwise promising trials [29], and in fact only 31 % of those eligible for the study declined participation.

However, like other interventions with low-income diabetic Latinos, retaining participants over time in an intensive intervention proved challenging. Other studies have reported similar challenges. Hawkins [30] designed an 11-session, CHW-delivered, group diabetes self-management intervention for low-income individuals. Only 39 % of Latino men and 74 % of Latinas completed the study.

We also found that, even among participants who stayed in the study, assuring attendance at sessions was

difficult. Other similar studies report these difficulties. For example, in the study by Hawkins described above [30], CHWs offered one-on-one make-up sessions for participants who missed group classes. Nonetheless, of the $n=71$ Latinos in the intervention, Latino men and Latinas attended an average of three and six sessions, respectively. Vincent [31] designed an 8-session, culturally tailored, group diabetes prevention intervention for Latinos. Of the $n=38$ randomized to intervention, 21 % never attended a treatment session.

Like CALMS-D, these interventions attempted an efficient delivery of the intervention through a group format, but found that groups pose particular logistical difficulties. Participants who enjoyed the SM program and wanted to participate sometimes had difficulty attending the sessions at the times that were convenient for the rest of the group. The primary reasons given for non-attendance in our study reflect the nature of the stressors and social determinants of health faced by this community. We transported individuals who needed it and attempted to allow make-up sessions by inviting participants to attend missed sessions with other study groups. However, understandably, most participants did not want to join an existing group for a single session. Individual sessions would be easier to schedule, as they were for diabetes education in the DIALBEST trial, but would lack the therapeutic benefit that group SM sessions provide. Rolling enrollment would also promote easier scheduling and attendance, but is not suitable for groups with session-specific content. A study by Two Feathers [32] with African American and Latino patients showed greater success by offering multiple opportunities over the intervention period for participants to attend each curriculum meeting, combined with one-on-one make-up sessions. These strategies, however, are very resource intensive. In addition to using a delivery format that balances flexibility with available resources, interventions should be designed with community-based participatory approaches so that they meet patients' perceived needs and are prioritized by the target population.

Individuals in CALMS-D who attended SM sessions reported suboptimal home practice and log-keeping. Yet rates of participation were high compared to a study of similar intensity among a high-SES sample [33]. Participants in that intervention reported completing 1.5 home practice sessions of approximately 15 min each per week (vs. 6.2 lengthier home practice sessions in ours). Future studies should consider the possibility of adding a home visit from the CHW to increase compliance with home exercises and log-keeping.

Despite the aforementioned challenges, CALMS-D was able to successfully engage an acceptable percentage of participants relative to aforementioned studies of similar intensities. We attribute this success to the thoughtful anticipation of barriers, and the dedicated,

knowledgeable, and highly skilled staff who tracked and maintained communication with participants over time.

Limitations

First, for many of the process outcomes, only those participants who attended specific sessions completed assessments, potentially positively biasing the outcomes. Second, social desirability may have biased participant responses, and process measures that were collected at the intervention site may have been biased by demand characteristics. Third, only one CHW delivered the intervention so we cannot show that delivery of the intervention would be similar across interventionists. Our team's experience, however, indicates that if the CHW is carefully selected, trained, and supervised, these interventions could be delivered by other CHWs. On a related note, although we used structured training manuals, the interventionist training was tailored to our particular CHW, such that our training methods may not generalize to other CHWs. Results also may not generalize to other ethnic/racial or socio-demographic groups. Odds ratios for predictors of participation were based on a small subsample. Finally, this study did not specifically target diabetes-related distress, which has been shown to be higher among racial/ethnic minorities than among non-Hispanic Whites [9]. Limitations are generally outweighed by strengths including a novel intervention, delivered by a CHW, to an underserved population that is typically excluded from randomized trials.

Implications of the findings

These findings have implications for practitioners. Supportive services for people with diabetes—even insured, English speaking patients with transportation, are lacking in most but tertiary care treatment sites. Serious mental health issues should be assessed and treated by trained professionals; notwithstanding, this study provides evidence that stress management skills can be provided by a CHW supervised by mental health professionals. These findings also have policy implications. The Affordable Care Act formally recognizes the role of CHWs and offers reimbursement for CHW activities including providing culturally and linguistically appropriate health education, thus making CHW-led interventions more likely. Finally, these findings have implications for researchers. The participants in the present study are a demographic often excluded from randomized trials; they are primarily non-English speaking, with multiple medical problems, who face numerous barriers to participation, and can be difficult to retain over time. Yet, by employing supervised community research staff (rather than a research assistant based at an academic institution), engagement of this population was not only possible but on par with or even better than community-based trials of similar intensity (e.g., [34]).

CONCLUSIONS

CALMS-D was delivered with a high degree of treatment fidelity, was successfully implemented in and highly rated by the target community, and increased diabetes knowledge and short-term affect. Follow-up data collection for the randomized trial was recently completed, and we plan to report outcomes (biological, behavioral, psychosocial) in the near future. Future studies should be aimed at increasing retention among Latinos in such interventions.

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