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A Randomized, Controlled Trial of a Stress Management Intervention for Latinos with Type 2 Diabetes Delivered by Community Health Workers: Outcomes for Psychological Wellbeing, Glycemic Control, and Cortisol

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Abstract

Aims—To test the efficacy of a community health worker (CHW) delivered stress management (SM) intervention on psychosocial, glycemic, and cortisol outcomes among U.S. Latinos with type 2 diabetes.

Methods—A randomized, controlled trial compared CHW-delivered diabetes education (DE; one group session) to DE plus CHW-delivered SM (DE+SM; 8 group sessions). Psychosocial variables and urinary cortisol were measured at baseline and posttreatment. HbA1c was measured at baseline, posttreatment, and 3-month follow-up.

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Author Contributions. J.W. and R.P.-E. were the principal investigator for the study (multi-PI agreement), both contributed to the study concept and design, trial oversight, and data analyses. J.W. wrote the first draft of the manuscript and coordinated subsequent revisions. R.P.-E. contributed to manuscript and reviewed all drafts. A.B.M. was the University of Connecticut Health Center senior study coordinator, contributed to the conduct of the study, data quality control, data analyses, and reviewed drafts of the manuscript. G.D. contributed to the study concept and design, trial implementation oversight, and reviewed drafts of the manuscript. S.S.-P. was the Hispanic Health Council's senior study coordinator, she led the overall field coordinator of the trial, contributed to the study concept and design and reviewed drafts of the manuscript. J.C. was Hartford Hospital's senior study coordinator, contributed to the study and reviewed drafts of the manuscript. R.F. contributed to the study's medical director, contributed to the intervention design, and reviewed drafts of the manuscript. R.F. contributed to the statistical analyses and reviewed drafts of the manuscript. J.W. and R.P.-E. are the co-guarantors of this work and, as such, had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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Results—In intent to treat analysis, compared to DE (n=46), DE+SM (n=61) showed significantly improved symptoms of depression, anxiety, and self-reported health status. There were no significant group effects for HbA1c, diabetes distress, or urinary cortisol. However, there was a dose response effect for HbA1c and diabetes distress; increasing attendance at SM sessions was associated with greater improvements in HbA1c and diabetes distress.

Conclusions—This is the first randomized, controlled trial demonstrating that CHWs can improve psychological symptoms and self-reported health among Latinos with type 2 diabetes. Efforts to increase intervention attendance may improve HbA1c and diabetes distress.

1.1 Community Health Workers and Diabetes Care

The International Diabetes Federation estimates that in 2015, 415 million people, or 1 in 11 people globally, have diabetes [1]. If these trends continue, by 2040 some 642 million people, or 1 adult in 10, will have diabetes. In most regions of the world the healthcare workforce is insufficient in size to meet the enormous and growing need of people with diabetes. In some regions the healthcare workforce is also inadequately trained to meet the unique needs of racial, ethnic, and linguistic minorities. For example, In North America, Europe, and Australia the rising number of immigrants, refugees, and racial/ethnic minority citizens with diabetes creates challenges for provision of quality healthcare [2]. In these settings, task shifting of some healthcare functions from professionals to community health workers (CHWs) is considered to be an efficient means of improving the health of these communities [3]. CHWs are members of a community who are chosen by community members or organizations to provide basic care to their community [4]. They are usually bilingual, bicultural, and are chosen in part because they understand the unique cultural contexts of the health behaviors of their respective communities. CHWs increase access to treatment by overcoming financial, social, political, cultural, and linguistic barriers to care. They can also develop the skills to deliver education [5] and basic care [6] when properly integrated into the care team.

1.2 Latinos and Diabetes

Latinos are persons of Latin American origin or descent. They are the largest non-European ethnic and linguistic group - and one of the fastest growing groups - in the U.S. Latinos currently comprise 12.5% of the population, likely rising to 25% by the year 2050 [7]. Latinos are almost twice as likely to have diabetes compared to non-Latino Whites [8]. Whereas there is considerable variability among sub-ethnicities, Latinos as a group also report lower perceived health status compared with non- Hispanic Whites, which is a strong predictor of mortality across racial and ethnic groups, even after adjustment for socioeconomic status and comorbidities [9]. Latinos in the U.S. face a host of mental stressors including especially financial strain [10]. Whereas many immigrant groups come to the U.S. because of difficult conditions in their home countries, the population studied here faces a unique disadvantageous social context in the U.S. that may be quite different from what they faced in their country of origin. Issues unique to immigrant groups include immigration and for some the threat of deportation, discrimination, social marginalization,

separation from family and lack of social support, lack of access to both diabetes and mental health services, and language barriers when seeking healthcare and social services.

1.3 Psychosocial Distress in Diabetes

The day-to-day demands of diabetes are also stressful and can cause significant diabetesrelated distress [11]. Most studies show that people with diabetes have higher rates of elevated symptoms of depression [12] and anxiety [13] than non-diabetic controls. Distress, depression, and anxiety are important outcomes in their own right because they cause suffering and seriously decrease quality of life [14]. Moreover, negative psychosocial factors are associated with worse diabetes outcomes including glycemic control, long-term complications, and premature mortality (see [15] for a review of psychosocial factors among minorities with diabetes). Such associations may be direct, via elevations in stress hormones including cortisol [16] or indirect by compromising self-care behaviors, [17]. Thus, addressing the psychological wellbeing of minorities with diabetes is paramount. Although effective group-based psychosocial treatments for patients with diabetes exist (e.g., [18]), lack of access to psychosocial services is problematic for many, especially for low-income and limited English proficiency (LEP) patients [19]. Thus, there is an urgent need for - and untapped potential in - accessible treatments that address psychological wellbeing among Latinos with diabetes.

To date, there have been no randomized controlled trials (RCTs) testing the effects of CHWdelivered psychosocial interventions. To address this gap, we conducted an RCT called Community Health Workers Assisting Latinos Manage Stress and Diabetes (CALMS-D). CALMS-D compared 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. The development and implementation of the intervention has been described elsewhere along with the relevant CONSORT information [20]. In this current paper we report the primary outcomes of the trial. We hypothesized that, relative to DE only, DE+SM would produce greater improvements in symptoms of depression, anxiety, diabetes distress, self-reported health, HbA1c, and urinary cortisol. We also examined whether SM improved diabetes selfcare behaviors.

Methods

2.1 Recruitment

The study was approved by the institutional review boards of all institutions involved. Participants were recruited from the 'Brownstone Clinic', an outpatient clinic at Hartford Hospital, serving low-income patients with diabetes, approximately 80% of which are Latinos. Participants were adult Hartford residents, self-identified Latino or Hispanic, Spanish-speaking, ambulatory, with type 2 diabetes >=6 months, and most recent past year HbA1c>7.0. Chart review excluded patients for: medical instability or intensive medical treatment; bipolar disorder or thought disorder; or suicide attempt or psychiatric hospitalization in the past 2 years. Face-to-face screening excluded recruits for alcohol problems or enrollment in another research study.

Clinic recruits were referred to the Hispanic Health Council to be socialized to the study, provide informed consent and to participate in the intervention. The Hispanic Health Council is a community-based organization headquartered in a large Latino neighborhood in Hartford.

2.2 Treatment

All sessions were conducted in Spanish and delivered by the same CHW to avoid interventionist effects. (CHW training and excellent results for treatment integrity have already been reported [20].) Participants completed a 2.5 hour group DE session delivered by a CHW. The session covered basic information about diabetes and its management including nutrition, medications, physical activity and self-monitoring of blood glucose. Participants were provided with the United States Department of Agriculture's "ChooseMyPlate" resources for healthy eating, a glucose meter and strips, and a portable CD player with an audio CD of the National Diabetes Education Program's *Movimiento Por Su Vida* to encourage physical activity. Upon completing DE, participants were randomized to DE or DE+SM. Attrition would necessarily be higher in SM (8 sessions) than DE (1 session), so block randomization used greater assignment to DE+SM than DE. Blocks ranged from 9 to 16 participants. Participant codes were randomly drawn and SPSS (v.19) assigned participants to study group using a binary allocation procedure.

The SM intervention has been described in detail elsewhere [20]. In brief, it was a manualized, culturally based intervention comprised of 8 group sessions spread across 8–10 weeks that included psychoeducational skills training and physical relaxation training. Each session employed a culturally relevant analogy or story to introduce its learning objectives. The intervention also sequenced two relaxation techniques–progressive muscle relaxation and thermal biofeedback. In addition to in-session practice, participants were given a portable CD player and a CD of the relaxation exercises to use for home practice between sessions. The exercises were culturally tailored and recorded both in Spanish and English.

2.3 Data Collection

Face-to-face interviews and urine collection for cortisol assessment were performed at baseline and at posttreatment (within approximately 2 weeks of the end of the last SM session); HbA1c was assessed at baseline, posttreatment, and 3-month follow-up. Blood draws were performed by a community phlebotomist in participants' homes and delivered immediately to the UConn Health Center for processing and analysis. Participants were paid \$10 for each interview assessment and \$10 for each biological assessment.

All interviews were conducted in participants' homes in their preferred language. Data were collected using Remote Electronic Data Capture (REDCap; [21]) by two CHW interviewers (not the CHW interventionist). They were extensively trained in data collection methods. A 60-page pre-tested interviewer manual was developed for the project and used as the primary training tool. They also practiced administering the assessment battery with supervisors and study staff. They were accompanied by supervisors on participant home visits until the supervisors judged their administration to be satisfactory (approximately 6 home visits).

We employed several techniques to assure high quality self-report data in this population. First, all assessments were conducted during home visits at times that were convenient for the participants. Second, all assessments were read aloud to participants in the language of their choice. Third, we developed a 'practice question' for each scale that mirrored the content and response options for the respective scale. It allowed the participant an opportunity to practice responding to each scale's unique format, and allowed the interviewer to assess, and, if necessary, correct, the respondent's understanding of the task. This practice question was not included in the final scoring. Fourth, we developed pictographs to be used with each scale. These pictographs were piloted and modified accordingly. Fifth, we pilot tested English (n=5) and Spanish (n=5) versions of the full assessment battery with members of the target population and incorporated feedback regarding measures, items, response options, and pictographs.

2.4 Psychosocial Outcomes

Depressive symptoms—The Spanish version of the Personal Health Questionnaire (PHQ8; the PHQ9 without the suicidality item [22]) measures depressive symptoms over the past 2 weeks with higher scores indicating more depressive symptoms. We omitted the suicidality item so that CHWs working in the field would not be in the position to have to respond to suicidality. In our sample, coefficient alpha=0.79.

Anxiety symptoms—The Spanish version of the PROMIS Emotional distress/anxiety scale (Short Form 8a) assesses anxiety symptoms over the past 7 days [23]. The 8-item scale has response options from 1="never" to 5="always" with higher scores indicating more anxiety symptoms; alpha=0.91.

Diabetes Distress—The 5-item U.S. Spanish language version of the Problem Areas in Diabetes (PAID) scale assesses the patient's perspective of current emotional distress from living with diabetes. Each item is scored 0 ="not a problem" to 4="serious problem" with higher scores indicating more distress [24]; alpha=0.92.

Diabetes Self-Care—Self-care behaviors were measured with the Spanish language version of the Summary of Diabetes Self-Care Activities [25] which measures frequency of key diabetes self-care activities over the past 7 days. We administered items for physical activity, self-monitoring of blood glucose, medication adherence, and foot care with scores for each item ranging from 0="0 days" to 7="7 days"; for descriptive purposes, we also summed all items applicable to respective participants and divided by the number of items for a mean self-care score. For the two blood glucose testing items, alpha=0.75, and for the two foot care items alpha=0.75. All other behaviors were assessed with single items and these items would not be expected to be highly correlated with each other.

Self-reported Health Status—The single item measure from the National Health Interview Survey was asked, "Would you say your health in general is..." Participants reported their perceived health status on a scale from 1="excellent" to 5="poor".

2.5 Biological Outcomes

Glycemic Control—HbA1c was measured in the UConn clinical laboratory using high pressure liquid chromatography (HPLC). In this laboratory, HbA1c shows the following coefficients of variation for normal and high values: Level 1 mean=5.51%, CV=3.3 based on n=320, and Level 2 mean=9.01%, CV=3.2 based on n=304.

Cortisol—Urinary cortisol was measured from 24-hour urine samples. Participants collected and kept refrigerated all their urine over a 24-hour period after which study staff transported samples to the university laboratory for analysis. The UConn Clinical Research Center laboratory used a kit from Alpco Diagnostics. The assay has a normal range of 50–190ug/24hrs, sensitivity of 2.0 ng/mL, intra-assay CV%=7.4, and interassay CV%=7.8.

2.6 Statistical Analysis

Baseline group differences were tested using an independent samples t-test for continuous variables and cross-tabulation chi-square for categorical variables. Using intent-to-treat analysis, multilevel linear mixed model was used with fixed effects for group, time point, and the interaction, while the intercept was random and allowed to vary across subjects. A significant interaction indicates the change across time points (e.g. baseline to posttreatment) differed between the treatment groups and would be evidence for the efficacy of SM. For outcomes measured at three timepoints (i.e., HbA1c), linear contrasts were also included in the mixed model to test for group differences at posttreatment and at follow-up. As a measure of the size of the interaction effect the proportional reduction of residual variance (r-square) was calculated (29). To investigate if a dose effect existed, within just the DE+SM group, the number of SM sessions was included as a predictor in the models in place of the grouping variable. Since there were missing data at each time point multiple imputation using a Markov Chain Monte Carlo was employed to create 10 imputed data sets. Along with the observed biological and psychosocial variables, demographic variables were used to impute missing values. An alpha level of .05 was the criterion for significance and the analyses were conducted in SPSS v22.

Results

3.1 Participants

See table 1 for demographic and clinical characteristics of the sample. One-hundred and seven participants (78% of those consented and 88% of those who completed DE) were randomized (DE n=46; DE+SM n=61). Groups were similar except that a significantly higher proportion of high school graduates were assigned to the DE+SM group compared to DE group (34% vs 15%, p=.025). Therefore, education was entered as a covariate in analyses.

3.2 Psychosocial Outcomes: Intent to Treat Results

See table 2. For depressive symptoms, there was a significant group by time point interaction favoring DE+SM, yielding a medium effect size for the interaction. Moreover, the percentage of participants with mild to severe depressive symptoms (score of 5 or higher) increased slightly in the DE group (48% at baseline and 51% at posttreatment) but decreased

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in the DE+SM group (54% at baseline and 40% at posttreatment). For anxiety symptoms there was a significant interaction favoring DE+SM, yielding a small-to-medium effect size. For self-reported health there was a significant interaction benefiting DE+SM, yielding a small effect size. Average baseline diabetes distress was at the clinical cutoff of >=8 (M=7.97, SD=6.5) [26]. Diabetes distress decreased over time (M=6.8, SD=6.3; time point main effect p=.06), but the interaction was not significant, suggesting the reduction was similar across groups. For diabetes self-care there was no significant main effect for time, nor an interaction of time by group.

3.3 Biological Outcomes: Intent to Treat Results

See table 2. HbA1c was above clinical recommendations and stable between groups and across time at around 8.5%. The group by timepoint interaction was not significant, and neither the posttreatment (p=.17) nor followup (p=.57) group contrasts significantly differed. In addition, there was no main effect for time (p=.32). Cortisol was within the normal range and was positively skewed and so was natural log transformed prior to analysis. Although cortisol decreased more in the DE+SM group than in the DE group, the change was not significantly different across groups.

3.4 Dose-Response Effects

Participants had the opportunity to attend eight SM sessions but most subjects did not attend every session. Among the 61 subjects assigned to DE+SM, 11 (18%) attended every session. The average number of sessions attended was 4.5 (SD=3.1) and ranged from 0 to 8 sessions with a median of five sessions. There was a significant interaction between number of sessions and time point on HbA1c (p=.002, R²=.092). Compared to baseline, at posttreatment each additional session attended was associated with a 0.21 decrease in HbA1c (B=-0.21, t=-3.18, p=.002) and at follow-up each additional session was associated with a 0.19 decrease in HbA1c (B=-0.19, t=-2.92, p=.004). There was also a significant dose effect on diabetes distress. Compared to baseline, at posttreatment, each additional SM session was associated with a 0.6 point decrease in diabetes distress score (B=-0.59, t=-3-2.04, p=.047, R²=.060). There was no dose effect for any other outcome.

3.5 Multiple Imputation Results

The multiple imputation results were consistent with the previously mentioned results using all observed data. There were significant group by time point interactions for depressive symptoms (p=.024), anxiety symptoms (p=.039), and self-reported health (p=.020). There was also a dose effect for diabetes distress (p=.043) and for HbA1c at posttreatment (.017) and follow-up (p=.016).

Discussion

4.1 Main Findings

We tested the effects of a CHW-delivered stress management intervention for U.S. Latinos with type 2 diabetes. There are two main findings from this study. First, relative to DE only, DE+SM improved several indicators of wellbeing including symptoms of depression, anxiety, and self-reported health. To our knowledge, this is the first RCT to demonstrate that

CHWs can improve mental health symptomatology in persons with diabetes. Second, there was a SM dose-response effect for HbA1c and diabetes distress. Greater participation in the SM intervention led to increasing benefits for glycemic control and diabetes distress.

4.2 Implications for Diabetes Care

Whereas relatively effective non-pharmacological group-based interventions are available to improve psychosocial functioning among people with diabetes [18], there are limitations to them. In the U.S., those patients who do not speak English (or speak it as a second language) and those who lack adequate insurance for psychotherapy may be less likely to be prescribed non-pharmacological treatments. Pharmacotherapy may not be accepted by patients [27], nor properly implemented, and may cause side effects such as weight gain and problems with glucose and lipid metabolism [28] which are the very targets of medical management of diabetes. Finally, many patients who face significant life stressors and could benefit from intervention do not necessarily go on to develop a psychiatric disorder or need pharmacotherapy or treatment by a mental health provider per se. For these reasons, there is a critical need for culturally tailored, accessible, non-pharmacological treatments for stress and psychological symptoms accompanying diabetes.

In ITT analyses, diabetes distress, HbA1c and urine cortisol did not change differentially for the DE vs the DE+SM groups. Two recent reviews of CHW interventions found that some, but not all, randomized trials show benefit for HbA1c [29,30]. Our results may be due to the fact that stress management, rather than diabetes self-care per se, was the focus of the intervention. In CALMS-D, self-care behaviors did not improve, likely because of the relatively small dose of diabetes education. Alternatively, it may be due to the dose of SM that most participants received. ITT studies are designed to demonstrate what the intervention's effects would be if delivered to the population in a "real world" context, because they reflect not only the direct effects of the intervention, but also engagement, uptake, and adherence to the intervention. In contrast, dose-response analyses are designed to demonstrate the direct effect of the intervention. In our dose-response analyses, those participants who received a higher "dose" of the intervention (i.e., they attended more SM sessions) showed greater improvement in diabetes distress and HbA1c. Whereas the magnitude of change in HbA1c was modest, there is no HbA1c threshold for reducing risk for long-term complications; any reduction in HbA1c confers benefit [31]. These doseresponse findings mirror those of other group-based diabetes interventions including educational and supportive interventions [32]. We submit that SM may in fact improve diabetes distress and glycemic control if delivered at an adequate dose. Therefor the implementation research question should focus on engagement, uptake, and adherence.

CALMS-D did *not* face challenges with engagement or uptake. As previously reported [20], only 30% of those patients who were approached declined the study, and 78% of those who were consented and 88% of those who completed baseline assessments attended the first session (DE). However, CALMS-D *did* face challenges with maintaining adherence over time. Of the n=61 randomized to DE+SM, n=47 (77%) attended at least one SM session but only n=11 (18%) completed all 8 sessions. Of all individuals who attended at least one session, the mean number of SM sessions was M=5.8 (SD=2.0), a finding strikingly similar

to those reported in a recent 8-session, group-based mindfulness intervention for patients with diabetes in the Netherlands (M=5.5, SD=2.5; [18]). Low attendance at intervention sessions, especially group sessions without rolling enrollment or opportunities to make up missed sessions, is a problem that plagues many interventions (e.g., [33]). Future studies should focus explicitly on methods to enhance protocol adherence in this population and explore efficient delivery modalities that could preserve the benefits of group sessions while minimizing the use of scarce resources in community settings.

4.3 Implications for Community Health Workers

This study has major implications for the role of CHWs in the treatment of patients with diabetes. To date, CHWs have been involved in few psychosocial interventions that were rigorously tested. Roman et al. [34] randomly assigned 613 pregnant mothers to usual care or Nurse + CHW care. Compared to usual care, CHW care resulted in significantly fewer depressive symptoms. Notwithstanding that one report, the dearth of studies comparing CHW psychosocial interventions to usual care or alternative interventions represents a major knowledge gap because the need for culturally appropriate and affordable mental health services among Latinos with diabetes has been strongly documented in our target community and nationwide [10,19].

CHWs play an important role in caring for persons with diabetes because they infuse interventions with cultural relevance and sensitivity. A recent systematic review concluded that CHWs improve glycemic control in persons with diabetes [29]. Members of our own team have shown that CHWs and peer counselors improve other health-related behaviors, such as improving asthma and increasing breastfeeding among new mothers [35,36,37].

Yet, despite evidence from our own group and others that CHWs can develop the skills to deliver basic care when properly integrated into the care team [6], to date CHWs have been used primarily to provide language interpretation, enrollment facilitation, bureaucracy navigation, role modeling, advocacy, and in some studies to provide diabetes education [38]. Others have piloted CHWs for behavioral health care coordination, outreach, and screening, but not intervention [39]. The RCT reported here greatly expands the role of CHWs to the domain of *psycho*education and psychosocial intervention per se, thus addressing a major healthcare system gap. We do not suggest here that CHWs can, or should, treat or manage psychiatric disorders per se. Nothwithstanding, these findings do suggest that CHWs, under the supervision of mental health professionals, can deliver a stress management curriculum that can improve symptoms of depression, anxiety and self-reported health.

In the U.S., where CALMS-D was conducted, the utilization of CHWs to deliver care is made more likely by the Affordable Care Act which provides billable codes for CHWs using evidence-based interventions for health promotion. In the American CHW workforce study [40], special populations cared for by CHWs included the uninsured (as reported by 71% of respondents) followed by immigrants (49%), the homeless (41%) and isolated individuals and migrant workers (31%). A survey of 405 CHWs in Massachusetts found that they represented more than 20 ethnicities. Additionally, some states and private organizations train CHWs and help human service agencies integrate CHWs into their services. Because of provisions in the Affordable Care Act, the number of CHWs is expected to grow

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substantially in coming years. Thus, the workforce to deliver interventions like CALMS-D exists and is increasing in the U.S.

Members of our own team have also reported that CHWs are effective in low-and middleincome countries [41] including for diabetes prevention and control [5]. The World Health Organization conducted a systematic review of CHW services globally, ranging from preventive health education for communicable and non-communicable diseases, including common mental health problems, to their treatment and rehabilitation [42]. Whereas the services offered by CHWs were found to have improved objective indicators of health status, the coverage by such programs and the overall progress towards achieving health targets in the developing world remains very slow due to fragile health and economic systems. We believe that programs like CALMS-D could be implemented in the developing world, but that recognize that noncommunicable diseases and mental health may not be viewed as pressing priorities in resource poor countries.

4.4 Limitations

Findings from this study should be considered in light of limitations including a relatively small sample and long-term follow-up data for only biological, not psychosocial, outcomes so maintenance of benefits cannot be ascertained. We measured cortisol in urine, and might have found different results if we had measured cortisol in blood or saliva. In order to eliminate interventionist effects, only one CHW delivered the DE and SM sessions, but this methodological strength also limits our ability to generalize these outcomes to other interventionists. Whereas attendance at SM sessions was less than optimal, participation was good relative to similar group-based psychoeducational interventions [33] including those that are not specifically targeted to hard-to-reach populations [18], and those specifically delivered to individuals from higher socioeconomic status [43]. The sample studied here had a long duration of residence in the U.S. so findings may not generalize to newly arriving groups.

4.5 Conclusions

Latinos with type 2 diabetes face numerous life stressors and have extremely limited access to psychosocial care. CHWs can effectively improve symptoms of depression, anxiety, and self-reported health using a behavioral intervention designed for culture, literacy, and numeracy.

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Highlights

To date there have been no randomized, controlled trials testing the effects of *psychosocial* interventions delivered by community health workers to people with diabetes.

We randomized n=107 Spanish speaking Latinos with type 2 diabetes to either A) group diabetes education, or B) group diabetes education plus 8 sessions of group stress management. All intervention sessions were delivered by community health workers.

• We found that compared to diabetes education alone, the stress management group showed improved symptoms of depression, anxiety, and self-reported health.

We also found a dose-response effect for HbA1c and diabetes distress – greater attendance at stress management sessions was associated with greater decrease in HbA1c and diabetes distress.

• This study greatly expands the potential role of community health workers in treating patients with diabetes and emotional distress.

Table 1

Demographic Characteristics, n=107

Characteristic	DE only (n=46)	DE+SM (n=61)	P-Value
Gender			.815
Female	33 (72%)	45 (74%)	
Male	13 (28)	16 (26)	
Age			.709
Mean \pm SD	60.8 ± 12.1	60.0 ± 11.2	
Marital Status			.129
Single	35 (75%)	38 (62%)	
Partnered	11 (24)	23 (38)	
Education Level			.025
Less than high school	39 (85%)	40 (66%)	
High school or more	7 (15)	21 (34)	
Employment Status			.182
Working	2 (4%)	8 (13%)	
Not Working	44 (96)	53 (87)	
Monthly Household Income			.460*
0-\$500	5 (11%)	8 (13%)	
501 - \$1000	23 (50)	32 (53)	
1001 - \$1500	18 (39)	13 (21)	
1501 - \$2000	0 (0)	4 (7)	
2001 - \$3000	0 (0)	4 (7)	
Language Speak			.592
English & Spanish	24 (52%)	35 (57%)	
Spanish only	22 (48)	26 (43)	
Years in US			.643
$Mean \pm SD$	35.0 ± 13.9	33.8 ± 14.0	
Medical Insurance			.399
Yes	42 (91%)	59 (97%)	
No	4 (9)	2 (3)	
Insulin Using			.294
Yes	24 (52%)	38 (62%)	
No	22 (48)	23 (38)	

*Cochran-Armitage test for trend;

DE=Diabetes education; SM=Stress management

Tahla 2	5	

Means ± SDs of Outcomes by Treatment Group and Timepoint

Outcome	Baseline (n=107)	Post (n=96)	=96)	P-Value for the interaction	P-Value for the interaction R-Square for the interaction
* Depressive symptoms				.002	.086
DE only	5.3 ± 4.4	6.2 ± 5.8	5.8		
DE+SM	6.7 ± 5.9	4.7 ± 5.1	5.1		
* Anxiety symptoms				.005	.077
DE only	1.8 ± 0.8	2.0 ± 1.0	1.0		
DE+SM	1.9 ± 0.9	1.7 ± 0.9	0.9		
*^ Self-reported health status	S			.023	.048
DE only	3.3 ± 1.0	3.4 ± 0.9	0.9		
DE+SM	3.5 ± 0.9	3.1 ± 1.1	1.1		
$\dot{\tau}$ Diabetes distress				.410	000
DE only	8.1 ± 6.3	7.4 ± 6.7	6.7		
DE+SM	7.9 ± 6.7	6.3 ± 6.0	6.0		
Diabetes self-care				.720	000.
DE only	5.8 ± 1.3	5.7 ± 1.2	1.2		
DE+SM	5.8 ± 1.4	5.7 ± 1.0	1.0		
Cortisol 24hr				.390	.012
DE only	100 ± 49	99 ± 53	53		
DE+SM	134 ± 133	102 ± 46	: 46		
† HbA1c NGSP (ICFF)		Post (n=96)	FU (n=91)	.100	.015
DE only	$8.6(70) \pm 1.9(20.8)$	$8.5 (69) \pm 1.8 (19.7)$	8.4 (68) ± 1.6 (17.5)		
DE+SM	$8.5(69) \pm 1.4(15.3)$	8.8 (73) ± 1.6 (17.5)	$8.6(70) \pm 1.9(20.8)$		

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* significant time by group interaction;

 \dot{r}^{t} significant dose response effect;

 λ lower score indicates better health status. Effect size estimates for r-square are .01, .09, and .25 for small, medium, and large, respectively.