

## Home Visit Intervention Promotes Lifestyle Changes: Results of an RCT in Mexican Americans



Michelle L. Vidoni, PhD,<sup>1</sup> MinJae Lee, PhD,<sup>1,2</sup> Lisa Mitchell-Bennett, MS, MPH,<sup>3</sup>  
Belinda M. Reininger, DrPH<sup>3</sup>

**Introduction:** Hispanic populations are less likely than other ethnicities to meet physical activity guidelines. Community health worker (CHW) outreach is an effective delivery method for behavior change messages owing to shared culture, language, and life experience. This study examined the efficacy of a CHW-delivered intervention, *Tu Salud ¡Si Cuenta! (Your Health Matters!) at Home Intervention*, to promote physical activity among Mexican Americans.

**Study design:** RCT.

**Setting and participants:** Mexican Americans living along the Texas–Mexico border from June 2010 to April 2013.

**Intervention:** Eligible adults were randomized into intervention ( $n=250$ ) or standard care ( $n=250$ ). Intervention participants received 6 monthly CHW visits that included education, motivation, and support for lifestyle changes. Standard care was potentially exposed to a community-wide health promotion campaign. Data were collected at baseline and 6- and 12-month follow-ups.

**Main outcome measures:** Meeting physical activity guidelines was defined as  $\geq 600$  MET–adjusted minutes of moderate and vigorous exercise.

**Results:** Intervention participants were more likely to meet physical activity guidelines at 6 months (AOR=2.02, 95% CI=1.25, 3.26) than standard care, but the significance was not maintained at 12 months (AOR=1.53, 95% CI=0.92, 2.53). The results were similar in the as-treated and obesity-stratified analyses. The secondary analysis corroborated the primary results.

**Conclusions:** This study shows increases in physical activity among those exposed to a CHW intervention, including participants with obesity. It also indicates that the removal of CHW contact tapers the effect at 12 months.

**Trial registration:** NCT01168765.

*Am J Prev Med* 2019;57(5):611–620. © 2019 American Journal of Preventive Medicine. Published by Elsevier Inc. All rights reserved.

### INTRODUCTION

The burden of noncommunicable diseases (NCDs), including cancer, diabetes, and cardiovascular disease, poses a significant threat to public health. Ethnic minorities and low-income individuals are disproportionately affected by NCDs.<sup>1</sup> Preventive health behaviors that can reduce the impact of NCDs include smoking cessation, low-to-moderate alcohol intake, high-quality nutrition, and physical activity.<sup>2</sup> Studies have found that Hispanics living along the U.S.–Mexico border are significantly less likely to meet the physical activity

From the <sup>1</sup>Biostatistics, Epidemiology, and Research Design (BERD) Core, Center for Clinical and Translational Sciences (CCTS), University of Texas Health Science Center at Houston, Houston, Texas; <sup>2</sup>Department of Internal Medicine, Division of Clinical and Translational Sciences, McGovern Medical School, University of Texas Health Science Center at Houston, Houston, Texas; and <sup>3</sup>Health Promotion and Behavioral Sciences, Hispanic Health Research Center, University of Texas School of Public Health Brownsville Regional Campus, Brownsville, Texas

Address correspondence to: Belinda M. Reininger, DrPH, University of Texas School of Public Health Brownsville Regional Campus, Health Promotion and Behavioral Sciences, Hispanic Health Research Center, One West University Boulevard, SPH - RAHC Building, N1.102E, Brownsville TX 78520. E-mail: [belinda.m.reininger@uth.tmc.edu](mailto:belinda.m.reininger@uth.tmc.edu)

0749-3797/\$36.00

<https://doi.org/10.1016/j.amepre.2019.06.020>

guidelines (>600 METs/week)<sup>3</sup> compared to Hispanics nationally<sup>4</sup> and to white, non-Hispanic individuals.<sup>5</sup> Based on the overall burden of NCDs and the disparities found in their impact, there is a desperate need for effective interventions to increase physical activity among Hispanics and low-income populations.<sup>6</sup>

The delivery of behavior change programs through community health workers (CHWs) is an effective method to deliver health promotion programs owing to a shared culture, community, language, and life experience between the CHWs and participants.<sup>7–9</sup> Previous studies have examined the efficacy of CHW education and outreach on improving health outcomes among participants with NCDs,<sup>10,11</sup> although most interventions have not included a control group,<sup>12</sup> and some used a randomized trial study design.<sup>9</sup> A review of 26 interventions to promote physical activity among adults by CHWs indicated that most (62%) showed positive results for increasing physical activity, but only 9 were based on an RCT, and of these, only 4 were conducted among Hispanic populations.<sup>12</sup> A quasi-experimental pretest, post-test study conducted in a U.S.–Mexico border community demonstrated that participation in a 12-week CHW intervention led to increases in leisure-time physical activity after 3 months of follow-up.<sup>13</sup> In a study of Mexican Americans with diabetes, a CHW intervention significantly improved glycemic control; in the secondary analysis, intervention participants reported more physical activity compared with the control group.<sup>14</sup> Another study examined health indicators associated with CHW-delivered community exercise classes and showed significantly improved leisure-time physical activity and biometric measures over time.<sup>15</sup> Overall, there is sparse evidence from RCTs regarding the effectiveness of a CHW-delivered intervention using brief motivational interviewing techniques based on Social Cognitive Theory to specifically improve physical activity among Mexican Americans.

The aim of this study was to examine the efficacy of a CHW-delivered intervention with motivational interviewing strategies to promote lifestyle changes associated with physical activity among low-income Mexican American adults. The program, *Tu Salud ¡Si Cuenta! (Your Health Matters!) at Home Intervention* (TSSC), was designed to reach Mexican American adults through 6 monthly home visits that included education, motivation, and support for lifestyle changes focusing on physical activity and healthy food choices. This manuscript focuses on only the physical activity outcome of the TSSC intervention, and changes in healthy food choices will be reported in subsequent manuscripts. The authors hypothesized that adults randomized to the intervention group (standard care plus CHW home visits) would be more likely to report meeting the recommended guidelines of moderate and

vigorous physical activity compared with the standard care group.

## METHODS

Participants of the TSSC RCT were randomly selected after being enrolled into the ongoing Cameron County Hispanic Cohort (CCHC) study and then randomized into either the intervention arm or standard care arm. The sample size was determined based on the change in physical activity. The TSSC sample size (183 people/study arm) was calculated to detect an effect size of a 15-minute change in physical activity weekly (80% power and  $\alpha=0.05$ ). To allow for a 25% loss to follow-up at 6 months and adjusting this sample for a 27% dropout rate, 250 people were accrued per group. The trial was conducted at the UTHealth School of Public Health and approved by its IRB. The trial is registered with clinicaltrials.gov reference number: NCT01168765. The following adheres to the CONSORT guidelines for design, conduct, and reporting of clinical trials (Figure 1).<sup>16</sup>

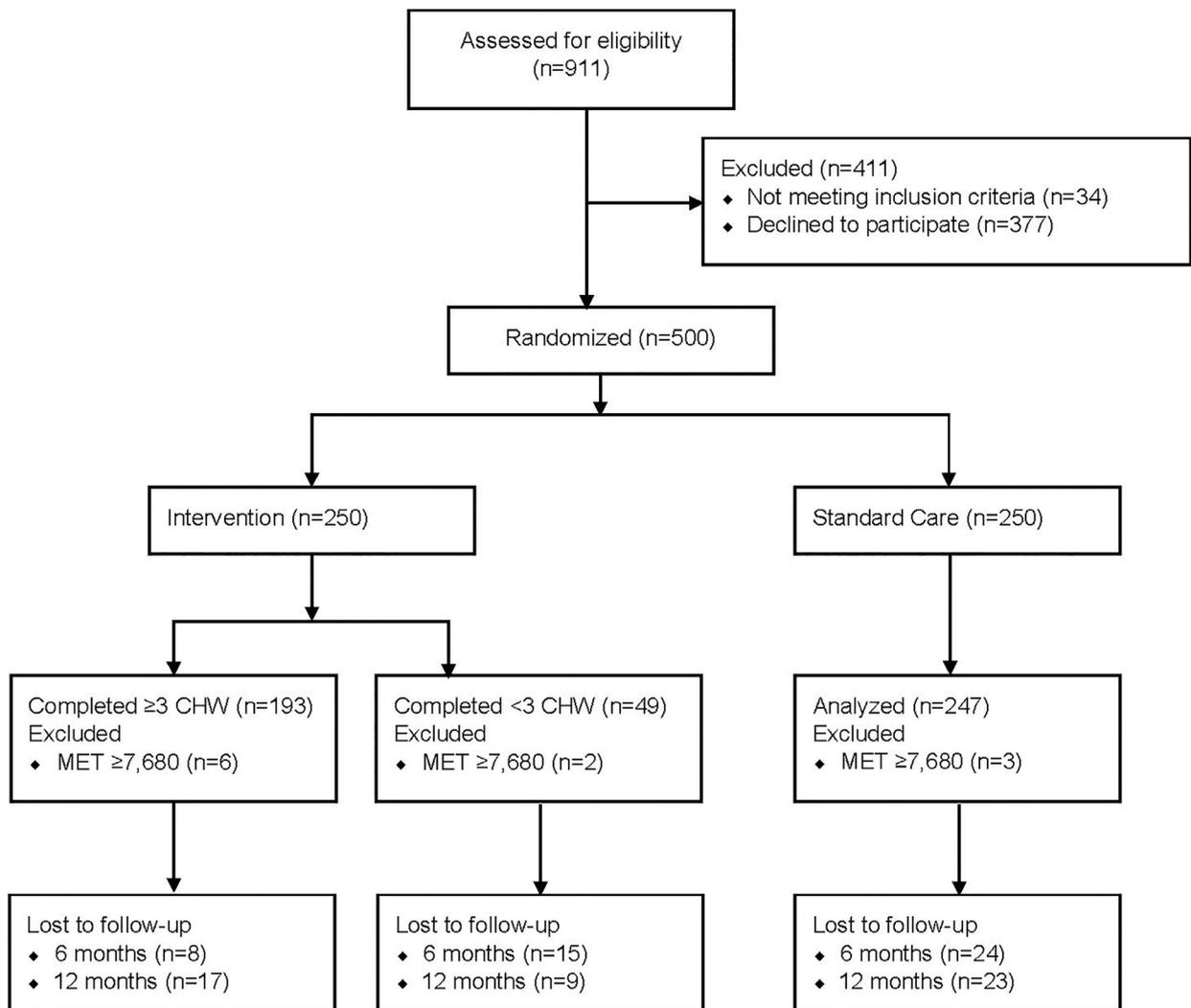
### Study Population

Mexican American adults aged 18–75 years were recruited and enrolled from the CCHC, which has been previously described elsewhere.<sup>17</sup> In brief, the CCHC utilized a two-stage systematic cluster sampling method to identify census tracts and blocks, then households stratified by SES. All eligible members, aged  $\geq 18$  years, of the selected households were recruited into the CCHC. For this study, newly enrolled or 5-year follow-up members from 4 economic quartiles in Brownsville, TX were recruited from June 2010 to April 2013. Two individuals, 1 male and 1 female, from randomly identified households across the 4 strata were recruited for enrollment in the TSSC trial; 34.8% of the participants included were from the same household. All the individuals provided informed consent. There was no racial or sex bias in the selection of participants. The cohort from which the sample was drawn has a greater percentage of female participants, thus female participants had a greater chance of being selected and were more likely to enroll.

Following consent by staff highly trained in good clinical practice protocol, eligible participants were selected and individually randomized to the intervention or standard care group. This study implemented a computerized minimization randomization schedule based on a dynamic random allocation algorithm for the minimization of unbalanced intervention assignment. Minimization randomization is one of the adaptive randomization procedures<sup>18,19</sup> that allocates participants to study arms based on similar characteristics already randomized to best balance the study arms across all stratification variables. Minimization randomization takes potential covariates into consideration at randomization to reduce imbalances between groups and does not suffer from some of stratification's limitations (e.g., increased probability of group imbalance when stratifying across several characteristics). In this study, the minimization schedule used for randomization balanced the 2 study arms with respect to sex and age by census tract/block. A random allocation of  $p=0.67–0.80$  was used in the minimization algorithm and was programmed using R, version 2.1.

### Intervention

Following baseline assessments, the participants randomized to the standard care group received an initial welcome TSSC newsletter and other TSSC media campaign materials to assure their



**Figure 1.** CONSORT flow chart.  
CHW, community health worker.

awareness of the various media outlets and programming of the campaign focused on physical activity and healthy food choices. The standard care arm of the study was potentially exposed to a community-wide campaign media outlets and its associated behavior change techniques, which are described in detail elsewhere.<sup>20</sup> The components of the TSSC that participants in the standard care arm of the study may have been exposed to included: mass media in Spanish language, radio segments in Spanish language, and weekly TV health segments on a Spanish TV station; free exercise classes in the community (Spanish and English options); and environmental changes, such as weekly farmers markets.

Participants in the intervention group received the first CHW home visit within 2 weeks of their enrollment. Each of the 6 monthly home visits consisted of a bilingual CHW delivering and reviewing that month's TSSC newsletter with the participant, emphasizing the role model story, and discussing physical activity and healthful food choices using brief motivational interviewing strategies and educational modules. The educational modules and

conversations were based on the Transtheoretical Model and Brief Motivational Interviewing, and topics included physical activity, fruit and vegetable intake, portion control, high blood pressure, diabetes management, and cancer. These strategies allowed the participant to discuss their own goals for making change, while the CHW reflectively listened and summarized their comments.

During monthly home visits, the CHW invited the participants to relevant and accessible opportunities for physical activity and healthful food choices, such as neighborhood walking groups, exercise classes, the farmers market, and nutrition and cooking classes. Other tools and resources the CHWs used at the home visits included showing the participant how to access recipes and resources on the TSSC website and viewing relevant TSSC TV clips on a laptop. The participants were invited to an annual celebration of the TSSC media campaign, which featured speakers, cooking, exercise demonstrations, and opportunities for networking.

Start and end times for home visits and goals set were logged in participants' records by the CHW. Most home visits (69.2%) lasted between 33 and 65 minutes with an SD of 18 minutes.

Although the content of each session was guided carefully, it was also designed to spark conversations that could be lengthy for some participants and more concise for others. Most participants ( $n=193$ ) in the intervention group completed 3 or more CHW home visits, whereas 49 completed fewer than 3 visits. The average number of home visits was 4.7.

## Measures

Data were collected at baseline, 6 months (immediate post-program), and 12 months (6 months post-completion) from June 2010 to April 2013. Data were collected in person by bilingual trained staff, who read the questionnaires to participants in their preferred language (English or Spanish) and recorded the responses.

Physical activity was assessed using the International Physical Activity Questionnaire (IPAQ)<sup>21</sup> during the first 5 months of data collection, and then the Godin Leisure-Time Exercise Questionnaire<sup>22</sup> was used for the remainder of the data collection. The instrument was changed to better assess intervention effectiveness, and additional items were added to the Godin Leisure-Time Exercise questionnaire to assist in obtaining MET-minute calculations. In both instruments, the questions asked about the frequency, intensity, and duration of minutes exercised per week. In the IPAQ, walking was considered mild activity. The IPAQ has previously been used to measure physical activity in Spanish-speaking populations.<sup>23,24</sup> Test–retest reliability studies have been conducted in samples of individuals of Mexican descent<sup>25</sup> and Mexican Americans<sup>26</sup> that showed the IPAQ had acceptable reliability. The Godin Leisure-Time Exercise questionnaire has also shown adequate reliability and validity among Latinos.<sup>27</sup> Data from the questionnaires were used to calculate MET–adjusted minutes of moderate and vigorous exercise to assess whether the participants met the physical activity guidelines at each observation.<sup>28,29</sup> Participants with <600 MET–adjusted minutes/week were categorized as not meeting physical activity guidelines.<sup>23</sup>

Interviewer-administered questionnaires were used to obtain demographics and other characteristics, including: age (18–29, 30–39, 40–49, and  $\geq 50$  years), sex, insurance (yes, no), language preference for data collection interviews and intervention content (English, Spanish, Bilingual), educational attainment ( $\leq 8$  years,  $>8$  years of school), marital status (married, other), employment status (employed, unemployed), and diabetes status.<sup>30</sup> Adiposity was measured using waist circumference, and obesity was defined as  $>102$  cm for male and  $>88$  cm for female participants.<sup>31</sup> High blood pressure was defined as  $\geq 140/90$  mm Hg from the mean of 2 blood pressure measurements taken at baseline by a sphygmomanometer.

## Statistical Analysis

Baseline characteristics of the study groups are presented as means (SD) and counts (percentages) and compared using Student's *t*-tests for continuous or chi-squared tests for categorical variables. Univariable and multivariable associations were assessed between the study groups and meeting physical activity requirements using mixed effect logistic regression models in longitudinal data analysis that accounted for family-level clustering and correlation of repeated measures over time. An intent-to-treat analysis was first performed. Participants in the intervention group were then classified as completers (those who finished 3 or more CHW visits) and noncompleters (those with fewer than 3

CHW visits). Potential confounders were included in the final models if they were theoretically relevant, or they were associated with both meeting physical activity requirements and the study groups, or if inclusion of the variable in the models resulted in a  $\geq 10\%$  change in the estimates. Those potential confounders included sex, age, insurance, language, education, marital status, employment status, diabetes, and obesity. An interaction term between the study group and follow-up visit was included in the models to test whether the study group effect changed over time and test whether the time effect differed by study group. Models were stratified by obesity status at baseline, and mixed effects logistic regression models were performed to estimate the odds of meeting physical activity guidelines for participants with or without obesity. Multivariable models that were adjusted for clinically relevant variables identified a priori: sex, age, diabetes, marital status, years in school, employment status, type of insurance, and preferred language.

A longitudinal trajectory of meeting the physical activity guidelines, which classified participants following a similar longitudinal pattern of meeting physical activity guidelines, was also explored, and its association with other factors was assessed in post-hoc analysis. The authors included 380 participants with complete outcome data at each study assessment time point. Eight patterns of meeting physical activity guidelines over time were determined and combined into 3 characteristically similar groups. Multivariable model building was conducted in a similar way to that described above except that mixed effects modeling that accounts for the correlations of observations within a family group was unable to provide stable estimates for inference, most likely because within the subgroup sample, there were few (17%) participants clustered at the family level. Thus, traditional generalized logistic regression was used to model the odds of being in each of the 3 particular trajectory patterns. SAS, version 9.3 was used to perform all statistical analyses, and statistical significance was assumed at the 0.05 level.

## RESULTS

Of the 911 screened participants, 877 met the inclusion criteria. Of this group, 500 provided informed consent and were randomized. Based on recommended scoring protocols, 11 participants were excluded from the present analysis for having total MET–adjusted minutes of moderate and vigorous physical activity  $\geq 7,680$ . The final study sample size was 489, with 247 in the standard care group and 242 in the intervention group (Figure 1). Retention was 90.4% at 6 months and 80.4% at 12 months with no significant differences in the retention rates between the study groups.

At baseline (Table 1), there was no statistical difference in the percentage meeting physical activity guidelines between study groups ( $p=0.8940$ ). No significant differences were observed in age, insurance status, language preference, education, marital status, diabetes status, or obesity. However, noncompleters were more likely to be employed than both the standard care ( $p=0.001$ ) and completer group ( $p<0.001$ ).

**Table 1.** Baseline Characteristics of Intervention Participants by Completion of CHW Visits (n=489)

Characteristics	Standard care (n=247)	Intervention group	
		Noncompleters (n=49)	Completers (n=193)
Number of CHW visits, mean±SD		1.2 ± 0.7	4.8 ± 1.0
Met physical activity guidelines, n (%)	82 (33.7)	18 (36.7)	63 (33.2)
Combined MET—adjusted minutes of moderate and strenuous activity, median (IQR)			
Baseline	0 (0–900)	212.5 (0–1,065)	0 (0–1,200)
6 months	0 (0–675)	570 (0–1,575)	385 (0–1,282.5)
12 months	0 (0–615)	400 (150–810)	67.5 (0–1,080.5)
Sex, n (%)			
Male	75 (30.4)	20 (40.8)	50 (25.9)
Female	172 (69.6)	29 (59.2)	143 (74.1)
Age, years, n (%)			
18–29	31 (12.6)	8 (16.3)	20 (10.4)
30–39	50 (20.2)	12 (24.5)	48 (24.9)
40–49	59 (23.9)	8 (16.3)	43 (22.3)
≥50	107 (43.3)	21 (42.8)	82 (42.5)
Insurance, n (%)			
No	166 (67.2)	34 (69.4)	135 (69.9)
Yes	81 (32.8)	15 (30.6)	58 (30.1)
Language, n (%)			
English	27 (11.0)	11 (22.5)	19 (9.8)
Spanish	185 (75.5)	32 (65.3)	151 (78.2)
Bilingual	33 (13.5)	6 (12.2)	23 (11.9)
Education, years, n (%)			
≤8	80 (32.4)	10 (20.4)	63 (32.6)
>8	167 (67.6)	39 (79.6)	130 (67.4)
Marital status, n (%)			
Married	163 (66.0)	28 (57.1)	132 (68.4)
Other	88 (34.0)	21 (42.9)	61 (31.6)
Employment status, n (%)			
Unemployed	126 (51.0)	16 (32.7)	112 (58.0)
Employed	121 (49.0)	33 (67.3)	81 (42.0)
Diabetic, n (%)			
No	192 (80.3)	38 (79.2)	134 (71.7)
Yes	47 (19.7)	10 (20.8)	53 (28.3)
BMI ≥30 kg/m <sup>2</sup> , n (%)			
No	121 (49.2)	24 (49.0)	89 (46.1)
Yes	125 (50.8)	25 (51.0)	104 (53.9)
Waist circumference obese			
No	67 (27.2)	15 (30.6)	39 (20.2)
Yes	179 (72.8)	34 (69.4)	154 (79.8)
High blood pressure, <sup>a</sup> n (%)			
No	181 (73.3)	34 (69.4)	136 (70.5)
Yes	66 (26.7)	15 (30.6)	57 (29.5)

Notes: Intervention group noncompleters <3 CHW visits; Intervention group completers ≥3 CHW visits.

<sup>a</sup>Blood pressure was only collected at baseline.

CHW, community health worker.

Results from the multivariable intent-to-treat analysis (Table 2) after controlling for other variables (i.e., sex, age, insurance, language, education, marital status, employment status, diabetes, and obesity) showed intervention

participants to be more likely to meet physical activity guidelines at 6 months (AOR=2.02, 95% CI=1.25, 3.26) and 12 months (AOR=1.53, 95% CI=0.92, 2.53) than the standard care participants. In addition, the intervention

**Table 2.** Adjusted Treatment Effects on Meeting Physical Activity Guidelines Based on Multivariable Mixed Effects Logistic Regression Analysis

Study group effect at each time point	All (n=489)		Obesity <sup>a</sup> stratified analysis			
	AOR (95% CI)	p-value	Obese <sup>b</sup> (n=367)		Not obese <sup>b</sup> (n=121)	
			AOR (95% CI)	p-value	AOR (95% CI)	p-value
Intent to treat <sup>c</sup>						
Intervention vs standard care						
Baseline	0.99 (0.63, 1.56)	0.9818				
6-month visit	2.02 (1.25, 3.26)	<b>0.0041</b>				
12-month visit	1.53 (0.92, 2.54)	0.1010				
As treated <sup>c</sup>						
Completers vs. standard care						
Baseline	0.94 (0.58, 1.53)	0.8178	1.11 (0.63, 1.93)	0.7200	0.66 (0.24, 1.88)	0.4396
6-month visit	1.94 (1.18, 3.20)	<b>0.0092</b>	2.15 (1.20, 3.84)	<b>0.0100</b>	1.44 (0.51, 4.05)	0.4834
12-month visit	1.59 (0.94, 2.69)	0.0825	1.70 (0.92, 3.14)	0.0914	1.52 (0.50, 4.60)	0.4532
Noncompleters vs standard care						
Baseline	1.06 (0.50, 2.24)	0.8784	1.17 (0.47, 2.86)	0.7365	0.82 (0.18, 3.62)	0.7891
6-month visit	2.63 (1.05, 6.61)	<b>0.0387</b>	3.27 (1.09, 9.82)	<b>0.0351</b>	1.28 (0.22, 7.52)	0.7867
12-month visit	1.07 (0.38, 3.04)	0.8975	1.02 (0.29, 3.54)	0.9749	1.11 (0.13, 9.47)	0.9245
Completers vs noncompleters						
Baseline	0.89 (0.41, 1.92)	0.7684	0.95 (0.38, 2.36)	0.9104	0.81 (0.17, 3.97)	0.7978
6-month visit	0.74 (0.29, 1.85)	0.5151	0.66 (0.21, 1.97)	0.4542	1.13 (0.19, 6.91)	0.8931
12-month visit	1.48 (0.52, 4.23)	0.4569	1.67 (0.48, 5.76)	0.4196	1.37 (0.15, 12.29)	0.7748

Note: Boldface indicates statistical significance ( $p < 0.05$ ).

<sup>a</sup>Obesity defined as having a waist circumference  $>102$  cm for males and  $>88$  cm for females.

<sup>b</sup>Adjusted for sex, age, insurance, language, education, marital status, employment status, and diabetes.

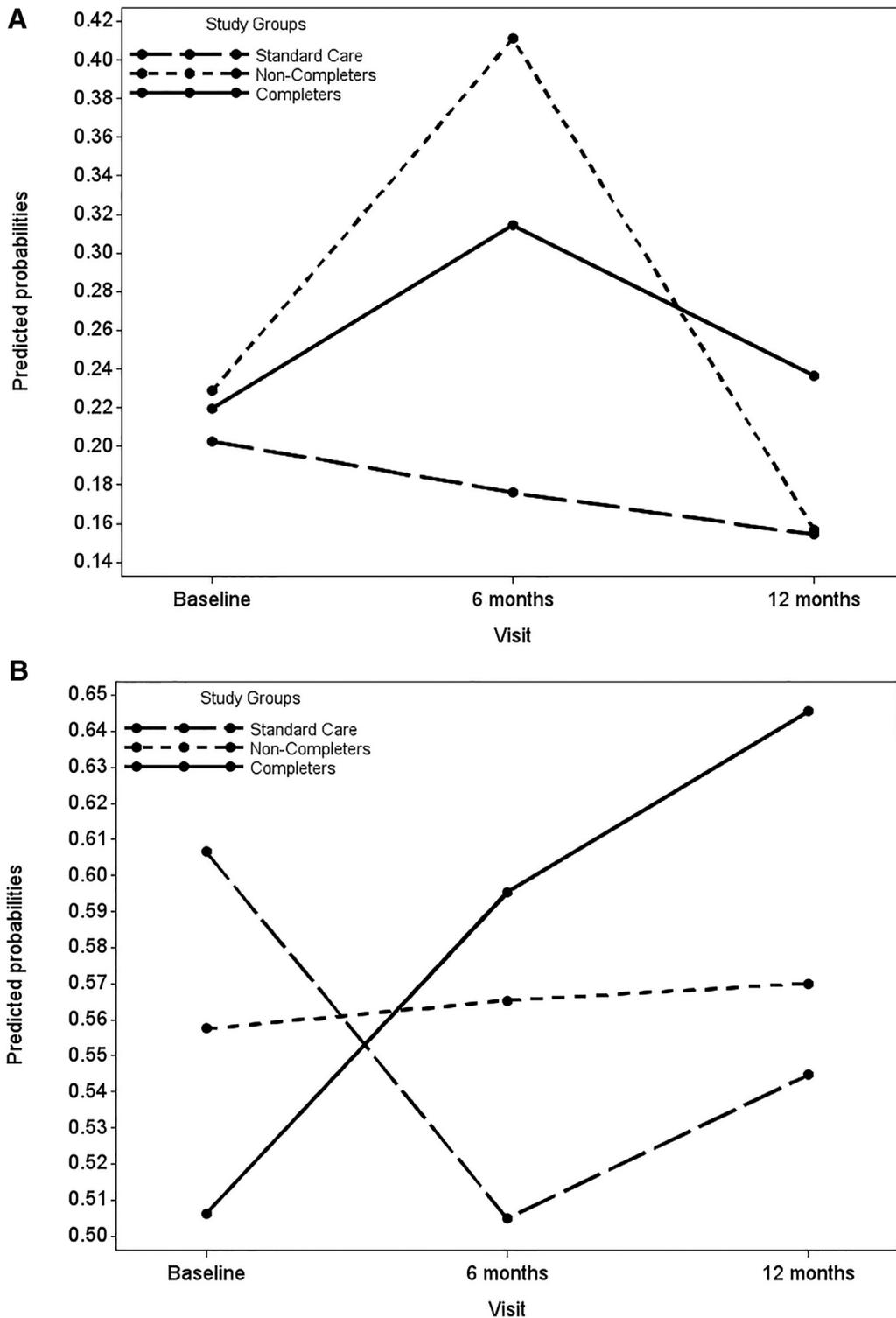
<sup>c</sup>Adjusted for sex, age, insurance, language, education, marital status, employment status, diabetes, and obesity.

group had a significant increase in the probability of meeting physical activity guidelines from baseline to 6 months ( $p=0.0263$ ; data not shown).

Table 2 and Figure 2A and 2B present the results for the obesity-stratified longitudinal model adjusted for covariates (i.e., sex, age, insurance, language, education, marital status, employment status, and diabetes). Although the overall interaction effect between the treatment group and time was not statistically significant (intent to treat,  $p=0.0668$ ; as treated,  $p=0.1707$ ; with obesity,  $p=0.7625$ ; without obesity,  $p=0.2531$ ), the interaction term was included in a final model to obtain the estimates of treatment effect at each time point. For participants with obesity ( $n=367$ ), compared with the standard care group, intervention completers were more than twice (AOR=2.15, 95% CI=1.20, 3.84) as likely to meet physical activity guidelines 6 months after the intervention. Intervention completers were 1.70 (95% CI=0.92, 3.14) times more likely to meet the physical activity guidelines 12 months post-intervention than the standard care group, although not significantly. Among the participants without obesity ( $n=121$ ), intervention completers were more likely than the standard care group to meet physical activity guidelines at the 6-month (AOR=1.44, 95% CI=0.51, 4.05) and 12-month

(AOR=1.52, 95% CI=0.50, 4.60) visits, although not significantly. Among obese participants (Figure 2A), there was a marginally significant increase in the probability of meeting the physical activity requirements between baseline and 6-month follow-up ( $p=0.068$ ) followed by a decrease between 6- and 12-month follow-up ( $p=0.1513$ ). The estimated probability of meeting physical activity requirements for intervention completers without obesity (Figure 2B) increased over the entire follow-up period ( $p=0.2944$ ). Noncompleters and standard care groups had no significant change in the probability of meeting physical activity requirements between baseline and 6- and 12-month follow-ups for participants either with or without obesity.

Longitudinal patterns of meeting physical activity guidelines are presented in Appendix Tables 1 and 2. From 8 patterns over time, 3 characteristically similar groups were determined and used for analysis to assess its association with other variables. Pattern 1 included participants who did not meet the guidelines at both baseline and 6 months and may or may not have met the guidelines at 12 months (i.e., consistent inactivity). Pattern 2 participants did not meet the guidelines at baseline but did meet the guidelines at 6 months and may or may not have at 12 months (i.e., improved



**Figure 2.** (A) Adjusted probability of meeting physical activity guidelines among obese participants by intervention group. (B) Adjusted probability of meeting physical activity guidelines among nonobese participants by intervention group.

activity). Pattern 3 included all the participants who met the guidelines at baseline and may or may not have met the guidelines at 6- or 12-month follow-up (i.e., consistent activity). Distributions of covariates across the

3 groups are presented. Given the reduction in sample size, many covariates had small cells, including the non-completers intervention group, which was collaped with the standard care group for this analysis. Most of

the participants, 49.5%, were in Pattern 1. Among the completers, 24% were in Pattern 2 versus 13% of standard care and noncompleters. More than 60% of participants in Pattern 1 were in the standard care or noncompleters group, whereas 58% of participants in Pattern 2 were completers. Stratified crude ORs are presented for participants with and without obesity comparing Pattern 1 to 2 and Pattern 1 to 3 (Appendix Table 2). Among the participants with obesity, completers were twice (OR=2.08, 95% CI=1.11, 3.88) as likely to be in Pattern 2 versus Pattern 1 as standard care participants and noncompleters.

## DISCUSSION

This study examined an intervention to promote lifestyle changes with a particular focus on the physical activity outcome among low-income Mexican American participants through CHW-delivered education and outreach in the home. Based on the intent-to-treat analysis, the TSSC results indicate that completers of the intervention were 2 times more likely to meet aerobic physical activity guidelines at 6 months than those participants assigned to standard care. However, the statistical difference was not maintained at 12 months in the overall sample, which would have been 6 months without a CHW home visit. This finding is similar to other literature indicating that after the intervention is removed from participants, the effects decline.<sup>32,33</sup> In the qualitative analysis on this sample, interactions with the CHWs promoted positive lifestyle behavioral change because of the professionalism and strong relationships.<sup>34</sup> However, once the home visits ended, the authors believe that the feelings of accountability and support faded, and old sedentary behavioral patterns re-emerged. Also, the CHWs helped to troubleshoot the barriers to physical activity associated with the social determinants of health with the participants. Once this support was no longer available, the improved physical activity behaviors waned. Future research should examine what frequency and intensity of CHW outreach is needed in the maintenance phase of lifestyle behaviors like physical activity, particularly in populations where many social determinants of health present barriers to successful behavioral modification over time. The study analysis examined the treatment effects by intervention completeness and participant adiposity. Roughly 20% of the intervention group did not complete at least 3 CHW home visits. The choice of cut off for completing the intervention was based on expert opinion, as fewer than 3 CHW visits would not be sufficient exposure to intervention content to account for behavioral outcomes. Though not significantly different, intervention noncompleters had higher total weekly MET-adjusted minutes, were more likely to meet

physical activity recommendations, and were less likely to have obesity than the standard care and intervention completer groups at baseline (data not shown). It is possible that healthier participants in the intervention group were more likely to decline CHW visits than their nonhealthy counterparts, believing that the visits required too much time. For some analyses, these participants were treated as an independent study group, reducing the sample size of the intervention group and overall statistical power. Despite separating the intervention noncompleters into their own study group, the results from the intent-to-treat and as-treated analyses did not differ meaningfully, leading the authors to conclude that there was no loss of power or indication of bias in isolating the intervention noncompleters.

The results of this study are similar to other RCTs conducted in Hispanic populations, although previous interventions have not focused on physical activity as a primary outcome. Babamoto et al.<sup>14</sup> utilized a CHW intervention to improve diabetes care with a secondary outcome of increased physical activity in African American and Hispanic participants. Those who were in the CHW intervention arm had greater increases in physical activity than those in the control arm. Additionally, in the Mexican American Trial of Community Health Workers RCT, secondary outcome physical activity increased from baseline to 2-year follow-up for CHW intervention participants, but this did not differ significantly from the control participants.<sup>35</sup> This study provides further support that interventions utilizing the CHW model with culturally appropriate materials have significant impact on participant health behaviors.

For those individuals with obesity, intervention completers were more likely to meet the physical activity guidelines at 6 and 12 months than the standard care participants. This result corroborates a systematic review evaluating the efficacy of interventions to improve physical activity in adults with obesity, which noted a positive association.<sup>36</sup> The strength of the association, though still positive, was attenuated in participants without obesity and not significant. The attenuation of the association is not unexpected. Participants without obesity were more likely to already be meeting physical activity guidelines at baseline (OR=0.58,  $p=0.036$ ; data not shown) than participants with obesity. Thus, the participants with obesity had more opportunity to progress over the study period. The lack of a significant relationship despite a positive association in the group without obesity is most likely owing to sample size considerations, as previous research has found significant increases in physical activity in healthy adults after participating in physical activity interventions.<sup>37</sup>

Strengths of the study included enrolling and retaining the sample necessary to have the power to detect changes in physical activity. Deriving the sample for this study from a randomly sampled cohort of Mexican Americans allows for the exceptional characterization of the sample and findings that are generalizable to this region of the Mexican Americas. The robust study design used randomization and a standard care control group to provide unique insight into the contributions that CHW home visits have even in a sample exposed to a community-wide campaign promoting lifestyle behaviors (standard care). Secondary analysis of the patterns of meeting physical activity recommendations corroborated the primary analysis results. Evidence for the benefits of CHW interventions continues to grow, showing advantages to their delivery of health messages and guidance on healthy lifestyle choices. This study examined intervention modules delivered by the CHWs that were designed to be delivered using brief Motivational Interviewing strategies and had content and learning strategies that would enhance self-efficacy, a construct of the Social Cognitive Theory.<sup>38</sup> The home modules also featured role model stories to provide opportunities for the observational learning of peers making healthy lifestyle changes, another important construct in Social Cognitive Theory.

### Limitations

There are study limitations that may influence interpretation of the results. First, physical activity was measured using self-reported instruments rather than direct measures. This study used both the IPAQ (for the first 5 months) and Godin Leisure-Time Exercise questionnaire, which have both been validated as reliable measures of physical activity in adults, despite these measures being subject to information bias and typically resulting in over-reporting. Another limitation was that 38.4% of the sample came from the same household rather than independent households. This study design can lead to unseen effects of peer support and unintended crossover if household members are in different study arms. The hierarchical nature of the study design was controlled for in analysis using a mixed effects regression model. Additionally, >30% of the noncompleter intervention group was lost to follow-up from baseline to 6-month assessment. This was greater than attrition seen in the standard care group (9.7%) and completer intervention group (4.1%). The attrition may have been because of the availability of the participant to be in the intervention, as the noncompleter intervention group had a higher percentage of employed participants than the other study groups. Finally, outcome assessors were not blinded to the intervention group assignment, which could lead to bias.

## CONCLUSIONS

The findings of this study expand the CHW intervention literature indicating that physical activity increases among those exposed to a CHW intervention, including those with obesity. The study findings also indicate that the removal of direct contact with the CHW delivering an intervention tapers the effect at 12 months, suggesting that future research is needed to examine how the CHWs may enhance maintenance of behavior change.

## ACKNOWLEDGMENTS

The authors of this manuscript would like to acknowledge the participants who so willingly participated in this study, our community partners, and Community Action Board members who are dedicated to eliminating health disparities. We would also like to acknowledge our Tu Salud ¡Si Cuenta! professional intervention team, including Vanessa Saldana, Marcelina Martinez, Angelica Muniz, Silvia Garcia, Arisve Ramirez, and others. We thank the cohort team, led by Drs. Susan Fisher-Hoch and Joseph McCormick and Ms. Rocio Uribe and her team, who recruited and documented the participants. We also thank Marcela Morris and other laboratory staff for their contributions, and Christina Villarreal for administrative support. We thank Valley Baptist Medical Center, Brownsville, TX for providing us space for our Center for Clinical and Translational Science Clinical Research Unit. We acknowledge the support provided by the Biostatistics/Epidemiology/Research Design component of the Center for Clinical and Translational Sciences for this project. The research presented in this paper is that of the authors and does not reflect the official policy of the NIH. The intervention and analysis work described in the manuscript was partially supported by the Clinical and Translational Science Award (UL1TR000371) from the NIH's National Center for Advancing Translational Sciences. This research was also partially funded by the Cancer Prevention & Research Institute of Texas award PP110163. This study was reviewed and approved by the UTHealth IRB. HSC-SPH-10-0015.

BR, LMB, ML designed intervention study and managed the data collection. MV and ML conducted analysis. MV, ML BR, and LMB drafted and edited the manuscript.

No financial disclosures were reported by the authors of this paper.

## SUPPLEMENTAL MATERIAL

Supplemental materials associated with this article can be found in the online version at <https://doi.org/10.1016/j.amepre.2019.06.020>.

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