

University of Texas Rio Grande Valley

ScholarWorks @ UTRGV

---

Health & Biomedical Sciences Faculty  
Publications and Presentations

College of Health Professions

---

2024

## Participant engagement in a community health worker-delivered intervention and type 2 diabetes clinical outcomes: a quasiexperimental study in MexicanAmericans

Belinda M. Reininger

*University of Texas Health Science Center at Houston*

Juliana Z. Lopez

*University of Texas Health Science Center at Houston*

Maria E. Zolezzi

*University of Texas Health Science Center at Houston*

MinJae Lee

*University of Texas Southwestern Medical Center*

Lisa A. Mitchell-Bennett

*University of Texas Health Science Center at Houston*

See next page for additional authors

Follow this and additional works at: [https://scholarworks.utrgv.edu/hbs\\_fac](https://scholarworks.utrgv.edu/hbs_fac)



Part of the [Public Health Commons](#)

---

### Recommended Citation

Reininger, B. M., Lopez, J., Zolezzi, M., Lee, M., Mitchell-Bennett, L. A., Xu, T., Park, S. K., Saldana, M. V., Perez, L., Payne, L. Y., Collier, C., & McCormick, J. B. (2022). Participant engagement in a community health worker-delivered intervention and type 2 diabetes clinical outcomes: a quasiexperimental study in MexicanAmericans. *BMJ open*, 12(11), e063521. <https://doi.org/10.1136/bmjopen-2022-063521>




This Article is brought to you for free and open access by the College of Health Professions at ScholarWorks @ UTRGV. It has been accepted for inclusion in Health & Biomedical Sciences Faculty Publications and Presentations by an authorized administrator of ScholarWorks @ UTRGV. For more information, please contact [justin.white@utrgv.edu](mailto:justin.white@utrgv.edu), [william.flores01@utrgv.edu](mailto:william.flores01@utrgv.edu).

---

**Authors**

Belinda M. Reininger, Juliana Z. Lopez, Maria E. Zolezzi, MinJae Lee, Lisa A. Mitchell-Bennett, Tianlin Xu, Soo Kyung Park, Mayra V. Saldana, LuBeth Perez, and Joseph B. McCormick

# BMJ Open Participant engagement in a community health worker-delivered intervention and type 2 diabetes clinical outcomes: a quasiexperimental study in Mexican Americans

Belinda M Reininger <sup>1</sup>, Juliana Lopez,<sup>1</sup> Maria Zolezzi <sup>1</sup>, MinJae Lee,<sup>2</sup> Lisa A Mitchell-Bennett,<sup>1</sup> Tianlin Xu <sup>3</sup>, Soo Kyung Park,<sup>4</sup> Mayra V Saldana,<sup>1</sup> LuBeth Perez,<sup>1</sup> Lisa Y Payne,<sup>5</sup> Cindy Collier,<sup>6</sup> Joseph B McCormick<sup>1</sup>

**To cite:** Reininger BM, Lopez J, Zolezzi M, *et al*. Participant engagement in a community health worker-delivered intervention and type 2 diabetes clinical outcomes: a quasiexperimental study in Mexican

Americans. *BMJ Open* 2022;**12**:e063521. doi:10.1136/bmjopen-2022-063521

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-063521>).

Received 07 April 2022

Accepted 27 October 2022



© Author(s) (or their employer(s)) 2022. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

## Correspondence to

Mrs Maria Zolezzi;  
maria.e.zolezzi@uth.tmc.edu

## ABSTRACT

**Objectives** This study helps to fill the existing research gap related to participant engagement in behavioural interventions and diabetes management. We examined type 2 diabetes control over time among Mexican Americans by level of engagement in a chronic care management (CCM) program that included community health worker (CHW)-delivered multilevel interventions. The programme complemented clinical care and promoted behaviour changes to improve diabetes self-management.

**Design** Quasiexperimental study.

**Setting** The study was implemented in the Rio Grande Valley region in the USA. Recruitment was conducted in clinics and community events. All other visits were provided in participant homes and community locations.

**Participants** 5649 adults (aged ≥18 years) with poorly controlled type 2 diabetes who enrolled in a community-delivered CCM programme between September 2013 and 2018.

**Interventions** The intervention comprised two components: CHW home visits conducted every 3 months and diabetes self-management education (DSME) classes provided in community locations.

**Primary outcome measures** The primary outcome was haemoglobin A1c (HbA1c) measured at baseline every 3 months for up to 24 months. We first examined changes in HbA1c levels over time. The number of completed CHW and DSME encounters was used to classify participants into engagement groups—high engagement defined as ≥10 encounters (n=2952); low engagement defined as 1–9 encounters (n=2697). We used univariable and multivariable longitudinal linear regression models with a generalised estimating equation method. We tested interactions between engagement groups and time.

**Results** Participants' mean HbA1c decreased from 10.20% at baseline to 8.93% (p<0.0001) at 3 months, remaining stable thereafter. Changes in HbA1c were statistically different between the engagement groups. High engagement participants had lower HbA1c levels over the first 15 months of the follow-up period compared with low engagement participants, as compared at 3 months (–0.44%, 95% CI –0.57% to –0.31%; p<0.0001), 6

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is among the first studies in the USA to report clinical outcomes for an intervention employing the innovative care for chronic conditions framework.
- ⇒ The sample size was robust, including 5600 Mexican-American participants.
- ⇒ Results include diabetes management outcomes up to 24 months.
- ⇒ This study lacks a control group of individuals who did not receive the intervention.
- ⇒ Unable to quantify participant engagement in their medical home.

months (–0.31%, 95% CI –0.43% to –0.14%; p<0.0001), 9 months (–0.27%, 95% CI –0.42% to –0.13%; p=0.0001), 12 months (–0.23%, 95% CI –0.37% to –0.08%; p=0.0025) and 15 months (–0.32%, 95% CI –0.54% to –0.10%; p=0.0040). At months 18, 21 and 24, the HbA1c differences were not statistically significant (18 months: –0.34%, 95% CI –0.77% to 0.08%; p=0.1086; 21 months: –0.22%, 95% CI –1.00% to 0.56%; p=0.5721; 24 months: –0.42%, 95% CI –1.38% to 0.55%; p=0.3966).

**Conclusions** Higher engagement in the CCM programme delivered by CHWs and coordinated with clinical care was associated with beneficial improvements in type 2 diabetes control, but both engagement groups showed strong improvements.

## INTRODUCTION

Type 2 diabetes continues to be a major health concern worldwide. In 2019, a total of 34.1 million adults (13.0% of all US adults) had diabetes<sup>1</sup> and the rate of increase is projected to be 0.3% per year until the year 2030 resulting in 1 million new cases of diagnosed diabetes annually.<sup>2</sup> The impact of diabetes among the US population varies significantly by ethnic group. In the USA, it is well known

that relative to non-Hispanic Whites, Hispanics and those of Mexican origin, in particular, have a disproportionate burden of diabetes.<sup>3</sup> One report of Hispanic health found that Hispanics are 1.7 times more likely to have diabetes while non-Hispanic Blacks are 1.6 times more likely to have diabetes when compared with non-Hispanic Whites. Diabetes mortality also differs among ethnic groups. Compared with non-Hispanic Whites, non-Hispanic Blacks and Hispanics are two times and 1.4 times more likely to die from diabetes, respectively.<sup>4</sup>

Hemoglobin A1c (HbA1c) is a primary clinical measure of diabetes self-management. A study using National Health and Nutrition Examination Survey data for years 2005–2016 revealed that glycaemic control among individuals with diagnosed diabetes declined every year. Only 64% of patients achieved HbA1c targets ranging from 7.0% to 8.5% depending on age and presence of complications among the 2013–2016 cohort. The study also found that Hispanics had 34% lower odds of achieving glycaemic (HbA1c) control compared with non-Hispanic Whites.<sup>5</sup>

Poor HbA1c control contributes to diabetes-related complications. Various studies have demonstrated high rates of diabetes-related complications in Hispanics when compared with non-Hispanic Whites. Hispanics are far more likely than white populations to have diabetic retinopathy (34.0% vs 26.4%),<sup>6</sup> experience lower extremity amputations (incidence rate of 7.4 per 1000 vs 4.1 per 1000)<sup>7</sup> and have higher rates of end-stage renal disease (incidence rate of 4.5 per 1000 vs 3.2 per 1000).<sup>8</sup>

Innovative models in disparate populations are needed to course correct these trends. The Wagner's chronic care management model has been an effective approach to delivery care redesign to improve patient care and health outcomes.<sup>9</sup> The Salud y Vida (SyV) programme uses the international adaptation of the expanded chronic care model<sup>10</sup> known as the innovative care for chronic conditions framework. This model creates linkages between the healthcare team and community partners to improve health outcomes.<sup>11</sup>

Diabetes self-management education (DSME) is widely known as the ongoing process of facilitating the knowledge, skill and ability necessary for diabetes self-care to support informed decision-making, self-care behaviours, problem solving and active collaboration between the patient and the healthcare team.<sup>12</sup> The impact of DSME on HbA1c control has also been widely evaluated. A meta-analysis evaluating interventions focused on Latinos identified that DSME resulted in a 0.24% reduction in HbA1c (p value <0.001).<sup>13</sup> Furthermore, DSME has been associated with significant reduction in all-cause mortality among patients with type 2 diabetes.<sup>14</sup> Chronic disease management programmes delivered in community settings are important to improve patient outcomes and help in addressing health disparities.

We use community health workers (CHWs) as part of the care continuum, by having CHWs trained on delivering behavioural modification. The American Public

Health Association defines a CHW as a 'frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served'.<sup>15</sup> CHWs conduct outreach, serve as patient advocates and deliver services such as education, informal counselling and social support in culturally appropriate ways.<sup>16–18</sup> In randomised controlled trials, CHWs have impacted patients' understanding of diabetes management, self-efficacy and HbA1c outcomes.<sup>16</sup>

This study helps to fill the existing research gap related to participant engagement in behavioural interventions and its relation to type 2 diabetes management. In this study, we measure diabetes control by tracking HbA1c over time among patients who were enrolled due to poorly controlled diabetes. We hypothesised that greater improvement in HbA1c over time would be found among those participants who were more engaged with CHW visits and DSME class attendance after enrolling in the SyV chronic care management. Participants joined the SyV management intervention services in community and home settings in addition to their usual clinical care.

## METHODS

### Patient and public involvement

A Collaborative Action Board (CAB), established in 2003 dedicated to creating a healthy, prosperous and resilient Rio Grande Valley binational region in which innovative practices that promote health are developed, helped initiate the SyV programme to transform the delivery of chronic care management. During the feasibility stage and initial stage, local organisational members of the CAB (primary care entities, healthcare providers, universities, health information management organisations and outreach organisations) and the public were involved in the design (research question, methods of recruitment and outcome measures) and implementation of the SyV programme. Through learning collaboratives and meetings of the partnering members, the multidisciplinary team established outcome measures and deliverables to improve chronic care services. Recruitment was supported through primary care entities, CHWs were provided through the university and outreach organisations and data management was maintained through a health information organisation.

Additional community engagement from actual participants of the SyV programme has also been important to the programme from the start. Participants were invited to Patient Advocacy Leader (PAL) board meetings on a quarterly basis to provide feedback about their experiences and input on quality improvement strategies for the programme. The current analysis conducted did not include public or participant involvement. For the current analysis and for this publication, the PAL board meetings discussed engagement strategies for those highly engaged and low-engaged participants and they provided feedback to categorise engagement. Ultimately, these discussions

led to the formation of the research question in this particular analysis.

### Recruitment

The SyV programme intervention occurs over 12–24 months and includes patients from low-income serving clinics who have poorly controlled type 2 diabetes (HbA1c  $\geq 8\%$  while on medication). The clinics refer these patients to the SyV programme. The intervention has been previously described.<sup>19</sup>

Recruitment and enrolment were conducted by patient navigators employed by hospital or university partners and located at participating clinics to screen patients for eligibility in the programme. Navigators recruited adult individuals residing in Cameron and Hidalgo Counties. We also enrolled patients with type 2 diabetes and no clinic home in some instances at community health fairs and through outreach community efforts. These individuals became patients of the participating clinics.

### Enrolment

Individuals meeting the criteria for enrolment were provided a written consent document. The consent was reviewed with the participant orally and patient navigators addressed all questions and concerns. Written consent was obtained during the in-person interview lasting approximately 1 hour. The following information was collected in the interview: demographics, medical history, self-monitoring behaviours, socioeconomic status, education level, physical activity and nutrition information. Also at enrolment, participants were registered in a DSME course offered by the SyV programme. Enrolled participants continued to receive primary care through their medical home as well as receiving enhanced services through SyV.

### Interventions

#### CHW visits

The CHW model has been widely used to promote health. All SyV participants were assigned a CHW who performed home visits on a quarterly basis, plus recurrent telephone calls and text messaging. The SyV CHWs are Hispanic, aged 30–61 years and with an average age of 44. Out of the 20 CHWs employed over this time frame (September 2013 and 2018), six have identified as male and 14 as female. Nearly half of the CHWs were born and formally educated in Mexico. The majority of CHWs have high school diploma or General Educational Development programme (from the USA or Mexico). All but four of the CHWs are bilingual (English/Spanish) with the four being monolingual Spanish speaking. CHWs participate in local CHW networks, attend community events and participate in community service efforts outside of their SyV job duties. CHWs are certified by the Texas Department of State Health Services through a 160-hour course covering core health worker skills. They also received continuing education and training.

CHWs also received training on the Diabetes Empowerment Education Program (DEEP) curriculum, the Tu Salud Si Cuenta curriculum that promotes healthy food choice and physical activity,<sup>20</sup> delivery and use of motivational interviewing (MI), clinical skills training and mental health 101 education for a cumulative total of approximately 100 hours of training per year. CHWs and supervisors participate in ongoing quality improvement to ensure fidelity over time including quarterly home visit observations, small group case review and peer mentoring to share best practices. Booster trainings are provided if needed.

SyV CHWs are trusted members of the community they serve and share many similarities with the participants—culturally, linguistically and socioeconomically. In the SyV programme, the role of the CHW is to bridge the gap between clinic and community services, build relationships and trust with participants and provide culturally relevant education, social support and tailored support based on understanding people's experiences, needs and challenges.

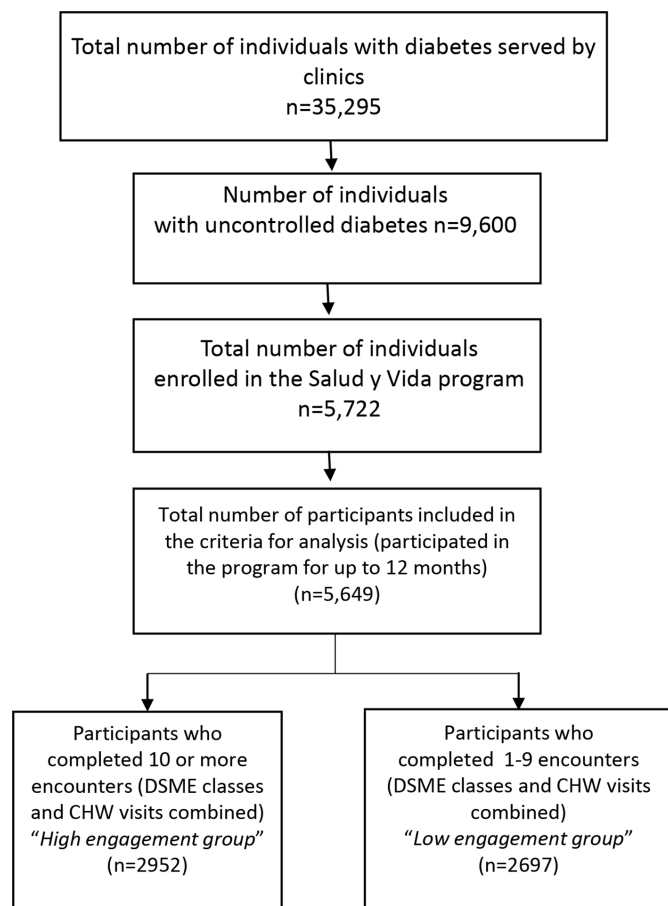
CHWs conducted their first home visit within 2 weeks of enrolment. Thereafter, individuals received home visits at minimum every 3 months. Visits, conducted in the language of choice of the participants (Spanish or English), included reviewing participant's self-management behaviours such as healthy eating, physical activity, glucose monitoring and medication adherence.

SyV used the transtheoretical model to support participants moving through the stages of change adapting strategies from MI by helping participants clarify and resolve ambivalence about behaviour change, assess importance and confidence to perform each behaviour, goal setting, and provide motivation and assistance to overcome barriers to self-management goals. Specific tools used in the individual and group setting include importance and confidence ruler and decisional balance and goal setting. Social cognitive theory constructs of self-efficacy, social support and outcome expectations guided the development of the SyV intervention.

CHWs also conducted behavioural health screening using the Patient Health Questionnaire-9. Scores of 10 or greater or the identification of other mental health concerns triggered referrals to the behavioural health case manager for additional support. Waist, weight, hip measurements and HbA1c measurements were assessed by CHWs at each quarterly visit and were reviewed with participants thoroughly. Glycaemic control was assessed via HbA1c measured at enrolment using the TRUE Result home test kit. Home-test HbA1c kits are reliable when used by both healthcare professionals ( $R^2=0.932$ ) and patients themselves ( $R^2=0.925$ ).<sup>21</sup>

#### DSME classes

Participants were also enrolled in a 6-week DSME course offered in community locations and in either Spanish or English. The course was taught by diabetes educators and CHWs trained to deliver the DEEP curriculum. Each class



**Figure 1** Study flow diagram. CHW, community health worker; DSME, diabetes self-management education.

was based on behaviour change theory using culturally tailored, low-literacy approaches such as providing all materials in both English and Spanish, embedding practices that are specific to participants' culture and having instructors who share common identity with participants. Participants were provided transportation assistance if needed as well as incentives to promote engagement. Repeat DSME classes were offered for participants who wanted to review the material. The DSME class is structured in a support group format which allows participants to share their experiences and provide supportive feedback to their peers.

### Programme completion

Successful completion of the programme was assessed at 12 months for participants who achieved an HbA1c result below 9% (target HbA1c), and those participants were graduated from the programme. Participants who did not achieve the target HbA1c continued in the programme for an additional 12 months. Criteria for completion have changed throughout the years based on funding and clinic partner needs to receive continued support to improve diabetes outcomes.

### Inclusion and exclusion criteria

In this study, we used data from the SyV participants enrolled between 2013 and 2018. Of the 5722 SyV study

participants, 5649 were included in the statistical analyses after excluding 73 subjects who dropped out before 12-month follow-up visit. We first examined changes in HbA1c levels over time among 5649 participants. Participants were then classified into two groups based on total number of DSME classes and CHW visits combined (ie, the number of encounters): (1) *high engagement* group consisting of individuals who completed 10 or more encounters and (2) *low engagement* group who completed one to nine encounters. We dichotomised engagements since we found that the amount of decrease/increase in HbA1c per one unit change in the number of encounters was not linearly associated with HbA1c levels. [Figure 1](#) illustrates the total number of individuals with diabetes served by the SyV partner clinics, out of which 5649 individuals participated in this study.

### Statistical analysis

We assessed the difference in longitudinal HbA1c levels between the high and low engagement groups by conducting univariable and multivariable longitudinal linear regression models using generalised estimating equation (GEE) method that accounts for potential correlations of repeated measures within a subject over time. We also evaluated whether the group difference in HbA1c levels changed over time by testing interactions between the engagement groups (high vs low engagement) and time (follow-up visit, month). We used score test for interaction testing. Potential confounding variables including demographic characteristics were examined and addressed during development of the final longitudinal multivariable models. We also checked and discussed if we missed any additional confounding factors that might cause residual confounding. SAS V.9.4 (SAS Institute) was used to perform all statistical analyses, and statistical significance was assumed at the 0.05 level.

### RESULTS

Baseline demographic characteristics are presented as means and SD for continuous variables, and counts and percentages for categorical variables in [table 1](#). Overall, participants were predominantly Mexican American (98.18%), female (68.45%), Spanish speaking (68.70%) and uninsured (77.46%). Demographic characteristics were also compared by engagement group. The mean number of encounters in the low engagement group was 4.7, and 13.3 in the high engagement group. Participants in the high engagement group were older than those in the low engagement group (56 vs 53 years). The high engagement group had more female than male participants (72% vs 65%), predominantly Spanish speaking versus predominantly English speaking (75% vs 62%), married versus unmarried (61% vs 57%) and had lower education attainment (48% vs 56%) when compared with the low engagement group.

Mean HbA1c levels over time were obtained and compared based on longitudinal linear regression model

**Table 1** Baseline demographic characteristics by engagement group

Variable	All n=5649	Low engagement n=2697 (48%)	High engagement n=2952 (52%)	P value*
Age, mean (SD)	54.41 (10.57)	52.98 (11.16)	55.72 (9.82)	<0.0001
Female, n (%)	3867 (68.45)	1743 (64.63)	2124 (71.95)	<0.0001
Mexican-American White, n (%)	5546 (98.18)	2648 (98.18)	2898 (98.17)	0.9722
Speak Spanish, n (%)	3870 (68.70)	1659 (61.72)	2211 (75.08)	<0.0001
Employed, n (%)	3655 (71.89)	1776 (72.14)	1879 (71.66)	0.7073
Married, n (%)	3104 (59.01)	1449 (57.20)	1655 (60.69)	0.0102
Insured, n (%)	1221 (22.54)	593 (22.97)	628 (22.13)	0.4644
Education, higher than 8th grade, n (%)	2555 (51.98)	1343 (55.61)	1212 (48.48)	<0.0001
HbA1c at baseline, mean (SD)	10.20 (1.66)	10.26 (1.68)	10.13 (1.63)	<0.01

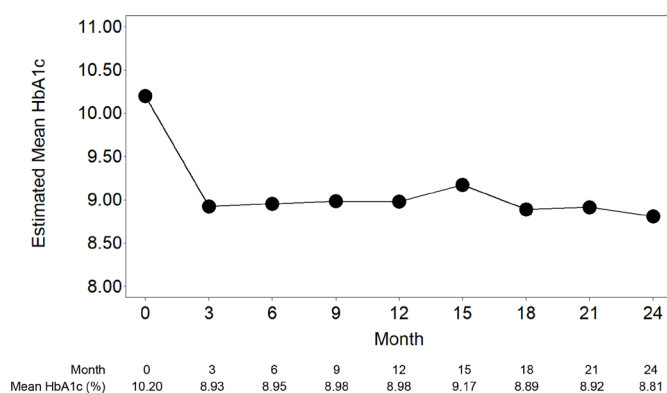
\*Student's t-test for continuous variables,  $\chi^2$  test for categorical variables.

using the GEE method after adjusting for programatically relevant variables identified a priori: age, sex, preferred language, ethnicity, employment status, marital status, insurance status and years in school. Adjusted mean HbA1c levels over follow-up visits are presented in [figure 2](#). There was a significant decrease in HbA1c levels from baseline to the 3-month follow-up visit (from 10.20 to 8.93,  $p<0.0001$ ), and the levels remained stable after month 3.

We then conducted comparisons of HbA1c levels between high and low engagement groups over time ([table 2](#) and [figure 3](#)). As shown in [table 2](#), the differences in HbA1c levels between the two groups are estimated at each follow-up point separately based on univariable and multivariable longitudinal models after adjusting for the aforementioned relevant variables. We found that there was a significant interaction ( $p<0.0001$ ) between groups and time (follow-up visit) from both univariable and multivariable models, which reflects that the group difference in HbA1c was significantly changed over time. Results from univariable longitudinal analysis showed the high engagement group had a lower level of HbA1c over the entire follow-up period (from month 3 to 24) when compared with the low engagement group, and this finding remained the same in the multivariable longitudinal model ([table 2](#)). Further, this group difference was

statistically significant up to the 15-month follow-up. For example, at month 3, the high engagement group had significantly lower HbA1c levels than the participants in the low engagement group (mean difference=-0.44; 95% CI -0.57 to -0.31;  $p<0.0001$ ) and this significant group difference was also found at month 15 (mean difference=-0.32; 95% CI -0.54 to -0.10;  $p=0.004$ ), although the differences were not significant at the final three follow-up points ([table 2](#)). The adjusted mean HbA1c levels over time by engagement group were calculated based on our final multivariable model and were plotted in [figure 3](#). There was a significant decrease in HbA1c levels between baseline and 3-month follow-up visit for both high and low engagement groups ( $p<0.0001$ ), and both groups maintained their HbA1c levels after month 3. HbA1c levels in the high engagement group were lower than those in the low engagement group from month 3 to 24.

In addition, we observed the percentage of participants who achieved good glycaemic control over time. Most participants had an HbA1c of  $>9\%$  at baseline (72%). Within this group, 48% shifted from poor control ( $>9\%$ ) to controlled ( $\leq 9\%$ ) within the first 12 months. Among the group with baseline HbA1c  $\leq 9\%$  at baseline (28%), 80% maintained HbA1c  $\leq 9\%$ .


**Figure 2** Adjusted mean HbA1c levels over follow-up visits.

## DISCUSSION

Among a low-income, Mexican-American patient population with poorly controlled diabetes, a community-based chronic care management intervention lasting 1–2 years that complemented the patients' existing medical care by providing CHW support and DSME was associated with improved HbA1c. Both the high and low engagement groups improved HbA1c results within the first 3 months in the programme. Participants engaged in 10 or more encounters showed an association with better HbA1c results at each time point, and results were statistically significantly different between the groups up to the

**Table 2** Group difference in HbA1c levels over time based on univariable and multivariable longitudinal linear regression models (n=5649)

Variable	Univariable model		Multivariable* model	
	Mean difference (95% CI)	P value	Mean difference (95% CI)	P value
High versus low engagement at each month†				
At month 0	-0.12 (-0.2 to -0.03)	0.0075	-0.03 (-0.13 to 0.07)	0.5012
At month 3	-0.45 (-0.56 to -0.33)	<0.0001	-0.44 (-0.57 to -0.31)	<0.0001
At month 6	-0.37 (-0.50 to -0.25)	<0.0001	-0.31 (-0.43 to -0.14)	<0.0001
At month 9	-0.29 (-0.42 to -0.16)	<0.0001	-0.27 (-0.42 to -0.13)	0.0001
At month 12	-0.25 (-0.38 to -0.12)	0.0002	-0.23 (-0.37 to -0.08)	0.0025
At month 15	-0.35 (-0.45 to -0.16)	0.0003	-0.32 (-0.54 to -0.10)	0.0040
At month 18	-0.39 (-0.79 to 0.01)	0.0606	-0.34 (-0.77 to 0.08)	0.1086
At month 21	-0.46 (-1.21 to 0.28)	0.2274	-0.22 (-1.00 to 0.56)	0.5721
At month 24	-0.46 (-1.41 to 0.49)	0.3479	-0.42 (-1.38 to 0.55)	0.3966
Age (year)	-	-	-0.02 (-0.02 to -0.01)	<0.0001
Sex, female versus male	-	-	0.03 (-0.06 to -0.13)	0.4911
Language, Spanish versus other	-	-	-0.07 (-0.18 to 0.04)	0.2208
Hispanic, yes versus no	-	-	-0.24 (-0.64 to 0.16)	0.2420
Employment, employed versus other	-	-	-0.07 (-0.16 to 0.03)	0.1850
Marital status, married versus other	-	-	-0.16 (-0.25 to -0.07)	0.0004
Insurance, yes versus no	-	-	-0.19 (-0.30 to -0.09)	0.0004
Education, 8th grade or higher versus other	-	-	-0.08 (-0.18 to 0.02)	0.1321

\*Multivariable longitudinal linear regression model after adjusting for age, sex, preferred language, ethnicity, employment status, marital status, type of insurance and years in school.

†Based on interactive models where interactions between engagement group and time (follow-up visit, month) were included and tested; p value of overall interaction effect was  $p < 0.0001$  for both unadjusted and adjusted models.

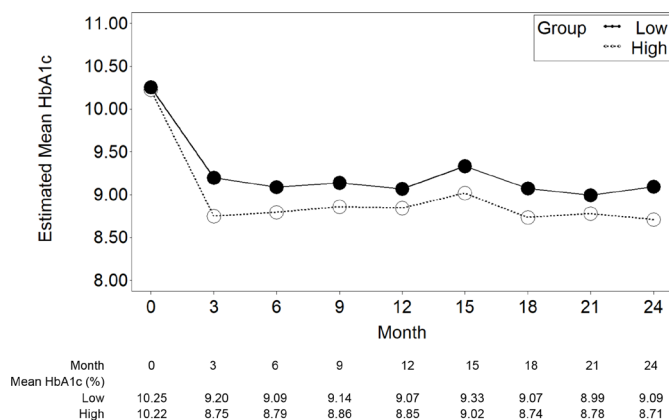
15-month time point, supporting the overall hypothesis. Our findings reflect associations not implying causality.

There was an increase in mean HbA1c at the 15-month time point in both groups that resulted from graduating participants from the programme with HbA1c values below 9% and retaining participants who needed additional time in the programme to achieve the HbA1c target. Within the high engagement group, participants

who did not achieve HbA1c targets by 12 months appear to have benefited from continuing in the intervention an additional 12 months, achieving better HbA1c outcomes at 24 months (8.73%) when compared with the mean HbA1c at 12 months (8.90%). This association and trend were not observed in the low engagement group.

The improvement observed in HbA1c outcomes in the low engagement group suggests that even some exposure to the intervention is associated with behaviour change. The low engagement group completed an average of 4.7 visits. It is important to note that this programme provides intensive support for individuals struggling with self-management. Engagement is a topic often addressed with the PAL board as well as CHWs. Feedback from both groups regarding reasons for lower engagement includes participants experiencing competing priorities (eg, job, being caregivers to their family), lack of social support from family members or employers which can impact their availability and feeling overwhelmed by mental health disorders.

There are other factors that were employed by the intervention that may have contributed to the associations found with lower HbA1c. Similar to many CHW-delivered interventions, SyV leveraged the trusting relationships



**Figure 3** Adjusted mean HbA1c levels over follow-up visits by engagement group (low vs high).



that are established between CHWs and participants to engage individuals in collaborative approaches to behaviour change.<sup>22 23</sup> As described by Boyd *et al*, this trust-based relationship was perceived by patients as being influential to the improvement in emotional well-being and health behaviours.<sup>24</sup> Chang *et al* reported that in a CHW intervention focused on HbA1c outcomes, patients acknowledged how CHWs increased their skills and confidence to modify behaviours and achieve their goals.<sup>25</sup> Another CHW quality that contributes to the SyV intervention is their ability to communicate complex information in a low-literacy manner, enhancing their communication with participants.<sup>26 27</sup> One example of a curriculum designed for lower health literacy populations is the DEEP curriculum. Research has shown that participants who received this CHW-delivered diabetes education programme demonstrated significant improvement in both HbA1c and diabetes knowledge.<sup>28</sup> Lastly, similar to other research showing MI as effective,<sup>20 29 30</sup> the SyV CHWs provided home visits over time during which brief MI strategies are used. Additionally, the SyV CHW interactions reinforce and complement information from the patients' clinical providers. The SyV CHWs support attendance at the provider visits through the coordination of transportation and appointment scheduling. Overall, the SyV programme approach complements the findings of a systemic review reported by Franklin *et al* that identified how patient and provider interactions shape self-management behaviours and opportunities in collaborative goal setting.<sup>31</sup>

The results of this intervention contribute to the growing literature demonstrating the effectiveness of CHWs delivering community-based interventions in addressing chronic diseases.<sup>20 32–36</sup> More specifically, the SyV programme contributes to the growing body of evidence that participation in CHW interventions is associated with improved HbA1c outcomes.<sup>22 37–41</sup> Expanding diabetes care to include these types of interventions for high-risk patients has been considered by providers and payers.<sup>42–46</sup> For example, an integrative literature review conducted by Franklin *et al* concluded that interprofessional teamwork and collaboration with CHWs is associated with positive health outcomes and therefore recommended that 'patient care should no longer be delivered within the silos of individual health professions'.<sup>47</sup> This SyV study adds valuable new knowledge demonstrating that CHW-delivered programmes are associated with improved HbA1c outcomes over time and provides an example model of care. Additionally, our study findings add to the body of literature for low-income Mexican-American populations with uncontrolled diabetes who are being served by Federally Qualified Health Centers. It adds to the literature for similar populations across the country and validates the efficacy of this model for this population. Future research should test this in different populations.

While potential confounding variables were examined and addressed during development of the final longitudinal

multivariable models (see table 2), other variables were identified after the completion of the study that could potentially lead to residual confounding. We evaluated the length of time in years since diabetes diagnosis, and found the mean difference between groups to be 0.03 year, which was statistically significant but small in the magnitude effect. It is also possible that individuals participated in other chronic disease management programmes during the study. Due to the potential role of residual confounding, we acknowledge that our findings reflect associations between variables, but not necessarily implying causality. Associations can occur both with and without a causal relationship.

### Limitations

This study lacks a control group of individuals who did not receive the SyV intervention. It is unclear what impact may be detected with the comparison to a no treatment control group. Participants in this study were patients under clinical care in four clinics prior to their enrolment in the programme and were identified because of elevated HbA1c values. A limitation on establishing a control group included that clinic leadership preferred that all patients with elevated HbA1c values be referred to programme for ethical reasons, rather than creating a control group.

Another study limitation included not specifically quantifying participant engagement in their medical home as a factor influencing outcomes. All participants in the programme were associated with a medical home that promoted SyV programme participation. Moreover, all participants received encouragement and navigation support to keep medical appointments. Because of these influences, it is likely that medical home participation was similar among those in the study but more specific quantification of their support or influence on patient outcomes was not captured. Additionally, while CHWs encouraged participants to adhere to provider recommendations to enhance medication adherence, data on medication use and changes in medication use over time were not collected by the programme. Therefore, changes in diabetes medication adherence could not be assessed in this analysis. Another study limitation was not being able to assess the HbA1c outcomes of the SyV participants after their time in the programme. While we tracked patients up to 24 months in some cases, HbA1c values beyond the actual programme enrolment are unknown. Also, even though we consider potential residual confounding factors (eg, length of time since diagnosis), there are still factors participating in other chronic disease management programmes that were not included in the analysis due to the lack of data. Further research on this programme should characterise if and for how long participants who have completed the SyV programme are able to maintain lower HbA1c levels.

### CONCLUSION

This study focused on testing the association between higher and lower participant engagements in two elements

of a chronic care management programme and HbA1c levels over time. Past studies have shown the effectiveness of CHW interventions to promote self-management<sup>40 48</sup> and other studies have evaluated the impact of DSME.<sup>40 48 49</sup> This study expands that knowledge base by exploring the connection between programme engagement levels and HbA1c. We showed that the participants with lower level engagement with CHWs and/or DSME had reductions in HbA1c, but that those with higher level of engagement had even further and maintained reductions in HbA1c. Despite the strong evidence supporting interventions like SyV that use CHWs and include behaviour change-focused curriculum delivered in community settings, the usual care for diabetes is often absent in this community-based continuum of care services. Growing evidence would suggest that community-based programmes can be an essential component of improving and sustaining diabetes control. The strongest element of improvement in this programme is the number of classes of DSME attended, but future evaluation of other elements is merited. This study found that a culturally relevant, community-based programme delivered to low-income Mexican Americans with uncontrolled type 2 diabetes, in addition to medical care, was associated with improved HbA1c outcomes, at least up to 24 months.

#### Author affiliations

<sup>1</sup>School of Public Health, Brownsville Regional Campus, The University of Texas Health Science Center at Houston, Brownsville, Texas, USA

<sup>2</sup>Division of Biostatistics, Department of Population and Data Sciences, The University of Texas Southwestern Medical Center, Dallas, Texas, USA

<sup>3</sup>Biostatistics, University of Texas School of Public Health, Houston, Texas, USA

<sup>4</sup>Department of Biostatistics and Data Sciences, The University of Texas Health Science Center at Houston, Houston, Texas, USA

<sup>5</sup>School of Public Health, The University of Texas Health Science Center at Houston, Brownsville, Texas, USA

<sup>6</sup>Public Health College of Nursing and Health Sciences, Texas A&M International University, Laredo, Texas, USA

**Twitter** Tianlin Xu @FrankXu\_UTH

**Acknowledgements** The authors gratefully acknowledge all the staff involved in the programme particularly the community health workers delivering the main services to participants. We also thank our clinic and community partners for their support and collaboration. We also acknowledge the data management work by Pablo Sanchez.

**Contributors** BMR and JBM provided study concept, secured funding and reviewed and approved the manuscript. BMR, JL, MZ and LAM-B wrote, reviewed and prepared the manuscript. ML, TX and SKP analysed the data and wrote the manuscript. MVS, LYP, LP and CC reviewed and edited the manuscript. All authors reviewed and approved the final draft. BMR is responsible for the overall content as the guarantor.

**Funding** This work was partially supported by the Delivery System Reform Incentive Payment programme through the Texas's 1115 Medicaid Transformation Waiver (93 778 20). The study was also partially supported by the Center for Clinical and Translational Science funded by the National Center for Advancing Translational Sciences (5UL1TR003167-03).

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants. The study was reviewed and approved under exempt status by the respective university's institutional review board (reference number: HSC-SPH-13-0532). Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available upon reasonable request.

**Open access** This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

#### ORCID iDs

Belinda M Reininger <http://orcid.org/0000-0003-4446-9735>

Maria Zolezzi <http://orcid.org/0000-0003-4783-0872>

Tianlin Xu <http://orcid.org/0000-0002-5699-5540>

#### REFERENCES

- Centers for Disease Control and Prevention. National diabetes statistics report, 2020. Atlanta, GA; 2020.
- Lin J, Thompson TJ, Cheng YJ, *et al*. Projection of the future diabetes burden in the United States through 2060. *Popul Health Metr* 2018;16:9.
- Chukwueke I, Cordero-Macintyre Z. Overview of type 2 diabetes in hispanic Americans. *Int J Body Compos Res* 2010;8:77–81.
- U.S. Department of health and human services office of minority health. Diabetes and Hispanic Americans, 2021.
- Kazemian P, Shebl FM, McCann N, *et al*. Evaluation of the cascade of diabetes care in the United States, 2005–2016. *JAMA Intern Med* 2019;179:1376–85.
- Zhang X, Saaddine JB, Chou C-F, *et al*. Prevalence of diabetic retinopathy in the United States, 2005–2008. *JAMA* 2010;304:649–56.
- Lavery LA, Armstrong DG, Wunderlich RP, *et al*. Diabetic foot syndrome: evaluating the prevalence and incidence of foot pathology in Mexican Americans and non-hispanic whites from a diabetes disease management cohort. *Diabetes Care* 2003;26:1435–8.
- Karter AJ, Ferrara A, Liu JY, *et al*. Ethnic disparities in diabetic complications in an insured population. *JAMA* 2002;287:2519–27.
- Coleman K, Austin BT, Brach C, *et al*. Evidence on the chronic care model in the new millennium. *Health Aff* 2009;28:75–85.
- Barr VJ, Robinson S, Marin-Link B, *et al*. The expanded chronic care model: an integration of concepts and strategies from population health promotion and the chronic care model. *Hosp Q* 2003;7:73–82.
- Alkenizan A. Innovative care for chronic conditions: building blocks for action. *Ann Saudi Med* 2004;24:148.
- Funnell MM, Brown TL, Childs BP, *et al*. National standards for diabetes self-management education. *Diabetes Care* 2011;34 Suppl 1:S89–96.
- Hildebrand JA, Billimek J, Lee J-A, *et al*. Effect of diabetes self-management education on glycemic control in latino adults with type 2 diabetes: a systematic review and meta-analysis. *Patient Educ Couns* 2020;103:266–75.
- He X, Li J, Wang B, *et al*. Diabetes self-management education reduces risk of all-cause mortality in type 2 diabetes patients: a systematic review and meta-analysis. *Endocrine* 2017;55:712–31.
- Community Health Workers. American public health association; 2016.
- Collinsworth AW, Vulimiri M, Schmidt KL, *et al*. Effectiveness of a community health worker-led diabetes self-management education program and implications for CHW involvement in care coordination strategies. *Diabetes Educ* 2013;39:792–9.
- Spencer MS, Kieffer EC, Sinco B, *et al*. Outcomes at 18 months from a community health worker and peer leader diabetes self-management program for latino adults. *Diabetes Care* 2018;41:1414–22.
- Walton JW, Snead CA, Collinsworth AW, *et al*. Reducing diabetes disparities through the implementation of a community health worker-led diabetes self-management education program. *Fam Community Health* 2012;35:161–71.
- Zolezzi M, Lopez J, Mitchell-Bennet L, *et al*. A chronic care management framework bridging clinic, home, and community care in a Mexican American population. *Health Promot Pract* 2022;23:367–371.

- 20 Reininger BM, Mitchell-Bennett L, Lee M, *et al.* Tu Salud, ¡Si Cuenta!: exposure to a community-wide campaign and its associations with physical activity and fruit and vegetable consumption among individuals of Mexican descent. *Soc Sci Med* 2015;143:98–106.
- 21 Chang A, Frank J, Knaebel J, *et al.* Evaluation of an over-the-counter glycosylated hemoglobin (A1c) test kit. *J Diabetes Sci Technol* 2010;4:1495–503.
- 22 Kim K, Choi JS, Choi E, *et al.* Effects of community-based health worker interventions to improve chronic disease management and care among vulnerable populations: a systematic review. *Am J Public Health* 2016;106:e3–28.
- 23 Kangovi S, Mitra N, Norton L, *et al.* Effect of community health worker support on clinical outcomes of low-income patients across primary care facilities: a randomized clinical trial. *JAMA Intern Med* 2018;178:1635–43.
- 24 Boyd LM, Mehra R, Thomas J, *et al.* Features and impact of trust-based relationships between community health workers and low-resource perinatal women with chronic health conditions. *Matern Child Health J* 2021;25:1866–74.
- 25 Chang W, Oo M, Rojas A, *et al.* Patients' perspectives on the feasibility, acceptability, and impact of a community health worker program: a qualitative study. *Health Equity* 2021;5:160–8.
- 26 Taani MH, Zabler B, Fendrich M, *et al.* Lessons learned for recruitment and retention of low-income African Americans. *Contemp Clin Trials Commun* 2020;17:100533.
- 27 Meherali S, Punjani NS, Mevawala A. Health literacy interventions to improve health outcomes in low- and middle-income countries. *HLRP: Health Literacy Research and Practice* 2020;4:e251–66.
- 28 Castillo A, Giachello A, Bates R, *et al.* Community-based diabetes education for latinos: the diabetes empowerment education program. *Diabetes Educ* 2010;36:586–94.
- 29 Perales J, Reininger BM, Lee M, *et al.* Participants' perceptions of interactions with community health workers who promote behavior change: a qualitative characterization from participants with normal, depressive and anxious mood states. *Int J Equity Health* 2018;17:19.
- 30 Heredia NI, Fernandez ME, van den Berg AE, *et al.* Coaction between physical activity and fruit and vegetable intake in racially diverse, obese adults. *Am J Health Promot* 2020;34:238–46.
- 31 Franklin M, Lewis S, Willis K, *et al.* Patients' and healthcare professionals' perceptions of self-management support interactions: systematic review and qualitative synthesis. *Chronic Illn* 2018;14:79–103.
- 32 Reininger BM, Mitchell-Bennett LA, Lee M, *et al.* Scaling a community-wide campaign intervention to manage hypertension and weight loss. *Front Med* 2021;8:661353.
- 33 Vidoni ML, Lee M, Mitchell-Bennett L, *et al.* Home visit intervention promotes lifestyle changes: results of an RCT in Mexican Americans. *Am J Prev Med* 2019;57:611–20.
- 34 Heredia NI, Lee M, Reininger BM. Exposure to a community-wide campaign is associated with physical activity and sedentary behavior among Hispanic adults on the Texas-Mexico border. *BMC Public Health* 2017;17:883.
- 35 Byrd TL, Wilson KM, Smith JL, *et al.* AMIGAS: a multicity, multicomponent cervical cancer prevention trial among Mexican American women. *Cancer* 2013;119:1365–72.
- 36 Rodriguez HP, Friedberg MW, Vargas-Bustamante A, *et al.* The impact of integrating medical assistants and community health workers on diabetes care management in community health centers. *BMC Health Serv Res* 2018;18:875.
- 37 DePue JD, Dunsiger S, Seiden AD, *et al.* Nurse-community health worker team improves diabetes care in American Samoa: results of a randomized controlled trial. *Diabetes Care* 2013;36:1947–53.
- 38 Katula JA, Vitolins MZ, Morgan TM, *et al.* The healthy living partnerships to prevent diabetes study: 2-year outcomes of a randomized controlled trial. *Am J Prev Med* 2013;44:S324–32.
- 39 Rothschild SK, Martin MA, Swider SM, *et al.* Mexican American trial of community health workers: a randomized controlled trial of a community health worker intervention for Mexican Americans with type 2 diabetes mellitus. *Am J Public Health* 2014;104:1540–8.
- 40 Spencer MS, Rosland A-M, Kieffer EC, *et al.* Effectiveness of a community health worker intervention among African American and latino adults with type 2 diabetes: a randomized controlled trial. *Am J Public Health* 2011;101:2253–60.
- 41 Heisler M, Spencer M, Forman J, *et al.* Participants' assessments of the effects of a community health worker intervention on their diabetes self-management and interactions with healthcare providers. *Am J Prev Med* 2009;37:S270–9.
- 42 Crespo R, Christiansen M, Tieman K, *et al.* An emerging model for community health worker-based chronic care management for patients with high health care costs in rural appalachia. *Prev Chronic Dis* 2020;17:E13.
- 43 Islam N, Nadkarni SK, Zahn D, *et al.* Integrating community health workers within patient protection and affordable care act implementation. *J Public Health Manag Pract* 2015;21:42–50.
- 44 Sabo S, Wexler N, O'Meara L, *et al.* Organizational readiness for community health worker workforce integration among Medicaid contracted health plans and provider networks: an arizona case study. *Front Public Health* 2021;9:601908.
- 45 Pinto D, Carroll-Scott A, Christmas T, *et al.* Community health workers: improving population health through integration into healthcare systems. *Curr Opin Pediatr* 2020;32:674–82.
- 46 Beasley JM, Shah M, Wyatt LC, *et al.* A community health worker-led intervention to improve blood pressure control in an immigrant community with comorbid diabetes: data from two randomized, controlled trials conducted in 2011–2019. *Am J Public Health* 2021;111:1040–4.
- 47 Franklin CM, Bernhardt JM, Lopez RP, *et al.* Interprofessional teamwork and collaboration between community health workers and healthcare teams: an integrative review. *Health Serv Res Manag Epidemiol* 2015;2:233339281557331.
- 48 Rothschild SK, Martin MA, Swider SM, *et al.* Mexican American trial of community health workers: a randomized controlled trial of a community health worker intervention for Mexican Americans with type 2 diabetes mellitus. *Am J Public Health* 2014;104:1540–8.
- 49 Chivala CA, Sherr D, Lipman RD. Diabetes self-management education for adults with type 2 diabetes mellitus: a systematic review of the effect on glycemic control. *Patient Educ Couns* 2016;99:926–43.