¡Sí, Yo Puedo Vivir Sano con Diabetes! A Pilot Self-Management Randomized Controlled Pilot Trial for Low-Income Adults with Type 2 Diabetes in Mexico City\textsuperscript{1,2,3}

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1) Abbreviations used: A1C, glycated hemoglobin A1c; BP, blood pressure; DSME, diabetes self-management education; ELCSA, Latin American and Caribbean Food Security Scale; GAM, mutual help groups; GLMM, Generalized Linear Mixed Models; GPAQ, Global Physical Activity Questionnaire; HAPA, Health Action Process Approach model; PHQ-8, Patient Health Questionnaire-8; RA, research assistant; SMBG, Self-monitoring of blood glucose; SDSCA, Summary of Diabetes Self-Care Activities questionnaire; T2D, type 2 diabetes.

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Short title: ¡Sí, Yo Puedo! DSME+Text Message Pilot RCT Results

Summary: Evaluation of a group based self-management + text message program for adults with type 2 diabetes on clinical (A1c), self-management and psychosocial outcomes at 6 months in Mexico City.

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Abstract

Background: Type 2 diabetes (T2D) is a world-wide epidemic and a leading cause of death in Mexico, with a prevalence of 15.9% and over 70% of diagnosed adults have poor glycemic control (A1C > 7.5%). We developed a diabetes self-management education (DSME) program contextualized to the study population (including dietary preferences, health literacy) and health system.

Objective: To evaluate the efficacy of a self-management + text message program (¡Sí, Yo Puedo Vivir Sano con Diabetes!) on primary (A1C), and secondary behavioral (self-management), clinical and psychosocial outcomes in adults with T2D in Mexico City.

Methods: Participants were recruited at public primary healthcare centers (Seguro Popular), and randomly allocated to treatment (n=26) or wait-list control groups (n=21) with data collected at 3 and 6 months. The program included 7 weekly sessions and 6 months of daily text/picture messages. Descriptive statistics and generalized linear mixed model (GLMM) with intent-to-treat analysis were calculated.

Results: Participants were 55.5 (±8.8) years of age, 68% female, 88.6% overweight/obese, and 57% lived in food insecure households. Mean T2D duration was 11.9 (±7.8) years and mean A1C was 9.2% (±1.5%). There was 89% attendance at sessions and 6.4% attrition across both groups at 6 months. Group-by-time effects were seen in self-monitoring of blood glucose (SMBG) (p<.01), diabetes self-efficacy (p<.04); and a trend for lower A1C in the intervention group at 6 months (p=.11). Significant improvements in dietary behavior (p <.01) were demonstrated in the intervention group over time, but this did not reach statistical significance compared to the control group.
Conclusions: The program was associated with significant improvements in T2D self-management, self-efficacy, and A1C over time. Thus, T2D self-management skills, including diet, was improved in a vulnerable metropolitan population. This trial was registered at clinicaltrials.gov as NCT03159299.

Key words: type 2 diabetes, mHealth, text message, Mexico, health disparities, self-management, low income

Introduction

The prevalence of diabetes is increasing worldwide, indicating a serious public health problem. The prevalence of diabetes in adults in Mexico is 15.8%, one of the highest in the world. This compares to 4.7% in the United Kingdom, 7.4% in Canada, 10.4% in Brazil, and 10.8% in the United States. While these statistics include adults with type 1 and type 2 diabetes (T2D), the prevalence of type 1 diabetes is only 0.4-1.4% in these countries (1). Globally, T2D is a major contributing factor to morbidity, mortality, and lower quality of life in adults with T2D, and has significant financial costs (2-4). In Mexico City, T2D is a leading cause of mortality and a high financial burden to the healthcare system (3, 4).

Meeting glycemic targets of glycated hemoglobin A1c (A1C) less than 7.5% has been shown to decrease morbidity and mortality in adults with T2D (5). Despite improvements in access to T2D care in Mexico, the majority of adults with T2D do not meet glycemic targets (i.e. HbA1c < 7.5%) (4, 6). Diabetes self-management is critical to improving A1C and health outcomes, yet it is complex, requiring healthy eating, physical activity, correctly taking medications, self-monitoring of blood glucose (SMBG), and quarterly health care appointments in the context of frequent problem-solving.
Diabetes self-management education (DSME) is a standard of care in many countries, providing education, skill development, and behavioral support for managing T2D (7). Considerable evidence supports the benefit of DSME on clinical, behavioral, and psychosocial outcomes globally (7, 8). However, diabetes self-management in Mexico is sub-optimal. In one study, 12% of adults with T2D were not performing any self-management (blood glucose monitoring, dietary modifications, physical activity), 60% were performing one or two behaviors, and only 28% were performing all behaviors (9). Limited understanding of the importance of self-management and low health literacy are contributing factors to poor self-management and glycemic control in Mexico (10).

There have been efforts to implement DSME in Mexico, such as “Mutual Help Groups” (GAM - acronym in Spanish) established in 2001. According to Mexico’s Health Department, in 2012 there were 7,059 GAM groups with 172,595 beneficiaries, yet only 30% of these groups were certified according to Health Department standards (11). Thus, the provision of DSME in Mexico City is insufficient, and there is need for evidence-based interventions. In addition, due to the obesogeneity of the built environment in the country and food insecurity challenges (12), it is critical to design DSME interventions with a strong nutrition education component (13).

Critical to the success of DSME programs is the need to target the program to the local socio-cultural context, dietary preferences, and health care system. Therefore, based on a systematic community participatory approach, that included extensive formative research and collaboration with stakeholders, we developed a DSME program for adults with T2D in Seguro Popular primary healthcare clinics (10, 14). These clinics are part of the Sistema de Protección Popular Social en Salud which provides public health insurance to those without social security health
coverage. Services for T2D care at Seguro Popular clinics include medical visits, referrals to specialists and nutritionist when needed, laboratory testing, and free medicines (11).

The purpose of this study was to evaluate the effect of our ¡Sí, Yo Puedo Vivir Sano con Diabetes! DSME program (¡Sí, Yo Puedo!) that included group sessions supplemented with daily text/picture messages on our primary outcome of A1C and secondary clinical [BMI and blood pressure (BP)], T2D self-management (including aspects of diet and nutrition), and psychosocial outcomes (depressive symptoms, self-efficacy) at 6 months compared to a wait-list control group. Our hypothesis was that the intervention group would demonstrate improvements in primary and secondary outcomes compared to the control group. We also hypothesized that the program would be feasible for adults with T2D at Seguro Popular clinics.

**Methods**

This study was a randomized wait-list control pilot study, approved by the institutional Review Boards at Yale University and the Center for Welfare Analysis and Measurement (CAMBS - acronym in Spanish, a civil association and research center, member of the National Registry of Scientific and Technological Institutions and Companies) in Mexico City. The research was conducted in accordance with the approved protocol. Inclusion criteria were: age 21-70 years, medically stable and able to exercise, diagnosed with T2D for at least one year with A1C >7.5%, receiving health care at a Seguro Popular clinic, and with access to a cell phone. Exclusion criteria included: cognitive impairment, major cardiac event in past 12 months, uncontrolled blood pressure, renal failure, and severe peripheral neuropathy. Participants in the wait-list control group were invited to participate in the program after completion of the 6-month data collection. Our sample size goal was 40 participants (n=20 per group). In a simulation study, 15-20 participants per group demonstrated reasonable bias-corrected estimations for a medium to
large (Cohen’s) effect size on the primary outcome of A1C (15).

The study was conducted in five Seguro Popular clinics in Mexico City. A coordinating official of the Mexico City’s Health Department recommended these clinics for the project because they had a sufficient number of adults with T2D with varying metabolic control, and these clinics lacked a certified diabetes program (GAM). Permission was obtained from clinic directors to conduct research at the clinic.

Flyers were distributed in the clinic settings and eligible adults with T2D were provided information about the study by a trained research assistant (RA). If interested, the study was explained and a screening questionnaire was completed. If eligible, an appointment was scheduled for informed consent, baseline data collection, and study enrollment. Informed consents and items on questionnaires were read to participants if needed, to ensure understanding. All study subjects signed the informed consent prior to study enrollment and data collection. According to the IRB approved protocol, no harms, unintended effects, or serious adverse effects directly linked to the program occurred during the study follow-up time period.

Study data were collected and managed using REDCap electronic data capture tools (16, 17). RAs entered data at the time of data collection into the database via tablets. Upon completion of data collection, eligible participants were randomly allocated to one of the two treatment conditions in a 1:1 allocation ratio using a computer-generated, block randomization procedure. At the end of the baseline data collection, an RA not involved in data collection told each participant their group assignment. Data collectors were blinded to treatment group assignment. All participants received a gift card for a department store after data collection; each participant received $200 Mexican pesos ($10 USD approximately) at baseline, $300 Mexican
pesos ($15 USD approximately) at 3 months, and $400 Mexican pesos ($20 USD approximately) at 6 months.

All participants received standard T2D care at the Seguro Popular clinic as described above. Participants allocated to the treatment group also received the ¡Sí, Yo Puedo! program which was developed after formative research with adults with T2D in Mexico and health care providers of the Seguro Popular clinics (10, 14). We incorporated relevant theoretical underpinnings, educational content, and interactive strategies of four evidence-based programs for Hispanic adults with T2D to meet the needs of adults with T2D with limited resources, expertise of providers, and systems of care of the Seguro Popular clinics in Mexico City. A description of the theoretical foundation for this intervention has been previously published (14). The ¡Sí, Yo Puedo! program was delivered by a registered nurse and social worker, who were provided one-week of interactive training and supportive supervision throughout the study. The group session leaders were closely supervised by the study leadership team who had extensive public health, nutrition, and T2D self-management expertise.

The program included seven interactive group-based educational sessions on diabetes self-management that were culturally relevant and appropriate for adults with low health literacy (Table 1). While the overall aim of the intervention was to strengthen diabetes self-management strategies through a multifaceted approach, the nutrition component was central in the delivery of the intervention. This component was designed to progressively increase the knowledge and abilities of participants to improve glucose levels through healthier eating. Nutrition education was based on the “the smart plate” – a plate method with modifications for T2D (18-21). Activities around the plate method allowed participants to identify foods and beverages high in carbohydrates (both simple and complex), and build knowledge around how to combine them
with other foods for balanced meals. At the same time, activities highlighted carbohydrate portions (through the fist and hand-palm method) and distribution throughout the day (22, 23). These activities were tailored to the socioeconomic and cultural context of participants.

Once nutrition knowledge and abilities were established, the intervention moved onto reading food package labels. This was key, as in Mexico 29.8% of daily energy consumption is linked to ultra-processed food and 6% to other types of processed foods (24-25). Therefore, participants were taught how to estimate portions of processed foods, to count carbohydrates, and to identify added sugars with different names. Intervention participants were provided with glucometers, test strips and lancets (Accu-Check Performa® glucometer, test strips and lancets, ROCHE), with the main objective to incorporate SMBG as a key T2D self-management strategy. A secondary objective of glucometers provision was for participants to clearly understand how healthier diets are linked to better blood glucose values. Additional education sessions included content on stress management, physical activity, medication adherence, and prevention of complications.

Behavioral support was provided in all sessions by class leaders to assist in problem-solving barriers to change and develop weekly goals (including follow-up phone calls every two weeks). Empowerment-based strategies were used to promote motivation and self-efficacy. Lastly, daily text/picture messages, based on the Health Action Process Approach model (HAPA) (26), were sent daily for six months to reinforce class content and promote intention and maintenance of behavior change. Pictures were used in text messages to enhance understanding and a positive outlook in the face of diabetes. Based on our formative research we provided text/picture message cards printed on paper secured with a binder ring in case participants could not access them via the cell phone. Classes were scheduled at the same time and day of the week,
were hosted at the clinic in which patients were enrolled, and phone reminders were sent the day prior to class.

**Data Collection and Measures**

Data were collected at baseline, 3 months and 6 months on primary and secondary outcomes. Demographic and clinical data (age, gender, education, known diabetes duration), including food security was collected at baseline. *Household Food Security* was measured using the Latin American and Caribbean Food Security Scale (ELCSA) modified for use in urban older adults. This validated questionnaire contains 8 items that assess if a household has not been able to access food of adequate quality in the last 3 months (27). Feasibility data were collected throughout study implementation.

**Primary Outcome.** *A1C*, a gold standard measure of glycemic control (28) was our primary outcome. A1C was measured using a fingerstick of blood and analyzed in situ with the A1CNow+ system (PTS Diagnostics, Indiana, USA). This point-of-care assessment of A1C has been validated with clinical laboratory measurement of A1C (29).

**Secondary Outcomes.** Additional outcomes included clinical (BMI, BP), behavioral (T2D self-management) and psychosocial (depressive symptoms and self-efficacy) measures. *BMI* was calculated according to the formula, BMI = kg/m\(^2\) with WHO cut-off points used to create BMI categories, ≥18.5 normal weight, ≥25 overweight and ≥30 obesity. Body weight was measured without shoes and with minimum clothing using an electronic scale (SECA 872, Hamburg, Germany) registered in grams. Height was measured without shoes with a portable stadiometer (SECA model 214, Hamburg, Germany) registered in centimeters. Measurements for both weight and height were taken twice and averaged. *Systolic and diastolic BP* were measured following standard procedures using an aneroid sphygmomanometer. Two readings separated by
one minute were averaged. Results from clinical measurements were provided to participants privately. *Self-management* was measured by the Summary of Diabetes Self-Care Activities questionnaire (SDSCA), a multi-dimensional 12-item scale with items on diet (follow a healthy eating plan, fruit-vegetable and high-fat foods consumption, spacing carbohydrates through the day), SMBG, foot care, and smoking. Sub-scales range from 0-7 (number of days in the last seven days each behavior was completed), with a higher score reflecting better self-management (30, 31). *Physical activity* was measured with the Global Physical Activity Questionnaire (GPAQ) (32), a 16-item questionnaire that assesses physical activity (intensity, duration and frequency) at work, during transportation and leisure time, as well as sedentary behavior (33). *Depressive symptoms* were measured by the Patient Health Questionnaire-8 (PHQ-8) consisting of eight items related to the diagnostic criteria for depressive disorder. The scale range is from 0-34, with higher scores reflecting a higher number of depressive symptoms (34). Participants who scored above the cut-off point for moderate depressive symptoms (greater than or equal to 10) were informed of their result, provided information on a mental health hotline, and recommended to make an appointment with the clinic psychologist as soon as possible. *Self-efficacy* was measured by the Stanford Self-Efficacy Scale, an 8-item scale that includes items on confidence in performing exercise, interpreting blood glucose levels, and following dietary recommendations. The scale range is from 1-10, with higher scores indicative of greater self-efficacy (35). All questionnaires have established reliability and validity in Spanish-speaking adults (31, 36-38).

**Feasibility outcomes.** *Feasibility data* included rates of recruitment, reasons for refusal, protocol implementation fidelity, attendance, and attrition. Our goal was >80% attendance across all sessions/participants and <20% attrition at 6 months. Protocol implementation was evaluated
with a 5-item fidelity checklist completed by the group session leaders. In addition, approximately 35% of sessions were observed by a trained RA to also assure protocol fidelity.

**Data Analysis.**

Sample characteristics were described using frequency distributions and summary statistics. Additionally, the groups were compared to make certain that randomization procedures were adequate. To test the hypothesis that adults with T2D who received the *¡Sí, Yo Puedo!* program demonstrated better outcomes than those in the control condition, Generalized Linear Mixed Models (GLMM) with an intent-to-treat analysis was used. Prior to running our analyses, we examined the homogeneity of variances at baseline across the 5 clinics (39). The GLMM incorporated within-subject correlations and included the random effect of clinics when the homogeneity of variances was rejected. The correlation structure was selected using goodness-fit criteria such as Akaike’s Information Criterion (AIC) and Bayesian Information Criterion (BIC), and residuals were assessed for normality assumptions. For repeatedly measured binary outcomes, the GLMM (also called Mixed Effect Logistic) included a link function of logit and incorporated correlations within-subjects. In this analysis, the odds ratio (OR) was calculated based on the estimated coefficient of time with an OR of greater than 1 representing increased likelihood of having vigorous/moderate activity or moderate depressive (PHQ8>10+) over 6 months from baseline.

Because it was likely that significant main effects may not be found for all variables due to the sample size, identification of marginally significant trends (e.g., p<.15) were considered. SAS software version 9.4 was used to conduct the analyses (SAS Institute Inc., North Carolina, USA). To evaluate feasibility and fidelity, a summary of the protocol implementation fidelity checklists, attendance, and attrition were calculated.
Results

Recruitment and data collection took place from January to December 2018. A total of 204 participants expressed interest in the study. Of those, 103 were eligible and 85 were scheduled for informed consent and baseline data collection. Of those who participated in baseline data collection, 65% were eligible and enrolled in the study (Figure 1). The sample (n=47) had a mean age of 55.35 (± 8.75) years, 68% were female, 51% employed within the past week, and 57% with moderate to severe food insecurity. Mean duration of diabetes since diagnosis was 11.85 (± 7.25) years, A1C was 9.20% (± 1.50), with 87% overweight or obese, and 38% with elevated depressive symptoms. No differences between the intervention (n=26) and the control group (n=21) where found at baseline in descriptive characteristics (Table 2). Attendance was high at 89% across all sessions and attrition was low at 6.4% (n=3) at 6 months. The majority of participants received the text (96% at 3 months; 100% at 6 months) and picture messages (83% at 3 months; 88% at 6 months). Adherence to protocol implementation was high with goals and objectives completely fulfilled in 91% of the sessions and mostly achieved in 7% of sessions.

Group by time effects were seen in SMBG (p<.001), diabetes self-efficacy (p=.04); and a trend for lower A1C in the intervention group at 6 months (-1.77% in treatment group vs. -1.96 in control group, p=.11). Time effects for the intervention group included improved diabetes self-care behavior (diet, exercise, SMBG), diabetes self-efficacy, depressive symptoms and A1C at 6 months. Time effects for the control group included A1C, exercise, SMBG, and depressive symptoms (see Table 3).
Discussion

Through this pilot study, we have demonstrated the potential of the ¡Sí, Yo Puedo! Program for adults with T2D living with limited resources in Mexico City and enrolled in Seguro Popular. There was a significant improvement in SMBG and diabetes self-efficacy and a trend for improved A1C in the treatment group compared to the control group at 6 months. Participants in the treatment group demonstrated a clinically significant decrease in A1C over time (-1.76% in treatment group and -.97% in control group at 6 months), supporting the critical importance of DSME in improving outcomes in a vulnerable population. Participants in the control group also improved A1C, SMBG, and physical activity over time. A1C improvement has been demonstrated in other T2D self-management clinical trials with Hispanic adults (40, 41), possibly due to systemic changes in care delivery in the clinic during the study, participants becoming more motivated in diabetes self-management due to monitoring by the research team, and participant expectations of receiving the program after 6 months. Alternatively, improvements in depressive symptoms in both groups may have also helped improve A1C through enhanced self-management (42). We would like to emphasize that the focus on healthy eating and nutrition in the program can also be reflected in two additional outcomes: a significant group by time effect in diabetes self-efficacy (which includes confidence in following dietary recommendations) and a significant time effect for better eating habits (general diet subscale of SDSCA), although it didn’t reach statistical significance in the group by time analysis due to sample size limitations.

The reported outcomes are particularly relevant when considering two baseline unfavorable nutrition-related indicators of the sample: a prevalence of overweight and obesity of
87% and the fact that 57% of the participants reported moderate to severe food insecurity. This highlights that well designed and contextualized culturally appropriate DSME plus text messaging programs can have positive outcomes even among highly vulnerable populations.

Increasing access to quality DSME programs is needed worldwide, particularly in countries like Mexico where access and delivery of DSME programs is inconsistent, with varying standards and quality (7). DSME that includes empowerment-based strategies may be particularly relevant to adults with T2D with low health literacy who may believe that they have limited control in improving their health trajectory. Empowerment-based DSME programs have demonstrated a positive effect on glycemic control in Latino adults living in the United States (41, 43). In our study, a significant improvement in diabetes self-efficacy was demonstrated in treatment group participants, which may have been a mediating factor to improved A1C.

Another factor that may have contributed to improved outcomes in the treatment group was improvement in SMBG. While SMBG may not be required daily for all adults with T2D, it is recommended when adults with T2D are learning about diabetes self-management to better understand the effect of diet, exercise, medications and stress on blood glucose levels (44). Teaching SMBG skills as well as how to interpret and problem-solve results are necessary to help adults with T2D, especially those with low health literacy, to make sound self-management decisions, particularly with dietary choices (26). Since participants were provided SMBG supplies as part of the intervention, coverage for SMBG supplies is critically important for those with limited resources and may be a cost-effective strategy to incorporate into future health policy initiatives. Access to SMBG supplies is limited for adults of low socioeconomic status in Mexico City (45).
High engagement with the ¡Sí, Yo Puedo! program may also have contributed to improved outcomes in this study. Elements of the intervention such as tailoring content to the local context, reinforcing content and motivation through text messages, group sessions, and follow-up phone calls from the class leaders may have contributed to high attendance and low attrition. Attendance in group-based sessions has been shown to be an important moderator to program effectiveness (40). In addition, using evidence-based programs, adapting programs to the needs of participants and providers, providing programs in local health care settings, and aligning the program with the health care delivery system are important strategies to enhance engagement, implementation, and sustainability of programs.

The use of picture/text messages aligned with a theoretical model of behavior change was an innovative component of the ¡Sí, Yo Puedo! program. Evidence supports the use of text messages as a supplement to clinical care in improving adherence and A1C in adults with T2D (46). While further research is indicated, providing theory-based behavioral support and positivity through picture/text messages may be an important strategy that enhances the effectiveness of clinical care in T2D.

In this pilot study, significant improvements in healthy eating, physical activity, depressive symptoms, BMI, and BP between groups were not demonstrated. While there were time effects for healthy eating, physical activity, and depressive symptoms, these effects were not different between groups, possibly due to sample size and psychological referral for all participants with elevated depressive symptoms. Significant effects on BMI and BP may require more intensive interventions, including adjusting pharmacologic treatment if indicated. The mild increase in BMI over time in the intervention group could be related to the lack of control the research group had over the pharmacologic treatment of the participants (i.e. hyperinsulinemia
can increase adipose tissue) (47) and the focus of the ¡Sí, Yo Puedo! Program on metabolic control (meeting A1C target) rather than weight loss.

Limitations of this study include a small pilot study, conducted in several geographic locations in Mexico City. Our sample also may represent a more motivated sample and it is important to emphasize that SMBG supplies were provided as part of the intervention in a setting where people with T2D hardly ever have access to a glucometer at home. Despite these limitations, we reached a vulnerable population with respect to income, working status, food insecurity, and elevated depressive symptoms. We also reached men with T2D (32% of sample), who can be challenging to engage in DSME programs.

In conclusion, we have demonstrated the potential of the ¡Sí, Yo Puedo! program, developed for the sociocultural context of adults with T2D of Seguro Popular clinics in Mexico City, to have a positive impact on self-efficacy, diabetes self-management, and A1C. Empowering adults with T2D self-management skills can improve health outcomes in vulnerable populations. High attendance and low attrition were also demonstrated. Providing theory-based picture/text messages may be a key strategy to support engagement in diabetes self-management over time. Future research toward scale-up of ¡Sí, Yo Puedo! is warranted.

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Figure 1 Legend: CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

Phases of a randomized controlled pilot study for diabetes self-management in low-income adults with intervention group and wait list (control Group) in a primary care setting in Mexico City, 2018-2019.
| Session number | Concepts/topics                                                                                                                                 |
|----------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| Orientation    | - Introduction to the program, expectations of participants, and class introductions                                                        |
| Session 1      | - Understanding diabetes and need for blood glucose monitoring, healthy eating, physical activity, and taking medication                         |
|                 | - Common cultural misconceptions                                                                                                           |
|                 | - Stress management activity                                                                                                              |
| Session 2      | - Self-monitoring blood glucose and relationship to food and activity                                                                      |
|                 | - Stress management activity                                                                                                               |
| Session 3      | - Relationship between carbohydrate intake and blood glucose levels.                                                                              |
|                 | - The plate method for T2D                                                                                                                                 |
|                 | - Food portion measurement.                                                                                                                |
|                 | - Menu planning with limited resources.                                                                                                     |
|                 | - Stress management activity                                                                                                               |
| Session 4      | - Physical activity (benefits, precautions)                                                                                                 |
|                 | - Stress management activity                                                                                                               |
| Session 5      | - Diabetes medicines and talking to health care professionals                                                                                 |
|                 | - Reading food & drink nutrition labels                                                                                                     |
| Session 6      | - Preventing diabetes complications and taking control of diabetes                                                                        |
Table 2. Baseline Characteristics Between Intervention and Control (N=47), ¡Sí, Yo Puedo Vivir Sano Con Diabetes! Self-Management Program for Low Income Adults with Type 2 Diabetes, Mexico City, 2018-2019

| Characteristic                          | Intervention (N=26) | Control (N=21) | Difference (p-value) |
|----------------------------------------|---------------------|----------------|----------------------|
|                                        | Mean (SD)/N (%)     | Mean (SD)/N (%)|                      |
| Demographic Characteristics            |                     |                |                      |
| Age (year)                             | 53.9 (9.2)          | 56.8 (8.3)     | .27                  |
| Sex (F)                                | 17 (65.4%)          | 14 (70.0%)     | .74                  |
| Working Status (worked in past week)   | 14 (53.8%)          | 10 (47.6%)     | .67                  |
| Married/Partnered                      | 15 (57.7%)          | 13 (61.9%)     | .77                  |
| Clinical Characteristics               |                     |                |                      |
| Duration of T2D (year)                 | 10.2 (7.2)          | 13.5 (7.3)     | .12                  |
| A1C (%)                                | 9.3 (1.4)           | 9.1 (1.6)      | .61                  |
| A1C>7.5%                               | 25 (96.1%)          | 20 (95.2%)     | .88                  |
| BMI (kg/m²)                            | 31.0 (6.1)          | 29.5 (5.0)     | .37                  |
| Overweight                             | 10 (38.5%)          | 10 (47.6%)     | .47                  |
| Obese                                  | 13 (50.0%)          | 8 (38.1%)      |                      |
| Overweight/obese                       | 23 (88.5%)          | 18 (85.7%)     | .78                  |
| Depressive symptoms (PHQ-8)            | 7.5 (5.0)           | 10.2 (6.6)     | .13                  |
| Moderate Depressive Symptom (PHQ-8 ≥10+) | 10 (38.5%)          | 8 (38.1%)      | .87                  |
| BP systolic (mmHg)                     | 126.0 (14.5)        | 126.6 (14.3)   | .90                  |
| BP diastolic (mmHg)                    | 79.7 (10.9)         | 79.9 (11.2)    | .98                  |
| ELCSA (Household food insecurity)      |                     |                |                      |
| Mild                                   | 11 (42.3%)          | 9 (42.9%)      | .26                  |
| Moderate                               | 9 (34.6%)           | 6 (28.6%)      |                      |
| Severe                                 | 4 (15.4%)           | 6 (28.6%)      |                      |

Difference in the baseline characteristics between two intervention groups were examined by independent T-test⁴, Chi-square test⁵, and Cochran-Armitage trend test⁶. A1C, glycated hemoglobin A1c; BP, blood pressure; ELCSA, Latin American and Caribbean Food Security Scale; PHQ-8, Patient Health Questionnaire-8; T2D, Type 2 Diabetes.
Table 3. Longitudinal Changes of Outcomes Between Intervention and Control Over 6 Months for Intent-to-Treat Analysis (N=47) in ¡Sí, Yo Puedo Vivir Sano Con Diabetes! Self-Management Program for Low Income Adults with Type 2 Diabetes, Mexico City, 2018-2019

| Outcome | Estimated Change for 6 months ± SE or Odds Ratio [95% CI] (p-value) | Difference of changes between Intervention and Control (p-value) |
|---------|---------------------------------------------------------------|---------------------------------------------------------------|
|         | Intervention | Control |                                                                 |
| Primary Outcome |                                                 |                                                                | .11                          |
| A1C (%) | -1.77 ± 0.34 (<.01) | -0.96 ± 0.37 (.01) |                                                                 |
| Clinical Outcome |                                                 |                                                                | .49                          |
| BMI (kg/m²): | 0.011 ± 0.009 (.22) | 0.002 ± 0.009 (.84) |                                                                 |
| log-transformed |                                                                 |                                                                | .72                          |
| Diastolic BP (mmHg) | 2.12 ± 2.71 (.44) | 3.57 ± 2.93 (.23) |                                                                 |
| Systolic BP (mmHg) | -1.23 ± 3.14 (.70) | -3.09 ± 3.38 (.36) |                                                                 |
| Behavioral Outcomes |                                                 |                                                                | .69                          |
| Self-Care (SDSCA) subscales | |                                                                 | .24                          |
| General Diet | 1.50 ± 0.55 (<.01) | 0.54 ± 0.60 (.37) |                                                                 |
| Exercise | 1.00 ± 0.58 (.09) | 1.56 ± 0.63 (.02) |                                                                 |
| SMBG | 4.97 ± 0.39 (<.01) | 0.86 ± 0.43 (.05) | <.01                          |
| Global Physical Activity (GPAQ) | |                                                                 | .23                          |
| Vigorous/Moderate Physical Activity for Work (Yes vs. No) | OR=1.42 [0.38, 5.30] (.5989) | OR=0.45 [0.11, 1.77] (.2483) | .72                          |
| Vigorous/Moderate Physical Activity for Recreation (Yes vs. No) | OR=1.27 [0.38, 4.26] (.6985) | OR=1.75 [0.46, 6.71] (.4090) | .04                          |
| Psychosocial Outcomes | |                                                                 | .74                          |
| Depressive Symptoms (PHQ-8) | -2.43 ± 1.21 (.0476) | -3.02 ± 1.33 (.0258) |                                                                 |
| Moderate Depressive Symptoms (PHQ-8=10+) | OR = 0.17 [0.04, 0.85] (.0307) | OR=0.53 [0.14, 2.07] (.3601) | .28                          |
| Diabetes Self-Efficacy | 1.24 ± 0.31 (<.001) | 0.29 ± 0.34 (.4030) |                                                                 |

P-value¹ stands for testing significant change in each group and P-value² stands for testing significant difference of changes between two intervention groups. The estimates and p-values were obtained from generalized linear mixed model (GLMM) with random effect of clinic (if necessary) and a specific covariance structure within-subject. A1C, glycated hemoglobin A1c; BP, blood pressure; GPAQ, Global Physical Activity Questionnaire; PHQ-8, Patient Health Questionnaire-8; SMBG, self-monitoring of blood glucose; SDSCA, Summary of Diabetes Self-Care Activities questionnaire.