Yo Puedo! Diabetes Self-Management Education + mHealth in Mexico City

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STUDY OBJECTIVES

1. To translate an evidence-based diabetes self-management education (DSME) program, Yo Puedo!, to the cultural norms, expertise of providers, and systems of care in Seguro Popular clinics in Mexico. The program will be adapted through a collaborative team of diabetes experts in the US and Mexico, Seguro Popular clinic administrators, physicians, nurses and adults with type 2 diabetes (T2D) in Mexico City, Mexico. This will include development and testing of a theory-based mHealth (pictorial text-messaging) component.

2. To evaluate the feasibility (process of implementation, fidelity of sessions, attendance, attrition), acceptability (interviews with program instructors, participants) and preliminary efficacy of Yo Puedo!+mHealth in adults with T2D in Mexico City. We will use a randomized, controlled pilot study design in which 60 adults with T2D are randomized to the Yo Puedo! + mHealth or a wait-list control condition with the hypothesis that clinical [A1C, body mass index (BMI), waist circumference (WC), blood pressure (BP)], T2D self-management, and self-efficacy outcomes will be greater in Yo Puedo!+mHealth participants compared to the wait-list control condition at 3 and 6 month follow-up. We also hypothesize that the Yo Puedo! + mHealth program is feasible and acceptable to adults with T2D and providers and that fidelity of the program will be maintained.

DESIGN

We will use a randomized, controlled pilot study design in which 60 adults with T2D are randomized to the *Yo Puedo* + mHealth or wait-list control condition with the hypothesis that clinical (A1C, BMI, BP), T2D self-management, and self-efficacy outcomes will be greater in *Yo Puedo* + mHealth participants compared to the wait-list control condition at 3 and 6 month follow-up. We also hypothesize that the *Yo Puedo* + mHealth program is feasible and acceptable to adults with T2D and providers, and that fidelity of the program will be maintained. Those in the control group will be invited to participate in the program after completion of the 6-month data collection. We will re-consent control group participants who chose to participate in the program after the 6-month data collection to have data collected one more time, approximately 3 months after the first class. Participants will be consented for this additional data collection in person at the last session of classes or prior to the data collection session itself. We will conduct interviews with the program instructors, participants, and select clinic personnel to identify barriers, facilitators, and acceptability of the program from multiple perspectives, recognizing the complexity of the health care system. Detailed notes on the process of implementation will be carefully recorded with the purpose of identifying successful and unsuccessful components of the program (positive and negative feedback loops in a complex system).

Setting. The study will be conducted in up to 10 Seguro Popular clinics. These clinics are part of the Sistema de Protección Social en Salud in Mexico. Individuals who obtain health care at these clinics are covered by public health insurance (Seguro Popular), and the services they get for T2D care include medical visits, referrals to specialists and nutritionist when needed, laboratory testing, and free medicines. The medical visits include medication prescription, blood pressure management, lipid monitoring, and eye/foot care. Laboratory analyses vary from patient to patient but generally includes 3 annual tests of A1C, although other glucose, urine, and lipids tests are also available. Patients with complications are referred to specialized health centers.

Interventions. All participants will receive standard T2D care at a Seguro Popular clinic as described above. The wait-list control condition group will receive a handout on T2D self-management and the opportunity to participate in the *Yo Puedo!* + mHealth program at the completion of 6-month data collection. The *Yo Puedo!* + mHealth DSME program includes: a) six

interactive group-based sessions (plus an initial orientation session) led by the program instructors on T2D self-management that is culturally relevant and at a low health literacy level (*Yo Puedo!* protocol adapted for Mexican context; see Table 1); b) behavioral support to collaboratively problem-solve barriers to change; and d) empowerment-based strategies to facilitate provider-patient communication. The *Yo Puedo*! program will be supplemented by one way text messaging provided by a web-based platform with privacy and security rules, which allows for automated and personalized messages and a database to store all messages. Automated daily text messages will include messages to promote understanding of T2D self-management, self-efficacy, and adherence to self-management goals. All text messages sent will initially be stored in the text messaging platform but will be archived to the REDcap database for subsequent data analysis. Participants in this group will also receive blood glucose monitors and will be instructed on how to use them as a part of the instruction provided in the Yo Puedo curriculum. The in-person component will be 6 weeks; daily text messaging will be for 6 months.

Participants will be randomized to a treatment condition in a 1:1 allocation ratio to one of the two treatment conditions using a computer-generated, block randomization procedure. Sequentially numbered opaque sealed envelopes will be used to conceal the allocation determination. The RA will inform participants about their treatment condition and protocol. After a group of 5 participants have been randomized to the *Yo Puedo!* + mHealth condition, the program will start. Within one week, participants will start the group sessions provided by the program instructors. The content and procedures in all sessions will be documented. Approximately 10% of sessions will be attended by one of the site Co-Is to evaluate protocol fidelity. The CHWs/MAs will remind participants about upcoming sessions at the end of a current session and will send a text or call participants the day before their next session. Attendance will be recorded. Written content from missed group sessions will be given to participants who will be asked to review at home and clarify questions with the program instructors. Follow-up data will be collected at 3 and 6 months.

At the end of the study, the program instructors, and select clinic personnel will be interviewed to identify successful and unsuccessful elements of implementing the protocol. Strategies for scale up will be identified. In addition, all participants will be interviewed upon completion of their 6 month data collection about their experience and satisfaction with the program. These interviews will be conducted by trained RA's who have not participated in any of the intervention protocol. We will carefully record any implementation issues.

Efficacy data will be collected at the clinic by a trained RA, blinded to participant group assignment and includes clinical (A1C, BMI, WC, BP), T2D self-management, dietary intake, physical activity, and self-efficacy data. All of this data will be collected three times, at baseline, 2-3 months, and 6 month follow-up. We will also collect data on depressive symptoms and food security at all three data collection time points. *A1C* is our primary outcome and will be measured using standard disposable analysis methods. *BMI* will be calculated according to the formula, BMI = kg/m^2 using a calibrated electronic scale and a portable stadiometer. WC will also be recorded using standard measurement practices. *Systolic and diastolic BP* will be measured according to practice standards. Two readings separated by 1 minute will be averaged. We will also collect data on change in medical status, medication and dosage via the medical record.

Self-management will be measured by the Summary of Diabetes Self-Care Activities questionnaire, a multi-dimensional 12-item scale with items on general diet, specific diet, monitoring blood glucose, foot care, and smoking. Reliability and validity have been established in Spanish-speaking adults. This self-report questionnaire was used successfully in the initial *Yo Puedo!* study.

Dietary intake will also be evaluated by a one-day diet history.[35] While there is no gold standard for self-report of dietary intake, the validity of Spanish dietary recall has been established. This diet history guide captures time, location, type of food and preparation, and amount consumed in past 24 hours. Calories, %fat intake, and fruit and vegetable intake will be calculated. We will

also assess diet intake with a brief modified version of a food frequency questionnaire which asks about how often a variety of foods was eaten in the past month, including culture specific foods. We will include a question regarding food label usage at the end of this questionnaire as the Yo Puedo curriculum teaches how to read food labels and emphasizes their use.

Physical activity will also be measured by accelerometer, using the Actigraph Actigraphy, a 3-axial accelerometer. The advantages of this accelerometer are wrist placement, continuous wear, water resistance and high data storage capacity. Wearing motion sensors day and night has been shown to increase adherence. Accelerometers estimate PA by measuring body movement and can capture frequency, duration and intensity of PA. Units of acceleration are expressed in meters per second squared and transformed into counts per second/minute/day. Cut-points converting counts into moderate-vigorous physical activity have been established (> 1535 counts = moderate PA; 3960 counts = vigorous PA). Both count data and cut-point data per day/week will be used in the analysis. Non-wear time will be calculated using established procedures and considered missing data. Three-axial accelerometers demonstrate excellent reliability with no evidence to suggest differences in brand or type of sensor. Participants will be asked to wear the accelerometer continuously for 1 week at each wave of data collection (baseline, 2-3 months, and 6 months). We will also assess physical activity with the Global Physical Activity Questionnaire developed by the World Health Organization. It is a 16-item questionnaire that assesses physical activity and sedentary behavior that has established reliability and validity.

Self-efficacy will be measured by the Stanford Diabetes Self-Efficacy Scale, an 8-item scale specific to T2D self-management self-efficacy. Items include confidence in exercise, interpreting blood glucose levels, and following dietary recommendations. Reliability and validity have been established in Spanish-speaking adults. This questionnaire was used successfully in the initial *Yo Puedo!* study.

Food Security will be measured using a version of the Latin American and Caribbean Food Security Scale (ELCSA) modified for use in urban older adults. This validated questionnaire contains 8 items that assess financially based food insecurity in households. It includes items related to the frequency at which a household has not been able to access enough food in the last 3 months. This version specifically modifies the questions for better comprehension in older urban Mexican adults of low socioeconomic status, which matches the target population of this study. An additional question to assess diabetes-related food insecurity will also be included.

Health information will be collected in a form which asks about any clinic visits, emergency room visits, episodes of hypoglycemia, diabetes-related health symptoms, medications, other health diagnoses, and A1C and blood pressure results in the previous 3 months.We will also collect data on participant demographics (age, gender, race/ethnicity, income) and depressive symptoms. We will use the Patient Health Questionnaire-8 (PHQ-8) to evaluate depressive symptoms, a well-established measure, with excellent reliability and validity in English and Spanish-speaking adults.

STATISTICAL ANALYSIS PLAN

To evaluate the preliminary efficacy of the program, initially the sample and variables will be described using frequency distributions and appropriate summary statistics. Additionally, the 2 groups will be compared to make certain that randomization procedures were adequate. If any baseline variables differ by group assignment, they will be included as covariates in subsequent analyses. The hypothesis that adults with T2D who receive the *Yo Puedo!* + mHealth will demonstrate better outcomes than adults with T2D in the control condition will be tested using Generalized Linear Mixed Models (GLMM) with an intent-to-treat analysis. While it is likely that significant main effects may not be found for all variables due to the sample size, identification of trends of significance (e.g., $p<.10$) and effect sizes will be possible. The results of analyses of the clinical outcomes of A1C and BP will require control for the impact of medication usage and dosage change (e.g., change in medications or dosage or no change, increased levels or not, and decreased levels or not).