FINAL REPORT

Learning to live with diabetes

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1. **Specific Aims/Hypothesis:**

Aim 1: Determine the feasibility of the intervention, including its acceptability, and further refine intervention materials and study procedures (recruitment, enrollment, intervention, retention, data collection).

Aim 2: Test the initial efficacy of the intervention on participants with T2DM on the following outcomes from Time 1 (Baseline-0 months), Time 2 (Post Intensive Intervention-2 months), and Time 3 (After 3 months on their own-5 months):

- The primary outcome included glycated hemoglobin (HbA1c) from Time 1 to Time 3.
- The secondary outcomes includes adiposity (waist circumference, triceps and subscapular skinfolds) and weight status (body mass index [BMI]), and diabetes self-management behaviors (Stanford Diabetes Questionnaire) from Time 1 to Time 2 and Time 1 to Time 3.

Hypothesis: The participants in the experimental group will decrease HbA1c, adiposity and weight and improve diabetes self-management significantly more than the control group from T1 to T3.

2. **Theoretical/conceptual framework**

**Theoretical/Conceptual Framework or Rationale**

The intervention was based on social cognitive theory ([Bandura, 1977, 1982, 1986, 1997](#)), which posits that learning and practicing new behaviors and coping skills enhance self-efficacy, which, in turn, increases the probability that new behaviors will be maintained ([Bandura, 1977, 1982, 1986](#)). Studies suggest that when an individual copes effectively with a problem, confidence is increased for dealing with the next problem ([Bandura, 1977, 1982, 1986, 1997](#)). The intervention was taught participants to improve diabetes self-management skills, thereby, improving glycemic control ([Bandura, 1977, 1982, 1986, 1997; Dix, 1991](#)). Patient will improve their diabetes self-management through gaining knowledge of T2DM, exercise goals, weight goals, cholesterol and blood pressure goals, portion control including fast food and sweetened beverages, and using social problem solving to improve diabetes self-management and nutrition and exercise. Participants who develop skills in social problem solving should be more able to make better choices in their diabetes self-management ([Bandura, 1982, 1986, 1997](#)) and by improving their self-efficacy they should be able to meet their glycemic goals.

3. **Methods, procedures and sampling**

**Research Design**

The study used a two-group (experimental group = 25 participants and control group = 25 participants) repeated measures design to evaluate the feasibility of the intervention with participants of Mexican heritage from Tampico, México. The experimental group received an intervention focused on T2DM self-management weekly for 8 weeks and then had 3 months on their own. The control group received usual care. Data collection will be at Time 1 (Baseline-0 months), Time 2 (Post Intensive Intervention-2 months), and Time 3 (After 3 months on their own-5 months). The Time 2 data collection determines the magnitude of the intervention post intensive intervention and the Time 3 data collection examines primary and secondary outcomes after they have had sufficient time to implement their new diabetes self-management skills. These times were chosen because 3 to 6 months after completion of an intervention represents a standard length of time for follow-up ([Oude Luttikhuis et al., 2009](#)).
Subjects and Settings

Since this is a feasibility and initial efficacy study a power analysis was not run. Inclusion criteria for participants was age 18 to 60 years old; self-identification as Mexican heritage; fluent in Spanish; diagnosed with T2DM for at least 1 year; and receive their medical care at the Community Health Center and had received permission from their health care provider to join the study. Participants were excluded if they were found to have a heart murmur, congenital heart disease, family history of sudden death, difficulty walking or exercising or history of psychological problems that would prevent participation in group classes. Participants were enrolled over a 2-month period.

Intervention

The diabetes group visits were developed according to the American Diabetes Association Clinical Practice Guidelines (ADA, 2014) by Dr. Berry. Each experimental patient received 8 weekly classes over 2 months in Spanish. A nurse interventionist with experience teaching participants with diabetes was trained by Dr. Compeán Ortiz, Ms. Aguilera Pérez, and Dr. Berry. The modules have been tested in English in the U.S. and have been highly successful (Berry et al.) and have been translated into Mexican Spanish. The classes included understanding T2DM and A1C goals, exercise goals, weight goals, cholesterol and blood pressure goals, portion control, fast food, and sweetened beverages, improving diabetes self-management goals using social problem solving, improving nutrition goals using social problem solving, and improving exercise goals using social problem solving.

Instruments

All measurements were conducted in a private room at the clinic. All instruments were in Spanish.

Glycemic Control. Glycemic control was measured by a portable kit of A1c and were donated by Dr. Berry to Dr. Compeán. Using cartridges, the analyzer calculates A1C in 5 minutes. This equipment meets lab-quality testing standards with an analyzer that speeds and simplifies diabetes tests and delivers accurate, clinically relevant results shown to improve decision-making, patient compliance, and outcomes. Good glycemic control was be defined as an A1C < 7.0% as defined by the ADA (American Diabetes Association, 2014).

Anthropometric Measurements. Anthropometric measures included height, weight, body mass index (BMI), adiposity (waist circumference) and subscapular and triceps skinfolds were measured in a private room. Dr. Berry has over 15 years of experience measuring height, weight, calculating BMI, waist circumference and triceps and subscapular skinfolds and personally trained Ms. Aguilera Pérez and Dr. Compeán Ortiz during a research stay. All equipment for the proposed study was loaned by Dr. Berry from previously completed studies.

Height was measured twice and averaged in street clothes without shoes, using a stadiometer, which was calibrated in 1/8-centimeter (cm) (Najjar & Rowland, 1987).

Weight was measured twice and averaged in street clothes without shoes to the nearest 0.1 kilogram using a Tanita BC-554 Digital Scale. The BC-554 self-calibrates to 0 before each weighing (Najjar & Rowland, 1987). Body mass index (BMI) in participants will be calculated by computer. In adults age 20 years and older, overweight is defined as a BMI between 25.0kg/m² and 29.9kg/m², and obesity is defined as a BMI equal to or greater than 30.0 kg/m² (Hedley et al., 2004).

Waist Circumference was measured three times and averaged by asking the patient to stand erect on both feet, lower the pants to the hips and pull up the shirt. One research assistant (RA) was in front of the patient and a
second RA was behind and to the right of the patient and palpated the hip area to locate the right ilium. Standing on the patient’s right side, the RA then placed the measuring tape around the trunk in a horizontal plane at the level marked on the right side of the trunk. The measurement was done at the end of normal expiration and was taken to the nearest 0.1 cm and called to the RA doing the recording (Najjar & Rowland, 1987). We used the classification of abdominal obesity which having 90 cm or more in men is considering abdominal obesity and high risk, while in women having 80 cm or more (Zimmet, Alberti & Shaw, 2005).

Triceps and Subscapular Skinfolds were measured in participants on the right side of the body using Lange skinfold calipers three times and averaged. The caliper method is based on the assumption that the thickness of the subcutaneous fat reflects a constant proportion of the total body fat (Davies, Gregory, & White, 1995). Two RAs were required to do skinfolds, with one RA measuring and one RA recording, as recommended by the National Center for Health Statistics (NCHS, 1987). The triceps site was determined using a tape measure to locate the midpoint between the acromion and olecranon processes with the elbow bent at 90 degrees. The subscapular measurement was taken diagonally 1 cm below the inferior angle of the scapula, following the natural fold of the skin (NCHS, 1987). The RA was trained to mark the skin with a nonpermanent marker, and gently grasp the skin and underlying subcutaneous adipose tissue between his/her left thumb and index finger. The skinfold was held with the thumb and forefinger 2.0 cm above where the measurement is to be taken, and the jaws of the calipers was placed perpendicular to the length of the fold. The skinfold was measured to the nearest 0.1 mm while the fingers continue to hold the skinfold. The actual measurement of the caliper was read about 3 seconds after the caliper tension is released and called to the recorder. To ensure reliability, RAs were trained and tested for inter-rater reliability prior to each data collection, by calculating correlations when measuring skinfolds on the same participants. Triceps and subscapular skinfold thickness were calculated using the gender-and race-specific methods of Slaughter et al. (Slaughter et al., 1988).

Sociodemographic Data (Spanish). A demographic questionnaire was used to collect data on age, education level, marital status, occupation, duration of diabetes, type of treatment and medical history, including the presence of hypertension, smoking and alcohol consumption.

Diabetes Self-Management Stanford Questionnaire (Spanish). The Diabetes Self-Management Stanford Questionnaire in Spanish measures general health, symptoms, fatigue, shortness of breath, pain, physical activities, confidence about doing things, daily activity, medical care, and health care utilized. Each question is measured according to a separate scale. The Diabetes Self-Management Questionnaire has been extensively tested in Spanish with excellent reliability and validity on all scales. See The Diabetes Self-Management Codebook and Psychometric Testing for individual subscale psychometric testing and references.

Procedure

Dr. Compeán Ortiz and Ms. Aguilera Pérez conducted an initial screening in the Area of Consultation of Community Health Center. They screened for the following inclusion criteria: participants with age of 18 years to 60 years old; self-identification as Mexican heritage; fluent in Spanish; diagnosed with T2DM for at least 1 year; and receive their medical care at the Center (Seguro Popular). Participants were excluded if they were found to have a heart murmur, congenital heart disease, family history of sudden death, difficulty walking or exercising or history of psychological problems that would prevent participation in group classes, which was asked on the demographic data sheet. If eligible, Dr. Compeán Ortiz and Ms. Aguilera Pérez did an appointment to meet at the Center and the patient received an oral description of the study in Spanish, requirements of participants, and the risks and benefits of participating; and all questions were answered. An appointment was done to collect data in a private room at the School of Nursing. RAs collected the following data in the same order: height, weight, waist circumference, triceps and subscapular skinfolds, finger stick A1C, and questionnaires. Data collection took a total of 45-60 minutes for each patient. At the completion of each data collection participants. The interventionist collected data on attendance at each class, reasons for non-attendance, and make-up sessions provided. Dr. Compeán Ortiz and Ms. Aguilera Pérez observed two
randomly selected classes per month to assess whether classes are engaging the participants and being taught according to the protocol.

4. Summary of findings

**Demographics**
The fifty participants were from 36.0 to 60.0 (Mean [M] = 49.84; Standard Deviation [SD] = 5.76) years of age. Seventy-six percent (n = 38) were female and 24% (n = 12) were male. Educational preparation was as follows. Two percent (n = 1) did not have any formal schooling, 42% (n = 21) attended primary school, 36% (n=18) attended secondary school, 8% (n = 4) had a baccalaureate degree, 10% (n = 5) attended an advanced university and 2% (n = 1) attended a technical school. A total of 18% (n = 9) were single, 46% (n = 23) were married, 2% (n = 1) were widowed, 30% (n = 15) were single, 2% (n = 1) were separated, and 2% (n = 1) were divorced. A total of 4% (n = 2) were on glyburide, 6% (n = 3) were on insulin, 20% (n = 10) were on metformin, 68% (n = 34) were on metformin and glibencl and 2% (n = 1) were on nothing.

**Clinical Data**
Independent t-tests were run and results are as follows between the intervention and control group. From Time 1 to Time 2 (p = .976) to Time 3 (p = .833) there were no significant differences in weight change. From Time 1 to Time 2 (p = .718) to Time 3 (p = .750) there were no significant differences in waist circumference change. From Time 1 to Time 2 (p = .079) to Time 3 (p = .748) there were no significant differences in triceps skinfold change. From Time 1 to Time 2 (p = .926) to Time 3 (p = .859) there were no significant differences in subscapular skinfold change. From Time 1 to Time 2 (p = .266) to Time 3 (p = .334) there were no significant differences in systolic blood pressure change. From Time 1 to Time 2 (p = .931) to Time 3 (p = .396) there were no significant differences in diastolic blood pressure change. From Time 1 to Time 3 (p = .518) there were no significant differences in hemoglobin A1C. The intervention group started at 9.92% and decreased to 8.73% and the control group started at 9.08% and decreased to 8.32%. Both groups decreased from Time 1 to Time 3, however, the intervention group decreased 1.19% and the control group decreased 0.76%.

**General Health**
The intervention versus the control group were examined using independent t-tests on the Stanford Diabetes Questionnaire. Patients rated their general health on a scale of 1 to 5 with 1 = excellent, 2 = very good, 3 = good 4 = fair, and 5 = poor. There were no significant differences between the intervention and control group from Time 1 to Time 2 (p = .401) to Time 3 (p = .208). There was no significant differences between the intervention and control group in the number of times that they saw their health care provider in the last six months at Time 1 to Time 2 (p = .434) or Time 3 (p = .174). There were no significant differences between the intervention and control group in number of emergency room visits that they had at Time 2 (p = .557) or Time 3 (p = .434). There were no significant differences between the intervention and control group in the number of nights they stayed in the hospital at Time 2 (p = .928) or Time 3 (p = .354). There were no significant differences between the intervention and control group in the number of times they had their eyes examined in the past 6 months at Time 2 (p = 0.61) or Time 3 (p = .899). There were no significant differences between the intervention and control group in the number of times they had their feet examined by their health care provider at Time 2 (p = .727) or Time 3 (p = .241).

**Medications**
There were no significant differences between the intervention and control group in the use of oral medication to control their diabetes at Time 2 (p = .638) or Time 3 (p = .162). There were no significant differences between the intervention and control group in the use of insulin to control their diabetes at Time 2 (p = .638) or Time 3 (p = .162). There were no significant differences between the intervention and control group in the use of medication to control their hypertension at Time 2 (p = .327) or Time 3 (p = .118). There were no significant
differences between the intervention and control group in the use of medication to control their cholesterol at Time 2 (p = .198) or Time 3 (p = .457).

**Exercise**

There was a significant difference at Time 2 (p = .002) in the number of times the intervention group did exercise a week compared to the control group, however, that significant difference was not maintained at Time 3 (p = .285). There were no significant differences at Time 2 (p = .090) or Time 3 (p = .636) in the number of times the intervention group walked a week compared to the control group. There were no significant differences at Time 2 (p = .167) or Time 3 (p = .167) in the number of times the intervention group exercised in the water a week compared to the control group. **There was a significant difference at Time 2 (p = .009) in the number of times the intervention group rode a bicycle a week compared to the control group, however, that significant difference was not maintained at Time 3 (p = .581).** There were no significant differences at Time 2 (p = .064) or Time 3 (p = .081) in the number of times the intervention group used machines to exercise a week compared to the control group. There were no significant differences at Time 2 (p = .717) or Time 3 (p = .607) in the number of times the intervention group did aerobic exercise a week compared to the control group.

**Nutrition**

There were no significant differences at Time 2 (p = .832) or Time 3 (p = .502) in the number of times a week the intervention group compared to the control group ate breakfast. **There was a significant difference at Time 2 (p = .34) in that the intervention group compared to the control group drank milk with their breakfast, however, by Time 3 (p = .783) there were no significant differences between the groups.** There were no significant differences at Time 2 (p = .083) or Time 3 (p = .613) in the number of times that the intervention group ate cheese with their breakfast meal compared to the control group. There were no significant differences at Time 2 (p = .329) or Time 3 (p = .162) in the number of times that the intervention group ate yogurt with their breakfast meal compared to the control group. There were no significant differences at Time 2 (p = .572) or Time 3 (p = .999) in the number of times that the intervention group ate eggs with their breakfast meal compared to the control group. There were no significant differences at Time 2 (p = .319) or Time 3 (p = .911) in the number of times that the intervention group ate beans with their breakfast meal compared to the control group. There were no significant differences at Time 2 (p = .329) or Time 3 (p = .951) in the number of times that the intervention group ate meat with their breakfast meal compared to the control group.

**Glucose Meters**

There were significant differences at Time 2 (p = .012) and Time 3 (p = .004) in that the intervention group were more likely to have a glucose meter than the control group. There were significant differences at both Time 2 (p < .001) and Time 3 (p = .051) in that the intervention group compared to the control group checked their finger stick glucose more days per week.

**Symptoms**

There were no significant differences at Time 2 (p = .824) or Time 3 (p = .629) in the intervention or control group in regards to having increased thirst in the past week. There were no significant differences at Time 2 (p = .636) or Time 3 (p = .629) in the intervention or control group in regards to having a dry mouth in the past week. There were no significant differences at Time 2 (p = .878) or Time 3 (p = .193) in the intervention or control group in regards to having less of an appetite than normal in the past week. There were no significant differences at Time 2 (p = .847) or Time 3 (p = .574) in the intervention or control group in regards to having nausea and vomiting in the past week. There were no significant differences at Time 2 (p = .217) or Time 3 (p = .911) in the intervention or control group in regards to having abdominal pain in the past week. There were no significant differences at Time 2 (p = .824) or Time 3 (p = .880) in the intervention or control group in regards to having to get up during the night to urinate at least three times in the past week. **There was a significant difference at Time 2 (p < .001) and Time 3 (p = .057) in that the intervention group had fewer episodes of**
hyperglycemia compared to the control group in the past week. There were no significant differences at Time 2 (p = .951) or Time 3 (p = .235) in the intervention or control group in regards to having morning headaches in the past week. There were no significant differences at Time 2 (p = .138) or Time 3 (p = .578) in the intervention or control group in regards to having nightmares in the past week. There were no significant differences at Time 2 (p = .365) or Time 3 (p = .235) in the intervention or control group in regards to having night sweats in the past week. There were no significant differences at Time 2 (p = .636) or Time 3 (p = .256) in the intervention or control group in regards to having lightheadedness in the past week. There were no significant differences at Time 2 (p = .217) or Time 3 (p = .578) in the intervention or control group in regards to having shakiness or weakness in the past week. There was a significant difference at Time 2 (p = .001) in that the intervention group had more intense hunger than the control group in the past week, however, by Time 3 (p = .602) this difference was no longer significant. There were no significant differences at Time 2 (p = .138) or Time 3 (p = .235) in the intervention or control group in regards to having nightmares in the past week. There were no significant differences at Time 2 (p = .149) or Time 3 (p = .578) in the intervention or control group in regards to feeling confident that they could eat their meals every 4 to 5 hours every day, including breakfast every day.

Confidence
There were no significant differences at Time 2 (p = .092) or Time 3 (p = .524) in the intervention or control group in regards to feeling confident that they could follow their diet when they had to prepare and share food with other people who do not have diabetes. There were no significant differences at Time 2 (p = .165) or Time 3 (p = .665) in the intervention or control group in regards to feeling confident that they could chose appropriate foods to eat when they were hungry. There were no significant differences at Time 2 (p = .171) or Time 3 (p = .356) in the intervention or control group in regards to feeling confident that they could exercise 15 to 20 minutes, 4 to 5 times a week. There were no significant differences at Time 2 (p = .504) or Time 3 (p = .137) in the intervention or control group in regards to feeling confident that they could do something to prevent their blood sugar from dropping when they exercised. There were was a significant difference at Time 2 (p = .009) and Time 3 (p = .011) in the intervention compared to the control group felt more confident that they knew what to do when their blood sugar went higher or lower than it should be. There were no significant differences at Time 2 (p = .067) or Time 3 (p = .067) in the intervention or control group in regards to feeling confident that they could judge when the changes in their illness meant that they should visit their doctor. There were no significant differences at Time 2 (p = .066) or Time 3 (p = .795) in the intervention or control group in regards to feeling confident that they could control their diabetes so that it did not interfere with the things they wanted to do.

5. Recommendations

We plan to publish the results and calculate effect sizes to properly power a larger study.