Impact of a Virtual Diabetes Self-Care and Education Program on Diabetes-related Outcomes in Latinos with T2 Diabetes

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PROGRAM DESCRIPTION/PLAN OF OPERATION

PURPOSE OF PROTOCOL:

The goal of this study is to evaluate the impact of a comprehensive diabetes education and management program based on frequent communication with patients using teleconsultation, text messaging, and phone calls on diabetes related outcomes in Latino patients with type 2 diabetes. We hypothesize that the decline in hemoglobin A1c value between the baseline and the six-month visit will be at least 0.5 percent greater in the intervention group than in the control group.

1. **Objectives:**
    a. Improve adherence to nutritional therapy, physical activity, glucose monitoring and medication use in Latino patients with type 2 diabetes by using a virtual diabetes education and self-management program in a six month period and in comparison to usual diabetes care and education received in diabetes clinics.
    b. Improve A1c levels, blood pressure, lipids and weight control in Latino patients with diabetes using this program within the same time frame.
    c. Improve adherence to clinic appointments and decrease diabetes related stress, depression, visits to the emergency room and hospitalizations with the use of this program in comparison to people receiving usual diabetes care.
    d. Evaluate the impact of each of the three components of the program (teleconsultations, text messaging and phone calls) on the adherence to basic diabetes self-care behaviors.

2. **Activities:**

Setting:
Joslin Affiliated Center at Doctor's Hospital at Renaissance in Edinburg (DHR), TX.

Duration:
18 months total:
1. 3 months for IRB approval and training at the partner site
2. 12 months of continuous enrollment (including 9 months of study)
3. 3 months of data analysis and manuscript preparation

Protocol:

Inclusion Criteria:
In order to participate in the program, all patients must meet the following criteria:

1. Have physician-diagnosed type 2 diabetes
2. Be self-identified as Hispanic or Latino
3. Age 21 to 80
4. An A1c value between 8-14% within the last three months.
5. Demonstrate the ability, either alone or with the help of a family member that will be with the patient at least once a week, to use the technology that will be used during the teleconsultations.

Exclusion Criteria:
Subjects will be excluded if they have any of the following conditions:

1. Severe diabetes related chronic complications such as chronic renal failure, blindness, amputations, stroke, etc.
2. Concomitant chronic illnesses that would affect their participation in the program, i.e. cancer, debilitating diseases, etc.
3. Any other condition that would affect participant's basic mental health skills.
4. Type 1 diabetes or gestational diabetes.
5. Patients with abnormal hemoglobin, anemia or any condition that may affect red blood cell turnover. Any of these conditions may be detected through participants' history or through the laboratory report at study screening.
6. Signs or symptoms of metabolic decompensation (polyuria, polydypsia, polyfphagia, unexplained weight loss, blurry vision, lethargy, etc.)

Elimination Criteria:
Development of any acute event during the study period that would affect participants' primary outcome at the discretion of the investigator, e.g. hyperosmolar coma, acute event of significant hyperglycemia or the use of certain medications like steroids.

Groups:
A total of 92 participants will be randomly assigned to one of the two study groups:

Group 1 – Intervention group – this group will complete activities described above. During scheduled follow-up clinical visits at months 3, 6, and 9, an additional A1c will be obtained. All measurements will be covered through the study grant if the patient does not have a recent laboratory result (2 weeks prior to the study visit) for the following test: A1c, lipid panel, ALT, AST, microalbumin, and chem 6 result.

Group 2 - Control Group –
This group will attend regular visits with their medical and education providers. As in the intervention group, these visits are expected to occur at 3, 6, and 9 months after the first visit. This group corresponds to the usual care that is provided at DHR.

Primary Outcome:
The primary outcome variable will be the change in hemoglobin A1c value from baseline to 6 months.

Sample Size:
We hypothesize that the decline in hemoglobin A1c value between the baseline and the six-month visit will be at least 0.5 percent greater in the intervention group than in the control group.

The sample size and power calculation is based on preliminary results of our study where the study aimed at behavioral change. Assuming a mean reduction of 0.504 (SD= 1.2) in A1c in the intervention group and no change in the control group a sample size of 37 per group will be needed to detect this reduction with 80 % at 5% level of significance (one-sided) using the t-test. Assuming a 20% dropout, 46 study subjects per group (total 92) will be needed.

Recruitment:

Study candidates will be identified at the partner site (DHR) where this protocol will take place. This will be done by creating flyers, videos, print and web-based ads, and letters to invite patients that attend the practice to join the study and/or by directly inviting patients that regularly attend the practice. Proper informed written consent will be obtained from all individuals prior to participation in the study.

Interventions:

a. Virtual diabetes self-management group

- **i.** Weekly conversations led by the diabetes educator (30-minute) using teleconsultation to deliver diabetes education and enhance adherence to treatment recommendations. These conversations will occur during the first 12 weeks of the intervention and will consist of the following elements: a) open question as to whether there is a particular item for discussion that the patient would like to address; b) review of blood glucose and physical activity results; c) review of the adherence to the four basic self-care behaviors (meal plan, physical activity, glucose monitoring and medications); d) identification of barriers to adhere to treatment recommendations; and e) provision of specific recommendations to overcome identified barriers. In order to provide diabetes education in a culturally and linguistically oriented manner, particularly to those patients with low health literacy, all participants in the virtual education program will be encouraged to listen to Rosa's or Jose's Story during the first 8 weeks of the intervention. These are audio-novellas developed by the Latino Diabetes Initiative at Joslin Diabetes Center to educate Latino patients with type 2 diabetes using the story telling method in a practical and engaging manner.
- **ii.** Since the teleconsultations will only last 12 weeks, phone conversations with the diabetes educator will be implemented starting in the 4th month of the program. These will be 15-30 minute conversations and will occur at weeks 14, 15, 16, 17, 19, 21, and 23. The goal of the phone calls is to provide support to the patients and they will follow the same protocol as the weekly conversations described above.
- **iii.** A weekly text message will be sent to patients during the 6 months of the education program. These messages will focus on assessing and addressing participants' beliefs about common myths and misconceptions in the area of diabetes. The text message will present the myth of the week and request people's participation in responding whether the concept is true or false and will also provide the correct answer to the question presented the prior week.
- **iv.** Observation period: the third quarter of the intervention (months 6-9) will allow the observation of the residual effect of the virtual education program; therefore no contact or education will be planned for the last 3 months (months 7, 8 & 9). Patients will be followed in their corresponding clinics as usual.

b. In-person diabetes self-management education or control group

- **i.** Patients in this group will attend their regular clinical and education appointments as offered by the center.

The table below presents the timeline for the interventions discussed above.

	Months								
	1	2	3	4	5	6	7	8	9
Virtual education	4w R/J 4T	4w R/J 4T	4w 4T	4p 4T	2p 4T	1p 4T			

W=weekly teleconsultation
P=Phone conversation
R/J=Rosa or Jose's Story
T=Text message related to a diabetes myths and misconceptions

Study Procedures:

Before randomization, all participants will go through the following steps:

1) Eligible patients will have their standard follow-up clinical encounter with their corresponding health care provider.
2) Screening visit. At this time, the research assistant or study coordinator will obtain the baseline A1c measured through each site's laboratory and will review inclusion and exclusion criteria with study candidates to assess eligibility for the study. If the patient qualifies for the study, clinicians will not be aware of this at the time of the initial visit, so that this value does not influence their treatment at baseline and the intervention is left as the main explanatory variable.

After the regular clinical visit and the screening visit the eligible participants will be randomized to one of the two groups.

After randomization, participants will go through the following steps:

3) All participants in the study will receive a healthy eating handout, pedometer with exercise handout, and pillbox and will be invited to come to the center for an initial 2-hour nutrition and exercise recommendation group session taught by the diabetes educator. The research assistant and/or study coordinator will provide these items and book to patients that want to participate in the group session.

4) Participants in the intervention group will receive education and training on how to operate the technology as well as copies of Rosa's or Jose's Story in their preferred language and based on their education needs. A calendar with specific dates and times for their weekly/monthly interaction with the diabetes team will be provided to participants.

5) All study participants will be given a follow-up appointment 3, 6, and 9 months after the baseline visit.

Project related materials:

Patient Education:
At baseline, all patients in the study will have the opportunity to come to the center for initial 2-hour nutrition and exercise recommendation group session. They will receive handouts regarding food, exercise, medication and will emphasize the need to take medications and insulin on time, follow meal plans, be physically active and monitor blood glucose levels as recommended by their health care provider. This information will be available in English and Spanish and will be based on culturally oriented materials for Latino patients with low/medium health literacy.

Resources for Providers:
All providers will receive training and log-in information for the teleconsultation.

The partner site will receive ***Patient Education Handouts*** (in English and Spanish) that providers can use whenever necessary to support changes to treatment plans for study participants. For instance, handouts on how to start and advance insulin therapy will be provided. Information on other pharmacologic interventions will also be available. Providers will have access to the electronic versions of all handouts

Patient Incentives:
Each participant will receive $35 every time they complete a study visit. Participants will be asked to complete four study visits in a period of nine months.

Study Visits:
Before any study procedure is done, the patient will be asked to read the consent form. A member of the study staff will discuss the study and the study procedures. Additional time from participants' regular clinical appointments will be necessary to collect study related information as follows:

Visit 1: This visit will last 60 minutes and will start by obtaining an A1c value to verify patient's eligibility. After a patient has been enrolled in the study (A1c value between 8-14%) they will be randomly assigned to the control or intervention group (virtual diabetes self-management education program using teleconsultation) and baseline information will be collected. Participants in the intervention group will be trained to use technology related to the teleconsultation, their own glucometer and the pedometer administered by this program.

Visit 2: This visit will last 60 minutes for questionnaires and will be completed 3 months after visit 1. All the tests and questionnaires detailed in table 1 will be administered at this visit.

Visit 3: This visit will last 60 minutes for questionnaires and will be completed 6 months after visit 1. All the tests and questionnaires detailed in table 1 will be administered at this visit.

Visit 4: This visit will last 60 minutes for questionnaires and will be completed 9 months after visit 1. All the tests and questionnaires detailed in table 1 will be administered at this visit.

Timeline Table for Study Procedures:

Study Variables (both groups)	Baseline Visit	3	6	9
Laboratories				
Blood drawn	x	x	x	x
A1c	x	x	x	x
Lipid profile	x	x	x	x
ALT (from patient record if available)	x	x		x
AST (from patient record if available)	x	x		x
Microalbumin (from patient record if available)	x		x	x
Chem 6 (from patient record if available)	x	x		x
Measurements				
Weight	x	x	x	x
Height	x			
Blood pressure	x	x	x	x
Questionnaires				
Demographic characteristics	x			
Diabetes history	x			
Diabetes treatment plan	x	x	x	x
Adherence to prescribed drugs	x	x	x	x
Measures of emotional distress (depression, anxiety and PAID)	x		x	
Health literacy	x			
Self-care behaviors	x	x	x	x
Executive function	x			
Depression scale	x	x	x	x
Physical activity: pedometer use and number of steps per day	x	x	x	x
24 hour recall	x	x	x	x
Food frequency questionnaire	x	x	x	x
Analysis of the photo of the content of the refrigerator (only for the intervention group)	x	x	x	x

IRB:
The Joslin Diabetes Center's Institutional Review Board will be in charge of approving this protocol according to current clinical research guidelines.

An informed consent for participation in the study will be generated to be approved by the IRB. This consent form will be given to all participants before the study begins. Only participants that have given full written consent will be able to participate in the study.

Adverse Events:
We don't anticipate any serious adverse events as this is a study that does not involve the use of any major procedure or the use of any pharmacologic intervention. The only potential adverse events are those related with answering questionnaires or drawing blood for the A1c test and other laboratories specified above.

Good Clinical Practice:
Whereas the primary objective of the protocol is to assess whether there is a significant difference in glycemic control with teleconsultations with the diabetes team at the patient's home, all participants in the study regardless of the **assigned study** group will be offered the best possible diabetes care according to current standards and approved treatment algorithms, particularly the recently published American Diabetes Association standards.

If at any point in time during the study, the investigators or practicing clinicians consider that it would be in the patient's best interest to terminate their participation in the study; this will be considered a priority.

Process and product study variables:

Primary outcome*:*

- **A1c levels:**

The values obtained through the laboratory at each of the participating sites will be used to evaluate the primary outcome of the study. The baseline A1c value will be used for eligibility for the study.

Other variables*:*

- **Demographic characteristics** (obtained at baseline)

The demographic variables of interest are: date of birth, years in the practice, household status (living with one or more persons, living alone), years of education, socioeconomic status, community of residence and insurance status.

- **Diabetes history** (obtained at baseline)

The variables of interest are: date of diagnosis, age at diagnosis, years with diabetes, family history of diabetes, diabetes specialist care and history of diabetes education.

- **Diabetes treatment plan** (obtained at baseline and during each clinical encounter in both groups and during the teleconsultations and telephone communications in the intervention group)
    - Current meal and exercise plan
    - Diabetes treatment (oral medications, injected medication, insulin)

- Glucose monitoring patterns (number of self-measured blood glucose (SMBG) per day and per week), use of logbook, barriers to SMBG, pre- and post-prandial glucose values.

- **General Medical Evaluation** (obtained at baseline and at every visit)

This evaluation will include: weight and height to calculate body mass index (BMI), waist circumference, blood pressure, capillary glucose level, A1c, smoking habits, aspirin therapy, last eye exam, last microalbumin test, last appointment with an educator, last dental exam and other co-morbidities affecting A1c results.
Lipid Profile: practice will be encouraged to measure lipid profile throughout the study.

- **Adherence to prescribed drugs:**

Medication adherence will be measured through the use of a validated questionnaire called the Morisky Scale.

- **Measures of emotional distress** (will be completed at baseline and last visit)

The Problem Areas in Diabetes (PAID) scale is a well-used and validated tool for measuring diabetes-related distress. The questionnaire has statistically significant power to predict diabetes control in long-term studies. More importantly, the self-reporting tool has been used to study people living with type 2 diabetes in the Latino community. Welch et al. reported a Cronbach's alpha coefficient of .95 in a study evaluating its usefulness in clinical settings. (9)

- **Health literacy:** (will be assessed at baseline)

Each of the participants will be assessed using the Newest Vital Sign (NVS) instrument. (10)

- **Self-care behaviors:** (will be completed at every visit)

We will use the Self-Care Inventory-Revised to measure behavioral changes among patients. This 19-question validated scale measures the subject's perception of the frequency of diabetes-specific tasks performed over the past 1-2 months, such as blood testing, exercising, adherence to medication, and healthy eating. Research supports reliability of the scale in people living with type 2 diabetes. Also, the scale supports an inverse relationship between glycemic control and the mean score of the SCI-R. Weinger et al. reported a Cronbach's alpha coefficient of .87. (11)

- **Depression scale** (will be completed at baseline and 6-month visit)

We will use the Patient Health Questionnaire-9 (PHQ-9). This measure has nine items, each of which is scored, providing a 0 to 27 severity score.

- **Anxiety scale** (will be completed at baseline and 6-month visit)

We will use the Generalized Anxiety Disorder-7 (GAD-7). This measure has nine items, each of which is scored, providing a 0 to 21 severity score. Scores of 5, 10, and 15 are taken as the cut off points for mild, moderate, and severe anxiety, respectively. When used as a screening tool, further evaluation is recommended when the score is 10 or greater

- **Refrigerator photo** (obtained at baseline and at every visit) – intervention group only

All participants in the intervention group will be asked to take a photo of their refrigerator using the camera in their smart phones. The study team will receive these images and

they will be analyzed to see the proportions of package food versus non-package foods present in each picture.

- **24 Hour Food Recall** (will be completed at every visit)

All participants will be asked to recall what they ate on two days prior to the recruitment visit and one day at the 3, 6, and 9 month visits.

- **Physical activity** (will be obtained at every visit)

All participants will be given a Fitbit physical activity tracker. Data recorded by the device will be downloaded at each study visit. In addition, intervention patients who wish to share the data with the diabetes educator can download the data at any time using the phone they will receive.

- **Glucose log** (will be obtained at every visit)

Glucose monitor data for every patient will be downloaded at each visit using the Glooko MeterSync Blue cable which is able to connect to most glucose meters and download data to the Glooko Population Management tool. Intervention patients will receive a cable to sync their meters at home using the phone they receive if they choose to share the information with their diabetes educator.