Written Consent to Participate in a Clinical Trial

Project Title: Effectiveness of and Implementation Strategies for 'Disfrutando': A Culturally Tailored, Bundled Intervention to Address Type 2 Diabetes Mellitus in High-Burden Populations
Principal Investigator Name: Dr. Maithe Enriquez
Sponsor: Center for Diabetes Translation Research Washington University and National Institutes of Health
IRB Assigned Project Number: *2127387*

Key Information About the Study

You are being asked to participate in a clinical trial. The purpose of the study is to evaluate the effectiveness and implementation strategies of 'Disfrutando,' a culturally tailored intervention designed to address type 2 diabetes mellitus (T2DM) in high-burden populations. You are being asked to participate in 7 group sessions by engaging in educational and skill building activities that are aimed at helping you learn about how T2DM impacts the body. You will learn how to check your blood sugar at home, learn about healthy foods, learn how physical activity impacts T2DM, and learn how to keep your feet healthy. Possible benefits of this study include gaining knowledge and skills that may help you to enhance self-care management of T2DM. Possible risks may include temporary discomfort when sticking your finger to check average blood sugar level. There is a remote risk of bruising or infection from a finger stick. Participants will use aseptic technique, clean the area with alcohol, and wash their hands before and after finge sticks to minimize any risk of infection. The device used for finger stick/checking blood sugars is FDA approved and is being used in an approved manner.

Food will be offered before each intervention session, and you will be screened for food allergies and food preferences. No food will be served that you identify as an allergen. Food preferences, such as vegetarian or gluten free, will be honored. You may opt not to eat the food.

Please read this form carefully and take your time. Let us know if you have any questions before participating. The research team can explain words or information that you do not understand. Research is voluntary and you can choose not to participate. If you do not want to participate or choose to start then stop later, there will be no penalty or loss of benefits to which you are otherwise entitled.

Purpose of the Research

You are being asked to participate in this study because you have been identified as a person impacted by pre-diabetes or type 2 diabetes mellitus (T2DM). The purpose of the study is to assess the effectiveness of the 'Disfrutando' intervention in helping individuals gain knowledge and skills that may help them self-manage and improve T2DM health outcomes.

What will happen during the study?

You are being asked to:

- **Initial assessment:** A survey and medical history review to evaluate your eligibility.
- **Intervention participation:** You will receive a tailored educational program and will be asked to attend 6 weekly sessions, and a follow-up session 6 weeks later (7 sessions in total). You will receive knowledge and skills at the sessions that may help you take better care of your health. Each session will last approximately 90 minutes. Sessions will be held at Holy Cross Church. Each session will focus on a different topic, and you will learn how to check your blood sugar at home, learn how to make healthy food choices, learn how to read food labels, learn how physical activity impacts T2DM, and learn how to keep your feet healthy. You will also learn about no-cost and low-cost resources in the community that you may access and may help you to enhance your diabetes health outcomes.
- **Community health workers:** There will be about 5 community health workers who are participating as group facilitators and they are also part of the study.
- You will be asked to check your average blood sugars 3 times during the study by obtaining a drop of blood with a finger stick. You will use an FDA approved device named A1CNow that is approved for home use to check average blood sugar level. Your finger may have slight, temporary discomfort during the finger stick.
- **Follow-up assessments:** There will be a follow-up assessment to evaluate the effectiveness of the intervention at 6 months (one follow-up session in total that will last approximately 60 minutes).
- Intervention sessions are not recorded and participants will be asked not to audio-record the sessions.

An overview of intervention program activities is seen in the table below:

Intervention Program Activities		
Session	**Cognitive Content**	**Behavioral Content**
Week 1	-T2DM: what is T2DM and how does it impact the body -Glucose (blood sugar) control	-Set goals -**Glucose (blood sugar) monitoring & glucometer practice
Week 2	-Physical activity & T2DM: how does physical activity help T2DM health outcomes - Low-/No-cost physical activity spaces	-Resources and linkage to access for physical activity classes/safe spaces to exercise
Week 3	-Healthy eating on a budget -Role of carbohydrates -*Portion control	-Measuring food portions -Reading food labels -Healthy, flavorful cooking
Week 4	-Making healthy food choices - Low-/No-cost fresh, healthy foods resources	-Accessing/growing fresh produce, community gardens
Week 5	- Uncontrolled T2DM complications - T2DM medications - Importance of primary/diabetes care	-Accessing/linkage to primary/diabetes health care & eye care
Week 6	- Foot care - Proper shoe and sock selection	-Self-inspection of feet, technique for cutting & filing toenails, how to apply lotion to prevent tinea pedis

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Week 12	- Booster Session reviews content from all sessions	-Review goals -Set new goals as needed
Week 24	-Follow-up visit	-Follow-up assessment and evaluation of the program
***Participants will receive a traditional glucometer (home glucose monitor) and glucometer supplies at the onset of the program.*		

Will you share with me any results or health problems/issues that you learn about me while in the study?

The study investigators are not medical doctors and the HbA1C Now testing is being conducted for research purposes only. The results of this procedure might detect or identify a health problem or issue of which you are not aware (or even one of which you are aware). But the primary purpose of this procedure is research, not the detection or identification of health problems or issues you may or may not know about. If the investigators identify potential health problems or issues as part of the research, you will be provided with this information and, with your permission, the investigators will share this information with your primary care provider or other healthcare provider of your choice. It is possible that you may need testing or treatment for a new or existing health condition. You and/or your health plan/insurance are responsible for the costs of this testing or treatment.

How long will I be in the study?

Your participation is expected to last approximately 6 months: 6 weekly 90-minute sessions; a follow-up 90-minute session 6 weeks later, and a follow-up 60-minute assessment visit at 6 months. Sessions will take place in a community setting (Holy Cross church).

There will be about 30 people with pre-diabetes or type 2 diabetes participating in this study. There will also be about 5 community health workers participating in this study.

If you are randomized to the immediate intervention program group, you will start the intervention now. If you are randomized to the wait-list group, you will have the opportunity to start the program in 3 months. You will be in the study for 6 months.

Regardless of which group you are randomly assigned; you will complete surveys two times during the first 3 months and you will check your HbA1C (average blood sugar) with a drop of blood 3 times over the 6 month period of the study.

Randomization and wait list process:

Randomize means putting you into a group by chance; like flipping a coin. You will have a one in two chance of being placed either in the immediate intervention group or the wait-list group. A computer program chooses which group you go into.

What are the expected benefits of the study?

You may or may not benefit from participating in this study. However, information learned from this study may help others with T2DM in the future. There are no guaranteed direct benefits to you, but you may gain knowledge and resources about preventing and managing T2DM.

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What are the possible risks of participating in this study?

There are minimal risks expected when taking part in this study. Some possible risks may include temporary discomfort during assessments or the possibility of feeling overwhelmed by learning about diabetes. There is a possibility of loss of confidentiality, and we will take steps to minimize this risk by having ground rules for group activities that include asking participants to protect the confidentiality of others in the group.

You will be allowed to abstain from activities (e.g., eating a meal with the group before the intervention starts) or not answer questions (i.e., survey questions) that make you uncomfortable.

We will inform you of food served as part of the session. Food served is low carbohydrate. You may abstain from eating food. You will be screened for food allergies. If you have new food allergies as the study progresses, please let us know.

You will be put into one of two groups by chance (see "randomization" section above). If you are in the wait list group, you will receive no intervention activities, you will just be completing surveys for the first 3 months. You will be asked to check your Hemoglobin (HbA1C) which measures average blood sugar for the past 3 months via a finger stick that requires one drop of blood. Your finger may have temporary discomfort during the finger stick. There is a remote risk of bruising or infection from a finger stick. You will use aseptic technique, clean the area of your finger with alcohol, and wash your hands before and after finger sticks to minimize any risk of infection.

To help lower these possible risks, we will ensure that you are well-informed throughout the process of the study and have all your questions answered.

We will tell you about any new important information we learn that may affect your decision to continue to participate in this study.

What other choices do I have if I don’t want to be in this study?

You are not required to be in this study. You can simply choose not to participate.

Will I receive compensation for taking part in this study?

You will be compensated for taking part in this study. For your time and effort, you will receive

- $15 Walmart store gift card at each program session/data collection visit that you attend
- one $25 BP gift card for gasoline/transportation at the first visit
- glucometer and supplies for checking home blood sugars (approximate value $55) at the first active intervention session

Are there any costs for participating in this study?

You should not expect any additional costs by participating in this study. However, there may be indirect costs such as transportation, parking, childcare, and/or time off work.

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You should discuss any questions about costs with the researchers before agreeing to participate.

Will information about me be kept private?

The research team is committed to respecting your privacy and keeping your personal information confidential. We will make every effort to protect your information to the extent allowed by law. Your records will be given a code number and will not contain your name or other information that could identify you. The code number that connects your name to your information will be kept in a separate, secure location.

When the results of this research are shared, we will remove all identifying information so it will not be known who provided the information. Your information will be kept as secure as possible to prevent your identity from being disclosed.

What we collected from you as part of this research will not be used or shared for future research studies. It will only be used for purposes of this study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Where can I get more information about this clinical trial?

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who do I contact if I have questions or concerns?

If you have questions about this study or experience a research-related injury, you can contact the University of Missouri researcher, Dr. Maithe Enriquez by phone at (816) 686-3242 or by email at enriquezm@missouri.edu.

If you have questions about your rights as a research participant, please contact the University of Missouri Institutional Review Board (IRB) at 573-882-3181 or muresearchirb@missouri.edu.

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The IRB is a group of people who review research studies to make sure the rights and welfare of participants are protected.

If you want to talk privately about any concerns or issues related to your participation, you may contact the Research Participant Advocacy at 888-280-5002 (a free call) or email muresearchrpa@missouri.edu.

Do I get a copy of this consent?

You will receive a copy of this consent for your records.

We appreciate your consideration to participate in this study.

Consent Signatures

Participant's Signature	**Date**

Independent Witness	**Date**

(Required when Participant or LAR cannot read or sign name, and as required by the IRB)

Investigator Authorized to Obtain Consent	**Date**

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