Study Title: Culturally Tailoring the Delivery of an Evidence-Based Diabetes Self-Management Program for Black Adults to Enhance Its Reach, Adoption, Implementation, and Effectiveness

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University of Wisconsin-Madison
Consent to Participate in Research

Study Title for Participants: Healthy Living For You (those who enroll in the study)

Formal Study Title: Culturally Tailoring the Delivery of an Evidence-Based Diabetes Self-Management Program for Black Adults to Enhance its Reach, Adoption, Implementation and Effectiveness

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Invitation

We cordially invite you to participate in a study that aims to improve the health of Blacks and African American adults. Because you self-identified as African American/Black, English-speaking, over the age of 18, and having type 1 diabetes, type 2 diabetes, gestational diabetes (diabetes related to being pregnant), or pre-diabetes, we are inviting you.

This consent form is intended to provide you with the details you need to decide about participating in the study. Any information in this form that is unclear? Ask questions about it. Before deciding, you are free to consult with your family and friends. You can decide on participation in the study once we have addressed all of your questions. We refer to this procedure as "informed consent."

Why are researchers doing this study?

The goal of the study is to conduct the Healthy Living with Diabetes (HLWD) program among Black individuals in a culturally appropriate manner.

Wisconsin offers a 6-week diabetes self-management education program called Healthy Living with diabetes (HLWD). The HLWD program concentrates on issues like diet, exercise, and stress and provide suggestions for controlling diabetes symptoms, talk about appropriate exercises, offer advice on healthy eating, go over medication use, and offer suggestions for interacting with medical professionals and raising concerns with family members. Wisconsin has widely implemented HLWD, yet few Black adults in Wisconsin take part in it.

To provide culturally appropriate and specialized HLWD content for Black adults, we will work with previous HLWD Black participants, Black community leaders, and Black leaders in organizations delivering HLWD. We're conducting this study to determine

whether it would be feasible to use the culturally adapted program, implement it, and help Black adults better manage their diabetes.

The University of Wisconsin-Madison is conducting the study in Milwaukee. This study will involve 24–30 participants in total. The UW Institute for Clinical and Translational Research (ICTR) is funding this project.

What will happen in this study?

If you want to take part in this research study, you will spend the first two months attending weekly group meetings that will be held in person at a community center. Each session will can run up to 2½ hours, will cover a different aspect of diabetes self-management, such as healthy nutrition, exercise and stress reduction.

Study visits in community location:
During the course of the study, we will ask every participant to show up for three in-person data collection appointments in the community:

- Once at the start of the study,
- Once at the last of the 6-week sessions
- Once at the end of the six-month study.

During these visits, we will ask you to complete a paper survey that examines your use of medicines, beliefs about medicines and illness, confidence in taking medicines and managing your diabetes.

In person interviews:

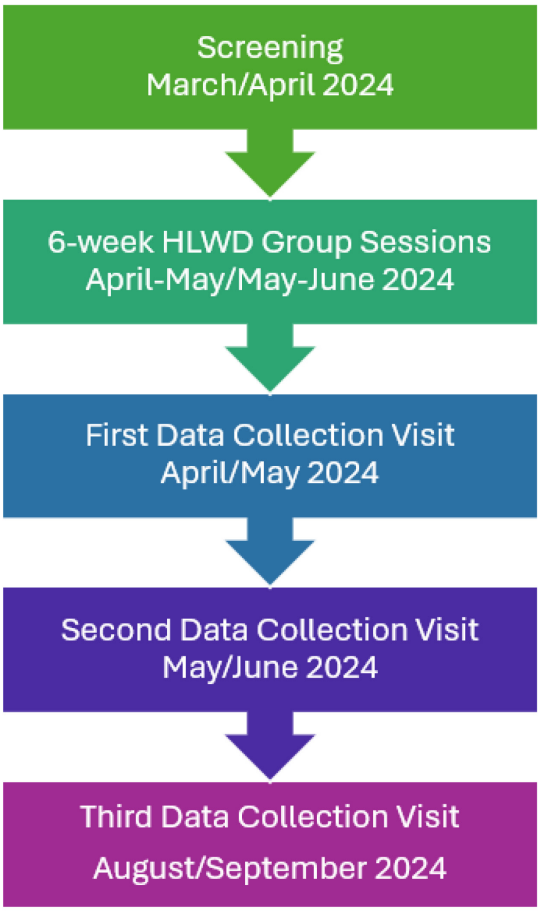
We will ask you to take part in a 25-minute in-person interview after the 6-week sessions and after the 6-month period has ended. In these interviews, your opinions of the program and its effect on taking diabetes medications will be discussed. Any survey or interview question that you do not want to answer can be skipped.

You may be invited to participate in an additional virtual 20-minute interview about being an HLWD facilitator. If you are invited and complete this interview, we will pay you $25.

As part of the study, we will collect sound and possibly video-recordings of the educational sessions and sound recordings of the discussion during the interviews. The sound and video recordings are being collected so that we don’t miss any information that will be discussed during the interview. A written copy of the audio recordings will be made for use in the research. The recordings, including sound and video, will be deleted after the study is finished. No sound or video recordings will be used in papers or publications that aren't related to the study. Both survey and interview data will be recorded and stored in a safe place that is only accessible to the researchers.

We may ask to take your photo, so that we can use it in our advertising materials about this study. We will first require you to sign a photo release form if you consent to having your picture taken.

Figure 1. Project Schedule



How long will I be in this study?

Participation in the study is around six months. Figure 1. provides details of the project schedule.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is something you choose to do, but it is not required. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time. If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study. Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health, or any connected organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Will being in this study help me in any way?

Being in this study may help you learn more about diabetes. However, we cannot promise this will happen. Even if the study does not help you directly, your participation

in this study may help other people in the future by helping us learn more about improving the health of Black adults with diabetes.

What are the risks?

There is a chance that your information could become known to someone not involved in this study.

Will being in this study cost me anything?

There will be no cost to you for the group discussions about diabetes or any other activities that are part of this research study.

Will I be paid or receive anything for being in this study?

In addition to your $10 screening payment, we will pay you a total of up to $225 for participating in this study:

- $25 in cash on the first day of the 6-week workshop at the beginning of the study,
- $50 in cash at the week 3 session of the 6-week workshop,
- $50 in cash at the week 6 session of the 6-week workshop,
- $50 sent as a money order vial postal mail for participating in the feedback session after the 6-week HLWD sessions, and
- $50 when you attend the final data collection after 6 months

Participants who are invited and complete the additional interview about being a facilitator will receive $25 sent as a money order via postal mail.

If you choose to leave the study before you complete the data collection visits, the interview or the final get-together, you will not receive payments for the activities that you do not complete.

How will researchers keep my research information confidential?
We have strict rules to protect your personal information. We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. Any knowledge we gain from this study that does not directly identify you will not be published or presented without your consent.

However, we cannot guarantee complete confidentiality. Federal or state regulations may allow or compel us to provide information to university or government representatives, as

well as the study sponsors who oversee the safety of this study. If we discover throughout the study that you or others are in danger (for instance, because of elder or child abuse, or suicidal ideas), we can also be required to inform the proper authorities, such as child protective services or healthcare providers. Without additional agreement from you, we may use the data we acquire during this study for future research or share it with other researchers with necessary institutional permits and confidentiality precautions.

Who at UW-Madison can use my information?

- Members of the UW-Madison research team
- UW-Madison regulatory and research oversight boards and offices

Will information from this study go in my medical record?
None of the information we collect for this study will be put in your medical record.

Request for email address:
We are requesting your email address so we can contact you to give you reminders about each upcoming meeting. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the lead researcher Olayinka Shiyanbola at 608-890-2091. You do not have to provide your email address to participate in this study.

Clinical Trials Information:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if I have questions?
If you have questions about this research, please contact the lead researcher, Olayinka Shiyanbola at 608-890-2091.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

Agreement to participate in the research study

If you sign the line below, it means that:

- You have read this consent form.
- You have had a chance to ask questions about the research study, and the research team has answered your questions.
- You want to be in this study.

_____

Printed Name of Participant

_____

Signature of Research Participant Date

_____

Signature of Person Obtaining Consent Date

You will receive a copy of this form*