Study Title: Michigan Men's Diabetes Project 2 Pilot RCT
NCT Number: NCT05370781
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Document: Participant Consent

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Michigan Men's Diabetes Project 2 Pilot RCT

Company or agency sponsoring the study: NIH

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Jaclynn Hawkins, MSW, PhD University of Michigan

Study Coordinator: Katherine Kloss, MS

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether utilizing men as peer leaders in diabetes self-management education and support (DSMES) has an impact as a treatment or outcome for type 2 diabetes for men. This research will evaluate participant recruitment and retention rates, treatment and intervention satisfaction and estimate intervention effect on A1C and self-management behaviors as well as on diabetes social support and diabetes distress. Your health-related information including A1C, height, weight, and blood pressure will be collected for this research study. This study involves a process called randomization. This means that the DSMES you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may discomfort during the finger prick at the health assessment, discomfort answering questions regarding diabetes self-management on questionnaires, and potential breach of confidentiality. More detailed information will be provided later in this document.

Although we cannot promise that you, personally, will receive any benefits from being in the study, we hope that you will benefit from the diabetes self-management training and support and be available to trained diabetes professionals and peer leaders who will assist you in managing your diabetes. This study may not offer any benefit to you now but may benefit others in the future by using the findings to improve care for men with diabetes in the future. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be about 15 months. Participation in this study is voluntary so the alternative is to choose not to participate.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this study is to understand the effectiveness of a gender specific peer leader approach to diabetes self-management support compared to enhanced usual care.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Individuals who wish to take part of the study must:

1) Have type 2 diabetes for six months or longer **and**
2) Be Black/African American **and**
3) Identify as male **and**
4) Be at least 21 years of age or older **and**
5) Have transportation to attend program activities **and**
6) Be under the care of a physician for diabetes **and**
7) Be willing to attend group delivered sessions.

3.2 How many people are expected to take part in this study?
64 total subjects from the metro Detroit area (30 in the peer leader intervention arm, 30 subjects in the enhanced usual care arm, and 4 subjects recruited and trained to be peer leaders for the intervention arm).

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
You will be randomized to the peer leader diabetes self-management education and support (DSMES) group or the enhanced usual care arm using a 50/50 randomization scheme (flip of the coin chance). You will be aware if you are in the DSMES group or the control group.

If you are randomized to the DSMES group, you will receive 10 hours of diabetes self-management education (DSME) over a 3-month period. The DSME will be delivered by a certified diabetes care and education specialists (CDCES) and co-facilitated by a peer leader (PL). After DSME, you will transition into 6 90-minute monthly DSMS sessions led by Peer Leaders. These sessions are intentionally designed for older Black men with type 2 diabetes. After DSMS, participants and peer leaders will transition into a 6-month period of ongoing support.

If you are randomized to the control group, will receive 10 hours of group delivered DSME provided by a CDCES; however they will not receive any DSMS or ongoing support from PLs and the PL will not participate in the DSME sessions.

All DSMES sessions will be held virtually, using the Zoom for Health platform. This is a U-M service that may be used for Protected Health Information (PHI).

All participants (including those in the control arm) will complete a health assessment at four different time points including at enrollment (baseline), then again at 3-, 9-, and 15-months. At every health assessment (4 total), each participant will complete one survey and have their blood pressure, hemoglobin A1C (an estimated average blood glucose), weight, and height measured. One drop of blood will be collected via finger stick to measure A1C. All data will be collected for research purposes by trained University of Michigan study staff. Height, weight, blood pressure and hemoglobin A1C will be measured in person at St. Patrick Senior Center or Ypsilanti Seventh Day Adventist Church while the survey will be completed in person, telephonically, or virtually. All participants will receive their lab results after each assessment session.

Your provider will be sent a copy of your health assessment measures after each assessment.

Randomly selected DSME and DSMS Zoom sessions will be recorded (audio and visual) for fidelity purposes. After the last health assessment, participants may be contacted and invited to participate in a focus group about the study intervention. Focus groups may also be recorded (audio).

4.2 How much of my time will be needed to take part in this study?
Although the total length of the study is three years, your participation will be for 15 months. We ask that participant complete all 15 months although there is no penalty for leaving the study at any time.

All participants will attend 4 health assessments, each taking approximately 1 hour each.

All participants will receive 10 hours of DSME delivered over a 3-month period. Each DSME session will be between 1 and 1.5 hours in length.

Participants randomized to the peer led DSMS arm, will also attend 9 hours of DSMS over a 6-month period with each session lasting 1.5 hours.

Participants that choose to participate in the focus group will also attend a 2-hour focus group session.

4.3 When will my participation in the study be over?
Your participation in the study will be over in about 15 months.

4.4 What will happen with my information and/or biospecimens used in this study?
Your biospecimens and collected information may be shared with the NIH.

With appropriate permissions, your biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

1. There is a small risk of some discomfort during the finger prick at the assessment sessions. There is also a small risk of dizziness and/or fainting from the finger prick procedure. The finger prick is done only for research purposes.
2. An additional risk is related to the series of questionnaires. Some participants find that certain questions or the information regarding diabetes self-management makes them uncomfortable.
3. There is a possible risk of breach of confidentiality; however, the likelihood of this risk is rare.

The researchers will try to minimize these risks by:

1. Only trained personnel will perform the finger prick to check your A1C level.
2. You can choose not to answer any question for any reason. You will can also talk with the research staff about any subject that is uncomfortable to you.
3. We will inform all participants that anything related to the study, or the participants of the study, must be confidential. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

We cannot promise that you, personally will receive any benefits from being in the study. If you are part of the peer leader intervention arm, we hope that you will benefit from the diabetes self-management education and support and the availability of trained diabetes professionals and peer leaders, who will assist you in managing your diabetes. Participants may also find it helpful to have their measurement results from the assessment sessions for both themselves and their doctor.

We hope that the findings of this study will be useful in improving care for all patients with diabetes in the future.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Participation in this study is voluntary so the alternative is to choose not to participate.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the

study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for all research-related items or services, including the A1C test, that are provided to you only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher’s telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan’s medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
Participants will receive a $50 cash, check, or gift card payment after each of the assessment sessions. These sessions will occur at enrollment, 3-month assessment, 9-month assessment, and 15-month assessment. If you remain in the study for the full 6 months and complete each health assessment you can receive up to $200 total.

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of this study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
Your research information will be kept in separate, locked research files with access limited to study staff only. Electronic files will be kept on secure, password protected servers with access limited to study staff only.

This research will be 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.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Demographic information
- Personal identifiers
- Medical records

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Jaclynn Hawkins, MSW, PhD
Mailing Address: 1080 S University Ave. Room 4708, Ann Arbor, MI 48109
Telephone: 734-764-3309
Study Coordinator: Katherine Kloss, MS
Mailing Address: 1080 S University Ave, Room 3603A, Ann Arbor, MI 48109
Telephone: 734-936-3773

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.*

12. SIGNATURE

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent to video/audio recording solely for purposes of this research

This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you cannot take part in the study.

_____ Yes, I agree to be video/audio recorded/photographed.

_____ No, I do not agree to be video/audio recorded/photographed.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my specimens for future research.

_____ No, I do not agree to let the study team keep my specimens for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____