Informed Consent Form

Leveraging peer support and vouchers for healthy food to increase engagement in diabetes prevention behaviors among low-income adults with prediabetes: the INSPIRing Action to Prevent Diabetes (INSPIRA) Intervention

NCT06001801

Approved 8.24.2023

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Leveraging peer support and vouchers for healthy food to increase engagement in diabetes prevention behaviors among low-income adults with prediabetes: the INSPIRing Action to Prevent Diabetes (INSPIRA) Intervention

Short study title: INSPIRA

Company or agency sponsoring the study: American Diabetes Association
Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Michele Heisler, MD, University of Michigan School of Medicine

Study Coordinator: Shelley Stoll, MPH, University of Michigan School of Medicine

1.1 Key Study Information

You may be eligible to take part in a research study to help evaluate new Community Health and Social Services (CHASS) programs to help patients prevent diabetes. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review it. After you finish, you should talk to the researchers about the study. Ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

This research is studying how to help people reduce their risk for getting diabetes. This research will compare participating in the Diabetes Prevention Program to participating in the same program plus two extra pieces. The first is getting matched with someone else in the program to provide each other support. The second is a chance to earn healthy food vouchers. Your health-related information will be collected for this research study.

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 prevent or 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

Consent Subtitle: _____
Consent Version: ___1_____

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. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

There can be risks associated with joining any research study. The type of risk may affect whether you decide to join the study. For this study, some of these risks may include no improvement of your risk of developing diabetes. More detailed information will be provided later in this document.

This study involves a process called randomization. This means that the program you participate in for the study is not chosen by you or the researcher. The study design divides participants into separate groups to compare different treatments or procedures. Which program you are assigned to is based on chance (like the flip of a coin). If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

This study may benefit you now or others in the future. You may learn how to eat better and move more. You may receive encouragement and support from others. More information will be provided later in this document.

We expect you will participate in the study for 6 months.

You can decide not to be in this study. Alternatives to joining this study include talking with your doctor about how to reduce your risk, seeing a nutritionist, and working on lifestyle changes on your own.

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:

People face many barriers to making changes in eating and physical activity that can help improve their health and prevent diabetes. The Diabetes Prevention Program (DPP) helps coach and support people to take steps to eat healthier, lose weight, and be physically active.

It is proven to be very effective in helping people prevent getting diabetes. We want to compare the DPP led by CHASS community health workers to a new program. This new program offers the same DPP plus more. In the new program, participants in the DPP get paired up to provide support and encouragement to each other between sessions. They also can earn healthy food vouchers for attending sessions and supporting each other. We want to learn whether these two programs can help patients here in our community.

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, you will not be penalized. You will not lose any benefits you are entitled to.

3.1 Who can take part in this study? Patients can participate in the study if:

- they are 18 years or older;
- and receive their healthcare at CHASS;
- and have a body mass index (BMI) of 25 or more;
- and have no prior diagnosis of type 2 diabetes;
- and have a recent blood glucose measure (A1c) that is higher than normal but not yet in the range of diabetes.

3.2 How many people are expected to take part in this study? We plan to recruit 142 patients who receive their care at CHASS.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you decide to take part in this study:

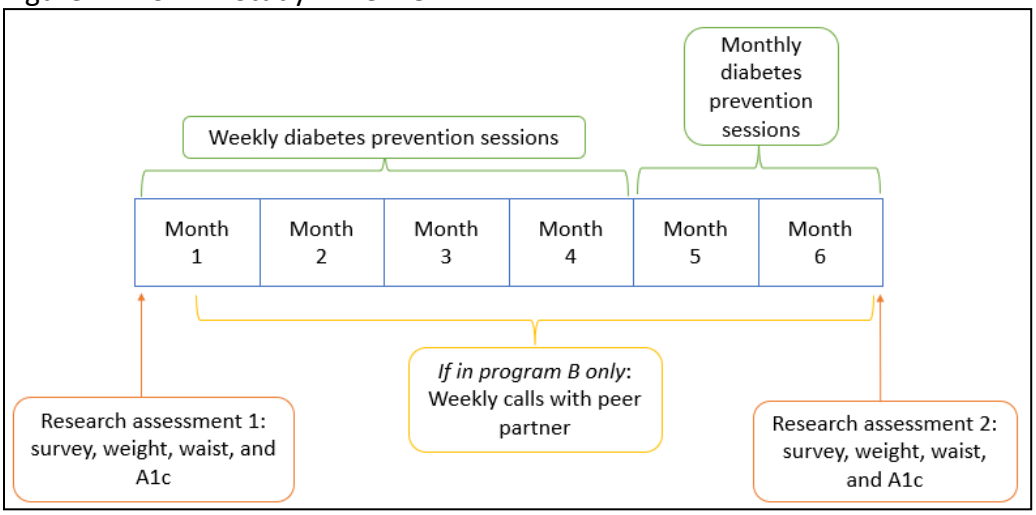
- You will be scheduled to come into CHASS to complete research assessment 1:
  - You will be asked to sign this consent form.
  - You will be asked to complete a survey at your enrollment visit. It usually takes about 25 minutes to complete.
  - You will be weighed, have your waist measured, and have your finger pricked to take a blood sugar test called an A1c.
  - You will be told the result of the A1c test and what it means. Based on the result of the A1c, you will be told whether you are eligible to continue participating in the study. You will be eligible if

your A1c is 5.7 to 6.4. If your result is 6.5 or higher, we will put a note in your health record for your provider so that they know.
    - If you are eligible, the researcher will randomly (like flipping a coin) put you into one of the two groups: Program A or Program B. You have a 50/50 chance of being assigned to either program.
    - You will receive $25 for completing the assessment, even if you are not eligible.
- You will meet with a Community Health Worker from CHASS to develop a personal plan to address your health care and social service needs. This typically lasts around 30 minutes.
- If you are in Program A:
    - Over the next 6 months, you will attend the Diabetes Prevention Program (DPP).
    - DPP will help you make healthy lifestyle changes. Examples are improvements in your eating and physical activity. The goal is that you lose some weight and reduce your risk of developing diabetes.
    - Each DPP session lasts 1½ hours.
    - You can attend each session in person at CHASS. Or, you can attend remotely using Zoom.
    - If you do not have a working scale to weigh yourself at home, we will give you a scale. It will be yours to keep even after the study
    - We may be able to provide transportation if you need it. You can bring your children if needed.
    - You will attend weekly sessions for the first 4 months (16), followed by two monthly sessions for the final 2 months (18 total).
    - At each session, you will get weighed. If you ever need to participate remotely, you will weigh yourself and share your weight with the staff person. Only the staff person weighing you will see or hear your weight. You will also share your logs that track your food and exercise.
- If you are in Program B:
    - You will do everything described for Program A above.
    - You will participate in an additional 30-minute session with the same Community Health Worker after each DPP group session.
    - You will be paired with another person in your DPP. You and your "peer partner" will be asked to call or text each other at least once a week. You will check in and provide each other with support to make changes.
    - If you are not comfortable sharing your phone number with your partner, study staff will assist you in setting up a way for you to

communicate with each other without sharing your phone number.
  - You will earn a $10 in healthy food voucher or grocery store gift cards each time you attend a session, in-person or remotely.
  - You can earn even more healthy food vouchers or gift cards if your peer partner also attends the sessions and you communicate with each other between sessions. Details about this and the food vouchers/gift cards are in section 8 of this document.

- All participants will be asked to complete another survey, get weighed, have their waist measured, and get another A1c test after 6 months. You will receive $25 for completing the assessment.
- We will also look in your medical record for information about your health. This includes: any more lab work and physical measurements, changes in your diagnoses; dates of your appointments; and your prescribed medicines.

Figure 1. INSPIRA Study Timeline



4.2 How much of my time will be needed to take part in this study?

Over 6 months, you can expect to spend between 30 and 43 hours. Most of this time will be time spent attending the Diabetes Prevention Program. Below are the times broken down by activity:

- Your enrollment visit will last between 1 and 1½ hours.
- Your visit with a Community Health Worker at CHASS will take about 30 minutes.

- There are 18 Diabetes Prevention Program (DPP sessions) that each last about 1½ hours.
- If you are assigned to Program B, you will also:
  - Attend the 30-minute sessions following the conclusion of the DPP session. There at 18 of these additional sessions.
  - Communicate with your peer partner for at least 10 minutes per week for about 22 weeks.
- Your final visit to complete a survey and get measured will likely last about an hour.

4.3 When will my participation in the study be over? About 6-7 months from today, if you sign this consent form and complete the assessments today. The Diabetes Prevention Program may not be offered by CHASS after the study.

4.4 What will happen with my information and/or biospecimens used in this study?
Your collected information may be shared with other researchers or with companies. The information may be used for other research studies. The information would not include anything that would let a person identify you. You will have the chance to "opt out" of this sharing later in this document.

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?

Risks		How researchers protect you
	You may feel some discomfort when your finger is pricked. There is a very small chance of infection.	We will clean your skin with alcohol, use gloves, and give you a band-aid. The prick may sting a little.
	You may feel uncomfortable getting weighed and having your waist measured.	You will be weighed and measured in private. The researcher will be sensitive to the fact that you may feel uncomfortable. If you prefer to measure your own waist, you can.
	You may feel uncomfortable when you respond to survey questions.	You can skip any survey questions that you feel uncomfortable answering.

	There is a small risk that your personal information could be seen by someone besides the research team.	Your personal information will be kept on secured computer files that meet the privacy standards that the University of Michigan research oversight board (IRB) has approved.
	If you are in Program B, you may feel uncomfortable talking with your peer partner.	You and your partner receive training and coaching on how to talk with your peer. You can contact the leader of your program if you have questions or concerns. You can be paired with someone else You won't be paired with someone of a different gender unless you say it's OK.

As with any research study, there may be risks that are unknown or unexpected. You may discontinue any study activity if it makes you feel uncomfortable.

We will work to keep your personal information private. But confidentiality cannot be guaranteed. We must keep the research records confidential following federal, state and local laws. All research data collected in this study will be stored according to the privacy and security guidelines set by the U.S. Code of Federal Regulations.

Signed consent forms and any other hard copies of research data will be kept in a locked file cabinet. This cabinet is behind a locked door at CHASS Center. All electronic files will be stored in folders and a server that are access restricted. Only authorized research staff will have access to the data.

Study researchers will analyze the data collected from this study. If the results of this study are reported in journals or at professional meetings, you will not be identified by:

- Name
- Recognizable photograph or
- Any other means without your specific consent.

No information that could identify you will be released or published unless required by law. Your health care provider may be informed if study staff learn of serious health conditions that need immediate attention.

After the study ends, we will share results with you directly. Your study data may be shared with researchers doing similar research, but only after all identifying information has

been removed. The data from the study may be shared indefinitely in a database that other researchers can access for their studies. By sharing data, researchers can learn more about preventing diabetes. If you do not want other researchers seeing or using information about you, you can opt out. To opt out, add your initials below:

☐ I do not want the researchers to share my information with other researchers. I understand that the information will not be linked to my name or anything else that identifies me.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

5.1 This is a low-risk study. The researchers have taken steps to reduce the risks of this study. They are described in the table on the previous page. Even so, you may still have problems. Please tell the researchers listed in Section 10 about any 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 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 at a time. If you want to enroll in another study, talk to the researchers from 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. Below are some benefits you may receive:

	You may learn new ways to improve your health and prevent diabetes.
	You may lose some weight and reduce your risk for diabetes.
	You may learn and practice new, effective ways to support others in their journey to become healthier. You may receive the same kind of support as well.

Also, others may benefit from the knowledge gained from this study.

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 information that may change your willingness to stay in this study. If this happens, you may be asked to sign a new consent form. The form would include the new information. If you are a woman and learn that you are pregnant, please tell the researchers. Participants who become pregnant cannot continue in the study.

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?

You can talk with your doctor about other ways to reduce your risk for developing diabetes. There are some medicines that can help. You can meet with a dietician or hire a personal trainer. You can join a weight loss program like Weight Watchers or Noom. You can also try to improve your eating habits and increase your physical activity on your own.

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 you are entitled to. 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 people 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, there are harms to you if you choose to leave the study.

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 because you become pregnant.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

Permission for Future Contact

In the future, we may want to contact you again to ask more questions. We may invite you to events where we share the data with the participants or community. (Note: You can still participate in the study, even if you do not want to be contacted in the future.) Please write your initials in one of the two boxes below.

	I agree that the researchers may contact me again in the future.
	OR
	I do not agree to have researchers contact me again in the future.

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?

There are no costs or billing for this study. 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?

Yes, you will be paid. All participants:

- will be paid $25 in a Visa gift card each time you complete an assessment visit. The visit includes a questionnaire, getting weighed, having your waist measured, and getting an A1c test. You will complete two assessment visits. This is a total of $50.
- Will be given a scale to weigh yourself if you do not have one at home.

If you are put in program B:

- You will also have the chance to earn a $10 food voucher or grocery store gift card every time you attend a Diabetes Prevention Program (DPP) session. There are 18 DPP sessions.
- The food vouchers will be good for purchasing produce and other healthy food. They can be used at the farmer's market at CHASS/CHASS Mercado (when in season), and a local grocery store.
- You are paired with your peer partner at the third DPP session. After that, if you both attend a session AND speak for at least 10 minutes using the study's phone system in that same week, each of you will receive an *extra* $10 food voucher or grocery store gift card that week.
- In the last two months of the study, you will attend just one DPP session

per month. During the weeks of the DPP session, you can earn up to $20 in food vouchers or grocery store gift cards each week. During the weeks without a session, you can earn a $10 voucher for each week that you and your partner provide support to each other and complete a worksheet about your conversation .

- If you and your peer partner attend all 18 DPP sessions, and you talk with your peer partner weekly during the 6 months of the study, you will receive a total of $390 in food vouchers or grocery store gift cards, plus $50 in Visa gift cards for the two assessment visits that all participants may receive.

8.3 Who could profit or financially benefit from the study results?

No person or organization has a financial interest in the results of this study. Research can lead to new discoveries, such as new tests or programs. Researchers, their organizations, and other organizations, including companies, may benefit from research 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

As part of this research study, we request your authorization (permission) to review your medical records to:

- compare your earlier test results to the findings from this study; and
- if possible, use your previous exam results in place of, or in addition to, some of the exams needed for this study.

Health Information We May Collect

diagnoses
demographic information
vital signs
prescriptions
preferred language
past medical history
diagnostic procedures
visits with CHASS providers

We will collect the information listed in the box as well as results of blood tests that were done as a part of your standard CHASS Center medical care.

9.1 How will the researchers protect my information?

- Your personal information will be kept on secured computer files that meet the privacy standards that the University of Michigan human subjects' protection group has approved.
- We will maintain a link between your name and contact information with your research information during the study.
- When the study ends, the research records will be kept in a separate research

file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you.
- The publication(s) of results from this study will not identify you.
- Section 5 of this form has more details about how your information is protected

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. This Web site 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.

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.

Your medical information and the information obtained during this study may be shared with other groups. This may include authorized officials from the University of Michigan's human subjects' protection group. They make sure studies are done safely and properly. Authorized people from CHASS Center or affiliated health care providers may also have access to this information. They may use it to provide services and address billing and operations issues.

We cannot guarantee the confidentiality of your research records after it is shared with others outside CHASS or the University of Michigan. This may include information from your medical records.

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:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records
- Alcohol/substance abuse treatment records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

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
- 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 it 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?

You can always withdraw your authorization (permission) to allow the research team to review your medical records. To do this, contact the investigator listed in Section 10. Make the request in writing. If you do this, you will no longer be allowed to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.

9.4 When does my permission to use my PHI expire?

This identifiable medical record information will be available to the research team for 18 months after the date you sign this form. You may cancel your permission at any time by writing to the researchers listed in the next section. 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
- 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: Michele Heisler, MD
Mailing Address: 2800 Plymouth Rd., Building 16-306E; Ann Arbor, MI 48109 Telephone: (734) 845-3614

Study Coordinator: Shelley Stoll, MPH
Mailing Address: 2800 Plymouth Rd., Building 16-306E; Ann Arbor, MI 48109 Telephone: (734) 232-0697
scstoll@med.umich.edu

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 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 a copy of this "Consent to be Part of a Research Study" document. In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.

12. SIGNATURES

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):

_____