Comparative Effectiveness of Family vs. Individually Focused Diabetes Education and Support

Consent Document – English

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Consent to Be a Participant in a Research Study

Study Title: Comparative Effectiveness of Family vs. Individually Focused Diabetes Education and Support

Sponsoring Agency: The National Institutes of Health

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1. Introduction

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

You do not have to take part in this study unless you want to. Your participation is your choice. You will still receive your usual care from CHASS Center whether you participate or not. The information below will help you weigh the possible risks and benefits of enrolling in the study.

Please take time to review this information carefully. If there are any words you do not understand, feel free to ask us. After you have finished, you should talk to the researchers about the study and ask them any questions you have. The researchers will be available to answer your current and future questions. You may also wish to talk to others (for example, your friends, family, or other healthcare providers) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. **Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.**

2. About This Study

2.1 Study Purpose and Overview

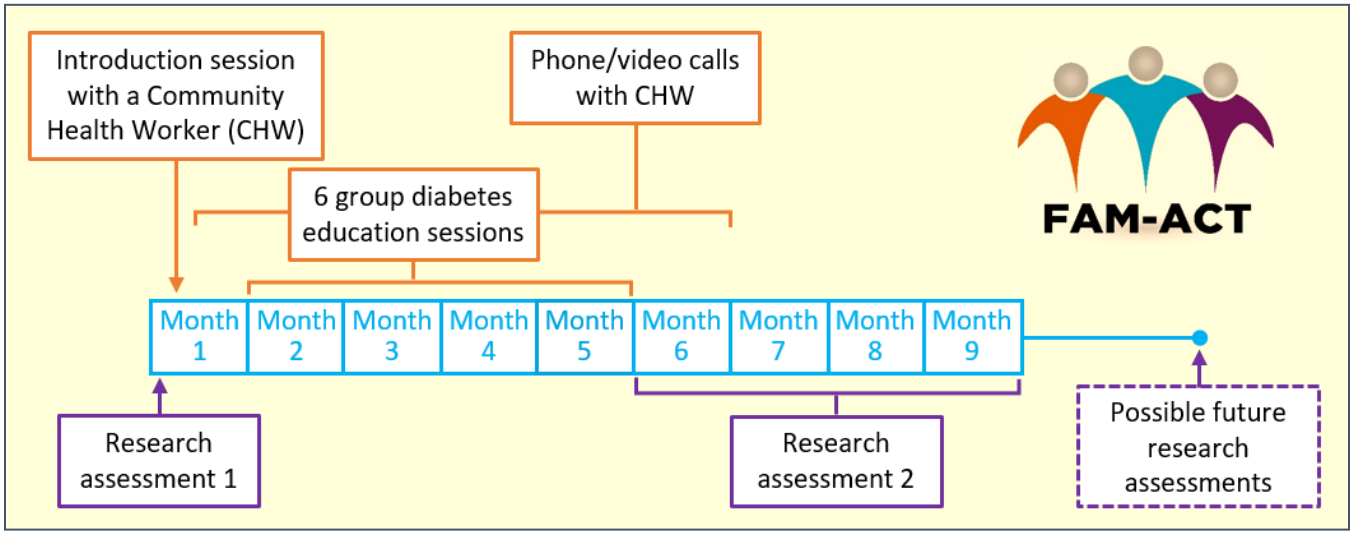
Researchers from the University of Pittsburgh will work with CHASS Center to offer two programs to adults with type 2 diabetes and at risk for diabetes complications. The purpose of this study is to compare how these two programs 1) help you improve your blood sugar control and health habits, and 2) lower your risk for diabetes complications. Your participation in the study would last between 6 and 9 months.

We plan to enroll about 270 patients with diabetes. We will also ask each patient to identify a family member or friend who supports them in managing their diabetes. We will then invite that person to join you in participating in this study. We call these family members or friends **Support Persons**.

If you decide to participate in this study you will:

- Attend an **Introduction Session** with a Community Health Worker (CHW).
- Attend between 4 and 6 group **diabetes education sessions** over about 3 months, each lasting between 45 minutes and 2 hours.
- Complete **2 research assessments**: One at the beginning of the study and one at the end, 6 to 9 months later. Each assessment will last about 1 hour. *If the study is still active, we may contact you 12-15 months after you were enrolled in the study to invite you to complete an additional assessment*.
- You also may receive occasional phone/video calls from your CHW while you are participating in the study.

The picture below shows the schedule you will follow.



3. Information About Study Participation

3.1 Study Interventions

When you register and complete the first assessment, you and your Support Person will be randomly assigned to be in one of two groups: either **Program A** (Individual Focused) or **Program B** (Family Focused). No matter what program you are in, you will continue to receive the usual care from CHASS Center in addition to the program.

Program A: Individual Focused

If you are assigned to Program A, we will ask you to follow the schedule described in the picture above. Below are more details about Program A.

- Education sessions will talk about different parts of diabetes management.
- During the phone/video calls or visits with your CHW you will discuss:
    - Any changes in your health or diabetes status
    - Your health goals
    - Your next medical appointment

We will ask you to participate in as many of these sessions and phone calls as possible. In this program, your Support Person can choose to participate in these sessions or phone calls. But they will not get separate advice on their role in your diabetes care.

Program B: Support Person Focused

If you are assigned to Program B, we will ask **you and your Support Person** to follow the schedule described in the picture above. Below are more details about Program B.

- Education sessions will talk about different parts of diabetes management, and **how your Support Person can help with diabetes management**.
- During phone/video calls or visits with your CHW you will discuss:
    - Any changes in your health or diabetes status
    - Your health goals
    - Your next medical appointment

Your Support Person will be invited to join in these sessions, phone calls and visits. The CHW may discuss their role in supporting your diabetes management.

3.2 Study Assessments

You will complete a questionnaire during each research assessment. A research assistant also may test your blood sugar, measure your weight, and take your blood pressure.

Questionnaires

We will ask you questions about:

- Your physical and emotional health, and health habits
- The support you receive from family and friends
- Your use of health care services

Fingerstick blood samples

We will test your blood sugar (A1c) using one drop of blood, obtained by pricking your finger. A research assistant may test your A1c and possibly lipids at the CHASS Center. There are a couple of other ways that we might collect A1c information.

- Your health care provider may want you to have your A1c checked around the time for your next study assessment. If so, we will use the results of the tests your health care provider ordered for you.
- In some cases, our study staff may make the appointment for you. **You or your insurance company may have to pay for this test if your health care provider wants you to have it done as part of your regular medical care.**
- If you can't come to the CHASS Center to get your blood tests at the time of your next study assessment, we may be able to send you supplies so that you can collect a fingerstick blood sample at home. Neither you or your insurance company will be billed for the supplies or testing.

Blood Pressure and Weight

When we measure your blood pressure and weight we will:

- Take your blood pressure twice with a digital monitor
- Ask you to remove your shoes, and measure your weight on a digital scale

Patient Information

The research team will look at your CHASS Center medical records to review your use of health services, prescriptions, and lab results. This information will be taken:

- One year before your registration date
- The 6-9 months during your participation in the study
- One year after you finish the study

3.3 Audio Recordings

Some education sessions, phone/video calls and surveys will be audiotaped to see how well the research staff is following the study protocol. These tapes will be used for quality assurance purposes only. These recordings are voluntary, and you will be asked for your permission ahead of time. If at any time you do not want to be recorded, you can still

participate in that activity and in the study. Even after you agree to a recording, you may ask that the recorder be turned off at any point. Audio recordings will be kept confidential. Only approved research staff will have access. Audio recordings will be destroyed after they are reviewed by study staff.

4. Information About Study Risks

The activities in this study may cause all, some, or none of the risks listed below.

	**Fingerstick blood tests:** pain from the needle stick, this is usually minor and brief. Sometimes bruising, swelling or redness of the skin, and on very rare occasion, infection.
	**Body measurements:** embarrassment when measuring weight.
	**Questionnaires:** minor discomfort in answering questions that are personal in nature. You may refuse to answer any question.
	**Confidentiality:** There is a rare risk that a breach of confidentiality may occur. Every effort will be made to prevent this from happening.
	**Hyperglycemia** (high blood sugar) or **hypertension** (high blood pressure): Rarely, in the process of changing self-care activities, blood sugar or blood pressure may temporarily rise to levels higher than recommended. In this case, participants may: • Have headaches, blurry vision and increased fatigue • Feel chest pain, difficulty breathing and irregular heartbeat
	**Hypoglycemia** (low blood sugar) or **hypotension** (low blood pressure): If participants try to lower their blood sugars or blood pressure to recommended levels, they may: • Temporarily be at levels that are too low • Feel lightheaded, dizzy, sweaty, and rarely have minor confusion

Very rarely, low sugar or blood pressure levels can be so severe that a participant will lose consciousness. This program advises slow, careful changes to health habits to reduce these risks. We will teach participants how to know if their sugars or blood pressure is low, and how to manage that situation.

However, in this study our goal is to help people keep their blood sugar and blood pressure at safe levels.

If you are assigned to **Program B**, the study may share some of your health information with your Support Person. This information would include:

- Diabetes-related health numbers such as Hemoglobin A1c, blood pressure, and lipids
- Medications prescribed by your CHASS Center healthcare provider
- Appointments scheduled at CHASS Center

If you feel uneasy sharing this personal information you can ask us to stop sharing this information with your Support Person at any time.

Your participation in this study may strain your relationship with your Support Person. However, the intent of the program is to:

- Better support people with diabetes and their family members
- Decrease their diabetes-related stress, and
- Improve diabetes-related communication between the patient and their family members

5. Information About Study Benefits

5.1 Possible Benefits

	You may learn new ways to handle concerns related to managing your diabetes
	You may improve your blood sugar or blood pressure control
	Your Support Person may learn about diabetes and how to help support you and help you stay as healthy as possible

There is no guarantee that you will receive these benefits. Your participation in this study may help others understand how to help people manage their diabetes and stay healthy.

6. Privacy & Confidentiality of Subject Records

Here is how your privacy and the confidentiality of your research records will be protected:

6.1 CHASS Center

Once a year, a Notice of Privacy Practices is given to patients. How a patient's medical information may be used and revealed, and how a patient can get their medical information is described in this notice.

6.2 University Researchers

We will strive to keep your personal information private. But confidentiality cannot be guaranteed. We will work hard to prevent a loss of confidentiality. 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.

Your identity is linked to your study assessment data by a case number and not by name. The information linking case numbers and your name is kept separate from these research records. The only people who may look at your identifiable information are:

- The investigators listed on the first page of this form and research staff members.
- Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office. They may monitor the conduct of this study. We must keep research records for 7 years after the final project report.

Printed copies of all research data and signed consent forms will be kept in a locked file cabinet, behind a locked door at CHASS Center. All electronic files will be stored in folders and server that are access restricted. Only authorized research staff will have access to the data. Audio recordings will be kept confidential and only authorized research staff can access them. We will do everything possible to protect your privacy and confidentiality. But confidentiality is not guaranteed since no electronic storage or information sent over the internet is perfectly secure.

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 by which you can be identified will be released or published unless required by law. Your health care provider may be informed if study staff learns of serious health conditions that need immediate attention, with your consent.

After the end of the study, 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. All general study information and results will also be posted at ClinicalTrials.gov, which you and the public can view at any time.

6.3 Online Communication Using a HIPAA-Compliant Video Chat Program

We may ask you to take part in study activities by phone/video call or online using a video chat program. To help protect your privacy, we will use a program that is HIPAA compliant. "HIPAA Compliant" means that the program protects personal information so it is safe enough for health care providers to use when talking to their patients.

Only the people who are invited to the online call will be sent information on how to join it. We will email this information to you or send it to you in a text message. Also, all online calls will be password-protected, and only the FAM-ACT team member on the call will be allowed to share their screen. Taking these steps will make it harder for someone who is not invited to join the call.

To further protect your privacy during the diabetes education classes, we will ask all participants to attend the class in a private place where there is little chance that someone else will enter the room. Even so, we can't guarantee that only study participants and FAM-ACT team members will be present during the class.

6.4 Mandated Reporting of Abuse

If the investigators learn that you, or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Michigan law.

Current Michigan law requires certain licensed professionals to report abuse or suspected abuse of adults and children. These laws do not distinguish between information gained through the role required to report and information gained as a researcher. It is the researcher's license, registration, or certification that drives the requirement.

The reporting individual will make immediately, by telephone or otherwise, an oral report or cause an oral report to the Michigan welfare department. Within 72 hours after making the oral report the reporting person shall file a written report as required by Michigan law.

A person who is employed as any of the following is required to follow all of the Michigan mandated laws: licensed, registered, or certified to provide health care, education, social welfare, mental health, or other human services or an employee of any agency licensed to provide health care, education, social welfare, mental health, or other human services. Physician, physician's assistant, nurse, person licensed to provide emergency medical care, psychologist, therapist, licensed professional counselor, social worker, licensed master's social worker, licensed bachelor's social worker, registered social service technician, social service technician, school administrator, school counselor or teacher, law enforcement officer, member of the clergy, or regulated child care provider.

7. Ending the Study

7.1 Alternate Courses of Action

If your provider is an investigator in this study, you may discuss your care with a healthcare provider who is not in the study. You do not have to participate in any study offered by your provider. You may choose to not be in this study and continue your current/usual care for diabetes at the CHASS Center.

7.2 New Information

We will tell you right away if we find information that may cause you to want to quit the study.

7.3 Withdrawal from Study Participation

You can leave the study at any time, even after signing this form. To quit the study, please contact Dr. Ann-Marie Rosland or Gloria Palmisano at the telephone numbers listed on the first page of this form. The data that you provided before leaving the study will be kept. Your decision to leave the study will not impact your medical care at CHASS Center or your relationship with a health care provider.

7.4 Reasons We May Withdraw You from this Study

The researchers may need to end your participation in the study without your consent for the following reasons:

- The study team thinks it will be in your best interest not to participate
- The study is suspended or canceled
- Threatening, violent or harassing behavior towards study staff
- You are put in jail or placed on parole during your participation period
- You become pregnant during your participation period

8. Financial information

8.1 Cost

There are no health-related costs or billing for this study.

8.2 Payments:

You will receive a $50 gift card for each of the 2 assessments you complete, for a possible total of $ 100 in gift cards during the 6-9 months you will be participating in the study. If you are invited to complete an additional assessment later, you will receive an additional $30 gift card if you complete it.

8.3 Injury:

CHASS Center does not provide compensation for injury.

9. HIPAA Authorization for Disclosure of Protected Health Information

As part of this research study, we are requesting your authorization or permission to review your medical records to

- determine whether you meet the conditions for participation in this study;
- 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.

This authorization is valid for an indefinite period.

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 above, as well as results of blood tests that were done as a part of your standard CHASS Center medical care.

As part of this research study, some information that we obtain from you will be placed into your medical records held at CHASS, including that you are participating in this study, your Support Person's name, and results of the fingerstick blood tests we perform for this study.

This identifiable medical record information will be made available to members of the research team for an indefinite period of time.

Your medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the National Institute of Health (NIH) and the University of Pittsburgh Research Conduct and Compliance Office, for the purpose of monitoring the study. Authorized representatives of CHASS Center or affiliated health care providers may also have access to this information to provide services and addressing billing and operational issues.

We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside CHASS or the University of Pittsburgh.

You can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.

10. Consent to Participate in Research Study

10.1 Voluntary Participation:

Taking part in this study is completely voluntary. You do not have to participate if you don't want to. If you do, or do not, agree to participate in this research study the services you receive from CHASS Center will not be reduced or affected in any way. You can sign this form and still decide not to participate later. 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.

10.2 Consent to Participate:

The information printed on this form has been explained to me. All of my current questions have been answered. I understand the following:

- The risks and benefits of participating in this study.
- I may ask questions, voice concerns or complaints about any part of the research during this study.
- I agree for you to re-contact me about this study or related studies over the next 5 years.
- Questions, concerns or complaints will be answered by research staff. Or, by the investigators listed on the first page of this form at the telephone numbers given.
- I may ask that my questions, concerns or complaints be addressed by an investigator.
- I may express a concern about a study by contacting the Human Subjects Protection Advocate of the Institutional Review Board by calling the University of Pittsburgh at 1-866-212-2668.

Research Subject Signature:

By signing this form, I agree to participate in this research study and provide my authorization to share my medical records with the research team. I understand that I will receive copy of this form once I sign it.

_____ _____

Participant's Signature Date

_____ _____

Participant's Printed Name Phone Number

Principle Investigator (or Designee) - Certificate of Informed Consent:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. I further certify that no research component of this protocol was begun until after this consent form was signed. Any questions the individual(s) have about this study have been answered, and a member of the research team will always be available to address future questions, concerns or complaints as they arise.

Signature of Person Obtaining Consent	Role in Research Study
Printed Name of Person Obtaining Consent	Date