Informed Consent

Study Title: Mindfulness-Based Diabetes Education for Adults With Elevated Diabetes Distress

Identifier: NCT05195138

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CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: Mindfulness-Based Diabetes Education for Adults with Elevated Diabetes Distress – Pilot Study

UAB IRB Protocol #: IRB-300008617

Principal Investigator: Caroline Presley, MD MPH

Sponsor: National Center for Complementary and Integrative Health

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to conduct a pilot randomized controlled trial comparing Mindfulness-Based Diabetes Education to Diabetes Self-Management Education in adults who have type 2 diabetes with blood sugar levels above target range and high diabetes distress. The purpose is to evaluate if the program is acceptable to participants and if it is feasible to deliver.
Duration & Visits	You will be in this study for up to 6 months. During the study, you will be asked to attend 3 study assessment visits, 8 group meetings for program sessions, 2 individual booster sessions, and (for some participants) 1 focus group. Study assessment visits will be completed at distinct times in the study (at time of enrollment, 2 months, and 6 months. Each study visit will last approximately 45-60 minutes, and participants will be asked to complete a questionnaire, as well as height, weight, blood pressure, and point-of-care hemoglobin A1c measurements by finger-stick sample. Some participants will be asked to attend one focus group after 2 months in the study. The focus group will take approximately 60 minutes, and participants will be asked for their thoughts and feedback on the program. This study will provide two programs called Mindfulness-Based Diabetes Education and Diabetes Self-Management Education. Both programs will include 8 weekly meetings occurring in-person in a group setting and lasting for 2 hours. Sessions will focus on education and ways to improve diabetes self-management including healthy eating, physical activity, medication taking, self-monitoring, and will also include instruction and stress reduction practices. After completing the 8 week program, participants will have 2 individual additional sessions occurring in months 4 and 6 of the study.
Overview of Procedures	This study will include 3 study visits and for some participants a focus group that will be run by a trained facilitator to get participants' feedback. If you are eligible and choose to participate, you will be randomized to receive Mindfulness-Based Diabetes Education program or Diabetes Self-Management Education.
Risks	The most common risks include breach of confidentiality, inconvenience, or emotional distress. You may experience minor pain or discomfort related to study activities; this is a minor risk and is reversible.
Benefits	You may or may not benefit from the study. This research may help develop an intervention and benefit future patient care.
Alternatives	Your alternative is not to participate in the research.

Purpose of the Research Study

We are asking you to take part in a research study to reduce stress and improve diabetes self-management in adults who have type 2 diabetes. Alabama is ranked 2nd for diabetes among all 50 states in the United States which means about 15% of people in the state have diabetes. Diabetes distress is common with adults with type 2 diabetes and impacts diabetes self-management and blood glucose (blood sugar) control. Currently, programs that improve both diabetes distress and diabetes self-management are lacking.

This study will include a pilot randomized controlled trial of Mindfulness-Based Diabetes Education versus Diabetes Self-Management Education in adults who have type 2 diabetes with blood sugar levels above the target range and high diabetes distress. The purpose is to evaluate if the program is acceptable to participants and if it is feasible to deliver. Participants' input will be used to inform a future, larger study of the intervention. This study will enroll up to 96 participants by the University of Alabama at Birmingham in conjunction with Cooper Green Mercy Healthcare Services Authority (CGMHSA) and Alabama Regional Medical Services (ARMS).

Study Participation & Procedures

You have been screened and are eligible to participate in this research study. *Eligibility*: To be eligible to participate in this study, you need to complete a prescreening questionnaire, be 19 years of age or older, have a diagnosis of type 2 diabetes, receive care at CGMHSA or ARMS, have elevated diabetes distress, and a hemoglobin A1c of 7.5% or higher. Participants who are non-English speaking, currently pregnant, or have a diagnosis of severe psychiatric comorbidity are not eligible to participate.

During the 6 month study, you will be asked to attend 3 study assessment visits, 8 group meetings for program sessions, 2 individual booster sessions, and (for some participants) 1 focus group.

Activity	**Activity Schedule**
Program sessions	Months 1-2: 8 weekly group sessions Months 3-6: 2 individual booster sessions
Study assessment visits – 3	1. Enrollment assessment visit
	2. 2 month assessment visit
	3. 6 month assessment visit
Focus Group – 1	1. Focus group at 2 months (for participants randomized to Mindfulness-Based Diabetes Education)

To enroll in this study, a questionnaire will be conducted, as well as height, weight, blood pressure, and point-of-care hemoglobin A1c measurements by finger-stick sample. If you decide to participate in this study, you will attend a total of 3 study assessment visits including today's visit. The study visits will take place at the beginning of the study, at 2 months, and at 6 months. These visits will last about 45-60 minutes and take place in a private room at CGMHSA, ARMS, or Medical Towers at UAB. Questionnaires include self-reported measures of your mood, stress, thoughts and feelings about managing diabetes, social support, diabetes self-management behaviors, and satisfaction or burden related to diabetes treatment. The following measures will be collected by trained research staff at each study assessment visit:

Measure	**Description**
Questionnaire	Questions about your mood, stress, thoughts and feelings about managing diabetes, social support, diabetes self-management behaviors, satisfaction or burden related to diabetes treatment
Biometric Measures	Study staff will obtain height, weight, and blood pressure measurements
Hemoglobin A1c	Study staff will complete hemoglobin A1c testing using a point-of-care test and fingerstick blood glucose sample.

Participants randomly assigned to Mindfulness-Based Diabetes Education will also be invited to attend one focus group. The focus group will be held at the completion of the 2-month program and run by a trained facilitator. It will last approximately 60-minutes and will ask for participants' feedback on the program.

If you decide to participate, you will be randomly assigned to receive the Mindfulness-Based Diabetes Education or Diabetes Self-Management Education program. Study staff will randomize participants to one of the two groups using computer-generated sequence. Mindfulness-Based Diabetes Education is a new program that combines Mindfulness-Based Stress Reduction and Diabetes Self-Management Education. Diabetes Self-Management Education is an existing evidence-based program. If you enter and complete this study, you will be in this study for a total of 6 months. The programs will be held in 8 weekly, in-person, group meetings run by a trained interventionist. You will receive a schedule at the beginning of the program with the sessions outlined. Approximately 10-15 participants will be assigned to each group.

Group meetings will be held in person in a conference room at CGMHSA, ARMS, or at Medical Towers at UAB. Meetings will last approximately 2 hours each. Group sessions will focus on education and discussion about on healthy eating, physical activity, medication taking, self-monitoring, preventing complications to improve diabetes management, as well as stress reduction and management techniques. A trained interventionist will deliver each session. Between each weekly session, participants will be asked to complete home exercises focused on stress reduction and will work towards a goal focused on improving diabetes self-management. The 2 individual booster (additional) sessions will be conducted by phone with the interventionist and participant. If you agree to join the study, the study will not make any changes to your medications.

Risks and Discomforts

The risks for this study are low. You will be assigned to a group by using computer generated randomization, which may prove to be less effective or to have more side effects than the other study group or alternatives. If you enter this study, you will be asked to attend group meetings that focus on skills to reduce stress and improve your diabetes self-management. Risks include discomfort, a loss of confidentiality, minor pain, and inconvenience. You may feel some discomfort in talking about personal health issues, emotional distress, or diabetes management. You will only be asked to discuss what you feel comfortable sharing and you may choose not to share. Study staff will explain to all participants that what is said in group meetings is confidential. However, a risk for entering this program is loss of confidentiality. This risk is very small, as study staff follow rules to make sure your information is shared only with people who are supposed to have it. We take precautions to minimize the risk of loss of confidentiality including storing study information with a code only, there is no participant's name or other identifying information. Access to study information will be restricted to study personnel. Study information will be stored electronically on a secure, encrypted, password protected server. Program sessions will be audio-recorded to assess fidelity of the program; names or other identifying information will be removed from the transcripts and only study staff will have access to these.

You will be encouraged to make changes to your habits around your diabetes self-management (including healthy eating, physical activity, self-monitoring, medication-taking, prevention of complications) as well as to use new techniques to reduce stress. You may feel tired or hungry when you first make these changes, but this is usually mild and often gets better with time. This study will include gentle, non-strenuous physical activity including walking and gentle stretching. Participants will be offered modifications based on their physical abilities. You could hurt yourself when exercising, such as spraining your ankle. On rare occasions, increased exercise can cause chest pain and undue shortness of breath. This is not common, and you will only be asked to make changes that are comfortable for you.

Over 6-months, you will be asked to attend 3 study assessment visits, 8 group meetings, 2 individual booster sessions, and 1 focus group (for participants assigned to the Mindfulness-Based Diabetes Education program). These study activities may be inconvenient and take time from your day-to-day activities. You will be assigned to the study program, which may prove to be less effective than alternatives.

Benefits
If you participate, you may experience reduced stress and improved diabetes self-management. Improved diabetes distress and diabetes self-management behaviors have benefits for diabetes outcomes and reduced risks of complications due to diabetes. You may or may not directly benefit from participating in this study.

Alternatives
The alternative to study participation is that you may choose not to take part at all. There are other available diabetes self-management education programs that are not associated with this research study. You may discuss these alternative treatment options with your primary care provider.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes
Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

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

Who may use and give out information about you?
Information about your health may be used and given to others by Dr. Caroline Presley, the study doctor, and study staff. They might see the research information during and after the study.

Who might get this information?
All Individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- the UAB Diabetes Research Center, a sponsor of this research
- National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK), a sponsor of this research
- the University of Alabama at Birmingham - the physicians and staff working on the research study (whether at UAB or elsewhere); the UAB IRB and its staff

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal
Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.
You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. Contact the study personnel if you want to withdraw from the study.

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

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 National Center for Complementary and Integrative Health 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 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.

Cost of Participation
There will be no cost to you for taking part in the study. The program and visits related to this study will be provided to you at no cost during the 6-month study period.

Payment for Participation
You will be paid $25 for the completion of each of the 3 study assessments including questionnaire, as well as height, weight, blood pressure, and hemoglobin A1c measurement. Focus group participants will receive $15 for their attendance. The total payment you may receive is $90. If you do not finish the entire study, you will only be paid for visits completed up to the time you decide to stop taking part in the study. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

Payment for Research-Related Injuries
UAB and National Center for Complementary and Integrative Health have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings
You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions
If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. Caroline Presley at 205-934-7609.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights
You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant	Date
Signature of Person Obtaining Consent	Date