Preventing Diabetes in the Deep South: Extending Partnerships and Adapting Interventions to Reach Rural Communities at High Risk

Principal Investigator: Andrea L. Cherrington, MD, MPH

Sponsor: NIH/NIDDK

National Clinical Trial (NCT) Identified Number: NCT04343872

Appendix A

CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: **Preventing Diabetes in the Deep South: Extending Partnerships and Adapting Interventions to Reach Rural Communities at High Risk**

UAB IRB Protocol #: IRB-300005012

Principal Investigator: Andrea L. Cherrington, MD MPH

Sponsor: National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK)
UAB Diabetes Research Center

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 gain a better understanding of how possible it is to provide a diabetes prevention program to adults living in rural Alabama at high risk of developing type 2 diabetes and to look at different ways to improve program delivery. This information will be used to create an intervention specifically for adults living in Alabama at high risk for developing type 2 diabetes.
Duration & Visits	You will be in this study for up to 14 months. You are being asked to attend 3 study visits – Enrollment, 6-month, and 12-month study visit. Each visit will take from 60 to 90 minutes where you will do study measures like body weight plus a questionnaire to learn more about you and your daily habits. This study will provide a diabetes prevention program called PreventT2 to help you make changes to reduce your risk for developing type 2 diabetes. PreventT2 is 12-month online lifestyle change program with weekly meetings for the first 6 months and then once or twice a month for the second 6 months. Classes will focus on healthy eating, strategies to lose weight, be more active and manage stress. You will also work with a peer coach who will help you put the skills you learn into practice.
Overview of Procedures	This study will include a questionnaire that will be administered by study personnel and measures like body weight, height, blood pressure, and a point-of-care hemoglobin A1c measurement by finger-stick sample. If you are eligible and choose to participate, you will be assigned to receive one of the two peer-led online lifestyle change programs for the prevention of type 2 diabetes called PreventT2 where you will work with a Peer Coach. Based on your primary care office, you will be assigned to: 1) peer-led lifestyle change program for weight loss or 2) peer-led lifestyle change program for weight loss and receive a metformin therapy recommendation.
Risks	The most common risks include breach of confidentiality, inconvenience, or emotional distress. You may experience minor pain, discomfort, or bruising at the site of the finger-stick; 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 prevent type 2 diabetes. Alabama is 3rd for diabetes among all 50 states in the United States which means about 14% of people have diabetes. Diabetes can be delayed or prevented for some people by making changes to their lifestyle. People at high risk for developing diabetes, often have prediabetes. Prediabetes is when a person has higher than normal blood sugars but do not yet have diagnosed diabetes. Almost 37% of people living in Alabama have prediabetes (higher than normal blood sugars). Lifestyle interventions that include weight loss, increasing physical activity, and changing eating habits have been shown to prevent diabetes among some people. This study will compare two lifestyle interventions for weight loss in primary care offices for prevention of type 2 diabetes among adults with prediabetes.

Although primary care offices can provide recommendations to change lifestyle and weight loss treatment, they often don't have the time or resources to provide targeted weight loss counseling and diabetes prevention classes. We are studying program strategies to deliver diabetes prevention education in rural areas to compliment primary care efforts. People who enter into the study will take part in an online diabetes prevention program called PreventT2 that provides peer support and education on healthy eating, physical activity, weight loss, and stress management. Peer support will be provided by a peer coach who is a trained person from the community that will work with you and others in this study. Primary care offices will be assigned to participate in either a *peer-lead PreventT2 program* or a *peer-lead PreventT2 program with metformin therapy recommendations*. This information will be used to create an intervention specifically for adults living in Alabama at high risk for developing type 2 diabetes. This study will enroll 100 participants by the University of Alabama at Birmingham in conjunction with four primary care clinics in rural Alabama.

Study Participation & Procedures
You have been screened and are eligible to participate in this research study. To enroll in this study, measures of your height, weight, blood pressure, and questionnaires will be conducted. If you decide to participate in this study, you will attend a total of three study assessment visits including today's visit. These visits will take place at the beginning of the study, and at month 6, and at month 12. These visits will last about 60 to 90 minutes and take place at your primary care office. Some of this information can be collected by telephone. Questionnaires include self-reported measures of your quality of life, physical and social functioning, mood, dietary intake, physical activity, healthcare utilization, treatment satisfaction/burden, side effects, self-efficacy, social support, and perceived stress.
The following measures will be done by trained research staff at each study assessment visit:

Measure	**Description**
Body weight, height	Digital scale (weight) and measuring stick (height)
Blood pressure	Automated blood pressure machine with arm cuff
Point of care hemoglobin A1c test	A test that measures your A1c (average blood sugars over 3 months) by trained study personnel using a finger-stick sample
Questionnaires	Questions about your health, eating and exercise habits, attitudes about weight loss, and side effects (these may be collected by phone)

Eligibility: To be eligible to participate in this study, you need to complete a prescreening questionnaire, be 19 to 65 years of age, have a body mass index over 30 kg/m2 and a point of care hemoglobin A1c test results of 6.0% to 6.4%, and meet eligibility requirements. A research staff member will assess your eligibility.

If you decide to participate, you will be assigned to receive one of the two peer-led online lifestyle change programs based on your primary care office. Both programs provide a lifestyle change program for weight loss called PreventT2 for the prevention of type 2 diabetes. If you enter and complete this study, you will be in this

study for a total of 14 months. The peer-led program will be a combination of online group-based meetings and individual telephone contacts with a trained peer coach. You will be loaned a Remote Monitoring Body Weight Scale to take a daily weight at home to help you monitor your weight and track your progress toward your weight loss goal. You will work with a peer coach who will be assigned to you based on the primary care office you were recruited from and the availability of peer coaches to take on new participants. You will meet your assigned peer coach at the initial group meeting and/or during the first telephone-based treatment call. Over 12 months, you will have a total of 26 online group meetings and 26 individual phone calls with a peer coach. A tablet device will be provided to you to help you join the online group meetings, track your physical activity and eating habits, and to review PREVENT T2 lifestyle program materials. These group meetings and telephone contacts will be more frequent early in the program and will be less frequent as you continue through the program. You will receive a schedule at the beginning of the program with meetings and calls outlined. The group sessions will occur every week for the first 4 months, twice a month for months 5 & 6, and monthly for months 7 to 12. The peer coach telephone calls will occur weekly for the first 4 months. For months 5 & 6, you will receive two calls a month and then in months 8 to 12, you will receive one call per month. Calls will be made 7 to 10 days before each group meeting. Your peer coach will call you directly, but you may also call him or her as needed. Approximately 8 to 13 participants will be assigned to each group.

Activity	**Activity Schedule**
PreventT2 online group meetings – 26 total	Months 1 to 4: 16 weekly meetings
	Months 5 & 6: meet 2 times a month
	Months 7 to 12: meet 1 time a month
Peer Coach phone calls – 26 total	Months 1 to 4: 16 weekly calls
	Months 5 & 6: 2 calls per month about 7 to 10 days before group meetings
	Months 7 to 12: 1 call per month about 7 to 10 days before group meetings
Remote Monitoring Body Weight Scale	Weigh yourself each day on the Scale over 12 months
Study assessment visits – 3	1. Enrollment assessment visit
	2. 6-month assessment visit
	3. 12-month assessment visit (study completion)

Group meetings will be held online using Zoom video conference call. Group meetings will last about 70 minutes, and telephone calls will last about 15 minutes. Group discussions will focus on dietary changes, physical activity, and other behavioral strategies shown to effectively promote weight loss. A health educator will deliver each session remotely using Zoom video conference call. Peer coaches will join each meeting to help answer questions, review printed materials and discuss your activity and food logs. Before each meeting, the peer coach will privately ask your weight to help you track your progress. Peer coach calls will include discussions of your progress, goal setting, and problem-solving strategies for weight loss challenges. You will be instructed to lose 7% to 10% of your current body weight. If you agree to join the study, the study will not make any changes to your medications.

If your primary care office is assigned to the *peer-led PreventT2 program with metformin therapy recommendations,* you will be asked to do the same as those in the peer-led group only and your provider may provide you with a recommendation to take metformin along with a prescription. Metformin is a medication that is recommended for people at high risk for diabetes. This medication helps your body to better use sugar that comes from the food you eat. For some people, this medication may also help them lose weight. This study is trying to understand how realistic it is for people like you with prediabetes to take metformin. Filling the prescription for metformin is up to you, you will be responsible for paying for metformin. If the metformin prescription is filled at chain pharmacies like Walmart or prescription mail delivery like Blink Health

(blinkhealth.com), it can cost as little as $4 for 30-day supply. You will be provided with a handout, *Understanding Metformin for Prediabetes.* A trained staff member will review this handout with you. If you have any questions, you may ask a staff member to talk directly with Dr. Andrea Cherrington who supervises this study or alternatively talk with your provider. Two weeks after enrolling in this study, a study coordinator will call you to follow up about how you are doing with the recommendation from your provider and to ask about taking metformin. Participants in both groups will continue to have contact with their primary care provider as needed for routine medical care.

Remote Monitoring Body Weight Scale

You will receive a Remote Monitoring Body Weight Scale that is to be used at home to weigh only yourself each day while you are participating in this study. The Scale is only for your use in tracking your weight in this study. Your body weight information will not be reviewed or monitored in real time. The information collected from the Remote Monitoring Body Weight Scale is part of the data collected for this study. Your peer coach may contact you if you are not monitoring your weight on a daily basis. Your body weight information is not reviewed or monitored 24 hours a day, seven days a week. The Remote Monitoring Body Weight Scale must be returned in good working condition to study staff if you complete the study, the study terminates, or if you are withdrawn from the study, or for any other reason.

Risks and Discomforts

The risks for this study are low. You will be assigned to a group by chance, 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 and work with a peer coach that focus on skills you need to lose weight, be more physically active, and manage stress. Risks include discomfort, a loss of confidentiality, feeling tired or hungry, minor pain, and inconvenience. You may feel some discomfort in talking about personal health issues, emotional distress, or risk for developing diabetes. 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, and what is said between the peer coach and you will not be shared with other participants. 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.

You will be encouraged to make changes to your eating and activity habits with the goal to lose weight. You may feel tired or hungry when you first make these changes, but this is usually mild and often gets better with time. 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.

If you are assigned to *metformin therapy recommendations*, your primary care provider may ask you to take metformin to help reduce your risk of developing type 2 diabetes. Metformin is a medication that helps your body use the sugar from foods better. Some people who starting to take metformin experience side effects like nausea or minor stomach discomfort (feeling sick their stomach), diarrhea, or an upset stomach. These effects are minor risks, temporary, and reversible. You will receive a handout, *Understanding Metformin for Prediabetes,* that talks about ways to lower the side effects such as taking a low dose at first and taking the metformin with food or at dinner.

Over 12-months, you will be asked to attend 3 study assessment visits and 26 group meetings and to talk with your peer coach 26 times. These study activities may be inconvenient and take time from your daily day-to-day activities. You will be assigned to a weight loss treatment program by chance based on your primary care office, which may prove to be less effective than the other study group(s) or alternatives.

Benefits
If you participate, you will be encouraged to make lifestyle changes shown to produce weight loss. Modest weight loss is related to a number of health benefits, including reduced risk for certain medical conditions such as diabetes, heart disease, and high blood pressure. Weight loss can also help you better manage these conditions if they are already present. Weight loss and associated lifestyle changes can also improve mood, physical functioning, and self-esteem.

Alternatives
The alternative to study participation is that you may choose not to take part at all. There are other available self-directed and supervised weight loss 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.

Who may use and give out information about you?
Information about your health may be used and given to others by Dr. Andrea Cherrington, 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, nurses 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.

Cost of Participation
There will be no cost to you for taking part in the life style modification program and the study. The life style modification program and exams related to this study will be provided to you at no cost during the 12-month study period. If you are assigned to the metformin group, the cost of metformin prescription is anticipated to be considerably low to free at some local pharmacies. Study staff will assist you to identify an affordable price. This cost will be your choice to pay or not.

Payment for Participation
You will be paid $40 for the completion of the initial study assessment including questionnaires and measures of your height, weight, and blood pressure. You will be paid after completing each study visit, $50 for the 6-month visit and $60 for the 12-month visit. The total payment you may receive is $150. A tablet device will be given to you valued at up to $90 for the special purpose of participating in the online group meetings. At study end or if you choose to leave the study, you must return your remote monitoring body weight scale. Upon returning the s remote monitoring scale, you will receive a body weight scale (valued at $25) for your home use. 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 NIDDK 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. Andrea Cherrington at 205-975-7940.

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