Document Coversheet

Study Title: Enhancing the Diabetes Prevention Program to Promote Weight Loss Among Nonresponders in a Community-Based Lifestyle Intervention

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	1/8/2025
NCT Number:	NCT04757519
IRB Number	58766
Coversheet created:	2/4/2025

IRB Approval
1/8/2025
IRB # 58766
IRB6

KEY INFORMATION FOR ENHANCING THE DIABETES PREVENTION PROGRAM TO PROMOTE WEIGHT LOSS AMONG NON-RESPONDERS IN A COMMUNITY BASED LIFESTYLE INTERVENTION.

We are asking you to choose whether or not to volunteer for a research study to find out if a weekly telephone call helps people lose more weight. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to: 1) deliver a healthy lifestyle program that can help lower the chance of developing diabetes; 2) increase your knowledge of healthy lifestyle choices; and 3) offer individual additional support through weekly telephone calls to help support lifestyle change.

By doing this study, we hope to learn if offering people more support through telephone calls will help support healthy lifestyle change. Your participation in this research will last about 6 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may directly benefit from being in this study because you will learn how to live healthier; you may lose weight; and you may decrease the chances of developing diabetes.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You might choose not to participate in this study if you are not interested in learning about healthy lifestyle choices that can help you to improve your health and if joining group classes makes you feel uncomfortable.

DO YOU HAVE TO TAKE PART IN THE STUDY?

Participation is voluntary. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Lovoria B. Williams, PhD, FNP-BC, of the University of Kentucky (UK), College of Nursing. If you have questions, suggestions, or concerns about this study or if you want to withdraw from the study her contact information is: phone number 859-323-5579 or email address: Lovoria.Williams@uky.edu

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the UK Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You would not qualify for this study if you are under 18 years of age, are pregnant or planning pregnancy during the next 6 months, are diabetic, are not overweight, are not Black or African American, are unable to participate in moderate level of physical activity, have a serious medical condition that contradicts weight loss, e.g. terminal illness and do not live within driving distance of participating Church/site.

WHERE IS THE STUDY GOING TO TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

This study will take place in 20 community sites, such as churches located in Kentucky. The amount of time you will be asked to volunteer for this study is about 18hours over the next 6 months.

WHAT WILL YOU BE ASKED TO DO?

There are two groups in the study. Both groups will receive a program called the Diabetes Prevention Program Group Lifestyle Balance (DPP-GLB) known as Fit & Faithful. Fit & Faithful gives information about improving health through nutrition and physical activity such as walking. In addition to Fit & Faithful, one group will receive additional support. In that group, the people who are not losing weight after 4 weeks will receive once weekly motivating telephone calls to discuss further ways to help them reach the weight loss goal. We will determine which site receives the additional support at random (like flipping a coin).We do not know which of the two programs works best. You will get the program assigned to your site. Both groups will be asked to come to attend a 1-hour long group class over UK-Zoom. The classes will be held once a week for 12 weeks and once every other week for 12 weeks (6 classes) for a total of 18 classes.

To participate, you will be asked to give some basic information by completing questionnaires about yourself such as your age, education, medical insurance, health behavior, lifestyle, your general wellbeing and medical history including medications. The questionnaires will be taken over REDCap software. You are free to skip or not answer any question that makes you uncomfortable. The participants will be asked to self-measure their height and blood pressure (blood pressure monitor will be provided by research team) at enrollment at 12 weeks and 6 months. Weight will be collected by cellular scale provided by the research team and participants will take their weight at enrollment, 4 weeks, 12 weeks, and 6 months. We will ask your physical activity level questions by telephone at enrollment, 12 weeks and 6 months.

At the classes you will receive handouts, weekly food and activity diaries and an activity tracker such as pedometer or FitBit. You will be asked to self-monitor your weight loss and to keep a record of your physical activity.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The researchers have taken steps to lower the risks of this study. Even so, you may experience some risks related to your participation.

The potential risks of participating in this study include: You may be asked to seek your own health provider's advice about your ability to take part in moderate activity such as brisk walking. You could get hurt if you start a walking program. For example, you could twist an ankle, pull a muscle, or break a bone. It is your choice to begin a fitness program. You may feel uncomfortable answering questions for the study. You may be uncomfortable in-group or individual classes. You can decide not to answer the question. There is no promise that other group members will keep what you share during your group meetings confidential. You will need to step up onto the platform for height and weight measurements. You should be careful when stepping onto and off of the platform. This will help to avoid injury. When the blood pressure cuff tightens, you will feel a squeezing of your arm. This may be uncomfortable. In addition, you may experience a previously unknown risk or side effect.

There is a small risk of loss of confidentiality of data. We will collect information that could be used to identify you such as (name, date of birth, address); however, the information will be collected in a confidential manner and will

be stored in a password protected computer program and in a locked file cabinet in the research office in the UK College of Nursing (509). We have lowered the risk of loss of confidentiality by giving you a number to put on the survey instead of your putting your name. We will use this code on your data and will keep your name and address separate from the code.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?
You will benefit by learning about how to be healthier by having nutritious food and being physically active. You will also learn about ways of losing weight which would lower your risk of developing diabetes and other illnesses.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?
If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?
There is no cost to participate in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?
Only the researchers will be able to see your information. We will try hard to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. We will use a code number on your electronic data. Surveys and electronic data will be collected on paper or with REDCap survey on a password protected tablet with encryption. REDCap is a secure, web-based program to capture and store information at UK. We will try hard to protect your information. We will ask for your social security number in order to process compensation for your participation. During data collections, we will keep all paper forms in a locked portable file cabinet. We will take the data to UK in a locked portable file cabinet. At UK, we will store the data in in locked cabinets in the UK College of Nursing secured access research office (509). The information kept on the researchers' computers will be protected with an additional password. When we write about or share the results from the study, we will write about the combined information. We will not use your name on any writings about the study. We will not use your name on any writings about the study. A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. You should know that in some cases we may have to show your information to other people. For example, the law may require us to share your information with:

- Officials from the University of Kentucky;
- The National Institute of Diabetes, Digestion, and Kidney (NIDDK)
- Authorities, if you report information about posing a danger to yourself or someone else.

We will make every effort to safeguard your information. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the UK.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?
You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study. If you choose to leave the study early, data collected until that point will stay in the study database and may not be removed. The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?
Yes, you may take part in this study if you are currently involved in another research study. It is important

to inform the person enrolling you in this study if you are in another research study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?
If you believe you are hurt or if you get sick because of something that is due to the study, you should call Lovoria Williams, PhD, FNP at 859-323-5579 immediately. It is important for you to understand that UK does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, UK will not pay for any wages you may lose if you are harmed by this study.

- Medical costs related to your care and treatment because of study-related harm while taking part in this study will be your responsibility. You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?
You will receive an incentive that is worth $10 after baseline data collection, $25 at 12-week, and $35 after 6- month data collection in the form of a gift card from a national retail center. At the end of the intervention (24 weeks), each non-responder participants of the 10 churches randomized to receive the weekly enhanced telephone delivered intervention will receive an additional incentive of $5 for each completed telephone call (maximum 20 calls) in the form of a gift card in the amount up to $100. Additionally, participants attending 80% or more of the sessions will be entered into a drawing at the end of the program for a health & wellness gift basket valued up to $100. With a few exceptions, study payments are considered taxable income reportable to the Internal Review Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?
We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?
The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to **2** times per year.

Do you give your permission to be contacted in the future by *Dr. Lovoria Williams or UK research staff* regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?
If you volunteer to take part in this study, you will be one of about 500 people to do so.

WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?
Your information collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name or date of birth.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

_____	_____
Signature of research subject	Date
_____	
Printed name of research subject	
_____	
Printed name of [authorized] person obtaining informed consent	Date
_____	
Signature of Principal Investigator or Sub/Co-Investigator	