CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Study: Nested Pilot Study Comparing Two Treatments to Reduce Type 2 Diabetes Risk in at-Risk Delawareans

Principal Investigator(s): Freda Patterson, PhD and Donna Paulhamus, RD

KEY INFORMATION

- **Purpose:** The purpose of this study is to test whether adding sleep health and time-restricted eating components to the standard Diabetes Prevention Program helps people lose more weight and improve their health as compared to the standard program alone.
- **Procedures**: If you choose to participate, you will be randomly assigned to 1 of 2 groups. Group 1 will continue with the regular Diabetes Prevention Program sessions as planned. Group 2 will receive the regular Diabetes Prevention Program + additional sleep health support through an online program + follow a time restricted eating plan where they will eat within a 10-hour window each day in addition to the standard Diabetes Prevention Program. Both groups will be asked to complete some assessments at the 4, 6 month and 12 month time points in the study that will involve: wearing a wrist device to track your sleep and activity for 14 days and nights, complete various health measurements (weight, waist size, blood pressure), and fill out surveys about your quality of life and health habits. You will be asked to complete an extra visit at the 4, 6- and 12-month time points to complete these measures.
- **Duration:** This will take about 12 months total, following the same schedule as your regular Diabetes Prevention Program. You will have 3 assessment visits that take about 30-40 minutes each (at 4 months, 6 months and 12 months).
- **Risks**: The main risks or discomforts from this research are minor physical discomfort during measurements, possible tiredness when adjusting to new eating schedules, stress from tracking your weight and health, and time away from work or family for study activities and a small risk of low blood sugar (hypoglycemia) if you take certain glucose-lowering medications.
- **Benefits:** You may experience weight loss, improved sleep, improved blood pressure, and reduced risk of developing type 2 diabetes.
- **Alternatives:** There are no known alternatives available to you other than not taking part in this study and continuing with the standard Diabetes Prevention Program.
- **Costs and Compensation:** If you decide to participate there will be no additional cost to you. You will be compensated up to $750 total ($200 at 4-months, $250 at 6-months, and $300 at 12-months) for completion of the study assessments.
- **Participation:** Taking part or not in this research study is your decision. You can decide to participate and then change your mind at any point. There will be no penalty should you choose not to participate.

Please carefully read the entire document. You can ask any questions you may have before deciding if you want to participate.

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will be asked to do if you decide to take part, and the risks and benefits of being in the study. Please read the information below and ask us any questions you may have before you decide whether or not you want to participate.

PURPOSE OF THE STUDY

The purpose of this study is to find out if adding sleep health support and time-restricted eating guidance to the Diabetes Prevention Program helps people achieve better health outcomes than the standard program alone. Specifically, we want to see if these additions help people lose more weight, and improve blood pressure, sleep, and quality of life, potentially leading to a reduced risk in the development of type 2 diabetes.

Many people with prediabetes (higher than normal blood sugar that isn't quite considered diabetes yet) struggle to lose weight with current programs. Research shows that healthy sleep and eating within specific time windows can help with weight loss and blood sugar control. We want to test if combining these strategies with the proven Diabetes Prevention Program works better than the standard program by itself.

WHO IS BEING ASKED TO PARTICIPATE?

You will be one of approximately 40 participants in this study.

You are being asked to participate because you are already enrolled in the University of Delaware Nutrition Clinic's Diabetes Prevention Program and you meet the requirements for this study.

To be in this study, you must be:

- Enrolled in the University of Delaware's Diabetes Prevention Program
- 18 years of age or older
- Diagnosed with prediabetes (by blood test result within 12 months of enrollment), previous diagnosis of gestational diabetes mellitus (GDM), or positive screening for prediabetes based on the Prediabetes Risk Test)
- Have a BMI of 25 kg/m² or higher (23 kg/m² or higher if you are Asian American)
- Not have been diagnosed with type 1 or type 2 diabetes

PROCEDURES: WHAT WILL YOU BE ASKED TO DO?

Your participation in this study will last 12 months and follows the same timeline as your regular Diabetes Prevention Program (DPP). Here is a timeline of study procedures:

Month 1: Complete the Diabetes Prevention program enrollment form, prediabetes risk test form, lifestyle change form, as well as measures of height, body weight, waist circumference, blood pressure and quality of life.

Months 2-4 of your DPP: You will have completed measures of weight and weekly moderate activity minutes and be invited to join this research study.

Months 5-12: If you agree to participate, you will be randomly assigned (like flipping a coin) to one of two groups:

1. **Standard DPP group:** You will continue with your regular Diabetes Prevention Program sessions as planned. You will also be asked to complete 3 assessment visits (about 30-40 minutes each) at the 4-month, 6-month, and 12-month marks (described below). Please note that if you are assigned to the standard DPP group, upon completion of the study, you will receive access to the DPP++ intervention materials (sleep health program and time-restricted eating materials).

2. **Enhanced DPP++ group:** You will continue with your regular Diabetes Prevention Program AND receive additional sleep health and eating guidance AND be asked to complete 3 assessment visits (about 30-40 minutes each) at the 4-month, 6-month, and 12-month marks (described below). **As part of the enhanced DPP++ group, you will receive:**
    - A 9-week sleep health video program with personal sleep tracking, weekly schedule adjustments, a participant workbook, and mid-week text messages to help improve sleep
    - Educational materials about time-restricted eating (eating all your daily food within a 10-hour window)
    - A 10-15 minute orientation call to: (1) review the sleep health and time-restricted eating program materials, (2) confirm your email address for receiving weekly video links, (3) review the need to consult with a health care professional before starting time-restricted eating if you take a glucose-lowering medication, and (4) review the symptoms of low blood sugar.

Months 4, 6, and 12: Health Assessments (<u>both groups</u>):

- Over a 14-day monitoring period (at the 4-, 6- and 12-month time points), wear a wrist device 24/7 to track your sleep and physical activity, complete a daily-diary that records the time of your first and last eating occasion, and information about your sleep (i.e., time in bed, sleep duration, etc.)
- Weight and waist measurements
- Resting Blood pressure measurements
- Complete surveys about your quality of life, sleep quality, insomnia, perceived stress, eating habits, and diet (takes about 30 minutes)

All health measurements will be taken by trained staff using standard procedures. We will share your individual results with you so you can discuss them with your doctor if you wish.

WHAT ARE POSSIBLE RISKS AND DISCOMFORTS?

Physical Risks:

- Minor discomfort during blood pressure measurements
- Possible muscle soreness or tiredness from increased physical activity (part of all DPP programs)

- Possible hunger, tiredness, or lightheadedness when first adjusting to eating within specific time windows
- Small risk of low blood sugar if you take diabetes medications and change your eating schedule. However, the likelihood of fasting hypoglycemia in people with prediabetes who are not taking glucose-lowering medications is very low to rare (estimated at less than 1-2%). Risk increases for those taking certain medications such as sulfonylureas or insulin, though metformin alone carries minimal hypoglycemia risk and these medications are not commonly prescribed for prediabetes.

Psychological Risks:

- Stress or anxiety about weight monitoring and body measurements

Social Risks:

- Challenges maintaining eating schedules during family meals or social events
- Time away from work, family, or social activities for study appointments

To minimize these risks, we will:

- Train all staff in proper measurement techniques and provide clear instructions
- Recommend that if you take medications that could cause low blood sugar, that you consult with your healthcare provider before implementing time-restricted eating
- Teach you to recognize signs of low blood sugar and when to contact us and a doctor
- Allow you to skip any measurement you're uncomfortable with
- We also recommend that you speak with your physician prior to making changes to your current physical activity routine.

WHAT ARE POTENTIAL BENEFITS FROM THE STUDY?

Potential benefits to you: You may experience weight loss, improved sleep quality, better blood pressure control, enhanced quality of life, and reduced risk of developing type 2 diabetes. However, we cannot guarantee that you will experience these benefits, and results vary from person to person.

Potential benefits to others: This research may help develop better diabetes prevention programs for people like you in the future. The results could lead to improved treatments that help more people successfully prevent type 2 diabetes, which could reduce healthcare costs and improve health in communities across Delaware and beyond.

NEW FINDINGS THAT COULD AFFECT YOUR PARTICIPATION

During this study, we may learn new important information. This may include information that could affect your decision about participating in the study. If any new important information becomes available while you are a participant, we will let you know.

CONFIDENTIALITY: WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used. Sessions will be recorded via Zoom and made available to participants who have missed a session for the sole purpose of allowing for make-up sessions. These recordings will not be used for research purposes. At the end of the 12-month DPP when all participants complete all make-up sessions, the zoom recordings will be deleted.

To minimize the risks to loss of confidentiality, we will assign you a unique study ID number that will be used on all study materials instead of your name. Your name and other identifying information will be stored securely and separately from your research data. Only essential study personnel will have access to identifying information, and all staff are trained in confidentiality procedures.

We may have to report certain information for legal or ethical reasons, such as child abuse, or intent to hurt yourself or others. If required, your records may be inspected by authorized personnel in the following groups and agencies: the University of Delaware Institutional Review Board.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

USE OF DATA COLLECTED FROM YOU IN FUTURE RESEARCH:

Identifiers about you will be removed from the identifiable private information and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

COSTS AND COMPENSATION

There are no costs associated with participating in the study.

You will be compensated for completing each of the three assessment timepoints using an escalating structure: $200 for the Month 4 (pre-treatment) assessment, $250 for the Month 6 (end of treatment) assessment, and $300 for the Month 12 assessment, for a possible total of $750.

For context, the assessments at the 4-, 6- and 12-month timepoints includes:

- 14-days of wearing a watch 24/7 that provides an estimate of your sleep and physical activity; during this 14-day period you will also keep a daily diary to track your first and last eating occasion and some information about your sleep (e.g., time to bed, time fell asleep, time of waking).
- Measuring your body weight, waist circumference, and resting blood pressure
- Completing surveys that measure your quality of life, sleep quality, insomnia, perceived stress,

dietary intake, and sleep disturbance(s).

Compensation will be in the form of a gift card (Amazon or visa) and paid at the completion of each time point.

WHAT IF YOU ARE INJURED DURING PARTICIPATION IN THE STUDY?

If you are injured during your participation in the study, you will be offered first aid at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of a third-party payer (for example, your health insurance). By signing this document, you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide later not to participate, or if you decide to stop taking part in the research, there will be no penalty or loss of benefits to which you are otherwise entitled. Your decision to stop participation, or not to participate, will not influence current or future relationships with the University of Delaware or affect your participation in the regular Diabetes Prevention Program.

INSTITUTIONAL REVIEW BOARD

This research study has been reviewed and approved by the University of Delaware Institutional Review Board (UD IRB), which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. If you have any questions or concerns about your rights as a research participant, you may contact the UD IRB at hsrb-research@udel.edu or (302) 831-2137.

CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues related to this research study you may contact the Principal Investigator, **Freda Patterson, PhD at (302) 831-6588 or fredap@udel.edu**, or Co-Principal Investigator **Donna Paulhamus, RD at (302) 831-1060 or donnag@udel.edu**.

CONSENT TO PARTICIPATE IN THE RESEARCH STUDY:

I have read and understood the information in this form and I agree to participate in the study. I am 18 years of age or older. I have been given the opportunity to ask any questions I had and those questions have been answered to my satisfaction. I understand that I will be given a copy of this form for my records.

_____	_____	_____
Printed Name of Participant (PRINTED NAME)	Signature of Participant (SIGNATURE)	Date
_____	_____	_____

Person Obtaining Consent (PRINTED NAME)	Person Obtaining Consent (SIGNATURE)	Date

OPTIONAL CONSENT TO BE CONTACTED FOR FUTURE STUDIES:

Do we have your permission to contact you regarding participation in future studies? If you agree to being contacted in the future, we will keep your contact information. Please write your initials next to your preferred choice.

_____ YES _____ NO