THE MINDFULNESS IN-HOME FOR DIABETES AND SLEEP HEALTH STUDY (MINDS)

NCT04160078

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IRB00112861

Emory University
Consent to be a Research Subject

Title: The Mindfulness in-home for Diabetes and Sleep Health Study, MINDS

Principal Investigator: Dr. Dayna A. Johnson, PhD, Department of Epidemiology and Dr. Unjali Gujral, PhD, Hubert Department of Global Health

Funding Source: Georgia Center for Diabetes Translation Research

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

Study Overview

The purpose of this research is to study the impact of reducing stress on sleep and diabetes. We will ask you to attend a 2-hour in person session where we will ask you questions via a questionnaire regarding your environment, stress, sleep, and health. We will ask you to participate in mindfulness-based stress reduction techniques via a phone application for 6 weeks while also wearing a wrist monitor that measures activity and sleep. Study participation also includes two blood samples at the start of the study and at the end. Following the 6 weeks, we will ask you to participate in a focus group to share your thoughts on the app, sleep and health. This research will provide direct information that can be used to target interventions to improve sleep and subclinical diabetes measures.

What to Expect

As a participant, you will be expected to complete the following:

1) Attend a baseline session to complete a survey about your health behaviors, stressors, environment, sleep and health, provide a blood sample, listen to a presentation on sleep health.
2) Download a mindfulness-based stress reduction app on your phone and engage in the breathing exercises daily for 6 weeks.
3) Wear an activity/sleep monitor to identify sleep/wake times, sleep timing and quality of sleep for 6 weeks as well as complete a daily diary.
4) Attend a check-in session after 3 weeks.
5) Attend a follow-up session to share your thoughts on the program and health and have another blood draw.

The activity/sleep monitor involves wearing a device on your non-dominant wrist that records information about movement during everyday activities such as walking and sleeping. The wrist monitor records light and movement but does not track your location or heart rate. The daily sleep diaries include questions about your sleep patterns, naps, and other activities each day.

Also, if any of the data collection from the sleep monitor are unsuccessful due to equipment failure, you will be asked to consider wearing the monitor for extra days. We will check the monitor after 3 weeks.

At the conclusion of the study the sleep monitor will be collected and appropriate compensation will be distributed. You will also receive a report with your sleep results within 30 days.

Risks and Discomforts

There are minimal risks and discomforts associated with participation. You may feel discomfort or experience skin irritation from wearing the activity/sleep monitor, particularly when the band is wet. You should discontinue use if skin reddening or inflammation appears. You may also experience discomfort from answering questions related to your sleep and/or showing us where you sleep. You can skip any questions you feel uncomfortable answering and can end participation in the study at any time. There is also a possible breach of confidentiality.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits

You will receive information about your sleep patterns based on the data recorded on the activity/ sleep monitor you wear. You may also receive information on referral for evaluation, based on your results.

Compensation

You will get $100 for the study baseline visit then an additional $150 at the follow-up visit after 6 weeks to compensate you for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You may be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Study records can be opened by court order. They may also be produced in response to a subpoena or a request for production of documents.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data [and specimens] from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

Once the study has been completed, we will send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

The samples and information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Voluntary Participation and Withdrawal from the Study

You have the right to leave a study at any time without penalty. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer. If you withdraw from the study, we will keep any information we collected during the study visit.

The researchers and funder also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- You refuse to use any of the required monitoring/collection devices
- or for any other reason.

Contact Information

Contact Dr. Dayna Johnson [redacted]

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted]

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant [redacted].

Consent

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

Name of Subject

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion **Date** **Time**