A Sleep Intervention for Young Adults At-Risk for Type 2 Diabetes

NCT03616171

IRB Approval Date: 4/29/2018

Georgia State University
Byrdine F. Lewis School of Nursing and Health Professions
Informed Consent

Title: A Sleep Intervention for Young Adults At-Risk for Type 2 Diabetes
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Sponsor: Georgia Center for Diabetes Translation Research

I. Purpose:

You are invited to take part in a research study. The purpose of the study is to compare 2 different programs for your health. We will look at the effect of these programs on blood glucose and insulin (a hormone) levels. These levels are used to see if you are at risk for type 2 diabetes. One program is about promoting sleep behaviors. The other program is about promoting health/safety behaviors. You are invited to take part because you are 18-25 years old and have short sleep. A total of 26 people will be recruited for this study. The screening procedures are described in the next section. If you meet screening requirements, taking part in this study will require about 2.5 hours of your time over a 5-week period. There are 3 study visits during the 5 week study period. The first study visit lasts about 45minutes. The second study visit lasts about 30-45 minutes. The third study visit lasts about 45 minutes. You will be asked to wear an activity monitor that looks like a watch all day long and also spend 1-2 minutes a day keeping a diary about your sleep for 5 weeks.

II. Procedures:

If you decide to take part in the study, you will be asked to complete an initial screening visit. After the screening visit, if you qualify and decide to continue, you will be asked to complete 2 additional visits. All 3 visits will take place in the School of Nursing at Georgia State University (GSU). During the entire study period, you will be asked to wear an activity monitor that looks like a watch. You will be asked to wear the activity watch all day long. You will also spend 1-2 minutes a day keeping a diary about your sleep for 5 weeks.

The first visit is for screening to see if you qualify for the study. This visit will last about 45 minutes. You will have your weight and height and body fat measured. The measurement of body fat will be done with a non-invasive hand-held device. It will take about 2 minutes. You will fill out 1 short questionnaire. The researcher will be present to answer any questions you may have. The questions will be about your sleep, health, and current medical conditions. You will not be able to eat for 10 hours before the first study visit. This is because your blood will be drawn. A blood sample will be taken from a vein in your arm by a registered nurse. The blood sample will be used to learn about blood levels that affect your body's blood sugar (lipids, insulin, inflammation). A registered nurse will pierce your skin (usually in a vein located on the

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inside middle part of your arm) with a very small needle. The blood will be put into a small tube. This method of taking blood is called a venipuncture. If it is difficult to obtain blood from the middle inside part of your arm, other places on your body may be pierced, such as your hand. The total amount of your blood drawn is about 5 ml or 1 teaspoon. Then the researcher will apply the activity watch to your wrist. You will wear the activity watch all the time for 1 week. The researcher will teach you how to use this watch on your own at home. You will also be asked to keep a daily diary about your sleep for 1 week. The researcher will teach you how to fill out the sleep diary. You can choose if you would like to use an electronic form of the sleep diary or a paper form of the sleep diary. It will take about 1-2 minutes to fill out the diary each day. The researcher will teach you about the wrist oximeter. This device measures your oxygen level while you wear it. You will be asked to wear the wrist oximeter all night for 2 nights. The researcher will teach you how to use this oximeter on your own at home. You will then return the wrist oximeter, activity watch and sleep diary after 1 week. If you have blood levels that are above a certain value, oxygen levels above a certain value and sleep levels below a certain value, the researcher will contact you as soon as possible. The researcher will ask if you are still interested in taking part in the study. If you are interested, an appointment will be made for the second study visit. If you do not have blood levels that are above a certain level, oxygen levels above a certain value or sleep levels below a certain value, you will not be able to continue to be in the study.

The second study visit will last about 30-45 minutes. You will fill out 5 short questionnaires. The researcher will be present to answer any questions you may have. The questions will be about your sleep, health, eating habits and physical activity habits. Then the researcher will apply the activity watch to your wrist again. You will wear the activity watch all the time for 4 more weeks. The researcher will remind you how to use this watch on your own at home. You will also be reminded to keep a daily diary about your sleep for 4 more weeks. The researcher will remind you how to fill out the sleep diary. You can choose if you would like to use an electronic form of the sleep diary or a paper form of the sleep diary. It will take about 1-2 minutes to fill out the diary each day. If you continue in the study, you will have an equal chance of being assigned to 1 of 2 groups. One group will receive the sleep program. The other group will receive the safety program. A computer program, similar to a 'flip the coin', will be used to decide your group. We hope to find out which program will benefit your health the most. Participants in the sleep program group will receive a sleep behavior program. Participants in the safety program group will receive a safety behavior program. Once a week you will receive a text or phone call (your choice) from a researcher to remind you to complete the diary. The researcher will also answer any questions you may have.

The third study visit will take place 4 weeks after the second study visit and last about 45 minutes. The third study visit is at the end of the study period. You will not be able to eat for 10 hours before your third study visit. A blood sample will be taken from a vein in your arm by a

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registered nurse. The blood sample will be used to learn about your blood sugar, insulin, lipids and inflammation levels. The blood will be drawn by a registered nurse using the same venipuncture technique described above to obtain blood samples for blood sugar, insulin, lipids and inflammation levels. You will also complete 5-6 short questionnaires on sleep and/or safety, stress, diet and physical activity. Your height and weight and body fat will also be measured. The researcher will remove the activity watch and collect the sleep diary information. At the end of the visit, people in the safety program group will have an opportunity to review the sleep program information if desired.

III. Risks:

There is the possibility that taking part in this study may cause you to have some mild discomfort. During the blood draw, you will feel a pinch that lasts several seconds when the blood sample is taken from your vein in your arm. You may have pain, dizziness, bleeding, or bruising at the site of the blood draw. There is a slight risk of infection and scarring at the site of the blood draw. However, the researcher will use proper technique while taking the blood sample in order to reduce unwanted effects. You may feel hunger at the time of each visit. You will be given a light snack and water or juice after the blood draws are completed. You will need to contact the researchers if you have pain or discomfort at the blood draw site that lasts more than 24 hours. The researcher will instruct you to get medical help from your health care provider or student health services (for students). Any medical care obtained as a result of participating in this study will need to be paid by you and/or your own medical insurance coverage.

IV. Benefits:

Participation in this study may not benefit you personally. You may learn more about your risk factors for diabetes. Overall, the information learned by the researchers may help in understanding how sleep habits affect blood sugar levels in preventing diabetes.

V. Compensation:

If you finish the entire study, you will receive a total of $60. You will receive $10 after first visit. If you join the study you will receive an additional $20 after the second visit and $30 after the third (final) visits.

VI. Voluntary Participation and Withdrawal:

Participation in research is voluntary. You do not have to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. You may skip questions or stop participating at any time. Whatever you decide, you will not lose any benefits to which you are otherwise entitled. If you drop out of the study, we will keep the information you have given us up to the time when you drop out, unless you ask us not to. Students' course

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grades and relationships with faculty will not be affected. Employees will not be treated differently in the workplace if they decide not to be in the study. Information collected about you will not be shared with GSU.

VII. Confidentiality:

We will keep your records private to the extent allowed by law. Only the researchers will have access to the information you provide. Information may also be shared with those who make sure the study is done correctly (GSU Institutional Review Board, the Office for Human Research Protection (OHRP), and the Byrdine F. Lewis School of Nursing and Health Professions Office of Research). We will use a study number rather than your name on study records and the blood sample. The information you provide will be stored in a locked filing cabinet in the principal investigator's locked office. A code sheet will be used to identify participants. The sheet will be kept separately from participants' data to protect privacy. The code sheet with your name will be kept until the end of the study, at which time it will be destroyed. The blood samples will be stored in a secure laboratory at Georgia State University until they can be analyzed by Cardiovascular Specialty Laboratories, Inc. in Atlanta, GA. The blood samples will be destroyed by Cardiovascular Specialty Laboratories, Inc. once analysis of blood levels is completed. All data will be entered into password- and firewall-protected computers. Your name and other facts that might point to you will not appear when we present this study or publish its results. The findings will be summarized and reported in group form. You will not be identified personally.

VIII. Contact Persons:

Contact Ashley Helvig at 404-413-1152 or at ahelvig1@gsu.edu if you have questions, concerns, or complaints about this study. You can also call if you think you have been harmed by the study. Call Susan Vogtner in the Georgia State University Office of Research Integrity at 404-413-3513 or svogtner1@gsu.edu if you want to talk to someone who is not part of the study team. You can talk about questions, concerns, offer input, obtain information, or suggestions about the study. You can also call Susan Vogtner if you have questions or concerns about your rights in this study.

IX. Copy of Consent Form to Participant:

We will give you a copy of this consent form to keep.

If you are willing to volunteer for this research, please sign below.

_____ _____

Participant Date

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Principal Investigator or Researcher Obtaining Consent	Date

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