Title of project:

Effect of stable sleep patterns on peripheral vascular function following sleep deprivation

NCT number:

NCT06201390

Document date:

January 25, 2024
This date is when the document was most recently approved by the IRB (human subject's protection review board)

Document Type:

Informed Consent Form

CONSENT FORM

TITLE OF STUDY
Effect of stable sleep patterns on peripheral vascular function following sleep deprivation

INVESTIGATORS
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WHY AM I BEING INVITED TO TAKE PART IN THIS RESEARCH?
You are between the ages of 35-64 years without a personal history of diabetes, heart disease, stroke, or sleep disorders. You do not smoke or vape, nor do you take medications for blood pressure or sleep. You are not considered to be obese, or have high fasting blood sugar (glucose). Lastly, you are considered to have normal sleep habits.

WHAT IS THE PURPOSE OF THIS STUDY?
The objective of this research is to examine the potential protective effect of stable sleep patterns on blood vessel function following one night of sleep loss.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?
This research study will take place in room 119 of the Kinesiology and Sport Management building at Texas Tech University. This study will involve one 1-hour visit and four 1.5-hour visits. It should take you six weeks to complete all the visits.

WHEN WILL THE VISITS BE SCHEDULED?
The visits will be scheduled in the morning hours (between 6:00 and 10:00am) since we ask that you arrive for all study visits after an overnight fast.

WHAT WILL I BE ASKED TO DO?
Professor Gonzales will fully explain each procedure that applies to your participation. Please sign your initials after each section to show that you understand the study procedures, measurements, and risks. The study and its procedures are outlined below:

- You will be asked to avoid food, caffeine and supplements (vitamins, aspirin, health or workout supplements) for at least 8 hours prior to each visit. _____ **(your initials)**

- You will be asked to wear a short-sleeve shirt for each visit. _____ **(your initials)**

- **Visit 1 (Screening Visit).** After reviewing and signing this consent form, you will be asked to complete a medical history and sleep questionnaire. Next, your resting blood pressure will be measured along with height and weight. One of your fingers will then be pricked for blood in order to measure fasting blood glucose with a hand-held device. After being familiarized with the vascular test(s) that you will perform in later visits, you will be given a physical activity/sleep tracker to wear throughout the entire study. _____ **(your initials)**

- **Sleep Schedule.** After visit #1, you will be asked to either keep your normal sleep schedule for two weeks or keep a consistent bed- and wake-time schedule for two weeks. At the end of two weeks, you will return for your second study visit which will be followed by one night of no sleep. Your third study visit will take place the morning after this single night of sleep loss. After a 2-week break, you will be asked to repeat this process again but this time sleeping normally for two weeks or keeping a consistent sleep schedule. Again, at the end of the two weeks you will be asked arrive for two study visits, one of which will be after one night of no sleep. Please note that you will be asked to keep a

sleep diary throughout the entire study to help keep track of when you go to sleep, when you awake during the night and morning, and when you take off the sleep tracker. Failure to comply with our instructions will lead us to exclude you from the study. _____ **(your initials)**

- **Visits 2 and 4.** Upon arrival for these study visits, we will measure your fasting blood glucose by finger prick. Then you will be asked to complete a sleep questionnaire. Next, you will perform a brief cognitive function task with a sensor secured to your forehead that will measure oxygen levels in your brain. Following this task, you will lie down on your back for testing of blood pressure waveforms at your neck, wrist, and leg. The blood vessel in your neck will also be imaged during this time to determine its size and blood flow characteristics. Following this test, blood pressure cuffs will be placed around your forearm and wrist. The cuff around your forearm will inflate to a high pressure for 10 minutes then deflate rapidly as blood flow is measured. The cuff around your wrist will inflate and deflate repeatedly during the blood flow measurement. Lastly, you will be asked to perform a continuous handgrip contraction for 2-minutes as we measure blood pressure. At the end of the contraction, a blood pressure cuff will inflate around your upper arm and will remain inflated for 3-minutes as we continue to measure your blood pressure. Before you leave this visit, you will be given a blood pressure monitor to wear for 24-hours. The blood pressure monitor will take measurements every 30 minutes during the night during the 24-hour period. _____ **(your initials)**

- **Visits 3 and 5.** We will ask that you return the morning after the single night of no sleep. This will be the morning immediately after visit #2 and #4 described above. At these visits, we will repeat all the measurements described above for visits #2 and #4. _____ **(your initials)**

The following measurements are involved in this study:

- **24-hour Blood Pressure.** A small device worn at the hip that is connected to a blood pressure cuff worn on the upper arm will measure blood pressure after you leave visits #2 and #4. Measurements will be taken every 30 minutes while you are awake and asleep for a 24-hour period. During each measurement you are asked to keep your arm still, relaxed, and fully extended.

- **Blood Flow Measurement**. Blood flow will be measured using a commonly used instrument. A Doppler ultrasound machine will also be used to measure blood flow at your neck (carotid artery) and arm (brachial artery). Lastly, blood flow during the cuff protocol will be measured using flexible strings wrapped around your forearm that will measure the change in size of your forearm as blood flows into the tissue.

- **Blood Measurements.** Blood will be collected by pricking your finger for measurement of glucose levels in your blood. Only a drop of blood will be needed for the test strip. The test may be repeated if errors are given by the machine. The test strip with blood will be discarded after analysis.

- **Blood Pressure and Pressure Waveform Measurements.** Blood pressure will be measured with an automated device that requires a blood pressure cuff around your finger and upper arm. We will also hold a pencil-like sensor on your skin at your wrist, neck, and leg. You will be asked to breathe normally and remain still as a machine measures the blood pressure waves moving through your blood vessel.

- **Cognitive Function.** A verbal fluency test will be given to you on a computer. This test will allow us to determine whether sleep loss influences cognitive function. During the test we will measure oxygen changes in your brain using a device that emits infrared light into your head. This device will be secured to your forehead using an elastic strap and black cloth.

- **Heart Rate Measurement.** For some of the tests, we will place three sticky electrodes on your chest (two just below your shoulder and one below your lowest left rib). The electrodes will be connected by wires to a computer that allow us to monitor heart rate during exercise.

- **Physical Activity/Sleep Measurement.** You will be asked to wear a small instrument (accelerometer) on wrist of your nondominant hand. The instrument records physical activity including the intensity and time spent physically active. In addition, the instrument can measure sleep characteristics like time in bed and sleep time.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?
The researcher(s) have taken reasonable safeguards to minimize any known potential risks.

- **Blood Sampling.** The risk associated with pricking your finger for blood includes one or all of the following: local discomfort at the puncture site, dizziness and nausea, and bruising. Infections are very rare, but are also potential risks. If you present with skin that is red, swollen, and painful or warm to the touch then seek medical attention contact the researcher. _____ **(your initials)**

- **Blood Pressure Cuff Inflation.** There is a risk of temporary discomfort at the site where the blood pressure cuff is inflated. The discomfort might be greater the longer the cuff is inflated. In addition, you may feel a tingling sensation in your fingers while the cuff is inflated; however, this feeling goes away quickly after the cuff is deflated. _____ **(your initials)**

- **Doppler Ultrasound.** There is a minimal risk that the ultrasound probe will irritate your skin. _____ **(your initials)**

- **Heart Rate.** There is a minimal risk that an allergic reaction could occur from the adhesive on the ECG electrodes. _____ **(your initials)**

- **Handgrip Exercise.** It is possible that you may experience irregular heartbeats and irregular blood pressures while holding a continuous contraction. Other potential risks include muscle strain and muscle soreness. These risks will be minimized by familiarization to the testing procedures. You will also be closely monitored throughout exercise and recovery to ensure a normal response to exercise. _____ **(your initials)**

- **Sleep Loss.** It is possible that you will experience more than usual sleepiness (drowsiness) the morning and evening after sleep loss. This may have a negative impact on your reaction time, response accuracy, and lapses in attention. These functions are important for driving, so to minimize the risk of a vehicle accident to and from the research lab, we ask that you consider the following: i) allow us to pay for your public transport (e.g., cab, Uber, bus) or ii) plan for a family member to transport you. Choosing not to pursue one of these options will not prevent you from participating in this study, but they are highly recommended to ensure your safety.
  _____ **(your initials)**

WILL MY HEALTH BENEFIT FROM TAKING PART IN THIS STUDY?
There are no direct health benefits to you in participating in this study. However, you will be given your blood pressure and fasting blood glucose level.

DO I HAVE TO TAKE PART IN THE STUDY?
Your participation in this research is voluntary. If you decide to participate in the study, you may withdraw your consent and stop participating at any time.

CAN MY TAKING PART IN THE STUDY END EARLY?
Your participation in the study could end early if you find any of the study procedures too difficult, you do not follow instructions on wearing the physical activity/sleep device or blood pressure monitor, or if you miss scheduled visits.

WHAT WILL IT COST ME TO PARTICIPATE?
There is no cost to you for participating except that associated with your transportation to our research facilities at Texas Tech University.

WHAT WILL HAPPEN TO MY DATA?
Identifiers might 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.

WHO WILL SEE THE INFORMATION THAT I GIVE?
Your information will be combined with information from other participants taking part in the study. In the event of any scientific publication resulting from the research, no personally identifiable information will be disclosed. Your name will be kept separate from your research records which will be given a code number. Your name and the associated code number will be stored in different places under lock and key. You should know, however, that there are some circumstances in which we may have to show your information to other people.

WILL I RECEIVE ANY COMPENSATION FOR TAKING PART IN THE STUDY?
Yes. Participants will be paid a total of $160 cash for their participation in the entire study. If for some reason you do not complete the study, you will be paid for the visits you did complete ($40 each for visits #2, #3, #4, and #5). There is no payment for visit #1 as it serves as a 'screening visit'. This study is funded by a Scholarship Catalyst Award from Texas Tech University.

WHAT HAPPENS IF I AM INJURED BECAUSE OF THE RESEARCH?
If this research project causes injury (physical, psychological, social, economic, legal, etc.), Texas Tech University or the Student Health Services, may not be able to treat your injury. You will have to pay for treatment from your own insurance. The University does not have insurance to cover such injuries. More information about these matters may be obtained from Dr. Alice Young, Associate Vice President, Research Integrity, Office of the Vice President for Research, (806) 742-3905, 355 Administration Building, Texas Tech University, Lubbock, Texas, 79409.

WHAT IF I HAVE QUESTIONS?
Drs. Joaquin Gonzales (806-834-5944) will answer any questions you have about the study. Questions about your rights as a research participant can be directed to the Human Research Protection Program (HRPP), Office of the Vice President for Research, Texas Tech University, Lubbock, Texas 79409, 806-742-2064.

_____ _____
Participant Signature Date

_____ _____
Printed name of person agreeing to take part in the study Name of Person Providing Consent