STUDY INFORMED CONSENT

The Combined Effects of Prolonged Sitting and Mental Stress on Vascular and Cerebrovascular Function in Middle-Aged Adults

NCT number NCT04207333
Consent Form Version Date: 12/05/19

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

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IRB Study # 19-1843
Title of Study: The Combined Effects of Prolonged Sitting and Mental Stress on Vascular and Cerebrovascular Function in Middle-Aged Adults
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CONCISE SUMMARY

We are looking to examine the vascular, cerebrovascular response to mental stress with or without prior exposure to prolonged sitting while also observing executive function. It is currently unknown whether (1) prolonged sitting and mental stress have systemic vascular health effects (2) whether sitting and mental stress impairs blood flow to the brain and perfusion of the prefrontal cortex (3) how mental stress affects vascular function and cerebrovascular function, and (4) what specific mechanisms explain these changes. The devices used in this study are non-invasive and no known adverse events have occurred with use of the stated devices. The findings from this study may result in a public health message regarding sedentary behavior and stress, and will help elucidate the mechanisms behind acute vascular, cerebrovascular, and cognitive dysfunction during prolonged sitting.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to (1) Explore the cardiovascular effects of mental stress with and without a bout of prolonged sitting on cerebrovascular function, and (2) Explore the effects of mental stress with and without a bout of prolonged sitting on vascular function.

Are there any reasons you should not be in this study?
You should not be in this study if you have known cardiovascular or metabolic diseases (e.g. Congestive heart failure, peripheral artery disease, type I and II diabetes, etc.), you smoke tobacco, take medications known to affect cardiovascular function (e.g. beta-blockers, ACE inhibitors) or you are pregnant.

How many people will take part in this study?
There will be approximately 20 people in this research study.

How long will your part in this study last?
Should you wish to participate in the study, you will be required to attend the Applied Physiology Laboratory at University of North Carolina at Chapel Hill on three occasions. The first visit will last approximately 35 minutes, the CON visit lasts approximately 60 minutes and the SMS approximately 160 minutes.

What will happen if you take part in the study?
If you would like to take part in the study, you would be required to visit the Applied Physiology Laboratory at UNC, Chapel Hill on three occasions. See below for overall study design:

Visit 1 - The first visit will be a familiarization session during which all experimental procedures will be described to you in full. You will provide informed consent before the study begins, then complete a brief questionnaire on your medical history to ensure you are eligible for this study. If you meet the requirements, we will then show you how each device is prepared for this study, how it functions and where it will be placed on the body for data collection. No data will be collected during this session for further analysis. The following devices will be used for study purposes:

- Transcranial Doppler (TCD) – A headset snugly placed on top of the head
- VICORDER® – Non-invasive device using blood pressure cuffs to assess arterial health
- Ultrasound Probe – Small probe lightly placed over several arteries running up the neck to assess blood flow to the brain
- Near-Infrared Spectroscopy (NIRS) – Small probe (about 1 x 3 inches in size) placed on the forehead

- Non-invasive Blood Pressure cuff (NIBP)– Device wrapped around the wrist with small cuffs encircling the middle and index fingers

This visit should take approximately 35 minutes.

Visit 2 & 3 - During the experimental visits (CON and SMS), you will be required to rest quietly for a period of 10 minutes in a supine (lying) position, During the CON visit, you will undergo a brief 20min sitting period. Measures of cardiovascular function will be taken by the VICORDER® and Ultrasound devices. For the SMS condition, you will be asked to sit still and quietly for 2 hours while watching a non-stimulating documentary. Measures of cardiovascular function will be taken by the VICORDER® and Ultrasound devices at the beginning and 10 minute before the cessation of the sitting period. At the end of the sitting period in each experimental condition we will then conduct a Mental Arithmetic Test (MAT). Data collections procedures will be completed again for the VICORDER® and Ultrasound devices. Finally, a battery of cognitive will be conducted after data collection is complete.

Prior to attending the Lab for visits 2 & 3, you will have to perform the following pre-assessment guidelines:

- Fasted (> 12 hours), consuming only water.
- No caffeine consumption 12 hours prior to testing
- No vigorous exercise 24 hours prior to testing.
- No alcohol consumption 24 hours prior to testing.

Pregnancy tests will be done on all females who might be able to get pregnant at the start of the study. The research team will pay for these pregnancy tests.

The total time commitment that will be required from you is approximately 265 minutes. Following the analysis of your data, we will happily provide a summary of your results in comparison to the group means.

What are the possible benefits from being in this study?
There is no direct benefit to participation.

What are the possible risks or discomforts involved from being in this study?
The data generated from this study will be used for the purpose of scholarly publication and potentially for research presentation. Your personal data will not be identifiable. However, there is an inherent risk for a breach of confidentiality due to the sharing of personal information with the research team for research purposes.

Breach of confidentiality will be minimized by limiting the number of research team members in the laboratory during any testing session. By needing key card access to the laboratory, we are limiting the number of individuals not on the research team who have access to the lab. Those

who do have key card access are exercise physiology professors, PhD candidates, and Master's candidates, and selected undergraduate students who are directly associated with the study and have performed all necessary trainings regarding sample handling, laboratory procedures, and confidentiality. All participants within the study are coded with an individual ID and no names will be identified in any document besides a master key document. This master key document will be kept in a locked drawer in the Cardiometabolic Laboratory within the Applied Physiology Laboratory.

The devices used in this study are non-invasive and there are no accounts of severe injury due to exposure to the stated devices. Physical harm due to participation in this study is likely very minimal:

VICORDER® - The system requires the placement of pressure cuffs over several arteries for the collection of PWV/A data. Pressure cuffs will only be inflated underneath a level of 65 mmHg. Physical harm or discomfort is unlikely and include, but are not limited to:

Risk 1: Discomfort/unease: Infrequent (1 – 10%) – Application of a slight pressure over the carotid artery may impose a sense of unease for the participant. However, the light pressure used for this experimental protocol will in no way significantly damage cardiovascular structure or place the participant in danger. Investigators will make certain that communication on the procedures during testing session are clearly conveyed to the participant for comfort and safety.

Near-infrared spectroscopy (NIRS): Risk of injury or discomfort is extremely low due to this device. Possible physical harms are, but not limited to:

Risk 1: Eye damage/irritation: Rare (<1%) – Please do not, at any point, stare into the light emitted from the NIRS probe

Risk 2: Skin heating and irritation: Rare (<1%) – Wearing the NIRS probe for extended periods of time at once can theoretically lead to a warm feeling at the area where the probe is placed. However, this risk is minimal because the light emitted from this probe is not powerful enough to heat the skin. If you let the investigators know of any discomfort due to the probe, we will follow manufacturer guidelines to ensure the device is functioning correctly.

Transcranial Doppler (TCD): Data collection from this system requires the affixation of a headpiece to the participant. Risk of injury due to this device is extremely low. Possible harms may include, but are not limited to:

Risk 1: Mild headache: Infrequent (1 – 10%) – High quality data from this device requires the placement of the probe over the middle cerebral artery (MCA) and posterior cerebral artery (PCA). The slight pressure applied to the area may be slightly discomforting and unusual for the participant.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect

your willingness to continue your participation.

How will information about you be protected?

Hard copies of any identifiable information will be stored in a locked file cabinet within an access-controlled laboratory in Fetzer Hall (Applied Physiology Lab) at the University of North Carolina at Chapel Hill campus. Only members of the research team will have access to the cabinet. Any electronic files with identifiable information will be kept separate in password protected files on password protected computers that will be accessible to only members of the research team. Upon completion of the study, all data will be transferred to an electronic storage device, files will become password protected, and all hard copies will be shredded.

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care.

The Sponsor of the study, Dr. Lee Stoner, has agreed to pay all reasonable medical expenses for the treatment of reactions, illnesses or injuries related to the use of the study drug/device, defects in the manufacture of the study drug/device, or as a direct result of properly performed study tests and/or procedures, except to the extent such expenses are due to the negligence of the study staff or due to your current disease or condition unless it is made worse because you are taking part in this study.

The Sponsor has not set aside funds to pay for lost wages or any other losses or expenses. Any costs for medical expenses not paid by the Sponsor will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call Jade Blackwell at (563) 381-7270. She will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will be compensated for your time. After each completed experimental session (Visit 2 & 3), you will receive a $50 Visa gift card. You will be compensated $100 in total for being in this study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you are a UNC student?
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?
Taking part in this research is not a part of your University duties and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent