

Sitting Interruption and Whole-body Cardiovascular Health (SWITCH)

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

Consent Form Version Date: 2025/October/16

IRB Study # 21-3195

Title of Study: Sitting with Interruption and Whole-Body Cardiovascular Health (SWITCH) Study.

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CONCISE SUMMARY

We are looking to determine a physiological sound and feasible strategy for breaking-up prolonged sitting. Strategies we will test including standing, walking and a combination of standing and walking. Long-term, our findings will inform a large clinical trial that can test whether sedentary behavior reduction can decrease cardiovascular disease risk

We seek healthy adults 30-60 years of age, free of cardiovascular disease, and who do not smoke nor vape. A total time commitment of 31 hours over approximately 1 month required: the study consists of six visits, the first being a familiarization visit (1 hour duration), four experimental visits (7 hours duration each), and one focus-group visit (1.5 hours).

No significant risks will occur should you take place in this study. There is no direct benefit to you for completing this study, though your participation will benefit our understanding of the health costs of sedentary behavior.

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 identify a strategy to break-up prolonged sitting, which: (i) prevents the negative cardiovascular consequences of prolonged sitting, and (ii) is feasible.

Are there any reasons you should not be in this study?

You should not be in this study if you are unable to stand or walk unassisted, you are currently enrolled in a weight loss or exercise program, have a recent history of cardiovascular disease, have high blood pressure (systolic blood pressure ≥ 160 mmHg or diastolic blood pressure ≥ 100 mmHg), or use anti-hypertensive or glucose-controlling medications.

How many people will take part in this study?

Approximately 66 people at this institution will take part in this study.

How long will your part in this study last?

Your total time commitment will be approximately 31 hours across 1 month. This includes 1 hour for familiarization, 7 hours for each experimental visit, then 1.5 hours for the focus group visit.

What will happen if you take part in the study?

You will be asked to make six visits to the Cardiometabolic Lab at UNC.

Familiarization (Visit 1): at the first visit, we will familiarize you with all procedures. We will also provide you with an accelerometer and bedside sleep monitor so that we can record your physical activity and sleep behavior for 2 days prior to each experimental visit. Lastly, we will provide access to an electronic survey which will ask questions about your diet, activity behaviors, and stress levels. During this visit we will ask you to provide your social security number to facilitate financial reporting at UNC.

Experimental Visits (Visits 2-5): these visits will occur in the morning. Upon arrival we insert a venous catheter into the vein in your arm and collect a 36 mL blood sample. We will then feed you a standard breakfast. Following breakfast, you will complete several questionnaires about your behaviors over the past week then rest supine for 20 minutes. We will then make a series of noninvasive measurements related to blood pressure and blood flow (see list of measurements below) and take a 10 mL blood sample. You will then be asked to sit for 4 hours while watching a television program. For one of the visits, you will sit the whole period. For three of the visits, we will break-up the sitting by asking you to stand and/or walk. During the sitting condition, a 10 mL blood sample will be collected each hour (at 1-, 2- and 3-hours). At the end of the 4-hour period, you will return to the supine position, we will repeat the noninvasive measurements, then collect a final 36 mL blood sample. Each time we sample blood we will push a small amount (2 mL) of sterile saline into the IV to keep the line clear.

The measurements we will make during the experimental visits include:

- Central blood pressure, which is estimated using a standard upper-arm blood pressure cuff and an analysis technique called pulse wave analysis.
- Cerebral (brain) blood flow, which will be measured in different ways using ultrasound and near-infrared spectroscopy.
- Blood pooling in the calves, using near-infrared spectroscopy.
- Heart rate, using an electrocardiogram.
- Blood pressure, measured continuously using a finger cuff.
- Blood markers (catecholamines, endothelial microparticles, glucose, insulin, lipids, circulating angiogenic cells, oxidative stress, aldosterone, renin).

Prior to these visits, you will have to adhere to 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.

Focus Group (Visit 6): for the final visit we will ask you to attend a 90-minute focus group, so we can ask you questions about the different strategies used to break up sitting. The group will be asked about some of the strategies to break up sitting and how they might use them day to day. No questions will be directed to you individually, but instead will be posed to the group. You may choose to respond or not respond at any point during the discussion. The focus group discussion will be audio recorded so we can capture comments in a transcript for analysis.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?

Lower limb or lower back discomfort: Infrequent risk (<1%) of mild discomfort. Participants will be asked to sit for a long period (up to 4 hours). This will be a typical behavior (the average adult sits for ~8 hr/day), but there is a likely chance of mild discomfort. Participants will be observed throughout

Blood Collection. There is a rare (< 1%) risk of infection following blood draws Venipuncture blood draws are relatively safe and low risk following standard safety procedures. Cleaning protocols, as well as needle safety, will be followed including proper disposal of biohazard waste. Adverse effects for subjects are rare but include minor effects such as pain or bruising at the site of puncture (14%), to more serious effects such as fainting (<3%). The blood draws will be performed by a trained phlebotomist and care will be taken to avoid these risks.

Noninvasive Devices. Infrequent risk (<1%) of mild discomfort All devices used in this study are noninvasive and widely used. No known adverse events have occurred with the use of the stated devices.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

Even though we will emphasize to all participants that comments made during the focus group session should be kept confidential, it is possible that participants may repeat comments outside of the group at some time in the future. Therefore, we encourage you to be as honest and open as you can but remain aware of our limits in protecting confidentiality.

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?

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.

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.

Check the line that best matches your choice:

_____ OK to record me during the study

_____ Not OK to record me during the study

Every effort will be taken to protect your identity as a participant in this study. You will not be identified in any report or publication of this study or its results. Your name will not appear on any transcripts; instead, you will be given a code number. The list which matches names and code numbers will be kept in computer file with limited access. After the focus group tape has been transcribed, the tape will be destroyed, and the list of names and numbers will also be destroyed.

Consent for unencrypted communication

The study team would like to message you by text messaging and/or email, however you may say “no” to receiving these messages and still participate in this study. If you say “yes”,

messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this addendum to the consent. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team contacting me using un-protected communication.

_____ No, I do not consent to receive un-protected communication from the study team.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen if you are injured by this research?

If you think you have been injured because of taking part in this study, contact the PI listed on the front page of this document as soon as possible. You can provide this information in person or call them at the phone number listed in this consent form. Someone on the study team can

help you get the care you need. If you are injured because of this study, UNC will provide necessary medical treatment. You can also see another doctor for treatment, or if you have an urgent injury call 911.

UNC at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses, or reactions, or for the related medical care. Any costs for medical expenses will be billed to you and your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study-related injuries.

By signing this form, you do not give up your right to seek payment or other risks 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.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?

You will be receiving up to \$600 in the form of a gift card for taking part in this study. For each of visits 2-6, you will receive \$100 for participating and \$20 towards transportation. Any payment provided for participation in this study may be subject to applicable tax withholding obligations.

In order to process payments, the University may share certain identifiable information about you, such as name, contact information, and Social Security Number where required with third parties that the University retains to process payments on its behalf. If you do not want to agree with sharing your information with these third parties, then you will be unable to receive payment/compensation for participating in the study.

Your name, address, and U.S. tax payer identification number (SSN or ITIN) are required to process payments and/or to report taxable income to the IRS. You must complete a W-9 (for U.S. persons) or W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents (for non-resident aliens) in order to receive payment for participation.

U.S. person participants must complete Form W-9 in order to receive payment for participation. If payment by UNC equals or exceeds \$600 per calendar year for U.S. persons, UNC will report the amount to the Internal Revenue Service on Form 1099. Nonresident alien participants must complete Form W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents in order to receive payment for participation. Payments to nonresident alien participants may be subject to tax withholding and are generally reported to the

Internal Revenue Service on Form 1042-S. This information will not be linked to any of the study data and will only be used for payment purposes.

If you do not provide your SSN or ITIN, or complete the appropriate documentation noted above, we cannot issue you a payment for participation. However, you may still choose to participate 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 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.

Who is sponsoring this study?

This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

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.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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

Signature of Witness if applicable; e.g. literacy issues,
visually impaired, physically unable to sign, witness/interpreter for
non-English speaking participants using the short form)

Date

Printed Name of Witness