PARTICIPANT WRITTEN CONSENT DOCUMENT
"Healthy Lifestyle Intervention"

STUDY TEAM

Principal Investigator: Sylvain Moreno, PhD
Co-Investigator: Alfredo Sherman (alfredo_sherman@sfu.ca)
Research Associates: Vasily Vakorin, PhD; Bernhard Riecke, PhD; Juliet Fowler; Taha Liaqat; Hanko Ng

STUDY SPONSOR

This study will be sponsored by the Canada Foundation for Innovation grant. In addition, circle Innovation is an SFU-associated non-profit sponsor of this project.

STUDY TITLE

Changes in the Brain After a Healthy Lifestyle Intervention
Corresponding Investigator's Name: Sylvain Moreno, PhD
Investigator Department: School of Interactive Arts and Technology, https://www.sfu.ca/siat.html

INTRODUCTION

Below is a description of what you will be asked to do in this study. Please do not hesitate to ask if anything should remain unclear:

INVITATION AND STUDY PURPOSE

You are invited to participate in this study, which investigates changes in the brain after completing a healthy lifestyle intervention, and explores how the experience of the intervention might affect its impact on the brain. The study comprises four stages: pre-assessment, instruction, intervention, and post-assessment. The pre-assessment and post-assessment will be in-person and occur in a designed laboratory space before and after the intervention. Both will have an approximate duration of 60 to 120 minutes. The instruction session will be in-person, take place in a designed laboratory space, and will be approximately 30 minutes long. The healthy lifestyle intervention lasts four weeks and will occur during your everyday activities. During the intervention, four weekly remote check-ins will be performed. The remote check-ins will occur remotely over a secured Zoom meeting every week and will be around 5 to 15 minutes long.

With each assessment, we will gather questionnaires, psychological assessments, recordings of brain signals, and recorded in-person and remote interviews from you, which will be analyzed using statistical and qualitative analysis software. As compensation, participants who complete at least 80% of the intervention goals and all assessments will receive an incentive of $50 plus $20 for transportation expenses per in-person session. In total, successful participants will receive a gift card (or similar) valued at $210 for the three sessions. In addition, successful participants will also enter a raffle to win one Apple Watch Series 8. If you win the raffle, you will be notified through e-mail and requested to pick up the prize in person at a designated laboratory space.

VOLUNTARY PARTICIPATION

Your participation is voluntary. You have the right to refuse to participate in this study without any negative consequence. You should not feel any pressure to participate because of an existing relationship with any study team member. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the education, employment, or other services you are entitled to or are presently receiving. If you decide to stop, we will ask you how you would like us to handle the data collected up to that point, which includes returning it to you, destroying it, or using the data collected up to that point. If you do not want to answer some of the questions, you do not have to, and you can still be in the study. You can also choose not to be audio-recorded during the interview. If you have any questions about this study or would like more information, you may contact any research personnel.

POTENTIAL BENEFITS & RISKS OF THIS STUDY

There is no guarantee of benefits after participating in this study. Potential benefits to you could include positive physical activity and sleep changes associated with a healthy lifestyle. Your suggestions and feedback could also help the researchers deepen their understanding of changes in the brain after changing lifestyle habits in the context of health.

Any increase in physical activity could lead to potential harm. However, no extreme or intense physical activities will be encouraged. All guidelines will be safe to follow for a healthy adult population. During the in-person assessments, the adhesive used to secure the electrodes in place may cause redness, and the EEG setup may cause slight temporary discomfort from gentle skin abrasion on your scalp. Redness and discomfort should disappear quickly once the electrodes and the EEG set-up are off. However, you may wish to abstain from participating if you are sensitive to adhesives. The study could be stopped early whenever any of the assessments or guidelines associated with the intervention cause harm or damage to you or any participants.

Any data from this research that will be shared or published will be the combined data of all participants. That means it will be reported for the whole group rather than for individual persons.

STUDY PROCEDURES: WHAT WILL YOU BE ASKED TO DO?

You are invited to participate in the four stages of this study. After reading and signing this consent form, you will follow the procedures as detailed below.

1. **Pre-assessment:** During the first in-person session, you will answer several tests. First, a cognitive ability test (Raven's SPM). The Raven's SPM is an IQ test where you will be asked to choose from different presented shapes, the option that completes the patterns presented. You will be asked to do this as fast as you can.

   Second, you will be asked to answer a lifestyle survey (SF-36) that will help us assess your current health indicators and how well you can do everyday activities. This questionnaire includes questions regarding physical and social functioning, limitations due to physical or

emotional problems, mental health, energy/vitality, pain, and general health perceptions. You will be asked to choose from the answers the option closest to how you feel.

Both tests will be done in front of a computer screen using a digital form. A research assistant will be available to help you when needed.

Third, you will be asked to focus on a fixation point appearing in the center of the screen while we record brain signals using a safe and non-invasive Electroencephalogram (EEG) cap. After this, we will ask you to close your eyes while we perform another recording. These tasks will help us measure your brain activity while at rest.

Finally, you will perform a behavioral test (Go/No-go). The Go/No-go task will help us measure your capacity to sustain attention and control your responses. It presents two different shapes where you will be required to either respond (e.g., pressing a designated key) or withhold a response (not pressing the designated key) depending on whether a go or a no-go shape is presented.

For the EEG recordings, a research assistant will clean your forehead using an alcohol swipe, then measure your head to know which cap size is best for the recordings. Next, five external electrodes will be placed (one on each temple, one beneath your left eye, and one on each mastoid), and then the cap will be placed and secured on your head with a chin strap. Conductive gel will be inserted into each cap cavity, followed by inserting the pin-type electrodes. The skin on your scalp will be gently abrased with the plastic device used to apply the conductive gel so that the external electrodes that will capture the brain signals will have better contact with the skin. Once the set-up is complete, the EEG system will provide real-time visualization of your brain's electrical signal. After evaluating these readings, study personnel will correct bad connections before recording data. Next, study personnel will record your brain's electrical signal data while you perform the aforementioned resting state and Go/No-go tasks. When the assessment is finished, study personnel will stop the recording and remove the cap with the electrodes.

2. **Instruction:** We will schedule an in-person onboarding session where the research team will explain the goals, expectations, and criteria for the success of the healthy lifestyle intervention.

3. **Intervention:** We will ask you to complete the healthy lifestyle intervention throughout your daily activities for four weeks. Your goals include but are not limited to motivating a moderate increase in everyday physical activity and changing behaviors related to healthy sleep. The three goals are 1) Stand and move, 2) Exercise, and 3) Sleep.

   Stand and move: for at least 1 minute during 12 different hours daily.
   Exercise: at least 30 minutes of moderate aerobic activity daily.
   Sleep: for at least 7 hours daily.

   Weekly remote check-ins will be scheduled in advance. These check-ins will be over a secured Zoom connection and consist of a brief interview and questionnaires. The check-ins will help us understand your experience with the intervention at different time points and track

the completion of goals. We will also ask you for any significant issues you might be facing. If you have any questions, you can always contact any research personnel.

4. **Post-assessment:** After completing the intervention, you will participate in the final in-person assessment. You will be guided through the same battery of tests as the initial pre-assessment stage (excluding IQ). In addition, you will be asked to answer a System Usability Scale (SUS) and participate in a recorded one-on-one interview of about 30—60 minutes. We will ask you questions about your experience, preferences, and feelings. For the one-on-one interview, researchers will take handwritten notes to record your answers and use an audio recorder to transcribe and ensure they don't miss what you say. You can opt out of the audio recording if you are unwilling to be recorded. The researchers will turn off the field recorder when you talk and take notes instead.

CONFIDENTIALITY

The study investigators will maintain the confidentiality of participants within the limits of the law and the study design. Recordings will be saved using a participant code instead of their names. A master list that links the code to its name will be kept during the study and destroyed whenever the results are published. No other record linking participant names to the participant code will be maintained after the study is published. Basic contact information (phone and e-mail address) will be used to contact you and follow up with any topic related to the intervention. This information could also be used to contact you if you win the raffle of one Apple Watch Series 8. This information will also be destroyed after the study is published. No personal information will be asked for, and no personal information will be reported on. Any information regarding anyone who has not agreed to participate in the research will not be kept or used in any way.

Remote interviews are hosted by Zoom, a US company. Any data you provide may be transmitted and stored in countries outside of Canada, as well as in Canada. It is important to remember that privacy laws vary in different countries and may not be the same as in Canada.

WITHDRAWAL FROM THE STUDY

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, we will ask you how you would like us to handle the data collected up to that point, which includes returning it to you, destroying it, or using the data collected up to that point. If you do not want to answer some of the questions, you do not have to, but you can still be in the study. You can also choose not to be audio-recorded during the interview. If you have any questions about this study or want more information, you may contact any of the research personnel, Dr. Sylvain Moreno (sylvain_moreno@sfu.ca) or Alfredo Sherman (alfredo_sherman@sfu.ca).

STUDY RESULTS

The main study findings will be published in academic journal articles and presented at academic conferences. Please email the principal researcher if you are interested in learning about the final results of this study: sylvain_moreno@sfu.ca. If you have any inquiries or questions about this study, please feel free to email the principal investigator.

CONTACT FOR INFORMATION OR COMPLAINTS

The University and researchers conducting this research study subscribe to the ethical conduct of research and to the protection of the interests, comfort, and safety of participants at all times. If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, please contact the Director, SFU Office of Research Ethics, at dore@sfu.ca or 778-782-6593.

PARTICIPANT CONSENT AND SIGNATURE

Taking part in this study is entirely up to you. You have the right to refuse to participate in this study. If you decide to participate, you may choose to withdraw from the study at any time without giving a reason and without any negative impact on your study or employment.
You have been informed that the research will be confidential. You understand the risks and benefits of your participation in this study and agree to participate:

- Your signature below indicates that you received a copy of this consent form for your records.
- Your signature indicates that you consent to participate in this study.
- You do not waive any of your legal rights by participating in this study.
- You understand the risks of this study, including that any increase in physical activity could lead to potential discomfort or harm.

_____	_____
Participant Last Name	Participant Given Name(s)

_____
Participant Signature

_____	_____
Researcher Signature	Date (YYYY/MM/DD)