UPMC | University of Pittsburgh Medical Center

Western Psychiatric Institute and Clinic 3811 O'Hara Street
Pittsburgh, PA 15213-2593

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Name: Mindfulness meditation and vibration effects on emotion regulation and task performance

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This research study examines whether mindfulness meditation and the use of a vest that vibrates can change mood, brain activity, physiology, and task performance. This study looks at healthy participants and is expected to run 100 people. You will be asked to fill out self-reports and do cognitive tasks after mindfulness meditation while wearing a vibrating vest in the laboratory.

RESEARCH ACTIVITIES

The study involves one-day laboratory visit, scheduled at your convenience. Before qualifying for the study, you will be asked to answer a screening survey, either on the phone, in person, or on the computer. If you qualify for the study, you will be notified. The answers from the screening survey will not be used for data analysis.

For those who qualify for the study, you will come into the lab for a one-day visit that lasts 3-4 hours. During the visit, you will first be interviewed for the following: a brief psychiatric history, and vision and reading exam. If you continue to meet criteria, you also participate in two brief guided mindfulness meditation sessions, one with vibration (delivered from a vest worn on your back) and one without vibration. You will do computer tasks in which we measure your brain's responses to emotion and cognitive tasks. During this, we will measure your brain and body responses using electrodes to understand your heart rate, other electrodes to measure sweat, a belt to measure your breathing, a video camera to measure/record you to detect changes in motor activity, another video camera to measure/record the dilation of your pupil and eye movements,

and electrodes that measure brainwaves.

Before starting the sessions, you will first answer some self-reports on the computer about your demographics, your mindfulness traits, your meditation history, your substance use history, your mood presently and in the past two weeks. During the sessions and after each tasks, you will also complete self-reports on the computer about your current mood. After the sessions and tasks are completed, you will be asked to complete a self-report on the computer about which session was more interesting, and there will be questionings asking how your consciousness changed with the more profound session. There will be a post-assessment interview as well that asks you about your experience with the meditation and the vibration during the study. **This visit will last approximately 3 to 4 hours.**

You will be asked to wear a vest that vibrates in during one of the two sessions of guided mindfulness meditation. The sensation can vary from barely noticeable to easily detected, but should always remain comfortable and will not be painful. Though unlikely, any discomfort will quickly subside with the removal of the vibration

To receive complete compensation (up to $50 + $5 for parking) for this study, you must come during the day of your scheduled visit. A psychiatrist will be available during lab study days in case of any adverse reactions. Participants may be removed from the study if they do not meet criteria, if the vibration causes pain, and if they behave inappropriately towards the staff.

POSSIBLE DISCOMFORT, INCONVENIENCE, AND RISK FROM THIS STUDY:
The study procedures each have risks.

Questionnaires and interviews	You may become bored, tired, and/or frustrated during this study. During the experiment, you will be asked questions regarding how you "feel". You may become aware of feelings of happiness, sadness, or other mood states that you had not considered before. If the study staff has concern for your safety during the tests, steps may be taken which could involve interrupting the tasks or seeking medical attention. Also, although extensive measures will be taken to keep all research records confidential, breach of subject confidentiality is a possible risk of this study. You may reveal thoughts of self harm or suicidal thoughts. Our trained staff will discuss with you to determine what the most appropriate step will be. This may range from figuring out a safety plan, discussing with your provider with your permission, to going with you to the psychiatric emergency room.

EEG and Measurement Electrodes	The frame holding the electrodes on your head may feel tight and thus, may be associated with headaches upon prolonged use which go away upon its removal. If you report a headache, we will remove the frame. Some of the adhesives we use with electrodes could cause skin irritation in people with skin allergies. We will ask if you have skin allergies before using these products with you.
Vibration Stimulation	Vibration used in this study are found to be generally comfortable (and not painful) as documented in the literature. Most subjects describe the vibration as soothing like a cat's purr. However, some individuals may find this experience uncomfortable. If such is the case, we will stop the vibration from the vest, which should lead to stopping the discomfort. It is possible that positive or negative emotions and thoughts from the past may come to the surface as a result of vibration leaving subjects feelings very happy or sad. You **may also feel differently than your usual sense of self**, such as increased feelings of oneness with others, increased openness, or increased connection to the environment. Clinical staff is aware of this possibility and will be present on site to address any discomfort, anxiety, or other feelings you may have. You should ask staff for assistance if you feel at all uncomfortable.
Mindfulness Intervention	While there are no common significant risks with mindfulness practices, you may become bored, uncomfortable, tired, and/or frustrated. Clinical staff are aware of the possibility of this occurrence. You are encouraged to ask staff for assistance if you feel at all uncomfortable with the mindfulness intervention, and the intervention can be stopped at any time.
Computer Tasks	You may become bored, tired, and/or frustrated with tasks. You may become aware of feelings of happiness, sadness, or other moods that they had not considered before. There are some images that can lead to negative emotions. You are encouraged to ask staff for assistance if you feel at all uncomfortable with the computer tasks, and the intervention can be stopped at any time.

POSSIBLE BENEFITS

This study is not expected to provide direct benefits to you. We will notify you if any other information, either good or bad, about this research study develops during this study and which may cause you to change your mind about continuing to participate.

One or more of the investigators conducting this research has a financial interest in Apollo Neuroscience, This means that it is possible that the results of this study could lead to personal profit for the individual investigator(s) and/or the University of Pittsburgh. Any questions you might have about this will be answered fully by the Principal Investigator, Dr. Greg Siegle, who has no financial conflict of interest with this research, or by the Human Subject Protection Advocate of the University of Pittsburgh (866-212-2668).

COMPENSATION

There will be no costs to you for your participation in this study. You will receive compensation for participation at the end of the lab visit. You will receive either compensation as follows:

Lab Visit: $50
Parking: $5

There will be no extra compensation if the visit is split into two sessions due to time or other constraints.

CONFIDENTIALITY

Any information we obtain about you will be kept confidential (private). All paper records will be stored in a locked file cabinet and computer data will be stored on password-protected computers. Your data will be stored by a case number rather than by your name. Information linking these case numbers with your identity will be kept separate from the data. You will not be identified by name in any publication from these data unless you sign a separate consent form giving your permission (release).

In addition to the investigators listed on the first page of this consent form and their research staff, authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Although every reasonable effort has been taken to secure your information, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

Your research data may be shared with investigators conducting similar research; however, this information will be shared in a de-identified manner and none of your personal information will be available outside of this study.

VOLUNTARY PARTICIPATION

Your participation in this research study is entirely voluntary. You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions.

Whether you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

WITHDRAWING AND REMOVAL FROM THE STUDY

You may stop participating at any time, even after signing this form. Your decision will not affect your relationship with the University of Pittsburgh or care at UPMC hospitals or affiliates or relationship with UPMC.

If you withdraw from the study, any identifiable research information recorded for, or resulting from, your participation in this research study prior to when formally withdrew may continue to be used and disclosed by the investigators for the purposes described above.

It is possible that you may be withdrawn from the research study by the researchers, for example, if one of our assessments suggests you are not eligible to continue. In this case, the researchers will inform you that you are not eligible to continue. You will receive compensation for the visit in which this was determined.

COMPENSATION FOR INJURY

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator, who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

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VOLUNTARY CONSENT: All of the above has been explained to me and all of my questions have been answered. I also understand that any future questions I have about this research will be answered by the investigator(s) listed on the first page of this consent document at the telephone numbers given. Any questions I have about my rights as a research subject will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668). By signing this form, I agree to participate in this research study.

Subject's Signature _____ Date _____

CERTIFICATION OF INFORMED CONSENT: I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about his study have been answered, and we will always be available to address future questions as they arise.

Printed Name of Person Obtaining Consent _____ Role in Research Study _____

Signature of Person Obtaining Consent _____ Date _____