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Document:

Informed Consent Form

Official Study Title:

Mind-body Awareness Training and Brain-computer Interface

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Consent Form for Participation in Research

Study Title: Mind-Body Awareness Training and Brain-Computer Interface

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Sponsor(s): NIH

Purpose of this Study

The purpose of the study is to evaluate new methods of improving subject performance of a brain wave based brain-computer interface.

Procedures

If you agree to participate in this study, we would ask you to complete several of the following components. We will tell you during the consent process which components we will ask you to complete.

Training Programs

If you are assigned to an intervention group, you would be asked to participate one of three possible training programs. You may be randomly assigned to one of these interventions based on the information you provide during the first session and any baseline experiments.

1. **Yoga Nidra**: 6-8 weeks, four 1 hour classes each week. These classes will involve a focus on meditation (standing, sitting, and lying down) and gentle yoga.
2. **MBSR**, or mindfulness-based stress reduction: 8 or 16 weeks, one 2.5-3 hour class each week, and an all-day retreat in the 6^{th} or 7^{th} week. If you are in a 16 week intervention group, there would be an additional all day retreat in the 14^{th} or 15^{th} week. This intervention will involve a focus on meditation (standing, sitting, and lying down) and gentle Hatha yoga. You will also be encouraged to practice the techniques you learn for 30-45 minutes at home on the days without scheduled classes. A calendar/diary will be provided to help you track your practice time.
3. **HEP**, or health-enhancement protocol: 8 or 16 weeks, one 2.5-3 hour class each week, and an all-day retreat in the 6^{th} or 7^{th} week. If you are in a 16 week intervention group, there would be an additional all day retreat in the 14^{th} or 15^{th} week. This intervention will involve a focus on exercise, nutrition, and music therapy. You will also be encouraged to practice the techniques you learn for 30-45 minutes at home on the days without scheduled classes. A calendar/diary will be provided to help you track your practice time.

Maintaining good attendance is an important part of participating in the study. If you do not participate in a sufficient number of classes in the assigned program, you will not be eligible to continue further with the study. If you are not assigned to one of the above training programs, you may be provided with the opportunity to attend a training program after the completion of the study.

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Classes will be taught at either the UPMC Herberman Conference Center at UPMC Shadyside (5230 Centre Ave. Pittsburgh, PA) or the UPMC-Center for Integrative Medicine (580 S. Aiken Ave, suite 310, Pittsburgh, PA), based on classroom availability .You will be notified of the exact location prior to each class. You may be asked to attend an orientation session before the class.

Surveys

You may be asked to complete brief surveys that provide subjective measures of cognitive factors such as stress or mindfulness.

EEG

We will record electroencephalogram (EEG - electrical signals from your brain) during various experiments. All EEG experiments will be conducted in Wean Hall. During experiments including EEG, a tight elastic cap covered in many EEG electrodes will be placed on your head, and conductive gel will be applied to each electrode. This gel will make direct contact with your hair and scalp but can be easily washed off after the session. Electrical signals from your scalp will be recorded using an amplifier system attached to a computer.

EMG

We may also record electromyogram (EMG - electrical signals from your muscles). In this case, adhesive electrodes will be placed on the surface of your skin on your hands and/or arms, and electrical signals will be recorded using an amplifier system attached to a computer.

BCI

During brain-computer interface (BCI) experiments, you will wear an EEG cap as described above. You will be asked to perform some simple activities, such as imagining moving your hand or subtraction of numbers while watching a computer screen. Visual stimuli on the screen may respond in real time based on your brain signals, e.g. to control the position of a cursor. In some experiments, we may ask you to listen to an audio recording immediately prior to using the BCI.

BCI experiments will typically take 1.5-2 hours.

Neurocognitive Measures

To measure several factors such as attention and mindfulness, we will ask you to perform several simple tasks while watching a computer screen. For example, you may be asked to press a key on a keyboard whenever a letter “X” appears in a sequence of other letters presented on the screen, or to lift up small weighted blocks that measure your grasp force, or to perform a breath counting task while wearing a standard respiration belt. We may also record EEG, as described above, during these tasks.

Neurocognitive measure experiments will typically take 2 hours.

MRI

We may perform one or more magnetic resonance imaging (MRI) scans at the Scientific Imaging & Brain Research Center (SIBR) at Carnegie Mellon University. We will decide whether we have you complete MRI scans based on how useful the MRI information would be for the experiments we have you complete and other factors including machine availability. MRI has no significant risks, as long as you do not have any implanted metal or medical devices, and other metal objects are kept away from the scanner. Prior to each MRI experiment, you will be asked to complete a SIBR screening form and change into scrubs or a gown provided by the SIBR to minimize these risks.

During an MRI scan, you will be asked to lie in a 3 Tesla MRI scanner, which is similar to devices commonly used in hospitals. You may be asked to lie still and rest, without falling asleep, or to complete several simple tasks (e.g. tapping your fingers, focusing on visual stimuli presented on a screen,

listening to task instructions, etc.). Experimental tasks may use visual or auditory stimuli (auditory stimuli will be presented through MRI compatible headphones). We will use the MRI data to create a 3-dimensional picture of your head and brain, and possibly to determine which areas of your brain are active during certain tasks. We may also record EEG during the MRI scans. In this case, you will wear an MR-compatible EEG cap on your head in the scanner. We may also record electrocardiogram (ECG - signals from your heart) with an electrode on your back, or EMG (signals from muscles) with electrodes on your hands or arms. MRI experiments will typically take 1-2 hours.

Example study schedule

One example of a typical study schedule is shown below. Your own participation may vary based on scheduling constraints, whether you are in an intervention group, whether we ask you to participate in MRI experiments, and other factors.

Week	Day	Duration	Procedure	Compensation
1	M	30 min	Consent and screening	$7.5
		90 min	Baseline neurocognitive measures	$22.5
	W	120 min	Baseline BCI	$30
	F	90 min	Baseline fMRI/EEG	$30
2 - 9	M	150 min	MBSR classes	None
	TWRFSU	30 min	At-home meditation (encouraged)	None
7	S	10 hours	MBSR all-day retreat	None
10	M	120 min	Post-intervention neurocognitive measures	$30
	W	90 min	Post-intervention fMRI/EEG	$30
11-12	MWF	120 min	BCI training days 1-6	$30 x 6
13	M	90 min	Post-BCI neurocognitive measures	$22.5
	W	90 min	Post-BCI fMRI/EEG Study conclusion	$30

Optional follow-up

After the completion of the BCI training, you may have the opportunity to participate in follow-up sessions and surveys. Follow-up sessions could include one or more of the above listed experiments. A typical follow up series may be 1-3 BCI training sessions 3 months after the completion of the initial BCI training. You will be asked whether we may contact you after the completion of the BCI training.

Participant Requirements

Inclusion criteria for all subjects will be:

- Apparently healthy volunteers
- Age 18-64, inclusive.
- Willing and able to provide written consent.
- Able to communicate in the English language.

Risks

The study has the following risks.

Risks associated with EEG/EMG:

There are no significant risks associated with EEG or EMG recordings that can be reasonably anticipated. You may experience minor discomfort from the EEG cap similar to wearing a tight

swimming cap, or some minor discomfort from removal of medical tape or adhesive electrodes used for EMG.

Risks associated with MRI:

MRI machines use a strong magnet and radiofrequency magnetic fields to take images of your body. The scanning process is similar to an X-ray or CT scan, but MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA) like X-rays or CT scans. The risks associated with MRI scans are:

- Projectiles: Objects with magnetic properties can be pulled into the magnet and turn into projectiles. To minimize this risk we ask that subjects remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner and by controlling access to the scanner.
- Claustrophobia: The scanner is a long narrow tube that may cause some people to feel claustrophobic.
- Hearing Damage: The noise generated by the operation of the scanner during a study is loud enough to cause hearing damage if you do not wear hearing protection. Hearing protection is required and is provided by the investigator.
- Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but if it is uncomfortable please notify the investigator.
- Disruption of Devices: Some devices can be damaged by magnetic fields and should not be brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. If you have any implanted device notify the investigator.
- Heating of Devices: The radiofrequency waves used in MRI can heat conductive materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. You will be asked to remove these items if possible. If they cannot be removed you will be asked to provide more information to allow MRI staff to be able to make determination on the safety of proceeding with the scan.

A thorough pre-scan questionnaire will allow us to minimize the risk of device disruption and heating. You will be in constant contact with the investigator and should notify the investigator immediately, via the squeeze ball, if you notice anything unusual, become claustrophobic, think that your hearing protection is not adequate, or if you experience nerve stimulation that is uncomfortable.

In addition, there is a risk of unknown effects related to participation in MRI research. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in their mouth, or sensations of flashing lights. These symptoms, if present, subside shortly after leaving the magnet. If any sensations experienced during participation cause discomfort or pain, notify the researcher right away and your participation will stop and you will be taken out of the magnetic field. The risks of exposure to high magnetic fields are unknown for fetuses. Therefore, if you are a female who is capable of becoming pregnant, and you have any reason to believe that you might be pregnant, you should not participate in this study.

Risks associated with Confidentiality:

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There is a potential for breach of confidentiality, however attempts will be made to minimize these risks.

Benefits

There is no direct benefit to you for participation in this study. Your participation may help to develop new methods of brain-computer interfacing which may be useful to help motor-impaired patients in the future.

Compensation & Costs

You will be compensated at $15/hour for your participation in sessions that take place in Wean Hall, and can be reimbursed for parking associated with these sessions. Most EEG sessions are at least 2 hours so participants of certain study designs will typically receive at least $30 per session. You will be compensated at $20/hour for your participation in MRI sessions, if any. Certain longer duration studies are eligible for bonus incentives including $50 for the first 3 sessions and $100 for completion of all experimental requirements. You will be notified if your particular study is eligible for bonus incentives. You will not be compensated for the intervention component of this study; class costs will be reimbursed upon completion of the study. Payment will be in the form of a check or cash to be handed or mailed to you after your participation. Attempts will be made to provide compensation to participants after each experiment. If this is not possible, compensation will either be available for pick-up the following business day or mailed to the participants in a timely fashion. Parking costs will be covered for your participation in each experimental session. There is no cost to participate in this study.

Medical Treatment Costs

Carnegie Mellon University is not offering financial compensation, payment for the costs of medical treatment, or emergency care should you be injured as a result of participating in this study.

Confidentiality

By participating in the study, you understand and agree that Carnegie Mellon may be required to disclose your consent form, data and other personally identifiable information as required by law, regulation, subpoena or court order. Additionally, the NIH has the right to access all research records. Otherwise, your confidentiality will be maintained in the following manner:

Your data and consent form will be kept separate. Your research data will be stored in a secure location on Carnegie Mellon property. Sharing of data with other researchers will only be done in such a manner that you will not be identified. By participating, you understand and agree that the data and information gathered during this study may be used by Carnegie Mellon and published and/or disclosed by Carnegie Mellon to others outside of Carnegie Mellon. However, your name, address, contact information and other direct personal identifiers will not be mentioned in any such publication or dissemination of the research data and/or results by Carnegie Mellon. Note that per regulation all research data must be kept for a minimum of 3 years. To these extents, confidentiality is not absolute. Study data will be encrypted according to current University policy for protection of confidentiality. Any original recordings or data files will be stored in a secured location accessed only by authorized researchers.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate 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

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action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Rights

Your participation is voluntary. You are free to stop your participation at any point. Refusal to participate or withdrawal of your consent or discontinued participation in the study will not result in any penalty or loss of benefits or rights to which you might otherwise be entitled. The Principal Investigator may at his/her discretion remove you from the study for any of a number of reasons. In such an event, you will not suffer any penalty or loss of benefits or rights which you might otherwise be entitled.

Right to Ask Questions & Contact Information

If you have any questions about this study, you should feel free to ask them now. If you have questions later, desire additional information, or wish to withdraw your participation please contact the Principal Investigator by mail, phone or e-mail in accordance with the contact information listed on the first page of this consent.

If you have questions pertaining to your rights as a research participant; or to report concerns to this study, you should contact the Office of Research Integrity and Compliance at Carnegie Mellon University. Email: irb-review@andrew.cmu.edu . Phone: 412-268-1901 or 412-268-5460.

Voluntary Consent

By signing below, you agree that the above information has been explained to you and all your current questions have been answered. You are encouraged ask questions about any aspect of this research study during the course of the study and in the future. By signing this form, you agree to participate in this research study. A copy of the consent form will be given to you.

PRINT PARTICIPANT'S NAME

PARTICIPANT SIGNATURE DATE

I certify that I have explained the nature and purpose of this research study to the above individual and I have discussed the potential benefits and possible risks of participation in the study. Any questions the individual has about this study have been answered and any future questions will be answered as they arise.

SIGNATURE OF PERSON OBTAINING CONSENT DATE