Consent Form for Participation in Research

Study Title: Stress Reduction Training for Healthy Aging

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Sponsor(s): National Institute of Health

Purpose of this Study

The purpose of the study is to test how training your attention can reduce stress and impact well-being.

Procedures

The study activities will take place over the course of 6 months. You will attend an 8-week stress reduction training program. You will complete questionnaires on a smartphone provided to you. During periods of time over the next 3 months we ask that you carry this phone with you wherever you go. We remind you to follow responsible phone practices; please refrain from using your phone for study procedures in situations where you normally would not use your phone (i.e., driving). You will have limited time to complete each questionnaire after the signal, but we ask you not to compromise your safety while completing study procedures.

Week 0: The first study session will take place at Carnegie Mellon University in our laboratory in Baker Hall, Room 340J. You will hear an outline of the study procedures in more detail, learn how to complete our study questionnaires and tasks, and complete questionnaires and tasks in the lab. After attending the first study session, we will signal you on your study smartphone to complete multiple questionnaire sessions each day for three consecutive days.

Weeks 1-8: You will provide a blood sample drawn by a trained phlebotomist. Blood pressure may also be assessed using a cuff placed on your non-dominant arm. To be enrolled in the study, a successful blood draw is required. Those who do not provide a sample at this initial blood draw may be eligible to attend

classes as an unpaid participant. Following the blood draw, you will attend the first training session and will be randomly assigned to an 8-week training program, at which point you will be enrolled in the study. You will return to this site for a 2-2.5-hour group session every week for the 8-week training program. During the sixth week, you will return for a day-long seven-hour retreat. You will also complete 45 minutes of daily home practice six days a week during the eight-week course. Again, for three consecutive days during weeks 4 and 8, we will signal you to complete multiple questionnaire sessions on your phone each day.

Week 9: You will return to the blood draw site for a blood draw taken by a trained phlebotomist. Blood pressure may be assessed using a cuff placed on your non-dominant arm. Then you will return to the study site to complete the same questionnaires and study tasks that you completed at baseline.

Week 21: You will return to provide a blood sample taken by a trained phlebotomist. Blood pressure may be assessed using a cuff placed on your non-dominant arm and cortisol will be assessed using a small hair sample taken. Then you will return to the study site to complete questionnaires and study tasks similar to those you completed at your first study session. Then you will be fully debriefed and informed of the study aims, and will also have an opportunity to discuss the study and ask any questions that you might have.

An application will be downloaded onto the study smartphone that may collect information about uses of the phone, such as: current time, cell tower IDs, Wi-Fi access points, Bluetooth usage, location information, movement, screen status, battery status, screen brightness, device proximity, other installed applications, network status, notification information, and call and SMS events. The data will be identified through the device ID only and not by participant name.

We are not collecting any content of the phone calls and texts - only meta-data: timestamp of when the text was sent/received, timestamp of when a call was received/initiated, and timestamp of when the call ended. We do not collect the names of individuals who you are calling/texting. So, we never see the original phone numbers and have no information about the communication partners. The data will be identified through the device ID and not by participant name.

Blood draw information: At the first training class, at the assessment one week after the training period ends, and at the 3-month follow-up we will collect blood samples from you following a commonly used protocol. We'll use these samples to measure aspects of your immune system. You will provide blood sample of 1.3 tablespoons (*or 20ml)* drawn by a trained phlebotomist using a vein in your non-dominant arm.

Blood pressure measurement information: During the first in-person assessment session at CMU, the final assessment one week after the training period ends, and the 3-month follow-up, we will measure your blood pressure using a cuff similar to those used in doctor's offices. This cuff will be placed

around your non-dominant arm and will automatically inflate every 2 minutes for a brief period during each session.

Hair cortisol measurement information: During the 3-month follow-up assessment session, we will collect a hair sample from you to measure your hormone levels. We'll collect the sample using clean scissors, cutting hair close to the scalp and taking 40 hairs from an inconspicuous position on the back of the head.

Participant Requirements

Participants must be English-speaking adults between the ages of 65-93 who indicate willingness and availability to participate in all study assessments and intervention sessions, and who agree to be randomized to one of two study conditions. Also, you may **not**:

- Have any significant chronic mental (e.g., schizophrenia, personality disorder) or physical (e.g., cancer, HIV, diabetes type 1) diseases in the last 3 months, including bleeding disorders, that alter inflammation levels or immune function, or prevent participants from completing study activities
- Have been hospitalized over the last 3 months
- Use recreational drugs, or drink more than 5 servings 2 times per week
- Use any prescribed medications that affect inflammation or immune system function
- Report severe depressive symptoms or suicidal ideation
- Report regular mind-body practice (90 minutes or more per week) currently or in the past year

All study exclusion factors described here were selected due to either safety concerns or because of their significant confounding effects on the primary study outcomes.

Risks

Potential risks include breach of confidentiality since we will be obtaining your email address and signature. This risk will be minimized in several ways. Your email address will be stored in our password-protected laboratory email account and linked only to your information by study ID number. A file linking study ID numbers to personal identifying information will be kept in a locked file cabinet in a locked room to which only a member of the Health and Human Performance Lab at Carnegie Mellon University will have access. Your signature will be stored in a separate locked file cabinet in the locked Health and Human Performance Lab as well, and will not be linked with other personal identifying information.

The risks and discomfort associated with the use of the study smartphone are no greater than those ordinarily encountered in daily life when using a mobile device (e.g., a cell phone). All collected

information from the study smartphone will not be labeled or stored with identifiers, but will be linked by a unique ID number.

It is possible that the blood draw procedure will be associated with slight pain from the needle prick. All procedures will be done using sterile procedures by a trained phlebotomist to minimize these risks. We will be using these blood samples to examine markers of inflammation and genetic inflammation. We will ensure privacy by labeling all biological samples collected with only non-identifiable study ID numbers. Within the limits imposed by technology and law, all efforts will be made to maintain the privacy of your genetic information.

The blood pressure and cortisol measurements we are collecting in this study are non-invasive and present minimal risk to participants. If you report discomfort during the blood pressure measurement, we will immediately adjust the cuff so that you are more comfortable or remove the cuff if needed. We'll collect the cortisol sample using clean scissors, cutting hair close to the scalp and taking 40 hairs from an inconspicuous position on the back of the head.

Potential risks also include possible discomfort or inconvenience from completing the questionnaires. If you are uncomfortable answering any of the questions on the questionnaires or while completing any of the tasks, you may decline to answer those questions and/or discontinue your participation in the tasks.

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.

Benefits

There may or may not be personal benefit from your participation in the study but the knowledge received will be of value to humanity. You may find the attention training program useful and decide to continue practicing upon completion of the study. We will provide you with the audio-guided trainings upon completion of the study if you do wish to continue practicing.

This study will collect blood samples for RNA gene expression analysis and protein biomarkers of inflammation. This information will not be provided to participants. If you are interested in learning more about your inflammatory biology, you are encouraged to seek out this clinical diagnostic information from your primary care physicians. The study cannot provide a clinical assessment of relative risk, as all inflammatory biology assays will be conducted in a single batch at the end of the study.

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Compensation & Costs

You will be compensated $15 per hour (on a pro-rated per hour basis) for your participation in all study activities (in-person assessments, smartphone assessments, and training program activities). You will not be compensated for the time it takes you to travel to and from these study related activities. Some payees may receive a lesser amount due to tax requirement up to 30% of payment. This refers to participants who are employees or foreign nationals. You will be compensated $20 for each participant that you personally recommend to the study if that participant is eligible and randomized to the study.

Completion of the W9 form is necessary for all payment over $75.

Costs of your participation in this study include transportation to Carnegie Mellon's campus for the in-person laboratory session.

Some payment may be delivered in the form of a check instead of cash to meet departmental accounting regulation standards.

Neither you, nor your insurance provider will be charged for the costs performed only for the purposes of this research 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. Otherwise, your confidentiality will be maintained in the following manner:

Your data and consent form will be kept separate. Your consent form will be stored in a locked location on Carnegie Mellon property and will not be disclosed to third parties. Your study responses will be stored separately from personal identifiers: all paper data in a secured room on campus, and all web-based questionnaire data on a secure website database. 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 in your consent form will not be mentioned in any such publication or dissemination of the research data and/or results by Carnegie Mellon.

The researchers will take the following steps to protect participants' identities during this study: (1) Each participant will be assigned a unique study number; (2) The researchers will record any data collected during the study by number, not by name; (3) Any original recordings of video and physiological data will be stored in a secured location accessed only by authorized researchers.

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To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family 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.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of offenses such as child abuse and neglect, or harm to self or others.

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.

Optional Parts of the Research

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In addition to the main part of the research study, there are optional parts of the research. You can participate in the main part of the research without agreeing to take part in these optional parts:

Banking of Hair and Blood Samples

As part of this study, we are obtaining blood and hair samples from you. If you agree, the researchers would like to store leftover samples so that your hair and blood can be studied in the future after this study is over. These future studies may provide additional information that will be helpful in understanding the impact of these treatment programs, but it is unlikely that these studies will have a direct benefit to you. Your samples will not be labeled with any of your personal information, such as your name. Once you give your permission to have your leftover samples stored, they will be available for use in future research studies indefinitely and cannot be removed due to the inability to identify them. You should initial below to indicate your preferences regarding the optional storage of your leftover blood and hair samples for future research studies.

I consent to allow my hair and blood samples to be banked for analysis in the future.
☐ YES ☐ NO (Please initial here _____)

I consent to allow my samples to be shared with other investigators or groups without any identifying information.
☐ YES ☐ NO (Please initial here _____)

Optional Future Study Involvement
The present study may be interested in the long-term effects of this training program. Please indicate by initialing below whether you are willing to be contacted after completion of the 3-month follow-up visit for future study of the long-term effects of this training program. If you consent to be contacted in the future, please write down contact information where we might be able to contact you.

I consent to be contacted in the future for study of the long-term effects of this training program.
☐ YES ☐ NO (Please initial here _____)

_____ (phone)

_____ (email)

_____ (other)

Participant: By signing below, you indicate that you have read the information written above and have indicated your choices for the optional parts of the research study.

_____	_____	_____
PARTICIPANT SIGNATURE	DATE	PRINTED NAME

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Version: 12
Date of Mod. Approval:
Date of Mod. Expiration:

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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.

_____	_____	_____
PARTICIPANT SIGNATURE	DATE	PRINTED NAME

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	PRINTED NAME