The BrainHealth Project - Pilot Study

Consent Form

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The University of Texas at Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research Project: The BrainHealth Project – Pilot 200

Investigators: **Contact Number**

Principal Investigator: Sandra Chapman, Ph.D. 972-883-3407

Key Information: During this pilot study, 200 participants will complete bi-annual online cognitive testing, as well as self-report questionnaires regarding lifestyle factors. For qualifying participants, imaging data will also be collected on an annual basis over the course of 2 years. **Purpose:** The purpose of this current research study is to teach 200 healthy adults skills and habits to optimize brain performance, and to track their progress for a two-year period, as well as to provide the research team with information that can be used to successfully launch the large-scale international study. The expectation is that all 200 participants will continue to be tracked in the larger, ten-year study. The main objectives are: (i) to characterize lifestyle, cognitive, and behavioral markers related to an individual's cognitive function from adolescent to elderly ages, (ii) to assess the neural/biological determinants predictive of maintenance of brain health, and (iii) to evaluate the impact of available cognitive and lifestyle interventions on improving and maintaining brain health.

Description of Study: For this pilot study of two years, participants will complete online assessments bi-annually (4 times). We will ask the first 50 participants to complete the online assessments at The Center for BrainHealth so we can receive preliminary feedback on the ease of the experience, field questions and technological difficulties, etc. After those initial 50 complete their first assessment at The Center for BrainHealth, all other testing points will take place online in the setting of their choosing. These initial 200 participants will then rollover into the 120,000 participant BrainHealth Project as the larger study population is enrolled.

We will also be incorporating brain imaging in the pilot and longitudinal study. For this pilot study, qualifying individuals (safe for MRI) will complete an imaging scan annually (2 times).

The assessments and training included in this protocol consist of:

ASSESSMENTS

1. **Online BrainHealth Physicals (2/year)** - a battery of measures of connected language, which have been found to be preserved in normal aging (see list of previous studies in the next section), combined with standardized neuropsychological measures that assess other areas of cognition such as attention, memory, visuospatial, executive and psychomotor functions. The entire battery can be completed within 2 hours.

A. The COGNITIVE evaluation looks at how you think. It looks at complex thinking capacities - such as reasoning, flexibility, and strategy - and specific thinking components, such as processing speed, attention, and memory.
B. The EMOTIONAL WELL-BEING evaluation taps into an individual's emotional sense of yourself. You will report on your quality of your life, level of happiness, levels of stress and sadness, and on your emotional resilience.
C. The SOCIAL evaluation looks at the complexity and quality of our social supports. We want to know how you feel about your social support networks and the meaningfulness of your social engagements.
D. The DAILY FUNCTION evaluation monitors the complexity (depth and breadth) of your daily responsibilities, habits, and challenges. We are interested in how you strive to optimize your life circumstances and habits.

2. **Brain Imaging (1/year)** - The following neuroimaging protocols will be collected annually: (T1, T2, FLAIR), functional connectivity (resting state functional MRI), blood flow (Arterial Spin Labeling), cerebrovascular reactivity (CVR – with breath hold task) and white matter integrity (Diffusion MRI). In this pilot study, as well as the larger BrainHealth Project study, the neural data will be analyzed in conjunction with non-neural measures (cognitive, well-being, social engagement, sleep, etc.) to support the development of a reliable set of metrics to assess brain health.

   The MRI scans in this study are designed for research, not medical purposes. The images are not useful for finding problems or diseases. Even though the researchers are not looking at your brain images to find or treat a medical problem, you will be told if they notice something unusual. You and your regular doctor can decide together whether to follow up with more tests or treatment. Because the MRI done in this study is not for medical purposes, the research results will not be sent to you or your regular doctor.

3. **Brain Gauge by Cortical Metrics (1/year)** – 15 minutes. The Brain Gauge is a cognitive assessment tool that measures brain health by testing sensory perceptions in the fingertips. As this must be done in person, we will only be collecting for individuals who come in for imaging. During each test, two orange tips on the Brain Gauge device will vibrate the pointer and middle finger on a participant's non-dominant hand in a specific way. The computer-based application will ask questions about what the participant felt. By measuring eight components of brain health (speed, focus, fatigue, accuracy, sequencing, timing perception, plasticity, and connectivity) the application will then analyze responses using clinically-proven neuroscience to provide a comprehensive mental fitness score called the CorticalMetric.

INTERVENTIONS

1. **On-line SMART** - (Strategic Memory Advanced Reasoning Training) is a curriculum that teaches information-processing strategies, in such a way that may improve brain health and performance.

2. **Stress Solutions** - provides individuals with practical tools to enhance performance, reduce stress, build resilience and improve quality of life. You will learn and practice skills in awareness, self-regulation, and emotional regulation with techniques grounded in mindfulness meditation.
3. **BrainHealth Awareness**– provides general education, tips, and new scientific findings to build awareness of how our daily habits may be impacting our brain health.
4. **BrainHealth Coaching** – Quarterly online coaching sessions will be offered to participants to address questions and provide support for implementation of intervention strategies and education.

Number of Participants: 200

Length of Participation: The time commitment for the pilot study is 2 years, but you will be invited to participate in the full BrainHealth Project, for which participation will be no longer than 10 years. However, if you decide to stop participating in the study at any time, we encourage you to tell the researchers.

Inclusion / Exclusion Criteria: Any English speaking, healthy adult, aged 18 and older that resides in the DFW Metroplex may elect to participate in the study, regardless of gender, race, or ethnicity.

Children are excluded from this pilot study, as are participants who do not understand the English language, as they must be able to benefit from the training, coaching, and assessment services as they are not offered in other languages at this time.

As this study is focused on the brain health of healthy adults, those with neurological disorders, injuries or disabilities (dementia, multiple sclerosis, Parkinson's, traumatic brain injury, stroke), psychiatric disorders (schizophrenia, bipolar disorder, clinical depression), and uncontrolled health issues (substance abuse, hypertension, hypo- or hyper-thyroidism) will be excluded. Those that initially meet inclusion will continue in the study, even if they do not continue to meet inclusion criteria.

Individuals that are not eligible for MRI scanning based upon the safety screening may still participate in all other aspects of the protocol and will not be removed from the study.

Possible Risks: Minimal risk is associated with the training and assessments. Boredom or fatigue may occur during both the training and assessments, but participants may take breaks or ask to stop during the testing and/or training sessions. The University of Texas at Dallas and the Center for BrainHealth is not responsible for medical emergencies unrelated to research procedures (i.e., off-site and/or during travel). Participants are responsible for medical emergencies during participation in the training.

Magnetic Resonance Imaging is non-invasive and very well-tolerated by most individuals. However, persons who have a fear of being confined in closed or narrow spaces sometimes cannot stay in the scanner. If you experience an uncomfortable feeling of being closed in, the scan will be stopped right away at your request, and the technician will take you out of the scanner immediately. Remember that your participation is voluntary, and we want you to be comfortable while taking part in this research.

It is known that the magnets used in the MRI machine disturb the functions of metal implants in your body. Therefore, prior to participating in neuroimaging, you will undergo a screening to make sure that it is safe for you to go into the MRI machine. We ask that you inform our technician about any metal implants in your body, including pacemakers, cardiac fibrillators, metal clips, plates, etc.

The scanner makes a loud, banging or tapping noise while it is taking pictures. You will be given a set of earplugs to help reduce the noise.

You may experience some discomfort and fatigue from lying still during imaging. You will be able to move some in between scan sequences that usually last only a few minutes. We can always take you out of the scanner if you are too fatigued and need to bend or stretch, or need a break.

There are no known effects from exposure to magnetic fields.

MRI may not be appropriate if you are pregnant or are trying to become pregnant. MRI may not be appropriate if you have permanent eyeliner or eyebrows or any pieces of metal in your body, such as the following:

- Heart pacemaker, heart valve replacement, or aortic clips
- Metal fragments in your/your child's eyes, skin, or elsewhere in your/your child's body brain clips or pieces of metal used in aneurysm surgery or intracranial bypass venous umbrella
- Pieces of metal in the body resulting from work as a sheet-metal worker or welder
- Clips placed in an internal organ
- Prosthetic devices, such as middle ear, eye, joint, or penile implants
- Joint replacement
- Hearing aid that cannot be removed
- Neurostimulator
- Insulin pump
- Intrauterine device (IUD)
- Shunts or stents
- Metal mesh or coil implants
- Metal plate, pin, screws, or wires, or any other metal implants
- Fear of being within narrow or confined spaces (claustrophobia).

Above conditions can be harmful if MRI scanner disrupts the function of the heart pacemaker or affects the implanted metal objects. Please give complete information about your health history and hospitalizations.

Other rare risks of MRI:

1) Neurostimulation - In some cases MRI has produced neurostimulation effects, such as muscle twitches and tingling sensations, due to the rapid switching of magnetic field gradients used, but there are no known risks associated with these effects.

2) Quench Hazard - the MR scanner uses liquid nitrogen and liquid helium. It is remotely possible that the liquid nitrogen and helium will boil off rapidly and fill the magnet room with extremely cold dense gaseous nitrogen and helium, which can be dangerous if breathed for more than a few moments. The scanner operator will detect this and immediately provide assistance to you and anyone in the magnet room should such an event occur.

There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please discuss this with the researchers.

Risks to an embryo, fetus or a breast-fed infant: A woman who is pregnant or is breast-feeding an infant should not participate in this research. Magnetic waves may harm an embryo/fetus. It is not known whether magnetic resonance imaging may harm an embryo or fetus or an infant who is breast-feeding. If you are a woman who can have children, it is your responsibility to inform research staff about any possibility that you may be pregnant.

During the MRI, subjects will be able to communicate through the intercom built into the scanner. The procedure will be stopped if the subject is unable to complete the study or shows any signs of intolerance such as frequent movements. Potential to heat tissue is present in all magnetic resonance imaging. The amount of power is monitored with appropriate built-in instrumentation to assure the power and heat absorption is under FDA standards. In any event of system failure or problems scanning will stop.

Participants will be informed about new research that provides additional information about risks or that may influence their decision to continue participation in this research.

Possible Benefits to the Participant: Participants may or may not benefit directly from this training. Potential benefits are as follows:

- BrainHealth Physicals– As a result of participating in this study, you will receive feedback on your performance in various areas of language and thinking, as well as recommendations about how to address or optimize any areas of concern.
- On-line SMART training – As a result of participating in this study, you will receive strategies that can be integrated into your daily life.
- On-line Stress Solutions training – As a result of participating in this study, you have the potential to reduce stress and improve overall well-being, which may have a positive influence in their daily lives in home, work, family, and community-related tasks.
- BrainHealth Awareness - As a result of participating in this study, you have the potential to learn healthier lifestyle habits to help improve your sleep, diet, physical activity, and social relationships.

Alternatives to Participation: Individuals may choose not to participate

Payments to Participate: Participants will not receive reimbursement for participation in this research project.

Voluntary Participation: All individuals have the right to agree or refuse to participate in this study. Individuals who consent to participate also have the right to change their minds while experiencing the experimental procedure. Participants may tell the investigator that they no longer wish to participate. Refusal or withdrawal of participation will not involve any penalty or loss of benefits to which non-participants are entitled. Refusal to participate will not affect participants' legal rights or the quality of instruction they may wish to receive at the Center for Brain Health/ Brain Performance.

Your decision whether or not to participate will not affect your grades or education in any way.

Records of Participation in this Research: All of the information participants provide to investigators as part of this research will be protected and held in confidence within the limits of the law and institutional regulation.

Within the dashboard that houses the online assessments, trainings and education, data automatically enters into a secure data management system through Amazon Web Services. Additionally, we are collecting usage analytics on online behavior in order to personalize the learning experience with customized content. Within the data management system, each participant will be assigned a unique code that will enable research staff to easily conduct group analysis and protect participant identity.

Only authorized researchers will have access to the password-protected Personally Identifiable Information.

Any paper copies collected at in-person visits (brain imaging) will be de-identified within 48 hours of scan and kept stored in a locked file cabinet accessible only to authorized researchers.

Information Available to Others:

Members and associated staff of the Institutional Review Board (IRB) of the University of Texas at Dallas may review the records of your participation in this research. An IRB is a group of people who are responsible for assuring the community that the rights of participants in research are respected. A representative of the UTD IRB may contact you to gather information about your participation in this research. If you wish, you may refuse to answer questions the representative of the IRB may ask.

Publications Associated with this Research: The results of this research may appear in publications but individual participants will not be identified.

Contact People: Participants who want more information about this research may contact any of the investigators listed at the top of page 1 of this document. Participants who want more information about their rights as a participant or who want to report a research related injury may contact:

The University of Texas at Dallas Institutional Review Board 972-883-4579

UTD Office of Research

Signatures

A participant's signature indicates that they have read, or listened to, the information provided above and that they have received answers to their questions. The signature also indicates that they have freely decided to participate in this research and that they know they have not given up any of their legal rights.

_____
Participant's Name (printed)

_____ _____
Participant's Signature Date

_____
Name of Researcher Obtaining Consent

_____ _____
Signature of Researcher Obtaining Consent Date

The University of Texas at Dallas
Institutional Review Board
NOV 22 2019
Approved