The University of Texas at Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research Project: Combined Mindfulness Meditation and Executive Control Training to Optimize Neurocognitive Functions in Older Adults

Investigators:	**Contact information**
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Key Information: If you participate in this study, you will be asked to train on a memory training video game over 8 weeks. We will test your memory and attention in a variety of ways before and after this training. You'll be required to attend a cognitive screening appointment at our lab before and after training so that your memory and attention can be tested, and to undergo an MRI (Magnetic Resonance Imaging) scan at the Brain Health Imaging Center, and a NIRS (Near-InfraRed Spectroscopy) scan at the Callier Center, both before and after training so that we can collect images of your brain. During the training period, you'll be asked to perform 2.5 hours training at home each week using a tablet computer that we provide you, as well as to participate in a phone check-in once each week. In total, you will undergo a screening session, attend two cognitive testing appointments, 2 neuroimaging sessions (MRI+NIRS scans), and participate in at least 8 phone calls during the course of this study, and will perform 20 hours of at-home training during the course of this study. Finally, you will complete online questionnaires 6 months after your last in-person visit.

Purpose: The purpose of this research study is to evaluate the effects of combined mindfulness meditation and cognitive training on the cognitive abilities and quality of life of individuals with age-related cognitive decline as compared to a cognitive training alone.

Description of Study:
If you volunteer to take part in this research study, you will be asked to sign this consent form and will have the following tests and procedures.

Screening Procedures
To help decide if you qualify to be in this study, the researchers will ask you questions about your health, including medications you take and any surgical procedures or major injuries you have had.

You will fill out certain forms and complete following exams, tests, or procedures:

- Demographic information
- Health history questionnaire
- Montreal Cognitive Assessment (MOCA)
- MRI Screening Form

Procedures and Evaluations during the Research

The following table summarizes what is included in the study and how many visits you need to make to our lab:

Appointment	Time	Location	Brief description
Appointment 1: Orientation, cognitive screening	0.5-1 hr	Remote Visit (via MS Teams)	Orientation to the study, health history screening. After this visit, if you are eligible to continue in the study, you will return for further sessions.
Appointment 2: Neuropsychological testing	2.5 hrs	Center for Vital Longevity; Home online	Computerized, paper-and-pencil, and experimenter administered cognitive assessments, online surveys, and online cognitive task
Appointment 13: MRI and NIRS neuroimaging	3.5 hrs	UTD Brain Performance Institute and Callier Center	MRI Scan and NIRS Scan
Home Training & Appointments 4-11	2.5 hrs of training per week, 1 phone consultation per week	Phone consultation	You will complete these training sessions at your leisure in your home
Appointment 12: Neuropsychological testing	2.5 hrs	Center for Vital Longevity; Home online	Computerized, paper-and-pencil, and experimenter administered cognitive assessments, online surveys, and online cognitive task
Appointment 13: MRI and NIRS neuroimaging	3.5 hrs	UTD Brain Performance Institute and Callier Center	MRI Scan and NIRS Scan
Appointment 14: Online Surveys 6 months after Appointment 13	0.25-0.5 h	Phone consultation	Online surveys to be completed at your leisure in your home

The day before and on the day of each visit you will be contacted via phone and questioned about possible COVID symptoms or exposure. If you indicate a possible infection, you will be scheduled at a later date, at least 3 weeks after the symptoms subside. Upon your arrival to the appointment, your temperature will be checked using a contactless thermometer. Your visit will be rescheduled if the measured temperature is above 99.5F.

Each of the appointments in the table are described in more detail below:

- **Appointment 1: Orientation and cognitive screening**. During this screening and orientation session, we will introduce you to the study and ask you to complete a survey to assess whether you qualify to continue in the study. You will be asked to complete a demographic and detailed health history questionnaire. The demographic survey asks for information about you (such as date of birth, sex, native language, educational background, occupation), about physical characteristics (handedness, hearing, color blindness), about your medications, hospitalizations, and medical conditions or medical diagnosis. We will also ask for your contact information and whether you agree to be contacted about other studies in this lab.

- **Appointments 2, 12, Neuropsychological assessment.** You will be asked to complete one neuropsychological testing session before the intervention, and one after the intervention. You will be asked to perform a variety of computerized and paper pencil tasks that measure cognitive, learning, and motor skills. You will be given breaks between tests. These in-person assessments will be conducted with strict health and social distancing measures in place. Experimenters will wear a mask and participants will be strongly encouraged to wear face masks for the duration of the assessment, and a minimum 6ft distance between experimenter and participant will be maintained throughout. Additionally, the testing room and all testing materials will be thoroughly disinfected before and after each session. After these sessions, you will receive an email with links to online surveys concerning your well-being, everyday activities, level of mindfulness, as well as a link to a sentence comprehension task, all to be completed from home.

- **Appointments 3 and 13: MRI and NIRS Scans.** You will be asked to complete two MRI scans and two Near-Infrared Spectroscopy (NIRS) scans as part of this study. The NIRS will be performed at the Callier Center in Dallas. This set of procedures will require an array with sensors to be placed on your head. The MRI scans will be performed at the UTD Brain Performance Institute. This set of scans will require you to lie as still as you can while resting quietly. Upon arrival at the UTD Brain Performance Institute you will be greeted by a lab researcher, who will perform a temperature check and will escort you into the waiting room. The researcher will guide you through the MRI screening procedures and familiarization with the tasks you will do in the MRI scanner. You will then be asked to change into metal-free protective clothing and to wear a surgical mask, which we will provide to you, and you will be asked to remove all metal objects.

An MRI scanner takes images of your brain by sending out a magnetic field and radio waves. Because the MRI scanner contains a very strong magnet, you may not be able to have the MRI if you have certain kinds of metal in your body (for example, a heart pacemaker, a metal plate, and certain types of heart valves or brain aneurysm clips). Someone will ask you questions about this before you have the MRI. Let us know if you have had surgery of any kind.

In particular, you should not participate in this study if you have any of the following in your body:

- Pacemaker
- Coronary Stent
- Defibrillator
- Neurostimulator

There are a number of conditions that will prevent you from having the MRI, we will review these with you to see if you can have the MRI.

Once cleared to have an MRI in this study, you will enter the MRI room with your experimenter and MRI technicians. The MRI scanner is a large machine that contains a hollow tube. You will be asked to lie on your back on a special table that slides into the tube. For this study a coil will be positioned around your head. The head coil is similar in shape to a helmet. The coil is the part of the machine that receives the MR signal and allows images to be captured. The sides of the tube will be fairly close to your body and the scanner makes a loud hammering noise while you are inside. You will be able to talk to people in the room through a speaker system. We will monitor you closely while you are inside the scanner. You will also be given earplugs to wear. The earplugs reduce the sharpness of the banging noise the MRI machine makes. However, you will still be able to hear us talk to you, and you will also be able to talk to us at any time. We will also give you a squeeze ball to press in case of an emergency. This sets off an alarm that notifies the technologist that you need help.

- Next, the bed will be moved into the magnet. The MRI technician will talk to you throughout the study and let you know how you are doing and what to expect next. Since we are interested in how your brain is functioning during two types of cognitive task performance and at rest, you will complete several blocks that require either reacting to visual stimuli by pressing buttons on the provided button box or resting quietly while being scanned. We will use a mirror mounted on the head coil so that you can see visual stimuli. You will be able to communicate with the technologist using a microphone that is built into the MRI machine. You will be informed prior to the scan of the exact procedure that will occur during the MRI. If you become uncomfortable and wish to stop the examination at any time, you may inform the technologist, and the study will be terminated and you will be moved out of the magnet. The technologist will also let you

know when the images are being acquired. You will need to hold very still during that time. You should hold relatively still in between images as well. You will be in the magnet for approximately 60 minutes. For most of this time you will not have to actively do anything except lie quietly while we collect images of your brain. When the scan is complete, you will be moved out of the magnet. You should get up slowly to allow your body to get used to moving and being vertical again. Afterwards, you will be led to a testing room for additional behavioral testing which will last 20 minutes. At this point, your blood pressure will be measured twice in a span of 1 minute using an automatic blood pressure machine.

After the completion of your MRI scan, a member of the research team will electronically move the images that were taken to another secure computer. Any information that could be used to identify you as the subject of these images will be replaced with a unique ID code. The images and information about how they were taken will be stored in a central database so that other researchers can use them to evaluate how MR imaging could be used for their research projects. These investigators must submit a formal written request to the research team for approval to have access to the data. The data may then be copied electronically to their laboratory's computers. Your name and corresponding code will be kept in a locked cabinet that can only be accessed by the research team. The other investigators who have requested to use the images will not have access to the correspondence between the unique ID code and your name.

The MRI images for this study are not being used to evaluate your health. The images obtained for this study are for specific research purposes and are not being used to find medical abnormalities. These images will not routinely be reviewed by a radiology physician to diagnose existing abnormalities. There is a possibility that we will discover that you have an abnormal image. We cannot make a determination from the images that we are collecting if this abnormal image is associated with disease. If we notice an abnormality, we will show the image to a diagnostic radiologist who will then advise us on how to proceed. If the abnormal image presents a medical concern, you will be contacted with a recommendation to follow up with your physician. In order to reduce the risk that we unnecessarily upset someone about an abnormal image, we will not allow you or anyone with you to see the pictures at the time of the study. If you would like to see your images at a later time, you may set up an appointment. This appointment must be at least one week after your study date.

The psychological assessments in this study are designed for research, not for medical purposes. They are not useful for finding problems or diseases. Even though the researchers are not looking at your results 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 assessments done in this study are not for medical purposes, the research results will not be sent to you or to your regular doctor.

- Afterwards, you will be asked to drive to the Callier Center in Dallas for the NIRS scan. Upon arrival at the Callier Center, a lab researcher will greet you. Note: During the NIRS recording, a headband with wires attached to it will be places on your forehead with Velcro straps. The headband contains small electrode "buttons". Once in place, the headband presents minimal interference equivalent to wearing a tight-fitting sports sweatband, but you should not feel significant discomfort. You will perform a computer task, and then rest for a few minutes while wearing the NIRS system. During the post-training visit (Visit 13) you will be asked to shortly engage in mindfulness meditation while wearing the system. All sessions will take place in a quiet testing room in which you will be seated. For the NIRS studies, to make the visual stimuli easier to see on the monitor, the lights will be dimmed at the start of the experiment and the room with be lit indirectly.

  NIRS is a portable neuroimaging device using near-infrared light to non-invasively measure changes in blood oxygenation in the brain during cognitive task performance and rest. The are no known counter-indications or risk associated with using the NIRS system.

- **Appointments 4-11.** You will be asked to complete an 8-week combined mindfulness meditation and cognitive training intervention at home, which involves spending 2.5 hours per week training with programs that we provide to you.

  The psychological assessments in this study are designed for research, not for medical purposes. They are not useful for finding problems or diseases. Even though the researchers are not looking at your results 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 assessments done in this study are not for medical purposes, the research results will not be sent to you or to your regular doctor.

Number of Participants: Approximately 20 people will be involved in this study.

Length of Participation: The overall time commitment will be no longer than 33 hours over the course of 1 year. However, if you decide to stop participating in the study, we encourage you to tell the researchers.

Inclusion Criteria: Volunteers will be accepted for participation irrespective of their gender, racial, or ethnic background. However, individuals will be included in the study only if they are right-handed, aged 65 to 85, have at least high school education and learned English before age 5. Additionally, you can't be included in the study if you have claustrophobia or metal implants above the waist. If you are female, you cannot be pregnant or likely to be pregnant. To be included in the study, you need to meet a score threshold on the screening cognitive assessment (MoCA). Moreover, you need physical and sensory capacity sufficient to undertake an fMRI study, which we will determine during the prescreening session. Physical capacity includes the ability to stay still for the duration of the scan and sufficient finger dexterity to press buttons on

the provided button boxes during the scan. Sensory capacity includes vision acuity of at least 20/30 after correction and no color blindness.

Exclusion Criteria: You will be excluded from the study if you are left-handed or ambidextrous weigh over 300 lb, did not attain at least high school education, and have not learned English before the age of 5. You will also be excluded if you are color blind, have vision acuity worse than 20/30 after correction, or experience excessive hand tremor or other motor impairment related to hand movement, as you would not be able to perform the tasks successfully.

Additionally, there are multiple medical conditions which could preclude you from participation in this study, including, history of cardiovascular disease other than treated hypertension, diabetes, psychiatric disorder, illness or trauma affecting the central nervous system, including stroke and head trauma resulting in loss of consciousness over 5 seconds, substance/alcohol abuse, and use of medication with anti-depressant, anti-psychotic effects. Use of hypnotic medication is allowed only occasionally at bedtime. Hypnotics are prescribed to induce sleep or improve its length and/or quality, and include such prescription drugs as Xanax, Ambien, Valium, etc.

An MRI screening questionnaire will be administered prior to entering the scanner. This screening questionnaire assesses current and prior medical conditions that could potentially exclude participation in the study. The screening questionnaire also addresses medical devices or implants that you may have, as well as non-medical sources of metal, e.g., shrapnel, prior hobby/work with metal. These procedures are essential to your safety, as any metal objects or devices containing metal, pose a serious threat tin the proximity of the scanner. You can be excluded if your MRI image reveals evidence of pathology. Female participants that are pregnant or likely to become pregnant are not eligible for this study.

Possible Risks: You may experience some discomfort during the assessments. Assessments may be fatiguing for some individuals. To minimize the potential discomfort, breaks are encouraged.

You may experience some discomfort during program use such as boredom, fatigue, frustration, mood complaint, headache, tremor, eye strain, neck/shoulder discomfort, leg/hip discomfort, arm/wrist discomfort, back discomfort, headache and sleep difficulty. If you experience any discomfort, it is encouraged that you take a break from using the program.

Sensitive questions (e.g. about depression, other illness), that will be asked, may cause negative emotions or embarrassment. If you find these questions to be upsetting, we encourage you to discuss this with a trained professional.

You may be uncomfortable inside the MRI scanner if you do not like to be in closed spaces (“claustrophobia”). During the procedure, you will be able to talk with the MRI staff through a speaker system. You can tell them to stop the scan at any time.

The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given earplugs to reduce this risk. Participants will wear earplugs during all scanning.

A metal object flying through the air toward the magnet and hitting you presents the greatest risk associated with MRI. To reduce this risk, we require that all people involved with the study undergo MRI safety training and remove all metal from their clothing and pockets during the MRI session. No metal objects will be brought into the magnet room while you are inside the room. In addition, the door to the room remains closed throughout the study so that no one can accidentally bring a metal object into the room.

There are no known risks associated with limited exposure to magnetic fields. Magnets of this strength have been in use for medical imaging for over 15 years. However, we will keep a record of the length of time you were in the magnet as well as the amount of radio waves used during that time.

There is no known risk associated with MRI to the unborn child. In fact, MRI is often used to look at problems in unborn children. However, we cannot rule out the possibility that such a risk will be discovered in the future. Its effect on the unborn child is not known. Therefore, if you are a woman of childbearing age, you should not participate if you are pregnant, trying to become pregnant, or currently breastfeeding. There are no known risks associated with the NIRS technology.

Loss of Confidentiality

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

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: If you agree to take part in this study, there may or may not be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research. You may benefit from participation in this study, as you will have an opportunity to receive instruction in a novel simulation game, which has the potential to be an enjoyable activity, at no cost. You may also benefit by learning to follow a guided mindfulness meditation program, with the possible benefit of stress-reduction. The possible benefits of participation far exceed the risks. Other than the details noted above, there are no direct physical or medical benefits to the participants of this study.

We hope the information learned from this study will benefit others in the future. Information gained from this research could benefit individuals with age-related cognitive decline.

Alternatives to Participation: Individuals may choose not to participate

Payments to Participate: You will be issued a UT Dallas GalaxyPay card, which can be used as a credit or debit card (Mastercard). Compensation will be credited to the card after completion of each session. You will be asked to provide your name, mailing address, date of birth, and gender in order to receive the card.

Participants will be compensated in the following rate:

Sessions	Time (hour)	$/hour	Total Cost($)	Weeks
Appointment 1 (Phone Screening)	0.5	10	$5	Week 1
Appointment 2 (Neuropsychological Assessment)	2.5	10	$25	Week 1/2
Appointment 3 (Neuroimaging)	3	25	$87.5	Week 1/2
At-Home Training & Apts. 4-11	20	5	$100	Week 2-9
Appointment 12 (Neuropsychological Assessment)	2.5	10	$25	Week 10
Appointment 13 (Neuroimaging)	3	25	$87.5	Week 10
Appointment 14 (Online Surveys)	0.5	10	$5	6 Mo retention
Completion Bonus	-	-	$20	Upon Completion
TOTAL	**32**		**$355**	

Payment will be transferred to your card after each completed visit. In the case of at-home sessions, you will be given payment for those session at the conclusion of your next in-lab visit.

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 education/healthcare they may wish to receive at UTD or the Callier Center.

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. All possible steps have been taken to assure your privacy. The experimenter will assign you an arbitrary code number which will be used throughout the research. Only this code (and never your name) will be used when analyzing or reporting the data. Any identifying information will be kept in a locked location in the University of Texas at Dallas or via password protected platforms. All data will be password protected, stored/accessed using UTD-approved platforms, and accessible only by approved study personnel.

Identifiable Private Information: Private information that can be used to identify you will be removed from the data collected in the course of this study. After such removal, the de-identified

data could be used by Investigators for future research studies or distributed to another investigator for future research studies without additional informed consent.

COVID-19 Information: COVID-19. The novel coronavirus, COVID-19, has been declared a worldwide pandemic by the World Health Organization. COVID-19 is extremely contagious and is believed to spread by the kind of person-to-person contact that you may engage in by participating in this research study. Thus, as with any activity involving person-to-person contact, there is a risk that you might contract the virus and expose other individuals that you might come in contact with after participation in this study. Older adults and people of any age who have serious underlying medical conditions like heart disease, diabetes, cancer, or a weakened immune system, are at a higher risk for getting very sick from COVID-19.

Vaccines. The number of fully vaccinated individuals continues to grow, but there remains a portion of the population that has yet to be vaccinated. Studies indicate COVID-19 vaccines are effective at preventing disease and reduce the risk of people spreading the virus. However, some people who are fully vaccinated against COVID-19 will still get sick because no vaccine is 100% effective. Experts continue to monitor and evaluate how often this occurs, how severe their illness is, and how likely a vaccinated person is to spread COVID-19 to others.

Additional guidance from the Center for Disease Control (CDC) indicates there many things we are still learning about the vaccine, such as:
How effective the vaccines are against variants of the virus that causes COVID-19. Early data show the vaccines may work against some variants but could be less effective against others.
How well the vaccines protect people with weakened immune systems, including people who take immunosuppressive medications.
How long COVID-19 vaccines can protect people.

Investigators are taking extra precautions based on CDC recommendations. If you have questions about the safety measures that are in place, the investigators can provide you with this information. These measures have been approved by the Institutional Review Board.

Questionnaires to Assess COVID-19 Symptoms and Exposure: The investigators will be conducting pre-screening (before the in-person visit) and post-screening (after the in-person visit) questionnaires to assess your symptoms and exposure to COVID-19. The pre-screening questionnaire will be completed approximately 24 hours before the in-person visit and again when you arrive for your session, and the post-screening questionnaires will be completed approximately 1 week after the in-person visit. If you experience any symptoms related to COVID-19 or receive positive test results after your participation in this research study, you are strongly encouraged to contact the investigators or the IRB Office.

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 and Innovation

Additional information, including the nature and details of the researcher's or the research entity's financial interest, are available upon request.

Participation in Future Studies: With your permission, we will contact you for future studies with our lab that you may qualify for. If given, you may revoke this permission at any time.

Would you like to be contacted about future volunteer opportunities with our lab? (Circle One)

Yes No

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