Informed Consent Form

Impact of Challenging Engagement on Cognition in Older Adults (engAGE)

NCT03962439

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The University of Texas Southwestern Medical Center at Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research:	Impact of Challenging Engagement on Cognition in Older Adults
Funding Agency/Sponsor:	National Institute on Aging
Principal Investigator:	Denise C. Park, Ph.D. University Distinguished Chair in Behavioral and Brain Sciences and University Regents Research Scholar at the University of Texas at Dallas Adjunct Professor of Psychiatry at UT Southwestern Medical Center

You may call these study doctors or research personnel during regular office hours at 1 (888) 744-0582. At other times, you may call them at (972) 567-9789.

Instructions:
Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him or her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

Why is this study being done?
This research is being done because there is evidence that being deeply involved in intellectual activities in mid and late adulthood may be related to better cognitive functioning, health, and well-being. The present study is designed to examine this relationship and its durability.

Why is this considered research?
This is a research study because we are examining the cognitive consequences of new learning activities. We are varying conditions under which people learn and assessing what types of new learning facilitate or enhance cognitive functioning, health and wellbeing over the course of the lifetime.

The following definitions may help you understand this study:

- Standard medical care means the regular care you would receive from your personal doctor if you choose not to participate in this research.
- Researchers means the study doctor and research personnel at the Center for Vital Longevity at UT Dallas, the University of Texas Southwestern Medical Center, and its affiliated hospitals.

Why am I being asked to take part in this research study?
You are being asked to take part in this study because you are a healthy individual 60 years of age or older

Do I have to take part in this research study?
No. You have the right to choose whether you want to take part in this research study. If you decide to participate and later change your mind, you are free to stop participation at any time.

How many people will take part in this study?
About 90 people will take part in this study at UT Southwestern Medical Center, the Center for Brain Health and the Center for Vital Longevity. About 45 people will qualify and complete an MRI scan session.

What is involved in the study?
Participation in this study requires a significant time commitment on your part. Should you decide to participate in this study, you will be asked to participate in:

- Pre-testing in Weeks 1 and 2
- 15 hours of engagement activities during Weeks 3-16
- Keeping a weekly log of your time spent on intervention-related activities, as well as your enjoyment of them

You will be assigned to one of three engagement groups. Two of these groups will be receiving instruction in digital photography, and the other group will be engaging in interesting and enriching activities from the comfort of their home

Finally, a subset of participants will be selected based on a structured screening protocol for inclusion in two, 1½ hour magnetic resonance imaging (MRI) sessions in weeks 1-2 and weeks 15-16.

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<u>Group Assignment</u>
You will be assigned to to either a group that learns digital photography or that learns at home.. Your assignment to these groups will be determined by random assignment and the study needs

In signing this consent form, you are agreeing to participate in either photography classes or at home engagement. We cannot guarantee your inclusion in a specific group.

<u>Evaluations during the Research for All Participants:</u>
If you decide to participate in this study, you will be asked to come into the testing center to complete two cognitive assessments and questionnaires: once at the beginning of the

intervention, and once at the end of the intervention. . You will be taken into a quiet room and asked to fill out a number of questionnaires and complete various computerized and paper-and-pencil tasks. These questionnaires and tasks will cover various topics from your level of education to your general level of health. You will also be asked to complete a packet of take-home questionnaires and surveys at the beginning and the end of the intervention.

If you are selected to participate in the photography sessions, you will be loaned a digital camera. You will be assigned to a group that will meet for 2 ½ hours twice a week for 14 weeks. You will be required to spend an additional 10 hours each week working on your photo project at the training center.

If you are selected to participate in the at-home engagement group, you will be supplied with a range of stimulating activities to complete each week at home. You will come to the intervention center once a week to maintain contact with the researchers and to receive a new set of materials. You will have five hours of required activities each week and select an additional 10 hours of activities of your choice.. All materials associated with the activities will be provided to you by the research team.

Additional Procedures during the Study for Participants Selected to Participate in MRI
If you are selected to participate in the imaging portion of the study, you will participate in an MRI screening two times throughout the study – Weeks 1 or 2 and Weeks 15 or 16.

Each imaging session will take place at either the University of Texas Southwestern Medical School or the Center for Brain Health located on Mockingbird Lane, less than half a mile from UTSW. Scanning will take approximately 1.5 hours. These sessions may consist of completing some standard tasks of working memory and long-term memory. In each session, you will complete a number of practice sets of tasks followed by the actual tasks while in the magnetic resonance imaging (MRI) scanner. MRI is a noninvasive technology used to generate images of a participant's brain while the participant completes various tasks. Researchers then use these images of brain activity to gain an understanding of the functional organization of the brain. MRI images are generated from a magnetic field and low-power radio waves. There are no known effects from exposure to magnetic fields.

The MRI scans in this study are designed for research, not for medical purposes. They are not useful for finding problems or diseases. Because the MRI scans done in this study are not for medical purposes, the research results will not be sent to you or to your regular doctor.

How long can I expect to be in this study?
If you agree to participate in this study, you will be participating in a number of tasks over a 16-week period as detailed above. This includes the pre-intervention assessments (Weeks 1-2), the intervention itself lasting 14 weeks (Weeks 3-16), and the post-intervention assessments (Weeks 15-16).

You can choose to stop participating for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers. You may be asked if you are willing to complete some study termination tests.

What are the risks of the study?

Psychological Stress

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may feel emotionally distressed and feel that your performance is unsatisfactory. You may refuse to answer any of the questions, take a break, or stop your participation in this study at any time.

Study Intervention

By participating in the intervention portion of this study, you put yourself at no more risk than that which would normally occur on a daily basis. However, you will be monitored at all times in order to ensure safety and proper technique in all interventions. There is also a risk for disappointment as the interventions end.

Risks Associated with MRI (applies if you are selected for the MRI portion of the study)

You will have magnetic resonance imaging (MRI) of your head. For this procedure, you will lie quietly inside a large, doughnut-shaped magnet for about 1 hour. Your head will rest in a special helmet-like holder to help you keep your head still. The MRI scanner makes a loud, banging noise while it is taking pictures. You will be given a set of ear plugs and headphones to help reduce the noise.

You may experience nervousness from confinement in a tight space (claustrophobia). If you become anxious, you can stop the procedure at any time.

You may experience some discomfort and fatigue from lying still during imaging.

If you have any metal clips or plates in your body, you should tell the investigator.

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 eyes, skin, or elsewhere in your body
- brain clips or pieces of metal used in aneurysm surgery or intercranial 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

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

The researchers will not, in any case, disclose information about you or your participation in this study unless it is included in the Authorization for Use and Disclosure of Protected Health Information for Research Purposes or it is required by law.

Finally, you should understand that the investigator is not prevented from reporting information to authorities in order to prevent serious harm to you or to others. If the investigator suspects child, elder, or disabled persons abuse, they will report such concerns to proper authorities as required by law.

Other Risks:
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.

How will risks be minimized or prevented?
Potential risks and discomforts are minimized to the greatest extent possible because your procedures will be overseen and monitored at all times by well-trained, highly experienced individuals. If at any time, you do feel discomfort associated with the study, we will ensure that you are referred for any treatment, counseling, or other necessary follow-up.

What will my responsibilities be during the study?
While you are part of this study, it is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments.
- Follow the researchers' instructions.
- Let the researchers know if your telephone number or address changes.
- Answer all questions openly and honestly.

If I agree to this study, will I be told of any new risks that may be found during the course of the study?
Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

What should I do if I think I am having problems?

If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researchers right away. Telephone numbers where they can be reached are listed on the first page of this consent form.

If you have a sudden, serious problem, like difficulty breathing or severe pain, go to the nearest hospital emergency room, or call 911 (or the correct emergency telephone number in your area). Tell emergency personnel about any medications you are taking.

What are the possible benefits of this study?
The researchers cannot guarantee that you will benefit from participation in this research.

However, you will likely receive a direct benefit from participation in this study, as you will have an opportunity learn a complex task that has the potential to be a form of lifetime engagement and much pleasure at no cost. You also have the opportunity to increase your social connections, which is linked to increased health and decreased mortality

We hope the information learned from this study will benefit older adults in the future. Information gained from this research has the potential to demonstrate that engaging in meaningful work and play in late adulthood is a critical way to maintain one's cognitive and mental health. We believe that this research has the potential to create a social transformation in the way retirement decisions are made and the goals and activities individuals pursue in later adulthood.

What options are available if I decide not to take part in this research study?
This is not a treatment study. You do not have to be part of it to get treatment for any conditions.

Will I be paid if I take part in this research study?
Yes. You will be paid upon completion of every segment of this study as detailed below:

Pre-Intervention Behavioral Testing	$75
Pre-Intervention Take-Home Questionnaires	$50
Pre-Intervention MRI Scanning (for those who qualify)	$100
Post-Intervention Behavioral Testing	$75
Post-Intervention Take-Home Questionnaires	$50
Post-Intervention MRI Scanning (for those who qualify)	$100
Completion of each moth of the 3-Month Program	$ 150 ($50/month)

If you stop taking part in this study, you will receive payment for only the visits you have completed.

There are no funds available to pay for parking expenses, transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

You will be paid with a UT Dallas Greenphire ClinCard, which can be used as a credit or debit card. You will also receive instructions on how to use the card. If you are an employee of UT Southwestern, your payment will be added to your regular paycheck and income tax will be deducted.

Will my insurance provider or I be charged for the costs of any part of this research study?
No. Neither you nor your insurance provider will be charged for anything done only for this research study (i.e. the screening procedures or experimental procedures described above).

However, the standard medical care for any condition that you have (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care.

What will happen if I am harmed as a result of taking part in this study?
It is important that you report any illness or injury as a result of this study to the research team listed at the top of this form immediately.

Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas, University of Texas at Dallas, or the UTD Center for Vital Longevity.

You retain your legal rights during your participation in this research.

Can I stop taking part in this research study?
Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time.

If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

If I agree to take part in this research study, can I be removed from the study without my consent?
Yes. Most participants complete all of the study procedures. It is possible, however, that information may be revealed that indicates that you fall outside of the inclusion/exclusion criteria for the study. If that happens, you will not be able to continue in the study, but you will be compensated for procedures you have already completed. You may be withdrawn from the study at any time and may receive payment only for the procedures that you have completed.

Will my information be kept confidential?
Information about you that is collected for this research study will remain confidential unless you give your permission to share it with others, or if we are required by law to release it. You should know that certain organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- UT Southwestern Medical Center, UT Dallas, the Center for Vital Longevity, and the Center for Brain Health
- Representatives of government agencies, like the U.S. Food and Drug Administration (FDA), involved in keeping research safe for people;
- The UT Southwestern Institutional Review Board.
- Representatives of domestic and foreign governmental and regulatory agencies

In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details about how your information will be used for this research study, and who may see and/or get copies of your information.

Whom do I call if I have questions or problems?
For questions about the study, contact the engage Project main line at (972) 812-0248 or Avanti Dey (Research Coordinator) at (972) 883-3734 during regular business hours. Dr. Park can also be contacted at (972) 883-3255 or at (972) 567-9789 after hours and on weekends and holidays.

For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.

SIGNATURES:

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

_____

Participant's Name (printed)

_____ _____

Participant's Signature Date

_____

Name of person obtaining consent (printed)

_____ _____

Signature of person obtaining consent Date