Official Title: MIND Food and Speed of Processing Training in Older Adults with Low Education, The MINDSpeed Alzheimer's Disease Prevention Pilot Trial

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INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

MIND Food and Speed of Processing Training in Older Adults (MINDSpeed)

You are being asked to be in a research study. The study is looking at how brain health foods and game play affect thinking and memory. You were selected as a possible subject because you are at least 60 years old and meet other study criteria.

This consent and Authorization form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by Dr. Daniel Clark from the Regenstrief Institute and the Indiana University School of Medicine. It is funded by the National Institute on Aging.

STUDY PURPOSE

The purpose of this study is to learn how certain foods and games affect older adults' ability to process information.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree to participate, you will be one of up to 215 older adults participating in this research.

PROCEDURES FOR THE STUDY

If you agree to be in the study, you will do the following things:

Baseline Visit: At the beginning of the study, you will be asked to complete a Baseline visit at IU Health Neuroscience Center in downtown Indianapolis. This Baseline visit may take up to 2 ½ hours, but may be broken down into shorter visits as requested, and part of the visit may be completed over the telephone. Transportation will be provided for you at no cost, or should you choose to drive yourself, parking fees will be covered.

You will be asked NOT to eat or drink anything but water after midnight the day before your visit. At your visit, an experienced technician will draw 3 tubes of blood, equaling about 1 ¼ Tablespoons total. Your blood will be used to test for the presence of a gene called Apolipoprotein E (APOE), and biomarkers (characteristics) of the blood. After blood is obtained, we will ask you to provide a urine sample to evaluate your diet and nutrition. **Blood and urine collection are requirements of participation. If blood or urine cannot be obtained, the remainder of the in-person visit will be completed and you will be given the opportunity to schedule a second visit to reattempt these specimen collections. Otherwise, no other procedures will be performed for this study and your participation will end.**

You will be offered a drink and a light snack after these samples are collected; you may also bring items from home if you prefer.

You will be asked to complete thinking and memory activities, and questionnaires about your mood, memory, health, and daily activities. We will also take measurements like height, weight, and blood pressure. We will collect information from your medical records to identify health factors that may be associated with your response to the intervention activities.

You will be asked to complete 2 more appointments like this at IU Health Neuroscience Center approximately 3 months and 6 months after your Baseline visit.

You may be asked to repeat the blood or urine collection at any of these appointments if the first samples become compromised (i.e., not useable) in any way.

MRI Visit: At the beginning of the study, you will be invited to complete a brain scan called a magnetic resonance image (MRI). The MRI contains a series of scans to obtain pictures of your brain. This requires that you lie still inside the center of a large doughnut shaped magnet for approximately 30 minutes. Your head will be placed in a special helmet-like "head holder" to help you keep your head still. During some of the scans you will be able to relax and close your eyes; during other scans you will be asked to keep your eyes open while you view a slideshow of pictures.

These brain scans will be completed at the IU Health Neuroscience Center within 2-3 weeks of your Baseline appointment. This MRI visit may take about 1 ½ -2 hours. Transportation will be provided for you at no cost, or should you choose to drive yourself, parking fees will be covered.

If you agree to complete a Baseline MRI, we will ask you to complete another MRI approximately 3 months later.

Randomization and Tablet Orientation Visit: After all Baseline procedures are complete, you will be randomly assigned to one of four study groups; you cannot choose your group.

Study activities for all groups are completed on a small tablet computer device that you will be given for the study at the Tablet Orientation visit. At this visit, you will complete a questionnaire about your food habits and receive instructions for using the tablet. If you have problems with the tablet after this appointment, our study team is available to assist you over the phone or at your home if necessary.

This visit will last up to 2 hours and will be completed at IU Health Neuroscience Center, in combination with the MRI visit or separately. Again, transportation or parking will be provided for you at no cost.

Intervention Activities: Activities for all study groups include shopping for foods, recording eaten foods, and playing games on the tablet. Your group assignment will determine the specific foods and games that are available to you.

- You will be asked to play games for 75 minutes per week.
- You will be asked to shop for foods once per week. The foods you select will be delivered to your home once per week, or may be available for pickup at an Eskenazi Health location. These foods are in addition to your usual diet.
- You will be asked to record the foods you eat each day.

You will be asked to complete these activities for 12 weeks, though you will have use of the tablet for 24 weeks to continue game play as desired. This tablet can only be used for study tasks and will be collected at your 6 month appointment. You will receive a cookbook of study foods at your 3 month or 6 month appointment.

RISKS OF TAKING PART IN THE STUDY

While participating in the study, the potential risks are:

Risk of loss of confidentiality: Our study team makes every effort to ensure all information collected about you remains secure and is viewed only by study personnel, but we cannot guarantee absolute confidentiality. The exceptions are if you are about to harm yourself or others if the law requires we make information known.

The information which you enter into the tablet will not be identifiable. This means it will not have your name or any other information associated with you. Instead, you will be assigned a unique user ID for all information that is saved on the tablet. This information can only be accessed by the study team.

Risk of being nervous or tired during the survey and tests: It is possible that some of the study questions could make you uncomfortable or tire you. The research assistant who will be asking the survey questions and conducting the tests is trained to recognize and minimize this discomfort. You may skip any questions you do not want to answer. You may stop the tests at any point or ask the research assistant to contact you later.

Risks of drawing blood: As with any blood draw, possible risks include, pain, bruising, and rarely, infection. Blood will be drawn by experienced technicians.

Risks of scanner: The scanner is like a large tube with a hole at both ends that uses magnets to take pictures of the inside of your body. You will lie on a table that slides into the scanner. It is important to lie still while the pictures are being taken.

The risks of getting a scan are:

- **Noise**: the machine might sound loud to you when the pictures are being taken. The technician will offer you earplugs to use.
- **Metals:** Because magnets are used, no metal is allowed in the room. The technicians will ask you about any metal implants and devices you may have. Tell the technician if you think you might have steel, pins, or metal in your body.
- **Small spaces:** When the table moves into the machine, it will feel like a small space. Some people don't like the feeling of being in a small space. Tell the technician if you feel this way. You may stop at any time.

Your scan results will be read and interpreted by Indiana University School of Medicine faculty in the IU Health Neuroscience Center. In the event that clinical findings from this brain scan require further evaluation or action, this information will be communicated to you and your primary care provider by our study physician, Dr. Christopher Callahan, or his staff. You may need to meet with professionals with expertise to help you learn more about these clinical findings. The study will not cover the costs of any follow-up consultations or actions.

COMPENSATION FOR INJURY

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If you are participating in research that is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

BENEFITS OF TAKING PART IN THE STUDY

The potential benefits of participation in the study are that you may gain an increased awareness of healthy and unhealthy brain activities. You may also feel some satisfaction at having contributed to

scientific understanding of these activities and the potential of that understanding to benefit others in the future.

You will also receive feedback on blood pressure, height, and weight at your Baseline, 3 month, and 6 month study visits.
You will receive a cookbook of the study foods to incorporate into your diet if you wish.

COSTS

There are no costs to participate in this study.

PAYMENT

You will receive payment for taking part in this study in the form of gift cards which will be given to you in-person or mailed to you at the completion of the visit.

You will receive a $20 gift card when you complete your Baseline visit. You will receive a $15 gift card when you complete the Tablet Orientation visit.

You will receive a $35 gift card for completing the 3 month and 6 month appointments.

You will receive additional gift cards for reporting foods and playing games during the 12 week intervention. You will earn $1 each day you record your eaten foods, up to $7 per week. You will also earn up to $10 per week depending on the number of minutes of game play you do throughout the week. Remember that you are asked to complete 75 minutes of game play each week. Altogether, you have the potential to earn up to $204 for these intervention activities. You will receive a gift card with your total earnings at the end of the intervention.

In total, you have the potential to earn up to $309 in gift cards for completing these study procedures.

If you agree to optional brain imaging, you will receive an additional $25 gift card for completing the Baseline MRI, and a $50 gift card for completing the 3 Month MRI. You will receive these gift cards the day you complete these procedures.

ALTERNATIVES TO TAKING PART IN THE STUDY

The only alternative to taking part in this study is to not participate. If you do not want to participate in the optional MRI scans or genetic testing, you may still participate in the rest of the study.

HOW YOUR INFORMATION AND SPECIMENS WILL BE USED

The study team will collect information about you from your medical records. This information, some of which may identify you, may be used for research-related purposes. Your records may be accessed to ensure you meet the criteria to be in this study, to determine whether it is safe for you to complete a brain MRI, to gather information about your medical history to include in the research data, to check on your health in the future to help answer our research questions, or to inspect and/or copy your research records for quality assurance and data analysis. If you experience an adverse event during your participation, such as a hospitalization or injury, your medical records may be accessed for reporting purposes and to determine your continuation in the study.

The information released and used for this research will include:

- Information provided by you

- Medical history / diagnoses / treatment
- Medications
- Consultations
- Laboratory / diagnostic tests

If you agree to participate, you authorize the following to disclose your medical record information:

- Eskenazi Health
- Eskenazi Health Physicians
- Indiana University Health
- Other, not listed above: _____

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US or foreign governments or agencies as required by law
- Data safety monitoring boards and others authorized to monitor the conduct of the study
- The following research sponsors: National Institute on Aging
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - Office for Human Research Protections (OHRP)
    - National Institutes of Health (NIH)

Information or specimens collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

A description of this clinical trial will be available on **ClinicalTrials.gov**, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

HOW YOUR INFORMATION WILL BE PROTECTED

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use any information, documents, or specimens that could identify you in any legal action or lawsuit unless you say it is okay.

However, there are some types of sharing the Certificate does not apply to. The Certificate does not stop reporting required by federal, state, or local laws, such as reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate does not stop a government agency who is funding research from checking records or evaluating programs. The

Certificate also does not prevent your information from being used for other research when allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may still give them permission to release information to insurers, medical providers, or others not connected with the research.

RESULTS

We may learn things about you from the study activities which could be important to your health (e.g., blood pressure measurements, clinical findings from brain scan, results from questionnaires about your mood). If this happens, this information will be provided to you in person at a scheduled study visit or by phone following an assessment. Depending on the information, you might need to meet with professionals with expertise to help you decide what to do with the information. We do not have money or funds available to cover the costs of any follow-up consultations or actions.

GENETIC INFORMATION

We will not use the specimens collected as a part of this study for whole genome sequencing, which involves mapping all of your DNA. Your APOE genetic test results have no clinical value and will not be released to you, your doctor, or any other individual.

Some of the research findings could result in discrimination we can't anticipate. The risk of this occurring, however, is very small. The genetic information in this research study is protected by the Genetic Information Nondiscrimination Act (GINA), a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to request the genetic information we get from this research and to discriminate against you based on your genetic information.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher, Dr. Daniel Clark at (317) 963-7301. After business hours, please call the Eskenazi Switchboard at 317-880-0000 and ask for the attending physician.

In the event of an emergency, please seek appropriate medical treatment, such as calling your primary care physician, visiting an emergency department, or calling 911. If it is not a life-threatening emergency, please contact at 317-880-0000.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or offer input, contact the IU Human Research Protection Program office at 800-696-2949 or irb@iu.edu.

VOLUNTARY NATURE OF THIS STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Healthy Me or Eskenazi Health.

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Dr. Daniel Clark, Regenstrief Institute, 1101 West 10th Street, Indianapolis, Indiana 46202. If you withdraw your authorization, you will not be able to

continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

Your participation may be terminated by the investigator without regard to your consent in the event of clinical findings on your brain scan, if you decline to conduct study activities, or if you fail to communicate with or mistreat study staff.

SUBJECT'S CONSENT AND AUTHORIZATION

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Consent for Optional Study Procedures

MRI:

☐ I agree to complete brain imaging.

☐ I do not agree to brain imaging.

Participant's Printed Name:_____

Participant's Signature:_____**Date**:_____
(must be dated by the subject)

Participant's Address: _____
(Street)

_____
(City, State, Zip)

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date**:_____