STIM Alzheimer's Disease Disclosure Education & Decision-Making

NCT04818255

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UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:

STIM Alzheimer's Disease Disclosure Education & Decision-Making

Study Short Title:

STIM+ Part I

Company or agency sponsoring the study:

National Institute on Aging/National Institutes of Health

Names, degrees, and affiliations of the principal investigator:

Principal Investigator: Benjamin Hampstead, Ph.D., ABPP/CN, Department of Psychiatry, University of Michigan

Co-Investigators: Annalise Rahman-Filipiak, Ph.D., Department of Psychiatry, University of Michigan and J. Scott Roberts, Ph.D., School of Public Health, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

Participants and their study partners (e.g., family member, close friend) will see a brief educational presentation about one way in which Alzheimer's disease can be identified in the brain: through positron emission tomography (PET) scanning of abnormal proteins called amyloid and tau. Participants and respective study partners will also undergo an evaluation of how well they understood the information provided to them, including the risks and benefits of knowing your partner's personal amyloid and tau status. Your partner (the study participant) will not be receiving personal risk information during this study.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include increased anxiety or worry when learning more about AD indicators and thinking about the presence or absence of these indicators in your partner's brain.

This study may offer some benefit to you now such as increasing your awareness of Alzheimer's disease, Dementia-Alzheimer's Type, and one way we can identify AD in the brain. Additionally, this study may benefit others in the future by helping researchers to better understand how to educate the public about AD/DAT and PET scans for AD proteins, so patients and their families can use this information effectively when making future decisions about their health. More information will be provided later in this document.

We expect the amount of time you and the study participant will participate in the study will be 90 minutes (1.5 hours).

You can decide not to be in this study for any reason. Choosing not to be in the study will not affect the healthcare you receive in any way. The only alternative to participating in the study is to simply not take part. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues below.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Dementia is defined by a loss of cognitive (thinking) abilities and difficulty functioning in your everyday life. Dementia can be caused by several diseases, with Alzheimer's disease (AD) being the most common of these causes. When dementia is caused by AD, we refer to it as dementia of the Alzheimer's Type (DAT). The greatest risk factor for Alzheimer's Disease (AD) and DAT is advancing age, but DAT is not a normal part of aging. Studies have shown that changes in the brain happen before full symptoms of DAT develop. These changes include a buildup of two proteins within the brain, called amyloid and tau. Some research studies may measure these factors, but most do not share this information with participants, because it is not clear whether they will understand the information, or the risks and benefits of knowing it.

The purpose of this study is to learn about the best ways to communicate educational information about these factors to participants and their study partners (e.g., family members, close friends), and whether participants and respective study partners fully understand the decision to engage in risk disclosure.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Participant Eligibility: All participants who enroll in this study must also have previously taken part in a study through the Research Program on Cognition & Neuromodulation Based Interventions (Stimulation to Improve Memory, Brain-Behavior Characterization) or through the Michigan Alzheimer's Disease Research Center (Driving & Physiological Responses, Dementia in African American Population Phenotyping from Potential Elevated Risk) that involved PET scans for Alzheimer's disease markers. They must also have available data amyloid or tau from positron emission tomography (PET) imaging, which are collected as part of these studies. Participants with a diagnosis of Mild Cognitive Impairment are strongly encouraged to bring a trusted family member or friend to the session. Participants diagnosed with Dementia – Alzheimer's Type must be accompanied to the session by at least one trusted family member or close friend. If the participant has a legally authorized representative (LAR) or durable power of attorney (DPOA) for research and/or medical decisions, this individual must attend the appointment.

Additional inclusion and exclusion criteria are listed below:

Participant Inclusion Criteria:

- Completed all portions of previous research study.
- If diagnosed with DAT, the participant must bring a trusted family member or friend to the session.
- If the participant has a designated LAR/DPOA for medical and/or research decisions, that individual will be considered the study partner and must be present at the session.
- Participant or study partner demonstrates decision-making capacity to engage in PET, as determined in STIM+ Part I.

Participant Exclusion Criteria:

- Active diagnosis of moderate-severe depression or anxiety disorder
- Newly diagnosed (since completion of previous research study) neurologic injury or disease

Study Partner Inclusion Criteria:

- Study partners are those who are currently serving as a caregiver to the participant, or would hypothetically serve in this role should the need arise
- Must have known the study participant for at least five years
- Must be in contact with the study participant (any modality) at least once per week
- Cognitively healthy
- 18 years or older
- English speaker

Study Partner Exclusion Criteria:

- Has a diagnosis of cognitive impairment or dementia
- Does not demonstrate decision-making capacity

3.2 How many people are expected to take part in this study?

Approximately 100 participants are and their study partners, as applicable, expected to participate.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to my partner and me in this study?

Screening: All participants must be diagnosed with Mild Cognitive Impairment or Dementia-Alzheimer's Type and must have participated in one of the studies completed through the Research Program on Cognition & Neuromodulation Based Interventions (Stimulation to Improve Memory, Brain-Behavior Characterization) or through the Michigan Alzheimer's Disease Research Center (Driving & Physiological Responses, Dementia in African American Population Phenotyping from Potential Elevated Risk) that involved PET scans for Alzheimer's disease markers. Prior to study enrollment, the study team will review the data collected during your partner's participation in the previous study to ensure that your partner's PET amyloid and tau protein biomarker data are complete and available. All participants will be screened via phone to ensure that no changes have occurred since participation in the previous study, and to assess whether they meet all eligibility requirements for this study. Participants with DAT must have a study partner, and those with MCI are strongly encouraged to have a study partner. Those participants with a legally authorized representative (LAR) or durable power of attorney (DPOA) for medical decisions and/or research will be asked to provide contact information for this individual; the LAR/DPOA will be required to show documentation of this status and serve as the participant's study partner. The study team will make contact with all study partners to assure that they are able to attend the appointment and bring appropriate documentation with them.

Education: You and your partner (i.e., the study participant) will attend your appointment either in person or via video-conference using a HIPAA-compliant, secure platform (Zoom for Health), based on your preference and current University of Michigan guidance around Covid-19 safety. If you choose to complete your session in person, you must comply with all safety screenings and procedures, as will all study team members. If you choose to complete the session via video-conference, the session will be video-recorded to ensure that the study team are able to fully capture your responses. This session will be video-recorded to ensure that the study team are able to fully capture your responses. The study team will show you and your partner a brief educational presentation about three topics: (1) Alzheimer's Disease (AD) and DAT; (2) indicators for elevated AD risk that may

be present before your partner could be diagnosed, including abnormal protein build-up; and (3) risks and benefits of learning this information.

Assessment: During and after the presentation, the study team will ask questions to determine how well the study participant and/or you understand the information covered. These questions will assess how well you and the participant understand and can talk about the potential risks and benefits of learning about one's risk for AD based on personal health indicators. Both the participant and you will be asked to state whether you each would want to receive your personal PET amyloid and tau information if given the opportunity. Your partner will not actually receive any personal PET disclosure in this study.

4.2 How much of my time will be needed to take part in this study?

Participants and their LAR/DPOA or other study partner (e.g., family member or friend) will complete a single 90-minute education session via video conference.

4.3 When will my participation in the study be over?

Study participation, both for yourself and the study participant, will be finished after completion of the education session.

4.4 What will happen with my information and/or biospecimens used in this study?

Your partner's biospecimens and collected information may be shared with the National Institute on Aging/National Institutes of Health.

With appropriate permissions, your partner's biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies.

Your partner's identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Questionnaires: The study educational materials and questionnaires are entirely non-invasive and painless.

Psychological Distress: It is possible that thinking and talking about risk for AD may result in you and your partner (the study participant) experiencing some increased worry about the future or his/her own risk, and possibly yours. Researchers will try to minimize these risks by providing you and the study participant with educational and support resources. If you or your partner (the study participant) become so upset that you cannot continue, withdrawal from the study may be requested by the study team.

Confidentiality: Although unlikely, there may be a risk of breach of confidentiality or privacy. We minimize this risk by assigning the study participants and study partners an ID number that is used to collect and store your data in place of any personal identifiable information (e.g., your name, contact information). See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you (as the study partner) or the study participant may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, you may benefit from learning more information about AD and available indicators of risk for this disorder. You and your family may use this information to inform health decisions in the future. Additionally, others may benefit from the knowledge gained from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

If either the participant or their study partner decides that they are no longer interested in participating in the study, they may choose to halt participation at any time.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There will be no harm to the participant or any study partner if you decide to leave the study before completion.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study. The study team has given you instructions about this research study. It is important that you follow these instructions carefully. If you or the participant get sick, have a medical

complication, or are injured as a result of participating in the study, call Dr. Hampstead immediately, at (734) 936-3180. The doctor will either treat you/the participant or send you/the participant to another doctor for treatment. You and the participant will get free medical care for any complication, injury, or illness caused by the study procedure. The study sponsor and the study doctor are responsible for determining whether your and/or the participant's condition was the result of participating in the study. The study sponsor will pay for your and/or the participant's treatment only if the need for treatment has been caused by the study procedure. This means that you or your health plan, as well as the study participant or his/her health plan must pay for any treatment that is part of any usual medical care or that is related to a medical condition either of you had prior to participating in the study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

The participant and study partner will each receive $10 for completing this study session. You will each receive your incentive as a check mailed to you after your participation is finished.

8.3 Who could profit or financially benefit from the study results?

None of the study team members, nor any organizations with which they are affiliated, have a financial interest in the outcome of this study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

We will keep information collected from you and about you strictly confidential, including any research records we create, to the extent required by law. A breach of confidentiality of your personal, identifiable health-related information is extremely unlikely given measures taken to protect this information. Upon enrollment into the study, participants and study partnerss will be assigned a unique alphanumeric ID number, which will be used on all study documentation. The exception is this consent form, which will be stored in a folder separate from your study data. Your name, date of birth, address, or contact information will not be included on any study forms. The electronic file linking your name to your unique identifier, as well as other electronic databases containing de-identified study data, will be password protected and stored on a secure electronic drive. Paper copies of your data will be stored in a locked filing cabinet, in a locked office that can only be accessed by study team staff.

For all sessions, the study team will send you a secure link to sign this form and to join the appointment through your email. All sessions will be completed using University of Michigan BlueJeans or Zoom for Health, two HIPAA-compliant, secure video conferencing systems. It is possible that other secure video platforms may be used by the University of Michigan in the future. Only individuals with the unique link sent to you will be able to access the meeting, and protections are in place to ensure that noone else can join or see data from the meeting.

None of the results from your study participation will be included in your medical record; however, a scanned, signed copy of this Informed Consent form will be uploaded into your medical record to indicate that you have participated in this research study. This step allows your medical providers to know what research studies you have been involved in, so that they may contact the study team with questions related to your clinical care, if needed.

This research will be covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child or adult abuse and neglect, or harm to self or others. If you tell us or we learn something that makes us believe that you or others have been or may be harmed, we may be required to report that information to the appropriate agencies.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

As required by U.S. law, this trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. 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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Information about your study participation may be included in your regular UMHS medical record.

- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Benjamin Hampstead, PhD, ABPP/CN
Mailing Address: Arbor Lakes 1,
4251 Plymouth Road, Suite 2400, Ann Arbor, MI 48105
Telephone: (734) 936-6185

Study Coordinator: **Annalise Rahman-Filipiak, PhD**
Mailing Address: Arbor Lakes 1,
4251 Plymouth Road, Suite 2400, Ann Arbor, MI 48105
Telephone: (734) 936-3180

Study Social Worker: **Marie Milliken, LMSW**
Mailing Address: Geriatric Center Clinics
4260 Plymouth Rd, Ann Arbor, MI 48109
Telephone: (734)763-6701

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received a signed and dated copy of the following document:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Consent/Assent to be contacted about Future Research
I wish to be contacted about other research studies for which I may qualify.

Yes ☐ No ☐ Initial: _____ Date: _____

Consent to Participate in the Research Study
I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Consent to video recording solely for purposes of this research
This study involves video recording. If you do not agree to be recorded, you CANNOT take part in the study.

_____ Yes, I agree to be video recorded.

_____ No, I do not agree to be video recorded.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____