Informed Consent Form

Title: SPIRIT In Mild Alzheimer's Disease (AD)

NCT number: NCT03311711

Document approval date: August 18, 2021

You Are Being Asked to Be in a Research Study
(Surrogate)

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 120 people who are being studied, at Emory and elsewhere.

Why is this study being done?
This study is being done to answer the question: How can we best help people with memory or thinking problems and their family members or close friends prepare for tough medical decisions that may arise in the future? You are being asked to be in this research study because you may have memory or thinking problems

Do you have to be in the study?
It is your decision to be part of this research study. **You do not have to be in it**. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate actively for approximately 3-4 weeks. The researchers may ask you to do the following: two telephone surveys and one counseling session. You will be compensated with a $20 gift card after the first survey and $25 gift card after the second survey.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. You also may help other people with memory or thinking problems in the future prepare for future medical decision making.

What are the risks or discomforts I should know about before making a decision?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
There are no costs associated with this study.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject
(Surrogate)

Title: SPIRIT in Mild Alzheimer's Disease (AD)

IRB #: 00099738

Principal Investigator: Mi-Kyung Song, PhD, RN, FAAN, Professor, School of Nursing, Emory University

Funding Source: National Institutes of Health/National Institute on Aging

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

Study Overview

The purpose of this study is to learn about how to best help people with memory or thinking problems and their family members or close friends prepare for tough medical or care decisions that may arise in the future. We have developed a counseling intervention for this purpose and tested with other patient groups over the past 15 years. This counseling intervention is called SPIRIT, a short name for "Sharing Patient's Illness Representations to Increase Trust." With this study, we want to test SPIRIT to see if it can help people with memory or thinking problems and their family members or close friends with talking about these decisions.

You are being asked to be in the study because your loved one may have memory or thinking problems and has indicated an interest in participant in this study. People invited to be in this study must be adults and able to participate in a counseling session that is about hour and a half with their loved one. This person is often called a surrogate decision maker. If you decide to be in the study, you will be one of approximately 120 surrogate decision makers.

Procedures

If you agree to be in the study, these are the next steps:

Once you and your loved one have both agreed to be in the study, we will schedule three appointments as follows:

The first appointment is to complete surveys over the telephone. These surveys include questions to collect your personal information such as age, gender, and educational level, your understanding of your loved one's preferences for

future medical care, and your confidence in serving as a surrogate decision maker for your loved one. This will take about 15 minutes.

Shortly after the first appointment, you and your loved one will be assigned to one of the two groups: participating in the SPIRIT session remotely using computer-based videoconferencing or Usual Care provided at the clinic. This assignment will be done by chance, such as a flip of a coin.

If you are assigned to SPIRIT remote, you and your loved one will still receive usual care available at the clinic. Plus, we will schedule an appointment with you and your loved one. This second appointment is to participate in the SPIRIT counseling session at a distance, such as from home or similar private setting. One of our research assistants will call you and your loved one on the telephone to help you and your loved one set up this computer-based videoconference and help you feel comfortable using this technology. One of our trained counselors for these sessions will "meet" you and your loved one online. This discussion session is an interview format, which means that the trained counselor will ask your loved one about how he/she feels about the current illness and symptoms, his/her thoughts about future medical care, and how you feel about your loved one's preferences for future medical care. This session will take about an hour and a half and the conversations during the session will be recorded.

If you are assigned to usual care, you and your loved one will receive usual care at the clinic, which includes a healthcare provider, such as an advanced nurse practitioner, or a social worker, providing written information on advance directives and may refer to attorneys or others who can assist in completing such documents.

The third appointment is to complete the surveys over the phone like you did in the first appointment. For those assigned to the SPIRIT remote session, this third appointment will be scheduled to occur 2-3 days after the session. For those assigned to the usual care group, this third appointment will occur about 2-3 days following the first appointment. Like the first phone survey, we will ask you questions about your loved one's preference for future medical care and your confidence in serving as a surrogate decision maker for your loved one. This follow-up appointment should take about 20 minutes.

Finally, you will receive monthly check-in calls for the next 12 months At 12 months we will randomly select surrogates who completed a SPIRIT session remotely and ask them about the impact of SPIRIT. You may be randomly selected for this brief interview. This interview over the telephone will take about 15-30 minutes and will be recorded.

Risks and Discomforts

There are minimal risks taking part in this study. You may feel uncomfortable talking about your loved one's illness and future medical care options for the situation where he or she is not able to speak for him-/herself.

There is a risk that your information collected for this research study may be known to other people than the study investigators. We will make every effort to keep any information obtained from this study as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet or a password protected database. Your identity on these records will be indicated by a case number rather than by your name. You will not be identified by name in any publication of the research results.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits

This study is not designed to benefit you directly. However, patients and families have reported that sharing their beliefs about their illness, experiences, and concerns about future medical care are helpful. This study is designed to learn more about how to best prepare for future medical decisions. The study results may be used to help others in the future.

Compensation

You and your loved one each will receive a $20 gift card at the completion of the first appointment. You and your loved one each will receive a $25 gift card at the completion of the second phone survey. Finally, if you were selected and participated in the brief telephone interview at 12 months, you will receive a $30 gift card at completion.

Other Options Outside this Study

If you decide not to enter this study, there is care available to your loved one outside of this research. That is, you may wish to talk with his/her care provider about your loved one's future medical care.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your de-identified data to other researchers. If we do, we will not include any information that could identify you. If your data is labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

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Contact Information

Contact Dr. Mi-Kyung Song at [redacted]:

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewgkke.**

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

Name of Subject

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion **Date** **Time**