Informed consent document for SPIRIT for Persons with Dementia and Complex Multimorbidity

NCT #: NCT04108000

IRB approved on August 10, 2020

Emory University
Oral Consent and HIPAA Authorization Script/Information Sheet
For a Research Study

Study Title: **SPIRIT in ESRD plus Dementia**
IRB #: 00094859
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 and Study Overview

Thank you for your interest in our SPIRIT research study. We would like to tell you everything you need to think about before you decide whether or not to join 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.

The purpose of this study is to learn about how to best help people with End Stage Renal Disease (ESRD) plus memory problems and their family members who can speak on their behalf when they are unable. This family member can be a close friend, but it must be who the patient trusts to prepare for tough medical or care decisions that may arise in the future. We have developed a counseling intervention for the 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". The study is funded by the National Institutes of Health. This study will take about one year to complete.

If you join, you will be asked to:

1. Allow one of our research assistants to review your medical chart to record your medical information, such as dialysis history and when your memory or thinking problems began, related test scores, and other medical conditions.
2. Because SPIRIT, the counseling session, involves both you and your family member together, we will ask him or her to participate in the study with you. Half the participants will participate in this SPIRIT discussion session together during the study. Once you and your family member have both agreed to be in the study, we will schedule three appointments as follows.
3. **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 choices for future medical care, and level of difficulty or discomfort in making those choices. This will take about 15 minutes.
   Shortly after the first appointment, you and your family member will be assigned to one of the two groups: participating in the SPIRIT session or Usual Care provided at the clinic. This assignment will be done by chance, such as a flip of a coin.
4. **If you are assigned to SPIRIT, you and your family member will still receive usual care available at the clinic. Plus, we will schedule an appointment with you and your family member to meet with our Nurse.** This second appointment is to **participate in the SPIRIT counseling session with your family member decision maker**. This will take place in a private room at the Emory Dialysis clinic or similar private setting. One of our research staff nurses who has been trained for these sessions will meet you and your family member at the clinic or by video-conference. This discussion session is a guided interview, which means that the trained nurse will ask you about how you feel about your illness and

symptoms, your thoughts about future medical care how your family member feels about your 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 family member 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.

5. **The third appointment is to complete the surveys over the phone like you did in the first appointment.** For those assigned to the SPIRIT 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. This follow-up appointment should take about 20 minutes.
6. You will receive a monthly check-in call thereafter for about 12 months. We want to check-in to make sure you are doing well. This should only take a minute or two.
7. Finally, we will review your medical records at the clinic at 6 months to see if you have completed any documents, such as a living will or a medical power of attorney or changed your plan of care.

Risks and Discomforts

There are minimal risks to taking part in this study. You may feel uncomfortable talking about your illness and future medical care options for the situation where you are not able to speak for yourself. You may experience fatigue when answering survey questions or during SPIRIT discussion.

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.

Benefits

This study may or may not benefit you directly. However, patients and families have reported that sharing their beliefs about their illness, experiences and concerns about future medical care is helpful. **By being in the study you may benefit other patients and their family members in the future.**

Compensation

You and your family member each will receive a $20 gift card at the completion of the first telephone survey appointment. If you and your family member were assigned to SPIRIT and you will be traveling to the clinic, you will be offered transportation support based on your preferred method of transportation. If your session will be held remotely via Zoom, this support will not apply. You and your family member each will receive a $25 gift card at the completion of the second phone survey. You will receive $45 total, if you complete all study visits.

Your privacy is very important to us. There is a law that protects your health information kept by your medical provider; this law is called HIPAA. Your health information that identifies you is your “protected health information” (PHI). The PHI for this study includes medical information about you including your medical history and dialysis records, surveys, and cognitive tests you have before and during the study. To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act (HIPAA). If you join the study, the following persons or groups may use and /or disclose your PHI for this study:

- The Principal Investigator and the research staff.
- The National Institute of Health, who funds this Research, and people or companies they use to carry out the study
- Emory offices who are part of the Human Research Participant Protection Program, and those who are involved in research-related administration and billing
- Any government agencies who regulate the research including the Office of Human Subjects Research Protections (OHRP)
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

We will disclose your PHI when required to do so by law in the case of reporting child abuse or elder abuse.

The investigators have obtained a Certificate of Confidentiality for this study. If Emory received a subpoena for study records that identify you, we would say no, and the Certificate gives us this authority. The Certificate does not prevent you or someone other than you from making disclosing your information. The Certificate also does not prevent Emory from releasing information about you:

- Information to state public health offices about certain infectious diseases
- Information to law officials if child abuse has taken place
- Information Emory gives to prevent immediate harm to you or others
- Information Emory gives to the study sponsor as part of the research

You may revoke your authorization at any time by calling the Principal Investigator, [redacted]
If identifiers (like your name, address, and telephone number) are removed from your PHI, then the remaining information will not be subject to the Privacy Rules. This means that the information may be used or disclosed with other people or organizations, and/or for other purposes.

If we share your PHI with other groups who do not have to follow the Privacy Rule, then they could use or disclose your PHI to others without your authorization. Let me know if you have questions about this. If you do not give your authorization, you may still receive non-research related treatment. We will put a copy of this informed consent form for the research study into any medical record that you may have with Emory Healthcare facilities.
Your authorization will not expire because your PHI will need to be kept indefinitely for research purposes.

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 are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

Contact Information

If you have questions about this study, your part in it, or if you have questions, or concerns about the research you may contact the following:

Dr. Mi-Kyung Song, Principal Investigator: [redacted]

If you have questions about your rights at research participant, complaints about the research or an issue you rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or toll-free at 877-503-9797 or by email at irb@emory.edu.

Consent

Do you have any questions about anything I just said? Were there any parts that seemed unclear?

Do you agree to take part in the study?

Participant agrees to participate: Yes No

If Yes:

_____

Name of Participant

_____ _____

Signature of Person Conducting Informed Consent Discussion Date Time

_____

Name of Person Conducting Informed Consent Discussion