Informed consent document for An Effectiveness-Implementation Trial of SPIRIT in ESRD

NCT Number: NCT03138564

Institutional Review Board approval received on July 7, 2020

Emory University
Oral Consent and HIPAA Authorization Script/Information Sheet
For a Research Study
(Patient – SPIRIT Implementation Group)

Study Title: **An Effectiveness –Implementation Trial of SPIRIT in ESRD**
IRB #: 00094859
Principal Investigator: Mi-Kyung Song, PhD, RN, FAAN, Professor, School of Nursing, Emory University
Funding Source: National Institutes of Health/National Institute of Nursing Research

Introduction and Study Overview

Thank you for your interest in our dialysis 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. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

The purpose of this study is to learn about whether discussions about dialysis patient's preferences for future medical care with a dialysis care provider improve family's or friend's (who have been chosen to be surrogate decision makers by patients) understanding about the patient's choices, and whether those discussions are helpful to those who participate in them. This discussion session is called SPIRIT, a short name for "Sharing Patient's Illness Representations to Increase Trust." Patients and their chosen surrogates will participate in this discussion session, SPIRIT, together during the study.

You are being asked to be in the study because you have an advanced kidney disease and have been on either hemodialysis (center dialysis) or peritoneal dialysis (home dialysis). People invited to be in this study must be 18 years of age or older, able to participate in an hour-long discussion session with a family member or friend who is chosen by you to be a medical decision maker. This person is often called a surrogate decision maker. Your surrogate decision maker must be at least 18 years old. If you decide to be in the study, you will be one of 400 patients receiving dialysis included in the study. From Emory dialysis centers and Dialysis Clinics, Inc. (DCI), we anticipate that approximately 172 patients will participate in the study.

The study is funded by the National Institute of Health (NIH). This study will take about a year to complete.

If you join, you will be asked to:

1) Allow for our research team to review your medical chart to record your medical information, such as months on dialysis and medical conditions other than kidney disease.
2) Allow us to call your surrogate decision maker (your family member or a close friend chosen by you) to explain the study and ask his/her willingness to participate in the study with you.
3) Upon your surrogate decision maker's agreement, we will schedule four appointments: two for a survey completion and two for a SPIRIT sessions about 2 weeks apart.
4) **The first appointment** to complete surveys will be done over the telephone with you and your surrogate decision maker (family member or friend) separately. 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 in making those choices. This will take about 15 minutes.
5) **The second appointment** for a SPIRIT session with you and your surrogate decision maker together will take place in a private room at the dialysis center or a private setting. A dialysis care provider will facilitate this

discussion. This discussion session is an interview format, which means that the care provider will ask you about how you feel about your illness and dialysis therapy, your thoughts about future medical care, and how your surrogate decision maker feels about your preferences for future medical care. This session will take about an hour and the conversations during the session will be audio-recorded with your permission.

6) **The third appointment** for a brief follow-up session will be scheduled in about 2 weeks. This follow-up session is to review what was discussed during the first session and address any questions and concerns you and your surrogate decision maker might have. This follow-up on-site session will take no more than 30 minutes and will be done in person, over the phone or by video call.
7) After these sessions, one of our research assistants will contact you and your surrogate decision-maker to schedule your **fourth appointment** to take place 2 weeks later, if possible. As done for the first appointment, this follow-up appointment is to complete surveys over the telephone with you and your surrogate decision maker separately. You will be asked to complete a similar set of surveys that you did before. This will take about 15 minutes. This follow-up is important for us to know whether the SPIRIT sessions had any impact on you and your surrogate decision maker.

Finally, you will receive a monthly check-in call from one of our research assistants for the next 9 months. These calls are just to ask how you are doing, and no data will be collected from you.

Risks and Discomforts

There are minimal risks taking part in this study. You may experience fatigue when answering the surveys. You may stop and continue when rested or schedule another time to complete them. 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.

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.

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. By being in the study, you may benefit other patients and their family members in the future by what is learned about the SPIRIT sessions and from the surveys completed.

Compensation

You will receive a ($15) gift card after the completion of the first appointment and another ($15) gift card after the 2-week follow-up appointment for survey completion. If you do not finish the study, you will be paid for the visits you have completed. You will receive $30 total, if you complete all study visits.

Other Options Outside this Study

If you decide not to enter this study, there is care available to you outside of this research. That is, you can still talk with your dialysis care provider about your future medical care. You do not have to be in this study to be treated for kidney disease or to get dialysis services.

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 cause of end-stage renal disease, dialysis history, other medical conditions. 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 (NIH), who funds this Research.
- Emory offices who are part of the Human Research Participant Protection Program, and those who are involved in research-related administration and billing
- Other researchers and centers that are a part of this study.
- Any government agencies who regulate the research including the Office of Human Subjects Research Protections (OHRP).
- Dialysis Centers, Inc. (DCI)

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and dialysis records.
- Information about your hospitalizations and use of intensive therapies.

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, Mi-Kyung Song, PhD or by writing to her at Emory University, Nell Hodgson Woodruff School of Nursing, 1520 Clifton Rd. NE, Atlanta, GA 30322. 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 not participate in this study. 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.

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

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:

Mi-Kyung Song, PhD, 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.

Optional recording of SPIRIT Intervention Session: (Check space in front of response)

Would you allow for recording of your SPIRIT session? _____Yes _____No

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