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SPIRIT trial: A phase III pragmatic trial of an advance care planning intervention in ESRD

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ABSTRACT

Advance care planning (ACP) is a central tenet of dialysis care, but the vast majority of dialysis patients report never engaging in ACP discussions with their care providers. Over the last decade, we have developed and iteratively tested SPIRIT (**S**haring **P**atient's **I**llness **R**epresentation to **I**ncrease **T**rust), a theory-based, patient- and family-centered advance care planning intervention. SPIRIT is a six-step, two-session, face-to-face intervention to promote cognitive and emotional preparation for end-of-life decision making for patients with ESRD and their surrogates. In these explanatory trials, SPIRIT was delivered by trained research nurses. Findings consistently revealed that patients and surrogates in SPIRIT showed significant improvement in preparedness for end-of-life decision making, and surrogates in SPIRIT reported significantly improved post-bereavement psychological outcomes after the patient's death compared to a no treatment comparison condition. As a critical next step, we are conducting an effectiveness-implementation study. This study is a multicenter, clinic-level cluster randomized pragmatic trial to evaluate the effectiveness of SPIRIT delivered by dialysis care providers as part of routine care in free-standing outpatient dialysis clinics, compared to usual care plus delayed SPIRIT implementation. Simultaneously, we will evaluate the implementation of SPIRIT, including sustainability. We will recruit 400 dyads of patients at high risk of death in the next year and their surrogates from 30 dialysis clinics in four states. This trial of SPIRIT will generate novel, meaningful insights about improving ACP in dialysis care.

Trial registration: ClinicalTrials.gov NCT03138564, registered 05/01/2017.

1. Introduction

End-stage renal disease (ESRD) currently affects nearly 660,000 people in the United States [1]. While over 70% of patients with ESRD are treated with dialysis, the likelihood that dialysis can restore health or prolong life is limited; only 50% of dialysis patients are alive 3 years after the onset of ESRD [1]. Thus, many dialysis patients and their family members or surrogate decision-makers have to face difficult end-of-life decisions. Although advance care planning (ACP), in which patients and surrogate decision-makers discuss future health states and treatment options, is a central tenet of dialysis care [2–5], the vast majority of dialysis patients (> 90%) report never engaging in ACP discussions with their care providers [6,7]. The lack of effective ACP to prepare patients and their surrogates for making end-of-life decisions with sufficient time before death has deleterious consequences at all levels of society. Patients may experience physical and emotional suffering from the prolonged use of futile treatment at the end of life, surrogates may have high levels of stress from making decisions about care both during the loved one's hospitalizations and after their death, and the costs of care that had little or no impact on survival burden hospitals and society as a whole [8–14].

SPIRIT (Sharing Patient's Illness Representation to Increase Trust), a patient- and family-centered ACP intervention based on the Representational Approach to Patient Education [15,16], is a testable

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model of how end-of-life care discussions can occur between a dialysis patient and his/her chosen surrogate (usually a spouse or adult child). The discussions, which are facilitated by a trained care provider, are framed around addressing each individual's representations of (beliefs about) the illness and views of life-sustaining measures at the end of life. SPIRIT follows a six-step process over two sessions, which together take about 60 min. The care provider guides the patient in examining his/her values related to end-of-life care, helps the surrogate understand the patient's illness progression, and prepares the surrogate for his/her role as a surrogate in a highly emotionally charged medical setting.

Over the last decade, we have iteratively tested SPIRIT to establish feasibility, patient-surrogate acceptability, and efficacy [17–20]. In these explanatory trials carried out in dialysis clinics, SPIRIT was delivered by trained research nurses. Patients and surrogates in SPIRIT showed significant improvement in preparedness for end-of-life decision making, including the extent to which: a) the patient and surrogate agreed on end-of-life care goals, b) the patient had reduced conflict about the benefits and burdens of life-sustaining treatments, and c) the surrogate had increased confidence about the role of surrogate. In addition, surrogates who received SPIRIT reported significantly improved post-bereavement psychological outcomes after the patient's death compared to those who did not. The purpose of this paper is to describe the rationale, design and methods of the next logical step in this program of research, a pragmatic trial of SPIRIT.

2. Methods

2.1. Study design overview

The study is a phase III, dialysis clinic-level cluster randomized trial with two groups, SPIRIT (initial implementation) and usual care followed by delayed SPIRIT (delayed implementation). See Fig. 1. We will recruit 400 dyads of patients on chronic ("prevalent") dialysis who are at high risk of death in the next year and their surrogate decision-makers (total 800 individuals) from 30 free-standing dialysis clinics in four states (GA, NM, NC, and PA). The primary outcomes are patient and surrogate self-reported preparedness for end-of-life decision making (Aim 1). Implementation evaluation data will be obtained throughout the study course (Aim 2). Upon patient death, we will assess surrogates' post-bereavement distress (Aim 3). Medicare claims data will be obtained to assess end-of-life treatment intensity (Aim 4).

Clinics will be randomized to either SPIRIT or usual care in Study Year 1. Clinics randomized to usual care will implement SPIRIT in Year 4, after they serve as control for effectiveness evaluation. The process outcomes from the initial implementation of SPIRIT will be used to determine if any modifications to SPIRIT are necessary. Clinics in the delayed implementation phase will be evaluated on the process outcomes, which will provide data on the iterated version of SPIRIT without having to conduct another trial.

2.2. Study participants

The study requires both the patient and his/her chosen surrogate decision maker to participate as a dyad (pair). Patients meeting the following criteria will be deemed eligible for the study: 1) 18 years or older; 2) on either hemodialysis or peritoneal dialysis; 3) seriously ill based on clinician's heuristic prediction of survival using the validated [21–23] Surprise Question (SQ): "Would I be surprised if this patient died in the next year?" (patients for whom the answer is "No, I wouldn't be surprised" are 4 times more likely to die in the next year); and 4) able to understand and speak English. Patients who lack an available surrogate, are too ill or cognitively impaired to participate based on clinicians' judgment, or are already enrolled in hospice will be excluded. We will use a short investigator-developed set of questions [24] to help patients identify a surrogate decision-maker if they have not already done so. We will not exclude patients who already have an advance directive or a medical order; previous completion of those documents was not associated with the study outcomes in previous trials [18–20] and a study of physician orders for life-sustaining treatment (POLST) suggested that these medical order forms are often completed without an in-depth ACP discussion [25].

Surrogate eligibility criteria are 1) 18 years or older (to serve as a surrogate decision-maker, the individual must be an adult); and 2) being chosen by the patient. Those who cannot complete questionnaires due to physical or cognitive limitations will be excluded. Roughly 76 providers at the 30 clinics, including all medical directors, nurse managers, social workers, and those who are selected to conduct SPIRIT sessions will participate in the implementation evaluation.

Quarterly, in both groups, a dialysis care provider at each clinic will generate a list of patients each quarter for whom the SQ answer is "No". The care provider will then assess whether the patient meets the other criteria and whether the patient is willing to meet with a recruiter from the research team. The recruiter will approach eligible and willing patients during their scheduled dialysis clinic appointment to explain the study purposes and procedures. The recruiter will then provide the patient with a study brochure, obtain a written consent, and encourage him/her to talk to the surrogate regarding the study within the next 2–3 days. Several days later, the recruiter will telephone the surrogate to assess his/her willingness to participate. Upon the surrogate's verbal

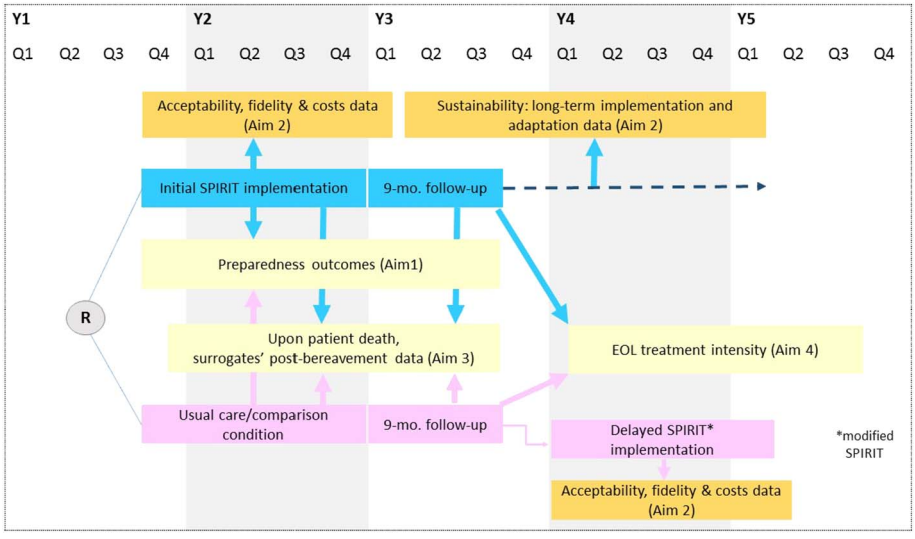

Fig. 1. Study design and overview.