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Advance Care Planning and End-of-Life Decision Making in Dialysis: A Randomized Controlled Trial Targeting Patients and Their Surrogates

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Abstract

Background—Few trials have examined long-term outcomes of advance care planning (ACP) interventions. We examined the efficacy of an ACP intervention on preparation for end-of-life decision making for dialysis patients and surrogates and for surrogates' bereavement outcomes.

Study Design—A randomized trial compared an ACP intervention (Sharing Patient's Illness Representations to Increase Trust [SPIRIT]) to usual care alone, with blinded outcome assessments.

Setting & Participants—420 participants (210 dyads of prevalent dialysis patients and their surrogates) from 20 dialysis centers.

Intervention—Every dyad received usual care. Those randomly assigned to SPIRIT had an in-depth ACP discussion at the center and a follow-up session at home 2 weeks later.

Outcomes & Measurements—Primary outcomes: preparation for end-of-life decision making, assessed for 12 months, included dyad congruence on goals of care at end of life, patient

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Contributions: Study concept and design: M-KS, SEW, JPF, LCH, JBH, GAH; data acquisition: M-KS; data analysis/interpretation: M-KS, JPF, F-CL, SEW, LCH, JBH, GAH, JCB; statistical analysis: F-CL, JPF; Funding obtainment: M-KS; administrative, technical, or material support: M-KS, JCB; study supervision: M-KS, JCB. Each author contributed important intellectual content during manuscript drafting or revision and accepts accountability for the overall work by ensuring that questions pertaining to the accuracy or integrity of any portion of the work are appropriately investigated and resolved. M-KS takes responsibility that this study has been reported honestly, accurately, and transparently; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned and registered have been explained.

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decisional conflict, surrogate decision-making confidence, and a composite of congruence and surrogate decision-making confidence. Secondary outcomes: bereavement outcomes, assessed for 6 months, included anxiety, depression, and posttraumatic distress symptoms completed by surrogates after patient death.

Results—Primary outcomes: adjusting for time and baseline values, dyad congruence (OR, 1.89; 95% CI, 1.1–3.3), surrogate decision-making confidence (β = 0.13; 95% CI, 0.01–0.24), and the composite (OR, 1.82; 95% CI, 1.0–3.2) were better in SPIRIT than controls, but patient decisional conflict did not differ between groups (β = −0.01; 95% CI, −0.12 to 0.10). Secondary outcomes: 45 patients died during the study. Surrogates in SPIRIT had less anxiety (β = −1.13; 95% CI, −2.23 to −0.03), depression (β = −2.54; 95% CI, −4.34 to −0.74), and posttraumatic distress (β = −5.75; 95% CI, −10.9 to −0.64) than controls.

Limitations—Study was conducted in a single US region.

Conclusions—SPIRIT was associated with improvements in dyad preparation for end-of-life decision making and surrogate bereavement outcomes.

INDEX WORDS

Advance care planning (ACP); end-of-life decision making; surrogate decision maker; medical decision; patient-surrogate dyad; dyad congruence; treatment options; life-sustaining treatment; bereavement; death; emotional distress; hemodialysis; end-stage renal disease (ESRD); advanced kidney disease; randomized controlled trial (RCT); patient education intervention

Advance care planning (ACP) is a process in which patients and family members or surrogate decision makers anticipate and discuss future health states and treatment options.[1,2] It has the potential to improve end-of-life care and reduce costs associated with unwanted or nonbeneficial aggressive treatment near the end of life.[3–6] Initial ACP efforts focused on documenting patients' decisions about end-of-life care.[7] However, given evidence that advance directives do not adequately improve end-of-life care, ACP for patients with serious chronic illness has evolved to focus on preparing patients and surrogates for treatment decision making at the end of life.[8–12] The importance of surrogates also has been recognized because they are frequently involved in key medical decisions at the end of life.[2,13,14] However, rarely have trials examined the long-term impact of ACP, including surrogate outcomes.

For patients with end-stage renal disease (ESRD), with mortality exceeding that for most types of cancer,[15,16] dialysis may extend life but it might not improve the quality of survival time. Experts suggest that clinicians initiate timely discussions with patients with ESRD and surrogates to help them express desires about end-of-life care.[17] However, these discussions often focus narrowly on advance directives and are delayed until near death.[18,19] Further, no trials have examined whether ACP helps both patients with ESRD and their surrogates prepare for end-of-life decision making, the beneficial impact of ACP sustains over time, or ACP improves surrogates' bereavement outcomes.[18]

Our ACP intervention, Sharing Patient's Illness Representations to Increase Trust (SPIRIT), was based on the Representational Approach to Patient Education[20,21] reflecting theories of

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illness cognition and conceptual change. In the representational approach, the interventionist first obtains a clear understanding of the patient's perspective on their illness, symptoms, or prognosis before providing information to correct misunderstandings. SPIRIT sessions establish comprehension of the cognitive, emotional, and spiritual facets of the patients' representation (understandings) of their illness, laying the groundwork for the interventionist to provide individualized information such as the effectiveness of mechanical supports at the end of life and to aid patients in examining their own values about such supports.

In a pilot study, SPIRIT had beneficial effects on patient and surrogate preparation for end-of-life decision making.[14] The present trial tested the long-term effects of SPIRIT on preparation for end-of-life decision making (preparedness outcomes) for patients with ESRD and their surrogates and bereavement outcomes for surrogates.

METHODS

Design

We conducted a 2-group randomized trial with measures of patient and surrogate preparedness at baseline and 2, 6, and 12 months later and measures of surrogate bereavement outcomes at baseline, 2 weeks, and 3 and 6 months after the patient's death. Before the first dyad reached the 12-month follow-up, the protocol was modified to ask dyads to extend their participation until study end in order to maximize the number of surrogates with bereavement outcomes. The University of North Carolina at Chapel Hill Institutional Review Board approved the study.

Setting and Participants

Patients were recruited from March 2010 through December 2012 from 20 outpatient dialysis centers in 8 counties in North Carolina. Inclusion criteria were 18 years or older, self-identified African American or white (acceptability of SPIRIT had not been tested with other groups), on dialysis therapy for at least 6 months, Charlson Comorbidity Index[22,23] score of 6 or higher or Charlson Comorbidity Index score of 5 and hospitalization in the last 6 months (criteria associated with 1-patient-year mortality of 30%[24]), English-speaking, no hearing impairment, fewer than 3 errors on the Short Portable Mental Status Questionnaire, [25] and an English-speaking surrogate older than 18 years who could participate.

A short battery of questions[26] was used to help patients identify and confirm a previously designated surrogate. Patients and surrogates provided written consent and received compensation for completing measures ($15 at baseline, $20 at 2 months, $25 at 6 months, and $30 at 12 months). Each dyad received $15 at baseline for transportation to the dialysis center. Surrogates who completed bereavement measures received $20 at 2 weeks, $25 at 3 months, and $30 at 6 months.

Randomization and Interventions

Group assignments were generated prior to enrollment and concealed in sequentially numbered opaque envelopes opened after participants completed baseline measures. Patient-surrogate dyads were randomly assigned (1:1 ratio) to usual care plus SPIRIT or usual care

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only (control) using permuted blocks (size of 4) stratified by race (African American vs white), dialysis center type (university affiliated vs nonaffiliated), and dialysis modality (hemodialysis vs peritoneal dialysis).

Usual Care—As required by the Centers for Medicare & Medicaid Services (CMS),[27] written information for advance directives was provided to every patient on the first day of dialysis, and a social worker encouraged patients to complete an advance directive and addressed questions about life-sustaining treatments. A nephrologist, physician assistant, or nurse practitioner reviewed resuscitation statements with the patient to determine whether the patient wanted a do-not-resuscitate (DNR) order in the center. If there was no DNR order in the record, a desire for "full code" (receiving cardiopulmonary resuscitation) was presumed.

Intervention—Dyads randomly assigned to intervention received usual care plus SPIRIT, conducted by 1 of 3 nurse interventionists using a structured intervention guide. The interventionists had at least 2 years of clinical experience and completed a 3½-day training program designed for competency in communication skills and knowledge in ESRD and end-of-life care.

SPIRIT is a psychoeducational intervention designed to assist patients to clarify their end-of-life preferences, help surrogates increase their understanding of the patient's wishes, and prepare surrogates for the role and responsibilities of being a surrogate. The SPIRIT intervention included 2 sessions, and all sessions included both patient and surrogate. During the first session in a private room at the dialysis center, the interventionist assessed cognitive, emotional, and spiritual/religious aspects of the dyad's representations of the patient's illness, prognosis, and end-of-life care. This allowed the interventionist to provide individualized information about topics such as the effectiveness of life-sustaining treatment for people with end-organ failure and assisted the patient in examining his or her values about life-sustaining treatment at the end of life. The interventionist aimed to help the surrogate prepare for being a decision maker and for the emotional burden of end-of-life decision making by actively involving the surrogate in the discussion. A goals-of-care document was completed at the end of the session to indicate the patient's preferences.

In a brief second session delivered 2 weeks later at the patient's home (to reduce travel burden), the goals-of-care document and resuscitation preferences were reviewed. If the surrogate was someone out of the order of the hierarchical compensatory model[28] (eg, a sibling was chosen when the patient had a spouse), the interventionist explored potential family conflicts and encouraged the dyad to talk with other family members and complete a health care power of attorney.

The interventionist then summarized the patient's end-of-life preferences, listed the surrogate's name and relationship to the patient, and indicated whether the patient desired a DNR order or assistance in completing an advance directive. The interventionist communicated this information to dialysis staff (the social worker and nurse manager or the medical director), and the document was placed in the medical record.

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Sessions were audiorecorded. The first author reviewed every session for 6 months and provided one-on-one feedback to interventionists. After that, 20% of sessions were randomly selected every 6 months for evaluation of adherence using the Treatment Fidelity Assessment Tool.[29] Refresher training was offered as needed.

Outcomes and Follow-up

At baseline, a research assistant collected outcome variables and sociodemographics. At follow-up, research assistants blinded to group assignments collected measures by telephone.

Preparedness Outcomes—Preparedness outcomes were dyad congruence, patient decisional conflict, and surrogate decision-making confidence (Table 1). Dyad congruence was assessed using the goals-of-care document,[14] which included 2 scenarios describing medical conditions commonly occurring in patients with ESRD. In the first, the patient developed a severe complication and could not speak for him- or herself; the medical team believed recovery was unlikely and continuing life-sustaining treatment, including dialysis, would no longer be beneficial. In the second scenario, the patient developed advanced dementia. Each scenario had 3 response options: “The goals of care should focus on delaying my death, and thus I want to continue life-sustaining treatment,” “The goals of care should focus on my comfort and peace, and thus I do not want life-sustaining treatment, including dialysis,” and “I am not sure.” Patients and surrogates completed this document independently and their responses were then compared to determine dyad congruence: either congruent in both scenarios or incongruent. If both members of the dyad endorsed “I am not sure,” they were considered incongruent.

Patient decisional conflict was measured using the 13-item Decisional Conflict Scale, a validated measure in the context of end-of-life decision making[30]; higher scores indicate greater difficulty weighing benefits and burdens of life-sustaining treatments and decision making (range, 1–5). Surrogate decision-making confidence was measured using the 5-item Decision Making Confidence scale,[14,31] on which higher scores reflect greater comfort in performing as a surrogate (range, 0–4).

We created a composite outcome combining dyad congruence and surrogate Decision Making Confidence scale score because surrogates can feel highly confident even if they misunderstand patients’ wishes.[14,31] Thus, to differentiate surrogates who understand the patient’s wishes and feel confident in their role from those who do not (ie, understand the wishes but lack confidence, misunderstand the wishes but feel confident, or neither understand nor feel confident), dyads were grouped as congruent in both scenarios and surrogate Decision Making Confidence scale score of 3 or higher (“confident” to “very confident”), or not.[14]

Bereavement Outcomes—The 3 most common bereavement outcomes were measured: symptoms of anxiety, depression, and posttraumatic distress.[32,33] Anxiety and depression were measured using the Hospital Anxiety and Depression Scale[34] (subscale score range, 0–21; higher scores indicate greater symptom severity). The intensity of post-traumatic distress

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symptoms was assessed using the Post-Traumatic Symptoms Scale 10 (PTSS-10)[35] (range, 10–70; higher scores indicate more intense symptoms).

Statistical Analysis

Based on pilot data,[14] a priori power analysis of a 2-sample test of proportions at each time point indicated that to detect an odds ratio (OR) of 3.5 for the composite outcome with 2-sided $\alpha \leq 0.017$ (= 0.05/3 for multiple tests at 3 points), 80 dyads per group were needed for 90% power, and 100 dyads per group, for 95% power. The sample size allowed for ~30% patient deaths so that surrogate bereavement outcomes could be assessed. Analyses were intention to treat with all available data.

Most missing data on preparedness outcomes were due to deaths of patients (n = 30). Baseline characteristics of those lost to follow-up (n = 8) were similar in the groups, suggesting data missing at random.

Generalized estimating equation (GEE) methods[36] with exchangeable working covariance structure were used to examine group differences in preparedness and bereavement outcomes, adjusting for changes over time. The GEE provides unbiased estimates of intervention effects.[36] Logistic link function for binary outcomes and identity for continuous outcomes were used. Additional GEE analyses were performed for preparedness outcomes with an intervention group indicator, time, the baseline value, and the interaction between intervention and time. For bereavement outcomes, the intervention-time interaction was not analyzed due to the small sample (n = 45). Analyses were conducted using SAS, version 9.3 (SAS Institute Inc).

RESULTS

Sample Description

Of 890 patients screened, 436 were eligible; of those, 210 (48%) patient-surrogate dyads were randomly assigned (Fig 1). The groups were slightly imbalanced (n = 109 vs 101) because several dyads consented but did not come for baseline assessment and randomization. After numerous attempts to reschedule appointments, these dyads were considered passive refusals. Their randomization envelopes were neither opened nor reused.

Of the 85 dyads receiving the SPIRIT intervention and the 86 in the control group completing 12-month follow-up, 33 (39%) and 18 (21%), respectively, consented to extend participation until December 2013. Patient survival at 12 months and in December 2013 was similar between groups ($P = 0.5$ and $P = 0.3$, respectively). Mean survival, from randomization to patient death, was 11.4 (interquartile range [IQR], 5.3–18.0) months for SPIRIT and 13.1 (IQR, 5.5–15.5) months for control. There were 45 deaths by December 2013. Attrition over 6 months for surrogate bereavement outcomes was 6 (13%). The last 6-month assessment was completed in April 2014.

African Americans constituted 67.4% of participants (141 patients and 142 surrogates). A higher percentage of control patients than SPIRIT patients had no religious preference (19.8% vs 2.8%; $P < 0.001$); there were no other baseline group differences (Table 2).

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Baseline characteristics of dyads who agreed to extend study participation were similar between groups.

Mean age of the 45 patients who died was 64.6 ± 12.6 (standard deviation) years. Twenty-one (47%) were women, 24 (53%) were African Americans, and 44 (98%) were on hemodialysis therapy. Mean age of bereaved surrogates was 57.1 ± 13.7 years, 34 (76%) were women, and 25 (56%) were African Americans. Infection and cardiovascular complications were causes of death for many patients (n = 18 [40%]). Ten patients (22%) died suddenly, requiring no surrogate decision making, but 35 surrogates (78%) were involved in end-of-life decision making. These characteristics were similar between groups.

Intervention Participation and Fidelity

Of the 109 dyads randomly assigned to SPIRIT, 107 (98%) received the first session; of those, 102 (95.3%) received the second session (Fig 1). The first session averaged 82 minutes and the second session averaged 20 minutes. No session was stopped because of participants' emotional distress. Interventionist adherence to SPIRIT using the Treatment Fidelity Assessment Tool[29] averaged 2.6 of 3.

Outcomes

Preparedness—Dyad congruence in goals of care for both scenarios was higher in SPIRIT than in controls at 2 and 6 months, but that effect was not significant across all time points (Table 3). Patient Decisional Conflict Scale scores decreased over time in SPIRIT while increasing in control, a significant intervention effect across time points ($\beta = -0.12$; 95% confidence interval [CI], −0.22 to −0.02; $P = 0.01$). Surrogate Decision Making Confidence scale scores were high at all time points and did not differ by group. The composite outcome did not differ at any point.

Adjusting for time, baseline value, and the intervention-time interaction using multivariate GEE models (Table 4), the intervention effects on dyad congruence (OR, 1.89; 95% CI, 1.1–3.3; $P = 0.03$), surrogate Decision Making Confidence scale score ($\beta = 0.13$; 95% CI, 0.01–0.24; $P = 0.03$), and the composite outcome (OR, 1.82; 95% CI, 1.0–3.2; $P = 0.04$) were statistically significant. However, the intervention effect on dyad congruence significantly decreased by 12 months (OR, 0.46; 95% CI, 0.2–1.0; $P = 0.04$), whereas dyad congruence in controls significantly improved from 2 months to 6 ($P = 0.02$) and 12 ($P = 0.02$) months.

The intervention effect in reducing patient Decision Making Confidence scale score was significant at 12 months ($\beta = -0.19$; 95% CI, −0.33 to −0.04; $P = 0.01$). In contrast, Decisional Conflict Scale scores in controls significantly increased by 12 months ($\beta = 0.12$; 95% CI, 0.02–0.22; $P = 0.02$). Baseline values of all preparedness outcomes significantly predicted outcomes at follow-up points (all $P < 0.01$).

Bereavement—In both groups, surrogates' anxiety, depression, and PTSS-10 scores increased at 2 weeks' bereavement (Table 3). In SPIRIT, scores decreased over time, returning to or below baseline scores. Among controls, these scores never returned to baseline. By 3 months, scores stabilized in both groups. Depression scores in SPIRIT were significantly lower at 3 ($P = 0.01$) and 6 ($P = 0.01$) months than among controls, resulting in

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a significant intervention effect across all time points (β = −2.2; 95% CI, −4.2 to −0.3; *P* = 0.02).

Adjusting for time and baseline scores, GEE models (Table 5) showed significant intervention effects on anxiety (β = −1.13; 95% CI, −2.23 to −0.03; *P* = 0.04), depression (β = −2.54; 95% CI, −4.34 to −0.74; *P* = 0.006), and PTSS-10 scores (β = −5.75; 95% CI, −10.9 to −0.64; *P* = 0.03). Over time, anxiety was significantly reduced by 6 months (*P* = 0.04), and so was depression by 3 (*P* = 0.01) and 6 (*P* = 0.02) months and PTSS-10 scores by 3 months (*P* = 0.04). All baseline values significantly predicted outcomes at follow-up (either *P* = 0.01 or *P* < 0.001).

DISCUSSION

SPIRIT was superior to usual care alone in enhancing dyad congruence in terms of goals of care, surrogate decision-making confidence, and the composite outcome combining the 2. These effects decreased by 12 months. SPIRIT significantly reduced patient decisional conflict and was superior to usual care alone in reducing surrogates' bereavement anxiety, depression, and posttraumatic distress symptoms.

Previous studies[14,30,37–39] have demonstrated short-term ACP intervention effects, but have not examined long-term effects and changes over time. In the current trial, SPIRIT's effect on dyad congruence decreased after 2 months, decreased to two-thirds by 6 months and to half by 12 months. Although the importance of ongoing periodic ACP discussions has been emphasized,[2,11] to date, no randomized trials supported that need. Our data suggest that improvement in dyad congruence may not be sustained over time, underscoring the need for repeated discussions. Patients might change their preferences or surrogates might not recall the patient's wishes expressed during the discussion.

SPIRIT helped surrogates recover from bereavement distress by 3 months. Although another trial found similar results with geriatric patients and their surrogates,[38] our trial is the first to show effects on bereavement outcomes of surrogates of patients with ESRD and to demonstrate changes over time. Knowing their loved ones' wishes may have reduced surrogates' bereavement distress,[3,38] but reduced distress could also have been due to SPIRIT's attention to preparing surrogates for being a surrogate and the emotional burden they might experience.

To our knowledge, this is the only randomized trial to demonstrate positive long-term effects of an ACP intervention in a sample with a majority of African Americans. For African Americans, ACP has been considered challenging because they are reportedly less amenable to using advance directives.[40,41] However, African Americans in our study were clearly interested in discussing end-of-life care because no participant asked that the SPIRIT sessions be halted. We believe this occurred because instead of aiming at completion of an advance directive, SPIRIT focused on assisting patients and surrogates to think and talk about the possibility of end-of-life decision making and to explore how they would feel about care options near the end of life.

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The preparedness outcomes, especially dyad congruence, also improved in the control group. As far as we are aware, our trial is the first randomized controlled trial of an ACP intervention with repeat measures of the preparedness outcomes. Simply answering these thought-provoking questions may have served as an intervention, a phenomenon known as assessment effects.[42–44]

Although this study included 20 dialysis centers representing both community and academic practice settings, caution is needed in generalizing because it was conducted in a single US region. The control group received usual care, not attention control, but usual care reflected CMS requirements for coverage of ESRD facilities; patients were encouraged to participate in their plan of care, including discussing advance directives and end-of-life concerns.[27] Finally, the sample for bereavement outcomes was small, although estimates of intervention effects were stable.

In conclusion, SPIRIT was associated with improvements in dyad preparation for end-of-life decision making and surrogate bereavement outcomes. These findings may be useful in addressing the critical need to implement ACP for patients with advanced kidney disease.[45] Advanced nurse practitioners or physician assistants might be appropriate to deliver the SPIRIT intervention after training. Future studies should include trials to determine SPIRIT's effectiveness when implemented in clinical practice and with other racial/ethnic groups.

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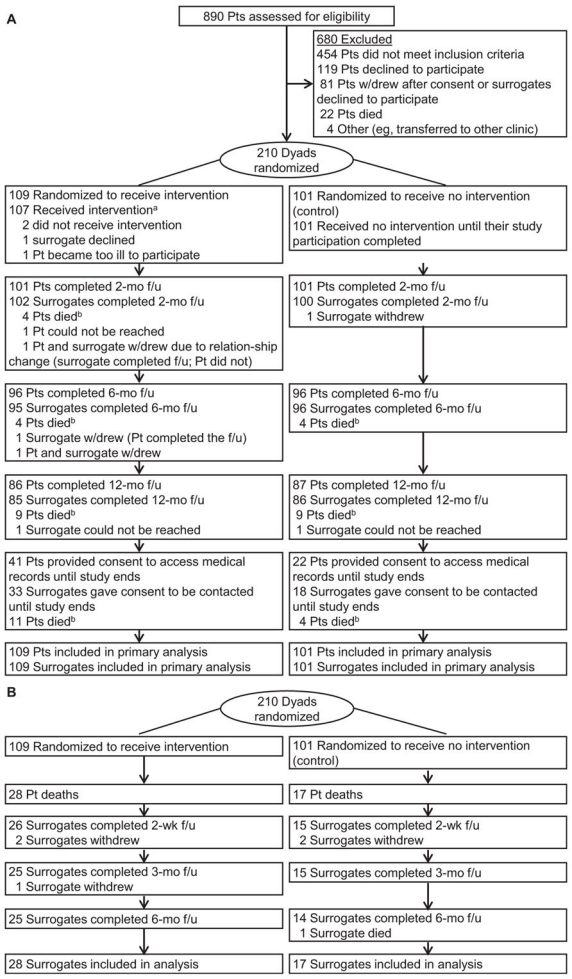

Figure 1.

Flow through the Sharing Patient's Illness Representations to Increase Trust (SPIRIT) trial of an advance care planning intervention for long-term dialysis patients (pts) and their chosen surrogates. (A) Participant flow. [a]Five dyads did not receive the second SPIRIT session (a brief follow-up [f/u] discussion): 3 dyads repeatedly canceled, 1 patient died before the scheduled session, and 1 home visit could not be made due to safety concerns for the interventionist. [b]See Fig 1B for surrogate participant flow after patient's death. (B) Surrogate participant flow after patient's death.

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Table 1

Summary of Instruments to Assess Outcomes

Outcome and Variable	Instrument	Completed by		Measurement Time Point
		Patient	Surrogate	
Preparedness				
Dyad congruence	Goals-of-care document (2 end-of-life scenarios)	✓	✓	Baseline and 2, 6, and 12 mo
Patient decisional conflict	Decisional Conflict Scale (range, 1–5)	✓		Baseline and 2, 6, and 12 mo
Surrogate decision-making confidence	Decision Making Confidence scale (range, 0–4)		✓	Baseline and 2, 6, and 12 mo
Bereavement				
Anxiety symptoms	HADS–anxiety subscale (range, 0–21)		✓	Baseline and 2 wk postdeath and 3 and 6 mo postdeath
Depression symptoms	HADS–depression subscale (range, 0–21)		✓	Baseline and 2 wk postdeath and 3 and 6 mo postdeath
Posttraumatic distress symptoms	PTSS-10 (range, 10–70)		✓	Baseline and 2 wk postdeath and 3 and 6 mo postdeath

Abbreviations: HADS, Hospital Anxiety and Depression Scale; PTSS-10, Post-Traumatic Symptoms Scale-10.

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Table 2

Baseline Characteristics of Randomly Assigned Participants

Characteristic	SPIRIT (n = 109)		Control (n = 101	
	Patient	Surrogate	Patient	Surrogate
Sociodemographics				
Age, y	61.1 ± 11.4	54.1 ± 13.1	63.2 ± 11.1	54.1 ± 14.2
Female sex	65 (59.6)	75 (68.8)	55 (54.5)	77 (76.2)
African American race[a]	72 (66.1)	74 (67.9)	69 (68.3)	68 (67.3)
Marital status				
Married/living with partner	56 (51.4)	73 (67.0)	43 (39.9)	63 (62.4)
Divorced/separated/widowed	40 (36.7)	19 (17.4)	49 (48.5)	22 (21.8)
Never married	13 (11.9)	17 (15.6)	9 (8.9)	16 (15.8)
Formal education completed, y	12.5 ± 2.8	13.5 ± 2.5	12.8 ± 2.9	13.3 ± 2.0
High school graduate or equivalent	54 (49.5)	50 (45.9)	56 (55.4)	47 (46.5)
Have a religious preference	106 (97.2)	99 (90.8)	81 (80.2)	91 (90.1)
Protestant	96 (90.6)	89 (89.9)	74 (91.4)	89 (97.8)
Extent of following religious customs				
Never/sometimes	28 (26.4)	17 (17.2)	20 (24.7)	10 (11.0)
Frequently/always	78 (73.6)	82 (82.8)	61 (75.3)	81 (89.0)
Importance of spirituality in life				
Not at all/somewhat important	18 (16.5)	8 (7.3)	14 (13.9)	14 (13.9)
Very/extremely important	91 (83.5)	101 (92.7)	87 (86.1)	87 (86.1)
Annual income				
<$20,000	53 (48.6)	28 (25.7)	53 (52.5)	28 (27.7)
$20,000–$50,000	40 (36.7)	51 (46.8)	33 (32.7)	43 (42.6)
>$50,000	14 (12.8)	26 (23.9)	12 (11.9)	25 (24.8)
Refused to answer	2 (1.8)	4 (3.7)	3 (3.0)	5 (9.0)
Have had a close family member/friend die	108 (99.1)	103 (94.5)	98 (97.0)	98 (97.0)
Have been involved in tough medical decisions for family member/friend who died	36 (33.3)	39 (36.4)	25 (25.0)	35 (34.7)
Surrogate’s relationship to patient				
Spouse/partner	—	44 (40.4)	—	37 (36.6)
Parent	—	27 (24.8)	—	38 (37.6)
Sibling	—	16 (14.7)	—	11 (10.9)
Child	—	8 (7.3)	—	4 (4.0)
Friend	—	6 (5.5)	—	4 (4.0)
Other	—	8 (7.3)	—	7 (6.9)
Patient medical history and records				
Hemodialysis	105 (96.3)	—	96 (95.0)	—
Years on dialysis				
Median [IQR]	3.8 [4.3]	—	2.4 [3.8]	—
Mean ± SD	4.5 ± 3.4	—	4.2 ± 4.9	—

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	SPIRIT (n = 109)		Control (n = 101	
Characteristic	**Patient**	**Surrogate**	**Patient**	**Surrogate**
CCI illness severity[20]	8.2 ± 1.8	—	8.1 ± 1.8	—
Has an advance directive	21 (19.3)	—	18 (17.8)	—
Surrogate listed in the medical record	2 (1.8)	—	2 (2.0)	—
DNR order at clinic	5 (4.6)	—	3 (3.0)	—

Note: Unless otherwise indicated, values for categorical variables are given as number (percentage); for continuous variables, as mean ± standard deviation.

Abbreviations: CCI, Charlson Comorbidity Index; DNR, do not resuscitate; IQR, interquartile range; SD, standard deviation; SPIRIT, Sharing Patient's Illness Representations to Increase Trust.

[a] Assessed by self-report using National Institutes of Health reporting categories for federally funded clinical research.

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Table 3

Preparedness and Bereavement Outcomes by Treatment Group

Outcome	SPIRIT	Control	OR or β[a] (95% CI)	*P*
Preparedness outcomes	(n = 109)	(n = 101)		
Dyad congruent[b]			1.4 (0.9 to 2.1)[c]	0.2
Baseline	47 (43.1)	43 (42.6)	—	
2 mo	64 (63.4)	48 (48.0)	1.9 (1.1 to 3.3)	0.03
6 mo	66 (69.5)	59 (61.5)	1.4 (0.8 to 2.6)	0.2
12 mo	51 (60.0)	52 (60.5)	1.0 (0.5 to 1.8)	0.9
Patient DCS[d]			−0.12 (−0.22 to −0.02)[c]	0.01
Baseline	1.6 ± 0.5	1.7 ± 0.5	—	
2 mo	1.7 ± 0.5	1.7 ± 0.5	−0.03 (−0.15 to 0.09)	0.6
6 mo	1.6 ± 0.5	1.8 ± 0.4	−0.16 (−0.28 to −0.04)	0.007
12 mo	1.6 ± 0.4	1.8 ± 0.5	−0.23 (−0.36 to −0.10)	<0.001
Surrogate DMC scale[e]			0.09 (−0.02 to 0.19)[c]	0.1
Baseline	3.5 ± 0.5	3.6 ± 0.4	—	
2 mo	3.7 ± 0.4	3.6 ± 0.5	0.12 (−0.002 to 0.23)	0.05
6 mo	3.7 ± 0.4	3.6 ± 0.5	0.10 (−0.02 to 0.23)	0.1
12 mo	3.7 ± 0.4	3.7 ± 0.5	0.03 (−0.10 to 0.16)	0.7
Composite outcome[f]			1.4 (0.9 to 2.2)[c]	0.1
Baseline	46 (42.2)	43 (42.6)	—	
2 mo	62 (61.4)	47 (47.0)	1.8 (1.0 to 3.1)	0.04
6 mo	64 (67.4)	55 (57.3)	1.5 (0.9 to 2.8)	0.2
12 mo	51 (60.0)	49 (57.0)	1.1 (0.6 to 2.1)	0.7
Bereavement outcomes	(n = 28)	(n = 17)		
HADS–anxiety[g]			−1.2 (−2.8 to 0.3)[c]	0.1
Baseline	6.1 ± 4.2	6.1 ± 4.0	—	
2 wk	6.3 ± 2.6	6.6 ± 4.0	−0.4 (−2.5 to 1.8)	0.7
3 mo	5.1 ± 2.6	6.4 ± 2.7	−1.3 (−3.0 to 0.5)	0.1
6 mo	4.7 ± 3.4	6.6 ± 2.7	−1.9 (−4.0 to 0.3)	0.09
HADS–depression[g]			−2.2 (−4.2 to −0.3)[c]	0.02
Baseline	4.1 ± 3.1	3.1 ± 3.2	—	
2 wk	4.8 ± 3.2	6.4 ± 4.4	−1.6 (−4.1 to 0.9)	0.2
3 mo	3.3 ± 3.1	5.9 ± 3.2	−2.7 (−4.7 to −0.6)	0.01
6 mo	3.4 ± 2.8	5.9 ± 3.2	−2.6 (−4.6 to −0.6)	0.01
PTSS-10[h]			−4.0 (−10.2 to 2.2)[c]	0.2
Baseline	20.2 ± 8.7	17.3 ± 8.1	—	
2 wk	23.6 ± 11.8	27.0 ± 14.0	−3.4 (−12.1 to 5.2)	0.4
3 mo	19.3 ± 9.9	22.5 ± 8.3	−3.2 (−9.4 to 3.0)	0.3
6 mo	20.3 ± 11.1	25.5 ± 12.4	−5.2 (−13.0 to 2.6)	0.2

Note: Unless otherwise indicated, values for categorical variables are given as number (percentage); for continuous variables, as mean ± standard deviation.

Abbreviations: CI, confidence interval; DCS, Decisional Conflict Scale; DMC, Decision Making Confidence; HADS, Hospital Anxiety and Depression Scale; OR, odds ratio; PTSS-10, Post-Traumatic Stress Symptoms-10; SPIRIT, Sharing Patient's Illness Representations to Increase Trust.

[a] Unadjusted treatment effect; using all available data; a negative coefficient indicates the intervention was associated with a lower score; significance based on 2-sided $P < 0.017$ (Bonferroni correction) for the comparison at each time point.

[b] Dyads congruent in both scenarios of the goals-of-care document.

[c] Overall treatment effect, adjusted for time; significance based on 2-sided $P < 0.05$.

[d] Patient DCS scores range from 1 to 5, with higher score indicating greater conflict.

[e] Surrogate DMC scale scores range from 1 to 4, with a higher score indicating greater confidence.

[f] Dyads were grouped into either dyads congruent in both scenarios and surrogate DMC scale score ≥ 3 or not (being one of the following: dyads congruent in both scenarios and surrogate DMC scale score < 3, dyads congruent in 1 or none of the scenarios and surrogate DMC scale score ≥ 3, or dyads congruent in 1 or none of the scenarios and surrogate DMC scale score < 3). The numbers (%) indicate dyads congruent in both scenarios and surrogate DMC scale score ≥ 3.

[g] HADS anxiety and depression scores each range from 0 to 21, with higher score indicating greater symptom severity.

[h] PTSS-10 scores range from 10 to 70, with a higher score indicating greater symptom severity.

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Table 4

Multivariate Models for the Preparedness Outcomes

	Dyad Congruence		Patient DCS		Surrogate DMC Scale		Composite Outcome	
	OR (95% CI)	*P*[a]	β (95% CI)	*P*[a]	β (95% CI)	*P*[a]	OR (95% CI)	*P*[a]
Treatment								
SPIRIT	1.89 (1.1 to 3.3)	0.03	−0.01 (−0.12 to 0.10)	0.9	0.13 (0.01 to 0.24)	0.03	1.82 (1.0 to 3.2)	0.04
Control	1.00 (reference)		(reference)		(reference)		1.00 (reference)	
Time								
2 mo	1.00 (reference)		(reference)		(reference)		1.00 (reference)	
6 mo	1.89 (1.1 to 3.2)	0.02	0.07 (−0.01 to 0.15)	0.08	0.03 (−0.06 to 0.12)	0.5	1.63 (1.0 to 2.7)	0.06
12 mo	1.84 (1.1 to 3.1)	0.02	0.12 (0.02 to 0.22)	0.02	0.08 (−0.03 to 0.19)	0.1	1.66 (1.0 to 2.8)	0.06
Baseline	3.43[b] (2.1 to 5.6)	<0.001	0.30 (0.21 to 0.39)	<0.001	0.20 (0.07 to 0.33)	0.002	3.42[c] (2.1 to 5.5)	<0.001
Treatment × time								
Treatment × 6 mo	0.66 (0.3 to 1.3)	0.3	−0.11 (−0.24 to 0.03)	0.1	−0.02 (−0.13 to 0.09)	0.7	0.76 (0.4 to 1.5)	0.4
Treatment × 12 mo	0.46 (0.2 to 1.0)	0.04	−0.19 (−0.33 to −0.04)	0.01	−0.08 (−0.21 to 0.05)	0.2	0.57 (0.3 to 1.2)	0.1

Abbreviations: CI, confidence interval; DCS, Decisional Conflict Scale; DMC, Decision Making Confidence; OR, odds ratio; SPIRIT, Sharing Patient's Illness Representations to Increase Trust.

[a] Significance based on 2-sided $P < 0.05$.

[b] Reference indicates dyads not congruent in both scenarios.

[c] Reference indicates dyads not congruent and/or surrogate DMC scale score < 3.

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Table 5

Multivariate Models for the Surrogate Bereavement Outcomes

	HADS–Anxiety		HADS–Depression		PTSS-10	
	β (95% CI)	*P*[a]	β (95% CI)	*P*[a]	β (95% CI)	*P*[a]
Treatment						
SPIRIT	−1.13 (−2.23 to −0.03)	0.04	−2.54 (−4.34 to −0.74)	0.006	−5.75 (−10.9 to −0.64)	0.03
Control	(reference)		(reference)		(reference)	
Time						
2 wk	(reference)		(reference)		(reference)	
3 mo	−0.91 (−1.85 to 0.03)	0.06	−1.06 (−1.89 to −0.24)	0.01	−4.52 (−7.59 to −1.45)	0.004
6 mo	−1.00 (−1.94 to −0.07)	0.04	−0.90 (−1.66 to −0.14)	0.02	−2.34 (−5.04 to 0.35)	0.09
Baseline	0.39 (0.24 to 0.54)	<0.001	0.30 (0.07 to 0.52)	0.01	0.63 (0.32 to 0.95)	<0.001

Abbreviations: CI, confidence interval; HADS, Hospital Anxiety and Depression Scale; PTSS-10, Post-Traumatic Stress Symptoms-10; SPIRIT, Sharing Patient's Illness Representations to Increase Trust.

[a]Significance based on 2-sided $P < 0.05$.

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