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Subject Recruitment and Retention against Quadruple Challenges in an Intervention Trial of End-of-Life Communication

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Abstract

Studies of end-of-life care face difficulties associated with enrollment and attrition. Information and exemplars can help end-of-life care researchers anticipate such difficulties and customize recruitment and retention strategies to achieve planned sample sizes. We analyzed data on recruitment and retention efforts used in a clinical trial of an end-of-life communication intervention that involved African American dialysis patients and their chosen surrogate decision makers. Despite the challenges the trial faced (e.g., recruiting a minority group of patients who were seriously ill, had a surrogate decision maker willing to join the study, and were willing to engage in end-of-life discussions), the planned sample size was met, and nearly 90% of the participants completed the study. Various strategies were used to sustain accrual during the study. Although a total of 16 contacts per dyad had been planned from enrollment to 3-months data collection, 27 contacts were actually needed. The strategies and procedures used in this study may be pertinent to other studies that involve African Americans with serious illness and require dyadic participation.

Keywords

End-of-life research; recruitment; retention

As the body of literature in end-of-life-care grows, increasing attention is being given to the unique challenges of accruing subjects for such research (e.g., Kirchhoff & Kehl, 2007; McMillan & Weitzner, 2003; Northouse et al, 2006; Steinhauer et al, 2006).^{1–4} End-of-life-care research inevitably involves multiple challenges of recruitment and retention because the scientific questions require, for example, identifying and recruiting racially and ethnically diverse samples of seriously ill or dying patients and/or caregivers facing end-of-life decision making, and collecting data at critical times, such as near or after the subject's death. Moreover, when the research involves testing an intervention near end of life, the complexity increases due to additional challenges associated with intervention studies (e.g., constructing

intervention conditions, ethical issues, and selecting an appropriate design to test the intervention).^{5,6}

Several investigators^{1,3,4} have noted challenges in recruiting seriously ill patients: eligible patients often are too sick to participate and thus refuse to participate or are not referred to the study by their healthcare providers; attrition can be high due to patients' disease progression or death. When studies require both patients and their family (or designated) caregivers to participate as dyads, recruitment is even more difficult. This is because both members of each dyad must meet inclusion criteria and family caregivers often express that they are too overwhelmed by caregiving duties to participate.^{3,4,7}

Recruiting African-American patients to research studies has been continuously challenging. Baquet et al⁸ described multiple levels of barriers to minority participation in clinical trials. These barriers include patient factors, such as lack of understanding and knowledge of the role of clinical trials and mistrust. This mistrust stems in part from knowledge of unethical and exploitative research endeavors from our recent past. The consequences of these unethical studies continue to be a barrier to recruitment of African Americans.^{9–13} Other barriers include healthcare providers' lack of understanding of clinical trials, investigators' failure to recognize the importance of using a culturally tailored approach to recruitment and retention, and organizational factors that impede potential participation, such as lack of flexibility in scheduling follow-up visits.

Discussing end-of-life issues with seriously ill patients and their family members is often considered distressing and even harmful even though empirical evidence has proven otherwise.^{14,15} Investigators studying end-of-life discussions or communication interventions experience challenges in convincing the Institutional Review Boards and/or participating study sites' healthcare providers that such research can advance the science and clinical practice without harming participants. Healthcare providers may play a gatekeeper role by not referring eligible patients to the investigators.¹

Given these challenges, it is often difficult to predict the resources and time required to achieve recruitment and retention goals.¹⁶ Most researchers learn to make such predictions by trial and error after their own pilot tests. More information and exemplars would help end-of-life-care researchers anticipate challenges, develop strategies customized to their projects, and estimate resources required to recruit and retain the planned sample size.

In this paper we describe the results of recruitment and retention efforts made during a 2-year randomized controlled trial of an end-of-life communication intervention, the SPIRIT (Sharing the Patient's Illness Representations to Increase Trust) intervention, conducted with African American dialysis patients and their chosen surrogate decision makers.¹⁷ The investigators used strategies to overcome quadruple challenges of an end-of-life intervention trial: the first challenge was identifying and enrolling patients who were seriously ill; the second challenge was that the study required both patients and surrogates willing to join the study; the third challenge was to enroll African Americans who have been considered difficult to recruit in research studies; and finally, the nature of the study itself, discussing end-of-life issues, was the fourth challenge. The purposes of this paper are to describe the recruitment and retention strategies used in the study and to identify the extent to which the recruitment/retention efforts achieved success in participants' consent and study completion.

Study overview

The primary objectives of the trial were to determine the feasibility, acceptability, and preliminary efficacy of the SPIRIT intervention among African American patients with end-stage renal disease (ESRD) and their chosen surrogate decision makers.¹⁷ The study was

approved by the appropriate Institutional Review Boards. A total of 58 dyads were enrolled in the study. The planned sample size ($N = 56$) was based on the feasibility of recruiting and retaining participants for 18 months given the latest census data at the study sites and assuming 11% attrition. Patients were recruited from 6 free-standing dialysis centers located in Pennsylvania. The inclusion criteria were: self-identified African American, receiving dialysis (either hemodialysis or peritoneal dialysis) for at least 3 months prior to enrollment, availability of a surrogate chosen by the patient who could be present during the intervention, over 18 years of age, and able to read, write, and speak English. Social workers at the dialysis centers approached patients to assess their eligibility and interest in the study. Subsequently, the research staff obtained informed consent from those who indicated an interest and conducted a cognitive function test using the Short Portable Mental Status Questionnaire (SPMSQ).¹⁸ Patients with > 2 errors on the SPMSQ were deemed ineligible. Upon patients' consent, the research staff contacted their surrogates and invited them to join the study if they were over 18 years old, able to read, write, and speak English, and willing to participate in the intervention with the patients.

Upon surrogates' verbal consent, the research staff scheduled the first appointment at the dialysis center for the baseline data collection. Immediately after baseline data completion, the dyad was randomized to intervention or control and participated in a SPIRIT intervention session (if randomized to the intervention group). The intervention was a single session (45 minutes to 1.5 hours) interview with a patient-surrogate dyad, delivered by a trained nurse interventionist. Based on the Representational Approach to patient education,^{19,20} the SPIRIT intervention assisted the dyad to share illness representations, examine values related to life-sustaining treatment at the end of life, and discuss what role the surrogate decision maker would have to play during end-of-life decision making.

The baseline data collection required 45 minutes to 1 hour to complete for each member of the dyad. Follow-up data collection (questionnaires and semi-structured interviews) was conducted over the telephone at 1 week and 3 months post-intervention. The follow-up data collection session required about 1 hour for each member of the dyad.

Recruitment Strategies

Eligible patients were initially contacted by the social worker at each dialysis center, a trusted member of the community. Then, the research staff met with patients who expressed an interest to obtain written consent and contact information about their surrogate decision maker.

Upon the patient's consent, we asked him/her to talk to the surrogate about the study in the next day or two to minimize research staff's cold calling (calling a potential participant who had never been told that they would be contacted about the study) and inquired the best time to reach the surrogate. We also implemented specific procedures for calling surrogates for verbal consent, which included, for example, the staff did not leave a message until having talked to the surrogate once; if the first attempt to contact the surrogate failed, the staff called at three different times of day for three consecutive days. If all attempts failed without a known reason (we asked the patient about any possible reason that the staff could not reach the surrogate), no further attempt was made. Such occasions were recorded as a passive or implicit refusal.

We assigned designated recruiters to the study sites whenever possible to help build familiarity and rapport with potential participants and the staff at the site.¹⁰ A recruitment script was used to provide consistent information and approach.⁷ At the beginning of the recruitment period, we received a long list (~ 30 names) of potential patients from the social worker. Because of the time lag until we approached the patients, many patients did not remember that they had been asked by the social worker and refused to participate. We later asked the social worker

to approach fewer than 10 potential participants per week so that the recruiter could talk to those interested in the study within 2–3 days, a time during which their interest would have been sustained after the social worker's first introduction of the study. We used study brochures and posters at the sites to advertise the study information.

Retention Strategies

Except for the baseline data collection session, all follow-up data collection sessions were done over the telephone. This method of data collection was chosen based on the surrogates' preference and limited availability for face-to-face follow-up sessions due to their life circumstances (e.g., having multiple jobs and attending school, and so forth). The follow-up data collection sessions were scheduled at the completion of baseline data collection, and the dates and times were given to the dyad on an appointment card with a call-back number. We used the same data collectors whenever possible⁴ and made monthly check-in calls to each member of the dyads to help retain them until the 3-month follow-up. A postcard reminder was sent to the dyad a week before the scheduled appointment, and a reminder call was made 2–3 days prior to the appointment to confirm or reschedule the appointment. Special occasion cards (e.g., birthday cards) were sent if we were aware of those occasions.

We carefully selected the method of subject payment based on the social workers' recommendation and investigators' experiences with previous studies conducted at the study sites. Participants were given \$25 in cash at the baseline completion to support their transportation because many of them did not have a car and used the public transportation. At the completion of each follow-up data collection sessions, a \$25 money order was mailed to each subject. We used money orders issued by the U.S. postal service because many participants did not have a bank account to deposit or exchange them for cash. Gift cards were not preferred due to their limited usability for the target sample. The implemented recruitment and retention activities are summarized in Table 1.

Documentation of recruitment and retention activities

During the trial, all research staff members completed weekly reports summarizing their activities of subject contacts for recruitment, data collection, and retention for the week. Participants' progress in the study was tracked through a web-based clinical trial management system (R-Track[®]). The information (e.g., dates and methods of subject contacts, recruitment and retention status, amount of time spent, completion of data collection sessions) documented in the weekly activity reports and the clinical trial management system was entered into an excel database.

Data analysis

The data were analyzed using SPSS. Descriptive statistics (e.g., means, standard deviations, and frequencies) were computed to summarize recruitment and retention activities. Mann-Whitney U tests (because of the skewed distributions of the data) were performed to identify whether there were differences in the number of contacts between those who consented and those who refused and between patients and surrogates.

Results

Recruitment and retention rates and human resources used

Social workers assessed 125 patients for eligibility, and 118 patients were deemed eligible and approached by the research staff for written consent. Seven patients were ineligible for the following reasons: failed the SPMSQ ($n = 1$), had no available surrogate ($n = 5$), and hearing impairment ($n = 1$). Of the 118 eligible patients, 87 (73.72%) consented, but only 58 of their

surrogates (66.67%) joined the study, leaving 29 patients who had consented could not participate due to the lack of surrogate consent. Three surrogates withdrew from the study (two from the intervention group and one from the control group), 1 surrogate and 2 patients in the control group died, and therefore, 89.7% of the dyads completed the study. The two groups did not differ in retention.

The research team consisted of 4 members; one FTE (full time employee) project manager who also devoted her 50% time as an interventionist, two .5 FTE research assistants and one hourly-based research assistant (10–12 hours per week). All members participated in subject recruitment and retention activities. It took 14 months (instead of the estimated 18 months) to complete recruitment of 58 dyads after the first potential patient was approached. On average, 1.71 ($SD = 2.06$; Range = 1 – 7; $IQR = 1 – 2$) and 4.49 ($SD = 3.64$; Range = 1 – 18; $IQR = 2 – 5$) contacts were made before patients and surrogates provided written consent or expressed refusal, respectively.

Associations between the number of contacts and subject enrollment

The number of contacts until the decision to consent versus refuse did not differ for patients ($M \pm SD = 1.63 \pm 1.98$ vs. 2.00 ± 2.35 ; $U = 912.5$, $p = .42$). However, compared to surrogates who consented, surrogates who refused did so after significantly more contacts ($M \pm SD = 1.91 \pm 2.03$ vs. 4.50 ± 4.56 ; $U = 627.5$, $p < .001$). As dyads, dyads who consented did so after 3.21 ± 2.10 ($M \pm SD$) contacts whereas dyads who refused (because of surrogate refusals) did so after 5.00 ± 5.32 ($M \pm SD$).

Number of subject contacts for data collection and retention activities after enrollment

From enrollment to 3-month follow-up data collection, 8 contacts had been planned for each member of the dyad, thus a total of 16 contacts per dyad. These contacts were made primarily via telephone, except for one-time postcard reminders. For patients and surrogates who reside together, occasionally there was no need to make all 16 contacts. Nonetheless, on average 26.83 such contacts ($SD = 8.67$; Range = 11 – 58; $IQR = 22 – 29$) were actually needed until study completion.

Discussion

Despite the quadruple challenges the research posed, the study achieved 104% of the target sample size. Compared to the recruitment of patients who were first approached in person on their dialysis day, surrogate recruitment required nearly 3 times more contacts on average. Roughly 33% of the surrogates who were approached did not join the study (explicit and implicit refusals). While the strategy to first introduce the study to potential patients by a trusted member of the clinic²¹ and face-to-face interactions to inform of the study^{22–24} enhanced patient recruitment, surrogate recruitment was challenged because there was no opportunity for clinic staff to interact with the surrogates in person to introduce the study. Surrogates were difficult to reach even after their verbal consent was given. The investigators set a rule (described earlier) to discontinue attempts to contact ‘difficult-to-reach’ surrogates for recruitment so that expensive staff time might not be further dispensed for unfruitful outcomes. In fact, our data indicate that those who consented did so within three attempts. For surrogates who simply could not spare time to participate in the study, more phone calls likely would not have made a difference.

We implemented several recruitment and retention strategies developed based on the relevant literature review and our own previous study²⁵ as described above. Of those strategies, we found the following to be helpful in accrual: (1) the potential patients were approached by research staff within 2–3 days after the social worker conversed with them about the study

(most patients who refused to participate had been approached by the social worker several weeks prior to being contacted by research staff); (2) participants welcomed the types of monetary incentives provided (cash and U.S. postal service money orders); (3) follow-up data collection was performed over the telephone (a preferred mode of follow-ups); and (4) short (< 5 minutes) monthly check-in calls between follow-up sessions.

Although participants preferred telephone-based data collection to face-to-face completion, challenges still arose during the course of the study. Many participants had a cellular phone (no landline) and expressed concerns that their phone minutes would run out. A toll-free number is no longer helpful today because cellular phones are replacing landlines. To address this issue, investigators could provide subjects with cellular phones that match participants' cellular phone service provider. But this strategy still leaves a small group of pre-paid phone users who would not benefit.

The difference between the number of planned contacts (=16) and the number of actual contacts (=27) was primarily due to the difficulty in contacting surrogates who had more than one job, ever changing work schedules, child care responsibilities, and/or attended school at night. Data collection appointments with these surrogates were often rescheduled, contributing to the higher number of contacts than had been planned.

As noted above, healthcare providers played an important role in the study in that recruitment was most successful when research staff were able to reach potential subjects shortly after they had been informed about the study by the clinic social worker. On the other hand, there were some ways in which providers undermined recruitment efforts. Despite our efforts (e.g., initial orientation and training) to help healthcare providers at the dialysis centers be acquainted with our recruitment procedures and eligibility criteria, they often acted as gatekeepers. That is, rather than refer all potentially eligible subjects, they often pre-screened potential patients for the investigators and approached only those patients they thought would be *good* for the study or would *need* the end-of-life communication intervention. Those clinicians who bought into the potential benefits of the study expressed frustration when patients whom they thought most needed the intervention were determined to be ineligible or were eligible but were randomized to the control group. Periodic re-orientation sessions and on-going dialogues would help participating healthcare providers understand their role in subject identification and recruitment and the purposes of clinical trials.

Limitations of this paper include that the study did not have data to evaluate the effectiveness of the individual recruitment and retention strategies used. Also, there might have been undocumented contacts for recruitment and retention because the analysis was based on those documented in the tracking system and weekly reports.

Conclusion

The strategies and procedures for recruitment and retention employed in this study may be pertinent to many other studies involving African Americans, or both patients and surrogates (or caregivers) participating as dyads, or end-of-life issues. The keys to successful recruitment and retention are to plan carefully from the outset to customize strategies to the target participants, to consider carefully any pilot data that can inform study plans, to work closely with clinic staff, and to be willing to modify plans as the need arises.

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Table 1**Recruitment and Retention Strategies (including data collection)**

	Contact	Patient	Surrogate
1	Initial contact to explain the study and obtain patient's written consent	X (face-to-face)	-
2	Initial contact to obtain surrogate's verbal consent	-	X
3	Contact to schedule or confirm a baseline session	X	X
4	Reminder call for the baseline session	X	X
5	Baseline session for surrogate's written consent data collection, and intervention	X (face-to-face)	X (face-to-face)
6	Contact to schedule a 1-week follow up	X	X
7	Reminder call for 1 week follow up	X	X
8	1 week follow up data collection	X	X
9	1-month check-in call	X	X
10	2-month check-in call	X	X
11	Contact to schedule a 3-month follow up	X	X
12	3-month follow up data collection	X	X