Enhancing Recruitment and Retention in Randomized Clinical Trials of Cancer Symptom Management

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Purpose/Objectives: To describe techniques to overcome challenges of collaborating with multiple clinical sites and participants to enhance recruitment and retention for cancer symptom management randomized clinical trials (RCTs).

Data Sources: Personal experiences and publications related to recruitment and retention of sites and participants in RCTs, which were found by searching MEDLINE®, CINAHL®, and PsycINFO records.

Data Synthesis: Techniques to overcome challenges related to multisite research, patient confidentiality guidelines, and work with an at-risk population were identified and applied successfully in an RCT designed to modify fatigue during and following adjuvant breast cancer chemotherapy.

Conclusions: Successful recruitment and retention depended on the value that site personnel placed on symptom management research, identification of a designated contact person at each site, and flexibility in maintaining communication among the project director, contact individuals, and participants.

Implications for Nursing: Initial and ongoing collaboration with participants and a contact person at each site, assurance of privacy of protected health information, and emotional support are critical to recruitment and retention throughout cancer symptom management RCTs.

Key Points . . .

- Recruiting and retaining multiple sites and participants for cancer symptom management randomized clinical trials (RCTs) require different techniques compared to traditional drug or device trials.
- When recruiting multiple sites and participants to an RCT, the approach should be tailored to each site, and nurses should have close communications with designated contacts and participants in accordance with patient confidentiality guidelines.
- To retain multiple sites and participants in RCTs, nurses should nurture relationships at the sites willing to collaborate and refer patients and be sensitive and flexible about participants' needs throughout the study.
- Conducting a symptom management RCT increases awareness of nursing research by clinical nurses and awareness of the realities of clinical nursing practice by researchers.

Clinical trials testing the efficacy of investigational drugs or regimens or medical devices have dominated oncology research since the "War on Cancer" began in 1971; however, studies about symptoms that accompany drug regimens have not kept pace with more traditional trials (Forcina, 2004). Prior to 1990, studies testing interventions to manage cancer symptoms during and after treatment rarely were conducted. Recently, studies that focus on reducing pain, depression, fatigue and the effect of those symptoms on quality of life for patients with cancer have become more prevalent. Although clinical trials have been conducted at cancer centers, they have not been as accessible at community oncology clinics (Go et al., 2006).

Conducting randomized clinical trials (RCTs) related to symptom management is important because patients with cancer may discontinue treatment as a result of intolerable side effects. Symptom management RCTs are critical in determining the effectiveness of nursing interventions and establishing evidence-based practice guidelines, yet they present unique challenges to researchers. The purpose of this article is to describe techniques to identify and overcome challenges of collaborating with multiple sites and participants to enhance

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recruitment and retention for cancer symptom management RCTs. Information about an RCT designed to modify fatigue during and after adjuvant chemotherapy for breast cancer will be presented first, followed by a discussion of the successful techniques used to overcome challenges in site and participant recruitment and retention. Published articles related to recruitment and retention of sites and subjects in RCTs were found by searching MEDLINE®, CINAHL®, and PsycINFO records. No limits were set on year of publication. The database searches were constructed by combining the search terms adherence, behavior retention and attrition, random, compliance, and patient dropouts. Results of the literature search and the applied techniques are presented to assist researchers conducting cancer symptom management RCTs.

The Fatigue and Breast Cancer (FBC) Study is a five-year RCT (2002–2007) funded by the National Institutes of Health (NIH) and National Institute of Nursing Research ([NINR], 5R01NR007762-05) that accrued 219 women with stage I, II, or IIIA breast cancer after surgery and before adjuvant anthracycline-based chemotherapy. Details of the pilot study with a similar methodology are found elsewhere (Berger et al., 2002, 2003). Potential participants were recruited from two cancer centers and 10 community sites prior to receiving their first dose of chemotherapy, which often is less than a week after a consultation visit with an oncologist. The FBC study had a full-time project director, a full-time research nurse, and a part-time research nurse; thus, a research nurse could not be present in all of the sites where potential participants were identified.

FBC study participants completed paper-and-pencil instruments, wore a wrist actigraph, and scheduled frequent visits with a nurse over one year. Participants continuously wore a Motionlogger™ (Ambulatory Monitoring, Inc., Ardsley, NY) actigraph for seven to nine days during each treatment period and follow-up visit to measure sleep, activity, and circadian rhythms. Hemoglobin and hematocrit values were obtained from medical records. Participants in the experimental arm of the study designed and followed an Individual Sleep Promotion Plan (ISPP), developed by the principle investigator (PI) and the research team, and those in the control arm received equal time and attention and healthy eating information. Accrual to the study began in April 2003, coinciding with the mandated compliance with the Health Insurance Portability and Accountability Act (HIPAA) (Erlen, 2005), and ended in May 2006.

Recruiting Sites for Symptom Management Research

Symptom management clinical trials typically test behavioral interventions and occur outside of established cooperative groups and industry-sponsored pharmaceutical trials. Symptom management behavioral research most commonly is funded as an investigator-initiated NIH study (R01, R03, R15, or R21). A PI must establish relationships with oncologists and nurse managers at each site and gain their support to receive approval from the institutional review board (IRB). A PI typically does not pass NIH funds on to the sites for the time and effort involved in recruiting potential participants for symptom management behavioral studies. The value that site personnel place on symptom management research is a major factor in gaining access to a site.

Clinical researchers have expressed concern about the effects of HIPAA legislation on recruitment, data access, and data acquisition (Ness, 2005). Variability in interpretations of HIPAA guidelines that protect individuals' rights and control use and disclosure of health information can be challenging for researchers. Flexibility in problem solving is imperative to determine the most efficient and effective method within HIPAA guidelines to work with each site.

Identifying and building collaborative relationships with designated contacts at sites where researchers do not have direct patient access can have positive results in obtaining permission from patients to be contacted by a research team (Butterfield, Yates, Rogers, & Healow, 2003; Motzer, Moseley, & Lewis, 1997; Neumark, Stommel, Given, & Given, 2001). In the FBC study, RNs, office technicians, or receptionists at each site who expressed genuine interest in helping with the research study were identified and designated as contacts. The recruitment method was described prior to HIPAA enactment but became more essential in the post-HIPAA research era. A designated contact person, also labeled an intermediary by Eaves (1999), requests and obtains permission for contact from potential participants and communicates that information to a research team. The infrastructure is critically important to optimize communication when recruiting at multiple sites.

Several techniques were used to overcome recruitment challenges in the FBC study, including providing ongoing education about the value of symptom management behavioral trials through formal and informal presentations and professional education meetings. In addition, strategies were pursued to identify ways to conduct the study with minimal disruption to the clinics' daily routines, develop procedures for the project director to use in explaining the study to potential participants, and establish procedures to ensure compliance with each site's interpretation of the HIPAA privacy rule. Although the intent was to include all local sites, identifying techniques to overcome challenges at every site was not always possible; therefore, the FBC clinical trial was not available to every eligible participant in the area.

Recruiting Participants for Symptom Management Research

Recruiting participants to any research study can be challenging in an oncology clinical site where the priority function is patient care delivery. Sites typically hire clinical trial nurses whose primary role is to identify and enroll eligible patients in cooperative group trials. When a study focuses on the symptom of fatigue, rather than on breast cancer treatment, it may not be valued as a high priority despite fatigue being the most frequent and distressing symptom affecting quality of life in patients receiving chemotherapy.

HIPAA regulations stipulate that within the informed consent document, patients must be informed fully about the use of the data that will be collected and who will have access to it (Pace, Staton, & Holcomb, 2005). HIPAA regulations prohibit researchers from performing run-in tests (i.e., practicing a study before consent and randomization occur). All participants are required to sign the consent form and be randomized prior to participation.

Many other factors are associated with patients' choosing to participate. Fear of breach of privacy or suspicion regarding research itself may impede authorization. Conversely, a

tendency toward altruism and contributing to research that may help others might enhance willingness to release information (DiMattio, 2001). Patients with cancer have been found to be most likely to enter a trial for personal benefit, support, and the sake of future patients (Wright et al., 2004).

The context in which a request to participate is made and the mode of initial contact are relevant to patients' decisions to enroll in a study (Eaves, 1999). Anticipating a patient's emotional state when he or she is invited to participate in a study is difficult. Fears of chemotherapy and a pervasive feeling of loss of control frequently are identified by patients with cancer when they first visit a medical oncology clinic and make decisions about treatment (Petersen et al., 2003). Emphasizing that cancer treatment is not compromised by participation in a symptom management behavioral study is imperative (Connolly, Schneider, & Hill, 2004). Patients may be approached to participate in other clinical trials testing drugs or devices at the same time. Feeling overwhelmed is a common reaction; yet the time to obtain consent is limited.

Several techniques were used successfully in the FBC study to address participant recruitment challenges and enhance accrual for the study. The contact person at each site worked with the project director to identify a preferred technique for timely communication after obtaining permission from potential participants. When a contact person obtained permission from a potential participant to be contacted, she was trained to inform the project director as soon as possible. Using pagers and talking via phone proved to be more successful than sending facsimiles or e-mails or leaving phone messages. Timing was important because the study design stipulated that the initial visit with the research nurse and start of data collection needed to occur at least two days prior to the first treatment.

Once permission to access protected health information was obtained, the project director screened potential participants to determine eligibility and then introduced the study. She was aware that the period between the initial visit and first treatment is a highly distressing and vulnerable time for patients. A specific challenge in the FBC study was that potential participants were invited to participate in a trial addressing chemotherapy-related fatigue before experiencing the symptom. When talking with potential participants, the project director focused on the significance of learning to manage fatigue during cancer chemotherapy and on the nursing support that was provided in the study.

Recruitment strategies were individualized based on sensitivity to cues from patients. The project director learned to assess a potential patient's likelihood to consent by listening for red-flag responses (e.g., "I don't like forms," "I just can't handle another thing") or green-flag remarks (e.g., "I want to do anything to help," "that sounds interesting"). Patients were encouraged to become more informed by visiting the study Web site (http://www.unmc.edu/nursing/grant_fatigue/fatigue_home.htm) and then make a voluntary decision regarding participation. Each patient was given adequate time to read the consent form and have questions answered.

A technique that was not successful was the distribution of flyers at the clinics and area businesses frequented by newly diagnosed patients (e.g., wig shops) because patients were required to make first contact with the research team. Another challenge that arose was when a clinical trial nurse presented the FBC study to a potential participant. The presentation of a symptom management study at the same time as a cooperative group treatment trial without partnership with a nurse scientist can create a conflict of interest and result in lower recruitment to a symptom management study.

The ambitious goal of the FBC study was to recruit 6–10 new participants per month. Using a variety of techniques, five to six new participants were accrued each month for a total of 219 during the 38 months of accrual (see Table 1).

Retaining Sites in a Five-Year Symptom Management Study

Retaining sites over the course of a five-year study can be very challenging. Nurturing positive relationships with designated contacts and other site personnel is imperative. The level of enthusiasm and cooperation with the study by site personnel directly affects access to and retention of participants. A PI and project director need to anticipate changes in personnel and wavering interest that may occur over time; thus, the research team must work with contacts and site personnel to generate and maintain excitement for the study.

In striving to effectively and efficiently use resources over the course of a five-year study, prioritizing where to invest time and energy is important. Sustaining relationships with personnel at multiple sites can be a daunting challenge for a PI and project director. Maintaining current IRB approval at low-enrollment sites is time consuming with limited returns. Collaboration with sites needs to be reviewed annually. Although retaining sites where patients from ethnic and minority groups seek care may be useful, retaining other sites that have not referred potential participants may not be necessary. A PI must carefully weigh the risks and benefits of meeting with site personnel who do not demonstrate support for a symptom management study.

The implications of study procedures need to be reviewed carefully prior to designing symptom management behavioral

Table 1. Recruitment and Retention Statistics

Dates	Consenting Patients	Medical Withdrawals[a]	Self-Withdrawals[b]	Attrition Rate (%)
4/1/03–3/31/04	59	7	5	8.5
4/1/04–3/31/05	69	2	11	15.9
4/1/05–5/31/06	78	1	8	10.3
4/1/06–1/31/07	13	1	2	15.4
Total	219	11	26	11.9

[a] Includes those withdrawn by study personnel because of changes in treatment plan

[b] Includes those initiated by participants

studies. A PI must consider whether to attempt to influence an oncologist's practice patterns, such as requesting that chemotherapy treatments be scheduled with adequate time for the researcher to collect data for two days prior to the first treatment.

The regulatory effects of HIPAA also influence site retention. Privacy of protected health data remains a high priority when accessing participants' information and records for laboratory results during study involvement. Researchers must ensure continuing protection of patients' privacy when obtaining information contained in their records. Site personnel and the research team should reach decisions that are mutually agreeable. Flexibility was vital in the FBC study when negotiating procedures for collecting laboratory values from patient records at each site in the post-HIPAA environment. In some cases, only a designated contact person was allowed access to records; at other sites, research team members were able to access the information directly.

"Work with the workable" was a theme in guiding decisions about retaining sites in the FBC study. Four clinics yielded more than 75% of the enrolled participants, whereas the remaining eight clinics referred less than 25% of the sample. The project director consequently spent the majority of her time promoting the study in the four active sites. Personnel at the sites demonstrated support for the study, conducted research consistent with HIPAA rules without imposing additional barriers, and willingly identified a designated contact person to assist the project director in identifying potential participants.

The most important lesson learned to maintain enthusiasm for the FBC study was for the project director to regularly visit designated contacts and nursing and support staff. A newsletter was shared that reported each quarter's accrual and the total number of participants recruited from each site. The newsletter was informative and created competitive excitement among the sites. A drawing was held and token prizes awarded each quarter to a contact person who referred potential participant names and contact information to the project director. Using a logo (see Figure 1) to represent the study in all communication and presentations also helped sites recognize the continuing presence of the study (Ott, Twiss, Waltman, Gross, & Lindsey, 2006). These and other techniques that were used by the FBC study to retain sites appear in Table 2.

Retaining Participants for a One-Year Study

Retaining participants for a one-year study depends on several factors. Repetitive data collection and contact with staff who are perceived as poorly trained are factors that have hindered retention in longitudinal clinical trials (Davis, Broome, & Cox, 2002; Eaves, 1999). Establishing frequent and consistent communication between participants and the well-trained research team through telephone contact, e-mail, and home visits is important. Willingness to take part in a study may depend on the amount of time involved and the ease of following the protocol (Motzer et al., 1997; Neumark et al., 2001). Many authors offer retention techniques that can be incorporated into RCTs (e.g., Coday et al., 2005; Davis et al.; Sterling & Peterson, 2005).

Treatment fidelity is important to study reliability. The treatment needs to be given as intended, which can be monitored by evaluation of the design, training, and delivery of the intervention (Resnick et al., 2005). Difficulty in adhering to a behavioral protocol may entice participants to withdraw. Dropouts occur when participants perceive that their time and effort are exceeding benefits, particularly when interventions are too complicated and different from normal routines (Fogg & Gross, 2000; Pruitt & Privette, 2001). Compared to studies in which interventions are relatively inflexible, behavioral interventions are perceived as nonprescriptive and negotiable, which improves retention (John & Ziebland, 2004).

Figure 1. Fatigue in Breast Cancer Study Logo

Initially, an ambitious attrition rate of 10% per year was estimated for participation in the FBC study; however, during the first 38 months of data collection, the cumulative withdrawal rate was 12% (27 of 219). An additional 11 participants consented but were withdrawn from the study when changes in their medical treatment plans made them ineligible. The research team remained sensitive when interacting with an at-risk population, who experience higher-than-usual stress, as evidenced by the relatively low withdrawal rate. In the early phase of the FBC study, considerable time was spent with skills training and team-building activities that capitalized on each team member's strengths and contributed to the retention of all original research team members and a stable participant retention rate.

A tracking system to record withdrawals was helpful in identifying reasons for discontinuing participation and in developing techniques to overcome issues. During the week after the first chemotherapy treatment, the majority of self-withdrawals (19 of 26, 73%) occurred when participants reported feeling very overwhelmed by numerous life events and symptoms. Lower attrition occurred after participants completed their first chemotherapy cycle and became familiar with the study requirements and research nurse. In future research studies, procedures will be designed to lower participant requirements at the first data collection time or recruit prior to the second treatment.

Many techniques were used to increase participant retention, which are included in Table 2. The study provided a $20 stipend to compensate for the time and effort in completing instruments and wearing the actigraph. The team made home visits to eliminate transportation or caregiving issues and offered flexibility when scheduling appointments. Information about healthy eating was given to pique the interest of participants in the control group at each visit. The time and

Table 2. Comparison of Strategies to Increase Retention

Strategy	Davis et al. (2002)	Coday et al. (2005)	Fatigue in Breast Cancer Study
Establish a study identity.	Established a project identity	Used study logos on incentives and small tokens of appreciation	Created Health Insurance Portability and Accountability Act (HIPAA) regulated flyers, logo, quarterly newsletter, Web site, business cards, and actigraphs
Emphasize the benefits of participation.	Emphasized the significance of the study	Emphasized the benefits of participation	Emphasized fatigue management and nursing support
Minimize the burden for participants.	Performed a run-in test	Minimized the burden and gave control to patients	Eliminated a run-in test because HIPAA regulations require all participants to sign the consent and be randomized
Provide incentives.	Provided incentives and travel tokens	Provided incentives or small tokens of appreciation	Paid participants a $20 stipend and gave tokens each time; provided incentives for a designated contact person, nursing support, and home visits
Retain a control group.	Offered an appealing control group	Gave instrumental or tangible support	Shared healthy eating information and offered the intervention at the end of the study
Retain project staff and participants.	Performed skills training	Were patient yet persistent	Performed skills training and role play to retain staff and offered initial and ongoing team-building activities
Offer support.	Made between-assessment contact	Enlisted support from others and provided support	Sent greeting cards and made phone calls
Be flexible.	Individualized data collection	Were flexible with patients	Were flexible regarding wearing the actigraph after the first treatment; offered more assistance in completing forms
Maintain tracking systems.	Used a participant tracking database	Maintained a participant tracking system	Maintained several methods for tracking participants, such as log books and data files with addresses, phone numbers, and e-mail addresses

attention from a nurse become invaluable as treatment effects are experienced and can lead to lower withdrawal rates. When participants experienced debilitating symptoms, the team encouraged and reminded them of their value to the study. Cards were sent for special occasions or difficult times, and token gifts were obtained from pharmaceutical representatives, such as lip moisturizer and antibacterial hand and skin cleanser, were given at each visit. The number and length of instruments were kept to a minimum at the first data collection time to avoid participant fatigue and stress. Less than 30 minutes was needed to complete the research instruments at later times.

The research team allowed shared decision making with participants when possible. Participants often indicated that the actigraphs were cumbersome and irritating and viewed them as a negative aspect of the study. The research team negotiated the complaints by allowing flexibility in wearing time, offering skin-protecting sweatbands, and allowing participants to continue in the study without wearing the actigraph if they were unwilling to wear it after the first nine days. When participants experienced difficulty adhering to the ISPP intervention, the team discussed the case at a team meeting and sought advice from a behavioral sleep psychologist coinvestigator in regard to revising the ISPP while maintaining the integrity of the study protocol. For example, one participant was permitted to modify the time for going to bed at night and getting up in the morning.

Summary

Although site and participant recruitment and retention have always been challenging components of conducting clinical trials, they can be more difficult when testing behavioral interventions to modify cancer-related symptoms such as fatigue. The current clinical research environmental culture is less familiar with cancer symptom management RCTs than with traditional drug and device trials. Conducting a symptom management RCT increases clinical nurse awareness of nursing research and researcher awareness of the realities of clinical nursing practice. The most successful techniques to overcome the challenges focus on the value of testing symptom management behavioral interventions, the need for a designated contact person at each site, the assurance of privacy of protected health information, and the value of nursing support throughout the study.

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