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Successful recruitment methods in the community for a two-site clinical trial

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ABSTRACT

Effective screening and recruitment are essential to the success of randomized clinical trials. This report is to describe key screening and recruitment strategies in a two site randomized clinical trial (RCT) conducted in community settings with a vulnerable chronically ill population and to suggest valuable approaches when planning trials. Differences between sites in a complex study with two considerably different environments (academic versus home care) and their participant pools presented challenges which required different screening and recruitment methods. A high level of communication between sites, creative problem solving and the ability to be flexible when problems were encountered were needed for successful screening and recruitment.

1. Introduction

Most recruitment for research is not easy, and conducting a study in multiple sites further complicates the usual challenges. The purpose of this report is to describe how the different needs in screening and recruitment in two sites required modifications in approach and to suggest methods which might be valuable to others planning trials.

1.1. Background

Recruitment issues are dependent on the nature of the research and the needs and characteristics of study participants. Flexibility and adaptation to recruitment issues that arise are the keys to success (McCormick et al., 1999). Barriers to successful recruitment can involve patients, providers, and system level issues (Payne & Hendrix, 2010). For instance, patients do not always know enough about research and thus need information for informed choices about participation, particularly when a trial is lengthy, when physical limitations make participation difficult (Ackerman, Buchbinder, & Osborne, 2012) or when the intervention assignment is favored by patients (Jones & Reiner, 2010). Providing detailed information through screening scripts or presentations is essential so that patients can get consistent and accurate information prior to deciding about participation, particularly when randomization to a control group is a possibility. In one study with a favored treatment for fibromyalgia, the drop-out rate was 7% after group presentations about the study, which allowed for attrition prior to enrollment (Jones & Reiner, 2010). Research is plentiful about barriers in obtaining primary care providers' support for community-based research, such as a lack of time, limited research staff and/or research training concerns about the consent process, (Asch, Connor, Hamilton, & Fox, 2000; Jowett, Macleod, Wilson, & Hobbs, 2000; Ross et al., 1999). Likewise, it can be a challenge to engage providers to participate in practice based research unless they can see the value of a new approach to caring for their patients (Ellis et al., 2007; Herber, Schnepp, & Rieger, 2009).

Systems issues, such as the need of study participants to repeatedly return to a clinic or lack of institutional support and resources, are harder to address. With knowledge of these issues and careful planning, even these can be overcome. For example, in a study recruiting adults with cancer, adaptations were made so that the data collection and intervention components could be conducted in the study participants' homes since mobility was an issue for many in this patient population (Payne & Hendrix, 2010).

Multiple step recruitment is a strategy for enrolling certain populations who are not easily included in research. In one study, this involved database preliminary screening, letters, phone call screening, invitational letters, and group information sessions (Jones & Reiner, 2010). However, databases are not always able to identify the eligible persons for research, and complementary sources are needed (Lock et al., 2012; Potter et al., 2011).

Theoretical approaches are also used to broaden and strengthen strategies. For example, specific strategies were chosen for

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recruitment and tracking retention in a study on preventing weight gain in African American girls (Stockton, McClanahan, Lanctot, Klesges, & Beech, 2012). Likewise, Gemmill, Williams, Cooke, and Grant (2010) used Swanson's caring theory to shape their approaches for caring encounters which were used in recruitment of a vulnerable population undergoing cell transplants.

In summary, common barriers to research recruitment involve patients, providers, and system level issues. Multiple step and theoretically based approaches are developing to address the complexity in clinical trials, particularly in multi-site studies. In this report we address our challenges related mostly to providers and system level issues: in one site how we addressed providers helping with recruitment and in the other site how we overcame the limits of our database recruitment and better engaged potential study participants.

2. Overview of study

The randomized clinical trial was a test of a new self-management intervention for persons with long-term indwelling urinary catheters based on a pilot study of self-monitoring of urine flow in a similar population (Wilde & Brasch, 2008a, 2008b; Wilde & Dougherty, 2006). The study took place from 2008–2012 with a sample of 202 persons (103 males, 99 females), with equal numbers in the experimental and control groups. Participation lasted 12 months for each person in the study with 74% completing the study. The information for this report is based on the detailed minutes from 163 team meetings and recruitment reports, as well as personal recollections. A full description of the sample at the beginning of the study has been published (Wilde et al., 2013), and the analysis of major outcomes are underway and will be described elsewhere.

2.1. Participating sites

The study was conducted in two sites in one state in the northeast USA in: 1) a university medical center in a medium sized city and 2) a large home care agency (HCA) in a very large eastern metropolitan area. The university site sought participants not only from its urban location but also from 33 adjacent suburban and rural communities. The home care agency, which is a well-established not-for-profit organization with a research division, recruited from their patients in their geographical service region.

2.2. Study participant enrollment criteria

Study participant enrollment criteria included: 1) 18 years and older; 2) expected use of an indwelling urethral and/or suprapubic catheter for at least 1 year; 3) ability to communicate in English; 4) ability to self-complete the study measurements or with the help of a care-giver; 5) have telephone access; and 6) be in the area and available for home visits for 4 months after enrollment. Those with known cognitive impairments or terminal illnesses were excluded, as were those without a urinary tract infection (UTI) within the past year or catheter dislodgements or blockages within the previous 6 months. However, patients who had a catheter for less than 1 year were eligible even without an adverse event, as they would be likely to experience problems in the future and could learn a great deal from the intervention.

3. Screening and recruitment

3.1. Approach at the university site

Six local home care agency administrators initially agreed to assist with recruitment of known indwelling catheter users in their patient population and distributed a Research Subjects Review Board (RSRB) approved recruitment letter. Interested potential study participants either: 1) gave permission to the agency to release their contact information to researchers, who in turn called the potential participants with more study information, or 2) initiated the contact by calling the researchers directly at the study phone number. When recruitment through home care agencies failed to result in sufficient participants, additional recruitment approaches were developed. Each week, the principal investigator (PI) and project coordinator (PC) met for about a half hour to assess recruitment and to strategize about other approaches.

In consultation with the university's IRB and an administrator at a home care agency who had collaborated with the PI on a previous catheter study, 10 people from this agency who had granted permission to be contacted for future studies were approached, and six of them were interested in discussing the study. Other university site recruitment strategies included: registration on Research Match (a U.S. federal government sponsored site), development of a study Website that was linked to other Websites serving people with spinal cord injury or multiple sclerosis, advertisements in local print media, a large scale recruitment email distributed through the U.S. Paralyzed Veterans Association, recruitment through area Veteran Administration hospitals, and networking with community social workers and Wound, Ostomy, and Continence Nurses (WOCNs). An additional recruitment strategy involved a sizable mailing of provider oriented recruitment letters and follow up phone calls to urologists and other specialty medical practices in the recruitment area.

Despite the multiple approaches to recruitment at the university site, many were not successful (see Table 1). One large home care organization, which seemed very interested initially in the study, provided only one referral, and later did not return researchers' phone calls or emails. After it became clear that home care agencies' referrals were not providing the number of participants originally anticipated, one-to-one personal networking was used with several key personnel in clinics and urology practices. This was a moderately successful strategy, and these key personnel ultimately became the “champions” of our recruitment, making a personal effort to refer prospective participants. Other than the home care agency referrals ($n = 23$), the majority of direct referrals ($n = 12$) came from nurses or nurse practitioners who were working primarily in academic-based specialty clinics or urology practices Some physicians who were contacted by the urologist on the study team did make a few referrals, but these did not yield eligible study participants.

At the university site, the eligibility rate was high, and the refusal rate was very low since referrals came directly from providers who knew their patients with indwelling catheters well and rarely referred people who would have been excluded (Table 2). Only 7 people declined to participate when contacted.

Table 1
Recruitment strategies-university site.

Types of recruitment	Number approached	Number of contacts	Number of referrals
Catheter suppliers	3	11	0
Community print media	3	9	0
Community social workers	5	19	0
Clinics/Organizations-disease specific	11	32	2
Home care agencies	9	81	23
Study Website	4	4	0
Urology/Rehab clinics & organizations	9	38	12
VA sites	3	38	0
WOCN referrals	4	67	0
Friends discussed study & self-referred	NA	5	5
Permission to be contacted related to being in a previous catheter study	NA	10	6
Unknown source	NA	2	2