Published in final edited form as:

Appl Nurs Res. 2014 November ; 27(4): 254–257. doi:10.1016/j.apnr.2014.04.002.

Successful Recruitment Methods in the Community for a Two-Site Clinical Trial

Eileen Fairbanks, RN, MS, PNP¹, Shivani Shah, MPH², Mary H. Wilde, RN, PhD¹, Margaret V. McDonald, MSW², Judith Brasch, RN, MS¹, and James M. McMahon, PhD¹

¹University of Rochester, School of Nursing

²Visiting Nurse Service of New York, Center for Home Care Policy and Research

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.

Keywords

Patient selection; methods; urinary catheterization; clinical nursing research

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 adapting 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

© 2014 Elsevier Inc. All rights reserved.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

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, Schnepf, & 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 recruitment and tracking retention in a study on preventing weight gain in African American girls (Stockton, McClanahan, Lanctot, Klesges, & Beech, 2012). Likewise, Gemmill and colleagues (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 & Dougherty, 2006; Wilde & Brasch, 2008; Wilde

& Brasch, 2008). 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 one 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 four 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 six months. However, patients who had a catheter for less than one 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 or two 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 were contacted 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.

3.2 Approach in large home care agency (HCA)

Recruitment efforts at the agency began after Institutional Review Board approval and the granting of a Waiver of Authorization (HIPAA) to the HCA study team which allowed the agency-employed researchers to identify potentially eligible participants by searching the organization's electronic health records. An electronic algorithm was used to search item M0520 (Urinary Incontinence or Urinary Catheter Presence) on the mainframe information database from the Outcomes Assessment and Information Set (OASIS), a U.S. nationally mandated home care form collected as part of usual care. Those who answered yes to the item *requires a urinary catheter* (i.e. external, indwelling, intermittent, suprapubic) initially qualified. Patients were excluded if their assessment data indicated they had significant cognitive impairment or met one of the other exclusion criteria. A list of catheter users was generated based on this search process and refreshed every week. The HCA site recruited from their patient rosters in their close geographical area, and later expanded to include a wider region with their patients.

The HCA list of contact information for current and past patients was used for placing initial "cold" screening and recruiting phone calls. Trained field interviewers, with varied

backgrounds (e.g., public health, psychology) made initial contact with the potential participant, described the study, and screened for eligibility if the person expressed interest.

In order to contact those on the list who were not being reached by phone, a letter was mailed describing the study and including the number to call if interested, but this was unsuccessful. As another HCA recruitment strategy, an approved study flier was distributed to the agency WOCNs, requesting them to contact the project coordinator with information on possible eligible participants on their patient rosters. This flier was successful in the identification of 15 potential participants.

One primary screening and recruitment issue at the HCA centered on the fact that the OASIS database information search was based on standardized codes. These codes could successfully identify catheter users, but unfortunately they could not be specifically limited to those with indwelling long-term catheters, including in addition those with short term, intermittent, or condom (external) catheters. This resulted in much larger numbers of ineligible persons than expected. Interviewers ultimately made three times the originally projected number of phone calls in order to identify sufficient numbers of long-term catheter users (see Table 2). Because the HCA participants came exclusively from a home care population who are generally in poorer health and have more chronic conditions, the refusal rate at this site was higher.

Another main issue was the use of interviewers with various professional backgrounds to complete the screening process. The study eligibility was clinically complex and it was ultimately determined that a nurse would be able to more smoothly move patients through the screening and recruitment process. Therefore, in the last 11 months of the recruitment when enrollment was lagging, the HCA intervention nurse began reviewing clinical charts of potential participants to get more information about eligibility and joined the interviewers in making screening and recruitment calls. Once recruited, the nurse transferred the case back to the next available interviewer to schedule the in-home enrollment visit. For any clinically complex study, changes might need to be made to match the skills of recruiters to better recruit a specific study population.

3.3 Additional approaches at both sites

At both sites, return calls were made if a potential participant requested time to decide about participation or if it was not yet known whether a catheter placement was short-term or long-term. This strategy was useful in individual cases.

To maximize success with enrollment, we allotted time during each team conference call to discuss recruitment problems and approaches, and in addition we held a special team conference call to focus solely on recruitment when enrollment had become sluggish. This resulted in new and successful strategies. Meeting with a recruitment consultant helped us identify ways to be more successful in recruitment, such as reestablishing relationships with those who had helped us successfully recruit in the past. Building upon these previous relationships and nurturing new ones resulted in engaging the community champions who ultimately were very valuable to our recruitment. Distributing monthly recruitment reports helped us identify the trends and patterns, as is commonly done in multi-site trials (Kutner et

al., 2010), and although it was somewhat disheartening to see when either or both teams were falling behind in recruitment, it was a valuable reality check that helped keep us focused on the task of obtaining the sample. Often the team would demonstrate renewed vigor and determination after viewing disappointing numbers, leading to a subsequent surge in the recruitment totals. With 202 persons with long-term catheters recruited, we were satisfied with obtaining close to our original sample goal of 220, which gave us the statistical power to evaluate our primary outcomes. Overall, we believe that routine evaluation of progress in recruitment and the flexibility to adjust the original plan is essential in reaching recruitment goals.

4. Discussion

The University site was dependent upon direct referrals from providers for participant recruitment. This worked relatively well with nurses in home care organizations, but not as well with physicians. Physician-to-physician recruitment has been examined and shown to be the most effective method of engaging community physicians in the research which involves their office staff or themselves (Asch et al., 2000). However, we found, that as nurse researchers, it was difficult to obtain access to discuss recruitment with physicians due to the routine “gatekeeping” by office staff. Heber, Schnepp, & Rieger (Herber et al., 2009) reported that when the research recruiter is a non-physician, access to the physician is generally denied.

The development of “friendship networks” formed during the course of the University site’s recruitment efforts yielded good results in recruitment. The nurse researchers at this site, who were being routinely denied access to physicians, eventually developed personal relationships with nurse providers as a result of their on-site visits and frequent phone calls and emails.

Multistep recruitment at the HCA--using direct contact of the WOC nurses with patients they knew or letters from the study staff--yielded only a few recruits. One of the key insights, based on our experience at the HCA site, was that a nurse might have better success than a trained interviewer with screening and recruiting patients in a timely manner when the study eligibility is clinically complex and when the database searching cannot sufficiently sort out eligibility (Potter et al., 2011). Home care nurses, in particular, routinely assess their patient’s condition by phone in order to make a decision about the need for home visits or other assistance. We also concluded that well trained interviewers, with access to medical records in home care or clinics, can also determine eligibility better than using “cold calls.” No matter what setting, a successful recruiter for a clinically complex study will need to possess superior interpersonal skills as well as expert clinical knowledge.

5. Conclusion and recommendations

In our study, flexibility and modifications in the initial approaches made it possible to achieve the large sample in a community population of chronically ill persons. Although for different reasons, both sites needed more time for recruitment than anticipated. Additional time for screening and recruitment should be built into proposals when recruiting across

sites, particularly when the site type differs, as well as time for interdisciplinary teamwork (Bindler, Richardson, Daratha, & Wordell, 2012).

Databases which could be useful in aiding recruitment might vary in different parts of the world. The OASIS database, used by U.S. home care agencies, proved to be a major barrier to recruitment of long-term catheter users, slowing down research in this vulnerable population and contributing to excessive personnel costs. In the particular case of this research, determining whether a long-term catheter was in place (likely to be used permanently) was a key issue in identifying potential participants, and the database was not able to differentiate this population.

We suggest that when feasible, alternative or supplemental recruitment methods be developed and piloted to test the best ways to identify and recruit for the study. Recruiting individuals who are not easy to identify is a major challenge, and we suggest two strategies which worked well for us: 1) collaborating with “champions” who have demonstrated interest and support for the study and 2) enlisting the skills of a clinically oriented person for recruiting in studies with clinically complex eligibility.

Although we used multiple approaches and expanded our recruitment strategies over time, we had not considered using a theoretical or stepwise approach to plan recruitment, and it might have helped us recruit more quickly. Also a brainstorming session and a consultation with an expert in the field probably could have been undertaken at the beginning of the trial instead of when we began to run into difficulties.

The assumption that a consistent recruitment protocol will work well for all sites in a multi-site study is a barrier to effective recruitment. A proactive assessment of site differences and the development of a recruitment protocol with enough flexibility to allow for customization per site can lead to recruitment success. Our descriptions of how we handled recruitment provide useful examples of “how to” make recruitment work well between different types of sites, which can be implemented by other researchers. With vastly different research sites, dissimilar acuity levels in prospective participant bases, and teams with varied professional backgrounds, we were able to capitalize on each other’s strengths and adjust recruitment strategies to achieve our sample goal.

Acknowledgments

The authors wish to thank team members who contributed their substantial efforts toward successful study recruitment: Yessica Terrero, Laura Edilitz, Paula Wilson, Manny Schwimmer, and Maria Viterbo-Verna. In addition, we are grateful to the information technology recruitment assistance provided by Sridevi Sridharan, Timothy Peng, and Richard Dumpson.

We would particularly like to thank Margaret Kearney, RN, PhD, FAAN for her generous and thoughtful review of this manuscript and her valuable suggestions.

Funding: National Institute of Nursing Research, National Institutes of Health (U.S.) #R01 NR01553 (MHW, PI; JMM, Co-I).

References

- Ackerman, IN.; Buchbinder, R.; Osborne, RH. Factors limiting participation in arthritis self-management programmes: An exploration of barriers and patient preferences within a randomized controlled trial. *Rheumatology*. 2012. www.rheumatology.oxfordjournals.org
- Asch S, Connor SE, Hamilton EG, Fox SA. Problems in recruiting community-based physicians for health services research. *Journal of General Internal Medicine*. 2000; 15(8):591–599. [PubMed: 10940152]
- Bindler RC, Richardson B, Daratha K, Wordell D. Interdisciplinary health science research collaboration: Strengths, challenges, and case example. *Applied Nursing Research*. 2012; 25(2):95–100. [PubMed: 20974103]
- Ellis SD, Bertoni AG, Bonds DE, Clinch CR, Balasubramanyam A, Blackwell C, Goff DC. Value of recruitment strategies used in a primary care practice-based trial. *Contemporary Clinical Trials*. 2007; 28(3):258–267. [PubMed: 17030154]
- Gemmill R, Williams AC, Cooke L, Grant M. Challenges and strategies for recruitment and retention of vulnerable research participants: Promoting the benefits of participation. *Applied Nursing Research*. 2010; 25:101–107. [PubMed: 20974092]
- Herber OR, Schnepf W, Rieger MA. Recruitment rates and reasons for community physicians' non-participation in an interdisciplinary intervention study on leg ulceration. *BMC Medical Research Methodology*. 2009; 9(1):61.10.1186/1471-2288-9-61 [PubMed: 19682354]
- Jones KD, Reiner AC. A multistep recruitment strategy to a participant-intensive clinical trial. *Applied Nursing Research*. 2010; 23(4):227–232. [PubMed: 21035033]
- Jowett S, Macleod J, Wilson S, Hobbs F. Research in primary care: Extent of involvement and perceived determinants among practitioners from one English region. *The British Journal of General Practice*. 2000; 50(454):387. [PubMed: 10897537]
- Kutner J, Smith M, Mellis K, Felton S, Yamashita T, Corbin L. Methodological challenges in conducting a multi-site randomized clinical trial of massage therapy in hospice. *Journal of Palliative Medicine*. 2010; 13(6):739–744. [PubMed: 20597707]
- Lock J, Brandt H, Woodside B, Agras S, Halmi WK, Johnson C, Wilfley D. Challenges in conducting a multi-site randomized clinical trial comparing treatments for adolescent anorexia nervosa. *International Journal of Eating Disorders*. 2012; 45(2):202–213. [PubMed: 21495052]
- McCormick LK, Crawford M, Anderson RH, Gittelsohn J, Kingsley B, Upson D. Recruiting adolescents into qualitative tobacco research studies: Experiences and lessons learned. *Journal of School Health*. 1999; 69(3):95–99. [PubMed: 10332644]
- Payne JK, Hendrix CC. Clinical trial recruitment challenges with older adults with cancer. *Applied Nursing Research*. 2010; 23(4):233–237. [PubMed: 21035034]
- Potter JS, Donovan DM, Weiss RD, Gardin J, Lindblad R, Wakim P, Dodd D. Site selection in community-based clinical trials for substance use disorders: Strategies for effective site selection. *The American Journal of Drug and Alcohol Abuse*. 2011; 37(5):400–407. [PubMed: 21854283]
- Ross S, Grant A, Counsell C, Gillespie W, Russell I, Prescott R. Barriers to participation in randomised controlled trials: A systematic review. *Journal of Clinical Epidemiology*. 1999; 52(12):1143–1156. [PubMed: 10580777]
- Stockton MB, McClanahan BS, Lanctot JQ, Klesges RC, Beech BM. Identification of facilitators and barriers to participation in weight gain prevention research by African American girls. *Contemporary Clinical Trials*. 2012; 33(1):38–45. [PubMed: 21924381]
- Wilde MH, McDonald MV, Brasch J, McMahon JM, Fairbanks E, Shah S, Scheid E. Long-term urinary catheter users' self-care practices and problems. *Journal of Clinical Nursing*. 2013; 22(3–4):356–367. [PubMed: 23301577]
- Wilde MH, Brasch J. Teaching self-management to long-term urinary catheter users. *International Journal of Urological Nursing*. 2008; 2(2):62–71.
- Wilde MH, Dougherty MC. Awareness of urine flow in people with long-term urinary catheters. Commentary by B. Roe. *Journal of Wound, Ostomy, and Continence Nursing*. 2006; 33:164–75.
- Wilde MH, Brasch J. Self-monitoring of urine flow in people with long-term urinary catheters. *Research in Nursing and Health*. 2008; 31(5):490–500. [PubMed: 18418847]

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

Table 2

Screening Contacts Both Sites

Types of Contacts	HCA	University	Total
Screened:	1886	68	1954
Eligible and enrolled:	152	50	202
Ineligible:	1246	11	1257
No longer using catheter	268	0	268
Uses intermittent catheter	189	2	191
Uses urinary diversion catheter	159	1	160
Uses condom catheter	80	1	81
Expects to use catheter for <12 months	71	1	72
No primary catheter problems in last 12 months	68	5	73
No one to help record information	3	0	3
Will not have a phone available	2	0	2
Will not be available for home visits	4	1	4
Deceased	164	0	164
Hospitalized past recruitment window	12	0	12
In a nursing home/assisted living/hospice	17	0	17
Moved out of catchment area	33	0	33
Language difficulties	78	0	78
Hearing difficulties	45	0	45
Cognitive impairment per phone	53	0	53
Unable to reach:	216	0	216
No answer to phone	97	0	97
Phone disconnected/wrong number	119	0	119
Refused:	272	7	279
Not interested (patient)	140	3	143
Health reasons (patient)	80	1	81
By proxy (any reason)	50	3	53
Refused at home – any reason	2	0	2