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Recruitment and Retention for Pelvic Floor Disorders Clinical Trials

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Abstract

Objective—Utilize focus group methodology to gather information about women’s knowledge and attitudes regarding research participation.

Methods—Two in-person focus groups at 7 clinical sites were conducted, one composed of women with pelvic floor disorder (PFD) clinical trial study-experience; the other was composed of PFD clinical trial study-naïve participants. One web-based focus group that combined groups was also conducted.

Results—105 women (average age 58.6 years) participated. Participants in both groups believed that their physicians were the best source of information about clinical trials, yet felt that other sources of trial information were important. Financial compensation was not a primary motivating factor for PFD trial enrollment, however was cited as an important consideration. Internet-collection of data was feasible and provided information comparable to in-person focus groups.

Conclusions—This study identified central themes guiding successful recruitment to and retention in PFD-related trials providing insight regarding strategies that may guide future trials.

Keywords

Research; Focus Group; Web focus group; Pelvic Floor Disorders; Incentives

Introduction

Pelvic floor disorders (PFD) have a significant impact on women’s quality of life and on the health care system because of the large number of affected women and the costs associated with the diagnosis and management of these disorders. Luber et al estimated that over the next thirty years, the demand for services will increase at twice the rate of growth of the population, outstripping current resources for care [1]. An increase in patient-centered comparative effectiveness research and well done prospective cohort studies has improved our understanding of the pathophysiology of these disorders as well as improved treatment

outcomes. However, given the burden of PFDs on women and the health care system, continued research is needed to further optimize treatment outcomes.

Little is known about the factors influencing patients' decisions to initiate and continue participation in PFD research studies. Qualitative research involving the use of focus groups specific to the recruitment and retention of women in PFD studies is lacking. Furthermore, special population groups in clinical research, such as ethnic and racial minorities, may pose additional recruitment and retention challenges [2]. As a part of the NCI funded Community Retention Intervention Study [3], researchers found that the use of focus group information can be effectively applied to understand retention and compliance strategies of underserved women in clinical trials

Efficient use of research resources is imperative, given the economic limitations of research funding opportunities. Increasingly, potential and active patients utilize web-based methods for acquiring information regarding clinical care and research opportunities. Literature specific to Web-based focused groups of women with PFD does not exist, however, Web-based methods have been assessed in other populations providing preliminary evidence that comparable levels of data quantity and quality [4] can be achieved, with the additional ability to reach remote, small, and hard-to-include populations [5–7]. Additionally, Web-based focus groups provide subjects with a comfortable and convenient way of joining group discussions [8].

The aim of this multisite study was to employ focus group methodology to gather data to inform PFD researchers about the knowledge and attitudes of women regarding research participation. We hope to use this data to develop new incentive strategies aimed to increase recruitment and retention of research participants in long term clinical trials. We also explored web-based focus groups as this approach is becoming an increasingly popular method for collecting qualitative data.

Methods

We conducted 2 in-person focus groups at 7 clinical sites of the Pelvic Floor Disorders Network (PFDN). At each site, one focus group was conducted with women with previous or current PFD randomized clinical trial (RCT) participation (study-experienced); the other focus group was conducted with women without PFD study participation (study-naïve). In addition to these 14 focus groups, we also conducted two web-based focus groups, one each for study-experienced and study-naïve women. The goal of this sampling method was to include each PFDN site as well as to reach saturation on the topic area.

Following Institutional Review Board (IRB) approval by all research entities, study coordinators at each site identified women who met eligibility criteria. Adult women > 21 years old, living independently with English fluency, who had a current or prior pelvic floor diagnosis, were approached for participation. Targeted recruitment of minority women was individualized per site to be consistent with the clinical sites historical minority recruitment rate. We excluded women who had participated in a nonclinical, non-interventional research study, such as interviews, focus groups, or other market research methodology on the topic of PFDs or clinical trial participation in the prior 6 months.

Interested, eligible women contacted the designated local qualitative research firm for additional screening information (e.g., age, employment, education, and ethnicity) and focus group arrangements. The local qualitative research facility offered the fourth eligible participant (and each subsequent participant thereafter if the fourth declined) an opportunity to participate in the Web-based focus groups to minimize a selection bias in the participants of the Web-based groups.

To ensure consistency across groups, the investigators developed semi-structured discussion guides for study-experienced and study-naïve participants. Three experienced moderators co-led or observed the first two focus groups in order to identify any areas of the discussion guide that needed to be adapted or revised for the remaining groups. After the initial two groups, a training session was held with all of the moderators for the remaining groups to review the guide and ensure that all of the groups were conducted using a consistent approach.

Each of the remaining focus groups was conducted by two experienced female moderators, providing additional assurance that all of the content in the discussion guide would be addressed in each group. Informed consent was obtained at the beginning of each group. Participants provided written responses to the Pelvic Floor Distress Inventory-20 (PFDI-20), range 0–300, [9] and questions about previous PFD treatments. The groups then proceeded with the content as outlined in the discussion guide regarding their thoughts and experiences with RCTs in general and PFD clinical trials, including RCTs specifically.

Analysis of results was conducted by detailed evaluation and review of the transcripts, as well as the field notes from the focus groups.

Results

One hundred five women, with an average age of 58.6 years, participated in the focus groups; 93 were in the in-person groups and 12 were in the Web-based groups. Fifty-eight participants were study-experienced; the remaining 47 were study-naïve. Two study-experienced participants were incorrectly assigned to and participated in study-naïve focus group sessions. Study group demographics are presented in Table 1. Demographic and PFD characteristics were similar for the study-experienced and study-naïve participants. More study-naïve participants had received their PFD diagnosis within the last year than study-experienced participants (38% vs. 14%, respectively). The overall mean $\pm$ SD (range) PFDI -20 score was 80.3 $\pm$ 56.3, (0–235). Study-naïve participants had a slightly higher mean score, reflecting greater symptoms, 97.7 $\pm$ 57.3, (0–235) than study-experienced participants 66.7 $\pm$ 52.0, (0–205), $P < 0.01$.

The types of treatments most commonly reported by study participants are noted in table 2 reflecting a wide range of treatments received or suggested to these participants. The impressions of the study-naïve participants regarding PFD clinical trial participation are listed in Table 3 and in general represent the potential benefits and risks that are discussed with participants of most types of research trials regardless of medical condition studied.

Themes relating to participant recruitment and retention within PFD RCTs were generally similar across the focus groups and are described below.

Initial Decision to Participate in Study

While most participants reported being recruited by their physicians, some first heard about a clinical trial through newspaper or radio advertisements ($n=7$), at work (5), from a friend (1), in a local city magazine (1) or from a women's health research registry newsletter (1). All 5 women who heard about a study at work were employed at the university or hospital conducting the research; 2 heard about a study from coworkers and 3 saw a posting in an internal newsletter, on a bulletin board or in the restroom. Of all of these approaches to recruitment, physicians were most often cited as the best source of information about a clinical trial:

- “I thought it was an excellent approach because I felt like the doctor and her staff notified me as a candidate... I usually do trust my medical people.”

- “I had the opportunity to ask questions of someone I trusted before doing the study.”
- “I thought it was a great way to hear about it... hearing it from a physician that I trust made me want to pursue it because I trusted her.”

While some participants expressed concerns about recruitment from sources other than a physician, positive points of other methods of recruitment were also reported, including being able to learn more about the clinical trial at a time convenient for the patient, the confidentiality of being the one to initiate the contact about a trial, and the ability to reach participants that may have not yet seen a physician for their PFD. Examples of these statements include the following:

- “I think it was good for the advertisement to do it. It’s private and confidential... it gave me the ability to call them on my time and ask questions.”
- “I could call after work and talk to somebody... without feeling that I was being pressured into doing something one way or another.”

No participant reported finding out about their PFD study via the Web. However, several participants used the internet to find out more information about the details of the study including information about the physician. Likewise, participants found that information about the study on a website as a positive factor. Institutional reputation was important to some participants who said that the recruitment materials that referenced a university or teaching hospital would increase the perception of credibility.

Most focus group participants reported being interested in PFD clinical trial participation when first approached about a study. Participants varied in their reports about the extent to which spouses or other family members shared in the decision for them to participate in a study. Prior to participating, women reported taking into consideration various benefits to their participation, with an improvement in their condition and the ability to help others being themes that were consistently reported as important by participants. Other reported benefits included receiving the most advanced care by experts, free medical care, monetary incentives, being included in a group of women with similar problems, and learning more about their condition.

Concerns or questions that participants recalled as they made their decisions to participate included the potential for side effects, not getting the optimal treatment or receiving placebo due to randomization, the discomfort of treatment, the time commitment that would be required, how soon before treatment benefits could be expected, and being treated by an unknown physician (for those not recruited by their own physicians). Study naïve participants reported various questions and concerns that they would like to have addressed prior to deciding to participate in a PFD clinical study, including an RCT. Many of these issues focused on whether the trial would include medication, whether there would be placebo, and questions about the study logistics and overall time commitment that would be required for participation (including trial duration, frequency and duration of visits and the distance that would be required to travel). Additional questions and concerns raised by participants included short- and long-term side effects of treatment, amount and type(s) of compensation, credibility of the providers, and wondering whether the researchers would care about the individual patients.

Study naïve participants often stated that incentives would be a deciding factor but not the primary motivation for participation. In some groups, compensation was not even spontaneously reported as a benefit of clinical trial participation. However, when probed or when discussing the questions and concerns related to a clinical trial, several participants in each group typically stated that compensation was an important consideration. An amount

that would factor in time and gasoline costs was often cited by participants as the key components of compensation.

Study-experienced Thoughts on Research Participation

Study-experienced participants were very positive about their PFD study experiences. In particular, participants highlighted the improvements in their condition and the relationships they formed with the study staff as key benefits to their participation. In addition to the relationships with the study staff and improvements in their conditions, participants cited the quality of care they received, for example, noting the following: little to no wait for appointments, procedures were quick and easy, seeing the same physician for each visit, receipt of follow-up care and that they could be seen by a physician if they had an issue (versus being a “regular” patient where it may be more difficult to be seen). Participants also found the education they received about their PFD to be a benefit of participation. In addition, they cited the emotional benefits of helping others and contributing to research as well as feeling a part of a large group of women who shared the same condition. Finally, monetary and other incentives such as free parking were also seen as a positive aspect of study participation.

Some participants reported finding nothing to dislike about their trial experience. Negative study experiences that were cited by participants were often considered as minor disappointments or inconveniences but not “deal breakers.” Some of the negative experiences cited were aspects of the study design or the study procedures. Procedures to maintain study blinding such as not knowing what treatment had been received, the fact that they were committed for the duration of study even if the treatment did not work, completing the study diary, and measuring fluid input and output were all concerns raised by participants. Participants often cited concerns about the frequency and repetitive nature of the study questions.

- “I just feel like it’s kind of repetitive and you should just say this or this.”
- “You don’t have to keep saying ‘on a scale from 1 to 5 blah, blah, blah’ and again ‘on a scale from 1 to 5.’”

Some participants also disliked the mode of survey administration included in the study (eg phone, in-person, pen and paper), but participants’ experiences (the type of mode used in her particular study) as well as the mode preferred for use varied. Participants also expressed concerns about treatment-related issues, such as pain, discomfort, or complications.

Statements included the following:

- “The catheter was awful.”
- “The bladder test gets uncomfortable.”
- “I have mixed feelings about (study drug)...someone told me that it stays in your system forever, I wasn’t crazy about that.”
- Some participants reported that logistical issues were negative aspects to their participation, including finding appointment times that worked with their schedule, having to wait for appointments, and the driving distance. A few participants cited a specific negative interaction with a study staff member, one of which caused the participant to consider withdrawing from the study. In addition, some participants discussed that the negative aspects of their participation were not anticipated by them prior to the study.
- “I thought I was going back to the same doctor for an internal and it wasn’t.”

- “I didn’t have a complete picture of what the study was about.” “I think they should have explained better or used more lidocaine or whatever it was that they had.”

Time Involvement in Trial Participation

Many study-experienced participants viewed annual follow-up visits, even for up to 10 years, as a positive aspect of clinical trial participation. A few participants mentioned hesitancy around an extended follow-up period, primarily around concerns of not remembering her original experience after such a long period of time had passed.

Themes around the importance of improvement in the participant’s PFD, as well as the benefit of helping others were commonly cited in the both groups.

- “I think for future patients that they have a chance if they find something that would help treat them.”
- “I have two daughters. If they were to develop this condition and this medicine was tested and it worked, then they might get more help and they won’t have to live through all these years like I have.”

In addition, improved medical care, receipt of free medical care, feeling part of a larger group, educating others and compensation were also identified by some participants as perceived benefits.

Web-based Focus Group Approach

The demographics of the women who participated in the two Web-based groups are displayed in Table 4. The women who participated in the two Web-based groups were slightly younger on average than the in-person participants.

Positive aspects of the Web-based groups included that the women in these groups stayed more “on topic” with less peripheral participant interaction. The Web-based format also reduced the likelihood of 1 or 2 participants dominating the group discussion. Furthermore, the format allowed participants from multiple geographic locations to participate in one group.

Drawbacks of the Web-based format included decreased interaction among participants, reducing some of the synergistic benefit of focus group methodology. Web-based participants also seemed more likely to provide “yes” or “no” responses or simply indicate agreement with others where they may have been more likely to expand upon their thoughts if speaking rather than typing. Finally, as individuals type and respond to questions at various speeds it was a challenge to set a pace that kept fast responders interested but slow enough for everyone to respond. Because there was also no way to know when a participant was working on a response, there were instances when participants were cut-off as the group moved to the next question. Overall, for the purposes of the content of these focus groups, the Web-based methodology worked well for the two groups conducted and provided similar results to the in-person groups.

Discussion

Among women with pelvic floor disorders, our study identifies central themes guiding successful recruitment to and retention in pelvic floor disorder-related clinical studies, including RCTs. We also show that internet-based collection of qualitative data is feasible in a pelvic floor disorder population and provides similar information compared with in-person focus groups.

Both study-experienced and study-naïve women believed that their physicians were the best source of information about a clinical trial. However, other sources of trial information are necessary, and study-naïve women specifically recommend that detailed information about the study investigators and the trial including information on study medications, inclusion of a placebo, study logistics and overall time commitment be available for review as this would make them feel more comfortable calling the clinic to learn about participation. Recruitment materials that reference a university or teaching hospital lent increased credibility to studies. Further, the study-experienced patients suggested providing an additional information session prior to the first study visit to ensure that all of the study procedures and expectations were understood by the participants. Providing this additional visit may address some of the concerns reported by study-experienced patients regarding not being aware of certain aspects of the clinical trial in which they had participated.

Based on the reports provided by the study-naïve participants, one would anticipate that medication trials, particularly those that include a placebo arm, will require greater recruitment efforts than those that are focused on other types of pelvic floor disorder treatments. In addition, the time commitment required in terms of duration and frequency of study visits, as well as the duration of the trial, should be considered at the study design and planning phases with an emphasis on ensuring that the process is as timely and convenient for potential participants as possible.

Both study-naïve and experienced patients have an expectation that through research participation, they will see improvements in their health condition, but these patients also appreciate the ability to potentially help other women through study participation. The perception of research participants was that they often received (or would receive) a higher level of care than patients not involved in a study including more direct access to the research team and to the same physician, decreased waiting times, and a more thorough education about their disorder. An unexpected benefit of study participation reported by the study-experienced women (and thus not generally cited by the study-naïve women) was the value of a quality relationship established with the research staff. This benefit seems likely to be an important factor in retention efforts, particularly for women who do not experience improvement in their condition during the study. This relationship benefit should be communicated to study-naïve women considering clinical study participation as it may assist with recruitment efforts. One possible method of communicating this and other benefits (as well as drawbacks) of participation is to provide a forum for women who had or were currently participating in clinical studies to share their experiences with those considering participation. Such groups would allow study-naïve women to ask questions and learn more about clinical study participation as well as to feel connected to a larger group of women who share the same condition.

Less important, but not unimportant, is the issue of financial compensation for study participation. Financial compensation does not appear to be a primary motivating factor for enrollment in PFD clinical studies, however it was cited as an important consideration nonetheless. Study-experienced patients suggested that compensation strategies should take into consideration the overall time commitment (including the time and expense of traveling) required by participants.

The collection of high quality qualitative data is an integral part of patient-centered effectiveness research, and focus groups serve as an important tool in collecting these data. We found that in a PFD population, there were benefits and drawbacks to the web-based modality: these groups stayed more “on topic”, provided a greater level of anonymity, and prevented discussion domination by a few participants, but they decreased participant interaction with each other, a component thought to be critical for traditional focus groups.

Nonetheless, we found conducting web-based focus groups feasible and yielded similar themes as those reported by in-person participants.

This study's strengths include participation by a diverse group of women: both research-experienced and naïve with a spectrum of pelvic floor disorders. A wide age range was also represented with geographic and ethnic diversity and a broad range of levels of education. A limitation of this study is responder bias; our focus group results may not be fully generalizable to the PFD patient population if focus group participants view research more favorably. Concerns and deterrents to study participation were gleaned from both study-experienced and naïve patients, but interviews with these focus group participants cannot identify *all* substantial barriers to participation in clinical studies. While these results should be regarded with some caution, common themes emerged from both study-experienced and naïve participants, and potential strategies for improved recruitment and retention were reported. Overall, the experiences reported by the women who had or were currently participating in pelvic floor disorder clinical studies including RCTs, speak to the successful conduct of such studies. The information from this report will be useful in designing future PFDN studies as this input from the focus group participants will guide study design, compensation, and follow up strategies.

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Table 1

Focus Group Participant Demographics

Characteristic	Study-Experienced (n = 58)	Study-Naïve (n = 47)	Overall (N = 105)
Age, years; mean± SD (Range)	59.9 ±10.7, (32–81)	57.1± 12.5, (30–83)	58.6± 11.6, (30–83)
Race, n (%)			
White	34 (58.6)	34 (72.3)	68 (64.8)
Black	10 (17.2)	7 (14.9)	17 (16.2)
Hispanic	10 (17.2)	4 (8.5)	14 (13.3)
Other	4 (6.9)	2 (4.2)	6 (5.7)
Education, n (%)			
High school degree	10 (17.2)	11 (23.4)	21 (20.0)
Some college	17 (28.3)	16 (34.0)	33 (31.4)
College degree	22 (37.9)	11 (23.4)	33 (31.4)
Some postgraduate work or degree	9 (15.5)	9 (19.2)	18 (17.1)
Type of PFD ^a n (%)			
POP	24 (41.4)	24 (51.1)	48 (45.7)
Urinary incontinence	47 (81.0)	38 (80.9)	85 (81.0)
Fecal incontinence	14 (24.1)	17 (36.2)	31 (29.5)
Duration of PFD, ^b n (%)			
Less than 1 year	8 (14.3)	18 (38.3)	26 (25.0)
1–5 years	30 (52.6)	16 (34.0)	46 (44.2)
6–10 years	9 (15.8)	7 (14.9)	16 (15.4)
11 years or more	10 (17.5)	6 (12.8)	16 (15.4)

^aPFD-pelvic floor disorder, self report, participants could endorse more than one type of PFD condition;

^bself report

Table 2Types of Recommended or Provided Pelvic Floor Disorder Treatment^a

Characteristic	Study-Experienced (n = 58)	Study-Naïve (n = 47)	Overall (N = 105)
POP			
Surgery	30	18	48
Pessary	9	6	15
Other	4	6	10
Characteristic	Study-Experienced (n = 57)	Study-Naïve (n = 48)	Overall (N = 105)
Urinary incontinence			
Surgery	20	18	38
Medication	25	16	41
Pessary	8	4	12
Timed voiding/fluid management	10	5	15
Supervised pelvic muscle exercises	12	14	26
Biofeedback	1	4	5
E-stim or Interstim	4	1	5
Periurethral injection	3	0	3
Botox injection	14	2	16
Other	2	7	9
Fecal incontinence			
Surgery	1	2	3
Supervised pelvic muscle exercises	0	2	2
Biofeedback	0	1	1

^aParticipants could report more than one type of PFD treatment.

Table 3

Study-Naïve Participants' Impressions Regarding Clinical Trials

Positive	Negative
Potential benefit to patients/society	Could be a risk to health
Improved strategies and treatments	Could receive placebo or a treatment that didn't work
Free medical care provided by experts on the cutting edge	Investigational drugs might react with other medicines
Might help me and might learn something	Could be treated as "a number"
They are important, useful, necessary	
Knowing someone else has similar problems	

Table 4

Demographics of In-Person and Web-based Participants

Characteristic	In-person (n = 93)	Web (n = 12)
Age, years		
Mean± SD, (range)	59.5 ±11.5, (30–83)	51.8±10.6, (34–67)
	11.5	10.6
	30	34
	83	67
Race, n (%)		
White	60 (57.1)	8 (66.7)
Black	15 (16.1)	2 (16.7)
Hispanic	12 (12.9)	2 (16.7)
Other	6 (6.5)	0 (0)
Education, n (%)		
High school degree	19 (20.4)	2 (16.7)
Some college	30 (32.3)	3 (25.0)
College degree	28 (30.1)	5 (41.7)
Some postgraduate work or degree	16 (17.2)	2 (16.7)
Type of PFD, ^a n (%)		
POP	43 (46.2)	5 (41.7)
Urinary incontinence	75 (80.7)	10 (83.3)
Fecal incontinence	28 (30.1)	3 (25.0)

^aParticipants could report more than one type of PFD