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Feasibility of a Longitudinal Study of Women Anticipating First Pregnancy and Assessed by Multiple Pelvic Exams: Recruitment and Retention Challenges

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Abstract

Objective—To better understand the relationship between childbirth and pelvic floor disorders the ideal study design would begin with data collection prior to but close in time to first pregnancy and follow participants through post-partum. We conducted a feasibility study to determine a) whether women desiring to get pregnant would agree to pre-pregnancy data collection including a one-time urethral catheter measure and repeat pelvic exams to ascertain a baseline within 6 months of pregnancy; b) effectiveness of various recruitment and retention methods, c) number achieving pregnancy, and then d) number expressing willingness to continue follow-up through pregnancy and postpartum.

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Methods—Advertising included newspaper ads, targeted emails and flyers. Post-enrollment, four data collection visits were scheduled and occurred every 6 months or until pregnant. If pregnancy occurred, women were asked to indicate their willingness to continue assessments.

Results—The most successful advertising strategy for both recruitment and retention was local newspaper ads. 94 women inquired about the study, 30 enrolled. Post-baseline retention was 23 women at 6 months, 17 at 12 months, and 13 at 18 months. Nine of the 30 women achieved pregnancy; two remained eligible and willing to participate through pregnancy and postpartum.

Conclusions—This study provides data on feasibility of recruiting women to establish near-pregnancy clinical baseline measures that include pelvic exams. Close to 30% reached pregnancy within two years of study start and within 6 months of most recent pelvic exam measure. Of those who became pregnant, 22% expressed willingness to continue follow-up into the childbearing year.

Keywords

Childbirth; Pelvic Floor Disorders; Recruitment; Retention; Longitudinal Studies; Pregnancy, Incontinence, Pelvic Organ Prolapse

Introduction

Recruitment and retention for longitudinal studies is a challenge [1,2]. Insufficient recruitment may render a study underpowered whereas poor retention can endanger study validity. The Center for Disease Control suggests a 70% retention rate for confidence in validity [3], but result bias can occur with attrition rates as low as 20% [4].

Research attempting to determine relationship between pregnancy, birth, and pelvic floor disorders has been difficult in part because of time between pregnancy, suspected point of injury (birth), and development of symptoms (incontinence and/or pelvic organ prolapse). Traditionally longitudinal studies of pelvic floor changes associated with pregnancy and birth have involved recruiting women during first pregnancy or after their first birth [5]. In our previous longitudinal study of women during pregnancy and postpartum, retention rate was 62% [6]. Since many physiologic and anatomic changes occur early in pregnancy, obtaining baseline data once pregnancy has occurred is less than ideal. Data collection prior to pregnancy offers a more complete picture of changes associated with the entire gestational period and beyond. While optimal from a research perspective, this strategy adds further challenges to recruitment and retention. Intention to become pregnant does not always result in conception and term pregnancy. Longitudinal studies involving pre-pregnancy data collection have the added challenge of unpredictability in conception and finite gestation, limiting recruiting flexibility and scheduling, particularly if the study has fixed data collection points. Subsequently, a number of these women may experience pregnancy or life events prohibiting further participation (e.g. multiple gestation, or unexpected move). Additionally, if the study includes post-partum data collection points, some women may become pregnant again during that time, leading to additional attrition.

These challenges led to a feasibility study to determine if enough women desiring pregnancy within a few years would agree to pre-pregnancy data collection and multiple follow-up visits designed to mimic data collection as it would occur in a study requiring baseline within 6-months of pregnancy, follow-up during pregnancy and through a postpartum period. This data collection would include clinic visits involving a onetime urethral catheter measure at baseline and pelvic exams at each visit. We hoped to determine if such a study was possible, and ascertain the best methods for recruiting and retention. Our longer term goal was to evaluate research designs for testing hypotheses regarding childbirth-related pelvic floor disorders taking into account pelvic floor pre-pregnancy status. These participants also served as controls

for the parent study; a randomized control trial of urinary incontinence interventions during pregnancy and post-partum (manuscript under construction).

To our knowledge, studies examining feasibility of longitudinal trials including pre-pregnancy baseline data and data during pregnancy have not been conducted. The ideal study design would begin prior to first pregnancy—we test feasibility of that design in the pilot work presented here.

Methods

Design

This feasibility study was designed in order to evaluate four components necessary for conducting a full longitudinal trial on the development of pelvic floor disorders from pre-pregnancy to post-childbirth. The components evaluated were: 1) Recruitment: willingness of women who are intending to get pregnant within a few years to respond to recruiting materials or advertisements for a longitudinal trial that entails repeat pelvic exams, 2) Screening and consent: how many of the initial responders who meet inclusion/exclusion criteria sign consent forms for participation, 3) Pre-pregnancy clinic visits that involve a pelvic exam: assessments every 6-months or until becoming pregnant, whichever comes first, 4) Willingness for additional study including pelvic exams: while pregnant and during the first post-partum year.

Recruitment

The study began in 2003 and recruitment was completed in 2005. Following approval from the university institutional review board, the participants were recruited through a variety of methods similar to those used for recruiting pregnant women from the community in earlier work [6]. Advertisements were placed in the hospital electronic newsletter (for faculty and staff) and in the local newspaper. Targeted emails were sent to faculty, staff and student groups at the university nursing school. Flyers were posted around campus. Of note, obstetrician/gynecologists and midwives were not tapped for recruiting these participants because previous yield from this strategy in recruiting pregnant women was low despite high staff investment in educating the practitioners [6]. Informally, practitioners' feedback spoke to the difficulty of taking time to recruit patients for studies within an already busy office schedule.

Recruitment materials included payment information; \$260 would be made if all of the clinic visits with pelvic exams were completed. Distribution of payment across the clinic visits was: \$40 at the first visit, \$40 at the second visit, \$80 at the third visit, and \$100 at the fourth visit.

Screening and consent

Advertisements provided a contact number so that if a woman was interested she could contact the study coordinator to discuss participation. During this phone conversation women were screened for eligibility to participate in the study. Women were invited to participate if they were: 1) essentially healthy, 2) hoping to become pregnant "within the next few years", 3) age eighteen years or older, and 4) not currently pregnant. Exclusion criteria included: 1) vaginal or bladder related surgery, 2) history of, or current pregnancy, and 3) light-headedness or more than mild discomfort with pelvic exams. Women with certain chronic conditions such as spinal cord injury, multiple sclerosis, muscular dystrophy, cerebral palsy, or chronic urinary tract infections (more than four in the last year) were also ineligible.

If women met criteria, and were interested in enrolling, the baseline data clinic visit was scheduled. A packet including an informed consent and survey materials was mailed prior to the initial visit so that each woman was familiar with the requirements of the study prior to signing the informed consent. The actual consent was signed at the onset of the first clinic visit

after the study coordinator reviewed it with them in detail. The study coordinator scheduled subsequent visits via phone and mailed survey materials to the participants prior to each visit.

Data collection procedures

Participants completed mailed questionnaires prior to, or at each visit. Participants provided demographic information including age, ethnicity, and level of education. Prior to each clinic visit participants received questionnaires evaluating incontinence, performance of pelvic muscle strengthening exercises, and occupational activities. Participants were also instructed to complete a three day fluids and voiding log prior to their clinic visit.

A single nurse practitioner with extensive experience in the type of data collection techniques used, including pelvic exams, conducted all of the clinic exams. Four physiologic variables were collected: 1) pelvic muscle strength measured using an instrumented speculum adapted for measuring intra-vaginal closure pressure [7]; 2) presence of pelvic organ prolapse using an objective quantification measure: the Pelvic Organ Prolapse Quantification system (POP-Q) [8]; 3) urine leakage during hard coughs measured as an area of wetness on a tri-fold paper towel held beneath the urinary meatus; 4) bladder neck mobility during cough and during pelvic muscle contraction visualized using ultrasound. Height and weight were also obtained at every visit. At the first visit only, a measure of urethral pressure (with a Gaeltec pressure catheter) was also taken [9].

All women were advised to inform the study coordinator if they became pregnant at any point in the study. When a woman became pregnant, she was asked by the study coordinator about potential participation in the parent study that would require additional clinical exams including one visit during pregnancy, one six weeks after delivery, and one at 6 and 12 months postpartum.

Analysis

The data analysis for this study was limited to that related to recruitment and retention of study participants as well as pregnancy achievement. Statistical analysis relied mainly on description, simple counts and percentages. Between group comparison of demographic information for participants who completed and those who did not were undertaken using Chi square and independent t-tests.

Results

Prior to attaining our target sample size of 30 women, a total of 94 women were telephone screened after they called the project director in response to recruitment material. Of those women only three were excluded (two due to pregnancy and one due to interstitial cystitis). The remaining 61 women declined participation after learning of the study commitments. The majority gave no explanation; however 14 indicated the urinary catheter as reason for declining and two indicated time constraints. Table 1 provides demographic characteristics of the 30 women enrolled in the study, the majority of whom self-reported as being of White race and well-educated. The breakdown of successful recruitment by advertising medium is shown in Table 2, indicating university or local town newspaper advertising as the most successful method of recruitment. Two forms of recruitment that resulted in 100% retention for the duration of the follow-up visits were a) two women who entered this study when they did not qualify for another study that was enrolling concurrently and b) one woman who responded to posted fliers.

Of the 30 women who enrolled in the study, 23 (77%) completed the second pelvic exam, 17 (57%) completed the third, and 13 (43%) completed the fourth exam. There were no statistical

differences in age, ethnicity, or education between those who did and those who did not return for a fourth pelvic exam visit however, numbers in each group were small.

In total, 9 (30%) of the participants informed the study coordinator of a pregnancy within the first two years of the study. Each of these women were asked about willingness to enter the parent study following the same protocol of pelvic exams during pregnancy and throughout the first postpartum year. Responses were as follows; one participant felt she lived too far away to make the additional clinic visits that would be necessary, two did not want the bother of clinic visits during pregnancy and after birth, one had moved out of state, one was delivering at another hospital (which would have excluded her from local Institutional Review Board approved chart reviews). Two women declined but were lost to contact before indicating a reason for not continuing. The remaining two of the nine women who became pregnant indicated they would be willing to continue with additional study participation during pregnancy and through the first postpartum year if enrollment in an additional arm of study were available. Figure 1 shows detail on recruitment and study participant flow and results.

Discussion

Data on recruitment and retention in general is scant and often provides information on discrete populations such as a particular minority group [1]. Certain populations, including women, are underrepresented in research, contributing to ongoing health disparities. However, there are other recruitment and retention factors that also challenge researchers conducting longitudinal studies. For example, the more demanding or burdensome the protocol is, the more challenging the recruitment and retention for that study [1,10]. Our study included several factors that may have added further difficulty. Studies that involve procedures that may be construed as embarrassing, painful or uncomfortable could deter participants from enrolling [11]. Although women are subjected to pelvic exams as part of their routine gynecological care, they are viewed by many women as uncomfortable and embarrassing [11] which could deter them from responding to advertisements for this type of study. The inclusion of urethral pressure with a Gaeltec catheter was a deterrent to enrollment for a substantial number of potential participants. When studies involve numerous data collection points, potential participants may be reluctant to commit or may enroll but underestimate the commitment involved in participating. Our study included clinic exams which may have added considerable burden even though every effort was made to minimize discomfort. Spacing the visits to decrease the number to two or three pelvic exams may improve acceptability and retention in future studies, but may compromise a tight timeline of baseline measures that occur close to a pregnancy. Time constraints could also be a deterrent since each of the clinic visits lasted approximately one hour, a significant participant burden. Additionally, participants were asked to complete three questionnaires and fill out a three-day fluids and voiding log prior to each clinic visit, also a substantial burden. We were not able to ascertain reasons for declining from all women who expressed an initial interest in the study. Moreover, most women in this study were White and well-educated limiting generalizability of our experience to other populations.

Although recruiting within an academic setting using targeted email and newsletters may result in greater numbers of initial study enrollees, they may be less likely to remain for the duration as they graduate and move away. For longitudinal studies where retention is critical to study success, more narrow inclusion criteria/exclusion criteria (such as requiring that women are trying to conceive at the present time) may result in fewer participants but those that enroll may be more likely to complete. Of note, recruitment for this study occurred between 2003 and 2005; currently social media such as Craig's list or Facebook may be more successful methods of recruitment.

While optimal from a research perspective, recruiting women prior to first pregnancy for long-term follow-up into pregnancy and beyond is challenging. Intention to become pregnant does not always result in conception and a successful term pregnancy. Prior studies show that if 100 women actively trying to conceive are recruited as study participants, statistically only 80% [12] will become pregnant over a 12 month period and 20% to 30% of these women will spontaneously miscarry [5], reducing the number of research participants for follow-up to as low as 64. Longitudinal studies involving pre-pregnancy data collection have the added challenge of unpredictability in successful conception and a finite gestational period, which limits flexibility in recruiting and scheduling, particularly if the study design requires data collection at fixed time points. Subsequently, a significant number of these women may experience pregnancy or life events that prohibit them from further participation (such as an unexpected move, or a multiple gestation). Regarding intention to become pregnant, the language we used for recruitment was fairly broad. We asked “would you like to get pregnant in the next few years?” Thus, we allowed into the study women who were not at that moment in time actively attempting conception. Consequently, the number of women in this study who did become pregnant (30%) may be lower than in studies that use more rigorous recruitment criteria.

We have identified several strategies that may increase the likelihood of recruiting and retaining participants for longitudinal studies. In order to retain current participants and recruit former participants to subsequent studies we mail out a quarterly newsletter. Similar to other studies [13] we found that having consistent and personable study staff helps both in recruitment and retention. We found, as others have [14], that distance to study site was a reason why some participants dropped from the study. Clearly explaining the commitment needed for the study prior to enrollment may decrease initial study enrollment, but may increase the likelihood of retention.

Report of this feasibility study is offered to provide data for investigators trying to balance a scientifically superior study design, which begins at the pre-pregnancy condition, following through pregnancy and birth, and the logistical realities of implementing that design. In this study where 94 women expressed interest, the majority declined when given details regarding the rigors of the study which included multiple pelvic exams, survey instruments, voiding logs and a one-time insertion of a Gaeltec catheter only at the first visit. Of the 30 women who did agree to participate 43% completed all clinic visits. Although all 30 women indicated at screening a desire to become pregnant within the next few years, only 9 did so during the two year time period of this study. We maintain however, that while challenging, conducting a longitudinal study of this nature may be possible. Given the challenges it is important that investigators and funding agencies thoroughly understand the resources required. Should the design be undertaken, implementation should target maximizing recruitment of women most likely to remain in the study (for instance by using more rigorous inclusion/exclusion criteria), having very experienced project directors who can manage these multiple challenges and attention to adequate length of funding.

Conclusion

We conclude that feasibility of a large scale longitudinal study designed to follow women from a pre-pregnancy state and into their first pregnancy and post-partum year is challenging and would depend on resources adequate to cover the time needed to recruit and retain an adequate number of participants (we project a minimum of 7 years). High attrition rate should be anticipated, therefore we recommend oversampling initially. Results of such a study would need to guard carefully against loss of external validity due to potentially a non-representative sample at long-term follow-up.

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Figure 1.
Pregnant Participant Attrition

Table 1

Participant sample characteristics.

Characteristics	Participants who did not complete		Participants who completed entire study	
	N = 17		N = 13	
Ethnicity	N	%	N	%
Black	0	0%	2	15.4%
American Indian	1	5.9%	0	0%
White	15	88.2%	11	84.6%
Other	1	5.9%	0	0%
Education				
Some College	3	17.6%	2	15.4%
4 years of college	7	41.2%	5	38.4%
Graduate school	7	41.2%	6	46.2%
Age	Mean	Standard Deviation	Mean	Range
	27.5 years	2.9	31.9 years	7.8

Table 2

Retention by recruitment method.

Method of recruitment	Local newspaper	University staff/student newspaper/bulletin	Flyer	Word of Mouth	Recruited from another study	Targeted email
Baseline	11	6	1	2	2	8
6 month	9 (72%)	5 (83%)	1 (100%)	1 (50%)	2 (100%)	5 (63%)
12 month	9 (72%)	2 (33%)	1 (100%)	1 (50%)	2 (100%)	2 (25%)
18 month	6 (55%)	2 (33%)	1 (100%)	(0%)	2 (100%)	2 (25%)