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Perspectives on Successes and Challenges in the Recruitment and Retention of Pregnant Women in a Research Study

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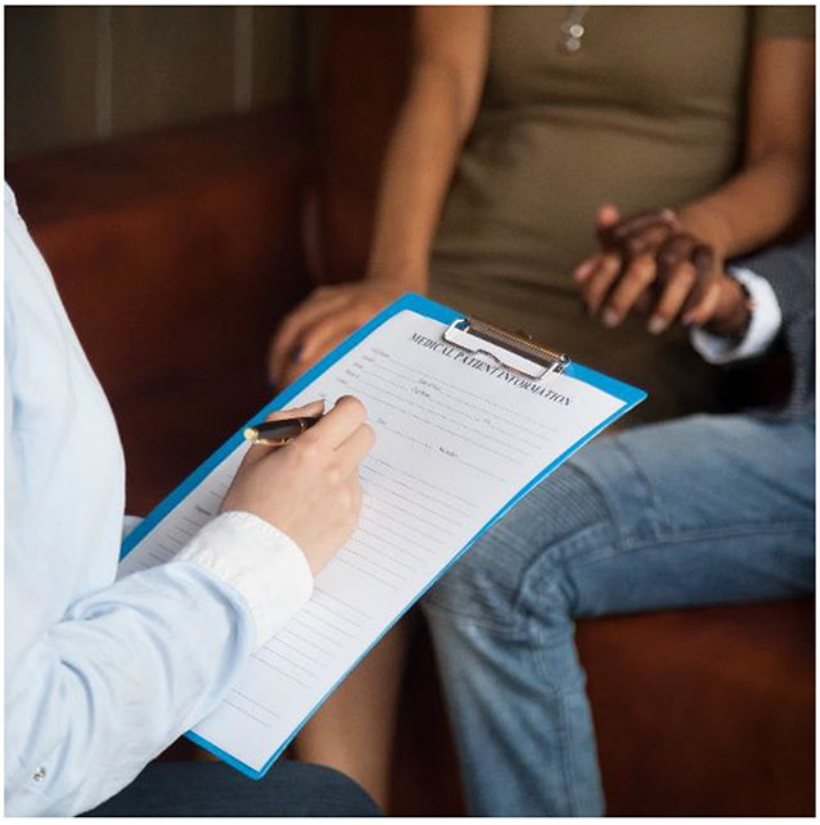
Graphical Abstract



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Pregnant women have historically been excluded from clinical trial research, given their former “vulnerable population” status and in consideration of potential impacts to the developing fetus. However, the National Institutes of Health (NIH) and the NIH Office of Research on Women’s Health have called for more expansive research to address areas of high clinical need and to promote evidence-based clinical practice related to pregnancy.{1}

To promote an inclusive research environment and to enhance the rigor of future studies, it is essential to discuss the multiple challenges that may arise regarding recruitment and retention of pregnant women in clinical trials, and to share perspectives on successes and failures in individual studies.

In this paper, we focus on the importance of consistency, flexibility, and compassion by the research nurse/clinical research coordinator. We present perspectives on challenges and successes regarding recruitment and retention of pregnant women in a longitudinal pilot study designed to evaluate the feasibility, acceptability, and preliminary effects of a self-management intervention for depressive symptoms.{2} We also discuss successes and “lessons learned” within the context of recruitment methods, study design, and retention strategies.

Consistency, Flexibility, and Compassion in Recruitment Methods

To engage in effective recruitment, we found that the process of building trusted relationships{3,4} was at the heart of our study’s success. Collaboration with community stakeholders and clinic staff and establishing trusted relationships are steps that take much effort prior to the initiation of the study, but when done well, contribute to success in both recruitment and retention.{3,5}

In our study, we built effective relationships in several ways. First, we capitalized upon contacts within our academic institution (Virginia Commonwealth University), from healthcare providers to registration staff, to provide layers of access as entry points to successful recruitment.{6}

For example, speaking with the local director of CenteringPregnancy® Care (a group prenatal care approach of the Centering Healthcare Institute) led to a meeting with the clinical coordinator of the ambulatory care center; their collegial relationship paved the way for research staff to have access to vacant rooms, print-outs of the daily schedule, and computers. The director also allowed research staff to speak to prenatal care groups as an active recruitment strategy.

As another example, a key contact within the academic institution was the social worker for the high-risk obstetrics clinic, with whom our principal investigator (PI) and head research nurse met at a local cafe in the community prior to the start of the study. Meeting outside the busy clinic setting meant that the social worker could get to know the study details and staff in an unrushed environment and feel confident about making study referrals.

Second, our study team used both active and passive recruitment methods, with the goal of reducing recruitment bias and facilitating access to a diverse community population.{7}

Although passive methods, including flyers, Facebook posts, and e-mails to listservs, were successful for reaching many interested individuals, we found that active recruitment was essential, and the only way to effectively do so was to develop relationships with clinic staff.

For example, active recruitment in busy clinic waiting rooms can be challenging, so orientation to the “ins and outs” of clinic operations was critical. By meeting with clinic nurses at staff meetings, study research nurses gained credibility and learned how to minimize intrusions on clinic operations; thanks to this credibility, clinic staffers offered use of vacant rooms and computers and referred patients to the study. These informal orientations allowed study research nurses to feel less intrusive while recruiting in the clinic waiting rooms. By cultivating mutual respect between the clinic and research nurses, the two could co-exist working toward equally important missions of the academic institution: research and clinical care.{4,6}

Research suggests that engagement of healthcare providers is a critical component for recruitment. Previous studies have suggested that participants are more likely to sign up for research if it has been recommended by their healthcare provider.{7,8} Similarly, engaging in informal networking with clinicians and having regular presence at key events has been found to be key to the successful recruitment of pregnant women.{9}

In our study, the clinics of midwives, obstetricians, psychologists, and primary care providers were targeted as access points because it was clear to us that it was critical for healthcare providers to have confidence in, and a connection with, the research nurses in order to make referrals. Further, our presence at local clinician conferences, Grand Rounds in the academic health system, and local conferences were important aspects of recruitment.

For example, we secured a booth at a conference of the local Association of Certified Nurse Midwives chapter, during which we were able to communicate with midwives who showed enthusiastic interest and actively referred interested individuals. It was important that we maintained active staffing at this event, rather than simply placing materials at an unstaffed booth; this is consistent with previously mentioned studies{4,9} that found certain techniques to be fruitful (such as attending healthcare provider conferences) and certain techniques to be unfruitful, such as lack of staff presence at events, newspaper advertisements, and recruitment postcards. As another example, the PI talked with the academic health system’s chief resident for Obstetrics/Gynecology after Grand Rounds, who acted as a “champion” of the study—providing brochures for fellow obstetricians and who subsequently sent us several participant referrals.{6}

Two additional important recruitment methods were “flyering” and thinking “outside of the box.” First, although it is a time-consuming practice, “flyering” involves spreading flyers/brochures in multiple venues throughout a community, from churches to busy restaurants.{10} An important aspect of “flyering” is to maintain professionalism while posting flyers: this includes asking permission to post when necessary and following the rules of the bulletin board. In addition, because of our commitment to reaching women of all socioeconomic backgrounds, flyers were delivered to health department resource centers in

lower income communities; during this time, study research nurses briefly educated health department staff about the study.

Second, in order to increase recruitment numbers, study research nurses accessed “outside the box” entry points such as car-seat installation sessions at a large retail store, yard-sale events at local low-income housing developments, childbirth education classes and doula sessions at a local library, and “electronic flyering” via social media. Although recruitment was minimally successful at several of these sites, important connections were established with community members in attendance. In addition, fruitful social media sources included individual doulas’ Facebook pages, new mom/baby Facebook pages, and university-wide e-mail blasts.

A key lesson learned from the experiences described above is that in-person visits, rather than e-mails or phone calls, to recruitment sites will enhance success in connecting with clinicians about the study. Engaging the “gate-keepers” of offices (typically the receptionist or clinic manager) was essential and is consistent with other research{5}; an effective manner to pique interest is for the research nurse to briefly state how the study goal overlaps with the mission of the practice and that it is run by a reputable academic institution. For future success, we recommend building upon a network of interdisciplinary connections to enable scheduled meetings with office managers and clinicians.

Another lesson learned is that low-income housing developments may be rewarding targets for recruiters of future studies wishing to access a diverse population. Many housing developments have onsite childcare, which may address the common barrier of time and need for childcare.

In our study, we made a successful connection with a social worker at a local low-income housing development who arranged space in the community center for intervention delivery. Unfortunately, the individual was unable to identify pregnant residents. Nonetheless, this setting should be considered as an important option for future studies, given previous researchers’ successful experiences with low-income housing community partnerships.{11}

Consistency, Flexibility, and Compassion in Study Design

Striking a balance of consistency, compassion, and flexibility in the study design was important in its implementation.{12} Within a context of respect for the initial pilot study design, our team collaborated with Virginia Commonwealth University’s Institutional Review Board (IRB) and our Data and Safety Monitoring Board (DSMB) to implement small changes to the recruitment and retention plan to afford a more compassionate, flexible approach to participants’ needs, as supported by previous work.{6}

Creating ease for depressed, pregnant woman study participants became a goal for recruitment and retention. With the creative and flexible thinking of the study PI, we were able to make subtle changes that not only increased recruitment numbers, but also met the needs of the women.{12}

One example of a change to the study design intended to enhance flexibility for participants involved obtaining IRB and DSMB approval to allow participants a choice of in-person or phone-based baseline study visit. This was in response to our realization of the added burdens of potential participants' anxiety/anhedonia and their concerns with parking, directions, and childcare. For anyone who preferred an in-person visit but who lacked childcare at the last minute, study research nurses demonstrated flexibility by allowing the participant to bring her child to that visit.

A second IRB-approved change in study design addressed a need for active recruitment techniques. By seeking a waiver of consent through the IRB, we were able to conduct a basic medical record review prior to approaching potential participants in clinic waiting rooms. With this active recruitment approach, no information was documented about the individual prior to enrollment in the study, but the processes for potential participants who were already deemed potentially eligible were streamlined. Similarly, this prevented any potentially distressing situations for women in the waiting room who were experiencing a fetal loss or other major pregnancy complications.{13}

Consistency, Flexibility, and Compassion in Retention

As a key aspect of the research endeavor, retention of participants required careful planning with efforts to maintain consistency, flexibility, and compassion. Clearly, establishing trust between the research team and participants is important.{3,5,9} Compassionate communication between study staff and participants was essential to keeping study participants engaged and encouraged during the 12-week intervention.

Consistent with other research studies, personalized and non-judgmental communication led to participants stating that they felt cared for and motivated to complete the intervention. {6,11,14} In our study, we conceptualized this in several ways; for example, the first study visit involved a brief, motivational interviewing session during which the research nurse left time for participants to talk about their depressive symptoms. A simple statement to participants (e.g., "I am so sorry that you have been dealing with this") led some to report that no one had ever acknowledged the difficulties of their symptoms and others stated they felt the study environment was a safe space. Similarly, study research nurses checked in frequently with participants (weekly by phone or e-mail) for data collection and to monitor for adverse events, and weekly in-person at the intervention site.

Another aspect of successful retention was the wise and non-judging personality of the intervention instructor. Participant after participant reported through qualitative interviews that much of the success of the study was due to the compassionate personal qualities of this research team member.

A final aspect of retention involved the use of gift cards as IRB-approved compensation to participants at each data collection study visit ($25 per study visit). This financial compensation proved to be important to many participants.

Lessons were learned regarding retention of participants with communication and transportation limitations:

- First, one difficulty during the study was keeping in touch with several participants, all of whom who had a lower socioeconomic status. They encountered problems having enough minutes on their mobile phones and/or lack of reliable wireless access to text or talk and/or with frequent changes to phone numbers. Creativity proved to be key in order to keep these individuals in the study; for example, a particularly complex participant had a social worker who was affiliated with the academic healthcare system. With permission of this participant, the research nurse and social worker coordinated communication and study visit information. As another example, a Google voice account was used to send/receive text messages to and from eligible participants.
- Second, transportation was a common concern for several participants. In response, our research nurse developed a working relationship with the director of a perinatal health community agency; through this collaboration, the agency organized a van to transport interested women to the study visits.

Discussion: Thoughts for Future Studies

In reviewing the literature and following up on our “lessons learned,” we propose that future studies could benefit from the following strategies:

- Map the research team’s network of academic, public, and private organizations with overlapping goals related to perinatal health early in the project timeline; recognize that the most fruitful partners for recruitment are those with whom the research team has a previously established connection.
- Identify influential individuals within the healthcare community who may serve as “champions” for the study, demonstrating their strong belief in the study goals when communicating with patients and colleagues.
- Chart out a plan for a mix of active (e.g., screening and recruitment in waiting rooms) vs. passive (e.g., flyering, social media) recruitment to help enhance diversity of participants and ensure expeditious recruitment.
- Demonstrate early flexibility in research design to minimize burden to participants, while communicating with appropriate ethical/regulatory bodies.
- Consider methods to meet the needs of individuals for whom issues with technology, childcare, and transportation might limit their ability to participate.
- Convey professionalism and give an empathetic, respectful, and knowledgeable voice to the study when advertising its availability.
- Finally, and most importantly, demonstrate consistency, flexibility, and compassion in all decisions and communications regarding study recruitment and retention processes.

Conclusion

Locating productive recruitment entry points, fostering relationships, and allowing for flexibility in a study's design can help bridge the gap when recruitment is a challenge. Through thoughtful relationships with key academic and community providers, effective recruitment can be achieved.

Understanding the nuances of the clinical setting will help research nurses gain trust from clinic staff and secure access to eligible individuals. Flexibility around study design can prevent additional burdens to the pregnant participant.

At the heart of successful recruitment and retention of pregnant women is consistent and compassionate attention from study research nurses.

References

1. Blehar MC, Spong C, Grady C, et al. 2013. Enrolling pregnant women: issues in clinical research. Women's Health Issues 23(1):e39–45. [PubMed: 23312713]
2. Kinser P, Moyer S, Mazzeo S, et al. 2019 (in press). Protocol for pilot study on self-management of depressive symptoms in pregnancy. Nursing Research.
3. Blaisdell LL, Zellner JA, King AA, et al. 2016. The national children's study: recruitment outcomes using an enhanced household-based approach. Pediatrics 137(s4), 219–30.
4. Jessiman WC. 2013. 'To be honest, I haven't even thought about it'—recruitment in small-scale, qualitative research in primary care. Nurse Researcher 21(2): 18–23. [PubMed: 24171633]
5. Coleman-Phox K, Laraia BA, Adler N, et al. 2013. Recruitment and retention of pregnant women for a behavioral intervention: lessons from the maternal adiposity, metabolism, and stress (MAMAS) study. Preventing Chronic Disease 10(2): 120096.
6. Goff SL, Youssef Y, Pekow PS, et al. 2016. Successful strategies for practice-based recruitment of racial and ethnic minority pregnant women in a randomized controlled trial: the IDEAS for a healthy baby study. J Racial Eth Hlth Disp 3(4):731–7.
7. Maghera A, Kahlke P, Lau A, et al. 2014. You are how you recruit: a cohort and randomized controlled trial of recruitment strategies. BMC Medl Res Meth 27(14): 111.
8. Sutton EF, Cain LE, Vallo PM, et al. 2017. Strategies for successful recruitment of pregnant patients into clinical trials. Obst & Gyn 129(3):554–9.
9. Webster GM, Teschke K, Janssen PA. 2012. Recruitment of healthy first-trimester pregnant women: lessons from the chemicals, health, and pregnancy study (CHirP). Mat Child Hlth J 16(2):430–8.
10. Choi J, Lee J, Vittinghoff E, et al. 2016. mHealth physical activity intervention: a randomized pilot study in physically inactive pregnant women. Mat Child Hlth J 20(5):1091–101.
11. Spadola CE, Rottapel R, Khandpur N, et al. 2017. Enhancing yoga participation: a qualitative investigation of barriers and facilitators to yoga among predominantly racial/ethnic minority, low-income adults. Compl Thrp Clin Bract 29:97–104.
12. Cartagena D, Noorthoek A, Wagner S, et al. 2012. Family-centered care and nursing research. Newborn Infant Nurs Revs 12(3): 118–9.
13. Lapato DM, Moyer S, Olivares E, et al. 2018. Prospective longitudinal study of the pregnancy DNA methylome—United States pregnancy, race, environment, genes (PREG) study. BMJ Open 8(5):e019721.
14. Carpenter RE, Emery SJ, Rassi D, et al. 2016. Recruitment of pregnant women to an exercise-intervention study. J Obstcs Gyn 36(2):200–7.