

Increasing Participation of Women with Intellectual Disabilities in Randomized Control Trials through Enhanced Recruitment and Consent



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January 2012

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Overview

Although significant barriers impede the participation of women with developmental disabilities in randomized controlled trials, recruitment and consent can be improved. 75% of women with intellectual disabilities who attended an information session to learn about a health care intervention study in one state agreed to participate. The women were interested in learning how to improve their health, responded with understanding and interest to visual depictions of research activities, and appreciated receiving compensation for their time.

Researchers can increase the engagement of women with developmental disabilities in randomized controlled studies by using multi-modal activities to explain the purpose and procedures to all parties. Reading each section of the consent form aloud, explaining in detail, and illustrating key concepts on the forms not just to women with disabilities, but to family members, guardians, and professionals, were effective in increasing enrollment and informed consent.

It is vitally important that women with intellectual and developmental disabilities participate in health research studies and receive the benefits of evidence-based health interventions. Ethical guidelines require that participants in research studies be fully informed, free from coercion, and understand their participation is voluntary.^{1,2} Barriers to participation include: difficulty gaining guardian consent, limited access to potential participants, organizational procedures within community agencies, and an individual's unfamiliarity or apprehension about research³⁻⁵

This *Lurie Institute for Disability Policy Brief* reports the recruitment of 203 women with developmental disabilities living in community (vs. institutional) settings across North Carolina. The recruiting and consent procedures are part of a larger study designed to promote cervical and breast cancer screenings.

Enhanced Recruitment, Enrollment, and Consent in a Health Promotion Intervention Study

- Consistent with the principles of autonomy and self-determination, women were asked if they wished to participate in the study first, and if they were interested, then guardian consent was also obtained. If a woman declined, the guardian was not contacted.
- Although women with and without guardians consented at approximately the same rate (83%, 85%), those with guardians enrolled at lower rates due to lower rates of guardian consent.
- Conducting group and individual information sessions as a research team facilitated thorough explanations and clarification for all attendees.
- If a member of the research team thought a woman did not understand the consent form, the researcher did not enroll the woman.
- Women participating in the study received financial compensation, demonstrating the value of their time and effort.

Summary & Recommendations

Although the value of including adults with intellectual disabilities in research has been recognized, little empirical evidence has been produced on effective practices to invite and enroll women with intellectual and developmental disabilities.

The following strategies were successfully utilized to recruit and enroll women with intellectual disabilities in a health promotion intervention:

- Video and print materials showing other women easily and enjoyably learning the health intervention were utilized to decrease anxiety about the research process and the intervention itself.
- Researchers recognized that women with intellectual disabilities care about their health, have encountered breast cancer in friends and families just as women without disabilities, and desire to learn and proactively protect their health.
- Recruitment took place through a familiar community site that is known and comfortable for the women,
- Participants were compensated for their time with a small cash payment (\$15).

This *Lurie Institute for Disability Policy Brief* is based on the following paper: Swaine, J.G., Parish, S.L., Luken, K., & Atkins, L. (2011). Recruitment and consent of women with intellectual disabilities in a randomized controlled trial of a health promotion intervention. *Journal of Intellectual Disability Research*, 55, 474-483.

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Support for this research was provided by the: National Institute on Disability and Rehabilitation Research Grant No. H133G090124; Lurie Institute for Disability Policy, Brandeis University; and the NC Office on Disability and Health, University of North Carolina at Chapel Hill.

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