Recruitment & Consent of Women with Intellectual Disabilities in a Randomized Control Trial/Health Promotion Study

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Background

- Women with developmental disabilities have among the worst rates of cervical and breast cancer screening in the United States
- Our focus: Empowering women to be informed, assertive patients

Brandeis University

Women Be Healthy intervention

- Intervention designed to improve women's knowledge and empowerment related to cervical and breast cancer screening
- Eight classes include hands-on experiential learning, field trip to GYN office, focus on empowerment AND knowledge
  - How to assert needs and ask questions with health care provider
  - How to describe symptoms
  - How to relax for stressful procedures (particularly pelvic exam)
  - Schedule of recommended procedures

- *Women Be Healthy* used with ~500 women with intellectual disabilities
- Satisfaction reported in initial pilot testing

Brandeis University

Study Design

- Randomized control trial (wait-list controls)
- 21 sites across North Carolina
  - Community rehab programs
  - Community colleges
  - Other disability service provider organizations
- Pre-test, post-test interview design
  - Computer-assisted interviews
- Randomized sample at each site
- Curriculum taught by on-site instructors who were not members of the research team (5 hrs of training provided)
- Interviewers did not know the status of the participants
- Post-test interviews mean of 13 days after intervention

Challenges

- How do we ethically enroll women with developmental disabilities in health promotion research?
  - Erroneous assumptions that they cannot consent
  - Erroneous assumptions that their consent is not necessary
    - Research literature is replete with examples of proxy consent

Approach to Recruitment

- Open information sessions at community partner sites for potential participants, guardians, staff
  - In practice, few guardians attended
- Research team:
  - Played video that depicted *Women Be Healthy* activities & included interview with former participant
  - Explained study purpose & research studies in general
  - Explained consent forms
    - Used numerous pictures; designed for people with limited literacy
  - Assisted with signing the consent forms
  - Did not permit on-site staff to "help" women to sign consent forms
- AFTER a consented, her guardian was contacted for consent as well (if necessary)

Description of the Sample (n=203)

Characteristic	Percent of Sample
Race is Black[1]	47%
Lives alone or with partner	8%
Lives in formal residential setting	42%
Lives with family caregiver	50%
Age (mean)	40 years

[1] <2% of the sample were Latina, Asian or Native American

Consent & Enrollment by Guardianship Status

Guardianship Status	Consented	Did not Consent
Independent	86%	14%
Has Guardian	83%	17%

Guardianship Status	Enrolled	Did not Enroll
Independent	86%	14%
Has Guardian	61%	39%

No statistically significant group differences at consent; Significant differences in enrollment (Chi-square = 21.13; p<.001)

Discussion

- This process (required by IRB and the community partners) disempowered women who wanted to participate but were not their own guardians
- We felt that seeking consent or assent ***first*** from the women with disabilities was critical to empower them to choose to participate or not
- We felt that consent rates <100% (achieved at all sites) was a success and indicative that we were not coercive
- Obtaining consent from guardians was challenging
- We do not know the reasons guardians did not consent; anecdotally, we heard that the content was objectionable

Thank you!

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