

ICI ABSTRACT

Enhancing Participation of Older Women in Surgical Trials

Patricia S. Goode for the Pelvic Floor Disorders Network

Introduction and Objective: Recruiting and retaining representative numbers of older participants in trials of therapies that will be prescribed for older persons, particularly surgical therapies, is challenging. Our objective was to describe methodologies used for successful recruitment and retention of older participants in two multisite surgical trials.

Methods: Using qualitative and quantitative methods we examined recruitment and retention of older women with pelvic organ prolapse in two surgical trials: the randomized Colpopexy And Urinary Reductions Efforts (CARE) study (N=343 women; age range 31-83 years) and the Pelvic Symptoms and Patient Satisfaction After Colpocleisis cohort study (N=169 women; age range 64-93 years). Using focus groups, we developed a questionnaire addressing factors facilitating and impeding the recruitment/retention of older study participants and administered it to research staff. Dropout and missed visit rates for older and younger participants were compared using Fisher's Exact Test, with cut-points of 70 and 80 years for the CARE and Colpocleisis studies respectively due to their differential age ranges.

Results: Questionnaires were completed by 23 physician investigators and 11 nurses/coordinators (92% response rate). Respondents indicated it was more difficult to recruit older research participants (32%), obtain informed consent (56%), and retain participants to study completion (50%). Recruitment challenges included family involvement in the participation decision and participants' co-morbidities. Perceived barriers to retention were transportation, family or driver availability, and participant fatigue. Strategies to overcome these barriers included: physician reassurance to older patients that they are viable candidates for study participation, family inclusion in the consent process, scheduling all study visits far in advance with linkage to other medical appointments as possible, not changing previously scheduled visits unless requested by the patient, seeing patients on time, offering rest breaks whenever observing fatigue, personalized attention, escorting patients to other destinations in the clinic or to their car, and extending thanks to both the patient and the family member or driver for their contributions to advancement of women's health care. For long-term follow-up, reminders about the next study visit and its purpose as well as participant newsletters were suggested. In the Colpocleisis study, data quality was challenged when participants struggled to complete telephone interviews due to hearing difficulty as well as memory impairment, i.e. remembering multiple choices, resulting in a change to in-person administration. Strategies to help insure data quality included screening for dementia with a short validated instrument, use of an inexpensive hearing amplification device, good lighting in the interview rooms, large font forms, and large font "flash cards" with the choices listed for multiple choice questions. For both studies, older participants did not have higher dropout rates than younger participants (6% overall). There were no differences in missed in-person visits or telephone interviews between age groups (7% overall).

Conclusions: Use of these strategies could assist investigators in planning surgical trials that successfully enroll and retain older women.

Keywords: Research Subject Recruitment, Gynecologic Surgical Procedures, Geriatric, Patient Participation Rates