

Enhancing Participation of Older Women in Surgical Trials

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Objective: Older participants are often excluded from clinical trials, precluding a representative sample. The purpose of this study was to use qualitative and quantitative methods to examine recruitment and retention of older women with pelvic organ prolapse in two surgical trials: the randomized Colpopexy and Urinary Reductions Efforts (CARE) study and the Longitudinal Pelvic Symptoms and Patient Satisfaction After Colpocleisis cohort study.

Methods: Using focus groups, we developed a questionnaire addressing factors facilitating and impeding recruitment/retention of older study participants and administered it to research staff. Enrollment-to-surgery ratios, missed visit rates, and dropout rates for younger and older participants were compared using Fisher's Exact Test, with cut-points of 70 and 80 years for the CARE and Colpocleisis studies respectively.

Results: Questionnaires were completed by 23 surgeons 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%). Challenges to recruitment included caregiver involvement in the decision to participate and participants' co-morbidities. Perceived barriers to retention were transportation, caregiver availability, and participant fatigue. Data quality was challenged by sensory and cognitive impairment, resulting in a change from telephone interviews to in-person visits in the Colpocleisis study. Older participants did not have higher dropout rates than younger participants. There were no differences in missed in-person visits or telephone interview rates between age groups.

Conclusion: Strategies and the use of additional resources may overcome the challenges of enrolling and retaining older women in surgical trials.