

# Gender Differences in Study Enrollment for a Mechanical Fall Prevention Study

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## Study Objectives:

Concordant with the National Institutes of Health policy on the inclusion of women in clinical research, Emergency Medicine (EM) researchers are focusing more on study designs that adequately represent populations impacted by the topic they study. We set out to see if there were gender differences in patients' willingness to participate in a mechanical fall prevention study and, specifically, what reasons they disclosed for lack of participation.

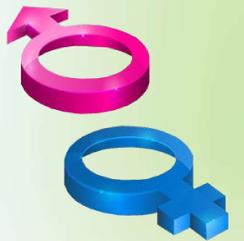
## Methods:

After IRB study approval, a randomized control clinical trial designed as an Emergency Department (ED) intervention to prevent future mechanical falls in high risk individuals was initiated. The trial setting was a suburban Level 1 trauma center in northeastern Pennsylvania with an annual adult ED census of approximately 75,000. A log was kept as potential participants were screened using the Centers for Disease Control's guidelines for identifying individuals who were vulnerable to falls. Those who screened positive were approached for enrollment. Demographics and reasons for not participating that were not specifically inclusion or exclusion criteria were recorded and assessed.



## Results:

Between June, 2014, and January, 2015, 406 adults aged 65 or older were screened for study participation. Of those without missing data, 186 (46%) were male and 218 (53%) were female. Despite having risks such as previous falls, family concerns for falling, and at-risk medications, 68 subjects (16.8%) did not consider themselves or want to be considered as a fall risk (n=27, 12.4% female and n=41, 22.0% male; p=0.01). One-hundred-sixty-six met eligibility criteria and were approached for study enrollment; 48 participants were enrolled. Study participation was independent of gender, with 23 of the eligible participants being female (47.9%) and 25 (52.1%) being male (p=0.25). Of the 118 eligible patients who declined participation, the leading reasons for declination were: Lack of interest (n=37, 31.4%), being admitted to the hospital (n=25, 21.2%) and reported pain (n=15, 12.7%). No differences in proportions were observed between genders for these reasons to decline (p-values >0.05).



## Conclusions:

There were gender-specific differences for subject participation in this trial. In particular, male prospective enrollees were less likely to consider themselves or want to be considered a fall risk. Whether this is due to fear of being stigmatized is unknown and a topic for future investigation. As EM gender-specific research becomes mainstream, researchers will have to carefully deliberate the designs of their trials. Consideration must be given to gender-specific barriers to willingness for study participation and what biases in enrollment they may cause in the selection process, if not controlled for.

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