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Home-Based Exercise and Hip Fracture Rehabilitation – reply

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In Reply

Dr Safer and colleagues identify several variables (vitamin D, nutritional status, and sarcopenia) that were not part of the full baseline assessment in our study. We acknowledge that these are among a number of variables that could potentially be associated with function after hip fracture, and that this could result in confounding if these variables were unevenly distributed between the intervention and control groups.

To minimize the potential for confounding, we used concealed and stratified randomization in the trial, which resulted in the intervention and control groups being balanced in all measures of comorbid conditions, demographic characteristics, impairments, and functional performance. At baseline, no significant differences between the intervention and control group were detected for muscle strength, mobility, or other physical performance measures that are associated with sarcopenia and vitamin D levels in older adults.¹

In addition, in a subset of participants (n = 56) from the trial, nutrition was measured at baseline using a food frequency questionnaire. No significant differences between the intervention and control groups were found for key indicators of nutritional status, including the intake of calories, protein, or vitamin D. Successful randomization within clinical trials addresses the equal distribution of known and unknown covariates. Thus, these findings make it unlikely that there were substantial between-group differences in these unmeasured variables at baseline.

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Conflict of Interest Disclosures: The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Bean reported receiving institutional grants from the National Institutes of Health and travel reimbursement from the American Geriatrics Society. Dr Jette reported holding stock in CRE Care, which is a small business that distributes outcome instruments including the Activity Measure for Post-Acute Care (AM-PAC); and receiving royalties from Boston University for instrument licenses. No other disclosures were reported.

The variables included (and excluded) from the trial were carefully considered when the protocol was developed. The trial was designed to accommodate the needs of older people after hip fracture who had functional limitations at enrollment. Recruitment and retention of participants is challenging in hip fracture clinical trials.² Our priority was to design a trial to reliably measure the key outcome variables but minimize the burden of the assessments on the participants as much as possible to ensure adequate recruitment, full completion of assessments, and long-term retention of participants. All assessments were conducted in the patients' homes, which would have made it difficult to conduct dual-energy X-ray absorptiometry testing for sarcopenia.

We recognize that the control group did receive in-person and telephone-based nutritional education that may improve dietary behaviors and increase consumption of protein and vitamin D, whereas the intervention group did not receive this nutritional education. However, it would be expected that if this did have a clinical effect, it would have biased our findings toward the null hypothesis. Combining the exercise program with a nutrition intervention might have increased the treatment effect, but our intent in this trial was to investigate the efficacy of a home-based program with minimal supervision. A combined intervention would have increased the cost and complexity of the intervention and limited its ability to be easily and widely disseminated.

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