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Improving community ambulation after hip fracture: protocol for a randomised, controlled trial

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Abstract

Introduction—After a hip fracture in older persons, significant disability often remains; dependency in functional activities commonly persists beyond 3 months after surgery. Endurance, dynamic balance, quadriceps strength, and function are compromised, and contribute to an inability to walk independently in the community. In the United States, people aged 65 years and older are eligible to receive Medicare funding for physiotherapy for a limited time after a hip fracture. A goal of outpatient physiotherapy is independent and safe household ambulation 2 to 3 months after surgery. Current Medicare-reimbursed post-hip-fracture rehabilitation fails to return many patients to pre-fracture levels of function. Interventions delivered in the home after usual hip fracture physiotherapy has ended could promote higher levels of functional independence in these frail and older adult patients.

Primary objective—To evaluate the effect of a specific multicomponent physiotherapy intervention (PUSH), compared with a non-specific multi-component control physiotherapy intervention (PULSE), on the ability to ambulate independently in the community 16 weeks after randomisation.

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Design—Parallel, two-group randomised multicentre trial of 210 older adults with a hip fracture assessed at baseline and 16 weeks after randomisation, and at 40 weeks after randomisation for a subset of approximately 150 participants.

Participants and setting—A total of 210 hip fracture patients are being enrolled at three clinical sites and randomised up to 26 weeks after admission. Study inclusion criteria are: closed, non-pathologic, minimal trauma hip fracture with surgical fixation; aged ≥ 60 years at the time of randomisation; community residing at the time of fracture and randomisation; ambulating without human assistance 2 months prior to fracture; and being unable to walk at least 300 m in 6 minutes at baseline. Participants are ineligible if the interventions are deemed to be unsafe or unfeasible, or if the participant has low potential to benefit from the interventions.

Interventions—Participants are randomly assigned to one of two multi-component treatment groups: PUSH or PULSE. PUSH is based on aerobic conditioning, specificity of training, and muscle overload, while PULSE includes transcutaneous electrical nerve stimulation, flexibility activities, and active range of motion exercises. Participants in both groups receive 32 visits in their place of residence from a study physiotherapist (two visits per week on non-consecutive days for 16 weeks). The physiotherapists' adherence to the treatment protocol, and the participants' receipt of the prescribed activities are assessed. Participants also receive counselling from a registered dietician and vitamin D, calcium and multivitamin supplements during the 16-week intervention period.

Measurements—The primary outcome (community ambulation) is the ability to walk 300 m or more in 6 minutes, as assessed by the 6-minute walk test, at 16 weeks after randomisation. Other measures at 16 and 40 weeks include cost-effectiveness, endurance, dynamic balance, walking speed, quadriceps strength, lower extremity function, activities of daily living, balance confidence, quality of life, physical activity, depressive symptoms, increase of ≥ 50 m in distance walked in 6 minutes, cognitive status, and nutritional status.

Analysis—Analyses for all aims will be performed according to the intention-to-treat paradigm. Except for testing of the primary hypothesis, all statistical tests will be two-sided and not adjusted for multiple comparisons. The test of the primary hypothesis (comparing groups on the proportion who are community ambulators at 16 weeks after randomisation) will be based on a one-sided 0.025-level hypothesis test using a procedure consisting of four interim analyses and one final analysis with critical values chosen by a Hwang-Shih-Decani alpha-spending function. Analyses will be performed to test group differences on other outcome measures and to examine the differential impact of PUSH relative to PULSE in subgroups defined by pre-selected participant characteristics. Generalised estimating equations will be used to explore possible delayed or sustained effects in a subset of participants by comparing the difference between PUSH and PULSE in the proportion of community ambulators at 16 weeks with the difference at 40 weeks.

Discussion—This multicentre randomised study will be the first to test whether a home-based multi-component physiotherapy intervention targeting specific precursors of community ambulation (PUSH) is more likely to lead to community ambulation than a home-based non-specific multi-component physiotherapy intervention (PULSE) in older adults after hip fracture. The study will also estimate the potential economic value of the interventions.

Acknowledgments

Trial registration: clinicaltrials.gov. **Registration number**: NCT01783704. **Was this trial prospectively registered?** Yes. **Date of trial registration**: 31 January 2013. **Funded by**: National Institute on Aging. **Funder approval number**: R01 AG035009. **Anticipated completion date**: April 2018. **Provenance**: Not invited. Peer reviewed.