Individually randomised controlled multi-centre trial to determine the clinical and cost effectiveness of a home-based exercise intervention for older people with frailty as extended rehabilitation following acute illness or injury, including embedded process evaluation.

Primary question

- Is the HOPE programme a clinically and cost effective means to improve health related quality of life for frail older people?

Trial Rationale

- Frailty is characterised by reduced biological reserves and vulnerability to adverse outcome
- Most people ≥ 65yrs in hospital have frailty
- Frailty linked with: decline in function, dependency, early readmission and death
- Exercise programmes based on progressive strength training show improved functionality and mobility in people with frailty
- In a pilot study, the HOPE programme showed evidence of benefits to functional mobility (TUGT = 30 secs faster than controls)

Trial Design

- A multi-centre randomised, single-blind, controlled trial comparing the HOPE programme + usual care versus usual care only.
- 718 older people with frailty admitted to acute hospital services will be recruited
- Participants will be recruited on discharge home once routine rehabilitation* pathways have finished
- Outcome measures will be obtained 6 & 12 months after randomisation by the study researchers

Intervention

- 24 week Home-based Older People’s Exercise (HOPE) programme
- Graded and progressive intervention, aimed at improving strength, endurance & balance
- Delivered by NHS physiotherapy teams
- Delivered via weekly contact including 5 face-to-face visits and 19 telephone contacts
- The HOPE programme will extend (not replace) existing NHS rehabilitation pathways after acute hospital admission

Patient Recruitment Pathway

- Patients admitted acutely to recruiting hospital/ward with acute medical illness or injury
- Researcher screens for potential participants (inclusion/exclusion criteria)
- Eligible
- Ineligible
- Decline
- Monitor patient through acute admission and rehabilitation pathway
- Approach to obtain informed consent
- Confirm eligibility complete (CFS, MoCA, TUGT**)
- Ineligible
- Complete baseline assessments (48hrs pre – 72hrs post discharge from rehab)*
- Randomise to trial once discharged from rehabilitation service*
- Consider Carer participation in Process Evaluation
- Usual care control
- Six and twelve month follow-up

Recruiting Centres

- Acute hospital trusts and linked intermediate care services from more than 10 trial sites
- Two geographical areas (Yorkshire and the South West), will recruit to the HERO trial target of 718 participants

Participants

Inclusion:

- Participants will: be older adults (aged ≥ 65yrs) with frailty (CFS level 5-7); be admitted acutely to hospital with medical illness/injury; normally reside in and be discharged to own home from hospital or intermediate care services*; complete TUGT** independently (+/- mobility aid); consent to study; score ≥20 on MoCA**; be able to adhere to intervention

Exclusion:

- Participants will not: be care home residents; have had recent MI or unstable angina (previous 3 months); be terminally ill or receiving palliative care; have been referred for condition specific rehabilitation programmes (i.e. lengthy rehabilitation programmes like cardiac, pulmonary, stroke, amputee, falls rehabilitation programmes)

Trial Outcomes

Primary Outcome

- Health related quality of life (SF36) measured at 12 months

Secondary Outcomes

- Mental health measured using mental health component summary of SF36
- Functional independence measured using Barthel ADL Index; Nottingham Extended Activities of Daily Living Scale
- Hospitalisation rates, care home admission rates, falls and overall health and social care resource use.
- Cost effectiveness analysis
- Mixed methods Process Evaluation

Main Trial Contacts:

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* Rehabilitation service includes acute hospital & intermediate care (bed and home based services), linked to the acute hospitalisation ** CFS - Clinical Frailty Scale; MoCA – Montreal Cognitive Assessment; TUGT – Timed Up and Go Test

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