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HERO - Home-based extended rehabilitation for older people

Submission date 03/04/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/04/2017	**Overall study status** Completed	
Last Edited 11/10/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Frailty is common condition in older adults. As people age, their bodies change and they can lose their inbuilt reserves. These changes mean that older people with frailty can become less mobile and unable to carry out day-to-day tasks when they have a minor illness, such as an infection, or an injury, such as a fracture. Older people with frailty are therefore likely to need a period of rehabilitation to improve overall muscle strength and function before returning home from hospital. Current NHS practice is for a relatively short rehabilitation period and research suggests any initial improvement during this period of rehabilitation may not be sustained. This study is looking at a new exercise programme called developed the Home-based Older People's Exercise (HOPE) programme, which involves a 24-week programme of exercises delivered via a manual under the guidance of a trained therapist. The aim of this study is to find out if the HOPE programme can improve quality of life for older people with frailty who have been discharged home from hospital or from intermediate care (community-based rehabilitation services) after illness or injury.

Who can participate?
Frail older adults who have been admitted to hospital following a sudden illness or injury.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive usual care only, which may differ according to individual needs and the hospital they have been admitted to. Those in the second group receive usual care with the addition of the HOPE programme. This involves taking part in a 12 week exercise programme exercises delivered via a manual under the guidance of a trained therapist, followed by 12 weeks of telephone-based support. At the start of the study and then after six and 12 months, participants in both groups complete a range of questionnaires in order to assess their functional abikity and quality of life.

What are the possible benefits and risks of participating?
Patients who take part in the exercise programme may benefit through an improvement in their functional abilities at home. This could lead to greater independence in the home environment and stabilise their frailty, potentially leading to a reduction in hospital admission and allowing them to continue living at home for as long as possible. It is not anticipated that the exercise

programme will cause significant pain, distress or inconvenience. However it is possible that exercises may result in minor discomfort, such as sore muscles. It is also possible that increased functional and walking ability could increase the risk of falls due to increased mobilisation, however therapists will work to increase muscle strength, and with practice may reduce risk of falls.

Where is the study run from?
Bradford Royal Infirmary and at least nine other NHS hospitals in Yorkshire and the South West of England (UK)

When is the study starting and how long is it expected to run for?
March 2017 to May 2023

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mr Matthew Prescott (Trial Manager)
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Contact information

Type(s)
Public

Contact name
Mr Matthew Prescott

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Additional identifiers

Protocol serial number
34138

Study information

Scientific Title

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

Acronym
HERO

Study objectives
The aim of this study is 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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 17/YH/0097

Study design
Randomised; Interventional; Design type: Treatment, Complex Intervention, Physical, Rehabilitation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Frailty

Interventions
Participants will be individually randomised using an automated 24 hour randomisation service on a 1.25:1 allocation ratio to either HOPE extended rehabilitation programme plus Usual Care, or Usual Care only. The randomisation service will use a computer generated minimisation programme incorporating a random element and stratification factors.

Intervention group: Participants receive the HOPE Extended Rehabilitation programme plus usual care. The HOPE programme is a 24-week home-based manualised, graded, progressive exercise intervention aimed at improving strength, endurance and balance, delivered by community therapy staff. The manual consists of five sections:
1. Information
2. Safety tips
3. Good posture
4. Exercises
5. Staying on track.
Following the 12-week programme participants will receive a further 12 weeks of telephone-based support for intervention sustainability. The core constituents of the HOPE programme are strengthening exercises for the muscle groups required for basic mobility skills like getting out of bed, standing up from a chair, walking a short distance and getting off the toilet. The

exercises require no special equipment and can be performed without professional supervision. At the beginning of the intervention participants are requested to perform five repetitions of each exercise in the routine. This progresses to 10 and then 15 repetitions as performance improves. The exercise routine takes less than 15 minutes to complete, and participants are requested to complete the routine 3 times a day on 5 days of the week. Progression is by increasing repetitions, introducing new exercises or advancing to the next HOPE programme level. In accordance with the pragmatic study design, and to best reflect clinical practice, the study protocol does not restrict access/referral to usual care services. Additional interventions during study participation will be documented as part of the usual care review.

Control group: Participants receive usual care only. Usual care is defined as 'The wide range of care that is provided in a community whether it is adequate or not, without a normative judgment'. Usual care will be provided by primary care, secondary care, community and social services and will be available to both intervention and control participants.

Participants in both groups are followed up after 6 and 12 months. Assessments can be completed by post, telephone, and face-to-face dependent upon the participant's needs. CTRU will co-ordinate follow-up assessments, confirming survival status and address, and determining the appropriate method of contact. Participants that require telephone or face-to-face contact will be highlighted to the recruiting team (CRN/local Research) to ensure continuity of care. Follow-up assessments will be completed by a blinded Researcher (where relevant), with the method of collection and Researchers completing information (where applicable) documented on data collection forms.

Intervention Type
Other

Primary outcome(s)
Physical Component Summary (PCS) derived from the Short Form 36 item health questionnaire (SF36) at baseline, 6 and 12 months.

Key secondary outcome(s))
1. Activities of daily living using the Barthel Index of activities of daily living and the Nottingham Extended Activities of Daily Living (NEADL) at baseline, 6 and 12 months
2. Quality of Life assessed using the EuroQol 5-Dimension Health Questionnaire (EQ-5D-5L) at baseline, 6 and 12 months
3. Healthcare Resource (i.e. hospital visits, GP appointments) assessed using the Healthcare Resource Use at baseline, 6 and 12 months
4. Mental Health assessed using the SF36 Mental Component Summary (MCS) at baseline, 6 and 12 months
5. Cost effectiveness assessed using the Short-Form health survey 6 dimension score (SF6D) at baseline, 6 and 12 months
6. Intervention delivery data (adherence) will be collected from HOPE trained therapists in the form of a Therapy Record completed weekly over 24 weeks per participant
7. Exercise is assesed using a weekly exercise diary kept during the course of intervention delivery (24 weeks)

Completion date
31/05/2023

Eligibility

Key inclusion criteria
1. Age 65 years and over
2. Admitted to elderly medicine / trauma & orthopaedics wards following acute illness or injury then discharged home from hospital or from intermediate care
3. Frailty, identified using a score of 5-7 on the 9-item Clinical Frailty Scale (CFS)
4. Mobility, identified by ability to complete the TUGT without additional external support (other than usual walking aids)
5. Willing and able to give informed consent to participate in the study or consultee declaration where the patient lacks capacity
6. Able to communicate by telephone (to support intervention delivery, and follow-up assessments - dependent upon allocation and method of completion)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
743

Key exclusion criteria
1. Permanent care home residents (but not those occupying temporary rehabilitation beds within a care home as part of intermediate care services)
2. Moderate/severe dementia at baseline* (defined as Montreal Cognitive Assessment test < 20)
3. Severe, disabling stroke at baseline* (defined as new or previous stroke with Barthel Index < 9)
4. Recent (< 3 months prior randomisation) myocardial infarction, or unstable angina
5. Another household member in the study
6. Very severe frailty (defined as score of 8 on CFS)
7. Terminally ill (defined as score of 9 on CFS)
8. Receiving palliative care
9. Referral at discharge for condition-specific rehabilitation (e.g. pulmonary rehabilitation, stroke rehabilitation)
10. Currently participating in HERO or another contraindicated study

Date of first enrolment
01/12/2017

Date of final enrolment
12/08/2021

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
St James' University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Royal Devon and Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
Harrogate District Hospital
Lancaster Park Road
Harrogate
United Kingdom
HG2 7SX

Study participating centre
Mid Yorkshire Hospital
Rowan House
Aberford Road
Wakefield
United Kingdom
WF1 4EE

Study participating centre
Hull University Teaching Hospitals NHS Trust
Alderson House
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Airedale NHS Foundation Trust
Skipton Road
Keighley
Bradford
United Kingdom
BD20 6TD

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 23/08/2022:
De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.

CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security), and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.

The CTRU encourages a collaborative approach to data sharing, and believes it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key

trial documents and any other information required to understand and reuse the released datasets.

The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree suitable requirements for release.

Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from CTRU-DataAccess@leeds.ac.uk. Data will be shared according to a controlled-access approach. Data will only be shared for participants who have given consent to use their data for secondary research. Requests will be reviewed by relevant stakeholders. No data will be released before an appropriate agreement is in place setting out the conditions of release.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	version 1.0	08/10/2024	11/10/2024	Yes	No
Protocol article		08/11/2021	23/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	A secondary analysis of the embedded process evaluation	23/05/2024	04/06/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes