ISRCTN13270387 https://doi.org/10.1186/ISRCTN13270387

A feasibility study investigating a programme to improve patient recovery following hip fracture through caregiver support

Submission date
16/07/2020

Recruitment status
No longer recruiting

Registration date
29/10/2020

Overall study status
Completed

Last Edited
19/11/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
A broken hip (hip fracture) is a common injury in older people. Not all people recover well, with most people less mobile and less independent afterward. Family members or friends often take on roles as caregivers, helping in tasks such as washing, dressing, cooking, and shopping, once their relative or friend is home from the hospital. Unfortunately, caregivers are often under-prepared to do this. They are left to work out what to do themselves, and often ask the patient to do less than they could do for fear of causing harm. This can create stress for patients and caregivers and may mean that patients do not recover as well as or as quickly as possible. A training programme to guide caregivers on what to do before patients are discharged home could solve many of these problems and improve outcomes.

The aim of this study is to conduct a feasibility study to see if a caregiver training programme, designed by health professionals and patients, can be provided in an NHS setting following hip fracture surgery, and how a future trial may be designed.

Who can participate?
In this study, people who have had an operation to fix their hip fracture, and one of their friend /family members who will be the patient's caregiver is able to participate.

What does the study involve?
Whilst on the hospital ward, people who have had an operation to fix their hip fracture will be introduced to the study and, if they wish, will be asked to sign a consent form. These individual's caregivers will also be asked at the same time to do this. If both sign their consent forms, they will join the study and will be asked to complete some questionnaires on their health and wellbeing. This should take about 30 minutes.

A researcher will then enter the patient's details into a computer and a computer program will make a decision about which group you will be in whilst in the study. Patients will be allocated to

a Usual Care group or the HIP HELPER group. This allocation is made by chance, rather like the toss of a coin. This is important because it ensures that the treatments are tested fairly and no one can guess the group the computer puts you into.

For patients who are in the HIP HELPER group, a member of the HIP HELPER team (ward physiotherapist, occupational therapist or nurse) will arrange a time convenient for the patient, caregiver, and themselves to start the skills and support training. This will start by 6 days after the patient's hip fracture operation. There will be 3 in total before the patient is discharged home. In these 3 sessions, the HIP HELPER health professional will teach both the caregiver and patient exercises to help the recovery after hip fracture, increase confidence in how the caregiver can support patients in walking, getting up from a chair, from a bed or in getting dressed. The HIP HELPER health professionals will also provide advice and guidance on what to expect during the recovery, how to manage problems that often arise during the first few weeks after discharge, and answer any questions caregivers or patients may have. Caregivers and patients will be provided with a Workbook to provide written advice and detailed exercises and activities which may help recovery. Each session will be done within the hospital ward or a side room within the therapy department. Each session will last no longer than 1 hour.

Once the patient has gone home, the HIP HELPER health professionals will phone the caregiver and patient once on Week 1, 3, and 6 after discharge to provide more advice and support and answer any further questions.
Usual NHS Care Group

Patients who are allocated to the Usual Care group will be provided with the usual NHS care on the hospital ward and provided with the usual advice on recovery on discharge from the hospital.

4 months after the hip fracture operation, both the patient and the caregiver will be sent some questionnaires in the post. These will take about 30 minutes to complete. Once the assessments have been completed that is the end of the study for them.

To understand more about people's experiences of being involved in this study, we will invite some participants (patients and caregivers) to have an interview with a researcher. This will involve a face-to-face discussion with one of the study researchers to ask about their experiences of being in the study including the assessments and treatments. This will help work out if a bigger study could be improved on. These meetings will last a maximum of 1 hour and will be in a location convenient to the patient and caregiver participants. Only 15 patients are required for the interviews. Taking part in this part of the study is entirely optional.

What are the possible benefits and risks of participating?
It is not known what the results of the study will be. This is why this study s being conducted.

The study will find out if it is possible to do a large trial investigating caregiving skills and training treatment for people who have had an operation after a hip fracture and their friends and family who may support (caregivers) during the recovery. If this study indicates that a larger study would be feasible, then this larger study will be planned. The results of that larger study would then be able to inform healthcare professionals if the HIP HELPER intervention is effective or not.

There may not be any benefit in taking part in this study. However, research like this helps to continually improve the treatments and care provided to all patients now and in the future by collecting information on what may or may not help.

There are only minimal risks involved in this research. There is a possible risk of patients feeling a little sore after exercising or walking with the HIP HELPER health professionals support and guidance. However patients will be guided by their health professionals and will be able to seek their opinions about bone, joint and muscle soreness recovering so they will be able to modify patient activities if needed.

Where is the study run from?
Norwich Clinical Trials Unit within the University of East Anglia (UK) and 4 NHS hospitals across England.

When is the study starting and how long is it expected to run for?
September 2020 to September 2022

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

Who is the main contact?
Dr Toby Smith
toby.smith@uea.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Toby Smith

ORCID ID
http://orcid.org/0000-0003-1673-2954

Contact details
Faculty of Medicine and Health Sciences
Queen's Building
School of Health Sciences
University of East Anglia
Norwich
United Kingdom
NR4 7TJ
+44 (0)1603.591686
toby.smith@uea.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
287314

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 287314

Study information

Scientific Title
A feasibility study to assess the design of a multi-centre randomised controlled trial of the clinical and cost-effectiveness of a caregiving intervention for people following hip fracture surgery

Acronym
HIP HELPER

Study objectives
What is the feasibility of a multi-centre randomised controlled trial design to test the clinical and cost-effectiveness of a caregiving intervention for people following hip fracture surgery?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/10/2020, North East- Newcastle & North Tyneside 1 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre Holland Drive Newcastle upon Tyne NE2 4NQ; +44 (0) 207 104 8084; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 20/NE/0213

Study design
Mixed-methods feasibility study comprising of a parallel, multi-centre, randomized controlled trial and an embedded qualitative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Hip fracture which is surgically managed

Interventions

Patient and caregiver dyads will be randomized to receive the intervention arm or control arm, using a secure online randomization service from the Norwich Clinical Trial Research Unit. Randomization will be at the individual dyad level (1:1) by minimization for: hospital; presence of patient cognitive impairment (AMTS score of either <8, or ≥8 points); age (either <75, or ≥75 years); whether the caregiver lives in the same house as the patient; and by whether the caregiver has been a caregiver previous to this hospital episode. Due to the participatory nature of rehabilitation, it will not be possible to blind patients, caregivers or treating health professionals to group allocation.

The intervention arm will receive standard NHS care plus three, 1-hour, one-to-one training sessions, delivered by a nurse, physiotherapist or occupational therapist in an in-patient hospital setting and 3 telephone call interventions post-discharge (or six video conference consultations post-discharge if hospital visiting is prohibited). Training in the hospital consists of practical skills taught to caregivers on transfers and walking; education to patients and caregivers on recovery goal setting and expectations, pacing and stress management techniques for caregivers and patients and the provision of the HIP HELPER workbook providing information on recovery, worksheets, goal-setting plans and checklists to inform both caregivers and patients on a 'good' recovery and how to facilitate this.

The three HIP HELPER in-patient sessions will be delivered on the hospital ward, prior to hospital discharge. These will be delivered to both patients and caregivers by either a nurse, physiotherapist or occupational therapist depending on staffing on the ward. Each session will take a maximum of 60 min.

Session 1 will involve:
1. Practical skills to teach caregivers how to aid transfer from bed to chair and how to safely walk with the patient using walking aids.
2. Education on patient-caregiver shared goal-setting in the early post-operative period.
3. Teaching principles of patient pacing and behaviour modification.
4. Explanation of normal recovery pathways and expectations on functional recovery.

Session 2 will involve:
1. Progress and re-enforce practical skills to teach caregivers how to aid bed-chair (and the like) transfers, mobility, washing, dressing and personal activities of daily living dependent on patient-caregiver needs.
2. Revision on constructed patient-caregiver shared goals and links to behaviour modification to support the initial postdischarge week.
3. Develop knowledge on caregiver stress management skills linked to goals in the first two post-operative weeks.

Session 3 will involve:
1. Revision on practical skills such as transfers, mobility, stress management, pacing and behaviour modification.
2. Working through case-study scenarios of the recovery pathway in the initial 6 weeks post-discharge, to re-enforce knowledge and critique competencies on HIP HELPER skills.
3. Introduction and explanation of the HIP HELPER Workbook, highlighting material on normal recovery, goal setting, problem-solving, the checklist for recovery and environmental hazard assessment for falls. The health professionals delivering the HIP HELPER intervention will explain how the workbook can be used and will highlight specific exercises which may be most important in the short and longer-term, for a collaborative, tailored plan for that patient-

caregiver dyad. This will promote wider physical activity action plans out of home, to help address social isolation and loneliness for both patients and caregivers.
4. Confirmation of dates for HIP HELPER Telephone Booster calls.

Throughout the three sessions, the HIP HELPER health professional will monitor the patient-caregiver competencies, providing continual feedback and critique to support the training.

Following hospital discharge, a HIP HELPER health professional will telephone each caregiver and patient (dependent on cognitive impairment) as a dyad during Week 1, 3 and 6 post-hospital discharge. Each call will be a maximum of 20 minutes. Topics covered in each call will include: recovery progress and current status based on patient-caregiver shared goals; discussion on HIP HELPER Workbook use and progress including home hazard falls assessment; problem-solving solutions and strategies; advice on any recovery difficulties and sign-posting to other health professionals when appropriate, based on NICE guidelines; and support to create collaborative goals for continued recovery.

Patients with cognitive impairment will be involved throughout the in-patient face-to-face sessions and with workbook and telephone activities. However, the degree of cognitive impairment will determine how actively engaged the patient is to the training element as determined by the HIP HELPER health professional. This variability in patient participation due to cognitive impairment will be recorded as a feasibility outcome.

HIP HELPER Programme Health Professional Training
Formal training on the HIP HELPER programme to the health professionals who will deliver the intervention is essential. This will aid standardisation across the sites and minimise the risk of contamination through controlling training only to those delegated to these tasks.

A member of the ward physiotherapy, occupational therapy and nursing team will be trained in the HIP HELPER programme during a formal training day. This will consist of: an introduction to the study and processes; teaching on the background, objectives and content of the programme; practical application (with role-playing) of the three HIP HELPER in-patient and telephone booster sessions; and explanation on the documentation for the HIP HELPER programme. This will be delivered by the research team who developed the HIP HELPER programme. Each health professional will be asked to self-assess their competency in delivering the intervention and monitored by team members who delivered the training. This competency will then be re-examined during the planned Quality Assurance and Monitoring programme.

The Control Group will receive standard NHS care. Participants randomised to this group will receive physiotherapy, occupational therapy and nursing care aimed to facilitate a safe hospital discharge and recovery with activities of daily living.

These health professionals provide support and advice during the hospital stay and prior to discharge on wound care, expectations for medical follow-up and advice on medication taking and self-care as required. There is no routine ‘training’ or hands-on skills taught to caregivers. Post-discharge physiotherapy and occupational therapy are not routinely provided for this population. Following standard NHS care, patients and their caregivers will not receive the HIP HELPER programme, with no additional training either as an in-patient or out-patient. Treatment logs will be used to record the components of standard care across the 4 sites. Where health professionals clinically reason that post-discharge therapy is required, this will be provided through NHS services and recorded. These participants and/or caregivers will be required to document the frequency, duration and nature of this intervention.

Respecting the pragmatic nature of this study design, patient-caregiver dyads in either group will not be asked to desist from receiving other forms of treatment during the study such as continuing rehabilitation, general practitioner consultations, medication changes or alternative treatments if required. Use of these treatments will be recorded through a health resource use questionnaire.
Contamination and Quality Control

The risk of contamination will be controlled by ensuring:
1. Only health professionals delegated to deliver the HIP HELPER programme will be taught the intervention and have the specific skills required to provide this. These trained health professionals will be told to only provide the HIP HELPER programme (both the training sessions and telephone boosters) to those patient-caregiver dyads randomised to that group.
2. The three HIP HELPER Booster Telephone Calls will only be made to dyads allocated to that group 3. The HIP HELPER Workbook will only be provided to those in the HIP HELPER group

Assessment will take place at baseline and 4 months follow up.

Intervention Type
Other

Primary outcome measure
1. Ability to screen and identify potential participants (patients and caregivers) across the 4 sites measured using screening log data at baseline and 4 months follow-up
2. Willingness of eligible participants to consent and be randomised to intervention measured using semi-structured interviews at baseline and 4 months follow-up
3. Fidelity of healthcare professionals to deliver the experimental intervention and caregivers to adopt these post-discharge measured using semi-structured telephone interviews at baseline and 4 months follow-up
4. Risk of intervention contamination measured using semi-structured interviews at baseline and 4 months follow-up

Secondary outcome measures
1. Patients without cognitive impairment will be assessed for the following at baseline and 4 months follow-up:
1.1. Health resource use using the 5-level EuroQol 5-Dimension (EQ-5D-5L) health resource use questionnaire
1.2. Independence in activities of daily living using the Nottingham Activities of Daily Living Scale (NEADL)
1.3. Perceived self-efficacy using the General Self-Efficacy questionnaire
1.4. Depression symptoms using the Center for Epidemiologic Studies Depression Scale (CES-D)
1.5. Pain using the Numerical rating scale (NRS) for pain
1.6. Complications and adverse events including mortality using semi-structured interviews
2. All caregivers will be assessed for the following at baseline and 4 months follow-up:
2.1. Health resource use of patients using the 5-level EuroQol 5-Dimension (EQ-5D-5L) health resource use questionnaire
2.2. Depression symptoms of patients using the Center for Epidemiologic Studies Depression Scale (CES-D)
2.3. Caregiver burden using the Short Sense of Competence Questionnaire (SSCQ)
2.4. Health resource use and caregiver time use of patients, using the Resource Utilization in Dementia (RUD) questionnaire
2.5. Complications and adverse events of patients including mortality using semi-structured

interviews
2.6. Patient and caregiver residential status using semi-structured interviews
3. Caregivers of patients with cognitive impairment will be assessed for the following at baseline and 4 months follow-up:
3.1. Functional ability of patients in activities of daily living using the Disability Assessment for Dementia Scale-6 (DADS-6) functional score
3.2. Neuropsychiatric symptoms of patients using the Neuropsychiatry Inventory (NPI) questionnaire
3.3. Pain of patients using the Abbey Pain Scale

Overall study start date
01/09/2020

Completion date
30/09/2022

Eligibility

Key inclusion criteria
Patients:
1. Community-dwelling
2. With or without cognitive impairment
3. Hip fracture which is operatively treated
4. Have an informal caregiver who is willing to provide support at home during recovery from surgery
5. A minimum of 10 patients with cognitive impairment, defined as Abbreviated Mental Test Score (AMTS) ≤8 points, will be recruited per group

Patients' caregivers:
1. In the case of a patient with multiple caregivers, a single caregiver, nominated by the patient or consultee, ‘principal’ caregiver will be selected

Embedded qualitative study:
1. Patient-caregiver dyads and physiotherapists, occupational therapists and nursing staff who deliver the HIP HELPER intervention who consent to participate in the qualitative study
2. Patient cognitive impairment in 30% of dyads includedin the qualitative study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 pairs of patient participants and their caregivers, and 12 healthcare professionals.

Total final enrolment

Key exclusion criteria
1. Acute, unstable, or terminal illness which would make participation in the rehabilitation strategies contraindicated and/or impractical
2. Expected by the clinical team to be discharged to a care home (residential or nursing) after their hospital admission
3. Principal (main) caregivers who have cognitive impairment (AMTS <8 points)

Date of first enrolment
12/04/2021

Date of final enrolment
28/02/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sunderland Royal Infirmary
Sunderland Royal Infirmary
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
James Paget University Hospitals NHS Foundation Trust
Lowestoft Road
Gorleston
Great Yarmouth
United Kingdom
NR31 6LA

Sponsor information

Organisation
University of East Anglia

Sponsor details
Registry and Council House
Norwich
England
United Kingdom
NR4 7TJ
+44 (0)1603 591482
t.moulton@uea.ac.uk

Sponsor type
University/education

Website
https://www.uea.ac.uk/

ROR
https://ror.org/026k5mg93

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

Publication and dissemination plan
Results will be provided to health professionals and patients through published articles in a peer-reviewed journal, conference presentations, social media blogs and newsletters. This will help the design of a larger trial to test the HIP HELPER programme in a wider population.

Intention to publish date
01/01/2024

Individual participant data (IPD) sharing plan
Data are available upon reasonable request. This includes access to the full protocol, anonymised participant level dataset and statistical code. Access to the de-identified dataset for purposes of research other than this study would be at the discretion of the Chief Investigator, Professor Toby Smith, and Norwich CTU. Requests for the de-identified dataset generated during the current study should be made to the Chief Investigator, Professor Toby Smith (toby.o.smith@warwick.ac.uk), or Norwich CTU (NorwichCTU@uea.ac.uk). Professor Toby Smith and Norwich CTU will consider requests once the main results from the study have been published up until 31/12/2028.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/11/2021	04/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Interim results article	Qualitative results from dyad interviews	17/11/2023	20/11/2023	Yes	No
Results article		09/12/2023	11/12/2023	Yes	No
Results article	Qualitative results	15/11/2024	19/11/2024	Yes	No