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Community-based rehabilitation for the elderly following hip fracture

Submission date
20/11/2018

Recruitment status
No longer recruiting

Registration date
23/11/2018

Overall study status
Completed

Last Edited
06/06/2025

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hip fracture is a common, major health problem in old age, especially for people with other health problems or who are frail. Some patients who suffer this type of fracture need surgery to repair it. They take a long time to recover, and others may not recover fully. Once patients are discharged, the routine care they receive can vary depending on local NHS policy. Some may not find it as easy to live independently afterwards.
An enhanced rehabilitation package has been designed for patients who are recovering from this surgery, which is delivered in addition to standard NHS care. FEMuR III will compare the enhanced package with standard NHS care to see if it can improve recovery for patients. The study will collect information that will hopefully show the best way to treat patients who are recovering from hip repair surgery after a fracture.
The enhanced rehabilitation package is made specifically for each patient and it is thought that this should improve their recovery. It is considered that the package should work better if it includes physiotherapy (to help patients recover movement), occupational therapy (to help patients with activities associated with daily living) and also provides tools to help build confidence and mood.

Who can participate?
People aged 60 years or older who have recently had a hip fracture repaired by replacement arthroplasty or hip fixation

What does the study involve?
This study will compare the enhanced rehabilitation package to standard NHS care and participants will be randomly allocated to receive one of these care packages. The enhanced rehabilitation package mixes extra therapy with self-help tools, which aim to help patients improve aspects of their own recovery, for example, building confidence in trying exercises by themselves. The enhanced rehabilitation package that has been designed involves additional rehabilitation at follow up visits. Participants will be given a workbook and a goal-setting diary to complete during the first few months of recovery. These follow up visits and the diary will help to collect information about their recovery.
Participants will have their progress followed-up in the 12 months after surgery and information will also be collected during that time so that the study can see how participants are.

What are the benefits and risks of taking part?
It is not known whether standard NHS care or the enhanced rehabilitation package is best, but it is anticipated that both will aid patients recovery following surgery. The aim is that the results from the study will help doctors, therapists, patients and their carers in the future when making decisions about treatment.
There are no foreseeable significant risks involved in taking part in FEMuR III. All of the physical exercises suggested are used in normal rehabilitation after hip fracture and will be supervised by trained healthcare professionals to minimise any risk. The enhanced rehabilitation package will take up more of participants time due to additional therapy sessions and having to complete the diary.

Where is the study run from?
The study is run from the Clinical Trials Research Centre at the University of Liverpool (UK) and will take place at 12 hospitals across the UK

When is the study starting and how long is it expected to run for?
August 2018 to January 2022

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

Who is the main contact?
Claire Soady
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Study website
https://www.Femur3study.co.uk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number
246828

ClinicalTrials.gov number

Secondary identifying numbers
38492, IRAS 246828

Study information

Scientific Title
Fracture in the Elderly Multidisciplinary Rehabilitation - Phase III (FEMuR III): a definitive randomised controlled trial and economic evaluation of a community-based rehabilitation package following hip fracture

Acronym
FEMuR III

Study objectives
The primary objective is to determine the effectiveness of an enhanced rehabilitation programme following surgical repair of proximal femoral fracture in older people compared with usual care, in terms of the performance of activities of daily living at the 52 week follow-up.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/10/2018, North East – Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 1048084; tyneandwearsouth.rec@hra.nhs.uk), ref: 18/NE/0300

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Physical, Rehabilitation

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Hip fracture

Interventions
Participants will be randomly allocated to the enhanced rehabilitation arm or the usual care arm. Randomisation is performed using a secure 24 hour web based randomisation program. Participants will be asked to complete a range of questionnaires at the baseline.
The intervention will be delivered by community teams either at the participants home or in a community hospital up to 4 months post start of intervention. Participants allocated to the usual care arm will receive usual care as per standard local NHS practice. Participants in the enhanced rehabilitation arm will receive standard rehabilitation care as per local NHS practice, plus up to 6 extra rehabilitation sessions.
All participants will be asked to record hospital admissions, concomitant medications and other visits to healthcare professionals. Participants in the enhanced rehabilitation arm will be provided with a workbook and a goal setting diary. The objectives of the workbook and diary are to:
1. Give patients better understanding of what has happened physically to them and broadly what to expect during their recovery
2. Provide information and contact details on rehabilitation services that are available to them as they progress in their rehabilitation (e.g. Intermediate care teams, social services enablement teams, outpatient physiotherapy, falls prevention groups, national exercise referral services). The information will enable patients to ask the therapist they are working with or their GP about available services and what benefit they might offer, and at what stages they would be most beneficial, and to contact the services themselves for more information
3. Enable them to work collaboratively with their therapist to set goals and monitor progress of their rehabilitation in order to improve the quality and the quantity of the physical and activities of daily living exercises they are performing
4. Improve patients' self-efficacy:
4.1. Encourage the patient to set goals they want to achieve and to discuss them with their therapist
4.2. Monitor the progress towards/attainment of these goals through keeping a diary of progress. This will provide feedback in the form of both self-reflection and reflection with the therapist. Feedback is recognised as an important component for improving self-efficacy
5. Improve communication between hospital and community services, and between the patient and all the different professionals and services they come into contact with during their rehabilitation.
6. Reduce patients fear of falling by improving self-efficacy for avoiding falls/ exercising, and providing information about local falls prevention services
7. Signpost patients to local follow-on community programmes such as exercise referral and falls prevention services with contact details.
The RSPO will visit each participant at the 4 month point and participants will be asked to complete the same questionnaires as at the baseline.
After the 4 month follow up visit and at a convenient date at time for trial participants, 30 participants from the usual care arm and 30 participants from the enhanced rehabilitation arm (together with up to 30 of their carers for both arms) will be contacted by telephone by a qualitative researcher to ask patients and carers questions about their experiences and views about their involvement in the trial, these interviews will be recorded so that they can be analysed following the call, consent for this will be obtained from each participant and their

carer.
The RSPO will visit each participant at the 12 month point and participants will be asked to complete the same questionnaires as at the baseline.
The 12 month visit will conclude trial participation in both arms for participants and their carers.
Throughout the trial safety monitoring will take place, adverse events will be reported routinely and serious adverse events will be reported to the Clinical Trials Research Centre (CTRC).

Intervention Type
Behavioural

Primary outcome measure
Difference in performance of activities of daily living, assessed using the Nottingham Extended Activities of Daily Living (NEADL) scale at the baseline, after 4 months and after 12 months

Secondary outcome measures
Current secondary outcome measures as of 21/03/2025:
The following will be compared between the enhanced rehabilitation programme and usual care:
1. Cost-effectiveness of the enhanced rehabilitation programme compared with usual care, assessed using a cost-utility analysis from a health service and personal social care perspective using the following:
1.1. EuroQol EQ-5D-3L, completed at the baseline and after 17 and 52 weeks of follow-up
1.2. Bespoke Client Service Receipt Inventory (CSRI)
2. Effectiveness in terms of performance of activities of daily living after 17 weeks, assessed using the NEADL scale at the baseline and after 17 weeks follow-up
3. Effectiveness in terms of anxiety and depression, assessed using the Hospital Anxiety and Depression Scale (HADS) at the baseline and after 17 and 52 weeks of follow-up
4. Changes in self-efficacy, hip pain, cognitive function measured using the Abbreviated Mental Test Score (AMTS), fear of falling and physical function as potential mediators for improving activities of daily living:
4.1. Self-efficacy, assessed using the International Self-Efficacy Scale at the baseline and after 17 and 52 weeks of follow-up
4.2. Hip pain, assessed using a Visual Analogue Scale (VAS) at the baseline and after 17 and 52 weeks of follow-up
4.3. Fear of falling, assessed using a Visual Analogue Scale (VAS) at the baseline and after 17 and 52 weeks of follow-up
4.4. Physical function, assessed using grip strength with a hand dynamometer and the Short Physical Performance Battery (SPPB) at the baseline and after 17 and 52 weeks of follow-up
5. Change in caregiver strain, anxiety and depression in carers, assessed using the following at the baseline and after 17 and 52 weeks of follow-up:
5.1. Carer Strain Index (CSI)
5.2. Hospital Anxiety and Depression Scale (HADS)
6. Mechanisms and processes that explain the implementation and impacts of the enhanced rehabilitation programme, assessed using a process evaluation including:
6.1. Qualitative interviews with a purposive sample of participants in each trial arm after the 17-week assessment
6.2. Qualitative interviews with the therapists delivering the enhanced rehabilitation programme after the 17-week assessment
6.3. Routinely collected data that therapists complete on their information management systems

Previous secondary outcome measures:
The following will be compared between the enhanced rehabilitation programme and usual care:

1. Cost-effectiveness of the enhanced rehabilitation programme compared with usual care, assessed using a cost-utility analysis from a health service and personal social care perspective using the following:
1.1. EuroQol EQ-5D-3L, completed at the baseline and after 17 and 52 weeks of follow-up
1.2. Bespoke Client Service Receipt Inventory (CSRI)
2. Effectiveness in terms of performance of activities of daily living after 17 weeks, assessed using the NEADL scale at the baseline and after 17 weeks follow-up
3. Effectiveness in terms of anxiety and depression, assessed using the Hospital Anxiety and Depression Scale (HADS) at the baseline and after 17 and 52 weeks of follow-up
4. Changes in self-efficacy, hip pain, cognitive function, fear of falling and physical function as potential mediators for improving activities of daily living:
4.1. Self-efficacy, assessed using the International Self-Efficacy Scale at the baseline and after 17 and 52 weeks of follow-up
4.2. Hip pain, assessed using a Visual Analogue Scale (VAS) at the baseline and after 17 and 52 weeks of follow-up
4.3. Fear of falling, assessed using a Visual Analogue Scale (VAS) at the baseline and after 17 and 52 weeks of follow-up
4.4. Physical function, assessed using the Short Physical Performance Battery (SPPB) at the baseline and after 17 and 52 weeks of follow-up
5. Change in caregiver strain, anxiety and depression in carers, assessed using the following at the baseline and after 17 and 52 weeks of follow-up:
5.1. Carer Strain Index (CSI)
5.2. Hospital Anxiety and Depression Scale (HADS)
6. Mechanisms and processes that explain the implementation and impacts of the enhanced rehabilitation programme, assessed using a process evaluation including:
6.1. Qualitative interviews with a purposive sample of participants in each trial arm after the 17-week assessment
6.2. Qualitative interviews with the therapists delivering the enhanced rehabilitation programme after the 17-week assessment
6.3. Routinely collected data that therapists complete on their information management systems

Overall study start date
01/08/2018

Completion date
31/01/2022

Eligibility

Key inclusion criteria
1. Aged 60 years or older
2. Recent proximal hip fracture including intracapsular, extracapsular (peri-trochanteric, inter-trochanteric, reverse oblique or sub-trochanteric)
3. Surgical repair by replacement arthroplasty or internal fixation
4. Living in their own home prior to hip fracture
5. Living and receiving rehabilitation from the NHS in the area covered by the trial centres

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
Planned Sample Size: 446; UK Sample Size: 446

Key exclusion criteria
1. Living in residential or nursing homes prior to hip fracture
2. Unable to understand English or Welsh
3. Lacking mental capacity to give informed consent

Date of first enrolment
01/04/2019

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Norfolk Community Health & Care NHS Trust
Ground Floor
137 West Pottergate
Earlham Road
Norwich
United Kingdom
NR2 4BX

Study participating centre
BETSI Cadwaladr University
LHB Executive Offices
Ysbyty Gwynedd Penrhosgarnedd
Bangor Gwynedd
United Kingdom
CF72 8XR

Study participating centre
Prince Charles Hospital
CWN TAF University Health Board
Gurnos
Merthyr Tydfil
United Kingdom
CF47 9DT

Study participating centre
St Helens and Knowsley Hospital Services NHS Trust
Whiston Hospital
Warrington Road
Prescot
Merseyside
Prescot
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L35 5DR

Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust
Arrowe Park Hospital
Arrowe Park Road
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Sponsor information

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University of Liverpool

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Sponsor type
University/education

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/167/09

Results and Publications

Publication and dissemination plan
Results from this trial will be presented at regional national and international meetings where interested doctors, therapists, specialist nurses and health service commissioners would be present. This would include specialist meetings relating to rehabilitation, musculoskeletal problems, orthopaedics, rheumatology, primary care and health economics. In addition to preparing a monograph for the Health Technology series, papers will be submitted to relevant international peer-reviewed journals in multiple disciplines, e.g. rehabilitation, medicine, physiotherapy, health psychology, and to ensuring that appropriate recognition is given to all who have worked on the study. Results will be distributed to policy makers, advisory groups and professional bodies, for example the Department of Health, the Welsh Government and NICE. We will communicate the key results to patient support groups, so that findings that could benefit patients rehabilitating following proximal femoral fracture can be disseminated to affected patient groups. We are also committed to making research data accessible for secondary analysis. We will also disseminate the results to the trial participants and the teams that look after patients with proximal femoral fracture in the participating acute hospitals, the community hospitals and the community rehabilitation teams.

Intention to publish date
31/01/2023

Individual participant data (IPD) sharing plan
Anonymised data collected during this trial will be available to access. Proposals should be directed to Professor Williams, on behalf of the FEMuR III Trial Management Group (Nefyn.Williams@liverpool.ac.uk). Access will be provided to researchers after the proposal has been reviewed and agreed by the trial data sharing committee.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/10/2020	20/10/2020	Yes	No
HRA research summary			28/06/2023	No	No
Results article		18/12/2024	19/12/2024	Yes	No
Results article	Effectiveness	12/05/2025	06/06/2025	Yes	No