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Fracture in the Elderly Multidisciplinary Rehabilitation (phase 2)

Submission date
10/07/2014

Recruitment status
No longer recruiting

Registration date
21/07/2014

Overall study status
Completed

Last Edited
23/10/2019

Condition category
Musculoskeletal Diseases

[_] 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. It is strongly associated with other health problems, under-nutrition, weakness, and poor physical and mental functioning. The death rate is high with 25% dying within the following 12 months. Many who were living independently before their fracture lose their independence afterwards, so it imposes a large cost burden on society amounting to about £2 billion a year. As the population ages the numbers of elderly people falling and fracturing their hips is increasing. As well as prompt surgical treatment the guidelines recommend that the associated medical needs are assessed promptly by a physician specialised in caring for such patients, who can also devise a multidisciplinary rehabilitation. Such rehabilitation starts whilst in hospital during the recovery period after the operation and continues in the community following hospital discharge. Multidisciplinary rehabilitation is thought to aid in recovery after a hip fracture, but more research is needed. In the first phase of the study we developed a rehabilitation programme from examples of good practice from a national survey and from what patients, their carers and rehabilitation staff told us in focus group interviews. We are now conducting a small-scale study to find out whether enough people are willing to take part, whether the intervention can be run, whether we can collect the necessary information, and how people feel about taking part and their views of the intervention.

Who can participate?
Adults aged 65 years or older who have recently had a hip fracture and had undergone surgery can take part.

What does the study involve?
The study involves agreeing to answer questions on your health and how your hip fracture has affected how you function in daily life, how you use health and social services, and also some tests of physical function such as your hand grip strength, and after 3 months how well you can get up out of a chair and walk. Participants will be randomly allocated to receive either the usual rehabilitation available or a different programme of rehabilitation.

What are the possible benefits and risks of participating?
The advantages are that taking part in a study such as this can give additional benefits to people

in whichever group they are in. We do not anticipate any disadvantage from participating as both groups will receive a programme of rehabilitation.

Where is the study run from?
The study is run from the three acute hospitals in North Wales, UK (Betsi Cadwaladr University Health Board): Gwynedd Hospital (Ysbyty Gwynedd), Glan Clwyd Hospital (Ysbyty Glan Clwyd) and Wrexham Maelor Hospital (Ysbyty Wrecsam Maelor).

When is the study starting and how long is it expected to run for?
The study started in June 2014 and is expected to run until April 2015.

Who is funding the study?
National Institute for Health Research (NIHR) (UK) - Health Technology Assessment (HTA).

Who is the main contact?
Dr Nefyn Williams
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 11/33/03

Study information

Scientific Title
Developing a multidisciplinary rehabilitation package following hip fracture

Acronym
FEMuR

Study objectives
1. To assess the acceptability of and compliance with the rehabilitation programme amongst patients, carers and clinicians and identification of any adverse events. To assess the feasibility of a future definitive RCT by assessing the number of eligible patients, monitoring recruitment and retention rates, and explore the willingness of patient participants to be randomised and the willingness of patients and carers to complete outcome measures. To produce means and standard deviations of the quantitative measures so that effect sizes can be calculated for planning the future RCT.
2. To explore the methodological issues for an economic evaluation alongside a future RCT including the most efficient way of measuring patient level costs and health benefits, programme costs, and potential payer stakeholders.
3. To explore the feasibility and quality of data on service use extracted from patient electronic records compared with patient-reported outcome measures. If successful, replacing patient-reported outcomes of service use with data collection by researchers and NHS IT staff for electronic records has potential to reduce participant burden in future studies.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/113303
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/81153/PRO-11-33-03.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
UK NHS Ethics Committee - Wales REC 5, ref: 13/WA/0402

Study design
Randomised feasibility study with embedded cohort

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Rehabilitation for people aged 65 and over following surgery for fractured neck of femur

Interventions
Participants are randomised to two groups:

1. Intervention group: A rehabilitation intervention consisting of a workbook and goal setting diary to be held and used by the patient collaboratively with their rehabilitation therapist. In addition to usual care patients will receive six extra sessions of supervised physiotherapy or occupational therapy rehabilitation, tailored to their individual needs

2. Control group: Usual rehabilation care available

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Barthel Index measured at baseline and at 3 months

Secondary outcome measures
1. Abbreviated Mental Test Score (AMTS)
2. Nottingham Extended Activities of Daily Living Scale
3. Hospital Anxiety and Depression Scale (HADS)

Measured at baseline and at 3 months.

Process outcomes:
1. Visual Analogue Scale (VAS) for hip pain intensity
2. General Self Efficacy Sale
3. Falls Efficacy Scale - International (FES- I)
4. Self-efficacy for exercise scale
5. Visual Analogue Score - Fear of Falling (VAS-FOF)

Health economic measures:
1. EuroQol EQ-5D
2. ICEpop CAPability measure for Older people (ICECAP-O)
3. Client Service Receipt Inventory (CSRI)
4. Discrete Choice Experiment

Objective Measures of Physical Function:
1. Grip strength
2. Thirty second sit to stand
3. Eight foot get up and go test

Fifty foot walk test:
Cohort-study outcomes include: number of patients aged over 65 years admitted with a proximal femoral fracture; the number who fulfil the inclusion criteria for the randomised feasibility study; the number of deaths, serious complications such as falls and repeat fractures,

serious illness requiring hospital re-admission and discharged to institutional care (including detail such as the type of ward and the type of residential care)

Overall study start date
09/06/2014

Completion date
30/04/2015

Eligibility

Key inclusion criteria
1. Age 65 years or older
2. Recent proximal hip fracture including the following types of fracture: intracapsular, extracapsular (pertrochanteric, intertrochanteric, reverseoblique or subtrochanteric)
3. Surgical repair by replacement arthroplasty or internal fixation within the previous week; recovering as an in-patient on an orthopaedic ward and not yet discharged home or transferred to an in-patient unit
4. Living independently prior to hip fracture, defined as living in their own home
5. Capacity to give informed consent
6. Living and receiving rehabilitation in the participating NHS site area
7. Carers of patient participants will also be recruited where they provide them with face to face support most days in a week including help with activities of daily living and or physical care

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
90 patient participants plus any of their carers recruited

Key exclusion criteria
1. Younger adults with hip fracture
2. Non-surgical treatment following hip fracture
3. Living in residential or nursing homes prior to hip fracture
4. Lack of capacity to give informed consent
5. Participants who are not able to understand Welsh or English
6. Participants who do not live and will not receive community rehabilitation in the participating NHS site area

Date of first enrolment
09/06/2014

Date of final enrolment
30/04/2015

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
North Wales Organisation for Randomised Trials in Health (& Social Care)
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Sponsor information

Organisation
Bangor University (UK)

Sponsor details
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Sponsor type
University/education

Website
http://Bangor.ac.uk

ROR
https://ror.org/006jb1a24

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Health Technology Assessment Programme - HTA

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/11/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/04/2015		Yes	No
Results article	results	05/10/2016		Yes	No
Other publications	process evaluation	08/08/2018	23/10/2019	Yes	No
HRA research summary			28/06/2023	No	No