



BMJ Open Protocol for a definitive randomised controlled trial and economic evaluation of a community-based rehabilitation programme following hip fracture: fracture in the elderly multidisciplinary rehabilitation – phase III (FEMuR III)

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To cite: Williams N, Dodd S, Hardwick B, *et al.* Protocol for a definitive randomised controlled trial and economic evaluation of a community-based rehabilitation programme following hip fracture: fracture in the elderly multidisciplinary rehabilitation—phase III (FEMuR III). *BMJ Open* 2020;**10**:e039791. doi:10.1136/bmjopen-2020-039791

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2020-039791>).

Received 25 April 2020

Revised 08 June 2020

Accepted 17 July 2020



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ABSTRACT

Introduction Proximal femoral (hip) fracture is common, serious and costly. Rehabilitation may improve functional recovery but evidence of effectiveness and cost-effectiveness are lacking. An enhanced rehabilitation intervention was previously developed and a feasibility study tested the methods used for this randomised controlled trial (RCT). The objectives are to compare the effectiveness and cost-effectiveness of the enhanced rehabilitation programme following surgical repair of proximal femoral fracture in older people compared with usual care.

Methods and analysis Protocol for phase III, parallel-group, two-armed, superiority, pragmatic RCT with 1:1 allocation ratio; allocation sequence by minimisation programme with a built-in random element; secure web-based allocation concealment. The two treatments will be usual care (control) and usual care plus an enhanced rehabilitation programme (intervention). The enhanced rehabilitation will consist of a patient-held information workbook, goal setting diary and up to six additional therapy sessions. Outcome assessment and statistical analysis will be performed blind; patient and carer participants will be unblinded. Outcomes will be measured at baseline, 17 and 52 weeks' follow-up. Primary outcome at 52 weeks will be the Nottingham Extended Activities of Daily Living scale. Secondary outcomes will measure anxiety and depression, health utility, cognitive status, hip pain intensity, falls self-efficacy, fear of falling, grip strength and physical function. Carer strain, anxiety and depression will be measured in carers. All safety events will be recorded, and serious adverse events will be assessed to determine whether they are related to the intervention and expected. Concurrent economic evaluation will be a cost-utility analysis from a health service and personal social care perspective. An embedded process evaluation will determine the mechanisms and processes that explain the implementation and impacts of the enhanced rehabilitation programme.

Strengths and limitations of this study

- Pragmatic phase III randomised controlled trial following phase I intervention development and phase II feasibility study.
- Concurrent economic evaluation with a health service and personal social care perspective.
- Embedded process evaluation to determine the mechanisms and processes that explain the implementation and impacts of the enhanced rehabilitation programme.
- Only patients with mental capacity to consent are eligible, therefore excluding a large number of potential participants lacking capacity.

Ethics and dissemination National Health Service research ethics approval reference 18/NE/0300. Results will be disseminated by peer-reviewed publication.

Trial registration number ISRCTN28376407; Pre-results registered on 23 November 2018.

INTRODUCTION

Proximal femoral fracture, more commonly referred to as hip fracture, is a common, major health problem in old age.¹ It is projected to increase further as the population ages.^{2 3} Mortality is high,^{4 5} and of those who survive to 1 year, 29% fail to regain their level of functioning, in terms of restrictions of activities of daily living⁶; many lose their independence. This imposes a large cost burden on society, estimated to be approximately £2.3 billion a year in the UK.⁷ The majority of costs is incurred in the community and social care setting in the 12 months

following hospital discharge, which are almost four times higher than the costs of the acute hospital admission.⁸ Frail individuals are at particular risk of secondary future proximal femoral fracture, resulting in worse morbidity and mortality outcomes.⁹

The National Institute of Health and Clinical Excellence (NICE) have issued guidelines for the management of hip fracture.¹⁰ This includes the provision of a co-ordinated multidisciplinary rehabilitation programme starting in hospital during postoperative recovery and continuing in the community following discharge.¹⁰ Where possible such rehabilitation programmes should consider individual patient goals, facilitate a return to prefracture independence and provide patients and carers with written information to support the rehabilitation programme and long-term outcomes. The Hip Sprint audit reported that community rehabilitation services were inconsistent.¹¹

Rationale

There have been four relevant Cochrane systematic reviews with inconclusive results.^{12–15} These have examined different types and intensities of in-patient rehabilitation,¹² mobilisation strategies,¹³ psychosocial functioning after hip fracture¹⁴ and rehabilitation for those with dementia following hip fracture surgery.¹⁵ Other systematic reviews have reported improved walking ability,¹⁶ strength and physical function,¹⁷ including those with mild to moderate dementia.¹⁸ These systematic reviews concluded that while individual components of rehabilitation programmes may aid recovery after a hip fracture, there is insufficient evidence to demonstrate clinical effectiveness or cost-effectiveness of an overall care pathway, and that further research is required.

A previous study¹⁹ completed the first two phases of the Medical Research Council framework for complex interventions.²⁰ The first phase developed an enhanced rehabilitation intervention which, in addition to usual care, included a patient-held workbook, a goal setting diary and up to six additional home-based therapy sessions.²¹ The second phase of the study was a randomised feasibility study, which assessed the acceptability of the new rehabilitation programme and the feasibility of trial methods for a definitive phase III randomised controlled trial (RCT).^{22–23} Although this feasibility study was underpowered to assess effectiveness, the intervention showed a medium-sized improvement in the Nottingham Extended Activities of Daily Living (NEADL) scale compared with usual care (Cohen's *d* 0.63). A process evaluation described the implementation of the rehabilitation programme and informed how to enhance recruitment and improve the intervention.²⁴

Risk and benefits

The enhanced rehabilitation programme demonstrated a potential improvement in activities of daily living in the feasibility study. Possible risks of rehabilitation interventions would include injury or falling when performing

therapeutic exercises, which must be weighed against the risk to health of sedentary behaviour.

Primary objective

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 52 weeks follow-up.

Secondary objectives

1. To compare the cost-effectiveness of an enhanced rehabilitation programme following surgical repair of proximal femoral fracture in older people compared with usual care at 52 weeks follow-up.
2. 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 17 weeks follow-up.
3. To determine the effectiveness of an enhanced rehabilitation package following surgical repair of proximal femoral fracture in older people compared with usual care, in terms of anxiety and depression at 17 and 52 weeks follow-up.
4. To assess whether the enhanced rehabilitation intervention creates change in self-efficacy, hip pain, cognitive function, fear of falling and physical function as potential mediators for improving activities of daily living at 17 and 52 weeks follow-up.
5. To assess whether the enhanced rehabilitation intervention creates change in strain, anxiety and depression in carers at 17 and 52 weeks follow-up.
6. To determine the mechanisms and processes that explain the implementation and impacts of the enhanced rehabilitation programme and whether there are adverse effects.

METHODS AND ANALYSIS

Trial design

This is a pragmatic, multisite, parallel-group, two-armed, superiority RCT with 1:1 allocation ratio and an internal pilot phase (figure 1). Outcome assessment and statistical analysis will be blinded; patient and carer participants and clinicians will be unblinded. A concurrent economic evaluation will be a cost-utility analysis from a health service and personal social care perspective. An embedded process evaluation will examine the mechanisms and processes that explain the implementation and impacts of the enhanced rehabilitation programme. The RCT was registered on 23 November 2018. Trial registration data can be found in online supplemental appendix 1.

Trial setting and selection of sites/clinicians

Sites were recruited by coinvestigators in different regions of England and Wales with a spread of socioeconomic conditions and a mixture of rural and urban locations: Kent (CS), Merseyside (NW), Norwich (TOS), North

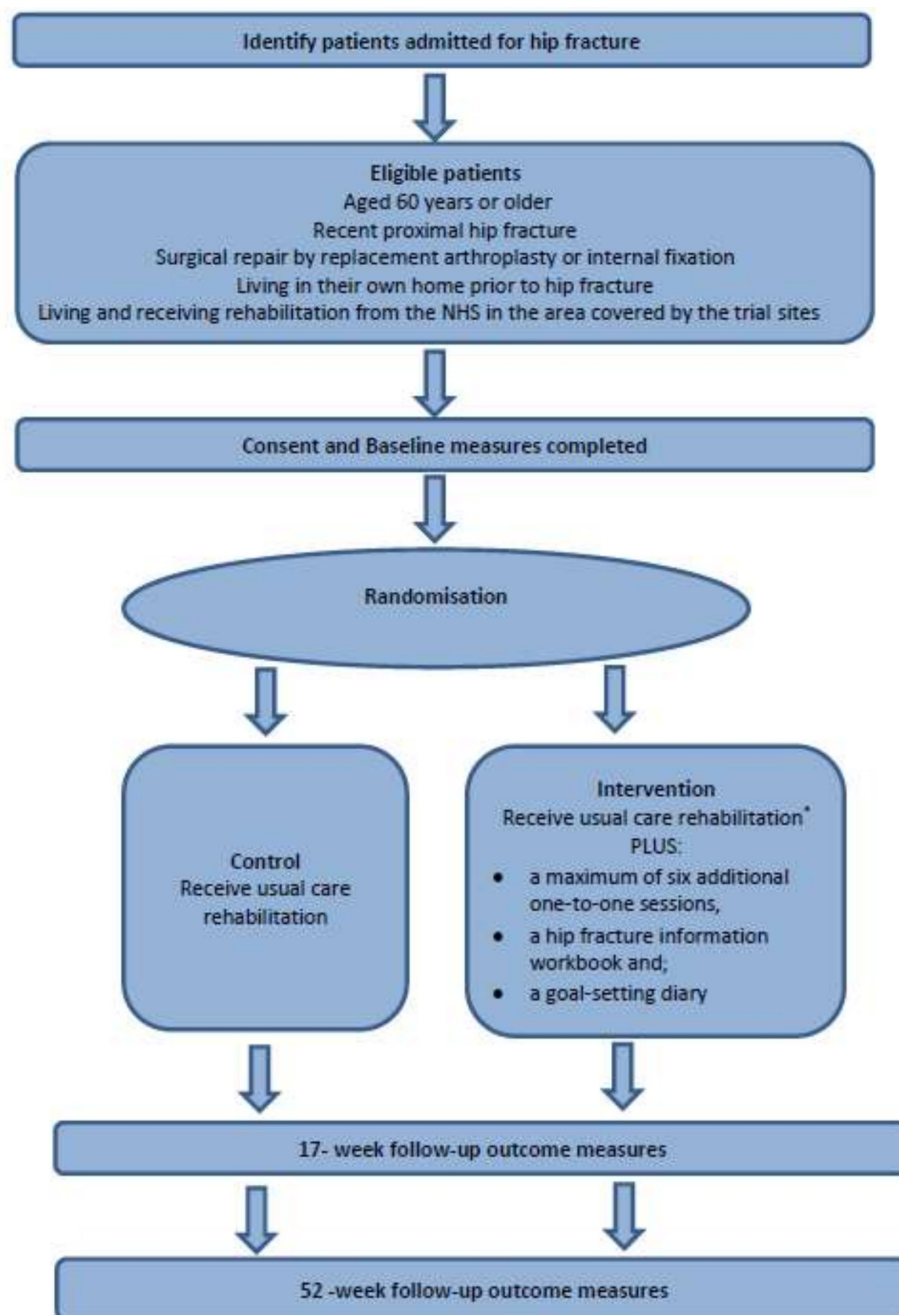


Figure 1 Participant flowchart for Fracture in the Elderly Multidisciplinary Rehabilitation—phase III (FEMuR III).

Wales (RL), Nottingham (PL) and South Wales (MB). The sites had to include trauma centres treating proximal femoral fracture and links to community rehabilitation teams, which could accommodate the extra community rehabilitation sessions.

Patients will be recruited on orthopaedic, rehabilitation and community hospital wards or after hospital discharge home. The intervention will be delivered in the community, following hospital discharge, by community teams receiving referrals from the acute hospital sites and their associated community hospitals.

Selection of sites/clinicians

Sites have been opened to recruitment in Nottingham, Norfolk, North Wales, South Wales and East Kent. Further

sites are planned in west Kent, Derby and Cheshire plus others. The site trial teams comprise principal investigators, hospital and community NHS staff, research assistants and support staff from clinical research networks.

Trial population

Inclusion criteria

1. Age 60 years or older.
2. Recent proximal femoral fracture.
3. Surgical repair by replacement arthroplasty, hemiarthroplasty 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 sites.

Exclusion criteria

1. Living in residential or nursing homes prior to hip fracture.
2. Participants unable to understand English or Welsh.
3. Lacking mental capacity to give informed consent.

Carer participants

We will also recruit carer participants to evaluate carer strain, anxiety and depression. These are defined as a relative or friend providing help with activities of daily living or physical care, at least 4 days a week. Carer participants will provide informed consent but will not receive any trial intervention, so will not undergo eligibility screening or randomisation.

Trial treatment/interventions

We plan to compare an enhanced rehabilitation intervention with usual rehabilitation care.

Usual rehabilitation care

Usual care consists of a multidisciplinary rehabilitation delivered by the acute hospital, community hospital and community services depending on patients' individual needs at different times during their recovery and on the availability and accessibility of services in different areas. The multidisciplinary team delivering care and rehabilitation may include: orthopaedic surgeons, orthogeriatricians, nurses, physiotherapists, occupational therapists, dieticians, pharmacists, general practitioners (GPs) and social workers. The settings for care include acute orthopaedic or orthogeriatric wards, rehabilitation units in community hospitals, rehabilitation beds in care homes, the patient's own home and care home settings, all delivered by a variety of community teams in both health and social care services. There will be no restrictions on concomitant medications or treatments.

Enhanced rehabilitation

The main aim of the intervention is to enhance usual rehabilitation by increasing patients' self-efficacy²⁵ and increasing the amount and quality of patients' practice of physical exercise and activities of daily living to improve functional outcomes at follow-up. Self-efficacy will be enhanced by means of a patient-held information workbook and a goal setting diary. The workbook will include:

- ▶ Information about what has happened to them and what to expect from their recovery.
- ▶ Information about NHS, council and voluntary sector services including falls' prevention programmes.
- ▶ How to manage their recovery, set goals and monitor progress of their rehabilitation; reduce fear of falling.

In addition to whatever community-based rehabilitation is provided as part of usual care, we will provide up to six additional therapy sessions, once patients are discharged home. These can be delivered by physiotherapists, occupational therapists or their assistants, who have been trained to deliver these extra sessions alongside the workbook, using the diary to set goals and monitor progress. The therapists will tailor these extra sessions, so

that the total number of sessions used, the time scale for their delivery and the sessions' content will vary between patients according to need but may include the practice of specific exercises and activities of daily living. Throughout the running of this trial, therapists will receive on-going support via emails, newsletters and refresher events.

Outcomes

Patient participants will complete outcome measures at baseline, 17 and 52 weeks administered by a research assistant blinded to participant allocation. Follow-up assessments will be completed within participants' homes (tables 1 and 2). The primary outcome will be the difference in NEADL scale^{26 27} at 52-week follow-up, between the usual rehabilitation arm and the enhanced rehabilitation arm. At baseline, the patient will be asked to recall the 4 weeks prior to hip fracture and not 4 weeks prior to completing this questionnaire. Secondary outcomes will include the Hospital Anxiety and Depression Scale (HADS),²⁸ economic measures will be EuroQol, EQ-5D-3L²⁹ and Client Service Receipt Inventory.³⁰ A reduced version of this will be used at baseline to reduce participant burden as they recover from hip fracture surgery. Potential mediators of outcome will include a Visual Analogue Scale (VAS) for hip pain intensity,³¹ Falls Efficacy Scale—International (self-efficacy)^{32 33} and Visual Analogue Scale—Fear of Falling (VASFoF).³⁴

The research assistant will assess patient participants' cognitive function at baseline, 17 and 52 weeks using the Abbreviated Mental Test Score.³⁵ The research assistant will measure physical function at baseline, 17 and 52 weeks using the grip strength test^{36–38} and using the Short Physical Performance Battery^{39 40} at 17 and 52 weeks.

Carer participants will complete the Caregiver Strain Index⁴¹ and the HADS²⁸ at baseline, 17 and 52 weeks.

Qualitative interviews will take place with patients and carers after 17 weeks. These will gather data on trial participation and intervention design (see the Process evaluation below).

Routinely collected demographic, clinical and recruitment data will include the numbers of patients who are eligible, willing to be randomised, withdraw after randomisation, complete outcome measurements, also reasons for non-completion, age, gender, hip fracture type, surgery type, comorbid conditions, place of residence prior to admission and place of discharge.

Sample size calculation

The phase II feasibility study results²³ informed the sample size calculation. The adjusted mean difference in the primary outcome measure (NEADL) between the intervention and control group in the feasibility trial was 3.0. Work completed by Wu *et al*²⁷ has suggested that the minimum clinically significant difference is 2.4; this has been used within the sample size calculation for this phase III RCT. A two-point score in the NEADL scale would equate to an improvement in function from being independent around the home to being able to use

Table 1 Outcome measures

Patient completed measures—primary	Description	Range
Nottingham Extended Activities of Daily Living scale ^{26 27}	Activities of daily living (mobility, kitchen, domestic, leisure) with higher score indicating greater independence	(0–66)
Patient completed measures—secondary		
Hospital Anxiety and Depression Scale (HADS) ²⁸	Anxiety and depression in patients with physical health problems. Two subscales (0–21) with higher score indicate greater anxiety or depression	(0–21)
Patient completed economic measures		
EuroQol EQ-5D-3L ²⁹	Health utility index with five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and three levels to give health states converted to a utility weight. Also Visual Analogue Scale (VAS) for health state today	Health utility weight from 0 (death) to 1.0 (perfect health) also with negative values VAS (0–100)
Client Service Receipt Inventory ³⁰	Use of health and social care services	According to activity
Patient completed process measures (potential mediators of outcomes)		
Visual Analogue Scale (VAS) for hip pain intensity ³¹	VAS of current hip pain intensity	(0–10 cm)
Falls Efficacy Scale— International (self-efficacy) ^{32 33}	How concerned a patient is about falling when performing 16 activities of daily living both inside and outside of the home, rated from 1 (not at all concerned) to 4 (very concerned)	(16–64)
VAS-Fear of Falling ³⁴	VAS with higher scores indicating greater fear of falling	(0–10 cm)
Assessment of cognitive function		
Abbreviated Mental Test Score ^{35 36}	Detecting and monitoring cognitive impairment. 10 items with lower scores indicating worse cognitive function	(0–10)
Objective measures of physical function		
Grip strength ³⁷	Hand dynamometer	According to metre reading
Short Physical Performance Battery ^{40 41}	Physical function tests assessing lower limb function in terms of balance, gait, strength and endurance. Higher score indicates greater function	(0–12)
Carer completed measure—secondary outcome		
Caregiver Strain Index ⁴²	13 items in the domains: employment, financial, physical, social and time. Positive responses to seven or more items indicate a greater level of strain	(0–13)
HADS ²⁸	Anxiety and depression in carers. Two subscales (0–21) with higher score indicate greater anxiety or depression	(0–21)

public transport or get in and out of a car. The adjusted mean difference between the groups in NEADL in the randomised feasibility study had an SD of 5.8. In this multisite phase III RCT, a more diverse sample would be expected, so a larger SD would be expected. Parker *et al.*⁴² used NEADL in a rehabilitation RCT and found an SD of 10. Based on the analysis of covariance (ANCOVA) with alpha of 5% and 90% power to detect a difference of 2.4 (SD=10, R^2 of covariate=0.52), 352 patient participants would be required to complete the trial over both treatment groups. When considering the 79% retention rate in the feasibility study,²³ the trial would need to recruit 446 patient participants.

Recruitment and randomisation

Screening and consent—patient participants

Patients with proximal femoral fracture will be identified and screened for eligibility, including mental capacity, by clinical staff on orthopaedic or rehabilitation wards. If the patients are eligible, and interested in the trial, the trial team researchers would then recruit patients following the trial's informed consent process. Assessment of eligibility may occur over an extended period, if, for example, the patient is experiencing temporary delirium postsurgery. If, during this period, patients are transferred to rehabilitation wards, community hospitals or discharged home, then assessment will continue in these

Table 2 Fracture in the Elderly Multidisciplinary Rehabilitation—phase III (FEMuR III) protocol schedule of forms and procedures

Procedures	Screening	Baseline/randomisation*	Trial intervention†	17 weeks postrandomisation follow-up	Qualitative interviews	52 weeks postrandomisation follow-up
Eligibility screening and consent						
Assessment of eligibility criteria	X					
Written and informed consent (patient/carer)	X					
Confirm consent		X	X	X	X	X
Randomisation		X				
Discharge data		X				
Outcome measurement—patient						
Nottingham Extended Activities of Daily Living		X		X		X
Hospital Anxiety and Depression Scale (HADS)		X		X		X
Abbreviated Mental Test Score		X		X		X
Visual Analogue Scale (VAS) hip pain intensity		X		X		X
Falls Efficacy Scale—International		X		X		X
Visual Analogue Score—Fear of Falling		X		X		X
EuroQol-5D-3L		X		X		X
Client Service Receipt Inventory		X		X		X
Grip strength		X		X		X
Short Physical Performance Battery				X		X
Outcome measurement—carer						
Caregiver Strain Index		X		X		X
HADS		X		X		X
Trial intervention†			X			
Qualitative interviews						
Re-affirm consent verbally specifically for qualitative phone interview. (patient/carer)					X	

Continued

Table 2 Continued

Procedures	Screening	Baseline/randomisation*	Trial intervention†	17 weeks postrandomisation follow-up	Qualitative interviews	52 weeks postrandomisation follow-up
Qualitative telephone interview					X	
Safety event reporting						
Monitoring of adverse events			X	X	X	X
Monitoring of serious adverse events			X	X	X	X

Participant follow-up visits should take place at 17 (± 2 weeks) and 52 (± 2 weeks) weeks postrandomisation.

*Randomisation and baseline should take place no later than 6 weeks after hip fracture repair surgery.

†If randomised to intervention arm.

alternative locations. These assessments will be recorded in a screening log, including any reasons for ineligibility.

Informed consent—carer participants

For the purpose of this RCT, carers are defined as either a relative or friend caring for a hip fracture patient, helping them with activities of daily living or physical care on at least 4 days a week. They will be identified and recruited following the trial's informed consent process. Copies of the participant information sheets and informed consent forms are found in online supplemental appendix 1.

Randomisation procedures

Patient participants who provide informed consent will complete baseline outcome measurements prior to randomisation. Randomisation will take place no later than 6 weeks after hip fracture repair surgery. The randomisation will have an allocation ratio of 1:1 within each stratum and across the trial. Randomisation will use a minimisation programme with a built-in random element using factors that will not be made known to individuals in charge of recruitment to minimise any potential for predicting allocation. Randomisation will be completed by secure web access to the remote randomisation site at the clinical trial unit. The therapists delivering the enhanced rehabilitation intervention will receive an automated email when a participant has been allocated to the intervention group.

Blinding

This is a pragmatic trial comparing two rehabilitation interventions. It will therefore not be possible to blind participants or their clinicians to treatment group allocation. The research assistants will collect outcome measurements blind to treatment allocation. They will not be informed to which group the patient participants have been allocated and will not be present at any of the therapy sessions. Before any home visits for follow-up assessments, they will ask participants not to reveal their treatment allocation. After the final follow-up assessment, they will complete a perception of allocation form, in

order to monitor the level of blinding achieved for these researchers. Data analysis will be performed blind to treatment allocation.

Internal pilot

An internal pilot-assessed site recruitment and participant recruitment and retention rates for the 6 months after the first site were open to recruitment from September 2019 to February 2020.

Progression criteria

- ▶ Number of sites open: seven or more (go); five to six (amend); four or fewer (stop).
- ▶ Open site recruitment rate per month: two or more (go); one to two (amend); less than 1 (stop).
- ▶ Retention rate: 69% or higher (go); 50%–68% (amend); 49% or fewer (stop).

Statistical analysis

Final analysis will take place once all participants have been followed up for 52 weeks, and the database has been locked. Analyses will be by 'intention to treat' for the primary and secondary outcomes on all randomised participants, in the group to which they were allocated and for whom the outcomes of interest have been observed or measured.

Baseline

Demographic and baseline characteristics will be summarised separately using descriptive statistics for each randomised group to allow clinical assessment of whether balance was achieved between randomised groups. No statistical testing of differences between groups will be performed.

Analysis of effectiveness

Primary and secondary outcomes at baseline, 17 weeks' and 52 weeks' follow-up will be summarised for each treatment group using descriptive statistics at each time point. If normally distributed, the difference between group means (with 95% CIs) will be reported from the

ANCOVA adjusted for baseline score and stratification factors.

Missing data and withdrawals

Predictors of missing data will be investigated using regression models (including type of surgery, age, living arrangements and comorbidities) and any significant predictors will be considered for inclusion in the models. In addition, given the two assessment points at 17 and 52 weeks, we will carry out a sensitivity analysis using a joint modelling approach to check whether there is any difference in outcome (here the longitudinal outcome rather than the outcome at 17 weeks or 52 weeks alone) between the randomised arms adjusted for dropouts or missing values.

Instrumental variable regression

The impact of engagement with the intervention will be assessed using instrumental variable (IV) regression, using the number of face-to-face direct rehabilitation sessions over 52 weeks' follow-up as a continuous measure of engagement. Additional exploratory IV regression analyses will use in turn: the total number of rehabilitation sessions (face-to-face plus telephone), total time (in minutes) spent in face-to-face direct rehabilitation sessions and total time (in minutes) spent in all rehabilitation sessions (ie, face-to-face and telephone). The suitability of using randomisation as the instrument in these IV regression models will be assessed using tests of exogeneity, redundancy and under/weak identification.

Mediation analyses

The hypothesised mechanism of change for the enhanced rehabilitation intervention is that participants' primary outcome (activities of daily living) is mediated by self-efficacy, hip pain, cognitive function, fear of falling and physical function. If the enhanced rehabilitation intervention has a significant effect on primary outcome ($p < 0.05$) for enhanced rehabilitation in ANCOVA, causal mediation analysis will be used to determine whether each of these potential mediators predict change in NEADL at 52 weeks. Initial assessments will determine whether the randomised intervention affects each putative mediator in turn. For those putative mediators that are significantly ($p < 0.1$) affected by the randomised intervention, mediation analysis will be carried out adjusting for baseline covariates that predict both the mediator and NEADL, potentially including type of surgery, age, living arrangements (alone/with others) and comorbidities. Sensitivity analyses will assess the potential impact of unmeasured confounding between the mediator and NEADL.

Economic analysis

The enhanced rehabilitation programme will be fully costed using unit costs from a public sector multiagency perspective. Unit costs will be obtained from national sources of reference costs^{43 44} and applied to information received from pilot questionnaires, namely, salary band of therapists, time spent with the patient conducting

rehabilitation, costs of travel and costs of any additional equipment. Costs of health and social care services used by the participants will also be costed using national sources of reference costs. The costs of service use and the cost of the intervention will be added together for use in a cost-effectiveness analysis.

The EQ-5D (3L) will be used to calculate Quality Adjusted Life Years (QALYs) over the 52-week trial period, using the area under the curve method.^{45 46} A cost-utility analysis will be conducted to calculate a cost per QALY of the enhanced rehabilitation intervention. This cost per QALY generated will be compared with the NICE threshold range of £30 000 per QALY.⁴⁷ We will bootstrap differences in costs and outcomes (EQ-5D-3L) between the two groups, producing a 95% CI around these differences.

Process evaluation

The process evaluation will aim to identify and explain all mechanisms and processes (ie, the intervention theory) that enabled or acted as a barrier to the implementation of the enhanced rehabilitation intervention. The process evaluation will help build a picture of how the intervention was carried out in reality and what factors shaped it. By carrying out a process evaluation, it will be possible to identify if observed impacts are solely due to the enhanced rehabilitation programme, or if these impacts are a result of a number of external and internal variables that are closely linked to the environment and the context in which the intervention takes place.⁴⁸⁻⁵¹

The specific objectives will be to:

- ▶ Refine the programme theory from the previous realist review that was used to develop the intervention.²¹ This programme theory will explain how the researchers envisage the intervention to work, to reach its expected outcomes.
- ▶ Investigate therapists' expectations and experience of implementation, their previous experience and training and their learning throughout the conduct of the trial.
- ▶ Investigate the mechanisms driving and shaping the tailoring of the enhanced rehabilitation intervention to individual patients.
- ▶ Investigate trial participants' (patients and carers) experiences and views about their involvement in the trial as well as their experience of care in either arm of the trial.
- ▶ Map and synthesise all data collected in order to test the refined programme theory and explain the trial findings.

Process evaluation data collection

Semistructured telephone interviews will be conducted with:

- ▶ A purposive sample of 60 patient participants in each of the two trial arms and up to 30 of their carers. Patients will be purposively sampled to ensure diversity based on age, functional impairment (using

baseline NEADL scores) and the presence or absence of a family carer. Interviews will take place after the 17-week assessment and will be audio recorded.

- ▶ The therapists delivering the enhanced rehabilitation programme, which will explore implementation from the therapists' perspectives. Interviews will be conducted midway through their involvement in the trial, and at the end, in order to investigate learning over time.

Data on intervention delivery and adherence

- ▶ Therapists will record key reflections on 'critical incident reports'.
- ▶ The visiting therapist will record the length and content of each extra rehabilitation therapy session on a case report form.
- ▶ All patient participants will be given a therapy session record, where visiting therapists will record the number, length and content of usual rehabilitation care. Whenever possible, routinely collected electronic data that therapists complete on their Therapy Manager system, or its equivalent, will be collected.
- ▶ An online questionnaire will be emailed to participating therapists in order to capture therapists' relevant training, previous experience and familiarity with the trial intervention.

Qualitative data will be analysed following a thematic analysis approach⁵² that will be guided by the proposed programme theory. Quantitative data (record forms and online questionnaires) will be analysed using descriptive statistics, which will allow the exploration of frequency of responses. All data sets will be synthesised in order to describe the complex nature of the enhanced rehabilitation intervention.

Patient and public involvement

There has been patient and public involvement (PPI) at all stages including refining the research question, choosing outcomes relevant to patients, commenting on the burden of the intervention and of trial participation. A PPI coinvestigator will continue to contribute to the trial management group, including comments on patient-facing materials and the dissemination plan.

Ethics and dissemination

NHS research ethics approval was obtained from North East—Tyne & Wear South Research Ethics Committee, reference 18/NE/0300. The current protocol is V.4.0 (11 December 2019). A Trial Steering Committee is providing overall supervision and an Independent Data Safety and Monitoring Committee is responsible for reviewing and assessing recruitment, interim monitoring of safety and effectiveness, trial conduct and external data.

All safety events will be recorded by researchers when they are made aware of the event by the patient, carer, the treating clinicians or therapists. Adverse event reports and serious adverse events (SAEs) not related

to the intervention will be entered on to the remote data entry system. Each SAE will be assessed by the relevant principal investigator (PI) to determine whether it is related to the intervention. A related SAE will be assessed by the CI to determine whether it is expected. If the SAE is related and unexpected, it will be reported to the Research Ethics Committee and sponsor in an expedited manner.

Reporting of the trial will be consistent with the Consolidated Standards of Reporting Trials 2010 Statement (patient-reported outcomes and non-pharmacological interventions).⁵³ We will submit the final report to a peer-reviewed academic journal, according to our publication strategy and authorship policy. Research data will be available for secondary analysis on reasonable request.

Trial status

At the time of submission, this trial had been open in nine sites and had recruited 96 patients and 10 carers, with a recruitment rate of two patient participants per site per month and a retention rate of 83%, which fulfilled the progression criteria of the internal pilot. However, recruitment to the trial is currently suspended because of the COVID-19 pandemic. Wherever possible, participants already recruited into the trial will complete their follow-up assessments over the telephone or by post, extra rehabilitation sessions will be delivered over the telephone. When trial recruitment resumes, updated recruitment information will be found on the website <http://femur3study.co.uk/>

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Acknowledgements The authors would like to thank all of the principal investigators, research nurses, hospital staff, community rehabilitation teams, physiotherapists, occupational therapists and their assistants who are providing the additional therapy sessions. In Nottingham: Miriam Golding-Day, Katie Robinson, Jane Horne, Frances Allen. In North Wales: Matthew Jones, Lauren Porter, Jane Stockport, Mary Roberts, Victoria Whitehead, Yogesh Joshi, Gareth Evans, Cathy Baker, Jeannie Bishop, Jane Heron, Llinos Davies. In South Wales: Rachel Lowe,

Rebecca Milton, Andrew Dean Young, Peter Lewis, Lisa Roche. In East Anglia: Stephanie Tuck, Catherine Mingay, Stephanie Howard. In East Kent: Danielle Pearce, Joanne Jackson, Sarah Chapman, Andrew Smith, Alex Chipperfield, Joanne Deery. Special thanks to the LCTC data management team Clare Jackson and Dianne Wheatley, LCTC information systems team Keith Kennedy and Janet Harrison, trial coordinator assistant Kieran Crabtree and quality assurance manager Katie Neville. Research assistants/research project support officers who perform follow-up visits. Others who have contributed to the trial management group Kevin Anthony, Gail Arnold, Janine Bates, Suzannah Evans, Mark Howells, Lara Lavelle-Langham, Nic Nikolic, Jessica Roberts. Also the North West Coast Clinical Research Network Lisa Cheng, Julia Murgaza. We very much appreciate the work of the Trial Steering Committee Gail Mountain (chair), Graeme Holt, Helen Hughes, George Kernohan, Tosan Okoro, Nikki Totton and the Independent Data and Safety Monitoring Committee Chris Robertson (chair), Diane Dixon, Peter Giannoudis, Barbara Hanratty.

Contributors NW was the chief investigator and grant holder, was responsible for study design, conduct and analysis and had overall responsibility for the study and acts as guarantor. LH and SH were the trial coordinators and BH was the senior trial coordinator overseeing day-to-day conduct, and provided methodological input. LH was the initial trial coordinator and contributed to writing the trial protocol and setting up the trial. SD wrote the statistical analysis plan. RTE and JMC wrote the health economic analysis plan. PM-A wrote the process evaluation analysis plan with NW. RL is a lead applicant from Bangor University and oversees sites in North Wales. MB is a lead applicant from Cardiff University and oversees sites in South Wales. PL is a lead applicant from University of Nottingham and oversees sites in Nottingham. CS is a lead applicant from Kings College London and oversees sites in Kent. TOS is a lead applicant from the University of East Anglia and oversees the site in East Anglia. VM and AL were coinvestigators responsible for study design, methodological oversight and provided health psychology and exercise science expertise respectively. All authors were involved in drafting, revising and approving this manuscript.

Funding This work was supported by the National Institute for Health Research's Health Technology Assessment Programme, grant number 16/167/09. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA, NIHR, NHS or the Department of Health. University of Liverpool: sponsor's reference: UoL001378. Contact: Mr Alex Astor, University of Liverpool, 2nd Floor Block D Waterhouse Building, 3 Brownlow Street, Liverpool L69 3GL. The university has appropriate clinical trials and professional indemnity insurance.

Competing interests NHW reports additional grants from NIHR HS&DR outside the submitted work and membership of the NIHR HTA programme funding committee (commissioned research).

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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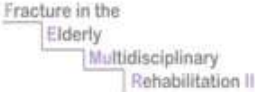
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Appendix 1 FEMuR III Trial Registration Data

Data category	Information
Registry and trial identification no.	ISRCTN28376407
Date of registration	23/11/2018
Funder	NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant code 16/167/09
Sponsor	University of Liverpool
Contact for public enquiries	LH email: femur3@liverpool.ac.uk
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
Countries of recruitment	United Kingdom
Health condition	Hip fracture
Intervention	Intervention comparator: Enhanced rehabilitation Control comparator: Usual care
Inclusion criteria	Aged 60 years or older Recent proximal hip fracture Surgical repair by replacement arthroplasty or internal fixation Living in own home prior to hip fracture Living and receiving rehabilitation from the NHS in the area covered by the trial centres
Exclusion criteria	Living in residential or nursing home prior to hip fracture Unable to understand English or Welsh Lacking mental capacity to give informed consent
Study design	Interventional Randomised controlled trial Treatment, education or self-management, psychological and behavioural, complex intervention, physical, rehabilitation
Recruitment start date	01/04/2019
Target sample size	446
Primary outcome	Nottingham Extended Activities of Daily Living scale
Secondary outcomes	EuroQol EQ-5D, Hospital Anxiety and Depression Scale, Abbreviated Mental Test Score, Falls Efficacy Scale – International, hip pain intensity, fear of falling, grip strength, short physical performance battery

Appendix 2 FEMuR III Patient Participant Information Sheet and Informed Consent Forms



<<Local NHS Logo to go here>>

<Trust/Site address 1>
 <Trust/Site address 2>
 <Trust/Site address 3>
 <postcode>
 Tel: <telephone numbers>

Patient Participant Information Sheet

Contents	Page	You are invited to take part in FEMuR III
You are invited to take part in FEMuR III	1	Important things to know about FEMuR III:
Why are we doing the FEMuR III study?	2	➤ FEMuR III aims to compare a new enhanced rehabilitation package with standard NHS care for patients who have had surgery to repair a hip fracture.
What is the Enhanced Rehabilitation Package?	2	➤ We are interested in the recovery of patients aged over 60 years old who lived independently before they suffered a hip fracture even if they were in receipt of personal care at home.
Why have I been asked to take part?	2	➤ Being part of the study means you will receive either standard care or standard care plus enhanced rehabilitation when you leave hospital.
What will I have to do if I take part?	2	➤ Standard care can vary but usually involves community-based physiotherapy. The enhanced rehabilitation package will provide additional physiotherapy, occupational therapy and some 'self-help' tools to aid recovery.
Timeline of visits	3	➤ You have been given this information sheet as you might be eligible to take part in this study.
How will I know which treatment I'm going to have?	3	➤ Before you decide whether or not to take part it is important for you to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully and discuss it with friends or relatives if you wish.
What are the benefits and risks of taking part?	3	➤ Taking part is voluntary. If you don't want to take part then you don't need to give a reason.
What are the alternatives for treatment?	3	➤ If you have someone who provides you with help for most days of the week with activities of daily living or physical care, we would also like them to be involved in the study.
Do I have to take part?	4	➤ Please ask a member of your clinical team if there is anything that is not clear, or if you would like more information.
What happens if I change my mind?	4	
Will my participation be kept confidential?	4	
What will happen to the results of the study?	5	
What if there is a problem?	5	
Additional information	5	
Additional information about future research	5	
Contacts for further information	6	
Consent Form	7	
Important Contact Information		
Thank you for taking the time to read this information sheet. We hope you will find this information helpful.		
If you would like a large print version of this information sheet please ask your research team.		
If you have any questions about this study please talk to your research team:		
<Add contact details for PI/RN i.e., name and telephone number>		
Website: Femur3study.co.uk		

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Why are we doing the FEMuR III study?

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.

We have designed an enhanced rehabilitation package 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.

What is the Enhanced Rehabilitation Package?

The enhanced rehabilitation package is made specifically for each patient and we think this should improve recovery. We think this 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.

The enhanced rehabilitation package we have designed involves additional rehabilitation at follow up visits. You will be given a workbook and a goal-setting diary to complete during the first few months of recovery.

In order to compare the enhanced rehabilitation package to standard NHS care we are asking 446 people to take part in our study. We will follow your progress in the 12 months after surgery and collect information from you during that time so we can see how you are. The information we collect will help us to see whether there is a difference between those people who have standard NHS treatment and those who receive standard NHS treatment **and** the enhanced rehabilitation package.

Why have I been asked to take part?

We are inviting you to take part in this study because you are a patient at one of the hospitals taking part and have recently had surgery to repair a hip fracture.

What will I have to do if I take part?

A member of the clinical team can talk to you in more detail about this study and you will be able to ask any questions that you have. If you have had all of your questions answered and are happy to take part then you will be asked to sign a consent form to confirm you want to take part. You will be given a copy of your consent form and this information sheet to keep.

This study is comparing standard NHS care with the enhanced rehabilitation package. Both of these will be tailored to individual patients so it is difficult for us to describe exactly what your rehabilitation will look like. However, the main differences between the two are that if you are receiving the enhanced rehabilitation package you will also:

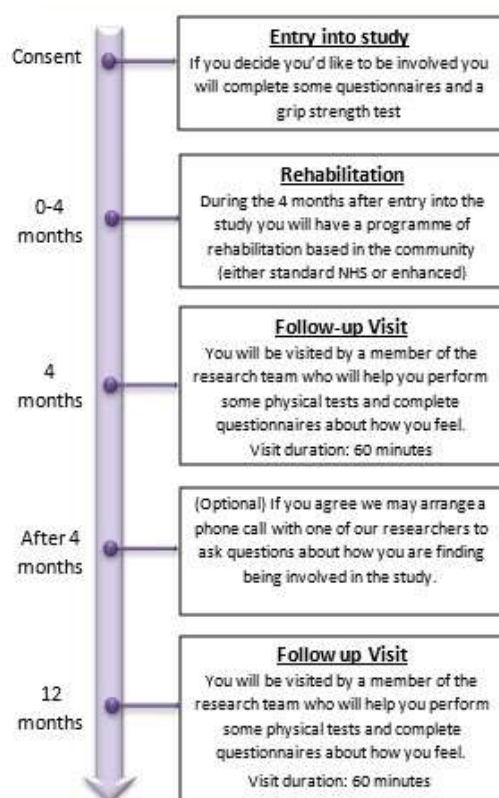
- Be given a goal-setting diary to complete which we would like you to use to set yourself targets and track your progress through your rehabilitation.
- Be given a workbook containing information about hip fractures: what to expect during recovery, tips to aid recovery, and useful contacts if you would like more information.
- Receive up to six community/home-based therapy sessions **in addition** to any provided by the NHS.

If you do decide to take part and have given your consent, we will ask you to complete some questionnaires and do a grip-strength test so we can get some information about how you are feeling both mentally and physically. This will allow us to see how you are recovering over time. The grip – strength test uses a special piece of equipment to measure this and will be carried out at home with a researcher.

We will arrange an appointment with you around 4 months after you have started the study to see how you are getting on. This visit may take place at your home or in a community hospital depending on what is best with you. At the visit, we will ask you to complete the same questionnaires and do some basic physical tests so we can see how you are recovering. At around 12 months after you started the study we will arrange one more visit to complete the questionnaires and physical tests again so we can track your progress. The physical tests are things you do every day. For example, the researcher will ask you to sit and stand up to five times (if you are able) and will record your progress.

We may also telephone you soon after the 4-month visit to ask some questions about how you are finding being involved in the study. This will give you a chance to give some feedback on your experiences and your views on the care you are receiving. Not all patients will receive a phone call, we aim to call 60 patients who have agreed to take part. We will offer you a £30 shopping voucher for your time and inconvenience in taking part in the telephone interview.

Timeline of visits



How will I know which treatment I'm going to have?

In the FEMuR III study patients will be split into two groups at random:

- One group will receive standard NHS care after discharge

- The other group will receive the enhanced rehabilitation package alongside standard NHS care after discharge

We use a computer programme that puts patients 'at random' into one of the groups – you might hear this described as 'randomisation' or 'random allocation', but they all mean the same thing. Neither you nor your doctor chooses which group you are in.

In this study you are equally likely to be in the group receiving standard NHS care as you are in the group receiving the enhanced package. Your healthcare team will let you know which group you are in as soon as possible.

What are the benefits and risks of taking part?

We are not sure whether standard NHS care or the enhanced rehabilitation package is best, but we anticipate that both will aid your recovery following surgery.

We do not foresee any 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 your time due to additional therapy sessions and having to complete the diary.

We hope that the results from the study will help doctors, therapists, patients and their [carers](#) in the future when making decisions about treatment.

What are the alternatives for treatment?

Patients recovering from hip fracture repair will get standard NHS treatment, though this may vary in different areas. In this study every patient will get standard NHS treatment even if they are in the enhanced rehabilitation group. Currently, there are no other alternative treatment programmes available.

Do I have to take part?

No, taking part is voluntary. It is up to you to decide whether or not you want to take part. If you choose to take part you can also choose to stop at any time without giving a reason. The standard of care you receive now or in the future will be the same whether you take part or not.

What happens if I change my mind?

If at any point you decide to stop taking part in the study you will receive the treatment and follow up usually offered in your area. The standard of care you receive will remain the same if you decide to stop taking part. If you do decide to stop taking part we will ask you if you would like to either:

- continue to complete follow up visits for the study
- stop taking part with no more study visits.

We will use any study information collected up until the time you stop taking part.

Will my participation be kept confidential?

Yes. All information collected about you during the course of the study will be handled according to relevant ethical and legal requirements. Your personal information will be kept strictly confidential and will only be accessed by people working on the study, or working to ensure the study is being run correctly.

You will be given a study number, which will be used along with your initials to identify you on each paper form. Your full name and date of birth, postcode, contact details and NHS number will be included on your consent form and a copy of this will be sent to the study team at the coordinating centre for the study, the Liverpool Clinical Research Centre (LCTC.) There may be instances (depending on your local NHS,) when a copy of your contact details will need to be sent to other locations or Universities within your local area to arrange your follow up visits. Only members of the FEMUR III team will be given access to your contact details, they will be held securely and destroyed after your final follow-up. Every effort will be made to ensure that any further information about you that leaves the hospital will have your name removed so that you cannot be recognised from it. This information will usually be removed by a member of the study team at your hospital/community care, but may also be removed by study team members at the LCTC upon receipt. We will also ask for your telephone number so that we can contact you for the telephone interviews during the study. Your telephone number will not be used for anything else without your consent.

With your consent, we will send a letter to your GP to let them know you are taking part and we will use your NHS

number and postcode to access data about your use of health services (for example your hospital admissions).

The University of Liverpool is the sponsor for this study based in the United Kingdom. The University of Liverpool along with Bangor University will be using information from you and your medical records in order to undertake this study and will act as joint data controllers for this study. This means that both joint data controllers are responsible for looking after your information and using it properly. The University of Liverpool will keep identifiable information about you for a maximum of 25 years after the study has finished. Arrangements for confidential destruction will then be made.

Details about the use of health services (health economics) will be collected in this study. Information will be obtained from your hospital finance department and NHS Digital. Health economics researchers at the Centre for Health Economics and Medicines Evaluation (part of Bangor University), who are part of the study team, will use these data to calculate the overall costs of care. Data will be provided to the study team by NHS Digital and in order to obtain this, your NHS number will be securely transferred to NHS Digital by the CTIC using an encrypted electronic transfer system.

We would also like to collect information regarding your therapy sessions from electronic data from Therapy Management systems. This data will include date of sessions, location of sessions and activities completed during the session. This data will help us to see how many therapy sessions you have completed during the study. This data will be extracted from Therapy Management systems by NHS IT personnel and transferred using an encrypted electronic transfer system to a researcher at the University of Liverpool.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information in the "How we use your information" section on the study website Femur3study.co.uk

Your NHS hospital and/or community health team will collect information from you and your medical records for this research study in accordance with our instructions.

Your NHS hospital and/or community health team will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the team and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your NHS hospital and/or community health team will pass these details to the University of Liverpool along with the information collected from you and your medical records. The only people in the University of Liverpool who will have access to information that identifies you will be people who need to confirm your participation in the study, to contact you after 4 months to ask you questions about taking part in this study or audit the data collection process. The people who analyse the information will not attempt to identify you or find out your name, NHS number or contact details.

Your NHS hospital and/or community health team will keep identifiable information about you from this study for up to a maximum of 25 years after the study has finished.

Additional information about future research:

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

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What will happen to the results of the study?

We want the results of the study to be presented at conferences and published in medical journals so that we can explain to the medical, nursing and therapies' community what our research results have shown. You will not be identified in any publication or presentations.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with one of your research team who will do their best to answer your questions.

If at any time during the study you feel distressed or anxious please speak to your research team, a therapist or contact your GP.

If you wish to make a formal complaint, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital.

Every care will be taken in the course of this clinical study. However, in the unlikely event that you are harmed by taking part in this research project, compensation may be available and you may have to pay your related legal costs. The University of Liverpool holds insurance against claims from participants for harm caused by their participation in this clinical trial. Participants may be able to claim compensation if they can prove that the University of Liverpool has been negligent. However, the NHS organisation that has provided your treatment has a duty of care to you, whether or not you agree to participate in the study, and the study sponsor accepts no liability for negligence on the part of your NHS organisation's employees. However, if you are harmed, and this is due to someone's negligence in the NHS, then you may have grounds for a legal action for compensation against the NHS organisation providing your treatment, but you may have to pay for your legal costs. The normal NHS complaints procedures should be available to you.

Additional information

The University of Liverpool is responsible for managing this study; they have asked that the day to day running of the study is carried out by the Liverpool Clinical Research Centre (LCRC,) part of the University of Liverpool. Additional support is provided by health economics researchers from the Centre for Health

Economics and Medicines Evaluation, part of Bangor University, and other researchers from participating universities (the study team).

This study is funded by the National Institute for Health Research's Health Technology Assessment Programme (ref: 16/167/09).

The study has been reviewed by the National Institute for Health Research (NIHR), Health Research Authority and the National Research Ethics Service Committee. Tyne and Wear South Ethics Committee has reviewed the study and given approval for it to take place.

The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

**Thank you for reading this
information sheet.**

Contacts for further information

If you would like more information or have any questions about the FEMuR III study please talk to:

Principal Investigator: <PI name to go here>

Research Nurse: <RN name to go here>

Telephone: <Hospital contact number to go here>

Or visit the website: Femur3study.co.uk

If you wish to discuss the study with someone independent of the research team you can contact the local NHS Patient Advice and Liaison Service (PALS) or local equivalent on: <Local PALS or equivalent telephone number to go here>



Williams N, *et al.* *BMJ Open* 2020; 10:e039791. doi: 10.1136/bmjopen-2020-039791

12. I agree to being contacted by a study researcher to conduct a qualitative interview and for the interview to be recorded. (if you agree to this statement provide your details below):		<input type="checkbox"/>
Telephone number:	<input type="text"/>	
Your full name (please print):	<input type="text"/>	
Your signature:	<input type="text"/>	Date: <input type="text"/>
To be completed by a witness only if participant is unable to sign the consent form:		
Witness full name (please print):	<input type="text"/>	Date: <input type="text"/>
Witness signature:	<input type="text"/>	Date: <input type="text"/>
To be completed by the Researcher (on the same day after participant has completed the form):		
Researcher full name (please print):	<input type="text"/>	
Researcher signature:	<input type="text"/>	Date: <input type="text"/>
Additional details required for health economic analysis:		
Participant postcode:	<input type="text"/>	<input type="text"/>
Participant NHS Number:	<input type="text"/>	<input type="text"/>

Appendix 3 FEMuR III Carer Participant Information Sheet and Informed Consent Forms

Fracture in the Elderly Multidisciplinary Rehabilitation III

<<Local NHS Logo to go here>>

<Trust/Site address 1>
 <Trust/Site address 2>
 <Trust/Site address 3>
 <postcode>
 Tel: <telephone number>

Carer Participant Information Sheet

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You are invited to take part in FEMuR III

Important things to know about FEMuR III:

- FEMuR III aims to compare a new enhanced rehabilitation package with standard NHS care for patients who have had surgery to repair a hip fracture.
- After surgery, some patients take a long time to recover, and others may not recover fully.
- Additional care is often provided by members of the family or close friends, and usually involves helping hip fracture patients with activities associated with daily living or physical care.
- You have been given this information sheet as you are a carer of someone who is potentially eligible to take part.
- Before you decide whether or not to take part it is important for you to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully and discuss it with friends or relatives if you wish.
- Taking part is voluntary. If you don't want to take part then you don't need to give a reason.
- Please ask a member of the clinical team if there is anything that is not clear, or if you would like more information.

Important Contact Information

Thank you for taking the time to read this information sheet. We hope you will find this information helpful.

If you have any questions about this study please talk to your research team:

If you would like a large print version of this information sheet please ask your research team.

<Add contact details for PI/RN i.e., name and telephone number>

Website: Femur3study.co.uk

Why are we doing the FEMuR III study?

The FEMuR III study hopes to collect information to help provide evidence about the best way to treat patients who are recovering from hip repair surgery after a fracture. Hip fractures are common and often need to be surgically repaired. Once patients are discharged, the routine care they receive can vary depending on local

NHS policy and they often require additional help at home from family members or friends.

FEMuR III will compare an enhanced rehabilitation programme we have designed against the normal care given by the NHS. We want to see if one offers any additional benefit over the other. To do this, we are asking 446 patients and their carers to take part. We will follow progress in the 12 months after surgery and collect information from you during that time so we can see how you both are.

What is the Enhanced Rehabilitation Package?

The enhanced rehabilitation package is made specifically for each patient and we think this should improve recovery. The enhanced rehabilitation package mixes extra therapy with self-help tools which aim to help patients improve aspects of their own recovery e.g., build confidence in trying exercises by themselves. We also hope that this will help the people caring for hip fracture patients by reducing the level of care they need to provide as patients may be able to recover independence quicker.

The enhanced rehabilitation package we have designed involves additional rehabilitation sessions and patients will be given a workbook and a goal-setting diary to complete during the first few months of recovery. Carers will be given questionnaires to complete so we can look at how much help you are providing and how you are managing.

In order to compare the enhanced rehabilitation package with standard NHS care we are asking 446 people aged 60 and over, who have had hip repair surgery, to take part in our study. We will follow their progress in the 12 months after surgery and collect information from them and from you (as their carer) during that time so we can see how you both are. The information we collect will help us to see whether there is a difference between those people who have standard NHS treatment and those who receive standard NHS treatment and the enhanced rehabilitation package.

Why have I been asked to take part?

We are inviting you to take part in this study because you are a carer of a patient who has recently had

surgery to repair a hip fracture at one of the hospitals taking part

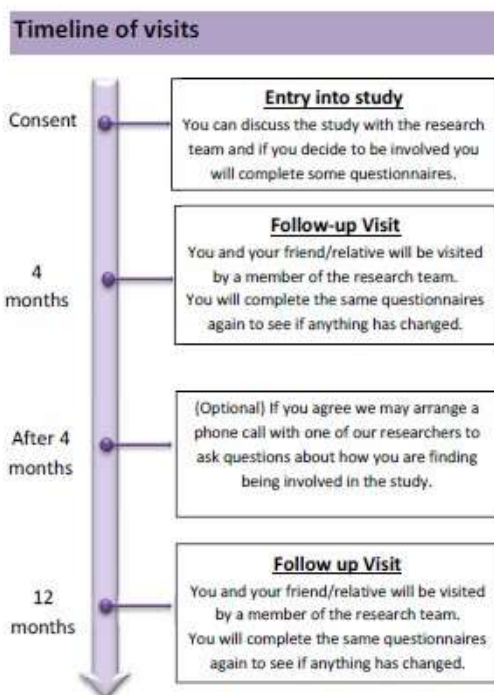
What will I have to do if I take part?

A member of the clinical team will talk to you first in more detail and you will be able to ask any questions that you have. If you have had all of your questions answered and are happy to take part then you will be asked to sign a consent form to confirm you want to participate. You will be given a copy of the consent form and the information sheet to keep.

If you do decide to take part and have given your consent, we will ask you to complete some questionnaires so we can see how you are feeling. These may take around 15 minutes to complete.

We will arrange an appointment with your friend/relative around 4 months after surgery to see how they are getting on. This will involve a member of the research team coming out to visit your friend/relative and we would like to ask that you be present too. At the visit, we will ask you to complete the same questionnaires that you completed at the start, so that we can see if there is any difference in how you are feeling. At around 12 months after the surgery we will arrange one more visit to complete the questionnaires again so that we can see if anything has changed.

We may also telephone you after the 4-month visit to ask some questions about how you are finding being involved in the study. This will give you a chance to give some feedback on your experiences as well as your views on the care your friend/relative is receiving. Not all carers will receive a phone call. We aim to call 30 carers who have agreed to take part. We will offer you a £30 shopping voucher for your time and inconvenience in taking part in the telephone interview.



How will I know which treatment my friend/relative going to have?

In the FEMuR III study patients will be split into two groups at random:

- One group will receive normal NHS care
- The other group will receive the enhanced rehabilitation package

In the FEMuR III study participants are equally as likely to be in the group receiving normal NHS care as in the group receiving the enhanced programme. The healthcare team will let you know which group your friend/relative is in as soon as possible.

What are the benefits and risks of taking part?

We are not sure whether routine NHS care or the enhanced therapy programme is best but we anticipate that both will aid patient recovery following surgery.

We do not foresee any significant risks involved in taking part in FEMuR III, although the assessments will take up some time. It is also possible that the enhanced rehabilitation programme will take up more of your time if your friend/relative receives additional therapy sessions that you may have to support them with.

We hope that the results from the study will help doctors, therapists, patients and their carers in the future when making decisions about treatment.

What are the alternatives for treatment?

Patients recovering from hip fracture repair will get standard NHS treatment, though this may vary in different areas. In this study every patient will get standard NHS treatment even if they are in the enhanced rehabilitation group. Currently, there are no other alternative treatment programmes available.

Do I have to take part?

No, taking part is voluntary. It is up to you to decide whether or not you want to take part. If you choose to take part you can also choose to stop at any time without giving a reason. This will not affect the care received by your friend/relative or how you are treated.

What happens if I change my mind?

If at any point you decide to stop taking part in the study we will not collect any further information from you. We will use any study information collected up until the time you stop taking part.

Will my participation be kept confidential?

Yes. All information collected about you during the course of the study will be handled according to relevant ethical and legal requirements. Your personal information will be kept strictly confidential and will only be accessed by people working on the study, or working to ensure the study is being run correctly.

You will be given a study number, which will be used along with your initials to identify you on each paper form. Your full name and telephone number will be included on your consent form and a copy of this will be sent to the study team at the coordinating centre for the study, the Liverpool Clinical Trials Centre (LCTC.) There may be instances (depending on your local NHS,) when a copy of your contact details will need to be sent to other

locations or Universities within your local area to arrange your follow up visits. Only members of the FEMUR III team will be given access to your contact details, they will be held securely and destroyed after your final follow-up. We will ask for your telephone number so that we can contact you for the telephone interviews during the study. Your telephone number will not be used for anything else without your consent.

The University of Liverpool is the sponsor for this study based in the United Kingdom. The University of Liverpool along with Bangor University will be using information from you in order to undertake this study and act as the joint data controllers for this study. This means that both joint data controllers are responsible for looking after your information and using it properly. The University of Liverpool will keep identifiable information about you for a maximum of 25 years after the study has finished. Arrangements for confidential destruction will then be made.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information in the "How we use your information" section on the trial website Femur3study.co.uk

Your friend/relative's NHS hospital and/or community health team will collect information from you for this research study in accordance with our instructions.

The only people working on the study who will have access to information that identifies you will be people who need to confirm your participation in the study, contact you after 4 months to ask you questions about taking part in this study or audit the data collection process. The people who analyse the information will not attempt to identify you or find out your name or contact details.

Your friend/relative's NHS hospital and/or community health team will keep identifiable information about you from this study for up to a maximum of 25 years after the study has finished.

FEMuR III Carer PISC V4.0 19/09/2019
IRAS Project ID: 246828

Additional information about future research:

When you agree to take part in a research study, the information you give may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

What will happen to the results of the study?

It is intended that the results of the study will be presented at conferences and published in medical journals so that we can explain to the medical, nursing and therapies' community what our research results have shown. Confidentiality will be ensured at all times and you will not be identified in any publication.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with one of the research team who will do their best to answer your questions.

If at any time during the study you feel distressed or anxious please speak to your research team, a therapist or contact your GP.

If you wish to make a formal complaint, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Every care will be taken in the course of this clinical study. However, in the unlikely event that you are harmed by taking part in this research project, compensation may be available and you may have to pay your related legal costs. The University of Liverpool holds insurance against claims from participants for

harm caused by their participation in this clinical trial. Participants may be able to claim compensation if they can prove that the University of Liverpool has been negligent. However, if you are harmed and this is due to someone's negligence in the NHS, then you may have grounds for a legal action for compensation against the NHS, but you may have to pay for your legal costs. The normal NHS complaints procedures should be available to you. The study sponsor accepts no liability for negligence on part of your NHS organisation's employees.

Additional information

The University of Liverpool is responsible for managing this study; they have asked that the day to day running of the study is carried out by the Liverpool Clinical Trial Centre (LCTC) part of the University of Liverpool. Additional support is provided by other researchers from participating universities (the study team).

This study is funded by the National Institute for Health Research's Health Technology Assessment programme (ref: 16/167/09).

The study has been reviewed by the National Institute for Health Research (NIHR), Health Research Authority and the National Research Ethics Service Committee. Tyne and Wear South reviewed the study and given approval for it to take place.

The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

**Thank you for reading this
information sheet.**

Contacts for further information

If you would like more information or have any questions about the FEMuR III study please talk to:

Principal Investigator: <PI name to go here>

Research Nurse: <RN name to go here>

Telephone: <Hospital contact number to go here>

Or visit the website: Femur3study.co.uk

If you wish to discuss the study with someone independent of the research team you can contact the FEMuR III Carer PISC V4.0 19/09/2019
IRAS Project ID: 246828

local NHS Patient Advice and Liaison Service (PALS) or local equivalent on: <<Local PALS or equivalent telephone number to go here>>

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Fracture in the Elderly Multidisciplinary Rehabilitation III

<<Local NHS Logo to go here>>

<Trust/Site address 1>

<Trust/Site address 2>

<Trust/Site address 3>

<postcode>

Tel: <telephone number>

Carer Participant Consent Form

To be completed by the Researcher:														
Site Name:														
Carer Study Number										Carer Initials:				
Participant Study Number														

To be completed by the carer:

Once you have read and understood each statement please enter your initials in each box	Initial
Example: I confirm that I have read and understand the Participant Information Sheet.	JS
1. I have read and understood the information sheet for this study. I have had the opportunity to ask questions and have had these answered satisfactorily.	<input type="text"/>
2. I understand that participation is voluntary and that I am free to withdraw from the study at any time, without giving a reason, and without my care or legal rights being affected.	<input type="text"/>
3. I understand that my data will be retained for a maximum of 25 years at site and by the Liverpool Clinical Trials Centre (LCTC) part of the University of Liverpool and that they will be stored in a confidential manner.	<input type="text"/>
4. I give permission for a copy of my consent form which will include my name and telephone number to be sent to members of the FEMUR III team (where it will be kept in a secure location), to allow confirmation that my consent was given.	<input type="text"/>
5. I understand that any data collected during the study may be looked at by authorised individuals from the study team and those listed under "Additional information" (NHS organisation, sponsor and regulatory authorities). I give permission for these individuals to have access to my records.	<input type="text"/>
6. I agree to allow information or results arising from this study to be used in future healthcare and/or medical research in a pseudo-anonymised form.	<input type="text"/>
7. I agree to take part in the above study.	<input type="text"/>
The statements below are OPTIONAL (you can still participate even if you only agree to the statements above):	
8. I agree that I may be contacted in the future in relation to this or other related studies.	<input type="text"/>
9. I agree to being contacted by a study researcher to conduct a qualitative interview and for the interview to be recorded.	<input type="text"/>
Telephone number: <input type="text"/>	
(if you agree to this statement provide your details below):	
Your full name (please print):	
Your signature:	Date: <input type="text"/>

To be completed by the Researcher (after carer has completed the form):

Researcher full name (please print):			
Researcher signature:		Date:	<input type="text"/>