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Synopsis

A community-based rehabilitation package following hip fracture: FEMuR III a multi-centre RCT, economic and process evaluation

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Abstract

Background: Proximal femoral (hip) fracture is common, serious and costly. An enhanced community rehabilitation intervention (Fracture in the Elderly Multidisciplinary Rehabilitation) was codeveloped with patients, carers and therapists. Trial methods have been tested previously in a feasibility study.

Objective: To determine the effectiveness and cost-effectiveness of the Fracture in the Elderly Multidisciplinary Rehabilitation intervention compared with usual NHS rehabilitation care. To determine the mechanisms and processes that explain the implementation and impacts of the Fracture in the Elderly Multidisciplinary Rehabilitation intervention.

Design and methods: Definitive, pragmatic, multisite, parallel-group, two-armed, superiority randomised controlled trial with 1 : 1 allocation ratio. Concurrent economic and process evaluations.

Setting: Participant recruitment in 13 hospitals across England and Wales, with the Fracture in the Elderly Multidisciplinary Rehabilitation intervention delivered in the community.

Participants: Patients aged over 60 years, with mental capacity, recovering from surgical treatment for proximal femoral fracture, and living in their own home prior to fracture.

Interventions: Usual rehabilitation care (control) was compared with usual rehabilitation care plus the Fracture in the Elderly Multidisciplinary Rehabilitation intervention, which comprised a patient-held workbook and goal-setting diary aimed at improving self-efficacy, and six additional therapy sessions delivered in the community (intervention), to increase the practice of exercise and activities of daily living.

Primary and secondary outcome measures: Primary effectiveness outcome was the Nottingham Extended Activities of Daily Living scale at 12 months. Secondary outcomes included: Hospital Anxiety and Depression Scale, Falls Self-Efficacy – International scale, hip pain intensity, fear of falling, grip strength and Short Physical Performance Battery. Economic outcomes were EuroQol EQ-5D-3L and Client Service Receipt Inventory.

Results: In total, 205 participants were randomised ($n = 104$ experimental; $n = 101$ control). Trial processes were adversely affected by the coronavirus disease discovered in 2019 pandemic and the target sample of 446 was not met. By 52 weeks, the intervention group had worse Nottingham Extended Activities of Daily Living scores than the control group (mean difference: -1.9 ; 95% confidence interval: -3.7 to -0.1), which was not clinically important. Joint modelling analysis testing for difference in longitudinal outcome adjusted for missing values, removed the apparent inferiority of the Fracture in the Elderly Multidisciplinary Rehabilitation intervention with a mean difference of 0.1 (95% confidence interval: -1.1 to 1.3). There was no statistical or clinically significant difference in secondary outcomes between groups. A median of 4.5 extra rehabilitation sessions were delivered to the intervention group, with a median of two sessions delivered in-person. Instrumental variable regression did not find any effect of the amount of rehabilitation on the main outcome. There were 53 unrelated serious adverse events including 11 deaths in the control group: 41 serious adverse events including nine deaths in the intervention group. The mean cost of delivering the Fracture in the Elderly Multidisciplinary Rehabilitation intervention was £444 per participant. The intervention group gained 0.02 (95% confidence interval: -0.036 to 0.076) more quality-adjusted life-years than the control group. This was not clinically or statistically significant. Mean health service use costs were higher in the intervention group.

Limitations: The trial was severely impacted by coronavirus disease discovered in 2019. Possible reasons for lack of detected effect included limited intervention fidelity (number and remote mode of delivery), lack of usual levels of support from health professionals and families, and change in recovery beliefs and behaviours during the pandemic.

Conclusion: The Fracture in the Elderly Multidisciplinary Rehabilitation intervention was not more effective and had higher costs than usual rehabilitation care.

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A plain language summary of this synopsis is available on the NIHR Journals Library Website <https://doi.org/10.3310/RBGD4741>.

Introduction

This randomised controlled trial (RCT) assessed the effectiveness and cost-effectiveness of an enhanced rehabilitation intervention, based in the community, for people recovering from proximal femoral (hip) fracture compared with usual rehabilitation care. The Fracture in the Elderly Multidisciplinary Rehabilitation (FEMuR) intervention was codeveloped with patients, carers and therapists. The feasibility of trial methods was established in a Phase II randomised feasibility study, conducted across three acute hospitals in North Wales, with the intervention delivered in community settings. Details of methods and findings are reported in our other outputs and planned outputs (Box 1), as well as in the trial protocol, and summarised in *Methods* and *Results summary*.

- Williams NH, Busse M, Cooper R, Dodd S, Dorkenoo S, Dougsong K, et al. Effectiveness of a community-based rehabilitation programme following hip fracture: results from the Fracture in the Elderly Multidisciplinary Rehabilitation – Phase III (FEMuR III) randomised controlled trial. *BMJ Open* 2025;5:e091603. <https://doi.org/10.1136/bmjopen-2024-091603>
- Dougsong K, Davies J, Ezefor V, Spencer LH, Williams N, Edwards RT. A cost-consequence analysis of a community-based rehabilitation programme following hip fracture (Fracture in the Elderly Multidisciplinary Rehabilitation – FEMuR III). *Osteoporosis Int* 2025. <https://doi.org/10.1007/s00198-025-07459-4>
- Ralph P, Dodd S, Dorkenoo S, Dougsong K, Edwards RT, Golding-Day M, et al. Process evaluation of a community-based rehabilitation programme following hip fracture: results from the Fracture in the Elderly Multidisciplinary Rehabilitation – Phase III (FEMuR III) randomised controlled trial. (not yet published)
- Harvey K, Ralph P, Spencer LH, Dougsong K, Morrison V, Lemmey A, et al. Perceived barriers and facilitators of staff recruiting participants to a randomised controlled trial of a community rehabilitation intervention following hip fracture. *Trials* 2024;25:826. <https://doi.org/10.1186/s13063-024-08655-z>

BOX 1 List of outputs from the FEMuR III RCT

- Williams NH, Dodd S, Hardwick B, Clayton D, Edwards RT, Charles JM, 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. <https://doi.org/10.1136/bmjopen-2020-039791>

Background and rationale

Proximal femoral fracture, more commonly referred to as hip fracture, is a common, major health problem in old age. The total number of patients entered onto the national hip fracture database in England, Wales and Northern Ireland in 2022 was 72,160.¹ As the

population ages the number of elderly people falling and fracturing their hips is projected to increase further.^{2,3} Hip fractures are associated with increasing age, female sex, falls, frailty, living situation, osteoporosis, cognitive impairment, poor nutrition and sarcopenia.⁴ Mortality is high with 28% dying in England and Wales within 12 months post injury.⁵ A review of the long-term disability associated with proximal femoral fracture found that survivors experienced worse mobility, less independence, worse quality of life and higher rates of institutionalisation than age-matched controls.⁶ Most recovery of walking ability and activities of daily living (ADLs) occurred in the first 6 months following fracture with only 40–70% recovering their pre-fracture level of mobility and ability to perform ADLs.^{6,7} Proximal femoral fracture costs the NHS in the UK more than £2 billion a year.⁸ The cost of hospital, community and social care are almost four times as costly in the 12 months after admission, compared with the costs of the admission itself, and the majority of costs occur outside of the acute hospital setting.⁸

Several systematic reviews of multidisciplinary rehabilitation following hip fracture have concluded that while individual components of rehabilitation programmes may aid recovery after a hip fracture, there was insufficient evidence of clinical or cost-effectiveness.^{9–18} The National Institute for Health and Care Excellence (NICE) have issued guidelines for the management of hip fracture that include the provision of a co-ordinated multidisciplinary hip fracture programme including the early identification of individual goals for multidisciplinary rehabilitation to recover mobility and independence, and to facilitate return to pre-fracture residence and long-term well-being.¹⁹ However, the 2017 Hip Sprint audit reported that community rehabilitation services were inconsistent.²⁰ Research recommendations from the NICE clinical guidelines included a RCT testing the effectiveness and cost-effectiveness of additional intensive physiotherapy or occupational therapy after hip fracture.¹⁹

Phase I: codeveloping the FEMuR intervention

A Health Technology Assessment (HTA) programme funded study²¹ followed the first two phases of the Medical Research Council's (MRC) framework for developing and evaluating complex interventions.²² The first phase codeveloped a coherent theoretical basis for the intervention from a realist review of the literature, a survey of current practice in the UK, and focus groups of the multidisciplinary rehabilitation teams, hip fracture patients and their carers.²³ This resulted in the following overarching working theory:

In the context of patients with a great range and variety of pre-fracture physical and mental comorbidities affecting their ability to meet rehabilitation goals, a tailored intervention incorporating increased amount of high quality practice of exercise and activities of daily living leads to better confidence, mood, function, mobility and reduced fear of falling.

There were three underlying programme theories:

1. Improve patient engagement by tailoring the intervention according to individual needs and preferences.
2. Reduce fear of falling (FoF) and improve self-efficacy to exercise and perform ADLs.
3. Co-ordination of services and sectors delivering the rehabilitation.

These theories informed the development of an enhanced rehabilitation intervention called FEMuR (Figure 1). In addition to usual care, this FEMuR intervention included:

- A patient-held workbook containing information on hip fracture, what to expect from rehabilitation, their role in their recovery, the importance of physical activity and of maintaining functional activities and signposting to other services. The workbook encouraged written self-reflection and explained how to set personal, achievable goals.
- A patient-held goal-setting diary to promote engagement, increase self-management and self-efficacy.
- Six home-based therapy sessions delivered by physiotherapists or occupational therapists with the assistance of technical instructors providing reliable and consistent care.

Phase II feasibility study

The second phase of the study assessed the feasibility and acceptability of the FEMuR intervention and the feasibility of trial methods.²⁴ It included a cohort study, a randomised feasibility study, economic evaluation and process evaluation. Patient-participants in the randomised feasibility study were recruited from three acute hospitals in North Wales, and the rehabilitation intervention was delivered in the community. Patient-participants were older adults aged 65 years or older who had received surgical treatment for hip fracture, had been living independently prior to the hip fracture, had mental capacity as assessed by their clinical team, and received rehabilitation in the North Wales area. They were randomised to usual care (control) or usual care plus the FEMuR intervention.

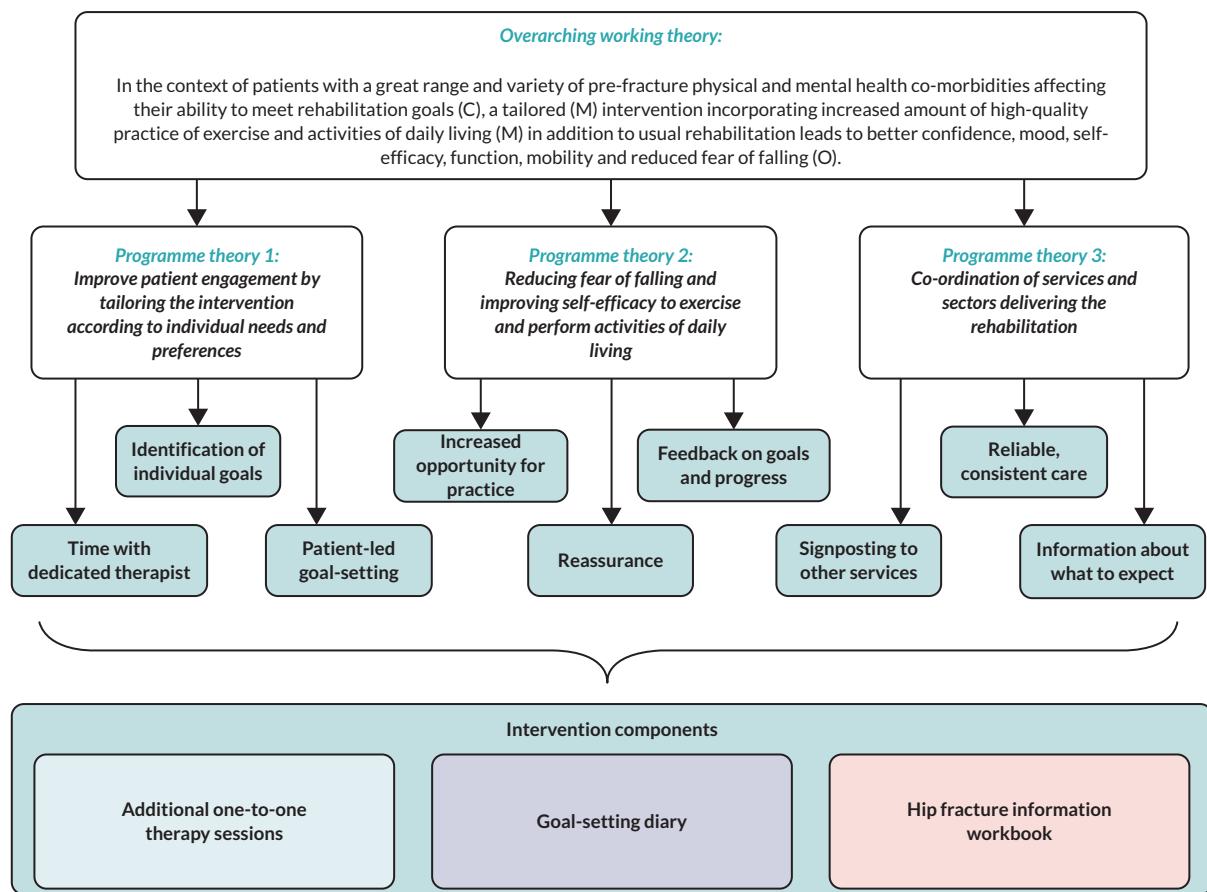


FIGURE 1 Development of the FEMuR intervention from programme theories.

Between June 2014 and March 2015, 593 patients were screened and, 266 (45%) were eligible, 193 (73%) were invited to participate and 62 (23% of the eligible population) recruited.²⁵ From the recruited patient-participants, 41 carers were identified with 31 recruited (76%). Patient-participant retention rate was 79% overall (intervention group 86%; control group 75%) and carer-participant retention rate was 44%.

At 3-month follow-up there were minimal differences between the two groups for most of the outcome measures, with a trend for a greater improvement in the intervention group, but with small effect sizes. However, the Nottingham Extended Activities of Daily Living (NEADL) scale^{26,27} showed a medium effect size, also in favour of the intervention group, with an adjusted mean difference of 15.8 (Cohen's $d = 0.63$).

The cost of delivering the intervention was £231 per patient. Both the intervention and control groups showed improvements in EQ-5D-3L health utility index²⁸ scores from baseline to the 3-month follow-up, but the intervention group had slightly higher mean quality-adjusted life-year (QALY) gains.

Four hundred hip fracture patients were recruited to an anonymised cohort study. The cohort population was older (mean age difference 4.5 years), more likely to be re-admitted to hospital and with higher mortality.

The embedded process evaluation found that usual rehabilitation care was very variable with a median of three appointments; the enhanced rehabilitation group received a mean of five additional therapy sessions.²⁹

The results of the feasibility study informed a sample size calculation (see later section), the final choice of outcome measures and refinement of the FEMuR intervention for this Phase III RCT. The inclusion criteria were broadened at the request of the funder to include people aged over 60 years.

Aims and objectives

The overall aim was to assess the effectiveness and cost-effectiveness of the FEMuR intervention, and to determine whether it had been delivered as intended. The specific objectives were as follows:

Primary objective

To determine the effectiveness of the FEMuR intervention following surgical repair of proximal femoral fracture in older people compared with usual care, in terms of the performance of ADLs at 52-week follow-up.

Secondary objectives

1. To compare the cost-effectiveness of the FEMuR intervention following surgical repair of proximal femoral fracture in older people compared with usual care at 52-week follow-up.
2. To determine the effectiveness of the FEMuR intervention following surgical repair of proximal femoral fracture in older people compared with usual care, in terms of the performance of ADLs at 17-week follow-up.
3. To determine the effectiveness of the FEMuR intervention following surgical repair of proximal femoral fracture in older people compared with usual care, in terms of anxiety and depression at 17- and 52-week follow-up.
4. To assess whether the FEMuR intervention created change in self-efficacy, hip pain, cognitive function, FoF and physical function as potential mediators for improving ADLs at 17- and 52-week follow-up.
5. To assess whether the FEMuR intervention created change in strain, anxiety and depression in carers at 17- and 52-week follow-up.
6. To determine the mechanisms and processes that explain the implementation and impacts of the FEMuR intervention and whether there were adverse effects.

Methods

Trial design

This was a pragmatic, multisite, parallel-group, two-armed, superiority RCT with 1 : 1 allocation ratio and an internal pilot phase (see *Figure 1*). Outcome assessment and statistical analysis were performed blind; patient- and carer-participants and clinicians were unblinded. A concurrent economic evaluation was a cost-consequences analysis from a health service and personal social care perspective. An embedded process evaluation examined the mechanisms and processes that explain the implementation and impacts of the enhanced rehabilitation programme.

Trial setting

Thirteen sites were recruited in different regions of England and Wales, with a spread of socioeconomic conditions and a mixture of rural and urban locations,

in Nottinghamshire, Norfolk, North Wales, South Wales, Kent, Derbyshire, Cheshire and Lincolnshire. Patient-participants were recruited on orthopaedic, rehabilitation and community hospital wards or after hospital discharge at home. The intervention was delivered in the community, following hospital discharge, by community teams receiving referrals from the acute hospital sites and their associated community hospitals.

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.
3. Lacking mental capacity to give informed consent.

Carer-participants

We also recruited carer-participants to evaluate carer strain, anxiety and depression. These were defined as a relative or friend providing help with ADLs or physical care, at least 4 days per week. Carer-participants provided informed consent but did not receive any trial intervention, or randomisation.

Trial interventions

We compared the FEMuR intervention with usual rehabilitation care.

Usual rehabilitation care

Usual care consisted 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 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 teams in both health and social care services. There were no restrictions on concomitant medications or treatments.

FEMuR intervention

The main aim of the FEMuR intervention was to enhance usual rehabilitation by increasing patient-participants' self-efficacy³⁰ and increasing the amount and quality of their practice of physical exercise and ADLs to improve functional outcomes at follow-up. Self-efficacy was enhanced by means of a patient-held information workbook and a goal setting diary. The workbook included information about: what had happened to them and what to expect from their recovery; information about NHS, council and voluntary sector services; how to manage their recovery, set goals, monitor progress of their rehabilitation and reduce the FoF. In addition to the variable community-based rehabilitation that is provided as part of usual care, we provided up to six additional therapy sessions delivered alongside the workbook, using the diary to set individuals' goals and monitor progress. The therapists tailored these extra sessions according to need.

Outcomes and potential mediators

Patient-participants completed outcome measures at baseline, 17 and 52 weeks administered by a research assistant blinded to participant allocation. Follow-up assessments were completed within participants' homes, or remotely during the coronavirus disease discovered in 2019 (COVID-19) pandemic lockdown restrictions. The primary outcome was 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 was asked to recall the 4 weeks prior to hip fracture and not the 4 weeks prior to completing this questionnaire. Secondary outcome was the Hospital Anxiety and Depression Scale (HADS).³¹ Economic measures were EQ-5D-3L²⁸ to derive QALYs and Client Service Receipt Inventory (CSRI) to derive costs.³² Potential mediators of outcome included Falls Efficacy Scale – International (FES-I) for falls' self-efficacy,^{33,34} a visual analogue scale (VAS) for hip pain intensity,³⁵ and visual analogue scale – Fear of Falling (VASFoF).³⁶ The research assistant assessed patient-participants' cognitive function at baseline, 17 and 52 weeks using the Abbreviated Mental Test Score.³⁷ The research assistant measured physical function at baseline, 17 and 52 weeks using the grip strength test³⁸⁻⁴⁰ and using the Short Physical Performance Battery (SPPB)^{41,42} at 17 and 52 weeks. Carer-participants completed the Caregiver Strain Index⁴³ and the HADS³¹ at baseline, 17 and 52 weeks.

Sample size calculation

Based on the analysis of covariance (ANCOVA) with an alpha of 5% and 90% power to detect a difference of 2.4 in NEADL score [standard deviation (SD) = 10, R^2 of

covariate = 0.52] with a 79% retention rate, 446 patient-participants would need to be recruited. Please see the protocol for justification of these sample size parameters.

Participant recruitment

Patients with proximal femoral fracture were identified and screened for eligibility, including mental capacity, by clinical staff on orthopaedic or rehabilitation wards. If a patient was eligible, and interested in the trial, they were recruited by the trial team researchers following the trial's informed consent process. Assessment of eligibility often occurred over several visits, if, for example, the patient experienced temporary delirium post surgery.

Randomisation procedures

Patient-participants who provided informed consent completed baseline outcome measurements prior to randomisation. Randomisation took place no later than 6 weeks after hip fracture repair surgery. The randomisation had an allocation ratio of 1 : 1. Randomisation used a minimisation programme with a built-in random element utilising the factors site and gender. Randomisation was completed by secure web access to the remote randomisation site at the Liverpool Clinical Trials Centre. The therapy team delivering the enhanced rehabilitation intervention received an automated e-mail when a participant was allocated to the intervention group.

Blinding

It was not possible to blind participants or their clinicians to treatment group allocation. The research assistants collected outcome measurements blind to treatment allocation. After the final follow-up assessment, they completed a perception of allocation form to monitor the level of blinding achieved for these researchers.

Statistical analysis

Primary and secondary outcomes at baseline, 17-week and 52-week follow-up were summarised for each treatment group using descriptive statistics at each time point. If outcomes were normally distributed, the difference between group means [with 95% confidence intervals (CIs)] were reported from the repeated measures ANCOVA (accounting for 17- and 52-week outcomes) adjusted for baseline score and stratification factors (site and gender); non-normal outcomes were transformed and analysed as difference from baseline to ensure normality (again using repeated-measures ANCOVA). Predictors of missing data were investigated using regression models. A sensitivity analysis used a joint modelling approach to check whether there was any difference in longitudinal outcome between the randomised arms adjusted for dropouts or

missing values. Additional sensitivity analyses were carried out excluding patients where the outcome assessor had become unblind (if the percentage of such patients exceeded 5%) and to account for the impact of COVID-19 restrictions on the ability for patients to undertake usual ADLs. The impact of engagement with the intervention were assessed using instrumental variable regression, using the number of rehabilitation sessions and total time spent in rehabilitation. If the FEMuR intervention were more effective than control, then mediation analysis would examine the hypothesised mechanism of change in terms of self-efficacy, hip pain, cognitive function, FoF and physical function.

Economic analysis

The FEMuR intervention was fully costed using unit costs from a public sector multiagency perspective (health service and personal social care). Unit costs were obtained from national sources of reference costs^{44,45} and applied to information received from pilot questionnaires, namely, salary band of therapists, time spent with the patient-participant, costs of travel and costs of any additional equipment. Costs of health and social care services used by the participants were also costed using national sources of reference costs. The costs of service use and the cost of the intervention were combined. The EQ-5D (3L) was used to calculate QALYs over the 52-week trial period, using the area under the curve method.^{46,47} Missing data on EQ-5D score were imputed with multiple imputations by chained equations, assuming data was missing at random (since there was no evidence that the missing data depended on baseline participant characteristics or any particular factors). Fifty imputed data sets were created using linear regression. Imputation was performed by type of fracture. After imputation, means were estimated using linear regression models controlling for age, type of fracture, comorbidity, and gender. Results were presented as a cost-consequences analysis.

Process evaluation

The process evaluation built a picture of how the intervention was carried out and attempted to identify if observed results were due to the enhanced rehabilitation programme, or to external factors such as the COVID-19 pandemic.⁴⁷⁻⁵⁰ Several data sources were used: semi-structured interviews of patient-participants, carer-participants, therapists and recruiters; descriptive data on rehabilitation sessions from case report forms and the completed workbooks and diaries. Qualitative data were examined using thematic analysis.⁵¹ The process evaluation followed an iterative process of explanation building across all data sources, revising findings from each data

source, reflecting on the potential insight that each could offer, and relating them to or challenging the initial programme theory. Data analyses were ongoing throughout the study, and all process evaluation data were analysed independently of effectiveness data before the two data sets were combined to provide a robust explanation of what did or did not work during the trial.

Results summary

We report the effectiveness results, followed by the economic evaluation and then the process evaluation, split between recruitment to the trial and fidelity and implementation of the FEMuR intervention. Please see the publications in *Box 1* for more detail. See *Figure 2* for patient-participants flow through the RCT.

Effectiveness analysis

Please see the effectiveness publication referenced in *Box 1* for more detail. In total, 205 patient-participants were randomised ($n = 104$ experimental; $n = 101$ control) between April 2019 and May 2022. Two patient-participants were ineligible after randomisation (one from each group). There were 20 deaths (11 control, 9 intervention), 34 withdrew consent from further follow-up (16 control, 18 intervention) and three were lost to follow-up (1 control, 2 intervention). Trial recruitment was adversely affected by the COVID-19 pandemic, which was paused on 19 March 2022, after 96 patient-participants had been randomised, until 26 June 2020. Sites varied in the timing of re-opening for recruitment and closed to recruitment in response to local outbreaks from December 2020 to March 2021. Intervention delivery and follow-up assessment were also adversely affected by COVID-19. Only 44% of the intervention group received the planned six additional rehabilitation sessions. The median number was 4.5, and only a median of two of these were delivered in-person with the remainder delivered remotely. The usual rehabilitation care received by both groups was very variable, with a large range and skewed distribution.

By 52 weeks, the intervention group had worse NEADL scores than the control group (mean difference: -1.9; 95% CI -3.7 to -0.1), which was not clinically important. Joint modelling analysis testing for difference in longitudinal outcome adjusted for missing values, removed the apparent inferiority of the FEMuR intervention with a mean difference of 0.1 (95% CI -1.1 to 1.3). There was no statistically or clinically significant between-group difference in secondary outcomes. Sensitivity analyses, examining the

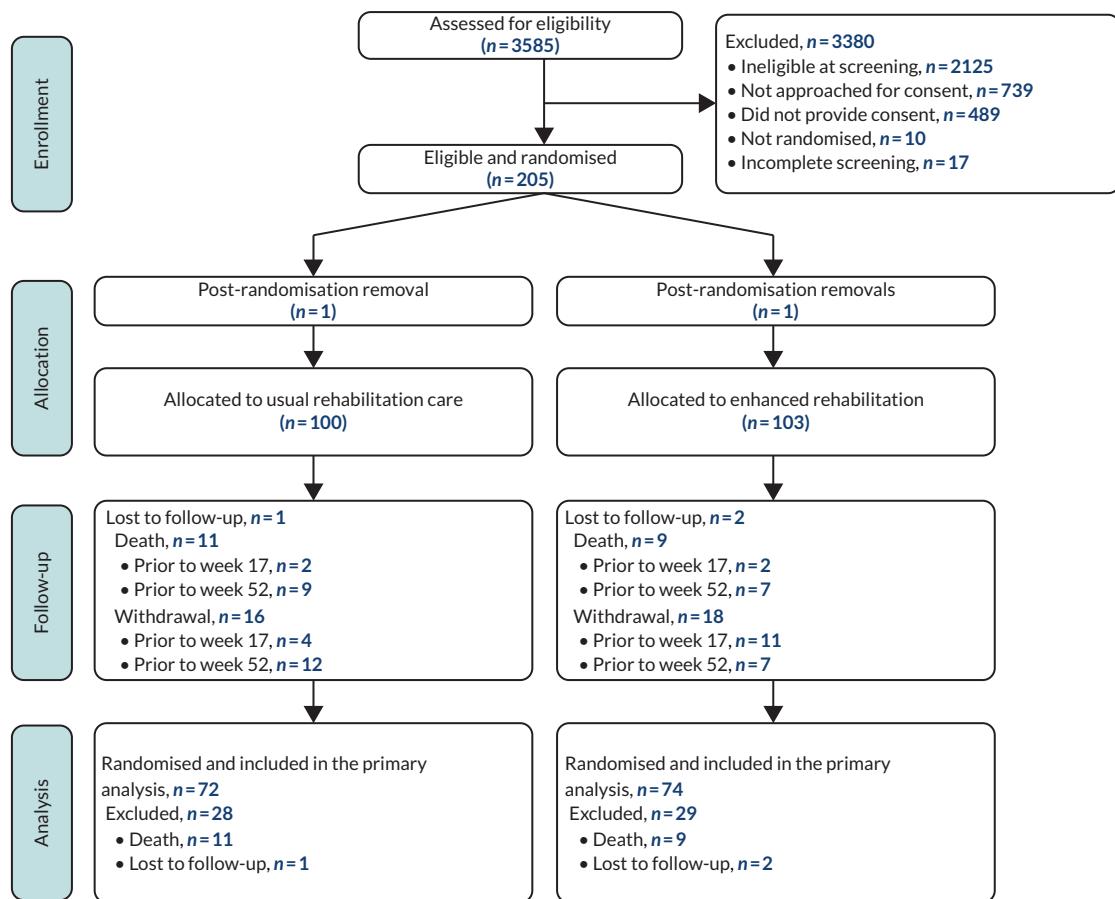


FIGURE 2 CONSORT flow diagram for FEMuR III trial. Reproduced with permission from Williams *et al.*⁵² This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: <https://creativecommons.org/licenses/by/4.0/>. The figure includes minor additions and formatting changes to the original text.

impact of COVID-19 restrictions, produced similar results. Instrumental variable regression did not find any effect of the amount of rehabilitation on the main outcome. There were 53 unrelated serious adverse events (SAEs) including 11 deaths in the control group; 41 unrelated SAEs including nine deaths in the intervention group.

Economic analysis

Please see the health economic publication referenced in *Box 1* for more detail. As there was no evidence of effectiveness for the FEMuR intervention, a cost-consequences analysis was performed. Mean intervention delivery costs per participant were £444 (SD: 337) for the FEMuR intervention group and £157 (SD: 190) for the usual care group. There was a large proportion of missing data (40%). For participants with complete EQ-5D data ($n = 142$), both groups showed improvement in EQ-5D index score from 0.53 (SD: 0.17) to 0.65 (SD: 0.29) in the FEMuR intervention group and from 0.51 (SD: 0.20) to 0.59 (SD: 0.32) in the control group. Index scores did not reach the UK population norm (0.73) in either group.

Participants in the intervention group gained 0.02 (95% CI -0.036 to 0.076) more QALYs than the usual care group, which was not statistically significant ($p = 0.312$). The small mean improvement was not clinically important either, but had wide confidence intervals which just included the minimum clinically important difference for EQ-5D. For imputed cases, participants in the intervention group gained less QALYs than the usual care group by 0.01 (95% CI -0.056 to 0.030). For participants with complete cost data ($n = 115$), at 52-week follow-up, mean health service use costs were higher in the intervention group from both NHS and wider societal perspectives. Mean costs from the wider societal perspective were £3346 (SD: 5343) for the FEMuR intervention group and £1743 (SD: 4224) for the usual care group. This was due to longer inpatient stays, which was 5 days longer for the FEMuR intervention group and was not related to the FEMuR intervention. Regarding hospital service use, both groups reported similar frequency of total admissions, outpatient and accident and emergency attendances, further falls requiring hospital treatment and further hip fractures.

Recruitment to the trial

Please see the barriers and facilitators to recruitment publication referenced in *Box 1* for more detail. Recruitment to this trial was severely affected by the COVID-19 pandemic and was halted after 205 had been recruited to the trial (68% women, 98% White UK ethnicity, mean age 81 years). Recruitment was affected by access to clinical notes and systems by the recruiting staff, as well as to patients with hip fracture and their carers. There were differing priorities of clinical and research staff, and sometimes disconnection between research sites and the trial team. The COVID-19 pandemic completely halted recruitment, then restricted access to research staff when recruitment resumed and increased patients' reluctance to participate. Establishing good rapport and approaching potential participants with health professionals, who had a pre-existing clinical relationship, was important. Perceived information overload in participant information sheets and a lack of knowledge of trial processes among recruitment staff were barriers to recruitment. Patients' participation was influenced by their perceptions of research, which in turn was influenced by their previous experience and their understanding of random allocation of interventions. Friends and family often did not identify themselves as carers. More than half of the recruitment staff reported ethical and moral dilemmas when deciding whether to approach potential patient-participants.

Process evaluation

Please see the process evaluation publication, which is not yet published, for more detail. COVID-19 also affected other trial procedures, including the fidelity and implementation of the FEMuR intervention, leading to adaptations to intervention delivery. Despite the lack of effectiveness of the FEMuR intervention, patient-participants and therapists reported that the intervention was acceptable and useful. The additional therapy sessions were the most important component of the FEMuR intervention. Patient-participants valued reassurance, tailored goal-setting, and consistent, person-centred support. Workbooks provided structure during initial interactions, especially when therapy was delivered remotely. Goal-setting diaries were useful for gauging progress during the early stages of rehabilitation.

Changes in FEMuR intervention delivery because of the COVID-19 pandemic affected intervention fidelity in terms of the number of sessions delivered and the switch to remote delivery, with a median of 4.5 extra rehabilitation sessions delivered to the intervention group, and a median of two of which were in person. The degree of patient-participants' motivation and determination and the therapists' skills, knowledge and experience affected

implementation. Usual care delivery was variable with many patient-participants receiving none, but a few received a high volume of support.

Adherence to the FEMuR programme theory was adversely affected by the pandemic. Although there was good evidence of tailoring, there were fewer opportunities to practise exercise and ADLs outside of the home. The amount and quality of therapist feedback were reduced with difficulties reassuring patients about which activities were safe, concerns around risk and limits due to shielding and lockdown. Although the workbook and diary provided structure, co-ordination with other community services was often poor, and made worse by the pandemic.

Discussion

Principal findings and achievements

Recruitment and retention in the trial were adversely affected by the COVID-19 pandemic. This reduced the power of the statistical analysis. Although by 52 weeks the FEMuR intervention group had worse NEADL scores than the usual rehabilitation control group, a joint modelling analysis removed the apparent inferiority of the FEMuR intervention, indicating that there was no statistical or clinical difference between the groups. There was neither statistical, nor clinically significant change in the HADS or the potential mediators (self-efficacy, hip pain intensity, FoF, grip strength and SPPB). Sensitivity analyses examining the impact of COVID-19 restrictions produced similar results. The median number of extra rehabilitation sessions delivered was 4.5, and only a median of two were delivered in-person, which has important implications for intervention fidelity.

The FEMuR intervention cost £444 per participant. Both groups showed improvements in EQ-5D scores, with a marginal improvement in QALY for the intervention group that was neither clinically nor statistically significant. Health service costs were higher in the intervention group, but these were due to inpatient costs unrelated to the FEMuR intervention delivered in the community. Inpatient stay was the largest component of total healthcare cost for both groups, but non-hip-related conditions accounted for the majority of total healthcare cost for both groups.

There were six broad themes identified as both barriers and facilitators to recruitment from the semistructured interviews with trial recruitment staff. These were: access and integration, information and knowledge, impact of COVID-19, rapport and relationships, perceptions of research and eligibility ambiguity. Key findings included

staffing difficulties, differing priorities of clinical and research staff, strong patient preference for or against the intervention, discussion about reducing the length of patient information leaflets, concerns about patient eligibility, equipoise and family members' resistance to being identified as carers.

Despite the lack of effectiveness in the RCT, the patient-participants interviewed found the FEMuR intervention to be beneficial. The additional therapy sessions were the most valued component of the FEMuR intervention, although their effectiveness was diluted by reduced numbers of sessions delivered and remote delivery. Goal setting and tailoring were key aspects of the FEMuR intervention, and therapists played a crucial role supporting patient-participants to achieve rehabilitation goals, as well as providing reassurance about safe activities. These key aspects were more difficult to deliver when using remote methods, which may help to explain the lack of effectiveness. The workbook and diary were useful tools, which provided structure during the initial stages of rehabilitation, but their usefulness diminished as patients progressed, and they were not as valued as the additional therapy sessions. Co-ordination with other community services was often poor, which was made worse by the pandemic. Finally, usual rehabilitation care varied greatly, and some patient-participants in the control group used their past experience to set and achieve their own rehabilitation goals, despite minimal input from therapists.

Contribution to existing knowledge

This RCT contributes to the limited evidence-base on the effectiveness of rehabilitation in community settings following hip fracture.^{9,15,16} Other studies have found that health status and quality of life improved in most patients in the first 6 months after hip fracture but did not return to pre-fracture levels.¹⁵ In contrast to the findings from this RCT, other studies have found that extended exercise rehabilitation programmes offered beyond the regular rehabilitation period improved physical functional outcomes.¹⁶ These programmes were more intensive than the FEMuR intervention with home-based in-person programmes lasting up to 12 months, offering up to 56 home visits. A systematic review of patient perspectives of recovery after hip fracture found that full recovery was perceived as a return to pre-fracture activities enabling independence.¹⁷ Participants felt vulnerable because of anxieties about FoF, ability to cope at home, going out in the community and attending social events, all of which would have been made more difficult by the COVID-19 lockdown. However, our sensitivity analyses, adjusting for the effect of COVID-19 restrictions on the performance of ADLs and follow-up assessment during the pandemic, did

not alter the findings. In the review, recovery was driven by a positive outlook and active engagement in the recovery process, which relied upon realistic expectations and goals tailored to individual needs and activities.¹⁷ Finally, patient-participants were reliant on both professional and social support,¹⁷ which was lacking during the pandemic. Our findings did not add any support to the limited evidence for the role of self-efficacy on recovery following hip fracture,¹⁸ nor did they contribute further data regarding the mechanisms and processes of successful rehabilitation.

The cost of the FEMuR intervention in the previous feasibility study was £231 per participant, or £310 taking into account inflation from 2015, which was lower than the £444 per participant in this larger RCT.²⁵ Participants from both groups reported better health scores, in terms of higher EQ-5D-3L index scores at baseline (0.65 for intervention and 0.59 for usual care), than participants with hip fracture in the Warwick Hip Trauma study (0.57).⁵³ The improvement in EQ-5D-3L index score is in line with the results of home-based and hospital-based rehabilitation in Taiwan.⁵⁴ The gain in QALYs of complete cases in this larger RCT was the same as in the feasibility study (0.02 QALYs).²⁵ The inpatient length of stay observed in this trial is consistent with national records of patients admitted with hip fracture in England and Wales between 2016 and 2019, ranging from 12 to 42 days.⁵⁵ The longer inpatient length of stay for the intervention group explained some of the increased health resource use costs in this group. These findings are consistent with the findings of the FEMuR feasibility trial.²⁵

The process evaluation from this trial reinforces many of the findings of the process evaluation in the preceding feasibility study.²⁹ These include variations in usual care, therapist uncertainty about implementation ambiguity, recruitment issues, the importance of goal setting, the role of the therapist for reassurance and guidance, and the acceptability of the FEMuR intervention. The median number of 4.5 extra rehabilitation sessions in the intervention group was slightly lower than the five extra sessions in the feasibility study, however only a median of two were delivered in-person compared with all five in the feasibility study. Unlike the feasibility study there were disparities between the qualitative and quantitative results.

The importance of setting personalised goals to encourage motivation and self-efficacy is well established.⁵⁶⁻⁵⁸ The FEMuR intervention relied on the expertise of the therapists, including individual tailoring and adjusting the rehabilitation programmes to support patients in re-establishing or adapting their everyday activities, which has been noted by others.⁵⁹⁻⁶⁵ Such expertise included the

use of coaching and motivational interviewing to support patient motivation and self-efficacy.^{56,66} The therapists and written materials also elicited forms of storytelling which support self-efficacy and functional recovery in hip-fracture patients.⁶⁷ As with the previous process evaluation in the FEMuR feasibility study, perceived outcomes were also influenced by the support patients received from carers, family, friends and neighbours.^{68,69} The importance of social support is widely acknowledged.⁷⁰ The disparities found in usual rehabilitation care reflect inconsistencies that persist across regions and healthcare settings.⁷¹ These inconsistencies influence the quality and intensity of rehabilitation services provided and impact on patient outcomes and healthcare equity.

Standardisation of complex interventions is difficult due to the impact of individuals, context, sites, settings and resources.⁷² Disparities were intrinsic to the FEMuR III intervention. Variations should be seen as adaptations rather than 'fidelity failure' with adaptations to local context viewed as acceptable if they are within the programme theory. Standardising components oversimplifies the form of a complex intervention; functional integrity is more important.⁷³ Disparities induced by COVID-19 may have impacted both function and form.

Strengths and weaknesses of the study in relation to other studies

This RCT followed previous work codeveloping the FEMuR intervention and assessing the feasibility of trial methods, according to the MRC framework for developing and evaluating complex interventions.²² However, this feasibility work could not foresee the impact of the COVID-19 pandemic on research project delivery, including the withdrawal of in-person visits by therapists to patient-participants' homes. We did not manage to recruit any patient-participants from ethnic minorities, despite recruiting in areas with large ethnic minority populations. There was active patient and public involvement (PPI) throughout all stages of the RCT.

We were unable to recruit the number of patient-participants suggested by our initial sample size calculation due to COVID-19 restrictions. The primary statistical analysis was therefore underpowered. There were also 20 deaths, 34 withdrawals of consent and 3 lost to follow-up, which reduced statistical power further. We know from our previous feasibility study²⁵ that compared with the total population who fracture their hip, we would likely recruit a younger sample with fewer complications. The patient-participants were also happy to participate in research projects and willing to participate in the enhanced rehabilitation programme. This might have meant that

many in the control group were motivated to recover their ADLs using their own resources. Lockdown restrictions imposed during the COVID-19 pandemic restricted in-person delivery of the FEMuR intervention, but we were able to continue delivering the intervention remotely. Instead of the planned six additional therapy sessions, patient-participants in the FEMuR intervention group received a median of 4.5 sessions, with only a median of two being in-person. Follow-up visits to patient-participants' homes were also restricted. However, we were able to continue follow-up assessments remotely, but recording of VAS, measurement of grip strength and physical function assessment using the SPPB was not possible, which limited the assessment of potential mediators. We were unable to recruit many carer-participants because of visiting restrictions in hospitals during the COVID-19 pandemic.

The concurrent economic evaluation was the first health economics study to investigate the cost of a multiagency hip fracture rehabilitation programme in England and Wales. This study contributes to a limited economic evidence base in hip rehabilitation.⁷⁴ The similarity of findings between the full economic evaluation and feasibility trial shows robustness of the results and trial methodology.²⁵ We used the version of EQ-5D with three response levels (EQ-5D-3L). The value set for the version with five levels (EQ-5D-5L) is still being developed. When it becomes available, the EQ-5D-5L value set should increase sensitivity and reduce the ceiling effect of EQ-5D-3L. This was the first-time subgroup analysis was undertaken in an economic evaluation of a hip rehabilitation RCT. However, the results were underpowered due to low sample size in this instance. Of relevance to the findings of this economic evaluation were the issues of missing data. This evaluation presents findings from both complete case and imputed data sets. Over 40% of the main trial sample had a form of missing data on CSRI. This is likely influenced by data collection processes moving to remote collection because of the COVID-19 pandemic. For the feasibility study, data were collected from researchers administering questionnaires in participants' homes. The rate of missing data when collected this way was around 10%.²⁵ Missing data are a known issue in economic evaluations and improper treatment of missing data can skew results. Presenting complete cases may not represent participants with missing data.

Challenges faced and limitations

This trial suffered recruitment difficulties because of the COVID-19 pandemic, which could not have been foreseen by the preceding feasibility study.²⁵ This was typical of other RCTs conducted during the pandemic, with one review reporting that 11 out of 13 RCTs had lower recruitment

rates than expected due to the pandemic.⁷⁵ Some of the recruiters described ethical dilemmas in deciding who to approach to consent, which could have resulted in selection bias and is paternalistic in its approach.⁷⁶ Previous research has found that recruiters were seemingly unaware of the negative impact on recruitment which resulted from their own uncertainty around equipoise and patient eligibility.⁷⁷ A lack of understanding of the principles of a RCT was demonstrated with some recruiters, who suggested selectively approaching patients who were more likely to take part. There appears to be an unmet need for further research methods' training, which has been noted in previous studies.⁷⁷

Some family members did not identify with the label of 'carer'. One recruiter felt that this made them more reluctant to take part in the study. Studies have previously explored how the identity of 'carer' is formed⁷⁸⁻⁸⁰ with personal care seen as part of a carer's role but other tasks⁸¹ seen as part of a loving and reciprocal relationship between partners, or parent-child.⁸² They may also view a carer as a purely professional role.⁸³ Qualitative studies have shown conflicting views on the label of carer with some accepting it, feeling uncertain, rejecting the term or feeling that their role changes depending on the circumstances.^{82,83} This requires studies to carefully consider how they define 'carer' in recruitment materials.

COVID-19 universally disrupted trial conduct and participant recruitment, necessitating rapid adaptations to trial protocols, recruitment strategies, and intervention delivery methods.⁸⁴ Lockdown measures, social distancing requirements, and restrictions on non-essential healthcare services hindered participant recruitment and retention and complex organisational and delivery challenges, particularly involving face-to-face contact in the community.^{84,85} Like FEMuR III, trials were forced to suspend recruitment or modify their protocols to accommodate remote assessments and interventions, leading to delays in trial timelines and potential biases in participant selection.^{84,86} Therapists and patient-participants adapted to remote modes of delivery, but this affected intervention fidelity and implementation. There were large variations in the FEMuR intervention delivered. This was partly due to the nature of a tailored intervention adapting to individual patient needs, contexts and goals, and differences in implementation from different therapists, but also the limitations imposed by the COVID-19 pandemic. The disruption caused by the pandemic may also have impacted the acute care of hip fracture patients, with more conservative clinical management, and longer inpatient waits for surgery impacting outcomes downstream.⁸⁷ This was reflected by therapists and recruiters who reported patients tended to

be fraailer as sites re-opened. Studies evaluating remote delivery have shown mixed results.⁸⁸⁻⁹⁰ Regular telephone contact may suit consultation, guidance and counselling to encourage continued engagement,⁹¹ but not feedback on the performance of exercises and ADLs. An important limitation was the large amount of missing data, particularly for the economic analysis, which reduced the precision of the results.

Only a small proportion of the workbooks and diaries used were collected and examined, because of restrictions on in-person follow-up assessments during the COVID-19 lockdown, and they may not be representative of all the patient-participants in the intervention group. The RCT had difficulty in recruiting carers, because of hospital visiting restrictions during the pandemic, and this was also the case with the process evaluation, so there is a lack of carers' opinion. Recording of usual rehabilitation care in patient-held diaries was also affected by the pandemic with only a small proportion completing these, which might not be representative of usual rehabilitation care.

A variety of different staff involved in recruitment, who worked as part of clinical and research teams, were interviewed to describe the challenges of recruiting into a multisite RCT during the COVID-19 pandemic. However, we only considered the perspectives of recruiters and not the perspectives of patient-participants, carer-participants or clinical staff. There was potential for recall bias as the interviews were conducted after recruitment had been completed. Seven recruiters were interviewed, which may not be representative of all the recruiters' views

Patient and public involvement

This report has been jointly written with ShD, the PPI representative throughout the project.

Aim of patient and public involvement

The aim of PPI in the FEMuR III RCT was to codevelop the trial proposal during the design phase, codevelop public facing documents, inform all aspects of trial delivery, to be involved with some components of trial analysis and to inform dissemination activities.

Patient and public involvement methods

ShD was recruited during the planning stage of the RCT and contributed to codevelopment of the RCT design. We originally had two PPI members, but the other member was unable to contribute for personal reasons. We later recruited a further PPI member with lived experience of hip fracture to the Trial Steering Committee, but she had

difficulty attending meetings in person or online. ShD has lived experience of caring for a relative following hip fracture. PPI codeveloped public facing materials such as participant information sheets and informed consent forms, as well as topic guides for qualitative interviews in the process evaluation. PPI contributed to the conduct of the RCT by regular attendance at monthly Trial Management Group meetings that provided trial oversight, ensuring adherence to the trial protocol. In the light of feedback from the feasibility study we refined the FEMuR intervention workbook and goal-setting diary, and PPI had a particular responsibility to ensure that the changes were an improvement for participants. PPI was also involved in aspects of data analysis, particularly informing the embedded process evaluation and informed the dissemination of trial findings.

Patient and public involvement results

During the trial development phase ShD was particularly influential in the decisions around carer recruitment into the trial and carer outcome measures. ShD contributed to the discussions about inclusion criteria for patient-participants, particularly around capacity and the choice of outcome measures, and reducing the burden of baseline measures while recovering from surgical repair of hip fracture in hospital. ShD helped to refine the FEMuR intervention workbook and goal-setting diary. Following feedback from recruitment staff, ShD codeveloped a shorter information sheet to reduce participant burden during recruitment and co-designed patient held therapy records to record usual rehabilitation care in both arms of the trial. ShD helped to produce regular trial newsletters for participants and wrote a short dialogue concerning her involvement in the trial ([Report Supplementary Material 1](#)). For data analysis ShD contributed to the selection of studies in a rapid review, which informed the economic analysis, and contributed to the process evaluation. She addressed the final meeting sharing the trial results with coinvestigators and researchers and there is a possibility of attendance at other scientific meetings presenting the trial findings.

Patient and public involvement discussion

Patient and public involvement was helpful in addressing many of the problems that affected the trial regarding recruitment and retention. This resulted in adaptation of trial processes to reduce the burden on patient and carer-participants during recruitment and outcome assessment by shortening participant information sheets, simplifying language used and prioritising outcome measures collected during remote consultations. There was also PPI in the production of trial newsletters to maintain participant engagement in the trial. Unfortunately, all trial

processes were affected by the COVID-19 pandemic and these amendments were insufficient to maintain high rates of recruitment and retention in the trial.

Patient and public involvement reflections/critical perspective

ShD writes, 'Reflecting upon the positive aspects of my involvement. I am grateful to Prof Williams and his team for giving me the opportunity to assist in FEMuR III. I have enjoyed the experience and found intrinsic value in the following. I felt proud to be representing members of the public in the certain knowledge that it would lead to improved treatment and care. I enjoyed utilising my knowledge and skills. I learnt more about hip fracture and rehabilitation. I have enjoyed meeting different people and gaining new knowledge and skills, and postretirement, it proved an excellent way of keeping my brain active.'

LS encouraged me to join her in assisting with the data extraction and the rapid review and spent time with me so as to familiarise me with the use of Covidence as a tool. PR was instrumental in including me in the process evaluation meetings. I am grateful to them both for their support and inclusion. I consider that most of the desired goals set out in the original plan for PPI involvement have been achieved.

Reflecting upon what could have been improved upon I would make the following observations. I regret to say that COVID-19 had a clear definitive impact upon all aspects of the research, members of the team, and timelines. This was beyond anyone's control. I am not entirely clear as to why further PPI members were not recruited and it may well have been a direct consequence of COVID-19. However, I believe that a PPI member who had personal experience of hip fracture and rehabilitation would have served to enhance the team, and this aspect of the original plan for PPI involvement was not adhered to.

When members of the public who have a 'lived experience' are involved, they can help to change practice and improve care.⁹²⁻⁹⁴ Involving the public can also improve enrolment of participants in studies,⁹⁵ as they can advise on the best design to suit the needs and customs of a particular community or population.⁹³

Sadly, this aim did not come to fruition. I personally feel that one person undertaking the role of PPI did have a negative impact at times. Although I tried my best to always attend meetings sometimes, I failed. Unfortunately, due to a personal tragedy during the process, there was a gap in my attendance for a short while and I was not in a position to assist Prof Williams in sharing my views

on an online conference. I consider additional members having a PPI role would have eased this potential problem. Notwithstanding that point, given the length of time from inception to completion such issues may still have proved inevitable. An additional PPI member would have served as an associate for me to discuss ideas with, which again may have established a more positive involvement for the team as a whole.

I would add that I felt fully supported, and indeed included, by everyone, but may have benefitted from a named person from the team for whom I could turn to for additional support. Throughout the process several members of the team left, and new persons joined. Whilst I realise that this was unavoidable there were times when I felt confused about people's roles and due to the nature of virtual meetings that aspect of the process was not always clear, as visual prompting of personnel and roles was lacking.

One final concern for me was the IT issues. I often struggled to join the meetings; the reasons in part were due to my rural location and my inability to be fully up to speed with technology. However, some additional IT support would have been welcome.

In conclusion, once the research has been completed and the result obtained it is imperative that prudently constructed dissemination of the findings is undertaken in order that there is measurable significant impact upon policy and practice. This is clearly being initiated. I have, as the PPI representative, been fully included in this process. I have been able to contribute and advise on the distribution of non-academic dissemination and to act in the role of co-author. Evaluating the impact of Public Involvement is never easy. Overall, it is also important that PPI members provide feedback to researchers during and at the end of the project. This will help identify any concerns and achievements and suggestions can be made how the role can improve. This will help improve and strengthen public involvement so that it is progressive. Again, my input has been welcomed and received. I sincerely hope that all those involved in FEMuR III have found my opinion and comment both positive and of value. Finally, I would like to thank everyone for their commitment to the PPI engagement process.'

Equality, diversity and inclusion

The following demographic characteristics related to equality, diversity and inclusion were collected at baseline:

gender, ethnicity, type of housing, highest educational attainment, occupation (or former occupation) and socio-economic deprivation decile according to postcode were collected at baseline ([Table 1](#)).

This RCT recruited a higher proportion of women (68%) as would be expected, but ethnicity was overwhelmingly White from the UK (see [Table 1](#)). Two participants were from America and Europe, but their ethnicity was not stated. This compares with the proportion of adults aged over 60 years with White ethnicity of 92.6% (www.ethnicity-facts-figures.service.gov.uk/uk-population-by-ethnicity/demographics/age-groups/latest/). The majority of patient-participants owned their own homes (87%). However, just under half had no qualifications or General Certificate of Secondary Education (GCSE) equivalent, there was a range of occupations (or former occupations) ([Appendix 1](#)) and there was a full range of deprivation deciles from their postcodes.

Although the RCT recruited patient-participants from both genders and across a range of socioeconomic variables, we failed to recruit anyone from ethnic minorities, despite recruiting from areas with large ethnic minority populations. Recruitment staff and therapists interviewed for the process evaluation were all White British. There was one therapist who was not, but unfortunately they moved away before they could be interviewed. In the interview topic guide recruitment staff were asked 'Are there patients you did not approach? Can you tell me more about that?' but ethnicity did not emerge as a theme.

Impact and learning

Implications for practice

The FEMuR intervention was not delivered as intended because of the COVID-19 pandemic lockdown restrictions. The intervention had to rely on remote methods of delivery, and the number of extra rehabilitation sessions delivered was fewer than planned. The FEMuR III intervention was no more effective than usual care. Because of the lack of effectiveness, the economic evaluation was limited to a cost-consequences analysis. As a result, we do not report an incremental cost-effectiveness ratio recommended by NICE and commonly used in policy making. For complete case analysis, participants in the intervention group gained higher QALYs than participants in usual care, but this was not clinically important. However, the mean total health resource use costs were higher for the intervention group, which was due to higher inpatient costs, unrelated to the community-based FEMuR intervention. We can conclude

TABLE 1 Characteristics of patient-participants in the FEMuR III trial

Characteristics	Patient-participants (n = 203)
Gender n (%)	
Female	139 (68%)
Ethnicity n (%)	
White (UK)	199 (98%)
American	1 (0.5%)
European	1 (0.5%)
White Canadian	1 (0.5%)
Missing	1 (0.5%)
Place of residence before admission n (%)	
Owner occupied	176 (87%)
Housing association/local authority property	16 (8%)
Private rental	10 (5%)
Missing	1 (0.5%)
Highest educational qualification n (%)	
None	50 (25%)
GCSE or equivalent	49 (24%)
A-level or equivalent	39 (19%)
Degree	14 (7%)
Higher degree	8 (4%)
Missing	43 (21%)
Deprivation decile (from postcode) n (%)	
1 (most deprived)	17 (8%)
2	20 (10%)
3	8 (4%)
4	17 (8%)
5	22 (11%)
6	28 (14%)
7	18 (9%)
8	18 (9%)
9	20 (10%)
10 (least deprived)	27 (13%)
Missing	7 (3%)

that, as delivered in the trial, the FEMuR intervention was ineffective and poor value for money, and so cannot be recommended in its current form. We can only speculate whether in-person delivery of the planned six therapy

sessions would have been more effective, and better value for money, by facilitating an improvement in self-efficacy, the practice of ADLs and exercise, with greater professional and social support from friends and family.

Lessons learnt for future research

Some of the staff recruiting potential participants described ethical dilemmas in deciding who to approach to consent, which could have resulted in selection bias. For example, some suggested that time would be better spent approaching only those patients who they felt were more likely to agree to take part. This suggests a lack of understanding of the fundamental principles of RCTs, and of evidence-based practice, and a clear need for further training. The practicalities of conducting a RCT were covered in training for recruiters but not the underlying trial principles. The recruiters also mentioned a disconnect between sites and felt that meetings, with recruitment staff across sites, would have been helpful. There were monthly drop-in sessions from June 2021 for all site team members for discussion, but these were poorly attended and stopped in February 2022. Refresher sessions for sites also took place after sites re-opened post pandemic. Further training in RCT methodology would be needed for future trials.

Recruiters also noted that some patients had a strong preference about the treatment group to which they were allocated. An alternative trial design, such as a patient preference design, would mean that those with a strong preference would be allocated to their preferred treatment group and the remaining participants randomised. However, patients' preference can lead to a substantial proportion of a specific patient group refusing randomisation.⁹⁶ As suggested by one recruiter, a cluster RCT may have been helpful in this situation. However, one of the main reasons for using a cluster design is to avoid contamination of usual care by the intervention,⁹⁷ and we found no evidence that this was the case. Indeed, we designed the trial to supplement usual care rather than to change it. Cluster RCTs have their own challenges including reduced power and precision, requiring a larger sample size; the potential for selection bias, as treatment group allocation is known prior to recruitment; imbalance between study arms and problems of generalisability.⁹⁷

Some family members did not identify with the label of 'carer', and this may have made them more reluctant to take part in the study. The trial protocol stated that carers were defined as helping the patient for four or more days per week with ADLs or physical care. This was a strict definition for carers and was not clearly highlighted in the carer information leaflet, nor did some recruiters appear aware of this definition from the interviews. The implication that carers needed to be involved consistently pre-admission may have made recruitment more challenging. Broadening the definition of carer would likely help to increase recruitment of potential carers, including those who provide 'care provision ... above and beyond that which is typical within

the particular relationship'.⁹⁸ Another approach would be to recruit family members of patient-participants to capture the full spectrum of the patient's support network and varying 'carer' roles.

Staff recruiting to the trial were concerned about reducing written information for patients and carers to read. A substantial amendment, approved in June 2020, implemented a shorter information leaflet for patients and carers. However, there is no evidence from previous trials that modification to the quantity of information presented to potential participants improved recruitment.⁹⁹ Recruitment was time-intensive, requiring several visits to potential patient-participants, and giving them time to read trial material. A log of recruitment time for each patient- or carer-participant would be helpful to allow for future recruitment planning.

The NEADL outcome measure did not take into account some aspects of modern living. For example, many patient-participants were unable to get to the shops but were able to shop online from home. Outcome measures need to account for ADLs in the digital era.

Staffing was an issue, with the COVID-19 pandemic causing staff shortages in many areas due to sickness, isolation rules or research staff being moved onto COVID-19 studies. Staff levels fluctuated due to staff shortages, sickness and maternity leave. Clinical staff were unable to recruit effectively due to ward pressures and prioritising clinical care. One site achieved effective recruitment, but the community team delivering the intervention did not have the capacity to implement the intervention, so recruitment was halted. Recruiters felt that involving the clinical team was important for increasing rates of recruitment but acknowledged that this may be difficult to implement in practice, given the lack of protected research time. However, split clinical/research posts may help to ensure that clinicians are embedded into research teams.

Ultimately, it is important to identify any recruitment issues early on during the trial. Effective approaches include embedding a qualitative study to inform recruitment practices,⁷⁶ such as the Qualitative Research Integrated within Trials (QuinteT) Recruitment Intervention (QRI).^{100,101} Application of the QRI method in 14 RCTs identified between three and 6 previously unrecognised issues per RCT.¹⁰¹ Further research is needed about how to improve recruitment to RCTs of rehabilitation interventions.

In conclusion, strategies to overcome the barriers to recruitment in this RCT included alternative trial design, broadening the definition of carer (or use of alternative terms), further training with recruiters emphasising the

principles of RCT, considering split clinical/research posts and acknowledging the time taken to recruit participants. It is key to identify and address issues early in the trial through an embedded qualitative analysis, although this would not have foreseen the COVID-19 pandemic, which was the main barrier to recruitment.

Climate, health and sustainability

The COVID-19 pandemic forced many of the trial activities to be conducted online rather than in-person, including FEMuR intervention delivery, training of sites on the trial methods and collecting follow-up outcome measurements. This reduced the need for travel by researchers, clinical staff and therapists delivering the FEMuR intervention, and reduced the carbon footprint of the trial. It probably had minimal effect on the quality of trial training delivered to research sites; however it reduced the fidelity of the FEMuR intervention delivered, and the range of outcomes that could be collected at follow-up. Finally, the final investigators' meeting presenting the results of the trial was delivered in a hybrid format, which reductions in travel for many of the coinvestigators.

Implications for decision-makers

We found no quantitative evidence that the FEMuR intervention was more effective, or better value for money, than usual rehabilitation care. As a result, it cannot be recommended for use as delivered in this trial. However, patient-participants interviewed in this process evaluation stated that they benefitted, and the process evaluation confirmed that there was still a need and desire for a community rehabilitation intervention following hip fracture. Further codevelopment work is needed to re-design the rehabilitation intervention with further testing of feasibility according to the MRC framework for developing and evaluating complex interventions. We recommend that future delivery of a refined intervention should be mainly performed in-person. There needs to be consideration of the number of rehabilitation sessions delivered to allow adequate reassurance of safe activities to perform and to provide adequate support, feedback, improvement in self-efficacy and adequate practice of exercises and ADLs to maximise functional recovery.

Research recommendations

- Further codevelopment work is needed to re-design the rehabilitation intervention with further testing of feasibility according to the MRC framework for developing and evaluating complex interventions. This

should include consideration of the optimal number of therapy sessions delivered in person.

- Consider how to include a broader range of people recovering from hip fracture including ethnic minority groups and those who lack mental capacity.
- Consider how to describe the support that people with hip fracture receive from friends and family, avoiding their description as carers.
- Update outcome measures to include ADLs that are pertinent to modern living, such as shopping online, and the use of digital devices and methods of communication.
- Consider how to improve recruitment into RCTs of community rehabilitation interventions, including research methods training for clinical staff recruiting participants.

Conclusions

Recruitment to the FEMuR III RCT was severely affected by the COVID-19 pandemic and trial recruitment was halted by the funder before the target sample size was reached, because of a low recruitment rate. The reduced sample size and the low completion rate for many outcomes reduced the statistical power and reduced the precision of the results. The FEMuR intervention was not effective in improving the performance of ADLs in older people recovering from surgical repair of hip fracture compared with usual care. However, trial recruitment, delivery of the enhanced rehabilitation, and follow-up were greatly affected by the COVID-19 pandemic, which may explain the lack of effectiveness.

In the economic evaluation, there was no evidence of clinical effectiveness either in terms of QALYs gained in the intervention group, despite total health service costs being higher in this group. The increased costs were largely because of higher inpatient costs in the intervention group that were unrelated to their hip fracture. All trial procedures, including retention of participants and follow-up, were adversely affected by the COVID-19 pandemic, which may explain the large proportion of missing data in the economic evaluation.

The lack of effectiveness of the FEMuR intervention may be because the COVID-19 pandemic did not allow the intervention to be implemented as planned. In particular, the number and mode of delivery of the additional therapy sessions were affected. While patient-participants interviewed in this process evaluation stated that they benefitted, FoF persisted. Lack of in-person supervision, persistent FoF, lack of support from friends and family and

restrictions on travelling outdoors and social interaction may all have reduced the opportunities to practise exercises and ADLs.

The original programme theories involved:

1. Improving patient engagement by tailoring the intervention according to individual needs and preferences.
2. Reducing FoF and improving self-efficacy to exercise and perform ADLs, by setting appropriate goals and improving the practice and quality of exercise and ADLs.
3. Co-ordination of services and sectors delivering the rehabilitation.

We re-visited these in the process evaluation and found that there was good evidence of tailoring the FEMuR intervention to individual needs and preferences. However, the practice of exercises and ADLs was impaired, and co-ordination of services and sectors delivering the rehabilitation was lacking.

There is still a need and desire for a community rehabilitation intervention following hip fracture. Further codevelopment work is needed to re-design the rehabilitation intervention with further testing of feasibility according to the MRC framework for developing and evaluating complex interventions.

Additional information

CRediT contribution statement

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Data-sharing statement

Research data will be available for secondary analysis on reasonable request to the corresponding author.

Ethics statement

NHS research ethics approval was obtained from North East – Tyne & Wear South Research Ethics Committee, reference 18/NE/0300 on 31 October 2018.

Information governance statement

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Monica Busse is a member of NIHR CTU standing advisory committee and was a member of HTA funding committee (commissioned research)

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Award publications

This synopsis provided an overview of the research award *A definitive multi-centre randomised controlled trial and economic evaluation of a community-based rehabilitation package following hip fracture. Acronym: Fracture in the Elderly Multidisciplinary Rehabilitation – Phase III (FEMuR III)*. Other articles published as part of this thread are:

Williams NH, Busse M, Cooper R, Dodd S, Dorkenoo S, Dougsong K, et al. Effectiveness of a community-based rehabilitation programme following hip fracture: results from the Fracture in the Elderly Multidisciplinary Rehabilitation – Phase III (FEMuR III) randomised controlled trial. *BMJ Open* 2025;5:e091603. <https://doi.org/10.1136/bmjopen-2024-091603>

Dougsong K, Davies J, Ezeofor V, Spencer LH, Williams N, Edwards RT. A cost-consequence analysis of a community-based rehabilitation programme following hip fracture (Fracture in the Elderly Multidisciplinary Rehabilitation – FEMuR III). *Osteoporosis Int* 2025;36:883–92. <https://doi.org/10.1007/s00198-025-07459-4>

Harvey K, Ralph P, Spencer LH, Dougsong K, Morrison V, Lemmey A, et al. Perceived barriers and facilitators of staff recruiting participants to a randomised controlled trial of a community rehabilitation intervention following hip fracture. *Trials* 2024;25:826. <https://doi.org/10.1186/s13063-024-08655-z>

For more information about this research please view the award page (www.fundingawards.nihr.ac.uk/award/16/167/09).

Additional outputs

Williams NH, Dodd S, Hardwick B, Clayton D, Edwards RT, Charles JM, 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) [ISRCTN28376407]. *BMJ Open* 2020;10:e039791. <https://doi.org/10.1136/bmjopen-2020-039791>

Conference presentations

International Collaboration Conference on Population Health and Wellbeing. 9–10 February 2022. Economic evaluation of a community based hip fracture rehabilitation intervention: FEMURIII RCT.

Society for Academic Primary Care Annual Scientific Meeting. 5 July 2022. Preliminary process evaluation findings for the Fracture in the Elderly Multidisciplinary Rehabilitation – Phase III (FEMuR III) randomised controlled trial (RCT), a community-based Rehabilitation package following hip fracture.

Society for Academic Primary Care North Regional Meeting. 10 November 2022. FEMUR III community based rehabilitation package as an approach for reducing inequity – an example of proportionate universalism?

PRIME Centre Wales Annual Meeting. October 2022. FEMuR III: Recruitment and adaptation during COVID.

Royal College of Occupational Therapy Annual Conference. 14 June 2023. 'I felt as though my independence had come back'. Patient and therapist experiences of supporting meaningful occupation in Fracture in the Elderly Multidisciplinary Rehabilitation – Phase III (FEMuR III) study, a community based rehabilitation programme.

Fifth annual Liverpool Dementia and Ageing Conference. 26 October 2023. Exploring the implementation of a community-based rehabilitation intervention following hip fracture – findings from the FEMuR III RCT process evaluation.

Chartered Society of Physiotherapy Annual Conference. 21–22 November 2024. Fracture in the Elderly Multidisciplinary Rehabilitation – Phase III (FEMuR III) study, a community-based rehabilitation programme. The role of therapist-patient relationships and tailored interventions in post hip fracture rehabilitation.

24th WONCA Europe Conference. 25–28 September 2024. Perceived barriers and facilitators of staff recruiting participants to a randomised controlled trial of a community-based rehabilitation intervention following hip fracture.

Society for Academic Primary Care North Regional Meeting. 19 November 2024. A cost-consequence analysis of a community-based rehabilitation programme following hip fracture (FEMuR III).

Society for Academic Primary Care North Regional Meeting. 19 November 2024. Results of the FEMuR III randomised controlled trial of a community-based rehabilitation intervention following hip fracture.

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List of supplementary material

Report Supplementary Material 1

Example of a newsletter to participants

Report Supplementary Material 2

FEMuR Workbook

Report Supplementary Material 3

FEMuR Goalsetting diary

Report Supplementary Material 4

Summary of protocol amendments approved by sponsor, funder and research ethics committee

Supplementary material can be found on the NIHR Journals Library report page (<https://doi.org/10.3310/RBGD4741>).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

The supplementary materials (which include but are not limited to related publications, patient information leaflets and questionnaires) are provided to support and contextualise the publication. Every effort has been made to obtain the necessary permissions for reproduction, to credit original sources appropriately, and to respect copyright requirements. However, despite our diligence, we acknowledge the possibility of unintentional omissions or errors and we welcome notifications of any concerns regarding copyright or permissions.

List of abbreviations

ADLs	activities of daily living
ANCOVA	analysis of covariance
CSRI	Client Service Receipt Inventory
FEMuR	Fracture in the Elderly Multidisciplinary Rehabilitation
FES-I	Falls Efficacy Scale – International
FoF	fear of falling

GCSE	General Certificate of Secondary Education
HADS	Hospital Anxiety and Depression Scale
HTA	Health Technology Assessment
MRC	Medical Research Council
NEADL	Nottingham Extended Activities of Daily Living
PPI	patient and public involvement
QALY	quality-adjusted life-year
QRI	Qualitative Research Integrated within Trials (QuinteT) Recruitment Intervention
RCT	randomised controlled trial
SAE	serious adverse event
SPPB	Short Physical Performance Battery
VAS	visual analogue scale

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Appendix 1 List of occupations or former occupations in patient-participants

Current or previous occupation	Usual rehabilitation n (%)	Enhanced rehabilitation n (%)	Overall n (%)
	(N = 100)	(N = 103)	(N = 203)
Accountant	1 (1.0%)	3 (2.9%)	4 (2.0%)
Admin	1 (1.0%)	1 (1.0%)	2 (1.0%)
Architect	0 (0.0%)	1 (1.0%)	1 (0.5%)
Baker, coal worker	1 (1.0%)	0 (0.0%)	1 (0.5%)
Bank clerk	0 (0.0%)	1 (1.0%)	1 (0.5%)
Bank worker	0 (0.0%)	1 (1.0%)	1 (0.5%)
Banker	1 (1.0%)	0 (0.0%)	1 (0.5%)
Barperson	1 (1.0%)	0 (0.0%)	1 (0.5%)
Book binder	0 (0.0%)	1 (1.0%)	1 (0.5%)
Book keeper	1 (1.0%)	0 (0.0%)	1 (0.5%)
Builder	0 (0.0%)	1 (1.0%)	1 (0.5%)
Bus driver	1 (1.0%)	1 (1.0%)	2 (1.0%)
Business manager	1 (1.0%)	1 (1.0%)	2 (1.0%)
Business owner	1 (1.0%)	0 (0.0%)	1 (0.5%)

Current or previous occupation	Usual rehabilitation n (%)	Enhanced rehabilitation n (%)	Overall n (%)
	(N = 100)	(N = 103)	(N = 203)
Cafe worker	1 (1.0%)	0 (0.0%)	1 (0.5%)
Carer	4 (4.0%)	3 (2.9%)	7 (3.4%)
Carpet fitter	1 (1.0%)	0 (0.0%)	1 (0.5%)
Catering manager	1 (1.0%)	0 (0.0%)	1 (0.5%)
Charity director	0 (0.0%)	1 (1.0%)	1 (0.5%)
Charity manager, teacher, tour operator	0 (0.0%)	1 (1.0%)	1 (0.5%)
Chemist	2 (2.0%)	0 (0.0%)	2 (1.0%)
Civil servant	2 (2.0%)	2 (1.9%)	4 (2.0%)
Cleaner	1 (1.0%)	0 (0.0%)	1 (0.5%)
Clerical manager	1 (1.0%)	1 (1.0%)	2 (1.0%)
Coal miner, army	0 (0.0%)	1 (1.0%)	1 (0.5%)
Colour matcher	1 (1.0%)	0 (0.0%)	1 (0.5%)
Company director	1 (1.0%)	0 (0.0%)	1 (0.5%)
Component researcher	0 (0.0%)	1 (1.0%)	1 (0.5%)
Comptometer operator	1 (1.0%)	0 (0.0%)	1 (0.5%)
Computer manager	1 (1.0%)	0 (0.0%)	1 (0.5%)
Counsellor	1 (1.0%)	0 (0.0%)	1 (0.5%)
Curate	0 (0.0%)	1 (1.0%)	1 (0.5%)
Dress maker	0 (0.0%)	1 (1.0%)	1 (0.5%)
Electrical engineer	1 (1.0%)	0 (0.0%)	1 (0.5%)
Electrical technician	1 (1.0%)	0 (0.0%)	1 (0.5%)
Engineer	1 (1.0%)	0 (0.0%)	1 (0.5%)
Engineer aircrafts	1 (1.0%)	0 (0.0%)	1 (0.5%)
Factory worker	2 (2.0%)	1 (1.0%)	3 (1.5%)
Factory worker, carer	0 (0.0%)	1 (1.0%)	1 (0.5%)
Factory worker, lunchtime school supervisor, receptionist, barperson	1 (1.0%)	0 (0.0%)	1 (0.5%)
Farmer	1 (1.0%)	1 (1.0%)	2 (1.0%)
Finance manager	0 (0.0%)	1 (1.0%)	1 (0.5%)
Food assistant	0 (0.0%)	1 (1.0%)	1 (0.5%)
HR assistant, administrator, carer	1 (1.0%)	0 (0.0%)	1 (0.5%)
Hairdresser	1 (1.0%)	1 (1.0%)	2 (1.0%)
Headteacher	1 (1.0%)	0 (0.0%)	1 (0.5%)
Health and safety consultant	1 (1.0%)	0 (0.0%)	1 (0.5%)
Healthcare assistant	1 (1.0%)	0 (0.0%)	1 (0.5%)
Housewife	0 (0.0%)	3 (2.9%)	3 (1.5%)
Housewife, carer, secretary	0 (0.0%)	1 (1.0%)	1 (0.5%)

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Current or previous occupation	Usual rehabilitation n (%)	Enhanced rehabilitation n (%)	Overall n (%)
	(N = 100)	(N = 103)	(N = 203)
Lab technician	0 (0.0%)	1 (1.0%)	1 (0.5%)
Landlord	1 (1.0%)	0 (0.0%)	1 (0.5%)
Landworker	1 (1.0%)	0 (0.0%)	1 (0.5%)
Laundry attendant	1 (1.0%)	0 (0.0%)	1 (0.5%)
Lecturer	1 (1.0%)	3 (2.9%)	4 (2.0%)
Lollipop person	1 (1.0%)	0 (0.0%)	1 (0.5%)
Lorry driver	1 (1.0%)	1 (1.0%)	2 (1.0%)
Manufacturing production manager	0 (0.0%)	1 (1.0%)	1 (0.5%)
Midwife	1 (1.0%)	0 (0.0%)	1 (0.5%)
Motor mechanics instructor	1 (1.0%)	0 (0.0%)	1 (0.5%)
Navy	0 (0.0%)	1 (1.0%)	1 (0.5%)
Navy medic	0 (0.0%)	1 (1.0%)	1 (0.5%)
Not known	9 (9.0%)	5 (4.9%)	14 (6.9%)
Nurse	2 (2.0%)	3 (2.9%)	5 (2.5%)
Nurse, housewife	0 (0.0%)	1 (1.0%)	1 (0.5%)
Nurse, shop assistant	0 (0.0%)	1 (1.0%)	1 (0.5%)
Office clerk	1 (1.0%)	1 (1.0%)	2 (1.0%)
Office worker	1 (1.0%)	0 (0.0%)	1 (0.5%)
Officer worker	1 (1.0%)	1 (1.0%)	2 (1.0%)
Optician	1 (1.0%)	0 (0.0%)	1 (0.5%)
Painter and decorator	0 (0.0%)	2 (1.9%)	2 (1.0%)
Personal assistant	0 (0.0%)	2 (1.9%)	2 (1.0%)
Plasterer	0 (0.0%)	1 (1.0%)	1 (0.5%)
Plumber	2 (2.0%)	0 (0.0%)	2 (1.0%)
Postal operative	0 (0.0%)	1 (1.0%)	1 (0.5%)
Programmer	1 (1.0%)	0 (0.0%)	1 (0.5%)
RAF	1 (1.0%)	0 (0.0%)	1 (0.5%)
Registry clerk	1 (1.0%)	0 (0.0%)	1 (0.5%)
Sales rep	1 (1.0%)	0 (0.0%)	1 (0.5%)
Secretary	2 (2.0%)	3 (2.9%)	5 (2.5%)
Security guard	1 (1.0%)	0 (0.0%)	1 (0.5%)
Sheltered housing manager	0 (0.0%)	1 (1.0%)	1 (0.5%)
Ship safety supervisor	1 (1.0%)	0 (0.0%)	1 (0.5%)
Shop assistant	0 (0.0%)	3 (2.9%)	3 (1.5%)
Shop assistant, factory worker	0 (0.0%)	1 (1.0%)	1 (0.5%)
Shop assistant, librarian	1 (1.0%)	0 (0.0%)	1 (0.5%)

Current or previous occupation	Usual rehabilitation n (%)	Enhanced rehabilitation n (%)	Overall n (%)
	(N = 100)	(N = 103)	(N = 203)
Shopkeeper, newsagent	0 (0.0%)	1 (1.0%)	1 (0.5%)
Spray painter	0 (0.0%)	1 (1.0%)	1 (0.5%)
Structural technician	0 (0.0%)	1 (1.0%)	1 (0.5%)
Teacher	4 (4.0%)	5 (4.9%)	9 (4.4%)
Training manager	0 (0.0%)	1 (1.0%)	1 (0.5%)
Trainline controller	1 (1.0%)	0 (0.0%)	1 (0.5%)
Vehicle inspector	0 (0.0%)	1 (1.0%)	1 (0.5%)
Waitress	1 (1.0%)	0 (0.0%)	1 (0.5%)
Welding instructor	1 (1.0%)	0 (0.0%)	1 (0.5%)
Missing	19 (19.0%)	26 (25.2%)	45 (22.2%)

