STUDY TITLE:

Developing a multidisciplinary rehabilitation package following hip fracture

Acronym: Fracture in the Elderly Multidisciplinary Rehabilitation (FEMuR) Phase 2

Study Identification

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1. Background & Rationale

Hip fracture is a common, major health problem in old age. It is strongly associated with other health problems, under-nutrition, frailty, and poor physical and mental functioning. Mortality is high with 25% dying within the following 12 months. Many who were living independently before their fracture lose their independence afterwards, so it imposes a large cost burden on society amounting to about £2 billion a year. As the population ages the numbers of older people falling and fracturing their hips is increasing. The National Institute of Health and Clinical Excellence (NICE) have issued guidelines for the management of hip fracture[1]. As well as prompt surgical treatment the guidelines recommend that the associated medical needs are assessed promptly by a physician specialised in caring for this patient group, who can also identify goals for a programme of multidisciplinary rehabilitation. Such rehabilitation should start whilst in hospital during post-operative recovery and should continue in the community following hospital discharge. Patients should be offered physiotherapy assessment and mobilisation on the day after surgery, unless medically or surgically contraindicated. They should be offered mobilisation at least once a day and receive regular physiotherapy. They should receive a formal hip fracture programme that includes all of the following: orthogeriatric assessment, rapid optimisation of fitness for surgery, 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, continued co-ordinated orthogeriatric and multidisciplinary review, and communication with the primary care team. Patients with cognitive impairment should be actively sought and offered individualised care to minimise delirium and maximise independence. The NICE clinical practice guideline for the assessment and prevention of falls in older people is relevant for the secondary prevention of falling in hip fracture patients[2]. The guidelines recommend that older people with recurrent falls should be considered for an individualised multifactorial intervention programme including: strength and balance training, home hazard assessment and intervention, vision assessment and referral, medication review with modification and withdrawal of psychotropic medication. Following treatment for an injurious fall, such as a hip fracture, older people should be offered a multidisciplinary assessment to identify and address future risks and individualised intervention to promote independence and improve physical and psychological function.

Systematic reviews of multidisciplinary rehabilitation[3-5 6-8] have concluded that they may aid recovery after a hip fracture, but the results are not conclusive and there is insufficient evidence that multidisciplinary rehabilitation programmes have overall effectiveness or cost-effectiveness. Individual components of such a package show promise, but it needs to be determined which components work for which patient group in which circumstances. More research is needed.

1.1. Results and findings of Phase One of the FEMUR Study

The FEMuR study has two phases corresponding to the first two phases of the MRC complex intervention framework[1]. The summarised findings from phase one are presented here to show how they have informed the development of the planned enhanced rehabilitation intervention.

In the first phase of this study we conducted a realist synthesis of the literature to identify the important, psychological, social and biological components and any evidence from behavioural economics for a multi-disciplinary rehabilitation programme following surgical treatment for hip fracture in older people, and to understand the mechanisms, contexts and outcomes of successful interventions. We completed a UK wide survey of Occupational Therapists, Physiotherapists and Therapies Senior Managers to assess the current provision of rehabilitation programmes following hip fracture surgery in the National Health Service throughout the UK. We conducted four focus groups with patients, carers and three with staff across North Wales (BCUHB) to explore their experiences of rehabilitation. We have synthesised the evidence from these three sources to inform the intervention for phase 2. The findings are the conjectured theories presented below. Conjectured theories in realist synthesis are descriptions of how we anticipate the underlying mechanism(s) in an intervention programme will work in certain contexts to produce outcomes.

We have developed conjectured realist theories to inform our intervention using the realist Context, Mechanism and Outcome format (CMO). This aims to provide a

theoretical basis for an intervention works (M) for whom and in what circumstances(C) to produce which outcomes (O). The full results of the phase 1 findings and synthesis will be reported to the funder and published in due course. The theories are:

1. Tailoring CMO

Proximal hip fracture patients present with a range of pre-fracture physical and mental functioning and a variety of co-morbidities affecting their ability to achieve rehabilitation goals **(C)** so they need a rehabilitation programme that is tailored to individual needs **(M)** in order to achieve appropriate outcomes such as improved physical functioning, greater mobility, reduced disability and independent living **(O)**.

In terms of the International Classification of Function (ICF) the intervention will address the assessment of:

Impairments

Psychological and physical impairments

Muscle strength and balance

Activities

The impact on activities

Participation in terms of

Discussion and agreement with patients and their family and carers regarding the short-term and longer term goals of rehabilitation

Personal and environmental factors.

Pre- fracture functioning, current cognitive status, other co-morbid conditions

2. Practice of physical activity, exercise and ADLs CMO

Proximal hip fracture patients with poor physical functioning, reduced independence in activities of daily living or low activity levels **(C)** require interventions that help them repeatedly practice these components **(M)** in order to improve independence in activities of daily living and mobility, improving confidence and reducing the fear of falling,

In terms of the ICF the intervention will address:

Impairments

Impaired muscle strength, balance, mobility is improved by practicing the tailored exercised programme

Activities

Improved performance of ADLs.

Reverse training – teach people how to stand up from when lying on the floor

3. Fear of falling, loss of confidence and/or lack of self-efficacy CMO

Hip fracture patients who fear falling, have low mood or who lack self-efficacy **(C)** require interventions that improve psychological tasks, provide motivation and sense of ownership to engage in exercises **(M)** in order to improve self-efficacy, reduce the fear of falling, improve confidence, quicker progression through a programme of recovery, increased functional outcomes, and increased mobility **(O)**.

In terms of the ICF the intervention will address:

Impairments

Low mood, lack of self-efficacy, fear can be improved with a psychological intervention that encourages goal setting self-monitoring and by the therapist

Activities

Improved performance of ADLs.

Participation

Sign positing to other services and sources of help/support such as falls prevention service

4. Co-ordination of services and sectors delivering intervention

The diversity of services provided by different disciplines, across sectors from a variety of funders **(C)** requires a co-ordinated provision of the multidisciplinary rehabilitation programme **(M)** in order to deliver appropriate physical, functional and psychological interventions to patients in a timely manner **(O)**.

5. Economic consequences of long inpatient rehabilitation

Older patients with a number of co-morbidities, poor pre-fracture functioning and living in a nursing home prior to fracture **(C)**, receive longer inpatient rehabilitation **(M)** which results in accrued additional costs **(O)**.

Findings from the focus groups and survey data indicate a variation in rehabilitation service provision as well as variation in patient access to the available services. It seems that acute NHS rehabilitation service provision aims to either discharge patients home directly from acute care with carer support if necessary, or to an inpatient rehabilitation unit before going home or directly to a care home.
In all these community settings rehabilitation services are available to support the patients' recovery, although care home services are much less accessible. For those patients in the focus groups who went back to their own homes, the amount and quality of rehabilitation they reported receiving appeared to vary considerably, from enablement carers coming in four times a day initially and home based therapy visits for 6 weeks, to a few visits by a physiotherapist or occupational therapist to the patient's home without further follow up, to on going out patient sessions with or without referral to a falls prevention programme, and for some they were referred on to a leisure centre based National Exercise Referral programme once NHS physiotherapy was complete.

Patients in our focus groups consistently reported fear of falling and recovering from that fear as a significant issue in their rehabilitation. The existence of falls programmes appears widespread, both locally in North Wales from staff focus group

reports and in different parts of the UK covered by our survey. This indicates there is service provision in line with NICE recommendations; however some patients in our focus groups reported they had not been offered the opportunity to attend a falls prevention group.

As the purpose of qualitative interviews was to gain in depth perspective and not generalizable data, we acknowledge that our sample of staff and patients attending focus groups is not necessarily representative of their respective populations in North Wales. However, while tailoring rehabilitation to individual needs may account for some patients not being referred, the inconsistency between staff and patient reports raises questions about the consistency of referral to on-going rehabilitation programmes and whether all patients who could benefit were given the choice to attend. The same issue appeared to apply to referral to the Welsh National Exercise Referral Scheme and falls prevention programme that provide on-going rehabilitation opportunities to this and other groups of patients.

Communication problems between different parts of the health service, while diverse and ranging from delays in getting appropriate equipment at home, a wait for referral to the next service on the recovery journey, to not knowing who was providing a particular service, or who to contact to find out more was also a common issue for patients which could be summed up by not always knowing what to expect from their recovery and the services available to support this or who to contact when particular issues arose.

In summary it appears that service provision and referral to these services is not always consistent in spite of the best efforts of health care staff. There is room to enhance rehabilitation to help patients make more of existing provision, by improving their knowledge of what could be available to them, to increase self-efficacy so they can work more effectively with the HCPs they come into contact with during their recovery to increase the quantity and quality of the rehabilitation they undertake. The intervention designed for phase two has been based on the findings of phase one and is described in section 4.1 below.

2. Phase Two Study Objectives and Design

2.1. Study Objectives

1) To assess the acceptability of and compliance with the rehabilitation programme amongst patients, carers and clinicians and identification of any adverse events. To assess the feasibility of a future definitive RCT by assessing the number of eligible patients, monitoring recruitment and retention rates, and explore the willingness of patient participants to be randomised and the willingness of patients and carers to complete outcome measures. To produce means and standard deviations of the quantitative measures so that effect sizes can be calculated for planning the future RCT.

2) To explore the methodological issues for an economic evaluation alongside a future RCT including the most efficient way of measuring patient level costs and health benefits, programme costs, and potential payer stakeholders.

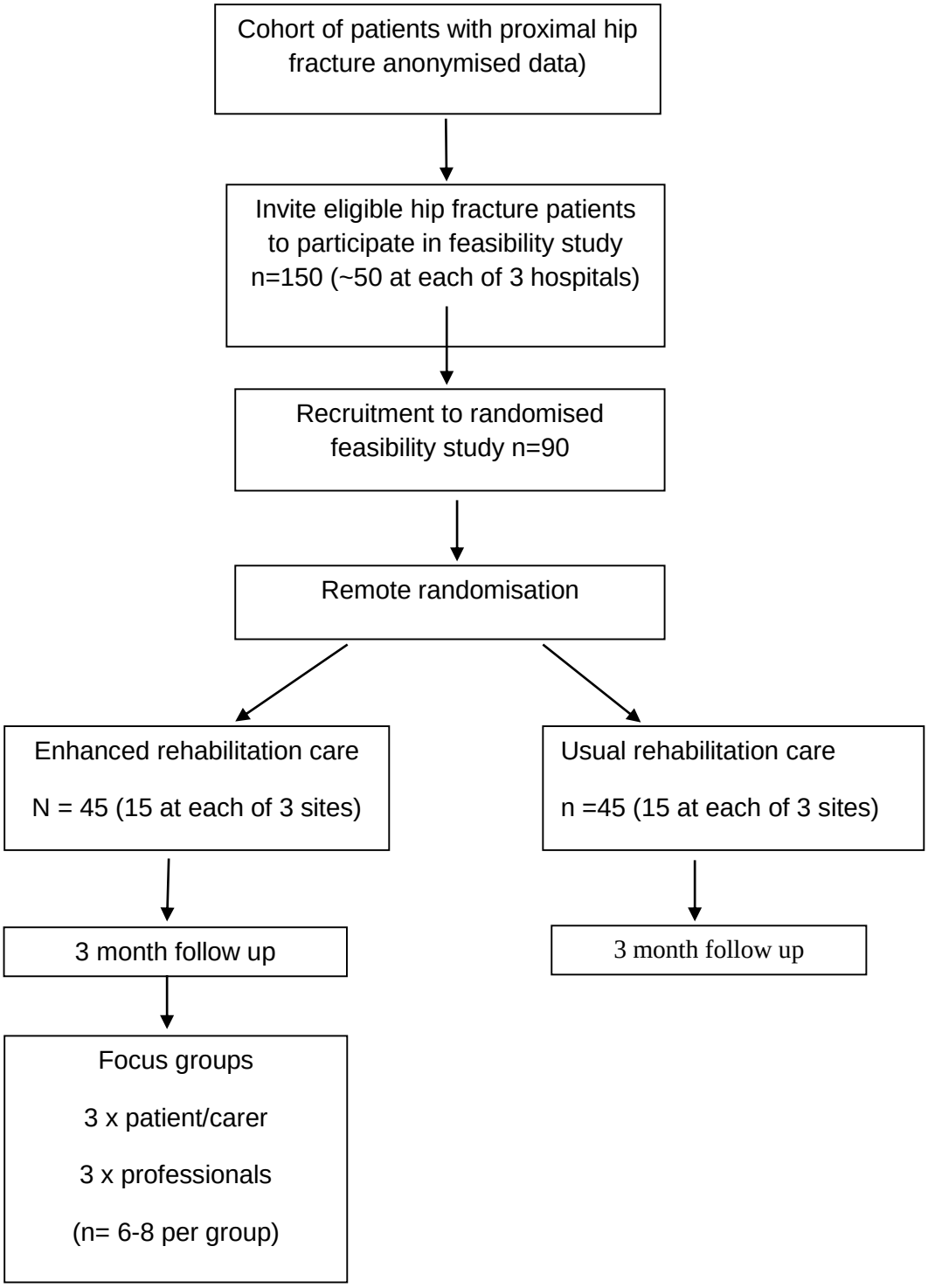
3) To explore the feasibility and quality of data on service use extracted from patient electronic records compared with patient reported outcome measures. If successful, replacing patient reported outcomes of service use with data collection by researchers and NHS IT staff for electronic records has potential to reduce participant burden in future studies. (This is referred to as the triangulation study later in the document)

2.2. Phase Two Study Design

Phase two comprises the second stage of the MRC framework for assessing complex interventions[1]. It will consist of a cohort study of all hip fracture patients with an embedded randomised feasibility study to assess recruitment and retention rates, acceptability of randomisation etc, and to inform the sample size calculation for a future definitive trial. The acceptability and feasibility of the new rehabilitation programme will be assessed with further focus groups of the multi-disciplinary rehabilitation teams, hip fracture patients and their carers.

2.3. Study Flowchart

Phase Two Cohort & Randomised Feasibility Study



3. Selection and withdrawal of subjects for Cohort and Feasibility Study (Phase Two)

3.1 Cohort and Randomised Feasibility Study

The cohort will consist of an anonymised data set of all patients 65 years of age and over admitted to the three main hospitals of Betsi Cadwaladr University Health Board (BCUHB) (Wrexham Maelor, Ysbyty Glan Clwyd and Ysbyty Gwynedd) with hip fracture during the first six months of study period and followed up for three months. Data collected will include type of fracture, type of surgery, length of stay in acute hospital, serious complications, mortality rates, repeat fractures, place of residence on admission, place of discharge from acute and community hospitals, and serious illnesses requiring hospital re-admission. Audit figures returned to the National Hip Fracture data base give a conservative estimate that approximately between 100 and 180 patients are admitted to each of these hospitals (a total of 300 – 540) in a six month period.

Of all those admitted we anticipate we will be able to identify and invite one hundred and fifty patients admitted to all three hospital sites across BCUHB during the six month study period to participate in the embedded feasibility study comparing usual care with the enhanced rehabilitation package using a randomised design. We aim to recruit 65 participants in order to have 50 participants who complete follow up. The purpose of this will be to assess the feasibility and acceptability of a future definitive randomised controlled trial and accompanying economic evaluation. The number of eligible patients, the recruitment and retention rates and the number who complete the outcome questionnaires will be recorded. It will be important to determine whether random allocation to either intervention is acceptable to patients, carers and clinicians providing the service. The feasibility study will also be an opportunity to test a package of outcome measures, including economic measures, for the main trial and to inform the effect size for a future sample size calculation. These patients will also be recruited to a triangulation study which aims to compare the quality of data collected about service use from patient reported outcome

measures compared with extracting the same information from patient electronic records.

3.2. Inclusion criteria for patient participants to feasibility study

We will aim to recruit older adults recovering on an orthopaedic ward with proximal femoral fracture who were previously living independently and who have recently received surgical treatment. The specific inclusion criteria are:

- Age 65 years or older
- Recent proximal hip fracture including the following types of fracture:
    - intracapsular, extracapsular (pertrochanteric, intertrochanteric, reverseoblique or subtrochanteric)
- Surgical repair by replacement arthroplasty or internal fixation within the previous week
- Recovering as an in-patient on an orthopaedic ward and not yet discharged home or transferred to an in-patient rehabilitation ward
- Living independently prior to hip fracture, defined as living in their own home
- Capacity to give informed consent.
- Living and receiving rehabilitation in the NHS in the area covered by BCUHB

3.2. Exclusion criteria

- Younger adults with hip fracture
- Non-surgical treatment following hip fracture
- Living in residential or nursing homes prior to hip fracture
- Lack of capacity to give informed consent.
- Participants who are not able to understand Welsh or English
- Participants who do not live and will not receive community rehabilitation in the BCUHB area

3.3 Carers of patients

Carers will be asked to complete a carer burden questionnaire at baseline and at follow up. Carers for the purpose of this study are defined as people caring for a hip fracture patient recruited to the study by providing them with face to face support

most days in a week including help with activities of daily living and or physical care. They may be a relative or a friend. Where professional care is provided by a team we will include them if feasible.

3.4 Focus group participants/recruitment

All patient participants with capacity and their carers, will be asked when initially consenting whether they agree also to be invited to a focus group later in their recovery. If they agree, they will be written to around the time of the three month follow up visit and asked if they would consider taking part in a focus group. The letter will include another PIS (which will include a section on focus groups), a specimen consent form, a topic guide, a reply slip and freepost envelope to return to the research team at NWORTH indicating whether they would be willing to participate in the focus group or not and giving details of how to contact them. We will ask patients if they would prefer to participate in the focus group through English or Welsh. If enough participants request it, we will run a completely Welsh group. Otherwise we will run one or more bilingual groups using simultaneous translation to facilitate patient language choice. We will offer patients who move into residential care the alternative of having a telephone or face to face interview.

Managers of therapy services will be approached by research staff to help identify staff (e.g. physiotherapists, occupational therapists, nurses, and social work staff) who have worked with patients in the intervention arms. Identified staff will be approached by e-mail, phone or letter by study researchers to ask if they would be willing to take part in a focus group and if they know of any other colleagues with experience of the intervention that the researcher could approach. Participants and contacts from the phase one focus groups will be approached to find out whether they have experience of the intervention and whether they would be willing to take part or know of colleagues who might be interested. Staff focus groups will be run in English, but we will check they agree to this and make other arrangements if requested.

All those approached will be sent a PIS and sample consent form. They will be asked to reply within a week to indicate whether they would be willing to take part or not. Researchers will then contact them with details of date, time and location of the focus group being held nearest their place of work.

3.5. Informed consent

Patient participants in the trial

Potential participants will be identified by clinical staff on the orthopaedic wards of the three main hospitals in Betsi Cadwaladr University Health Board following surgical treatment co-ordinated by the NISCHR CRC research professional network and a researcher from the study team.

Clinical staff will ask potential eligible participants who have capacity to give informed consent if they are happy to be approached by research staff. Potential participants, who have capacity and agree to be seen, will be consulted by NISCHR/research team research staff. Where participants give a specific reason for declining to take part this will be recorded as it will inform the feasibility of recruitment for a definitive RCT. The nature of the research project will be explained by the researcher and a patient participant information sheet (PIS) given. The PIS will have been approved by the ethics committee and will set out all key information including: the practicalities of the study, the possible benefits and risks, the study assessments, and the potential for participating in focus groups. Participants will be given 24 hours for reflection before written consent is obtained by the researcher.

If a patient has not been screened for mental capacity by clinical staff and the researcher or clinical staff have any doubts about participants' mental capacity to give informed consent, the NISCHR CRC nurses or researcher will talk to the patient and the clinical staff, friend or carer who knows the patient well to ascertain their capacity to give informed consent. Research staff will have training in the evaluation of mental capacity in this context. The guiding questions for this evaluation are:

- Is the person able to understand the information relevant to the decision (to participate or not)?
- Is the person able to retain the information provided (can be determined by a simple question of recall)?
- Can the person use or weigh that information as part of the process of making the decision (can be assessed by inquiring of the person's understanding or potential options for participation)?
- Is the person able to communicate his/her decision?

If the answer is no to any one or more of these questions, the patient will not be approached as they do not meet the eligibility criteria for inclusion in the study.

Where the participant has a visual impairment, the researcher will read the participant information sheet and the informed consent form to the participant. If the participant is not able to sign the consent form, a recording of the consent process will be made by the researcher or a witness will be asked to observe the process and sign the consent form indicating they have observed the process and the patient consenting.

Three copies of the consent form will be signed. The original will be kept by the research team, one copy will be kept by the patient and the third will be filed in the patients' medical records.

It is possible that during the study some participants' capacity may change. At follow up the researcher will be asked to assess whether the participant no longer has capacity to give informed consent when arranging the follow up visit. If the patient no longer has capacity no follow up data will be collected, but the baseline and any other data collected to this point will be used in the analysis.

All participant information sheets, letters of invitation, consent forms will be provided in Welsh and English.

After obtaining informed consent the NISCR CRC nurses/researcher from the team will assist completion of the outcome measures using paper versions if they prefer.

Participants will also be given the choice to complete validated versions in Welsh where they exist. The researcher will explain that most measures do not have validated Welsh versions.

After completing the baseline outcome measures, the participant will be randomized by the researcher using a remote web-based system. (See section 3.5 below). The researcher will write to the patients GP to inform them that the patient is taking part in the study and request that the GP make a note of this in the patient record. In addition GP's are requested to inform the study team if they become aware the patient has experienced an adverse event or serious adverse event during the study. (See section 5 below)

Patient focus group participants

Patients and carers who reply to the invitation to the focus group interviews will be contacted by a member of the study team by phone who will explain what will be involved and will go through the information sheet giving them an opportunity to ask questions. If they still wish to take part in the focus group they will be given information about when and where the most convenient one for them is taking place.

At the focus group, participants will again be given the opportunity to ask questions before being asked to sign the consent form by a researcher. They will be asked to sign two copies of the consent form: one copy for themselves and one for the research team's records.

Our experience of running focus groups in phase one of the study was that it is difficult for patients who move to residential care settings to attend. We will therefore offer those individuals an alternative, such as a face to face or telephone interview with a researcher instead.

Staff focus group participants

Staff identified by managers will be contacted by e-mail or telephone by researchers. Researchers will send copies of the participant information sheets, a topic guide and consent form to these staff and request that they respond within a week to confirm

whether they would like to participate or not. If no reply is received within a week then researchers will send a follow up e-mail or make a follow up telephone call.

Researchers will check that staff participants have received and understood the PIS and will give them opportunity to ask questions about the study at the beginning of the focus group. If they are still willing to take part, they will be asked to sign two copies of the consent form, one for themselves and one for the research team's records.

3.6. Randomisation

Consented patient participants will first complete baseline outcome measures before being individually randomised. The randomisation will be performed by dynamic allocation[9] to protect against subversion while ensuring that the trial maintains good balance to the allocation ratio of 1:1 both within each stratification variable and across the trial. Participants will be stratified by: (1) hospital; (2) gender.

Randomisation will be performed by the researcher who has taken informed consent, and will be achieved by secure web access to the remote randomisation centre at NWORTH, Bangor University. This system will be set up, maintained and monitored independently of the trial statistician or other trial staff.

For verification purposes, additional information will also be requested including:

Participant date of birth
Participant trial number
Participant gender
Hospital
Has consent been given?
Does the patient meet the inclusion criteria?

If a person requesting the randomisation responds 'Yes' to the final two questions then the participant can be randomised. The web-based system includes a step at which all entry details can be checked before the randomisation is performed. The randomisation will be carried out by the researcher who has recruited the participant. The randomisation procedures will be aligned with NWORTH standard operating

procedure 5.01 to ensure best practice. The allocated codes will be recorded in the research notes and the patient's clinical record. The key to the randomisation code will be held centrally by NWORTH. Outcome measurement and data analysis will be performed blind to treatment allocation, but because of the nature of rehabilitation interventions participants and clinicians will be aware of which treatment group has been allocated and will not be blinded.

3.7. Withdrawal of participants

Participant withdrawal from the study will not affect their medical care, and this point will be emphasised in the patient information sheet and during the informed consent process. The follow-up questionnaires will be administered by the researcher and the physical function tests by a physiotherapist. Participants will be contacted to arrange an appointment at their home for completion of the questionnaire and at the acute district general hospital physiotherapy gym nearest their home for the physical function tests. If the patient is not able to travel to gym physiotherapists will do the tests in the patient's own home.

Non-completion of the follow-up questionnaires or physical function tests will not constitute formal withdrawal from the trial, and unless the participant requests withdrawal of their data completely, it may be used to impute values for the analysis. The imputation of missing values will ensure that the dataset is utilised to its full power.

3.8. Expected Duration of Feasibility Study

We will recruit participants over a six month period and follow them up for three months. All those randomised to the intervention will also be invited to participate in focus groups after they have completed their three month follow up most convenient for them either by time or proximity. As recall of experiences decreases with time we would like to invite patients to focus groups close enough to their experience of the rehabilitation intervention to get accurate reports. We aim to recruit approximately eight participants to each of the focus groups and should more than eight of those

invited wish to attend, we will purposively select participants to cover a range of experiences of rehabilitation.

The three focus groups with staff will be conducted in the three centres in the last three months of the follow up period – all centres will then have had participants completing the study and staff will have had experience of the intervention by then.

4. Feasibility Study Procedures

4.1. Feasibility study interventions

We plan to compare an enhanced rehabilitation intervention with usual rehabilitation care. Usual care consists of a multi-disciplinary 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 includes orthopaedic surgeons, orthogeriatricians, nurses, physiotherapists, occupational therapists, dieticians, pharmacists, 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.

The main aim of the intervention is to enhance usual rehabilitation by increasing the amount and quality of patients' practice of physical exercise and activities of daily living in order to improve their functional outcomes at three month follow up. We hypothesise that improving patients' self-efficacy will increase their motivation to engage in the rehabilitation process and improve the quality and quantity of this practice/increase their engagement.

We will enhance rehabilitation by means of a patient held information and workbook and diary given to the participant in the acute hospital and kept with them throughout the follow up period of the study. Six additional therapist/technical instructor sessions will be available to patients once they return home or are admitted permanently to a care home. How the time is used will be at the discretion of the community OT or Physiotherapist responsible for their care in liaison with the therapists allocated to deliver the extra sessions to allow tailoring to individual needs.

The workbook will also include information about what to expect from their recovery and information about NHS, council and voluntary sector services they may be able to use. This will include a variety of community services such as falls preventions programmes.

The objectives of the workbook and diary are to:

1) Give patients better understanding of what has happened physically to them and broadly what to expect during their recovery.
2) Provide information and contact details on rehabilitation services that may available to them as they progress in their rehabilitation (e.g. Intermediate care teams, social services enablement teams, outpatient physiotherapy, falls prevention groups, national exercise referral services). The information will help patients know what services may be available to them, give them the opportunity to ask the therapist they are working with or their GP about them and what the benefits for they might be and at what stages they would be most beneficial, to contact the services themselves for more information.
3) To enable them to work collaboratively with their therapist to set goals and monitor progress of their rehabilitation in order to improve the quality and the quantity of the physical and activities of daily living exercises they are given.
4) To improve patients' self-efficacy
    a. To encourage the patient to set goals they want to achieve and to discuss them with their therapist.
    b. To monitor these goals through keeping a diary of progress – this will provide feedback in the form of self-reflection and reflection with the therapist – feedback is known to be an important component for improving self-efficacy.
5) To improve communication between hospital and community services and between the patient and all the different professionals and services they come into contact with during their rehabilitation.
6) To reduce patients fear of falling by improving self-efficacy for avoiding falls/ exercising, and providing information about local falls prevention services
7) To signpost patients to local follow-on community programmes such as exercise referral and falls prevention services with contact details.

A logic model of how the study team envisages the components of the intervention working and creating the anticipated outcomes and linked to high level theory and our CMO theories will be developed.

Delivery of the intervention

The intervention will be delivered by therapists and other clinicians employed by BCUHB. The therapy service managers in BCUHB have agreed to organise the extra sessions for patients in the intervention arm of the study, which will be funded by NHS excess treatment costs. They will also contribute to the development and finalisation of the workbook, in particular commenting on usability, accuracy and local information issues.

Because fractured neck of femur is unscheduled care it is not possible to identify in advance where study participants will need to access rehabilitation services, we will hold awareness raising sessions in the month before recruitment begins. The aim will be to alert therapists to the study and that they may be asked to work with a patient on the study. Researchers from the study team will liaise with the therapy managers and NISCR CRC team, who have agreed to assist with raising awareness, to organise and deliver presentations on the study. We will have access to BCUHB videoconference facilities to enable staff at more remote sites to participate in the presentations. We will also provide posters and flyers for therapies managers to disseminate to all their teams in the acute and community settings.

At each of the three centres across BCUHB (East, Central and West) a team consisting of a physiotherapist, an OT and an assistant therapist will be formed to deliver the extra six sessions of rehabilitation and to work with the patients on their workbook. This will done in collaboration with the existing therapists delivering the usual care. In addition to these extra therapy sessions, the intervention therapy teams will be alerted to which group the patient is randomised and will visit the patient in hospital, wherever possible, to introduce themselves and give them a workbook. A further additional session will be provided by the physiotherapists on

the intervention therapy team to conduct the three month follow up physical function tests. The physiotherapists will administer these physical function tests to participants from a different area from the one in which they have been delivering the intervention (e.g. a therapist working on the intervention in West will, take the outcome measures in the East or Central areas). This will be for the physiotherapist to perform the outcome assessment blind to treatment allocation.

In case a member of BCUHB therapy staff who has not heard about the study comes across a patient participant, we will also include a staff information sheet in the patient's workbook. Patients will be able to give this to staff working with them. The information sheet will give details of the study, the intervention, and contact details for the intervention therapy teams who can give them more information and to alert them they will be contacted by the intervention therapy teams to co-ordinate extra sessions.

4.2 Cohort Study Outcomes

From the cohort anonymised data set we will record:

- The number of patients aged over 65 years admitted with a proximal femoral fracture.
- The number who fulfil the inclusion criteria for the randomised feasibility study
- The number of deaths, serious complications such as falls and repeat fractures, serious illness requiring hospital re-admission and discharged to institutional care (including detail such as the type of ward and the type of residential care in order to calculate the cost per night).

4.3 Randomised Feasibility Study Outcomes

The outcomes will be collected in a variety of ways. Routinely collected data will be used to collect information about recruitment and demographics. Participants' cognitive function will be assessed using the Abbreviated Mental Test Score (AMTS)[10]. At baseline and three months follow-up patient completed outcome measures will be completed by participants, using paper versions, assisted by NISCHR CRC nurses or a member of the research team or carer. Participants will

also be given the choice to complete validated versions in Welsh where they exist. At baseline fewer patient completed outcome measures will be used than at three month follow up as, we wish to reduce the burden on patients at a time shortly after surgery. Objective measurement of physical function will be assessed by the researcher at baseline using the grip strength test. At three months follow up a physiotherapist will measure other tests of physical function. These will be performed in the physiotherapy gym or if the patient is unable to travel in their own home.

Routinely collected demographic, clinical and recruitment data

- The number of eligible patients who fulfilled the inclusion criteria and were willing to be randomised will be expressed as a percentage of the numbers in the cohort data set.
- The number who withdraw after baseline assessment and randomisation
- The number who complete the various outcome measurements at baseline and at three months follow up. The researchers who administer the outcome measures will record the reasons for any non-completion.
- Date of birth (age)
- Gender
- Type of fracture
- Type of surgery
- Marital status and living arrangements
- Important co-morbid conditions
- Place of residence prior to admission
- Place of discharge from acute and/or community hospital

Cognitive status

- Abbreviated Mental Test Score (AMTS)[10]

The AMTS is a validated test that is widely used in clinical and research settings in the UK for detecting and monitoring cognitive impairment. This will be used as a baseline description of the level of cognition. It is brief (10 items) and recommended for cognitive screening in acute settings in the Alzheimer's Society (2013) tool-kit[11] 'Helping you to assess cognition: a practical toolkit for clinicians. It is generally considered to be easily administered and well tolerated in raters and subjects.

Patient Completed Measures

Primary outcome

- Barthel Index[12]

This is a patient or assessor completed outcome measure of current functional status measuring the individual's ability to care for themselves. It is validated for use in patients with musculoskeletal or neuromuscular disorder and is considered easy to use, reliable and sensitive to change. It focuses on the person's level of independence on the following items: feeding, bathing, grooming, dressing, bowel function, bladder function, toilet use, transfers, mobility on level surfaces and stairs. It will be measured at baseline and at the three month follow-up assessment.

Secondary outcomes

- Nottingham Extended Activities of Daily Living Scale[13]

This is a patient completed outcome measure of activities of daily living from the previous four weeks which has been validated in stroke patients. The NEADL is a record of actual activity rather than capability, scoring patients in the areas of mobility, kitchen, domestic and leisure activities. A higher score indicates a greater level of independence. When assessed at baseline it will assess participants' functional capacity prior to hip fracture. It will also be used at the three month follow-up assessment to assess the degree of functional recovery.

- Hospital Anxiety and Depression Scale (HADS)[14]

This is a patient completed outcome measure of anxiety and depression. It is designed to measure anxiety and depression in patients with physical health problems. It has seven items related to common symptoms of anxiety and 7 for depression. Patients are asked whether they experience the symptom definitely, sometimes, not much or not at all. The HADS was designed for use in the hospital

setting but has been used successfully with the general population. This measure will be used at baseline and at the three month follow-up assessment.

Process Measures i.e. potential mediators of outcomes

- Visual Analogue Scale (VAS) for hip pain intensity[15]

This is a patient completed visual analogue scale of current hip pain intensity. Hip pain following surgery is an important factor affecting rehabilitation and will be measured at baseline and at the three month follow-up assessment. We have chosen a VAS as it has been reasonably well validated against the Oxford Hip Score[15 16] and is much simpler and quicker to complete, so reducing burden on patients

- General Self Efficacy Sale[17]

The GSES is not behaviour specific and is chosen as a measure of general confidence when facing challenge. In order to assess *change over time* in such expectancy based cognitions pre and post intervention, (*as well as* test between group differences at follow-up comparing Intervention vs Control) we have chosen this short self-efficacy scale for baseline. It has been validated in the populations of older people and surgical patients. The measure will also be completed at three month follow up with the more behaviour specific s Falls Efficacy Scale – International and the Self-efficacy for exercise scale (see below).

- Falls Efficacy Scale – International (FES- I) (Self efficacy)[18]

The FES-I measures how concerned a patient is about falling when performing activities of daily living both inside and outside of the home. The scales details 16 activities which the patient must rate from 1(not at all concerned) to 4 (very concerned) with regards to how concerned they would be about falling if they performed the activity. The FES-I has been used successfully in older patients both with and without cognitive impairment[19].

- Self-efficacy for exercise scale[20]

The self-efficacy for exercise scale is a revision of an unpublished self-efficacy barriers to exercise measure. The scale consists of statements regarding the participants' confidence that they could exercise for 20 minutes, three times a week, depending on factors such as pain and mood. The participants are instructed to use numbers from 0 (not confident) to 10 (very confident) to rate their expectations. This measure assesses the participant's present expectations and so will be used only at the 3 month follow up as pain from surgery would likely be the major factor in these expectations at baseline and would not measure normal levels of self-efficacy for the patient.

- Visual Analogue Score - Fear of Falling (VAS-FOF) [21]

This is a patient completed visual analogue scale for fear of falling. A VAS is useful as it is easy to administer and brief. The VAS-FOF uses a numeric scale to measure perceived fear, with 1 representing no fear of falling and 10 representing extreme fear of falling. It has previously been used in older adults with and without cognitive impairment with good results[21], and will be used to measure fear of falling in our study at 3 months follow up.

Health Economic measures

- EuroQol EQ-5D[22]

This is a patient completed index of health related quality of life, which gives a weight to different health states. It consists of five dimensions: mobility, self-care, usual activities, pain/discomfort, anxiety/depression. Each has three possible responses. The responses record three levels of severity (no problems/some /moderate problems and extreme problems). It will be used at baseline and at the three month follow-up assessment and allows the calculation of quality adjusted life years (QALYs), using area under the curve method which will be used as part of the economic analysis

- ICECAP-O[23 24 44]

This is a patient completed measure of capability in older people that focuses on well-being rather than health. It comprises of five attributes; Attachment (love and friendship); Security (thinking about the future without concern); Role (doing things that make you feel valued); Enjoyment (enjoyment and pleasure); Control (independence). Each attribute has four possible responses. The responses record the extent of capability (all/a lot/a little and none). It will be used at baseline and at the three month follow-up assessment as part of the economic analysis.

- CSRI – Client service receipt inventory[25]

The CSRI is a questionnaire for collecting retrospective information about study participants' use of health and social care services, including voluntary services (e.g., Charity services), including the components of the rehabilitation programme, This information will be and when combined with national sources of reference unit costs in order will be used to calculate health service and social care service costs for the economic evaluation. It will be used at baseline and at the three month follow-up assessment as part of the economic analysis.

- Discrete Choice Experiments[43]

A Discrete Choice Experiment asks the respondent about their preference for rehabilitation services. Hypothetical rehabilitation services (A and B) are presented to the patient according to five characteristics, these characteristics are described according to different levels, both are described below.

1. Time with Healthcare Professional to conduct follow-up rehabilitation exercises or activities.

   30 minutes

   60 minutes

   90 minutes

2. Qualifications of Health Care Professionals who provides my rehabilitation.

   Supervised Unqualified Assistant

Fully Qualified

3. How will my rehabilitation progress during rehabilitation be monitored?

   By healthcare professionals in your medical records

   By myself in a workbook/diary

4. Where will my rehabilitation take place?

   In Hospital with good gym equipment and healthcare professionals experienced in rehabilitation

   In the Community (e.g., leisure centre) with good gym equipment and experienced exercise instructors

   At Home with limited equipment (e.g., step)

5. Information about additional services to assist rehabilitation

   Hospital based services only (e.g. hydrotherapy pool)

   Community services only (e.g., National Exercise Referral Scheme)

   Both hospital and community services

These above characteristics and levels create a set of 16 alternative scenarios. In each scenario the respondent is asked which service they prefer by ticking A or B. These characteristics and levels were chosen based upon the outcomes of the literature review and focus groups conducted in phase 1. It will be used at the three month follow-up assessment as part of the economic analysis. An example of one of scenarios is provided below;

Question 1	Service A	Service B
Time with Healthcare Professional	30 minutes	60 minutes
Qualifications of Healthcare Professional	Supervised Unqualified Assistant	Fully Qualified
How will my rehabilitation progress be monitored?	By healthcare professionals in your medical records	By myself in a workbook/diary
Where will my rehabilitation take place?	In Hospital with good gym equipment and healthcare professionals experienced in rehabilitation	In the Community (e.g., leisure centre) with good gym equipment and experienced exercise instructors
Information about additional services to support rehabilitation	Hospital based services only (e.g., hydrotherapy pool)	Community services only (e.g., National Exercise Referral)
Which service would you prefer?	☐	☐

Objective Measures of Physical Function

- Grip strength[26]

This is an objective measure of physical function that can be administered by the researcher administering the patient completed questionnaires. Grip strength correlates well with general fitness and muscle strength relating to physical function. It is also a more appropriate measure for use at baseline, as performing other physical assessments may carry risk to patients at this time point or would be likely to only reflect post-operative pain and not overall function.

Grip strength will be measured at baseline and at the three month follow-up assessment. Other objective measures will be administered by a physiotherapist at three month follow up and these are listed below:

- Thirty second sit to stand[27]

From a seated position in a chair with no armrests, the participant rises to a full stand and returns to a fully seated position without using their arms to support themselves. An observer measures the number of stands completed in 30 seconds. The result is then compared to age and sex matched data to comparatively assess the patients function. The 30 s sit to stand is used to measure lower-body strength and is useful in older adults because it is part of everyday activities, e.g. getting in and out of a car, chair, walking and maintaining balance. It correlates reasonably well with other measures of lower body strength such as knee extensor and knee flexor strength and has been shown to have good test-re-test reliability in older adults living in a community setting.

- Eight foot get up and go test[28]

Timed up and go test (also known as '8 get-up-and-go') to assess agility and dynamic balance. An observer measures the time taken for a subject to stand up from a chair, walk eight feet, turn 180 degrees, walk back to the chair and sit down, which is important information in determining a person's safety to be discharged home[29]. There is evidence of reliability[30] including test retest reliability for the duration of its subcomponents[31]. The test-retest measure of reliability is 0.99[32].

- Fifty foot walk test[33]

Bring subject to start on a 50 foot walk test course (25 feet out and 25 feet back) and ask the subject, on the command "go" to walk as quickly as they can to the 25-foot mark and back. An observer records the amount of time taken from the command "go" until the starting line is crossed on the way back. It has been shown that there is a correlation between the recorded gait time and muscle strength[34]. The 50ft walk has also been successfully used to relate to the ability to carry out activities of daily

living. The 50ft walk has also been successfully used to relate to the ability to carry out activities of daily living in older people living in the community[34].

4.4 Therapist process outcomes and use of the intervention workbook

In order to describe the rehabilitation programme in both arms of the feasibility study we will access routinely collected data that therapists complete on the Therapy Manager System. This will only be collected on participants from the Central BCUHB where there is good coverage of the Therapy Manager System. The IT manager at BCUHB will extract the following data and return anonymised data to the research team identifiable only by participant study ID. The intervention therapy teams will complete a paper record of how they use the extra sessions which will form part of the patients clinical records. A BCUHB member of staff will extract the following from these records and return the data to the research team..

The following will be recorded:

- Patient study ID, Date of extra session
- Whether the session was face to face or indirect
- Where the face to face session was held
- If the session was face to face, how much time was spent on different aspects such as, physical exercises, ADL practice, working on the workbook and physical outcome measures (administered by a physiotherapist on behalf of the research team for the baseline and 3 month follow up).

We plan to describe how the intervention was delivered and patients' views and use of the workbook intervention. The workbook contains a page of questions and likert scale type response options to encourage participants to provide feedback on their workbook. Researchers will also collect in the diary sections to assess how they were used. We will evaluate engagement with the workbook including counting how many diaries were used, how regularly they were filled out, whether goals were set and quizzes completed.

4.5 Triangulation study service use information

The patient reported CSRI form will be used as a template to see how feasible it is to collect the same information from BCUHB IT systems and how comparable the data from the two sources are. The data will be collected by NWORTH and BCUHB IT staff.

4.6. Focus groups to assess acceptability and feasibility

Acceptability and feasibility of the different components of the study, of the new intervention and of being randomised will be assessed using focus groups of healthcare professionals and participants in the control and intervention groups.

Three focus groups will be carried out with members of the multidisciplinary rehabilitation teams in the community and the hospital participating in the rehabilitation intervention (either as a member of the intervention therapy delivery team or as part of a team working with them). Focus groups will be based around each of the main hospital sites across North Wales. We will purposively sample a multidisciplinary group containing orthogeriatricians, physiotherapists, occupational therapists, nurses, social workers based in community teams and on the hospital wards.

Focus groups of hip fracture patients and their carers who participated in the enhanced rehabilitation programme intervention will be convened, drawing from those participants who indicated a willingness to be contacted for a focus group when they originally consented and who were allocated to the intervention group.

Patient participants who were allocated to the control group will also be invited, along with their carers, to take part in a separate focus group. This aims to give insight into the acceptability and feasibility of taking part in the study from the point of view of those who did not receive the intervention, and what their experiences were.
We will aim to have six to eight participants in each focus group. All participants will give written consent to participate and will agree that their comments can be recorded, transcribed, anonymised, for analysis. The groups will be run by a

moderator and co-moderator, using a topic guide and notes will be taken of relevant points.

All healthcare professionals and participants who cannot attend the focus group but who would like to take part in this process will be offered a telephone or face to face interview where possible. In the case of telephone interviews, consent will be taken verbally and recorded and a hard copy of the consent forms will be sent out for completion and return by the participants.

5. Assessment of Safety

5.1. Recording Adverse Events

All Adverse events will be recorded in this study. There are adverse events (AEs) and serious adverse events (SAEs)

Adverse events will include:

- Non injurious Falls
- An exacerbation of a pre-existing illness.
- An increase in frequency or intensity of a pre-existing episodic condition.
- A condition (even though it may have been present prior to the start of the feasibility study) detected after the start of the study.
- Continuous persistent disease or symptoms present at baseline that worsens during the study.

The following will not be included as adverse events:

- Medical or surgical procedures - the condition which leads to the procedure is the adverse event.
- Pre-existing disease or conditions present before treatment that do not worsen.
- Overdose of medication without signs or symptoms.

Serious Adverse Event (SAE) will be any medical event that:

- Results in death.

- Is life-threatening [refers to an event during which the participant was at risk of death at the time of the event; it does not refer to an event which might have caused death had it been more severe in nature].

- Falls and repeat fractures

- Requires hospitalisation, or prolongation of existing hospitalisation.

- Results in persistent/significant disability or incapacity.
- Other important medical events that, based upon appropriate medical judgment, may jeopardise the participant and may require medical or surgical intervention.

5.2. Procedures for Recording Adverse Events

All AEs will be recorded by researchers when they are made aware of the event by the patient, carer, the treating clinicians, or therapists. Adverse reporting information will be included in the training given to the therapy teams delivering the intervention and they will be given copies of the AE reporting forms and details of how to return them to the research team. Details of the AE reporting procedure will also be included in letters to the patients GP and consultant informing them of the patient's study participation. The Adverse Event form will have 2 sections, the first is for the healthcare professional to complete and return to the Trial Manager. The Trial Manager will liaise with the Chief Investigator who will determine whether the AE is serious or not and whether it is related to the study. The Chief Investigator will complete the rest of the form. All serious adverse events, along with the Chief Investigator's assessment or whether it is related to the study, will be sent to the DMEC for a second opinion. The trial study manager will record the information on the study master file and inform the Clinical Trial Unit Manager. Study related SAEs will be reported to the sponsor and to the academic school (Schools of Medical and Healthcare Sciences, College of Health and Behavioural Science) within 24 hours of

being determined as serious. They will also be reported to the DMEC Chair and the Research Ethics Committee.

6. Statistics and qualitative data analysis

6.1. Sample Size

Cohort of hip fracture patients; patients who fracture their hip in BCUHB over a six month period will be identified and invited to participate. We expect approximately 300 patients will be admitted with a proximal femoral fracture within that timescale, and with a conservative estimate we will contact before discharge form the acute hospitals at least 50% of these n=150. We will invite all recruited to be randomised to either the enhanced rehabilitation programme or usual care.

In order to estimate the standard deviation for a power calculation for a future definitive RCT with a high level of confidence a sample size of at least 50 participants completing the trial is advisable[35]. We aim to recruit 60 participants to account for attrition.
Three focus groups of multidisciplinary team members (n=8) one in each of the centres across North Wales will be run. Focus groups of patients and carers in both the control and intervention groups (n=8) will also be run. These will take place across the BCUHB area to make them as accessible to participants as possible.

6.2. Statistical analysis

Descriptive statistics will be used such as recruitment and retention rates. Normally distributed outcome and process measure scores will be reported as mean scores with their standard deviations at baseline and at follow-up after three months. Change in mean score and standard deviation of this change score will be reported. Medians and interquartile ranges will be used for skewed outcome measure data. Differences between hospitals will be presented.

6.3. Economic analysis

In this feasibility study health economics analysis will:

- Fully cost the enhanced rehabilitation programme (e.g., salary band of therapists, time spent with the patient conducting rehabilitation, costs of travel and costs of any additional equipment) from a public sector multiagency perspective including health and social care. Unit costs will be obtained from national sources of reference costs[36 37].

• Contribute a discrete choice experiment (attribute and level) in the final patient completed outcome measure at the three months follow-up assessment. This will help build a picture of which aspects patients feel are most important in terms of contributing to their utility[38]. A full discrete choice experiment will be incorporated into the future definitive RCT.

- Explore the sensitivity of EQ-5D and ICECAP-O[39] as potential sources of utility scores for QALY calculation in a full RCT for use in cost-effectiveness analysis.

- We will scope out the potential of conducting an exploratory social rate of return analysis based on the data received from the feasibility study to inform whether a full SROI analysis is possible from a full scale RCT of the FEMuR multidisciplinary rehabilitation.

6.4 Qualitative data analysis

Transcripts of the focus groups will be analysed using the framework approach[40]. A framework will be developed based on the programme theories, logic model and the questions of feasibility and acceptability this study is designed to answer. The transcripts will be coded and grouped together into categories and used to populate and refine the framework. The framework will be used to develop themes that contribute to answering the study's feasibility and acceptability questions. Transcript coding and categorising, development of the framework and themes will be reviewed and discussed by the researcher leading on analysis and other members of the team to ensure a rigorous analysis process.

6.5 Triangulation study analysis

A comparative analysis of the participant completed service use questionnaire (CSRI) data set and the data set collected from electronic records will be conducted.

7. Trial Management

7.1. Study Management Group

A Study Management Group (SMG) consisting of individuals responsible for the day to-day running of the study has been established and is responsible for overseeing the progress of the study throughout all of its phases and has met regularly every one to two months. The SMG includes the chief investigator, study manager, study statistician, trial unit quality assurance manager, and study co-applicants. The group ensures that the protocol is adhered to, and takes appropriate action to safeguard participants, and ensure the overall quality of the study. The SMG reports to the study steering committee (SSC) and the DMEC.

7.2. Study Steering Committee

A SSC is being held every three to six months in order to provide overall supervision of the study and ensure that the study is conducted to the rigorous standards set out in the guidelines for good clinical practice. The SSC consists of the following members: an independent chair, other independent members, patient representative, chief investigator, study manager, members observing from Bangor University as the sponsoring organisation, and a representative from NISCHR-CRC. It considers study progress, adherence to the protocol, and provides advice to the study team.

7.3 Data Monitoring and Ethics Committee

Data monitoring and quality assurance will be overseen by the DMEC. It will consider study progress, recruitment and retention, patient safety and any new information relevant to the study. At least three members will be appointed including at least one statistician and experts in the field of rehabilitation of older people.

8. Ethics and Regulatory Approvals

Applications will be made for research ethics committee and NHS research and development approvals via the on-line Integrated Research Application System (IRAS).

All trial documentation, including participant information sheets, participant consent forms, template GP letters, and questionairres will be submitted for approval. To conform to the Data Protection Act and Freedom of Information Act, all data will be anonymised and stored securely. No published material will contain patient identifying information. If new evidence becomes available during the course of the study, for example suggesting that the intervention is substantially better or worse than usual care, it is the responsibility of the DMEC to consider such issues and make recommendations on the continuation of the study to the SMG.

Direct access to source data/documents

Source data will be the hospital written and electronic medical records and routinely collected data, community electronic and written records, audio recordings and transcripts of the focus group interviews. Access to this data will be through members of NISCHR CRC, BCUHB IT staff and researchers on the team who will have NHS research passports. Trial related monitoring, audits, Research Ethics Committee reviews and regulatory inspections will be permitted, allowing access to data and documents where required.

9. Quality Assurance and Quality Control

This study will be conducted in line with the study protocol and will follow the principles of good clinical practice outlined by the ICH- GCP[41] and will comply with the EU directive 2001/20/EC[42].

Regular monitoring activities will be put in place based on a study risk assessment and delegated to members of the study team to ensure that: the fidelity and dose of the enhanced rehabilitation programme delivered to participants is consistent with programme theory; collected data adhere to the requirements of the protocol; only authorised persons complete Case Report Forms (CRFs); the potential for missing

data is minimised; data are valid through validation checks (e.g. range and consistency checks); recruitment rates, withdrawals and losses to follow-up are reviewed overall and by hospital site. Only members of the research team who have completed GCP training and have training in focus groups or are supervised by an experienced team member will conduct or be co-moderator at these groups. The process of data analysis will include appropriate methods for ensuring the findings are plausible and credible.

10. Data Handling

10.1. Data capturing method

Quantitative data for the feasibility study will be entered into the MACRO data management program, which is a web-based system allowing controlled access to data by all centres and stores a full audit trail. Additional health service use data obtained from primary and secondary care records will be recorded electronically on encrypted laptop computers or collected by NHS staff on secure computers and anonymised in an electronic data set that is ready for secure transfer to NWORTH. Data from the focus group interviews will be digital recordings of the focus group discussion and notes taken during the focus groups by the moderator or co-moderator. At the end of the focus group the recording will be downloaded on to an encrypted NWORTH lap top and subsequently downloaded and stored on the university server in a folder with access limited to core members of the study team. Transfer of the recording to an approved transcriber and return of the transcript will be done by encrypting the recording and uploading to/downloading from a secure server. Written notes will be taken taking care to not to record personally identifiable data and they will be stored in locked cabinets in locked rooms in NWORTH.

10.2. Coding specifications

The design of the source documentation in MACRO will be documented specifying the design, format, derivation and validations used for each type of question in the Coding Specification. The data captured will be stored in a database running on servers maintained by Bangor University. Access to the complete database will be limited to the core team members of the project involved in data management, data

cleaning, analysis and study management. The physical storage of paper case report forms will be documented within the data management plan. The coding will be conducted in the design set up phase of the source documentation for MACRO. The code book will be shared along with the data in the data sharing process to allow meaningful interpretation of the data set by other researchers in the project.

10.3. Data transfer process steps

Data from the focus group notes and transcriptions of the discussion will be transferred to NVivo or Excel software for qualitative analysis. Data from the feasibility study on the MACRO data management programme will be made available for analysis via SPSS. Paper copies of case report forms (participant questionnaires) will be stored securely at the sites where possible during the trial. Photocopies will be made before returning any originals to NWORTH. The originals will be returned to NWORTH via recorded delivery/courier for data entry, if necessary, and for archiving at the end of the study. The photocopies held and the site will be destroyed at the end of the trial once all the final data set is closed.

Consent forms where ever possible will be stored securely at the NHS sites.
Any consent forms (e.g. focus group consent forms) and paper recorded data stored at Bangor University will be kept in separate locked cabinets.

10.4. Review of the quantitative data

A periodic review of the data will be performed to ensure accuracy of data entered into the database. This will be a general check to determine if all participant data has been entered, checked for missing values, to identify, if there are any obvious problems. A random check of ID, number of entries and out of range values will be performed.

10.5. Data Management

A data management plan will be written and it will cover processes for auditing, cleaning and monitoring quality.

The transcripts of the focus groups will be checked for accuracy of transcript by one of the researchers who attended the focus group and by using the audio recording as necessary. The transcripts will be checked for any identifying data such as names and places and these will be removed or replaced with a description of what sort of information it was so the transcript still makes sense and to ensure anonymity of the participants.

10.6. Data sharing

Data will be shared with the members of the research group when required. The member may formally request for a specific data set using a data request form which will be part of the data management plan. All such requests will need to be approved by the CI.
All quantitative data will be accompanied by a copy of the relevant codebook. The request and the data set provided to which member will be recorded and saved in respective folders named after the member.

10.7. Data archiving

Data archiving details the storage of the data post study complete with the relevant audit trail that will allow tracking from raw entered data to the final master data set used for analysis. The storage location of hard copy data will be recorded in the data management plan. At the end of the trial original data, analysis data and the data tracking file will be archived with access only to authorised people.

11. Publication Policy

A publication strategy has been developed. We are committed to publishing in a wide range of peer-reviewed journals and to ensuring that appropriate recognition is given to all who have worked on the trial. We are also committed to making research data accessible for secondary analysis.

12. Financial and Insurance Aspects

The study is funded by a grant from the NIHR Health Technology Assessment Programme to Bangor University, and will be managed in accordance with the

relevant policies and procedures. Bangor University has appropriate Clinical Trials Indemnity and Professional Indemnity insurance in place that will cover members of the research team to conduct the research as per protocol. NISCHR CRC staff have NHS contracts and will be responsible to ensure their work on this study is appropriately insured. NHS and Social Services staff who work with patients involved in the intervention will not be expected to do anything that is not covered by their contracts and will remain covered by the NHS or Social Services insurance arrangements.

13. Approval signatures

Chief Investigator: Date:

Print name:

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