

Title: Functional exercise for the rehabilitation of community dwelling people with dementia who fracture their hip – a feasibility study (protocol)

Research Question

Is it feasible and acceptable to deliver a dementia specific, progressive, home-based functional physiotherapy programme for community-dwelling people with dementia who fracture their hip?

Background

Hip fracture is a common injury, especially in the elderly, resulting in the estimated occupation of over 4000 inpatient beds at any time in the UK (1). With an estimated 65,000 such fractures occurring every year in the UK, hip fracture represents a significant economic burden to the UK each year.

People who fracture their hip often have multiple co-morbidities (2), of which it is estimated that dementia is the most prevalent, with one study estimating that 19% of older adults with a hip fracture have dementia (3). Indeed, it is estimated that people with dementia are 2.7 times more likely to fracture their hip than sex and age matched controls without dementia (4). The majority of people who fracture their hip will undergo a surgical intervention to repair the fracture, the type of which varies according to multiple factors including type of fracture and other co-morbidities. However, the recovery of people who sustain a hip fracture is complex and involves a challenging interaction of physical, psychological and social factors (5). Long-term functional recovery is frequently considered to be poor (6) with an estimated 27% to 59% of people moving into permanent long-term care within the first year after fracture (7, 8).

People with dementia who fracture their hip are often considered unsuitable candidates for physiotherapy, potentially as rehabilitation is often seen in terms of physical function rather than facilitating renewed personhood or wellbeing (9). Kitwood (10) described the importance of “person centred care” which sought to determine what a person wanted to achieve. This relates to the World Health Organisation (WHO) classification of impairment, disability and handicap, whereby outcomes

focus on the effect on the person's ability to function and participate rather than physical outcome measures such as strength. People with dementia who fracture their hip are often excluded from rehabilitation programs (11) however, the evidence for this being appropriate is contradictory.

The rehabilitation of people with dementia without hip fracture is more advanced, with several studies suggesting the use of functional exercise programs to rehabilitate people with dementia in community settings (12), as well as those in residential care settings (13). Despite the suggested use of functional exercise programs to rehabilitate people with dementia, no studies have sought to determine the effectiveness of such programs with people with hip fracture and dementia.

A scoping review we have undertaken (Hall et al, awaiting publication) found a paucity of literature to either support or negate the use of physiotherapy for this population. A significant failing of the existing evidence was found to be the lack of detail about the physiotherapy intervention, often describing the intervention as simply "physiotherapy" – assuming that this is a treatment in itself rather than an umbrella term for multiple potential treatment techniques. This is further supported by a recent systematic review who defined this ambiguity as the "black box of physiotherapy" (14).

Recently, research has focused on high intensity exercise interventions for people with dementia (15-20), frequently citing improvements in physical outcome measures such as strength and walking ability. However, the long-term effectiveness, compliance and adherence to such interventions have not been explored. Nor have these programmes been undertaken with this population following hip fracture. Results of qualitative studies we have undertaken (currently under review) suggest that adherence to high intensity interventions poor for this population, due to high levels of fatigue, poor exercise tolerance and reduced concentration levels.

There is no evidence to compare the effectiveness of low-intensity and high-intensity exercise in this population. A recent Cochrane review compared exercise intensity in patients with hip or knee osteoarthritis and determined that there was insufficient evidence to determine the effect of different types of intensity of exercise programs (21) but suggested that low intensity exercise could have benefits such as lower pain levels. Previous research suggested that low intensity exercise was effective in reducing indicators of frailty (22), balance (23), strength and flexibility (22, 24, 25). This study will incorporate both high and low intensity exercise depending on the physiological change that is being sought to be altered.

Aims of study

Therefore, this study aims to determine the feasibility and acceptability of delivering and receiving a dementia specific functional exercise programme to a population of people with dementia who fracture their hip.

The specific objectives of this feasibility study are to establish:

- a) Is it feasible to deliver the intervention?
- b) Is it feasible to recruit participants?
 - ii) Explore reasons why recruitment may not be possible
- c) What are the likely eligibility, recruitment and retention rates?
- d) Is the intervention acceptable to;

Patients /carers

Physiotherapists

In addition, the study will result in the refinement of an intervention manual for physiotherapists which would be used as part of a future randomised controlled trial (RCT). The aims of the full trial would be to compare the effectiveness of this intervention in relation to reducing impairment and disability of this population, compared to those people receiving normal care.

Methods/design

A multi-site, single arm, mixed and multiple methods feasibility study will be undertaken following the methodological framework stipulated in the Medical Research Council guidelines for development and evaluation of complex interventions (26). This feasibility study is an important step that offers excellent value for money before embarking on an expensive RCT. The aims and objectives form the main focus for this feasibility study to inform the design of a potential future randomised controlled trial exploring the effectiveness of this home based functional exercise for the rehabilitation of people with dementia after hip fracture. The MRC guidance suggests a ‘multiple-methods’ approach is essential to identify potential barriers and facilitators to delivering the intervention, therefore a

qualitative component will be incorporated into the feasibility study. A mixed methods analysis will seek to combine qualitative and quantitative data to help answer the question of ‘why’ the intervention is (or is not) acceptable and feasible to deliver.

Setting and participants

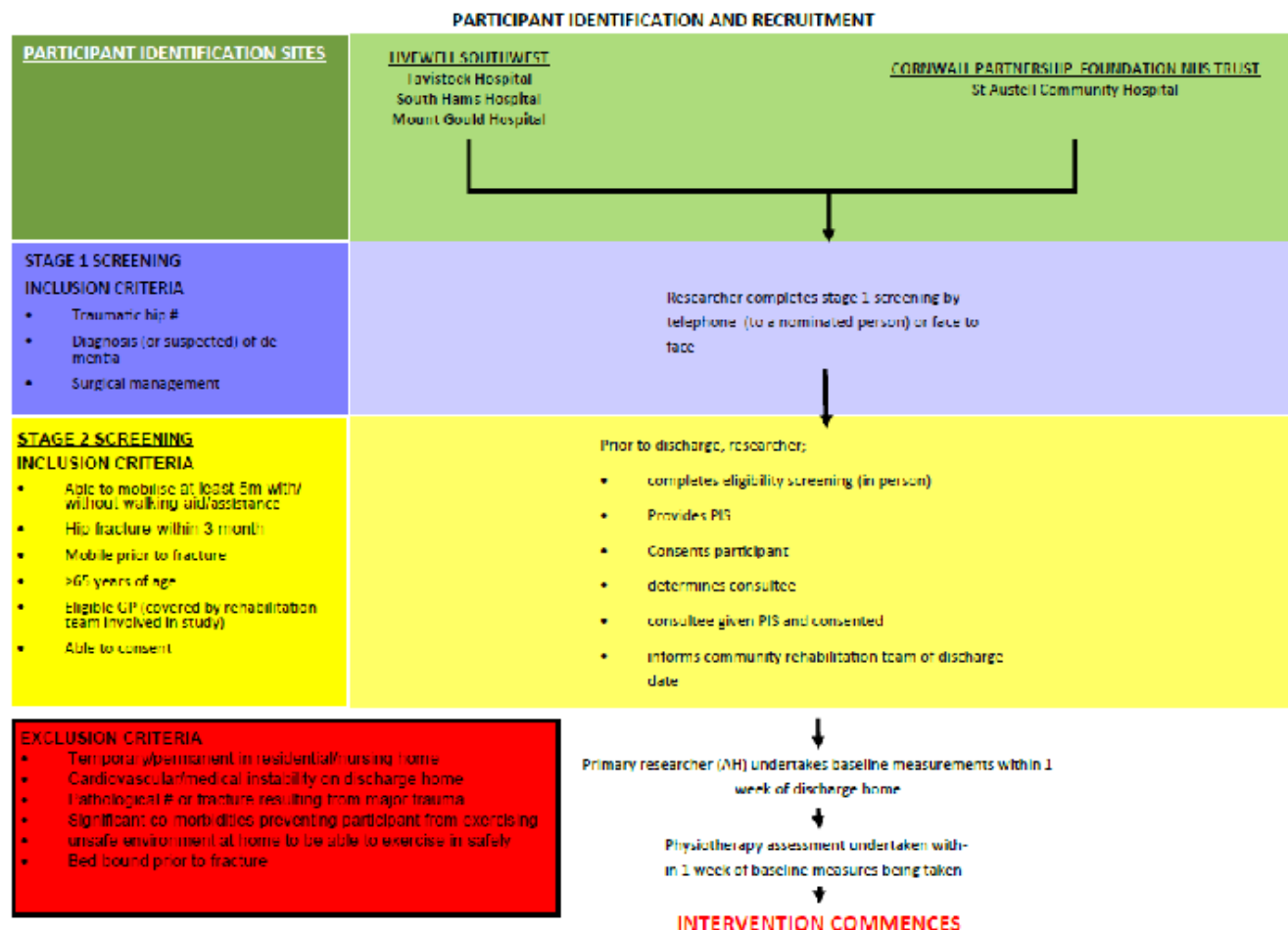
Participants will be sought who are referred to community based rehabilitation teams following discharge from acute (or community) hospital following hip fracture. Four separate rehabilitation teams (Tavistock, Kingsbridge, Ivybridge at St Austell) will be delivering the intervention to reduce burden on individual teams.

Recruitment

The South West Region has the second highest incidence of hip fracture in the UK (second only to the North West Region) with an estimated 7303 fractures in 2015 (1). The local Clinical Research Network (CRN) advised to seek participants who are discharged to community hospitals from three of the acute hospitals within the region. These have three of the highest annual incidences of hip fracture in 2015; Plymouth Hospitals NHS Trust (484 hip fractures), Torbay District General Hospital (471 hip fractures) and The Royal Cornwall Hospital, Treliske (606 hip fractures) (1).

Potential participants will be identified in the 4 Participant Identification Centres by the primary researcher (Mount Gould Hospital, Tavistock Hospital, South Hams Hospital and St Austell Community Hospital). An eligibility checklist will be used prior to discharge home. Reasons for ineligibility will be recorded.

Functional physiotherapy for the rehabilitation of community dwelling people with dementia who fracture their hip – a feasibility study



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Consent

The potential participants will be provided with a participant information leaflet. Should they wish to participate, they will be asked to give consent and sign a consent form.

All researchers involved in the study will have attended Good Clinical Practice (GCP) Training; including how to obtain consent from vulnerable people. All physiotherapists and assistants delivering the programme will be up to date with their mandatory training including Safeguarding of Vulnerable Adults. As physiotherapists will not be undertaking any research activities, they will not be required to undertake GCP training as the guidance on the HRA website (http://www.hra.nhs.uk/wp-content/uploads/2013/09/Training_requirements_for_Researchers_v1.5_2012-07-27.pdf) which suggests. *“If an activity is part of a person’s normal clinical role and all other protocol activities are undertaken by a member of the research team, then no GCP training may be required; however this should be reviewed as part of the risk assessment for a trial.”*

The ability to consent to participation will be guided by the principles of the Mental Capacity Act (2005). The Mental Capacity Act (MCA) states that a person is able to make a decision if they are able to understand the information relevant to the decision, retain this information and communicate his or her decision (by any means).

Should it be unclear as to whether the participant has capacity to consent, the MCA suggests consultation such as with other medical professionals, such as the participants GP. Further to this, a personal consultee will be nominated for each participant, ideally by the participant themselves, or by a medical professional who knows the participant when the participant cannot name someone themselves. The consultee will be given information about the project and will advise on what the participant’s wishes and feelings would be about taking part. The consultee will be given an information sheet explaining their role as a consultee as well as information about the study.

The advice of the consultee will be respected at all times during the study. If the consultee so advises, the participant must not take part and, if already taking part, must be withdrawn unless withdrawal of treatment would involve significant risk to the participant’s health.

Sample size

As a feasibility study, a formal sample size calculation is not required. Although there is currently no guidance as to appropriate sample sizes for feasibility studies, 12-15 participants would be considered appropriate in a pilot study (27) and therefore this will be used to guide this feasibility study. To reduce the burden experienced by individual physiotherapists delivering the intervention, four separate rehabilitation teams have been included in the study. Therefore, each site will only aim to recruit 3 to 4 patients each over the course of the study (anticipated to be 6-9 months).

Intervention

The intervention comprises of a dementia-specific physiotherapy intervention consisting of strengthening, balance and gait re-education exercises. These exercises will be delivered and taught by qualified physiotherapists and assistants by means of face to face contacts as set periods, supported with telephone contacts and support and exercise manuals. Each exercise will be demonstrated to the participant and the participant will be asked to copy the physiotherapist until they are able to reliably undertake the exercise. The exercise will be incorporated into daily activities where this is possible.

It is anticipated that many of these participants will have other rehabilitation interventions running concurrently which constitutes “usual care”. This may be occupational therapy or social care services aimed at improving independence. These interventions will be recorded for each participant, but these will not be affected by the involvement in the study. Therefore, the intervention will consist of usual care plus the following 4 component physiotherapy programme;

1. Strengthening

Functional strengthening exercises will form a component of the exercise intervention and will be based on functional movements in predominately weight bearing positions. There will be different levels of exercise which will be progressed as able. Muscle power will be targeted with a series of low repetition, high resistance exercises. The physiotherapist will aim to start the participant at the correct level so that they are able to undertaken 8-12 repetitions of the exercise. Once this is achievable without excessive fatigue they will be progressed onto the next level of the exercise. This may involve increasing the loads (using weights), increasing the

stepping height or rising from a lower chair. If the participant is unable to complete 8-12 repetitions, the level of the exercise should be reduced.

Justification

Functional exercises have been suggested to be more appropriate for older people following hip fracture than standard exercises (28, 29) and are also suggested to be effective in people with cognitive impairment (30). Indeed, functional exercises have been described by several authors as being effective to improve balance and functional ability for people with dementia (16, 17, 31), although they have yet to be tested in a population with dementia after hip fracture. The majority of studies incorporate high-intensity exercise into their programmes (12, 13, 15, 18-21, 31-33) although variation in definition of the term 'intensity' makes comparing these studies challenging. Therefore, the intensity of the prescribed exercises will be determined by the effect that is being targeted. To increase power, low repetition, high resistance exercise will be used (34). Qualitative work that we have undertaken supports the use of low repetitions of simple functional tasks to reduce time burden needed to undertake the exercise and difficulties undertaking complex exercises.

2. Balance

Functional balance exercises will be incorporated into the exercise programme. These will be designed to be progressive in their nature and sufficiently challenging to the participant until they are considered highly challenging. Initially support will be used to undertake the exercise by means of holding onto a stable surface. As the participant is able to undertake the exercise with confidence, the difficulty will be increased by decreasing base of support or reducing support (or stability of the support) while undertaking the exercise.

Justification

Balance exercises have been suggested to improve the physical function after hip and knee arthroplasty (35) and are suggested to reduce fear of falling (36) and falls (37) in older community dwelling older people. While no studies have sought to determine the effectiveness of isolated balance exercises in the rehabilitation after hip fracture, several studies include balance re-education as part of their intervention alongside other components such as strengthening in cognitively intact populations (38-41) and cognitively impaired populations (42).

3. Gait re-education

During each physiotherapy session, the physiotherapist/assistant will assess the potential to progress the patient's walking aid. It is anticipated that the majority of patients will be discharged from hospital using a walking frame, therefore the physiotherapist will be asked to practice mobility with elbow crutches/walking stick(s) where appropriate. Further encouragement will be given to the participant to increase their activity levels by means of the activity tracker. A target will be set for each participant and they will be encouraged to meet this target. The baseline activity will be measured on the initial contact and a target of 10% increase will be added on every therapy contact.

Justification

Functional disability after hip fracture is significant with lower limb function and mobility often severely affected (43), so a significant aim of physiotherapy is to restore mobility. Indeed, restoring mobility using a variety of different strategies is suggested to be the primary aim following fracture (44). The use of activity trackers has been shown to be feasible in people with dementia (45) and are suggested to be a successful motivational tool to increase walking activity (46).

4. Dementia specific components

○ Written/visual prompts

Instructions of how to undertake the exercises will be given to each participant. This will comprise of a single sheet of A4 paper with each exercise printed on, both with simple written instructions and an image signifying the exercise. These will be provided in an exercise brochure or the participant. Physiotherapists will be able to choose the appropriate exercises and add these to a ring binder which will be given to every participant. This ring binder will have more information about the study and the exercise intervention also as well as contact details, safety information and information about exercise progression. Exercises can be removed from the ring binder and placed around the house in locations that allow the exercise to be undertaken with ease (eg. Side stepping along the kitchen work surface, or stepping up on the bottom step of the stairs).

Justification

Results of our qualitative work demonstrated that people with dementia had varying preferences of how to remember and undertake exercises. It was suggested that some people prefer to follow written instructions, while other prefer visual images of the method of undertaking the exercise. The importance of simple instructions was highlighted by many, as they often felt that instructions were overly complex.

○ **Diary**

A written diary will be given to each participant as part of their information pack. This will have the physiotherapy face to face contacts detailed in them and the exercise prescription of independent exercises will be agreed and plotted in the diary. There will be space for the participant to make notes about the session and document any difficulties they may have had. The exercise sessions will also be plotted on any other memory aids that participants may use (eg. alarms on a mobile phone or writing on a calendar).

Justification

The diary will serve a dual purpose. Firstly it will allow the adherence to treatment to be determined. Secondly, it will enable any difficulties that a participant may have to be documented and therefore addressed, whereas the participant may not remember the difficulties faced on each session. It will act as a memory aid which was reported to be of use in the results of our qualitative work. Furthermore, it was suggested to be of benefit by several members of our Patient and Public Involvement (PPI) group.

Equipment needed

The intervention has been designed to require very little equipment as this replicates the lack of equipment that is commonly available in patient's homes. A fitness tracker will be provided for each participant (by the research team). Each participant will be issued a pedometer. This simple pedometer can be worn on the belt/pockets, put in a pocket or worn as a lanyard. The device is waterproof and has an 8 month battery life so does not require charging during the course of the study. A step will also be required to undertake some of the exercises. Should the patient have a

step/stairs in their house, this will be used, however if they have no step available, a small wooden step will be provided to each participant by the research team. Some simple weights/weighted vest may be required for participants.

Schedule of intervention

The intervention will run over a period of 12 weeks, during which there will be 8 face to face contacts (2 assessments and 6 treatments) with a further 6 telephone contacts.

	Home visit	Telephone contact
Initial assessment	√	
Week 1	√	√
Week 2	√	
Week 3		√
Week 4	√	
Week 5		√
Week 6	√	
Week 7		√
Week 8	√	
Week 9		√
Week 10		√
Week 11		
Week 12	√	
Final assessment	√	

The assessments are expected to take 45 minutes to undertake and each face to face contact to take 30 minutes in duration. A physiotherapy assistant may be used where this is appropriate. The feasibility of this delivery schedule will be discussed in the post-study focus groups.

Participants will be asked to independently complete their exercise intervention 3 times a week for approximately 30 minutes per session. The exercises can be spread over the day and do not need to

be completed together. The acceptability of the dose of intervention to patients and their cares will also be discussed in the post intervention interviews.

Telephone contacts will intersperse the face to face contacts at set intervals (as previously described). These contacts will aim to check that the participant is managing their exercises without problem and to determine if they are able to be progressed.

Training of Staff undertaking the Intervention

Training will be provided to each physiotherapist and assistant who will deliver the intervention by the researcher, who is an experienced physiotherapist. The effectiveness of this training will be discussed in the focus groups following completion of the intervention.

The content of the training will include information about hip fractures and dementia. Communication issues for people with dementia will be discussed in depth in order to ensure effective communication with participants. The training will also include the delivery of the exercise intervention and how to progress the exercises.

Physiotherapy assistants will be used to deliver the intervention where this is appropriate. The individual physiotherapist will assess the suitability of an assistant being able to undertake the exercise delivery. Therefore, physiotherapy assistants will be involved in the training programme also.

Intervention Manual

All potential exercises will be provided in a manual and the physiotherapist will select the most appropriate exercises according to the results of their individual assessment. This will include difficulty of the exercise, number of repetitions and also number of times the exercise needs to be repeated. Printed descriptions and pictures of the exercises will be provided to the participant as part of the patient facing intervention manual. The manual will have further information about the study, safety advice and hints about communication strategies that are effective for people with dementia. It will also give details about how to use the patient facing intervention brochure.

Involvement/Training of carers

The involvement of carers will vary with each participant. Results of our qualitative work provided varied responses to whether carers would be happy to be involved in the intervention. The majority carers were keen to be involved in the exercises, however, several were less keen to be involved.

Therefore, this will be ascertained in each individual circumstance and the treatment adapted accordingly. The involvement of carers will be recorded and discussed as part of the post intervention focus group and interviews.

Where participants have a carer who is able to undertake the exercises with them, training will be provided by the physiotherapist to ensure that the carer is able to help the participant replicate the exercise correctly. This will involve the carer being present at the assessment and the prescription of exercise. This will allow opportunity for the carer to ensure that they understand the exercise correctly and ask any relevant questions about it.

Commencement of the Intervention

The intervention will commence on discharge to the participants home either from the community hospital or directly from the acute hospital. There is little evidence to suggest how soon after discharge home that a rehabilitation program for people with dementia and hip fracture should commence. However, data from a recent qualitative study we have undertaken highlighted the importance of physiotherapy commencing as soon as possible following discharge from hospital.

The baseline assessment will aim to take place within 1 week of discharge home and be undertaken by the primary researcher. Following this, the physiotherapy assessment will aim to be undertaken within a further week. It is anticipated that some of the sites will be unable to meet these timelines; however this forms an important aspect of the feasibility of delivering the intervention and will be discussed as part of the focus groups. The sites will be advised to commence the intervention as soon as their service is able to do so and prioritise it according to their criteria. The time taken for the assessment and intervention to commence will be recorded.

Physiotherapy Assessment

A structured assessment of the participant will occur following discharge in their own home. This assessment will take place by the physiotherapist in the community who will deliver the intervention. This will allow the physiotherapist to tailor the intervention to ensure that it is appropriate for each

patient. This assessment will involve completion of the site's standard assessment paperwork which will include a physical assessment and assessment of functional abilities.

Data collection

Quantitative

At baseline, demographic data will be collected by the primary researcher. This will include details such as participant characteristics (age, type of fracture, date of fracture, type of dementia etc). This will be collected from face to face assessment in the persons own home. Outcome measures will be collected at baseline (within 1 week after discharge home and prior to commencement of the intervention) and within 1 week of completion of the intervention.

The results of the qualitative studies suggest that biomedical outcome measures are less important or frequently not appropriate for this population. Therefore outcome measures based on functional outcomes and quality of life will be mainly used. Therefore, the following outcome measures will be collected by the primary researcher: Dementia quality of life questionnaire (47); Elderly Mobility Scale; timed get up and go (48) and Goal Attainment Scale (49). Where appropriate the care-giver strain index will also be collected using the Caregiver Burden Inventory (CBI) (50).

Alongside this data collection, the activity of participants will be monitored by use of a pedometer. Each participant will be issued a pedometer. The simple display shows the amount of activity achieved in relation to a set target. This target can be changed by the physiotherapist as appropriate to encourage a greater amount of activity. The use of such pedometers was discussed with a member of our Patient and Public Involvement Group who found the idea of a set target to work towards to be very beneficial. The acceptability and usefulness of using this as a target will be discussed in the post intervention interviews with patients and carers. The device stores 30 days' worth of data. The participant will be encouraged to record their daily steps, but should they not remember to do so, the physiotherapist will be easily able to access this data on the device. The participant will be encouraged to use the tracker during waking hours. The feasibility of using such a device will be assessed following completion of the intervention by means of discussion during the post-intervention interviews.

Written records will be maintained by the physiotherapists in terms of content of the face to face sessions, duration of sessions and travel time.

Reasons for eligibility/ineligibility were collected during screening of potential participants, this data will be used to help inform the patient pathways and explore reasons for participants not being eligible. This data was also useful to help try and determine if the recruitment strategy needed altering.

Qualitative

Following completion of the intervention, semi-structured interviews will be undertaken with all participants and next of kin to determine the acceptability and experiences of receiving the intervention.

Acceptability of receiving the intervention

Semi-structured interviews will be undertaken with all participants and carers together (where possible) to determine the experiences of receiving the intervention. This will occur following collection of post-intervention data collection, however, should this be too tiring for the participant to undertake both aspects, a later date will be organised as soon after completion as possible. Any participant who withdraws from the study will be asked to complete a debriefing interview to establish any barriers.

Participants will be asked the same initial questions, but the questions will be worded so that responses are open-ended. This open-endedness allows the participants to contribute as much detailed information as they desire and it also allows the researcher to ask probing questions as a means of follow-up. The interview questions will then vary according to how the interview proceeds, although a guide to potential questions will be adhered to. Data collection and initial analysis will run simultaneously, with interviews audio recorded and transcribed verbatim immediately following completion of the interview. The audio recordings will be transcribed by a transcriber employed by the University of Exeter, who will comply with all confidentiality requirements of the study. These transcriptions will be checked by a second researcher (RW) to ensure accuracy.

Feasibility of delivering the intervention

The experiences of the physiotherapists and therapy assistants involved in delivering the intervention will also be considered. A single focus group will be undertaken in order to determine the feasibility of delivering the intervention. Physiotherapists will be encouraged to discuss the intervention and help guide the adaptation of the intervention for a possible future trial. Data from this focus group will be transcribed and themes developed about the intervention. Potential improvements to the intervention will be discussed. The focus group will be audio recorded and a second researcher (RW) will take field notes during the focus group. The audio recording will be transcribed verbatim following completion of the focus group. All participants in the focus group will give written consent to take part in the focus group. The data will be anonymised so that individual participants cannot be identified and all participants will be asked whether they are happy for all of their data to be transcribed and analysed.

Feasibility of Recruiting Participants

Difficulty recruiting to the study necessitated an amendment to the initial ethics application to enable exploration of the feasibility of recruiting participants to the study. During screening, it became apparent that the study was extremely difficult to recruit to. After screening 500 participants, it was concluded that people with dementia with hip fracture did not appear to be being referred to community hospitals, nor directly to community rehabilitation teams. This made the study impossible to recruit to. It was deemed important to determine the reasons why patients were not being referred for rehabilitation, so focus group(s) were added to the study in order to capture the reasons behind the difficulty recruiting. These focus groups would involve recruiting various healthcare professionals who are involved in the care of these patients including;

- Physiotherapist from the community hospital
- Physiotherapist from the acute hospital
- Community physiotherapy lead
- Discharge co-ordinator
- Dementia specialist nurse
- Ward sister from community hospital

The involvement of the listed professionals were aimed to be able to discuss the patient pathway as well as reasons why patients with hip fracture and dementia were not evident in rehabilitation settings or being referred for ongoing physiotherapy.

Participants will be given a participant information sheet explaining the purpose of the focus group and be asked to give written consent to take part in the study.

Analysis

Quantitative data

Descriptive statistics concerning recruitment will be collated. This will include the number of patients screened, percentage of people eligible for the study (including reasons people not being eligible) and numbers of patients who refuse to take part in the study. Further figures on, completion of the intervention and reasons for failure to complete the intervention will be explored. Reasons for non-participation and attrition will be collected to inform future recruitment and retention strategies.

Further to this, the effect of the intervention will be analyzed from those who complete the programme in order to conduct an initial exploratory analysis for the post effect of the intervention. The outcome measures will be collated and will be subjected to basic descriptive statistical tests, including calculation of means and frequencies. Paired statistical tests will be used to analyze changes in outcome measures between baseline and follow-up.

Qualitative data

Thematic analysis will be undertaken with the interview data as we are interested in determining any themes or patterns that emerge from the different interviews. An inductive approach will allow the development of themes that are of particular relevance to participants rather than testing any existing theory. Familiarization of the data will be undertaken immediately following transcription, followed by a process of open coding. Electronic software such as Nvivo will be used to manage this coding process. From this open coding, themes will be collated and core categories identified in a process of selective coding. In order to ensure reliability of the analyses, two researchers (AJH and RW) will independently analyze the transcripts. Any disagreement in analysis of the data and subsequent generation of themes will be resolved by discussion. Should consensus not be reached, it may be necessary to consult a third researcher.

The data gathered from the focus groups will be analysed in order to determine the acceptability of the intervention as well as practical aspects to help refine the intervention being delivered. Framework analysis will be used to make sense of the data and will follow the five key stages suggested; familiarization, identifying a thematic framework, indexing, charting, mapping and then the interpretation (51). The process will be undertaken by two reviewers separately and coding and framework development will be discussed and agreed.

Adherence

The use of a self-reported exercise diary in which the exercises undertaken can be recorded by the participant or their carer will be used alongside the use of the fitness tracker to monitor activity.

The involvement of carers will be determined by the physiotherapist assessing the patient. This will also be discussed as part of the focus group and participant interviews following completion of the intervention.

Fidelity of Intervention

In order to ensure the intervention was delivered as per the protocol, the physiotherapists delivering the intervention will have regular contact with the primary researcher to answer any questions or resolve any difficulties they may have. Further to this, the primary researcher will observe at least one of the physiotherapy sessions for each physiotherapist delivering the intervention.

Feasibility of Recruiting to the Study

Framework analysis will be used to make sense of the generated by the focus group(s) and will follow the five key stages suggested; familiarization, identifying a thematic framework, indexing, charting, mapping and then the interpretation (51). The process will be undertaken by two reviewers separately and coding and framework development will be discussed and agreed. The analysis will seek to understand the patient pathway and why they are not being referred for in-patient rehabilitation or referred for ongoing community based physiotherapy.

Mixed Methods Analysis

A mixed methods analysis may be undertaken following completion of the study. It is anticipated that this would combine qualitative and quantitative data to help determine why the intervention was (or was not) feasible. This may involve combining rates of attrition and the qualitative data from interviews. In a larger RCT, such mixed methods analysis would seek to determine why the intervention was (or wasn't) effective, however the aim of this feasibility study is not to look at effectiveness, so such mixed methods analysis will seek to determine reasons for issues relating to feasibility and acceptability.

Ethics

Ethical approval will be sought from the Health Research Authority. Confidentiality will be guaranteed at all times. Written consent will be sought prior to commencement of the intervention. Participants will also be asked to nominate a consultee who would act on their behalf, should their ability to give informed consent change during the course of the study. In accordance with the Mental Capacity Act 2005, assessment of capacity will be reviewed throughout the study.

All participants will be given written information sheets about the purpose of the study and potential risks/benefits of taking part. Written consent will be obtained from all participants prior to the interviews. During the interviews following completion of the intervention, they will be informed that they can refuse to answer one, or more, of the questions should they wish to without needing to explain their reasons for refusing to answer. Following the interview, participants will be asked whether they are happy for the whole of the discussion to be included in the transcript analysis, or whether there is anything they would like excluded. They will also be informed that they can withdraw from the intervention at any point without question and would return to the normal community rehabilitation pathway.

All participants of the focus groups will be given written information sheets about the purpose of the study and potential risks/benefits of taking part. Written consent will be obtained from all participants prior to the focus group. Following the focus group, participants will be asked whether they are happy for the whole of the discussion to be included in the transcript analysis, or whether there is anything they would like excluded. They will also be informed that they can withdraw from the focus group at any point without question.

Benefits for participants

This feasibility study will provide a structured rehabilitation programme to a population of people who are often excluded from rehabilitation programmes due to perceived lack of benefit.

Participation will also determine the feasibility of undertaking a larger RCT to test the intervention, which could improve the management and outcomes of people with dementia who fracture their hip. It is also hoped that this work will add to the controversial literature around rehabilitation of people

with dementia, to hopefully add weight to the argument that dementia does not prevent rehabilitation being successful.

Understanding the difficulties around recruitment to the study may help to understand the patient pathway and clarify reasons why people with dementia and hip fracture do not appear to be being referred for ongoing rehabilitation.

Risks for participants

The provision of physiotherapy always has potential negative effects such as injury caused during exercise. However, this is not deemed to be any greater than the “normal care” rehabilitation. The response to exercise will be monitored throughout the exercise programme as would be the case in any physiotherapy intervention. Any adverse events will be recorded.#

Project management

Project team details

The project management team will include Abi Hall (PhD researcher) and the supervisory team (Dr Vicki Goodwin, Dr Iain Lang and Professor Ruth Endacott).

Host institution/study sponsor and R&D contact person details

Sponsor - University of Exeter: Gail Seymour Research Ethics and Governance Manager,
Email: gail.seymour@exeter.ac.uk, Tel: +44 (0)1392 726621

Project Timeline

2017	-3	-2	-1	F	M	A	M	J	J	A	S	O	N	D	J
Ethics and governance approvals	X	X	X												
Site set up					X	X									
Training physiotherapists					X	X									
Participant recruitment						X	X	X							
Intervention delivery						X	X	X	X	X	X				
Quantitative data collection											X				
Qualitative data collection											X				
Analysis of quantitative data												X			
Analysis of qualitative data												X			
Write up/submit for publication													X	X	
Trial team meetings	X		X		X		X		X						

Storage of data

Personal and demographic data about the participants will remain confidential and held in accordance with the Data Protection Act 1998. Unique study identification numbers will be allocated to each participant prior to the study commencing. All documents will be stored separately so that the demographic data is kept separate from study data such as the transcripts.

Transcriptions of qualitative data will be anonymized and identified only by the unique identification number. Once interview transcriptions have been completed and checked, digital recordings will be deleted.

Hard copies of data relating to the study and participant information will be stored in a locked filing cabinet in the office of the main researcher.

Electronic data will be stored on a University of Exeter computer which is password protected. Electronic databases will be further password protected and any data analysis/storage files that may be used (such as Nvivo) will also be password protected. The University of Exeter regularly creates back-ups of files, but in addition a secure memory stick will be used to back up data which will also be password protected and stored in a locked filing cabinet in a separate location to the hard copies of data.

No data about the participants of the studies will be passed to any third parties and no individuals (patients or physiotherapists) will be named in the study.

Service user involvement

A 'Patient and Public Involvement' (PPI) team has been established to help advise on certain aspects of the project. This team comprises a variety of people including people who have had a hip fracture, people who have dementia and have experienced physiotherapy, a carer for somebody with dementia and a health professional working with people with chronic long term conditions. This group has helped to develop the participant information sheet, has reviewed other paperwork such as the consent form and have reviewed the exercise sheets that are given to patients. A physiotherapist with an interest in people with dementia has also reviewed the intervention manual to determine whether it is understandable to physiotherapists.

It is anticipated that the PPI team will be involved in refinement of the intervention following its completion. The results of the focus group with physiotherapists and the interviews with participants will help to refine the intervention further, which will then be discussed with PPI representatives.

Further to the involvement of the PPI team, an expert in Patient and Public Involvement at the University of Exeter was consulted to review patient information sheets.

Proposed outcomes of the research/dissemination

The aim of this study is to test the feasibility of the proposed intervention with a view to informing the development of a RCT. The study findings will be submitted for publication and will be presented at relevant conferences. Participants will be provided with a summary of the results of the study following its completion. We will work with our PPI advisors to explore the best ways of disseminating to participants and the wider public. The university communications team will be consulted to help promote the study using social media, websites and mainstream media where appropriate.

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