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A feasibility study to assess the design of a multicentre randomized controlled trial of the clinical and cost-effectiveness of a caregiving intervention for people following hip fracture surgery

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Aims

This study aims to assess the feasibility of conducting a pragmatic, multicentre randomized controlled trial (RCT) to test the clinical and cost-effectiveness of an informal caregiver training programme to support the recovery of people following hip fracture surgery.

Methods

This will be a mixed-methods feasibility RCT, recruiting 60 patients following hip fracture surgery and their informal caregivers. Patients will be randomized to usual NHS care, versus usual NHS care plus a caregiver-patient dyad training programme (HIP HELPER). This programme will comprise of three, one-hour, one-to-one training sessions for the patient and caregiver, delivered by a nurse, physiotherapist, or occupational therapist. Training will be delivered in the hospital setting pre-patient discharge. It will include practical skills for rehabilitation such as: transfers and walking; recovery goal setting and expectations; pacing and stress management techniques; and introduction to the HIP HELPER Caregiver Workbook, which provides information on recovery, exercises, worksheets, and goal-setting plans to facilitate a 'good' recovery. After discharge, patients and caregivers will be supported in delivering rehabilitation through three telephone coaching sessions. Data, collected at baseline and four months post-randomization, will include: screening logs, intervention logs, fidelity checklists, quality assurance monitoring visit data, and clinical outcomes assessing quality of life, physical, emotional, adverse events, and resource use outcomes. The acceptability of the study intervention and RCT design will be explored through qualitative methods with 20 participants (patients and informal caregivers) and 12 health professionals.

Discussion

A multicentre recruitment approach will provide greater external validity across population characteristics in England. The mixed-methods approach will permit in-depth examination of the intervention and trial design parameters. The findings will inform whether and how a definitive trial may be undertaken to test the effectiveness of this caregiver intervention for patients after hip fracture surgery.

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Introduction

Hip fracture is a prevalent and serious injury for older people.¹ Approximately 80,000 people aged 60 years and over experience a fragility hip fracture in the UK each year.² This has a combined health and social cost of £2 billion.³ Approximately 40% of these patients have cognitive impairment.^{1,4}

People have frequently experienced poor recovery following hip fracture.⁵ The majority never return to their pre-injury level of function and independence,^{3,6} quality of life is reduced, and mortality is high.^{6,7} Patients experience continued falls and re-injury, which ultimately leads to reduced independence and confidence in self-caring skills

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Table 1. HIP HELPER feasibility study objectives.

1. Feasibility of recruiting eligible people (patients (with/without cognitive impairment) and their caregivers) following hip fracture.
2. Acceptability to healthcare professionals of delivering a caregiver intervention to caregivers of patients with/without cognitive impairment.
3. Acceptability to caregivers of receiving a caregiver intervention for patients with/without cognitive impairment.
4. Fidelity of healthcare professionals to deliver the intervention in an NHS setting.
5. Fidelity of caregivers to deliver the intervention to patients at home.
6. Acceptability of randomization to caregiver intervention or standard NHS care for patients, caregivers, and healthcare professionals.
7. Risk of intervention contamination when experimental and control interventions are delivered in the same hospital ward.
8. Completeness of outcome measures (clinical and cost-effectiveness data collection tools) for people with/without cognitive impairment, and their caregivers.
9. To understand the patient and healthcare professional's experiences of participating in the trial.

to live at home. After sustaining a hip fracture, approximately 20% of patients who previously lived at home move into institutional care.⁸ For those who do return home, informal caregivers frequently experience physical and mental stress when trying to support their friend's/family member's recovery.⁵ A high caregiver burden has previously been reported by 20% of hip fracture caregivers at six months post-surgery.⁹

Family members and friends in the role of informal caregivers are expected to support the transition from hospital to the community, facilitating the patient's ongoing recovery.¹⁰ Tasks which informal caregivers may assist with range from personal activities of daily living (ADLs) such as toileting, washing, dressing, and eating, to more complex tasks such as managing money, shopping and household chores.¹¹

Qualitative evidence suggests that although informal caregivers want to support their friend/family member, they frequently feel under-skilled and have low confidence to do so.¹² A lack of information sharing, disorganized discharge planning, and unclear individual roles and responsibilities are possible challenges for hip fracture patients and their caregivers after returning home.¹³ Teaching caregiver skills to better support patients following hip fracture may improve quality of life and independence, and reduce the burden of impairment for patients and caregivers.^{12,14}

This study will investigate the feasibility of an intervention designed to help improve health and wellbeing outcomes for patients and caregivers following hip fracture. It will answer key research design uncertainties before further, definitive investigation is considered.

Methods

Aims and objectives. To assess the feasibility of conducting a pragmatic, multicentre randomized controlled trial (RCT) to test the clinical and cost-effectiveness of an informal caregiver training programme to support the recovery of people following hip fracture surgery. The main objectives of this study are listed in Table 1.

Trial design. A mixed-methods feasibility study comprising a parallel, multicentre, pragmatic RCT and embedded

qualitative study. The study flowchart is presented as Figure 1.

Study setting. Orthopaedic services providing hip fracture surgery in five NHS hospital trusts in England: James Paget University Hospitals NHS Foundation Trust, City Hospitals Sunderland NHS Foundation Trust, Northumbria Healthcare NHS Foundation Trust, University Hospital Southampton NHS Foundation Trust, and Barts Health NHS Trust. They will provide geographical and social diversity, which is important given the cultural differences which exist in caring for friends and family members after illness or injury.^{15,16}

Eligibility criteria. A minimum of 60 patient and 60 caregiver participants will be recruited.

Patient inclusion criteria:

1. Men and women aged 60 years and above who have undergone hip fracture surgery.
2. Has a nominated individual who will act as an informal caregiver and provides consent to participate in the study.
3. Community-dwelling prior to admission, alone or with a friend, relative, or caregiver.
4. Informed consent from the patient, or agreement from a consultee where the patient does not have capacity.

Caregiver inclusion criteria:

1. Is a caregiver for an eligible patient participant.
2. Willing and able to provide consent to participate.
3. If caregivers are unable to attend a hospital appointment for the face-to-face HIP HELPER intervention due to COVID-19 (or equivalent) social measures, caregivers must have access to a computer or tablet and internet services to receive a video consultation call.

An informal caregiver is defined as someone who has done or is expected to informally provide care, assistance, support, or supervision in ADLs for at least three hours

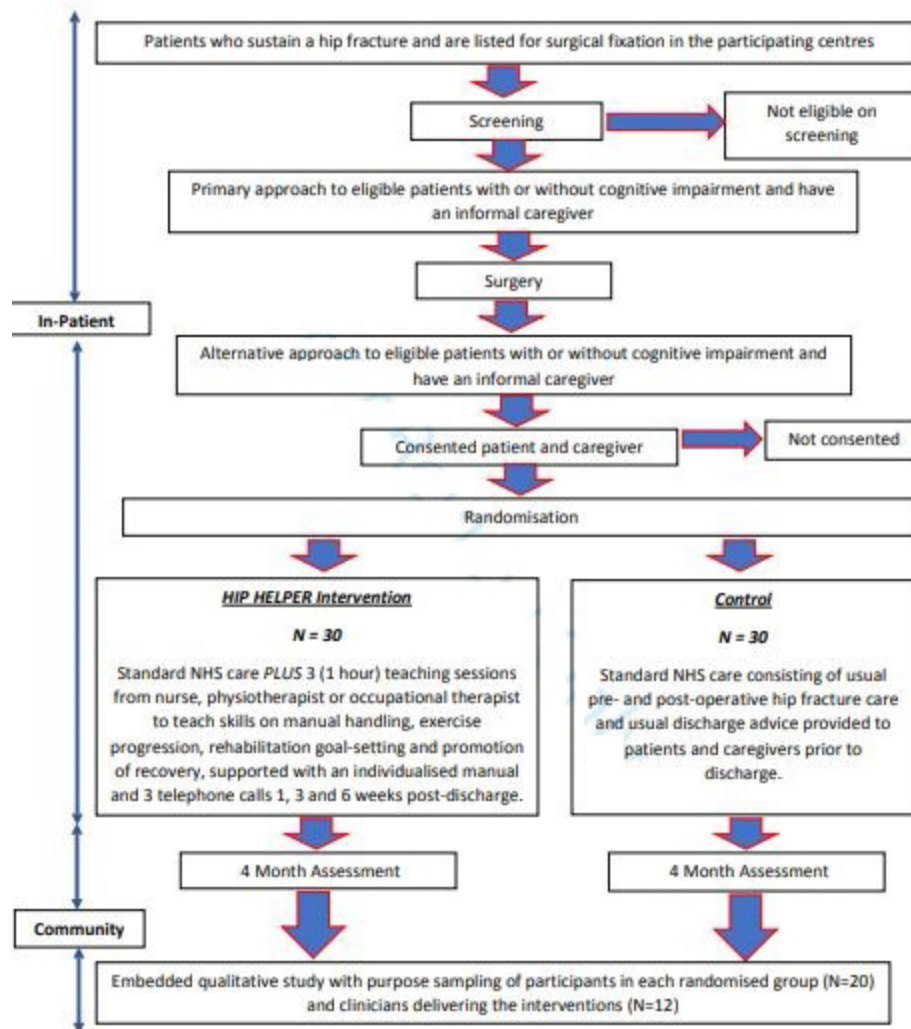


Fig. 1
Study flowchart.

per week, over two or more sessions per week, but is not contracted to do this on a paid basis. This may include activities ranging from personal ADLs such as toileting, washing, dressing, and eating, to more complex tasks such as managing money, shopping, and household chores.^{5,10}

Patient exclusion criteria:

1. Acute, unstable, or terminal illness which would make participation in the rehabilitation strategies contraindicated and/or impractical.
2. Expected by the clinical team to be discharged to a care home (residential or nursing) after their hospital admission or rehabilitation unit outside the recruiting site.

3. Participation in other treatment trials, where this has not been agreed in advance with both trial teams.

Recruitment

Site teams will aim to approach and consent eligible patients and caregivers within 72 hours postoperatively. Both will be provided with Participant Information Sheets (PIS). For eligible patients, the initial approach may be pre- or postoperatively on the hospital ward. For care providers, the approach may be on the hospital ward or by telephone, to provide both groups time to consider trial participation. Timing of approach and consent will be recorded as a feasibility outcome. Written informed consent (Supplementary File 1) will be obtained prior to any trial-specific procedures being performed.

Best efforts will be made to involve patients who may lack capacity in the decision to enrol. Potential patient

participants will be assessed by the site research team to determine whether they have the mental capacity to give informed consent. When a patient is deemed to have capacity by a healthcare professional, informed consent will be sought. When a patient is deemed to lack capacity by a healthcare professional (in accordance with the Mental Capacity Act),¹⁷ advice will be sought from a personal consultee on whether the patient should take part, and what their past wishes and feelings would have been about taking part. This will be supported with a Consultee PIS. If in agreement, they will be asked to sign a Consultee Declaration Form (Supplementary File 2). In agreement with the consultee, the researcher will discuss the trial with the patient participant to gain assent to participate wherever possible. Where the consultee is also the nominated caregiver, they will also be provided with the Caregiver PIS and asked to complete the Consent Form (Supplementary File 1) to consent for that role in the research.

Sites will record (during the trial's recruitment period), the number of people screened and reasons why potential participants were ineligible and/or not approached. Eligible participants who are approached but who decline to participate will be anonymously recorded as part of a screening log, providing information on sex and, when provided, the reason(s) for declining participation. Modifications to study processes as a result of COVID-19 social restrictions (when enacted) are outlined in Supplementary File 3.

Randomization and blinding. Consented patient participants will be registered for randomization by a member of the research team. Allocation will be concealed prior to randomization to prevent allocation bias. Electronic randomization will be performed through the Norwich Clinical Trials Unit (NCTU). Randomization will be at the patient-caregiver dyad level (1:1 experimental and control groups) by minimization for 1) hospital and 2) presence of patient cognitive impairment (Abbreviated Mental Test Score (AMTS))¹⁸ < or ≥ eight points.

The patient will be allocated a participant identification number at time of consent. Once the baseline data are collected, and pre-designated questions in the Case Report Form (CRF) entered, the research team will randomize that participant dyad. The treatment allocation will be revealed and linked to that participant number.

Due to the participatory nature of the intervention, patient and caregiver participants and the research team will be unblinded to treatment allocation.

Intervention

Control intervention: NHS usual care. This will be received by both control and intervention groups. Usual care will be NHS treatment as usual. This consists of pre-discharge care including nursing, physiotherapy, occupational

therapy, and social service assessment (where appropriate). Unlike the experimental intervention, there is no routine 'training' element for caregivers. Post-discharge physiotherapy and occupational therapy is not usually provided for this population.^{19,20} Following standard NHS care, patients and their caregivers will not receive the HIP HELPER programme, with no additional training as an in-patient or out-patient. Control intervention logs will be used to record usual care to monitor local service provision and any changes during the study.

Experimental intervention: HIP HELPER training programme. HIP HELPER is a patient-caregiver dyad training programme. The theoretical principle behind the programme is a social learning theory.²¹ The theoretical background of the intervention is presented in Supplementary File 4.

The first session will start within six days postoperatively. The following two sessions will be delivered after this time, but prior to inpatient hospital discharge. Session timings will be determined by the HIP HELPER clinical team based on clinical presentation, expected duration of hospital stay, and caregiver availability. These sessions will be delivered in the hospital, provided to both patient and caregiver as a dyad by either a nurse, physiotherapist, or occupational therapist, depending on ward staffing. All staff delivering the HIP HELPER programme completed a one-day training programme delivered by the HIP HELPER programme developers.

Each HIP HELPER programme session will take a maximum of 60 minutes. These sessions will include:

Session 1

- Explanation on normal recovery pathways and expectations on functional recovery.
- Practical skills to teach caregivers how to aid transfer from bed-chair and how to safely walk with the patient using walking aids.
- Education on patient-caregiver shared goal-setting in the early postoperative period.
- Teach principles of pacing and behaviour modification in the early post-discharge period.
- Introduction and explanation of the HIP HELPER Workbook, highlighting material on normal recovery, goal setting, action planning, problem-solving.

Session 2

- Refresher and reinforcement of practical skills to teach caregivers how to aid bed-chair (and the like) transfers, mobility and washing, dressing, and personal activities of daily living, dependent on patient-caregiver needs.
- Revision on constructed patient-caregiver shared goals.

- Develop knowledge on stress management, pacing, and behaviour modification linked to goals in the first two postoperative weeks.
- Revision throughout the session on how these skills link to normal recovery pathways and expectations on functional recovery.

Session 3

- Refresher and revision/reinforcement on practical skills to teach caregivers how to aid transfer from bed-chair and how to safely walk with the patient using walking aids.
- Discussion on stress management and caregiver pacing, and how these may link to defined goals and behaviour modification.
- Working through case-study scenarios of the recovery pathway in the initial six weeks post-discharge, to reinforce knowledge and critique competencies on HIP HELPER skills.
- Revision and refresher on the HIP HELPER Workbook.
- Confirmation of dates for HIP HELPER Telephone Booster calls.

HIP HELPER telephone sessions. Following hospital discharge, a HIP HELPER healthcare professional will telephone each caregiver and patient (dependent on cognitive impairment) as a dyad during Week 1, 3, and 6 post-hospital discharge. Each call is expected to take approximately 20 minutes. Both caregiver and patient participant should be in the same room during these telephone calls. Topics covered in each call will include:

- Recovery progress and current status based on patient-caregiver shared goals.
- Discussion on HIP HELPER Workbook use and progress including home hazard falls assessment.
- Review behaviour and outcome goals and problem-solve together.
- Advice on any difficulties and signposting to other healthcare professionals when appropriate, based on NICE guidelines.²²
- Support to create collaborative goals for continued recovery.

Patients with cognitive impairment will be involved throughout the inpatient sessions and with workbook and telephone activities. The degree of cognitive impairment will determine how actively engaged the patient will be with the training element, as determined by the HIP HELPER healthcare professional.

Co-interventions. Patient-caregiver dyads in either group will not be asked to desist from receiving other forms of treatment during the trial such as continuing rehabilitation, general practitioner (GP) consultations, medication changes, or alternative treatments if required. Use of

these treatments will be recorded through a health resource use questionnaire.

Assessments

Baseline assessment. Patient and caregiver baseline assessments will be undertaken after consent has been obtained, prior to randomization. Paper-based questionnaire will include patient data on hospital admission, age, sex, ethnicity, height, weight, patient cognitive impairment assessed using the AMTS,¹⁸ past medical history, American Society of Anesthesiologists (ASA) grade,²³ side of hip fracture, operative procedure, and hip fracture classification.

Caregiver demographic data collected will include: relationship of caregiver to patient, caregiver age, sex, ethnicity, past medical history, AMTS, whether they live with the patient (distance lived away), employment status, and experience of being a caregiver (for this patient and/or for another person).

Outcome measures. The data collection schedule is presented in Table II.

Outcomes. To answer our feasibility objectives we will assess recruitment feasibility by screening log data on: number of potential participants and their caregivers screened, assessed for eligibility, including reasons for exclusion/non-participation, and consented to be randomized, timing and location of approach, and consent.

1. Intervention acceptability – by qualitative interviews with participants; acceptability questionnaire, study attrition at the intervention phase.
2. Intervention fidelity (healthcare professionals) – by intervention log data on postoperative timing, HIP HELPER session duration, frequency, location (orthopaedic/orthogeriatric ward, rehabilitation ward, or other); Quality Assurance (QA) to monitor HIP HELPER programme delivery.
3. Intervention fidelity (caregivers) – by caregiver HIP HELPER programme intervention logs; qualitative interviews.
4. Randomization acceptability – by screening logs, eligibility assessment logs, and consent forms; participant attrition; qualitative investigation.
5. Risk of contamination – by HIP HELPER programme log data including QA monitoring visit checklists; delegation logs; and qualitative interviews with healthcare professionals.
6. Completeness of outcome measures – by completion rates (baseline and four months post-randomization).

At four months post-randomization, patient participants and caregivers will be sent a postal follow-up questionnaire. If participants have not responded within 14 days of posting, up to two telephone reminders will be made by the trial team. If required, a second postage of the questionnaires will be provided if requested by the participant

Table II. Participant timeline illustrating schedule of enrolment, interventions, and assessments.

Variable	Screening	Consent visit	Baseline	Randomization	Inpatient stay	Hospital discharge	Home	Follow-up
Timepoint		Up to 3 days postoperatively	+ 24 hrs after consent visit		As required	On discharge	Up to 6 wks post-discharge	4 mths from randomization (± 3 wks)
Enrolment								
Initial approach	[Bar]							
Informed consent			[Bar]					
Randomization				[Bar]				
Interventions								
Experimental (usual care + HIP HELPER)				[Bar]				
Control (usual care)				[Bar]				
Assessments								
Screening logs	[Bar]							
Adverse event reporting	[Bar]							
Date of hospital admission			[Bar]					
Age			[Bar]					
Sex			[Bar]					
Ethnicity			[Bar]					
Height and weight			[Bar]					
Past medical history			[Bar]					
AMTS			[Bar]					
Side hip fracture			[Bar]					
Hip fracture classification			[Bar]					
Patient residential status			[Bar]					
Patient (non-Clm) EQ-5D-5L			[Bar]					
Patient (non-Clm) NEADL			[Bar]					
Patient (non-Clm) GSE			[Bar]					
Patient (non-Clm) CES-D			[Bar]					
Patient (non-Clm) NRS Pain			[Bar]					[Bar]
Patient (Clm) EQ-5D-5L proxy			[Bar]					
Patient (Clm) DADS-6			[Bar]					
Patient (Clm) NPI			[Bar]					
Patient (Clm) Abbey Pain Scale			[Bar]					
Relationship of caregiver to patient			[Bar]					[Bar]
Caregiver age			[Bar]					[Bar]
Caregiver sex			[Bar]					[Bar]
Caregiver AMTS			[Bar]					[Bar]
Caregiver past medical history			[Bar]					[Bar]
Caregiver caregiving experience			[Bar]					[Bar]
Caregiver residential status to patient			[Bar]				[Bar]	[Bar]
Caregiver employment status			[Bar]				[Bar]	[Bar]
Caregiver EQ-5D-5L			[Bar]				[Bar]	[Bar]
Caregiver CES-D			[Bar]				[Bar]	[Bar]
Caregiver SCQ-16			[Bar]				[Bar]	[Bar]
Caregiver Resource Utilization in Dementia questionnaire			[Bar]				[Bar]	[Bar]
HCP intervention logs			[Bar]				[Bar]	
ASA			[Bar]					
Operative procedure			[Bar]	[Bar]				
Patient length of hospital stay			[Bar]	[Bar]	[Bar]			
Patient discharge destination			[Bar]	[Bar]	[Bar]	[Bar]		

Continued

Table II. Continued

Variable	Screening	Consent visit	Baseline	Randomization	Inpatient stay	Hospital discharge	Home	Follow-up
Patient complications/ adverse events								
Caregiver intervention home logs (intervention group only)								
Caregiver acceptability questionnaire								
Patient-caregiver semi- structured interviews								
HCP semi-structured interviews								

AMTS, Abbreviated Mental Test Score; ASA, American Society of Anesthesiologists; CES-D, Center for Epidemiological Studies Depression scale; Clm, cognitive impairment; DADS-6, Disability Assessment for Dementia Scale-6; EQ-5D-5L, EuroQol five-dimension five-level questionnaire; GSE, General Self-Efficacy questionnaire; HCP, healthcare professional; NEADL, Nottingham Activities of Daily Living Scale; non-Clm, non-cognitive impairment; NPI, neuropsychiatry inventory; NRS, numerical rating scale; SCQ-16, Short Sense of Competence Questionnaire for caregiver burden.

during these follow-up telephone calls. In the event of a COVID-19 (or equivalent) social measures limiting participants' abilities to return postal questionnaires, the trial team will initially telephone these participants (caregivers and care recipient) to offer the ability for telephone or postal questionnaire completion. If these methods fail, the participant would be categorized as a non-responder for that timepoint only.

Outcome measures collected will include:

Patients without cognitive impairment

- EQ-5D-5L health resource use questionnaire²⁴
- Nottingham Activities of Daily Living Scale (NEADL)²⁵
- General Self-Efficacy questionnaire²⁶
- Centre for Epidemiologic Studies Depression Scale (CES-D)²⁷
- Numerical rating scale (NRS) for pain²⁸
- Complications and adverse events including mortality (four-month follow-up only).

For all caregivers

- EQ-5D-5L²⁴
- CES-D²⁷
- Short Sense of Competence Questionnaire for caregiver burden (SCQ-16)²⁹
- Resource Utilization in Dementia questionnaire¹¹
- Complications and adverse events including mortality (four-month follow-up only).
- Patient and caregiver residential status (single question).

Plus for caregivers of patients with cognitive impairment

- EQ-5D-5L proxy²⁴
- Disability Assessment for Dementia Scale-6 (DADS-6) functional score³⁰
- Neuropsychiatry Inventory (NPI)³¹
- Abbey Pain Scale³²

These measures were selected due to their favourable psychometric properties and relevance as judged by Patient and Public Involvement (PPI) and clinician feedback. They satisfy Haywood et al's³³ core outcome

set for hip fracture trials, listed in the COMET Initiative database.³⁴

Data analysis

Sample size. As this feasibility trial does not aim to assess treatment effects, we have not undertaken a formal power sample size calculation. However, careful consideration has been made as to the number of participants required to answer the feasibility objectives.

In total, 60 participant dyads (60 patients/60 caregivers) will be recruited. A maximum of 30 patients with cognitive impairment (AMTS \leq 8 points) will be recruited, with a maximum of 15 patients per group. This sample size (and cognitive impairment subgroup) will be sufficient to answer our feasibility objectives and assess the a priori progression criteria (Table I).³⁵

Statistical analysis. The analysis of clinical outcome measures will be descriptive, reported as mean and standard deviations (SDs), or median and interquartile ranges if not normally distributed, for continuous outcomes and number and percentages for binary and categorical variables. Consent rates, recruitment rates, attrition, missing data rates, and intervention fidelity will be reported as proportions with 95% and 85% confidence intervals (CIs). The mean difference, SD, and effect size will be estimated to determine direction and magnitude of effect, and to inform a power calculation for a definitive trial. No formal statistical testing will be undertaken.

Qualitative substudy

The objective of the qualitative study is to determine the patient and healthcare professional's experiences of participating in this trial. The target population includes patient-caregiver dyads and physiotherapists, occupational therapists, and nursing staff who deliver the HIP HELPER intervention. A maximum of 30% of the dyads ($n = 6$ out of 20 dyads) in this qualitative study will include patients with cognitive impairment.

Patient-caregiver dyad interviews. Participant-dyads who have agreed to be contacted for the interview will be purposively sampled to ensure diverse representation.

Table III. Topic guide for the caregiving dyad interviews.

The interview will be structured on the following areas of interest	Sample questions
Introduction Determining participant views of their intervention	Overall, could you share your experiences of being involved with our research? First of all, can you talk me through what study treatment you received? (Prompt – clarify what was HIP HELPER and what was usual care/non-study intervention)
The approach and consent process and willingness to be randomized to either group The acceptability of the inpatient care (both groups)	Can you talk me through how you got into the study? You were allocated to X group. What did that feel like? Could we have dealt with that differently? Would you be happy to talk me through your treatment while you were in the hospital? As X's carer, what was your impression of the care. For both of you, what was helpful and less helpful to your care?
Inpatient HIP HELPER programme and telephone booster calls (experimental group)	How far did you find the HIP HELPER programme helpful – for both of you. Can you give specific examples? What didn't work as well? Did you get the telephone calls? Can you remember what you talked about? Can you give specific examples of what was helpful, and I helpful? Was there any advice that confused you or you weren't clear about?
What the strengths of the experimental intervention	What were the most helpful/good-bits of your HIP HELPER intervention? What was good about it. What didn't you like about it?
What the weaknesses of the experimental intervention What modifications they may recommend to interventions received (standard care and experimental groups)	What were the less helpful/worse bits of the HIP HELPER intervention? What could we improve? (Prompt: What do you think is lacking in the hospital? In the transition from hospital to home? In the home?) How do you think we could better support you and your carer to recover after hip surgery? What do you think is lacking in the hospital? In the transition from hospital to home? In the home?
The risk of intervention contamination between the groups	Did you talk to any other patients or caregivers while in hospital about the intervention? Was there any discussion between those who received it and did not receive it?
The ease and convenience of the data collection processes (baseline and 4 mths) (all participants)	As you were part of a trial, we had to collect a lot of measurements. Can you talk me through what these were? How easy were they? How convenient were they? Overall, do you have any points to make about the testing?
Applicability of the methods and measures used	How did you manage with the questionnaires we gave you at the start of the study and at the end in the post? Were they easy to complete or do you remember them being a problem?

Targeted demographics will include age, ethnicity, pre-fracture disability (measured using the baseline NEADL²⁵ or DADS-6³⁰), and cognitive impairment (AMTS).¹⁸ Interviews will be conducted virtually using Microsoft Teams (Microsoft, USA) or telephone if this is not available.

Up to 20 face-to-face interviews will be conducted, involving 12 participant-dyads from the HIP HELPER group and eight from the standard care group across the four sites. Based on our previous research,³⁶ this sample size should ensure a range of different viewpoints to answer our feasibility study questions. Thirty percent of the dyads (n = 6) will include patients with cognitive impairment.

We will invite the dyad to be interviewed together. If this does not suit the dyad for any reason, we will invite each member to be interviewed separately. Interviews will be conducted up to six weeks post-discharge from hospital. This allows exploration of the patient and caregiver's study experience at home in a reasonable recall period. Interviews will be semi-structured, following an open-ended question schedule, with a maximum duration of 60 minutes. Questions for the intervention group will capture acceptability of the intervention and the outcome measures, and any contextual influences and

adaptions that have affected fidelity. The caregiving dyad interview topic guide is presented as Table III.

Healthcare professional interviews. The healthcare professionals delivering the HIP HELPER intervention will be interviewed after delivering their first HIP HELPER programme session(s). A minimum of one physiotherapist, one nurse, and one occupational therapist who delivered the intervention will be interviewed from each site (12 participants in total). This will provide a range of contexts from different professional backgrounds. Interviews will be conducted virtually using Microsoft Teams or via telephone (15 to 30 minutes). They will follow a semi-structured, open-ended question schedule. The healthcare professional interview topic guide is presented as Table IV.

Data collection and analysis. All interviews will be audio-recorded, and transcribed. After transcription the audio data will be destroyed and data anonymized. Data will be analyzed thematically taking a two-stage approach to understand the important contextual factors that have influenced the implementation of HIP HELPER. We aim to initially analyze all data deductively guided by the MRC guidance for complex interventions and process evaluations,^{37,38} to assess the quality of implementation,

Table IV. Topic guide for the healthcare professional interviews.

The interview will be structured on the following areas of interest	Sample questions
Introduction	Overall, could you share your experiences of being involved with our research?
The randomized to either group	How did you feel about 50% of the patients not receiving the HIP HELPER intervention but getting normal care? Did this 'sit easy' with you?
The acceptability of the inpatient care	How did the delivery of the HIP HELPER inpatient sessions go? How did you work out who would do what? Did shift working play a part in deciding this? Was there a decision on professional background? Did you feel comfortable teaching all the content? Were any modifications made? How did the patients and caregivers get on with it in your opinion?
HIP HELPER telephone calls	How did you feel about doing the telephone calls? Were they helpful for caregivers and patients? Was it feasible to deliver one call to both members of the dyad? How did you get on with patients who had cognitive impairment? Did you make any modifications to the content of the call?
Training on intervention	Did you feel adequately prepared to deliver the inpatient and telephone HIP HELPER interventions? Would you recommend any changes to this? Did you need any additional 'top up' or 'refresher' training sessions?
The risk of intervention contamination between the groups	Do you think you used the HIP HELPER intervention on control or non-trial patients? Did other professionals not in the trial use the intervention? If either occurred, do you think anything could have been done to avoid this?
The ease and convenience of the data collection processes	As you were part of a trial, we had to collect a lot of measurements. How easy were the intervention data collection logs? How convenient were they? What changes would you recommend if any were needed?

Table V. Progression criteria.

	Green (Go)	Amber (Amend)	Red (Stop)
Recruitment	> 40% of patients screened across the 4 sites in 12 months would be eligible	30% to 40% would be eligible	< 30% would be eligible
Randomization acceptability	> 40% of eligible patients consent to be randomized	20% to 40% would be randomized	< 20% would be randomized
Intervention fidelity (healthcare professionals)	> 70% of participants compliant with their allocated intervention (3 face-to-face sessions and booster phone call) as randomized	50% to 70% received intervention as randomized	< 50% received intervention as randomized
Intervention fidelity (caregivers)	> 90% (or patients with and without dementia) of participants adopted HIP HELPER intervention post-discharge	60% to 90% adopted HIP HELPER post-discharge	< 60% adopted HIP HELPER post-discharge
Contamination	< 5% of participants in either group received majority of their allocated treatment crossover	5% to 10% of participants crossover	> 10% of participants crossover

clarify the hypothesized causal mechanisms identified in our logic model (for example, goal setting in the inpatient training and the support provided by the telephone coaching), and identify contextual factors associated with variation in outcomes. Data will then be analyzed more inductively and more broadly. This will include critiquing the conceptual approach of HIP HELPER, understanding any unintended consequences, and reflections on the intervention from the healthcare professional, patient, and caregiver perspective.

Progression criteria. A 'traffic light' system will be used as a guide for progression to a definitive trial.³⁹ The progression criteria are listed in Table V. If any of the criteria are not met, these will be discussed by the Trial Oversight Committee (TOC) to decide if a definitive trial is feasible.

Data management. All data will be processed according to the Data Protection Act 2018,⁴⁰ and all documents will be stored safely in confidential conditions. Trial-specific documents, except for the signed consent form and follow-up contact details, will refer to the participant with a unique study participant number, not by name.

Participant identifiable data will be stored separately from trial data. All trial data will be stored securely in offices or online in secure trial databases, only accessible by the central trial team in Norwich and authorized personnel.

Compliance, adherence, and quality assessment. The trial will be monitored and audited in accordance with the current approved protocol, good clinical practice,⁴¹ relevant regulations, and standard operating procedures (SOPs). A rigorous quality control programme will be adopted to ensure intervention fidelity. We will collect data on what interventions (control and experimental) are delivered. This is with respect to intervention parameters including content, mode of delivery, personnel delivered, frequency, timing of delivery, and variation/deviations from protocol. These will be collected through intervention logs completed by the healthcare professional delivering the intervention, and through relevant CRF questions.

Quality assurance checks through site visits will be conducted at Months 1, 3, and 6 from first randomization (approximately three weeks for each). These will be used to observe activities including (but not limited to) the

experimental intervention sessions. If there are concerns in relation to any aspect of the site visit, repeat visits with training may be undertaken to improve a site's protocol compliance.

Trial status. The trial is funded for 22 months and commenced in September 2020. Recruitment is expected to be complete by 31 October 2021 with the final follow-up visit for the final participant completed by 31 March 2022. The trial will be completed by 31 June 2022.

Patient and public involvement. Patient involvement began during protocol development and continues throughout the trial. A patient-member will attend TOC meetings. The same patient-member is a co-investigator, providing insights into the trial conduct, particularly on data collection processes, and will help interpret the findings to inform on the implications of the research during the trial's dissemination phase.

Ethics and dissemination. Ethical approval was gained from the North East - Newcastle & North Tyneside 1 Research Ethics Committee (REC) (20/NE/0213; 16 March 2021). The trial was prospectively registered (Current Controlled Trials: ISRCTN13270387), Protocol version 3.0. Any amendments will be approved by the REC and Health Research Authority before implementation.

Reporting of the trial will be consistent with the CONSORT 2010⁴² Statement (patient-reported outcomes and non-pharmacological interventions) and Template for Intervention Description and Replication (TIDieR)⁴³ guidelines. A summary of the results and trial materials will be made available via the trial website on completion. We will work with our PPI representatives to prepare materials to disseminate the findings to a lay audience. We will submit the final report to a peer-reviewed academic journal. Researchers outside the trial team may formally request a specific dataset using a data request form, which will be part of the Data Management Plan. All such requests will need to be approved by the Trial Management Group (TMG).

Trial management and oversight committees. Monthly TMG meetings will provide oversight for the day-to-day running of the trial.

A TOC, acting as a combined Trial Steering Committee and Data and Safety Monitoring Committee, is an independent group responsible for oversight of the trial to safeguard the interests of trial participants. It will comprise independent clinicians, specialist physiotherapists, statisticians, health service researchers, and PPI representatives with members of the trial team. They will also be convened to 1) detect any trends, such as increases in (un)expected events, and take appropriate action; 2) seek additional advice or information from investigators where required; and 3) evaluate the risk of the trial continuing, and take appropriate action where necessary.

The TOC will meet at least once every nine months for the duration of the study or more frequently as required.

Discussion

This paper presents the research protocol for the HIP HELPER study. It is hypothesized that supporting caregivers on how to progress patient function, mobility, and overall health will address important patient health challenges and facilitate early recovery after hip fracture.^{12,44} It may also reduce caregiver burden and depression associated with caring for individuals. Following the lessons learnt in this feasibility study, it is hoped that this project will investigate an intervention designed to help improve health and wellbeing outcomes for patients following hip fracture in a future definitive trial.



Take home message

- This study will investigate the feasibility of an intervention designed to help improve health and wellbeing outcomes for patients and caregivers following hip fracture.
- The findings will inform the basis for a definitive trial to assess the effectiveness of a caregiver intervention for people following hip fracture.

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Supplementary material



Participant (patient and caregiver) consent form, consultee declaration form, modifications to the protocol as a result of COVID-19 pandemic, and document outlining the theoretical underpinning of the HIP HELPER intervention.

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Ethical review statement:

■ North East - Newcastle & North Tyneside 1 Research Ethics Committee (20/NE/0213) 35 Date: 16 March 2021.

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