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TITLE PAGE

Title: A feasibility study to assess the design of a multi-centre randomised controlled trial of the clinical and cost-effectiveness of a caregiving intervention for people following hip fracture surgery

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ABSTRACT

AIMS: This study aims to assess the feasibility of conducting a pragmatic, multi-centre randomised 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: A mixed-methods feasibility RCT, recruiting 60 patients following hip fracture surgery and their informal caregivers. Patients will be randomised 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; and pacing and stress management techniques and introduction to the HIP HELPER Caregiver Workbook, which provides information on recovery, exercises, worksheets, 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-randomisation will include: screening logs, intervention logs, fidelity checklists, quality assurance monitoring visit data and clinical outcomes assessing quality of life, physical, emotional, adverse event 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 multi-centre 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.

Keywords: Trauma; Hip fracture; Rehabilitation; Recovery; Caregiver; RCT

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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 reduces and mortality is high.[6,7] Patients experience continued falls and re-injury. This ultimately leads to reduced independence and confidence in self-caring skills 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 patient's on-going 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, disorganised 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

AIM: To assess the feasibility of conducting a pragmatic, multi-centre randomised 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.

OBJECTIVES:

The main objectives of this study are listed in **Table 1**.

Trial Design

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

The study flow chart is presented as **Figure 1**.

Study Setting

Orthopaedic services providing hip fracture surgery in five NHS hospital trusts in England: XXX Hospitals NHS Trust, XXX NHS Foundation Trust, XXX NHS Trust, XXX NHS Foundation Trust and XXX NHS Foundation 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 per week over two or more personal contacts but is not contracted to do this on a paid basis. This may include activities from personal ADLs such as toileting, washing, dressing and eating, to more complex tasks such as managing money, shopping and household chores[5,10].

Participants are ineligible if they have:

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 post-operatively. Both will be provided with Participant Information Sheets (PIS). For eligible patients, the initial approach may be pre- or post-operatively 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 enroll. 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 sort 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**). With agreement from 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 as well.

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: gender 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**.

Randomisation and Blinding

Consented patient participants will be registered for randomisation by a member of the research team. Allocation will be concealed prior to randomisation to prevent allocation bias. Electronic randomisation will be performed through the Norwich CTU (NCTU). Randomisation will be at the patient-caregiver dyad level (1:1 experimental and control groups) by minimisation for:

- Hospital
- Presence of patient cognitive impairment (Abbreviated Mental Test Score (AMTS))[18] < or ≥ 8 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 randomise 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 routinely 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 inpatient 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

This is a patient-caregiver dyad training programme (HIP HELPER). The theoretical principle behind the programme is a social learning theory.[21] The theoretical background of the intervention is presented in **Supplementary File 4.**

HIP HELPER Inpatient Training Programme

The first session will start within six days post-operatively. The following two sessions will be delivered after this time, but prior to in-patient hospital discharge. The timing of sessions 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 post-operative 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 re-enforcement 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 post-operative weeks.
- Revision throughout the session on how these skills link to normal recovery pathways and expectations on functional recovery.

Session 3:

- Refresher and revision/re-enforcement 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 re-enforce 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 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 sign-posting 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 in-patient sessions and with workbook and telephone activities. The degree of cognitive impairment will determine how actively engaged the patient will be to 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 randomisation. 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 Anaesthesiologists (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 the 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 2.**

Outcomes

To answer our feasibility objectives we will assess:

1. 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 randomised; timing and location of approach and consent.

2. *Intervention acceptability* – by qualitative interviews with participants; acceptability questionnaire, study attrition at the intervention phase.

3. *Intervention fidelity (healthcare professionals)* – by intervention log data on: post-operative timing, HIP HELPER session duration, frequency, location (orthopaedic/orthogeriatric ward, rehabilitation ward or other); Quality Assurance (QA) to monitor HIP HELPER programme delivery.

4. *Intervention fidelity (caregivers)* – by caregiver HIP HELPER programme intervention logs; qualitative interviews.

5. *Randomisation acceptability* – by screening logs, eligibility assessment logs and consent forms; participant attrition; qualitative investigation.

6. *Risk of contamination* - by HIP HELPER programme log data including: QA monitoring visit checklists; delegation logs; qualitative interviews with health professionals.

7. *Completeness of outcome measures* - by completion rates (baseline and four months post-randomisation).

At four months post-randomisation, 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 during these follow-up telephone calls. In the event of a COVID-19 (or equivalent) social measures limiting participant's 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 categorised as a non-responder for that time-point only.

Outcome measures collected will include:

Patients without cognitive impairment:

- EQ-5D-5L health resource use questionnaire[24]
- Nottingham Activities of Daily Living Scale (NEADL)[25]
- General Self-Efficacy questionnaire[26]
- Center for Epidemiologic Studies Depression Scale (CES-D)[27]
- Numerical rating scale (NRS) for pain[28]
- Complications and adverse events including mortality (*Four Month follow-up only*).

For all caregivers:

- EQ-5D-5L[24]
- CES-D[27]
- Short Sense of Competence Questionnaire for caregiver burden (SCQ-16) [29]
- Resource Utilization in Dementia questionnaire[11]
- 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 proxy[24]
- Disability Assessment for Dementia Scale-6 (DADS-6) functional score[30]
- Neuropsychiatry Inventory (NPI)[31]
- Abbey Pain Scale[32]

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 Hayward et al's[33] 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 ≤8 points) will be recruited, 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 1**).[35]

Statistical Analysis

The analysis of clinical outcome measures will be descriptive, reported as mean and standard deviations 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, standard deviation 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 qualitive study is to determine 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. Targeted demographics will include: age, ethnicity, pre-fracture disability (measured using the baseline NEADL[25] or DADS-6[30]) and cognitive impairment (AMTS)[18]. Interviews will be conducted virtually using Microsoft Teams 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 3**.

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 4**.

Data Collection and Analysis

All interviews will be audio-recorded, and transcribed. After transcription the audio data will be destroyed and data anonymised. Data will be analysed thematically taking a two-stage approach to understand the important contextual factors that have influenced the implementation of HIP HELPER. We aim to initially analyse all data deductively guided by the MRC guidance for complex interventions and process evaluations [37,38] to assess the quality of implementation, clarify the hypothesised causal mechanisms identified in our logic model (for example, goal setting in the in-patient training and the support provided by the telephone coaching) and identify contextual factors associated with

variation in outcomes. Data will then be analysed 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 5**. 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 authorised 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 in respect of intervention parameters including: content, mode of delivery, personal 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 randomisation (+/- three weeks for each) at each site. These will be used to observe activities including (but not exclusive 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 31st October 2021 with the final follow-up visit for the final participant completed by 31st March 2022. The trial will be completed by 31st 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) Date: 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 2010 Statement (patient reported outcomes and non-pharmacological interventions)[42] 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 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 Trial Management Group (TMG).

Trial Management and Oversight Committees

Monthly TMG meetings will be provide oversight for the day-to-day running of the trial.

A Trial Oversight Committee (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 of independent clinicians, specialist physiotherapists, statisticians, health service researchers, and PPI representatives with members of the trial team. They will also be convened:

- To detect any trends, such as increases in un/expected events, and take appropriate action
- To seek additional advice or information from investigators where required
- To 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 hypothesised 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 to be subsequently investigated in a future definitive trial.

FIGURE AND TABLE LEGENDS

Figure 1: Study flow chart

Table 1: HIP HELPER feasibility study objectives

Table 2: HIP HELPER trial objectives, outcome measures and measurement time-points

Table 3: Topic guide for the caregiving dyad interviews

Table 4: Topic guide for the healthcare professional interviews

Table 5: Progression criteria

Supplementary File 1: Consent form (patient and caregiver)

Supplementary File 2: Consultee declaration form

Supplementary File 3: Modification for COVID-19 social restrictions

Supplementary File 4: Theoretical underpinning of the HIP HELPER intervention

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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 a NHS setting.
5. Fidelity of caregivers to deliver the intervention to patients at home.
6. Acceptability of randomisation 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.

Table 2: Participant timeline illustrating schedule of enrolment, interventions, and assessments.

	Screening	Consent Visit	Baseline	Randomisation	In-Patient Stay	Hospital Discharge	Home	Follow-Up
TIMEPOINT		Up to 3 days post-operatively	+ 24 hours after Consent Visit		As required	On discharge	Up to 6 weeks post-discharge	4 months from randomisation (+/- 3 weeks)
ENROLMENT								
Initial approach								
Informed consent								
Randomisation								
INTERVENTIONS								
Experimental (Usual care PLUS HIP HELPER)								
Control (Usual Care)								
ASSESSMENTS								
Screening Logs								
Adverse event reporting								
Date of Hospital Admission								
Age								
Sex								
Ethnicity								
Height and Weight								
Past Medical History								
AMTS								
Side hip fracture								
Hip fracture classification								
Patient residential status								
Patient (non-CIm) EQ-5D-5L								
Patient (non-CIm) NEADL								
Patient (non-CIm) GSE								
(contd.)	Screening	Consent Visit	Baseline	Randomisation	In-Patient Stay	Hospital Discharge	Home	Follow-Up
Patient (non-CIm) CES-D								
Patient (non-CIm) NRS Pain								

Patient (Clm) EQ-5D-5L proxy								
Patient (CIm) DADS-6								
Patient (CIm) NPI								
Patient (CIm) Abbey Pain Scale								
Relationship of caregiver to patient								
Caregiver age								
Caregiver sex								
Caregiver AMTS								
Caregiver Past Medical History								
Caregiver caregiving experience								
Caregiver residential status to patient								
Caregiver employment status								
Caregiver EQ-5D-5L								
Caregiver CES-D								
Caregiver SCQ-16								
Caregiver Resource Utilization in Dementia questionnaire								
HCP Intervention Logs								
ASA								
Operative Procedure								
Patient length of hospital stay								
Patient discharge destination								
Patient complications/adverse events								
Caregiver Intervention Home Logs(Intervention group only)								
Caregiver Acceptability Questionnaire								
Patient-Caregiver Semi Structured Interviews								
HCP Semi Structured Interviews								

1 HCP – Health Care Professional; Short Sense of Competence Questionnaire for caregiver burden (SCQ-16)

2

Table 3: Topic guide for the caregiving dyad 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?
Determining participant views of their intervention	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 randomised to either group	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?
The acceptability of the inpatient care (both groups)	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?
In-patient 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 l 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 were the less helpful/worse bits of the HIP HELPER intervention?
What modifications they may recommend to interventions received (standard care and experimental groups)	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 whilst 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 months) (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?

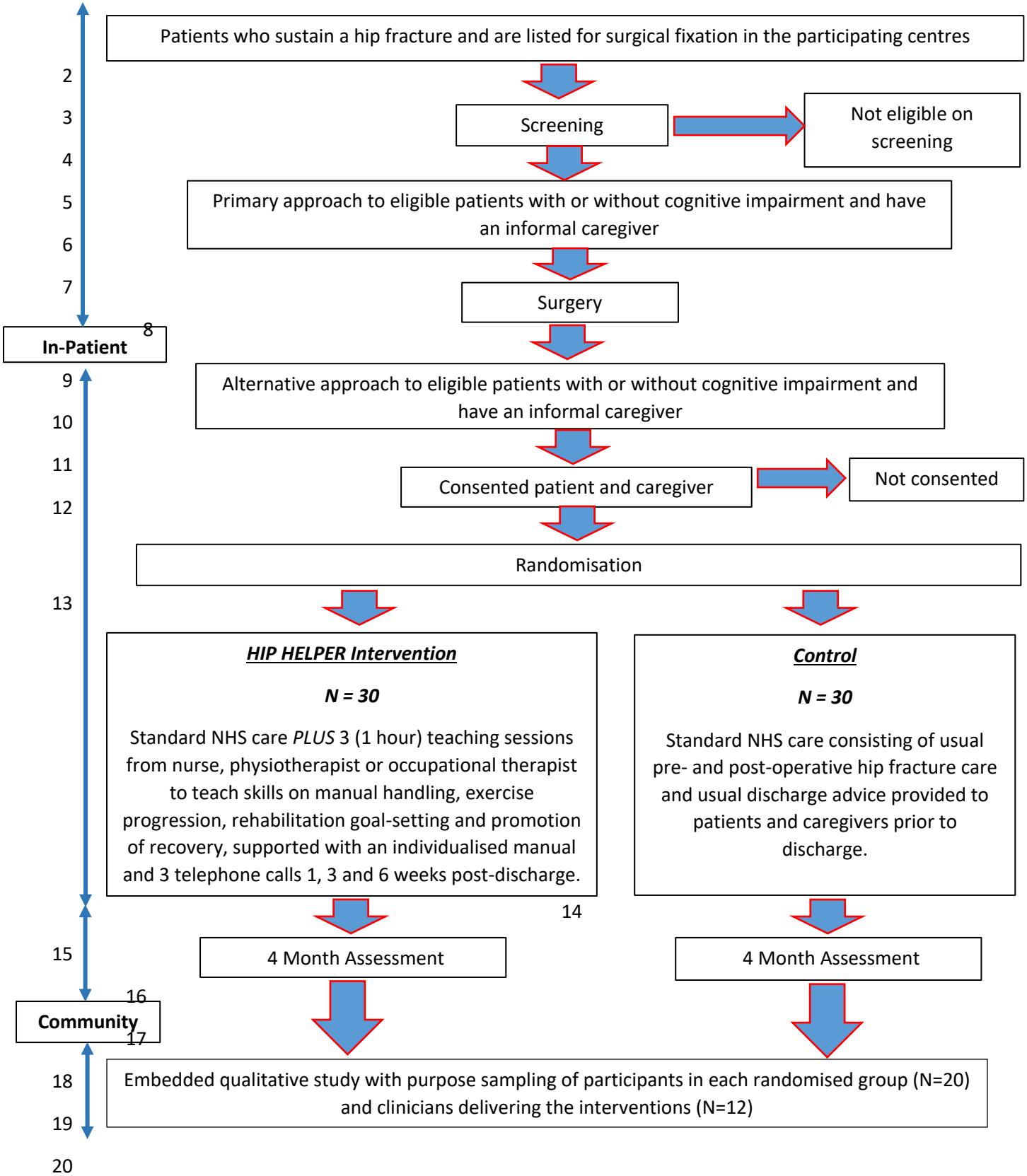
Table 4: Topic guide for the healthcare professional interviews

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 randomised 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 inf 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?

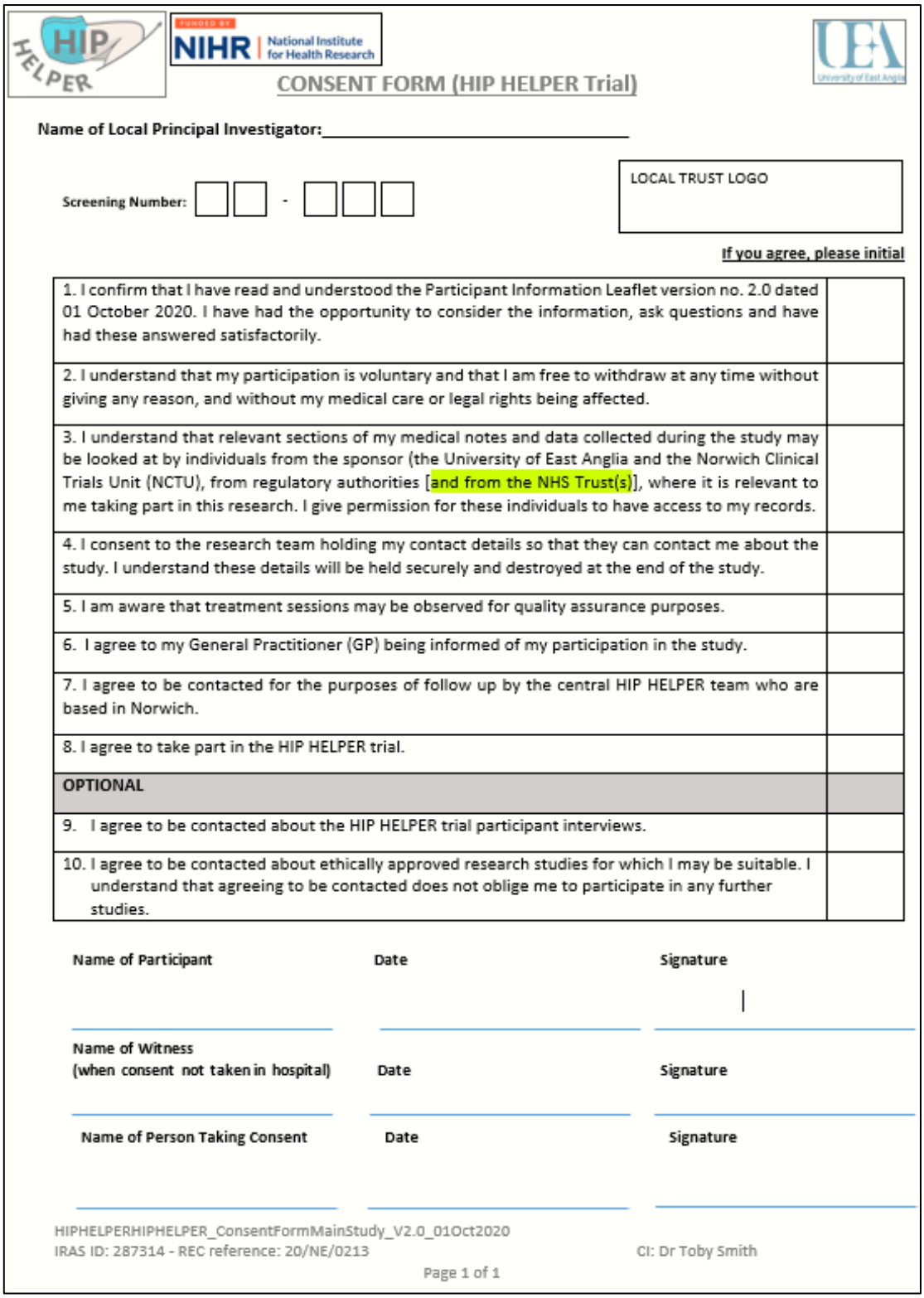
Table 5: Progression criteria

	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
Randomisation Acceptability	>40% of eligible patients consent to be randomised	20%-40% would be randomised	<20% would be randomised
Intervention Fidelity (Healthcare Professionals)	>70% of participants compliant with their allocated intervention (3 face-to-face sessions and booster phone call) as randomised	50% to 70% received intervention as randomised	<50% received intervention as randomised
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 cross-over	5%-10% of participants cross-over	>10% of participants cross-over

Figure 1: Study flow chart



Supplementary File 1: Consent form (patient and caregivers)



CONSENT FORM (HIP HELPER Trial)

Name of Local Principal Investigator:_____

Screening Number: ☐☐ - ☐☐☐

LOCAL TRUST LOGO

If you agree, please initial

1. I confirm that I have read and understood the Participant Information Leaflet version no. 2.0 dated 01 October 2020. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my medical care or legal rights being affected.	
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the sponsor (the University of East Anglia and the Norwich Clinical Trials Unit (NCTU), from regulatory authorities [and from the NHS Trust(s)], where it is relevant to me taking part in this research. I give permission for these individuals to have access to my records.	
4. I consent to the research team holding my contact details so that they can contact me about the study. I understand these details will be held securely and destroyed at the end of the study.	
5. I am aware that treatment sessions may be observed for quality assurance purposes.	
6. I agree to my General Practitioner (GP) being informed of my participation in the study.	
7. I agree to be contacted for the purposes of follow up by the central HIP HELPER team who are based in Norwich.	
8. I agree to take part in the HIP HELPER trial.	
OPTIONAL	
9. I agree to be contacted about the HIP HELPER trial participant interviews.	
10. I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	

Name of Participant	Date	Signature

Name of Witness (when consent not taken in hospital)	Date	Signature

Name of Person Taking Consent	Date	Signature

HIPHELPERHIPHELPER_ConsentFormMainStudy_V2.0_01Oct2020
IRAS ID: 287314 - REC reference: 20/NE/0213 CI: Dr Toby Smith
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Supplementary File 2: Consultee declaration form

LOCAL TRUST LOGO

CONSULTEE DECLARATION FORM – HIP HELPER Trial

Participant Identification Number: ☐☐/☐☐/☐☐☐

I (Consultee name)_____

agree to the participation of (Participant's name)_____

Please initial box

1. I the above named consultee have been consulted about the above named participant's participation in this research project. I have read and understand the Consultee Information Sheet version number 2.0 dated 01 October 2020 for the above study and have had the opportunity to ask questions. ☐
2. I understand that I can request that he/she is withdrawn from the study at any time, without giving any reason, and without their medical care or legal rights being affected. I understand that should I withdraw them from the study, then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of their medical notes and data collected during the study may be looked at by individuals from the sponsor (the University of East Anglia and the Norwich Clinical Trials Unit (NCTU), from regulatory authorities [and from the NHS Trust(s)], where it is relevant to them taking part in this research. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from their participation in this study. I understand that their personal details will be kept confidential. ☐
4. I agree to a researcher observing HIPHELPER treatment sessions if given to him/her for quality assurance purposes. ☐
5. I agree to their GP or other care professional being informed of their participation in this study. ☐
7. I agree to my contact details and a copy of this declaration form being held securely and Confidentially by the research team at the Norwich Clinical Trials Unit. I agree that the staff from the local HIP HELPER trial team may contact me by telephone or post. ☐
8. I agree to him/her being asked to participate in interviews about their experiences of the new treatment if given. (optional) ☐
9. In my opinion he/she would have no objection to taking part in the above study. ☐

Name of Consultee	Date	Signature

Please indicate if: personal consultee ☐ or nominated consultee ☐

Relationship to patient _____

Name of Person taking declaration	Date	Signature

Name of Person (when consent not taken in hospital)	Date	Signature

Supplementary File 3: Modification for COVID-19 social restrictions

Approach, Recruitment & Consent

In the event of COVID-19 pandemic restrictions resulting in caregivers not able to attend the hospital, a virtual approach and consent mechanism will be undertaken. Through this, once a patient participant as provided consent for their nominated caregiver to be contacted about the study, a member of the local research team will telephone the nominated caregiver and provided with a brief outline of the study. They will be informed that the patient participant has consented to them being contacted. If they agree, they will be sent a copy of the caregiver Participant Information Sheet either by email or postal. They will also be sent a copy of the Consent Form by post. The caregiver will be offered the opportunity for a further telephone call or video call with the local research team member to answer any further questions. This will be documented in the patient's medical notes.

Caregivers will be instructed, if they consent, to complete the Consent Form and for this signature to be witnessed by someone else such as a family member or friend, and for them to sign the form as well. They will be provided with a prepaid envelope to return this to the recruiting hospital. The research team at the site then sign and date the returned Consent Form and post a photocopied version this completed form back to the caregiver and store the original signed version in the site's Investigator Site File. The same approach will be taken for Consultee approach and consent.

HIP HELPER Intervention Delivery

In the event that caregivers are unable to visit their care-recipient and attend the face-to-face in-patient training sessions, the three HIP HELPER face-to-face interventions will be delivered via video consultation using a NHS approved software platform such as Attend Anywhere. This will be delivered by the trained HIP HELPER health professional. The first video consultation session will start within three days post-hospital discharge. The timing of sessions will be determined by the HIP HELPER clinical team based on clinical presentation and the availability of the caregiver. The content and duration of the sessions will be delivered as per the face-to-face sessions. Caregivers (with the patient participant present) will be required to access the video consultation on a computer or tablet and not a mobile telephone. Participants will be provided with the HIP HELPER caregiver manual prior to discharge in addition to the dates/times for the video consultation calls. Participants will be asked to take the video consultation call in a suitable environment where they will be able to practice some of the manual handling techniques i.e. sit to stand from a chair or bed with the patient whilst on the video consultation with the HIP HELPER health professional.

Telephone calls, in accordance with the HIP HELPER intervention, will then be conducted at the same time intervals as the face-to-face version i.e. Week 1, 3 and 6 post-hospital discharge. As per the HIP HELPER intervention, both caregiver and patient participants should be in in the same room. When this does not occur, the HIP HELPER Health Professional will record this on a trial intervention log CRF. When a video consultation approach is adopted, we will record the timings of intervention delivery and components of delivery within the HIP HELPER intervention logs. We will also explore healthcare professional and caregiver-dyad perspectives of the video consultation approach within the qualitative sub-study.

Supplementary File 4: Theoretical underpinning of the HIP HELPER intervention

The researcher's previous systematic review of caregiving interventions[42] indicates that, for this population, the HIP HELPER programme could improve functional outcomes, independence and quality of life for patients, but also could reduce the burden and improve quality of life for informal caregivers. The intervention is grounded in an underlying programme theory, based on the literature.[8,10,33,41,42,43,44,45] The three goals of the intervention are outlined below using the CONTEXT-MECHANISM-OUTCOME framework.[46] This is summarised in the schema below.

<u>To improve knowledge and skills by demonstrating and practicing patient manual handling in pre-discharge setting</u>

Caregivers of people following hip fracture surgery (CONTEXT) need the practical skills and knowledge (MECHANISM) to be able to support and progress recovery to increase health-related quality of life and functional outcomes for patients and to reduce caregiver burden (OUTCOME).

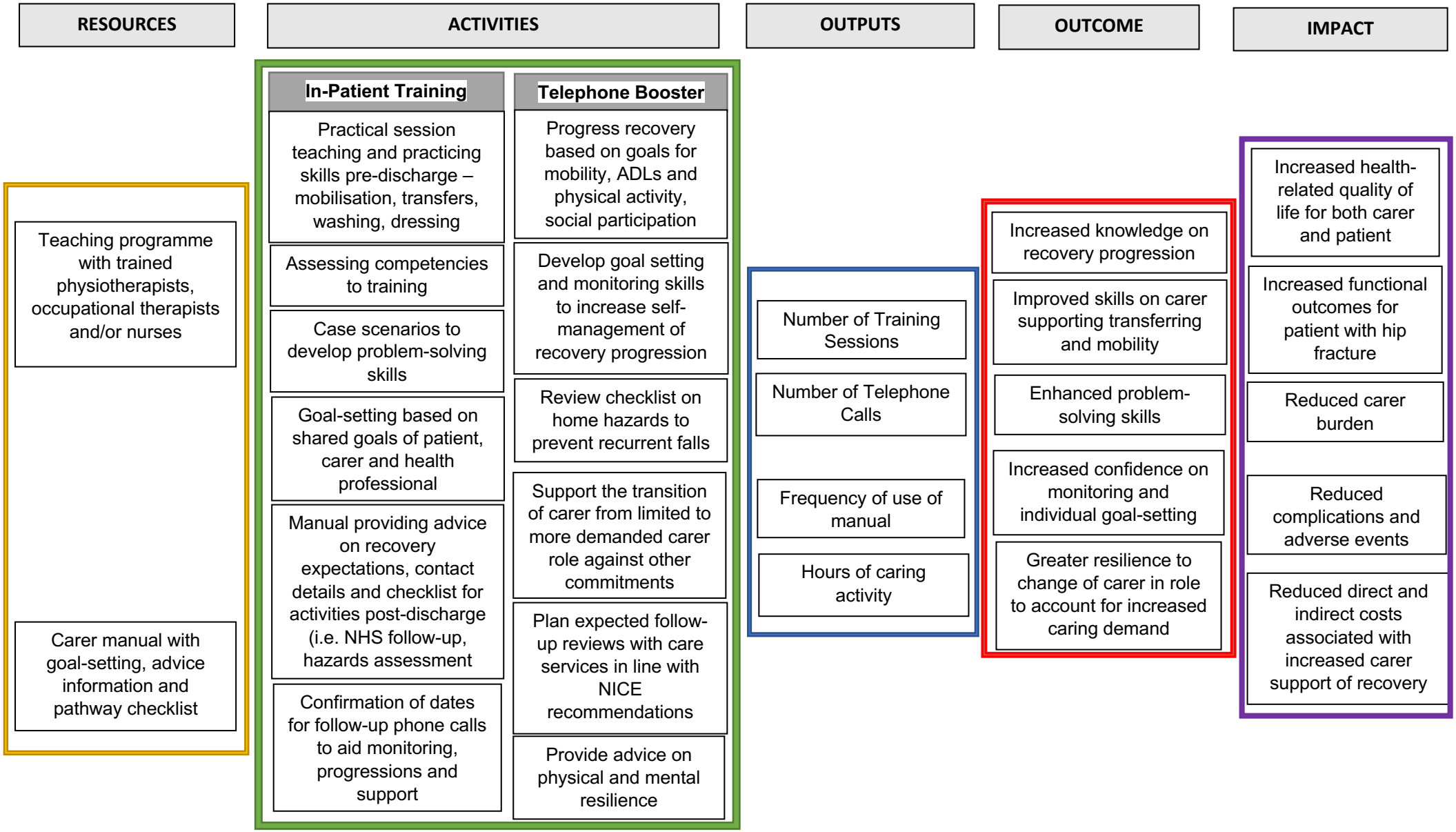
<u>To provide targeted and monitored goals to facilitate progression of recovery</u>

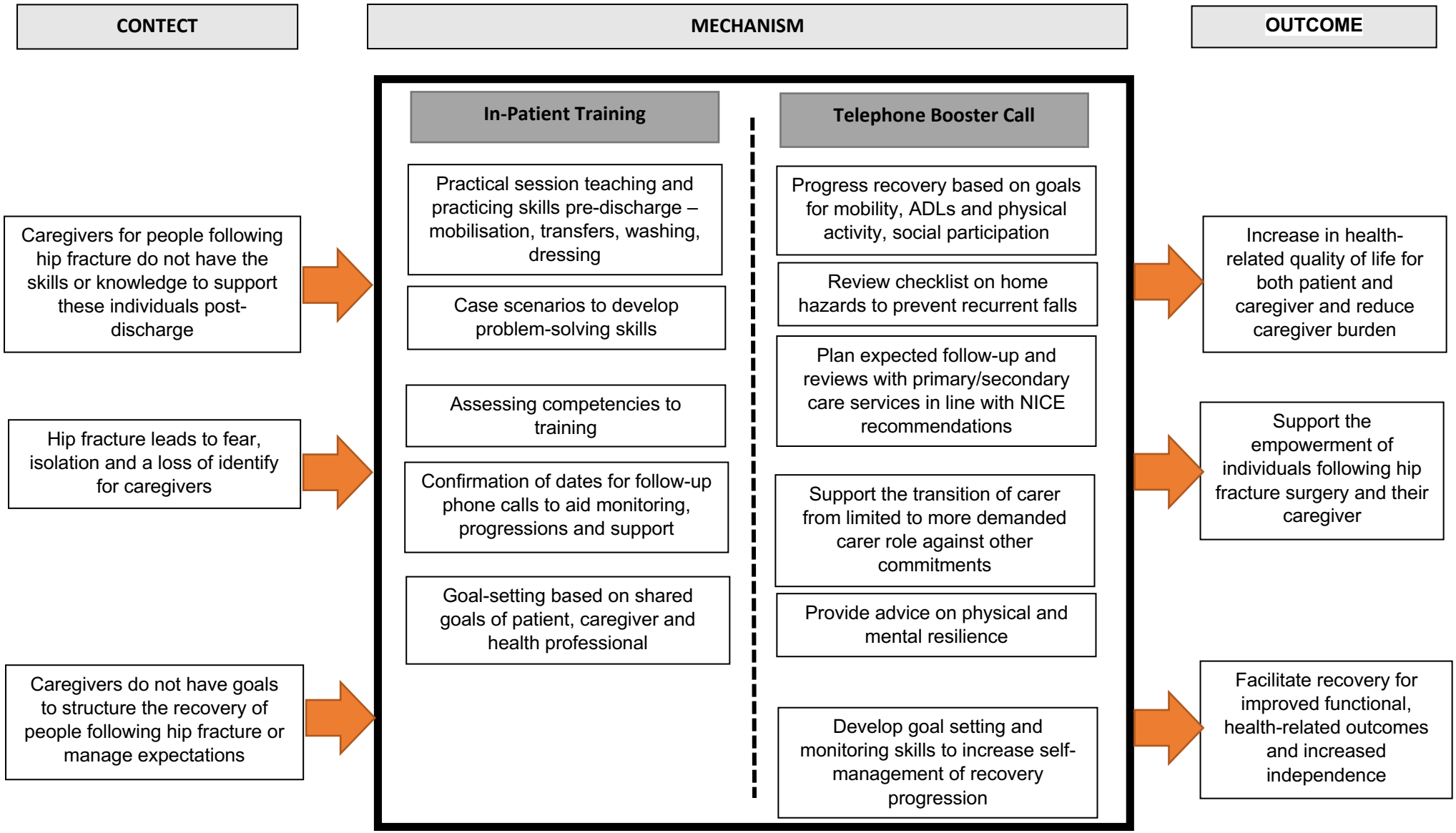
People following hip fracture surgery discharged from in-patient settings (CONTEXT) should have individualised shared goals by which they and their caregiver can meet (MECHANISM) to facilitate the pathway of recovery for improved functional, health-related outcomes and increased independence (OUTCOME).

<u>To reduce fear and isolation and improve self-efficacy to recovery strategies</u>

Hip fracture leads to an increase in fear, isolation and loss of identity for caregivers (CONTEXT) requiring re-evaluation of their role and identity (resilience in self-actualisation) (MECHANISM) to be able to support patients following hip fracture surgery (OUTCOME).

The HIP HELPER programme will be taught to participating healthcare professionals at each site, by the research team who developed it. Participants randomised to the HIP HELPER group will receive standard NHS care (control group intervention) PLUS three, 1-hour, one-to-one training sessions, delivered by a nurse, physiotherapist or occupational therapist in an in-patient hospital setting. This will be augmented with three, 20-minute telephone calls at one, three- and six-weeks post-discharge.


RESOURCES
ACTIVITIES
OUTPUTS
OUTCOME
IMPACT
In-Patient Training
Telephone Booster
Practical session teaching and practicing skills pre-discharge – mobilisation, transfers, washing, dressing
Progress recovery based on goals for mobility, ADLs and physical activity, social participation
Assessing competencies to training
Develop goal setting and monitoring skills to increase self-management of recovery progression
Case scenarios to develop problem-solving skills
Review checklist on home hazards to prevent recurrent falls
Goal-setting based on shared goals of patient, carer and health professional
Support the transition of carer from limited to more demanded carer role against other commitments
Manual providing advice on recovery expectations, contact details and checklist for activities post-discharge (i.e. NHS follow-up, hazards assessment
Plan expected follow-up reviews with care services in line with NICE recommendations
Confirmation of dates for follow-up phone calls to aid monitoring, progressions and support
Provide advice on physical and mental resilience
Teaching programme with trained physiotherapists, occupational therapists and/or nurses
Carer manual with goal-setting, advice information and pathway checklist
Number of Training Sessions
Number of Telephone Calls
Frequency of use of manual
Hours of caring activity
Increased knowledge on recovery progression
Improved skills on carer supporting transferring and mobility
Enhanced problem-solving skills
Increased confidence on monitoring and individual goal-setting
Greater resilience to change of carer in role to account for increased caring demand
Increased health-related quality of life for both carer and patient
Increased functional outcomes for patient with hip fracture
Reduced carer burden
Reduced complications and adverse events
Reduced direct and indirect costs associated with increased carer support of recovery


CONTECT
MECHANISM
OUTCOME
In-Patient Training
Telephone Booster Call
Practical session teaching and practicing skills pre-discharge – mobilisation, transfers, washing, dressing
Case scenarios to develop problem-solving skills
Assessing competencies to training
Confirmation of dates for follow-up phone calls to aid monitoring, progressions and support
Goal-setting based on shared goals of patient, caregiver and health professional
Progress recovery based on goals for mobility, ADLs and physical activity, social participation
Review checklist on home hazards to prevent recurrent falls
Plan expected follow-up and reviews with primary/secondary care services in line with NICE recommendations
Support the transition of carer from limited to more demanded carer role against other commitments
Provide advice on physical and mental resilience
Develop goal setting and monitoring skills to increase self-management of recovery progression
Caregivers for people following hip fracture do not have the skills or knowledge to support these individuals post-discharge
Hip fracture leads to fear, isolation and a loss of identify for caregivers
Caregivers do not have goals to structure the recovery of people following hip fracture or manage expectations
Increase in health-related quality of life for both patient and caregiver and reduce caregiver burden
Support the empowerment of individuals following hip fracture surgery and their caregiver
Facilitate recovery for improved functional, health-related outcomes and increased independence