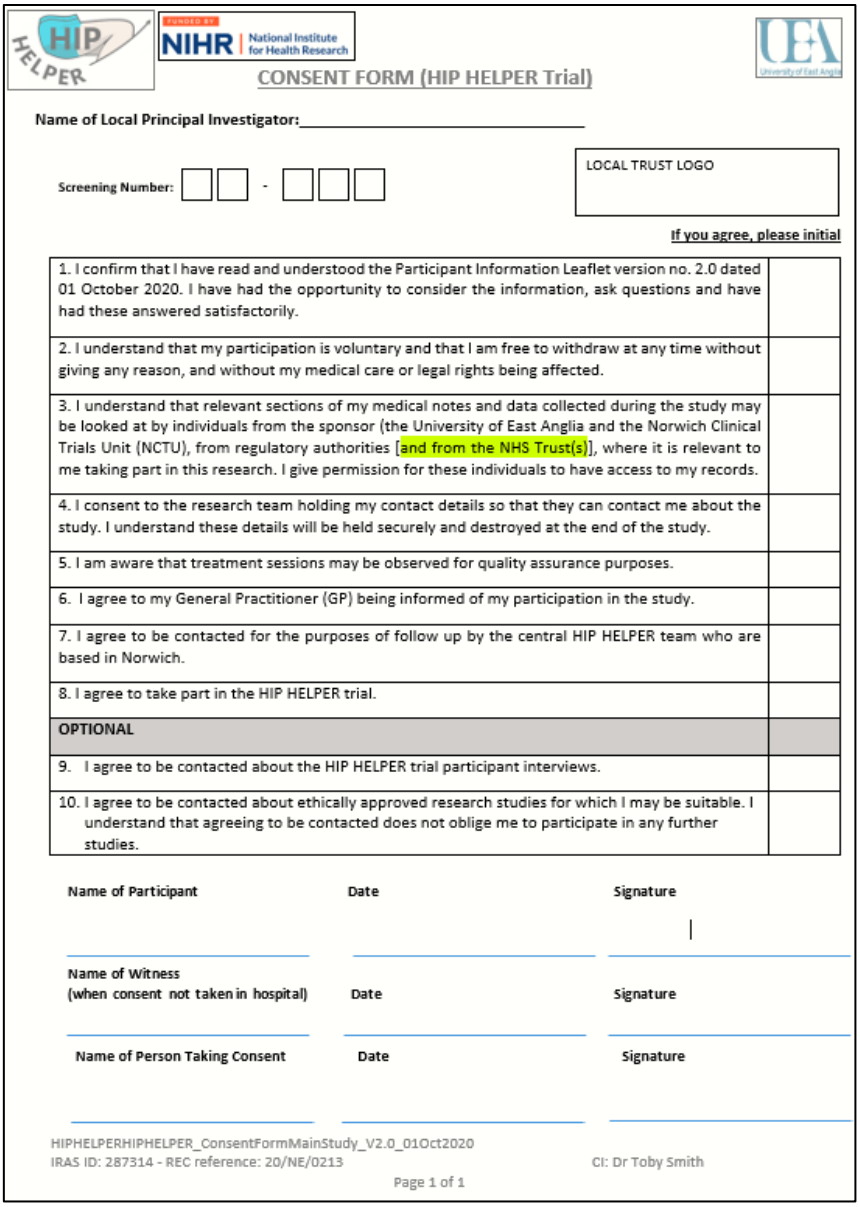
Bone & Joint Open

Supplementary Material

10.1302/2633-1462.211.BJO-2021-0136

Supplementary File 1. Consent form (patient and caregivers).



HIP HELPER

NIHR | National Institute for Health Research

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, and 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 has 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 provide them 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 post. 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 will then sign and date the returned Consent Form and post a photocopied version of this completed form back to the caregiver, storing 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 inpatient training sessions, the three HIP HELPER face-to-face interventions will be delivered via video consultation using an 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), and the video consultation must be accessed 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 while 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 case report form (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 work 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. The three goals of the intervention are outlined below using the CONTEXT-MECHANISM-OUTCOME framework. This is summarized in the schema below.

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

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).

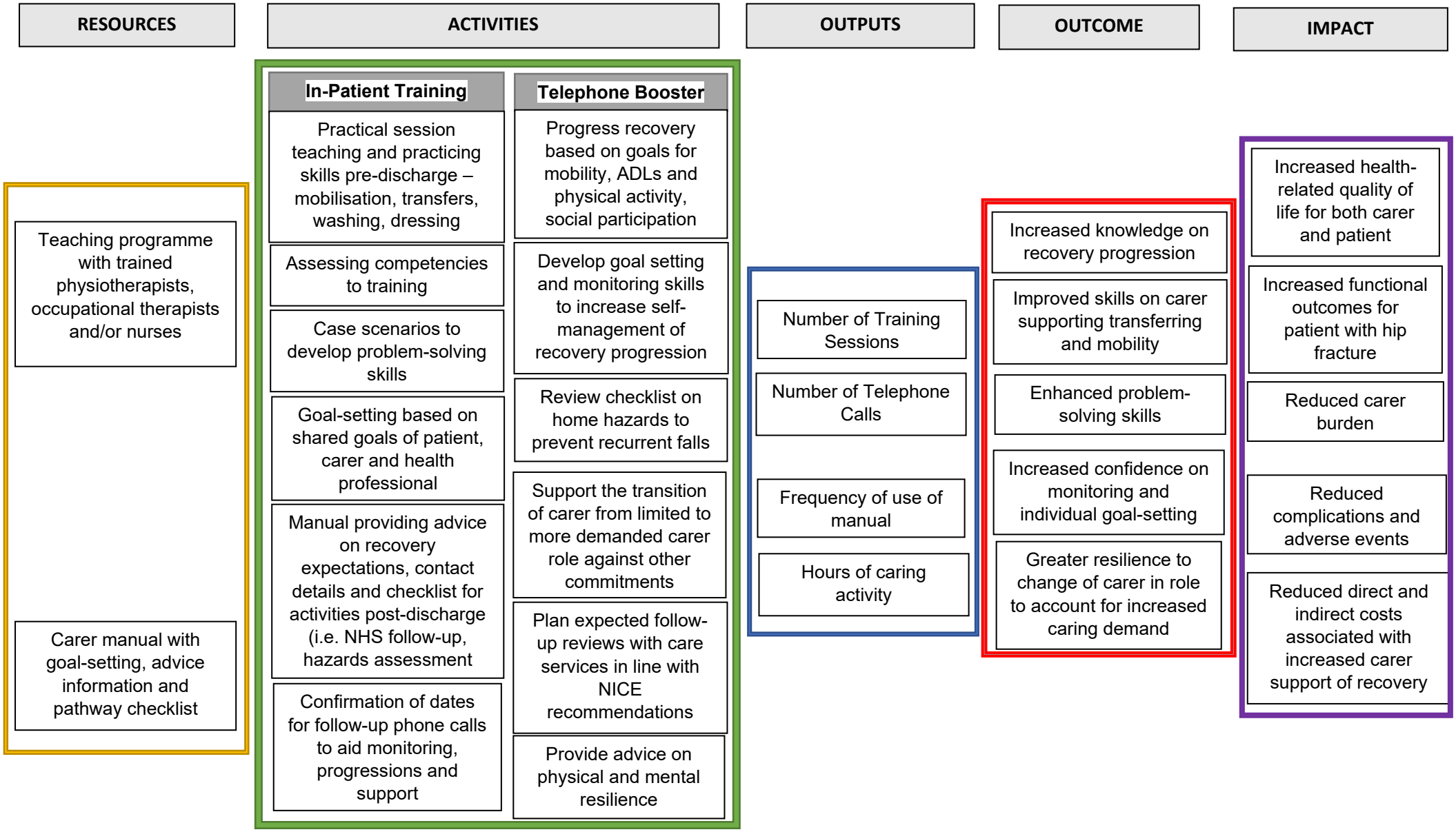
To provide targeted and monitored goals to facilitate progression of recovery

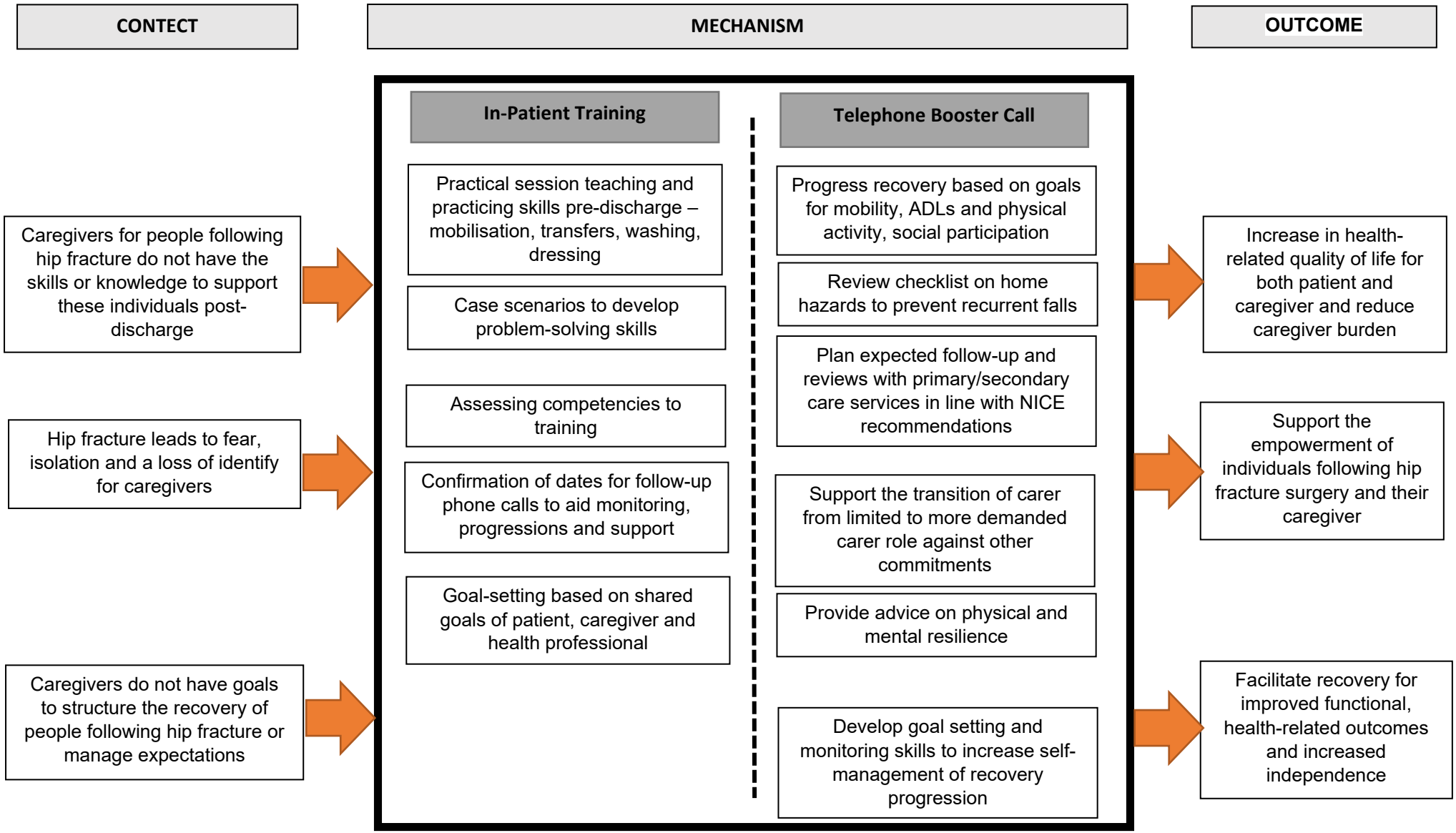
People following hip fracture surgery discharged from inpatient settings (CONTEXT) should have individualized shared goals by which they and their caregiver can meet (MECHANISM) to facilitate the pathway of recovery for improved functional, health-related outcomes, and increased independence (OUTCOME).

To reduce fear and isolation and improve self-efficacy to recovery strategies

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-actualization) (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 randomized to the HIP HELPER group will receive standard NHS care (control group intervention) PLUS three one-hour, one-to-one training sessions, delivered by a nurse, physiotherapist, or occupational therapist in an inpatient 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
Assessing competencies to training
Case scenarios to develop problem-solving skills
Goal-setting based on shared goals of patient, carer and health professional
Manual providing advice on recovery expectations, contact details and checklist for activities post-discharge (i.e. NHS follow-up, hazards assessment
Confirmation of dates for follow-up phone calls to aid monitoring, progressions and support
Progress recovery based on goals for mobility, ADLs and physical activity, social participation
Develop goal setting and monitoring skills to increase self-management of recovery progression
Review checklist on home hazards to prevent recurrent falls
Support the transition of carer from limited to more demanded carer role against other commitments
Plan expected follow-up reviews with care services in line with NICE recommendations
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