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Feasibility of a trial design to support recovery of outdoor mobility following a broken hip

Submission date
16/01/2024

Recruitment status
No longer recruiting

Registration date
29/01/2024

Overall study status
Ongoing

Last Edited
13/12/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English Summary
Background and study aims
Only one in four people can go outdoors four months after breaking their hip. Helping people get back to going outdoors could lower their chances of new illness, loneliness, or needing more support from friends and family. This NIHR-funded study wants to see if the NHS can better support people who break their hip to get back to going outdoors.
If this small study shows we can give this extra care in the NHS, and it may help patients, then we plan to do a larger study. The larger study will see if this extra care works to help older people get back to what they like to do outdoors and feel happier.

Who can participate?
Older people (aged 60 years or older) who broke their hip

What does the study involve?
All participants will get usual care. Half, selected by chance, will get extra care including:
1. A plan to help each of them get back to things they like to do outdoors on foot or with transport. A therapist will help them to practice going out and talk about the worry some have about falling again. Therapists will guide people to ask family and friends to help them practice going out.
2. Support to find community groups near their home to help them continue to go outdoors once therapist visits are over.
3. A video where other people talk about getting better after a broken hip.
The extra care will continue until the person is back doing what they like outdoors, six visits are completed, or when 12 weeks have passed.
We will collect information from people taking part, over the phone at the beginning, middle, and end of the study and again six months later.

What are the possible benefits and risks of participating?
There are no apparent benefits of taking part in this study but the results from this study might help improve the healthcare of patients in the future. There is no payment for taking part. The possible risks of participating include a potential burden to patients, as studies can take a lot of time. The researchers designed the study with patients, carers, and healthcare professionals to try to take as little of their time as possible. The research team has taken measures to ensure

data protects participants' confidentiality and is processed and stored securely and accurately in accordance with data protection principles. During the study the therapists and research team will monitor for any harmful events that may or may not be related to the new approach to rehabilitation. If these are identified, they will be reported to the direct care team and relevant organisation to take the appropriate next steps to ensure participant safety.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
July 2023 to June 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Prof. Katie Sheehan, katie.sheehan@kcl.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
329085

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 59181, NIHR204040, IRAS 329085

Study information

Scientific Title
Outdoor mobility after hip fracture: a feasibility randomized controlled trial

Acronym
OUTDOOR

Study hypothesis
The null hypothesis states that it is not possible for the NHS to deliver a new outdoor mobility intervention for older adults who break their hip. The alternative hypothesis states that it is possible for the NHS to deliver a new outdoor mobility intervention for older adults who break their hip. If the alternative hypothesis is accepted, a definitive trial will be planned to see whether the new outdoor mobility intervention is better than current care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/12/2023, East of England – Essex Research Ethics Committee (2 Redman Place, London, EC20 1JQ, UK; +44 (0)207 1048106; Essex.REC@hra.nhs.uk), ref: 23/EE/0246

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
See study outputs table

Condition
Support for older people who have broken a hip to recover enough to go outdoors

Interventions
A member of the direct care team will screen all patients admitted to the hospital ward with a broken hip to see if they could take part in the study. Patients aged 60 years or more, admitted to hospital from (and planned discharge to) home, who were able to go outdoors in the three months before their broken hip, who have surgery to fix their broken hip, and who are willing and able to provide consent can take part. Patients who are less than 60 years old, who are not scheduled to have surgery, admitted from (or planned discharge to) nursing/residential care, who were not able to go outdoors in the three months before their broken hip, who are likely to need two or more people to help them with their mobility when they are discharged, and/or who are unable to consent or participate cannot take part.
For patients who can take part, the suitably trained person will approach the patient to discuss the study and give the patient an information leaflet. At least one day later the patient will be asked by the suitably trained person if they want to take part, and if so, to either sign a form or agree to be contacted again once they go home. For patients who are approached on the day they are due to go home, on-the-day recruitment will be permitted should the suitably trained person be assured that the patient has understood the information and has had the opportunity to ask any questions.
Patients who agree to take part are called participants. All participants will then complete a series of questionnaires with a member of the research team over the telephone/MS TEAMS. Once the questionnaires are completed, participants will be assigned (by chance) to one of two groups. Both groups will receive usual care. One group of 30 participants will also receive the outdoor mobility intervention.
Usual care includes early supported discharge with community rehabilitation for four to six weeks or, discharged home under GP care with referral to community services as needed. Outdoor mobility is not included in routine community rehabilitation. Therapists involved in the study will take notes of what happens during usual care after each session with a participant.
Participants who are assigned to receive the outdoor mobility intervention will start the new approach within 30 days of going home and continue to receive the intervention until their outdoor mobility goals are achieved, 6-visits are completed, or 12-weeks have passes, whichever comes first. The intervention includes 1) a plan to help each of them get back to things they like to do outdoors on foot or with transport. A therapist will help them to practice going out and talk about the worry some have about falling again. Therapists will guide people to ask family and friends to help them practice going out; 2) support to find community groups near their home to help them continue to go outdoors once therapist visits are over; and 3) a video where other people talk about getting better after a broken hip.
Participants will be contacted 6-weeks and 12-weeks after they have been assigned to usual care or the outdoor mobility intervention group by telephone/MS TEAMS by a member of the research team when they will complete a series of questionnaires. Many of these questionnaires will be the same as the ones asked at the beginning of the study. Participants who agree to take part in the first 5 months of the study will also be followed up to collect information 6-months after they have been allocated to a group.
Therapists involved in the study will be asked to audio-record sessions and complete questionnaires at each session end to help to see whether the study was completed as planned.

A group of the older adults and service leads/managers involved in the study will also be interviewed over the telephone/MS TEAMS to help gain an understanding of their thoughts on the outdoor mobility intervention. Therapists involved in the study will take part in a focus group to discuss their views on the intervention.

Participants will be asked to take part over a 9-month period. Each individual participant will be in the study from the point when they agree to take part up to 12 weeks after they have been allocated to the outdoor mobility intervention or usual care group. Information will be collected from participants (questionnaires, audio-recordings, and interviews), service leads/managers (interviews), and therapists (questionnaires and focus groups) at the start, midpoint and end of the intervention. Participants who agree to take part in the first 5 months of the study will also be followed up to collect information 6 months after they have been allocated to a group. The researcher who collects information over the telephone/MS TEAMS about the participant and to complete questionnaires will not know whether the participant received the outdoor mobility intervention or not. The information will be stored in a database which will be cleaned before the information is analysed and written up in a report and scientific paper for publication within two months of the final information being collected from participants. There will be no analysis and write up before this point except to let an independent committee monitor how many patients were screened, eligible, approached, and agreed to take part during the study. This independent committee will meet every 6 months.
During the study, a local trial management group will meet monthly, a broader trial investigator group will meet quarterly, and a public and patient involvement advisory group will meet eight times.

During the study the therapists and research team will monitor for any harmful events, that may or may not be related to the outdoor mobility intervention. If these are identified, they will be reported to the clinical team and relevant organisation to take the appropriate next steps to ensure participant safety. An independent trial steering and data monitoring committee will meet every 6 months. They will provide advice, data monitoring, quality assurance, and safety monitoring.

Patients and their carers helped to plan this study. The public and patient involvement group 'TROOP' (Trauma Rehabilitation (Orthopaedic) research for Older People) helped choose who to invite into the study, what to include in the outdoor mobility intervention, and to choose what outcomes may be important. They helped us to write lay summaries of the proposed study for the funding application and to design participant-facing materials (participant information leaflet, consent forms, participant diary). The group will meet eight times during the study to discuss progress, provide feedback on the results, and help to develop materials for the public. One member of the group will also come to the trial investigator group meetings. The researchers have also recruited two independent patient/carer representatives to join the trial steering and data monitoring committee.

Intervention Type
Behavioural

Primary outcome measure
Fidelity measured using:
1. Therapist session audio recordings at each intervention session
2. Intervention and usual care questionnaires completed by the physiotherapist/occupational

therapist/therapy assistant after each supervised session with a participant
3. Semi-structured interviews/focus groups with participants, therapists, and managers of services involved in the delivery of the intervention 12 weeks post-randomisation

Secondary outcome measures
1. Acceptability measured using:
1.1. Semi-structured interviews/focus groups with participants, therapists, and managers of services involved in the delivery of the intervention, at 12 weeks post-randomisation
1.2. Theoretical Framework of Acceptability questionnaire completed by participants and therapists at 12 weeks post-randomisation
2. Barriers and enablers to intervention delivery will be measured using semi-structured interviews/focus groups with participants, therapists, and managers of services involved in the delivery of the intervention at 12 weeks post-randomisation
3. Acceptability, completeness, and descriptive comparison of patient-reported outcome data collection which will be assessed through the collection of patient-reported outcome measures:
3.1. Health-related quality of life measured using the EuroQoL EQ-5D-5L
3.2. Activities of daily living measured using the Nottingham Extended Activities of Daily Living
3.3. Pain measured using the Numeric Rating Scale
3.4. Community mobility measured using the University of Alabama Life Space Assessment
3.5. Mortality measured using medical records
3.6. Additional quantitative outcomes captured will include Falls related self-efficacy measured using the Falls Efficacy Scale-International
3.7. Hospital readmissions measured using participant self-report
3.8. Reason and resource use using a bespoke resource use data collection form
Data will be collected at baseline, 6 weeks post-randomisation, 12 weeks post-randomisation, and 6 months post-randomisation (if the timing of randomisation permits this follow-up within the trial data collection window)
3.9. Exercise adherence measured using the Exercise Adherence Rating Scale for the OUTDOOR intervention arm at 6 and 12 weeks post-randomisation
5. Count of eligible, recruited and retained participants measured from randomisation until final follow-up (6 months if the timing of randomisation permits 6-month follow-up within the trial data collection window, 12 weeks otherwise)
6. Count of inadvertent unblinding of outcome assessors measured from randomisation until final follow-up (6 months if the timing of randomisation permits 6-month follow-up within the trial data collection window, 12 weeks otherwise)
7. Count of adverse and serious adverse events measured from randomisation until final follow-up (6 months if the timing of randomisation permits 6-month follow-up within the trial data collection window, 12 weeks otherwise)

Overall study start date
01/07/2023

Overall study end date
02/06/2025

Eligibility

Participant inclusion criteria
Participants:
1. Adults aged 60 years or more
2. Admitted to hospital from (and planned discharge to) home

3. Self-reported outdoor mobility in the three-months pre-fracture
4. Surgically treated for hip fracture
5. Able to consent and participate
Participants recruited under the above 'inclusion criteria' whose circumstances change (e.g., planned discharge to home but then discharged to nursing/residential care) will be withdrawn before randomisation. They will not be replaced

Professionals:
Therapists involved in the intervention arm of the feasibility trial, and managers who oversee services involved in the delivery of the intervention within the feasibility trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
60 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Participant exclusion criteria
Participants:
1. Adults aged less than 60 years
2. Admitted to hospital from (or planned discharge to) nursing/residential care
3. No self-reported outdoor mobility in the three-months pre-fracture
4. Non-surgically treated for hip fracture,
5. Who are likely to require two or more persons to support mobility on discharge
6. Who are unable to consent or participate

Professionals:
Therapists not involved in the intervention arm of the feasibility trial, and managers who do not oversee services involved in the delivery of the intervention within the feasibility trial

Recruitment start date
01/02/2024

Recruitment end date
27/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Whipps Cross Hospital
Whipps Cross Road
London
United Kingdom
E11 1NR

Study participating centre
Norwich Community Hospital
Bowthorpe Road
Norwich
United Kingdom
NR2 3TU

Study participating centre
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
North Devon District Hospital
Raleigh Park
Barnstaple
United Kingdom
EX31 4JB

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
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Exeter
United Kingdom
EX2 5DW

Sponsor information

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Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
The protocol for the study will be published in an open-access peer-reviewed journal during the first year the trial is open. The results of the study are planned to be published in an open-access peer-reviewed journal 1 year after the trial ends. The findings will be presented at national and international conferences. The researchers will submit findings to guideline committees. They will share results directly with UK clinicians via the Chartered Society of Physiotherapists, British Geriatrics Society, and Fragility Fracture Network UK. The results of the study will be summarised in plain English and made available on the TROOP PPI group webpage (https://www.ppitroop.co.uk/) and Twitter page (@TROOP_PPI) as well as via charity newsletters. Participants will be offered the option of having the plain English summary posted directly to them during the consent process.

Intention to publish date
01/02/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. Following publication of the primary paper, anonymised electronic data will be exported and stored alongside anonymised transcriptions of interviews indefinitely on the King's Open Research Data System: https://www.kcl.ac.uk/researchsupport/managing/preserve (participants will provide consent for data sharing), with proof of ethical approval as a condition of access.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	10/11/2023	29/01/2024	No	Yes
Protocol article		12/08/2024	14/08/2024	Yes	No
Other files	Verbal consent form version 1	21/05/2024	04/10/2024	No	No
Protocol file	version 3	21/05/2024	04/10/2024	No	No