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INFORMATION SHEET FOR PARTICIPANTS

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of project

Outdoor Mobility After Hip Fracture: A Feasibility Randomised Controlled Trial

Invitation Paragraph

We would like to invite you to participate in this research project. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the project?

Older people who broke their hip said they felt better once they could go for a walk, go shopping, meet friends and family, or work as a volunteer again. However, we know from national records that only one in four people can go outside four months after breaking their hip. Helping people get back to going outside could lower their chances of new illness, loneliness, or needing more support from friends and family. But currently healthcare after a broken hip rarely includes support to go outside the home.

This study wants to see if it is possible for the NHS to support people who break their hip to get back to going outside their home. We worked with patients and carers to plan this study. They will keep helping us during the study.

Why have I been invited to take part?

You are being invited to participate in this project because you had an operation to fix a broken hip at an NHS Foundation Trust.

What will happen if I take part?

Can I take part?

We will invite 60 older people who broke their hip to take part. You can take part if you are aged 60 years or more, are willing and able to provide consent, and were living at home and were able to walk outdoors three months before breaking your hip. You cannot take part if you are younger than 60 years and/or were living in nursing care before you broke your hip, will go to nursing care after leaving hospital, or are in another study (and the two study teams think it is not possible for you to be involved in both).

Rehabilitation at home

All 60 participants will get the usual home care provided in your local area. Half, which will be selected by chance, will get an extra outdoor programme. This extra outdoor programme will include:

- Home visits and/or telephone calls from a therapist, to help you get back to things you personally like to do outside your home.
- Talk with therapist about how to overcome the understandable worry some people have about falling or having another broken hip.
- Support from your therapist to find community groups near your home to encourage you to go outside.
- Guide to help you ask your family and friends for help to go outside.
- A video about other people's journey after a broken hip.

The outdoor programme will start around 30 days after you return home. This extra care will continue until:

- you are back to doing the things you like to do outside your home, or
- six visits with a therapist are completed, or
- when 12 weeks have passed.

If you receive the extra outdoor programme, the therapist will audio record sessions done with you. We will also ask you to practice exercises independently and with/or family/friends between therapy visits. We will ask you to record in a diary every time you complete the programme by yourself and/or with someone else. This will help us evaluate the study.

Collection of data

If you agree to take part in the study, you will complete a series of questionnaires with a member of the research team at least three times. A researcher will call you over the telephone or MS Teams at the beginning, middle, and end of the study to complete these questionnaires. If you join the study early, we may call you again six months later. The questionnaires will help us evaluate the study. Each telephone/MS TEAMS calls is expected to take between 1 hour and 1 hour and 15 minutes.

We will also invite you (after obtaining your consent) to complete an interview over the telephone or MS Teams (an internet based telephone) to help us gain an understanding of your thoughts on the outdoor programme. We will use direct quotes from you when writing up the results of the interviews. We will ensure that you cannot be identified from these quotes.

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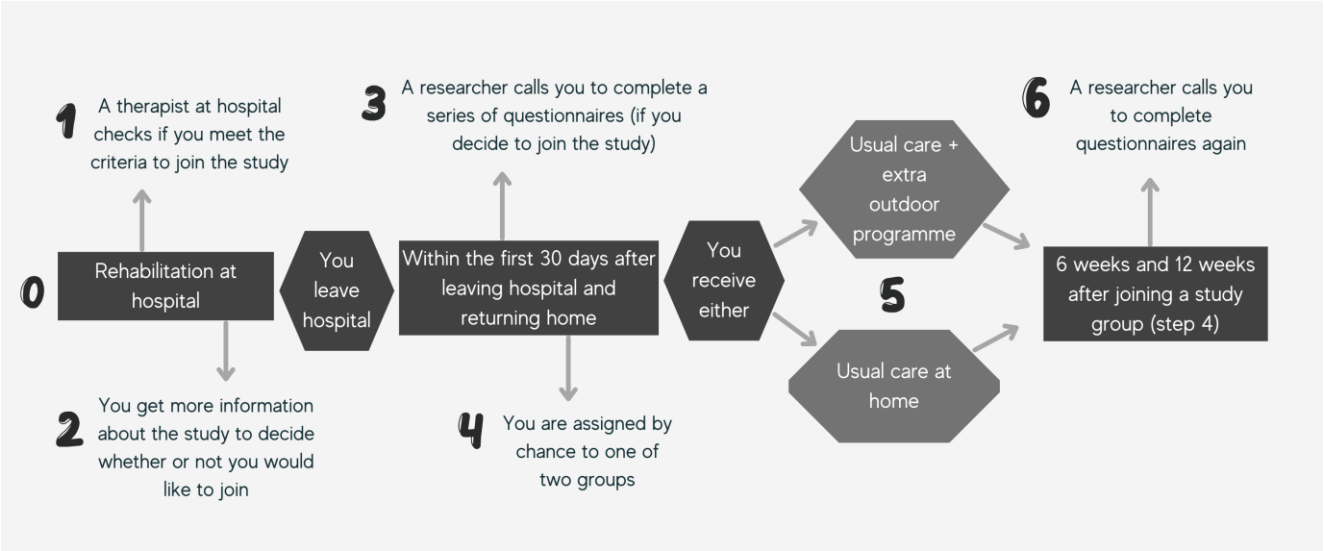

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to. Choosing not to take part will not affect your medical care or legal rights, and will not disadvantage you in any way.

Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part, we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

What are the possible benefits of taking part?

There are no apparent benefits to you taking part in this study, but results from this study might help improve healthcare of patients in the future. There is no payment for taking part.

What are the possible risks of taking part?

Potential burden

Studies can take a lot of time. We designed the study with patients, carers, and healthcare professionals to try to take as little of your time as possible.

- We are only collecting essential data from you.
- We will collect data over the phone or MS Teams.

Your data and safety

The research team has taken measures to ensure your data is processed and stored securely, accurately and in accordance with data protection principles. Your data will be pseudo-anonymised, so no one knows this data is from you. The research team will check results of the research to make they sure they do not reveal your identity.

Identifiable data about you, such as your initials, name, and telephone number, will be stored in REDCap, a secure database hosted by The Exeter Clinical Trials Unit. This data will be accessible to your direct care team and authorized members of the research team to arrange home visits, telephone assessments, telephone interviews, and to send the study results by post (if you select this option).

If you take part in an interview, everything that you tell the researcher will be kept completely confidential unless it is felt there was a risk of harm to yourself or others, in which case standard safeguarding procedures will be followed.

Safety and monitoring
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 your direct care team and relevant organisation to take the appropriate next steps to ensure your safety.

Relevant sections of your medical notes and data collected during the study, may be looked at by individuals from King's College London, from regulatory authorities or from the NHS Trust where it is relevant to your taking part in this research or for monitoring and audit purposes.

An independent trial steering and data monitoring committee will meet regularly. They will provide advice, data monitoring, quality assurance, and safety monitoring.

Who is funding and organising the study?
This project is being funded by the National Institute for Health Research, Research for Patient Benefit.

This project is co-sponsored by King's College London and NHS Norfolk and Waveney Integrated Care Board.

Who has reviewed this study?
External researchers not affiliated with the research team reviewed the design of the study to grant funding.

The study obtained regulatory approval from a Research Ethics Committee, the Health Research Authority, and the Research & Development Department of the NHS Trust supporting the delivery of the study.

How will we use information about you?
We will need to use information from you and your medical records for this research project. This information will include your initials, name, contact details. People will use

this information to do the research or to check your records to make sure that the research is being done properly.

We will keep all information about you safe and secure. As co-Sponsor King's College London has a responsibility to keep information collected about you safe and secure, and to ensure the integrity of research data. Specialist teams within King's College London continually assess and ensure that data is held in the most appropriate and secure way.

Your information will be stored in REDCap, a secure database hosted by The Exeter Clinical Trials Unit. Information on paper will be stored in a locked cabinet/drawer within a secure room at an NHS Foundation Trust site. Audio-recordings sessions will be uploaded to a secure King's College London SharePoint server accessible only to the research team. Your information will be stored in a pseudo-anonymised format, in other words, people who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Audio recordings from interviews and therapy sessions will be shared with a third party for transcription purposes via a secure, encrypted cloud. Transcripts will be anonymised, and audio recordings permanently deleted once transcribed.

Data from the study will be analysed by the research team at Kings College London. We will write our reports in a way that no-one can work out that you took part in the study. Data collected during the study will be converted to anonymised data and stored indefinitely in an open access repository - the King's Open Research Data System for future ethically approved research studies.

Identifiable data will be stored in a secure location for 5 years after which it will be destroyed in line with local Trust/King's College London policies on data destruction.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about you in questionnaires and interviews over telephone or MS teams. If you do not want this to happen, tell us and we will stop.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. With your consent, we will keep your contact details for 5 years so that we can contact you about future research projects of a similar nature.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- www.kcl.ac.uk/research/support/rgei/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research; or
- by looking at the King's Open Research Data System website: https://www.kcl.ac.uk/researchsupport/managing/preserve
- by asking one of the research team

What will happen to the results of the project?

The results of the project will be summarised in plain English and posted on a public and patient involvement website (www.troopppi.co.uk), Twitter page (@TROOP_PPI) circulated via the Royal Osteoporosis Society's Bone Matters e-newsletter, and will be sent directly to you, if you choose this option.

We will publish a paper with the results of the study that is free for anyone to see on the internet. We will also present the findings at academic and clinical conferences in the UK and abroad. We will also submit the findings to guideline committees and professional societies. After publication of the results, researchers can ask to access the study data to complete and write up further research. Their request will be considered by a committee. Any study data used for additional research will be anonymised, in other words you cannot be identified from this data.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions Emma Godfrey, emma.l.godfrey@kcl.ac.uk. You may also relay your concern (or raise a complaint) by contacting the NHS Patient Advice and Liaison Service (PALS) team at [Insert local PALS contact information], and/or the King's College London Research Governance Office: rgo@kcl.ac.uk.

In the event that something does go wrong, and you are harmed during the research then you may have grounds for legal action for compensation against King's College London, but you may have to pay your legal costs. King's College London maintains adequate insurance to cover any liabilities arising from the study.

Who should I contact for further information?

[Insert site logo]

If you have any questions or require more information about this project, please contact the research team using the following contact details: Emma Godfrey, emma.l.godfrey@kcl.ac.uk.

Thank you for reading this information sheet and for considering taking part in this research.