We would like to invite you to take part in our research study

- Before you decide whether to take part it is important for you to understand why the research is being done and what it would involve for you.
- Please take time to read the following information carefully.
- Please ask us if anything is not clear, or if you would like more information.
- This study aims to find out your experience of your relative participating in a research study assessing whether a functional standing frame programme (a type of physiotherapy treatment) early after a severe stroke is possible. This study also aims to explore the involvement of relatives in the decision for people who have had a stroke to agree or decline to participate in the standing frame programme research.

Important information

- If you take part in the study you will be interviewed to explore your thoughts, feelings and experience of supporting your relative in the decision to participate in and complete the functional standing frame programme study.
- During the interview you will be asked some questions and given the opportunity to share your experience about your relative’s decision to take part in our research study.
- The interview will not last any longer than one hour but can be as short as 20 minutes if you prefer. It will take place in a venue of your choice. You can be interviewed alone or your relative can be present.

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- If you have any questions about this study please contact:
  - [Enter name (local Principal Investigator)]
  - [Enter telephone number]

Or

Angie Logan
Chief Investigator
01872 256463 or 07891 336743
angie.logan@plymouth.ac.uk
What is the purpose of the study?

- Stroke affects over 152,000 people in the UK every year. People with severe stroke have significant muscle weakness which means they spend much of their time in bed or sitting. This inactivity can cause their muscles to become even weaker and stiff. It may also cause sudden drops in their blood pressure when moving from lying to standing (orthostatic hypotension) which may interfere with their ability to participate in their rehabilitation.

- Currently physiotherapy for people with severe stroke focuses on practise tasks such as getting in and out of bed or a chair. These activities are important for independence and achieving discharge home. Standing up early after a stroke may help strengthen muscles, reduce orthostatic hypotension and minimise or prevent muscles from becoming stiff and weaker. Our research aims to assess whether it is possible for people with severe stroke to use a standing frame to practice functional movements such as standing and moving between sitting and standing.

- Part of this research is to explore both participants’ and their relatives experience of being invited to participate in the research, the information they received, how agreement to participate in the study was gained, their experience of being randomly allocated into one of two different physiotherapy treatments and their reasons for completing the research study or withdrawing from the research study (declining to continue).

Why have I been chosen for the study?

You are being invited to take part because your relative has recently had a stroke and they were approached to participate in the functional standing frame programme study. We want to explore your involvement in the decision-making about whether your relative took part in the functional standing frame programme study or not. We would like to understand how you supported your relative during the research study even if they withdrew.

We also want to understand your experience of being consulted about whether your relative could participate in the functional standing frame programme study if they were unable to make this decision themselves due to communication or cognitive difficulties.

What would taking part involve?

If you agree to help us with this study you have an interview with the researcher, Angie Logan. You will be given the option of being interviewed face-to-face or via telephone or Skype. The interview last no longer than one hour. We acknowledge this is a busy and difficult time for you, therefore, any amount of time you can spare will be greatly appreciated.

The interview will be digitally voice-recorded and transcribed for data analysis. Interviews will take place at a location of your choice, either on hospital premises (but not on hospital wards e.g. a private, quiet meeting room), your own home or community venues, providing rooms are available for booking. Ideally we would like to interview you within two weeks of your relative finishing their physiotherapy programme. Interviews will be held on a mutually agreed date and time.

What are the risks?

We don’t expect you to be harmed in any way by taking part in this study. However, you may become upset during the interview when talking about your experiences and how the stroke has affected your relative and the impact this has had on you personally. The researcher is professionally trained and will ask questions sensitively. You do not have to answer questions which cause you to feel upset.
### Do I have to take part?

No. Participation is entirely voluntary. It is up to you to decide whether or not to take part in the study. If you decide not to take part, this will not affect the rehabilitation or treatment your significant other is receiving for their stroke. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. You are free to withdraw from the study at any time and without giving a reason.

### What happens if I don’t’ want to carry on with the interview?

You are free to withdraw from the interview at any time, without giving any reason, and without your legal rights or the medical care of your significant other being affected. If you want to withdraw from the study you do not have to give a reason for this; however, if you do give a reason, this will be useful to us when we design other studies in future. If you decide to withdraw from the study at any stage, information collected during the study may still be used unless you ask for it not to be.

### Will taking part in the interview cost me anything, and will I be paid?

You will not be paid to participate in the interview. However, we will arrange your interview at a time, date and location to suit you, so that you do not incur any expenses through participation.

### What are the possible benefits of taking part?

You may or may not benefit directly from this study but by taking part you will be contributing to a study which could potentially bring future benefit to large numbers of people with stroke. The aim of your involvement is to fully understand people’s experience of being involved in research early after stroke, specifically with the aim of testing a new physiotherapy treatment. Additionally, we want to find out if there are specific reasons why people agree or decline to be involved in physiotherapy research during their stroke rehabilitation in hospital and what impact their relatives have on their decisions. We will then look at these reasons and aim to make things as simple as possible to encourage them to participate.

### Will my taking part in this study be kept confidential?

All information collected about you whilst taking part in this study will be kept strictly confidential and be collected and stored in accordance with the Data Protection Act (1998).

You will be allocated a unique study number which will be used on all documents so that your name is kept confidential. Paper-based information will be stored in locked filing cabinets within a locked office in Peninsula Clinical Trials Unit (PenCTU). Information kept on computers will be stored securely on a system maintained by Plymouth University. The digital audio recording will be deleted once it has been transcribed. Only members of the research team and PenCTU at Plymouth University will have direct access to the study information. Copies of the study information (e.g. your signed Consent Form) will be held securely at your local hospital.

Authorised people from PenCTU and the research team may need to review the interview transcription check that the study is being carried out correctly. The Sponsor (Royal Cornwall Hospital NHS Trust) may also need to access the data for audit purposes. Everyone will have a duty of confidentiality to you as a research participant. As part of the consent process, you will be asked to consent to your contact details (name, address, telephone number) being kept by the research physiotherapist so she can contact you to make appointments for your follow up study visits. These details will be stored separately from the anonymised data at Plymouth University.

If you share any information with the researchers which suggests you may be at risk of any harm, this
**Will the study information be used to help other research?**

It is important that good quality research data can be shared with others in order to advance clinical research and to benefit patients in the future. After the end of the study, de-identified information collected during the study may be made available to other researchers under an appropriate data sharing agreement, but it will not be possible to identify you personally from any information shared.

We will use the information to inform future research to investigate the effectiveness of the functional standing frame programme if the results of this feasibility trial are favourable. Your interview data may help us to maximise the number of people willing to participate in the research.

**What happens at the end of the study? Will I find out the results?**

Once your interview is complete your participation in the study is complete. When every participant has completed the study, we will prepare the study results (this normally takes several months) and send you a summary of the findings if you would like to receive them. The study results may be presented at national and international conferences and published in medical journals but you will not be identified in any information included in any presentation or publication.

**What if there is a problem?**

*Complaints:* If you have a concern about any aspect of this study, please speak to someone in your research team or clinical care team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. *<Please add PALS number here>*

*Harm:* We don’t expect any harm to come to you as a result of participating in the study. If you are harmed and this is due to someone’s negligence than you may have grounds for a legal action for compensation against your hospital’s Trust but you may have to pay your legal costs. There are no special compensation arrangements in place. The normal NHS complaints mechanisms will still be able to help you.

**Who is organising and funding the research?**

The study is being led by Angie Logan, Clinical Doctoral Research Fellow and Specialist Physiotherapist in stroke rehabilitation. The study is funded by a grant awarded by the National Institute for Health Research. The study will be managed by the Peninsula Clinical Trials Unit at Plymouth University and overseen by Royal Cornwall Hospitals NHS Trust (RCHT).

**Who has reviewed the study?**

All NHS research is looked at by an independent research panel (Research Ethics Committee). The study has been reviewed and given favourable opinion by Wales Research Ethics Committee 4.