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 if it is possible to carry out a standing frame programme including repeated standing up and sitting down early after a severe stroke.

Important information

- If you take part in the study you will be randomly allocated to one of two groups: either the standing frame programme or your usual physiotherapy
- The study involves regular assessments over about a year with a total of eight study visits. Four or five visits will be held at the hospital where you are receiving your Stroke Rehabilitation depending on when you are discharged from hospital. The other visits will be held in your place of residence.

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- If you have any questions about this study please contact:
  - [Enter name (local Principal Investigator)]
  - [Enter telephone number]
Or
Angelie Logan
Chief Investigator
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What is a standing frame?

A standing frame can be useful in enabling people with severe stroke to stand safely and securely in a supported position. The electronic power mechanism on the frame can help gradually move people safely from sitting into standing, if they need assistance to do so. Straps at the hips, knees and ankles provide support throughout the stand. There are also straps that can help support your trunk (your body) if you need it once you are standing.
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 (this is called orthostatic hypotension) which may interfere with their ability to participate in their rehabilitation.

- Currently physiotherapy for people with severe stroke focuses on practising 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 practise functional movements such as standing and moving between sitting and standing.

Why have I been chosen for the study?

You are being invited to take part because you have recently had a stroke which means that you now need assistance from two people and/or some equipment to undertake your daily activities.

What would taking part involve?

We are aim for 50 people with severe stroke to take part in our research from four different stroke rehabilitation units across Cornwall and Devon in the UK. Half of those recruited will take part in the standing frame programme and the other half will receive their usual physiotherapy.

The standing frame programme involves standing and moving between sitting and standing for 30 minutes. Whilst you are standing you will be able to do activities that interest you - play table-top games to encourage your balance and use your arms, reading, or watching television etc. A further 15 minutes will provide time for usual physiotherapy where you may practise using a piece of equipment to help you get in/out of bed or your chair or specific activities that you or your physiotherapist suggests. The usual physiotherapy will involve activities chosen by yourself or guided by your physiotherapist.

- The standing frame programme will be undertaken ideally at least five days per week for three weeks and each session will last a total of 45 minutes

- The usual physiotherapy will be undertaken ideally five days per week for three weeks and each session will last a total of 45 minutes

At the end of every physiotherapy session your physiotherapist will ask you four very simple questions to ask you to rate your level of enjoyment, effort, tiredness and any aches or pains.

If you agree to take part in the study this will involve eight study visits over a period of about a year. Each study visit will include having a number of assessments which will be the same on every visit and be non-invasive.
Who decides which physiotherapy programme I receive?

If you agree to take part in the study, you will be allocated at random (by chance - like tossing a coin) by a computer to receive either the standing frame programme or usual physiotherapy. Once you have been allocated to either the standing frame programme or usual physiotherapy, you will continue to receive the same physiotherapy treatment throughout the study.

Does the standing programme frame have any side effects?

With any therapy there is a possibility of unwanted side effects. Side effects of the standing frame programme may include:

1) **Pain or discomfort**

Some people experience mild discomfort when they first begin standing such as muscle stiffness, back ache or a stretched feeling in the leg muscles. These are normal and should pass fairly quickly.

2) **Orthostatic hypotension**

Some people experience dizziness or feeling faint due to a drop in blood pressure. This can happen because your leg muscles are weak and not able to pump the blood back up to your head.

Your physiotherapist and doctor will monitor and manage any side effects. Be reassured however, that standing frames are used by physiotherapists regularly in their work and there are very few risks associated with them. Additionally, the physiotherapists are experienced at working with people with stroke.

Summary of study visits

- Below is a summary of what happens at each visit. The approximately time each visit will take is written in brackets by the title of each box. During all visits you will be able to take a break when you need it.

**Study visit 1: agreement to participate (20 minutes)**
- We will review your medical records to check that you will be safe and eligible to participate. We will give you information about this research study and answer your questions. You will be asked to sign or tick a form to agree your participation.

**Study visit 2: assessments for blood pressure and fatigue (15 minutes)**
A healthcare professional will check your blood pressure whilst you are laying down and again once they have helped you sit upright. They will also ask you to score your level of fatigue (tiredness) using a scale of 0-10.
Both of these measures will help the researchers ensure that each of the two physiotherapy groups have a similar amount of people. For example, each of the two physiotherapy groups will have a similar amount of people

**Study visit 3: baseline assessments (60 minutes)**
- Assessments.
These include your ability to carry out activities of daily living. They will also test your muscles (for strength, length and stiffness) and your balance.
- Washing, dressing, getting in and out of a chair or bed and moving around
Study visit 4: immediately after your physiotherapy programme (60 minutes)

- Assessments.

These include your ability to carry out activities of daily living. They will also test your muscles (for strength, length and stiffness) and your balance.

Washing, dressing, getting in and out of a chair or bed and moving around

Study visit 5: after your physiotherapy programme (60 minutes)

- Interviews.

We would like to interview you to find out your experience of the physiotherapy programme as well as understand how you felt about being randomly allocated into one of the two different groups. The interview will last no longer than one hour and will take place within seven days after you have finished the physiotherapy. This may take place in hospital or your place of residence, depending on whether you have been discharged from hospital on the date of the interview. The interview will be digitally

Study visit 6: 3 months after your physiotherapy programme (60 minutes)

- Assessments.

These include your ability to carry out activities of daily living, such as washing, dressing, getting in and out of a chair bed and moving around. They will also test your muscles (for strength, length and stiffness) and your balance. This visit will be undertaken in your place of residence (e.g. where ever you are living).

These will be the same measures in Study Visits 3 and 4.

Study visit 7: 6 months after your physiotherapy programme (60 minutes)

- Assessments.

These include your ability to carry out activities of daily living, such as washing, dressing, getting in and out of a chair bed and moving around. They will also test your muscles (for strength, length and stiffness) and your balance. This visit will be undertaken in your place of residence (e.g. where ever you are living).

These will be the same measures in Study Visit 6.

Study visit 8: 12 months after your physiotherapy programme (60 minutes)

- Assessments.

These include your ability to carry out activities of daily living, such as washing, dressing, getting in and out of a chair bed and moving around. They will also test your muscles (for strength, length and stiffness) and your balance. This visit will be undertaken in your place of residence (e.g. where ever you are living).

These will be the same measures in Study Visits 6 and 7.
Study visit 1 - screening and consent
At the first visit a member of the research team (the Principal Investigator) will explain what the research study is about. They will answer any questions you may have about the study. If you decide to take part you will be asked to sign a consent form and be given a copy to keep.

Study visit 2 - assessments for blood pressure and fatigue
During this visit a healthcare professional will check your blood pressure and ask you to score your level of fatigue (tiredness). There is a chance that study visits 2 and 3 could be on the same day, but you will have a break in between the two.

Study visit 3 - baseline assessments
Your third visit will be immediately before you start your physiotherapy programme.
At this visit you will undergo assessments to provide a baseline from which to compare any progress through the study. Firstly, the physiotherapist will assess your function by asking you questions about your ability to perform activities of daily living. Questions will be about your ability to care for yourself such as washing and dressing, shaving, eating and drinking as well as your ability to get yourself in and out of bed or chair.

You will then undergo some physical assessments. These will include:
- Assessing your muscles to test their strength, length and stiffness
- Assessing your ability to move and maintain your balance whilst sitting down

You can have a rest during these assessments. The physiotherapist will then ask you some questions about fatigue (extreme tiredness as a result of your stroke) and emotions (whether your stroke has affected your emotions/mood, e.g. you are tearful or feel frustrated).

Study visit 4 - immediately after your three week physiotherapy programme
Your fourth visit will be immediately after you have finished your three week physiotherapy programme. At this visit you will repeat all the assessments that you did at the start of the study (study visit 2). The aim of repeating these assessments is to find out how you are now that the study physiotherapy programme has stopped.

Study visit 5 - interviews
During your fifth visit the researcher, Angie Logan, will ask you some questions to find out:
- Your thoughts and feelings about the information you were given before and during the study
- Your thoughts, feelings and experiences of being randomly allocated into one of two physiotherapy programmes
- Your thoughts, feelings and experiences of undertaking the functional standing frame programme (if you were allocated to this group)
- Your thoughts, feelings and experiences about the assessments that you undertook.

You can have a rest during the interview. The interview will take place in a private, quiet location. You can have a family member or carer with you during the interview if you prefer.

The interview will be undertaken by the researcher who is professionally trained in interviewing people and highly skilled in working with people with stroke.

Study visits 6, 7 and 8
Study visits 6, 7 and 8 will be repeating the assessments conducted in study visits 3 and 4. Study visit 8 will be the final visit.
What are the possible disadvantages and risks of taking part?

We don’t expect you to be harmed in any way by taking part in this study. There is a possibility that you might experience some side effects - most commonly muscle aches and pains and tiredness. However, these are often short lived. During the interview and some of your study visits you will be asked questions about your experience of your stroke and its impact on your day-to-day life which might be potentially sensitive or upsetting. The researchers and physiotherapists are professionally trained and will ask questions sensitively. You do not have to answer questions which cause you to feel upset. You can also speak to anyone from the research or clinical care team, if you wish to do so.

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. If the study results suggest that it is possible for people with severe stroke to undertake a functional standing frame programme as part of their rehabilitation, this will allow us to find out what benefits the programme will have. This may lead to improved rehabilitation programmes for people with severe stroke.

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 you receive for your stroke. You do not have to take part and you do not have to give a reason for this. However, if you are willing to share your reasons with the researcher, this will be useful to us when we design other studies in the future.

If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form.

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

You are free to withdraw from the study at any time without your medical care or legal rights being affected. If you want to withdraw from the study you do not have to give a reason for this; however, if you are willing to 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.

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.<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
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 filling 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. Copies of the study information (e.g. your signed Consent Form) will be held securely at your local hospital. Only members of the research team and PenCTU at Plymouth University will have direct access to the study information.

Authorised people from your NHS Trust, PenCTU and the research team may need to review your medical records and the interview transcript to 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 researcher, Angie Logan, 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

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.

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

Once your participation in the study has ended, your usual stroke care will continue as before. 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. 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.

Involvement of your General Practitioner (GP) / family doctor

Your GP will be informed of your participation in this study.

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 PenCTU at Plymouth University and overseen by Royal Cornwall Hospitals NHS Trust.

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 <enter name> Research Ethics Committee and the Research and Development departments at Cornwall Partnership Foundation NHS and Royal Devon and Exeter.