Patient information Sheet (Main study)

Study Title: Does early targeted trunk training improve mobility outcome at 6 months for individuals who are unable to sit unsupported at admission after stroke? A mixed method feasibility study

Invitation

You are being invited to take part in the above study funded by the National Institute of Health Research (NIHR) Research for Patient Benefit. Before you decide to participate, it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully. You can also talk to others about the study if you wish.

Purpose and background to the study

Many people after stroke have difficulties moving about in their home and this continues to be an area of concern for many years. Previous research has shown that the function of the trunk (the area of the body between the neck and hips) is affected after stroke and importantly, this affects how well survivors recover from stroke. In fact, there is evidence which show that those individuals whose trunks are severely affected by stroke are very likely to have problems moving about at six months. It would be very beneficial to direct therapy at improving trunk function during rehabilitation especially because of this impact on recovery. Our study hopes to do this by adding a trunk training exercise intervention to the rehabilitation delivered by Physiotherapists early after stroke to improve recovery.

However, in order to find out if additional exercise training will work, we need to first find out if we can actually carry out such a study during early rehabilitation. This is why we are inviting you to volunteer for this study to enable us find out how easily we can do this.

What's involved in the study?

If you decide to participate, you will be given, in addition to your normal rehabilitation, a minimum of 16 hours of extra exercise in the first 6-8 weeks after your stroke to improve the strength and function of your trunk muscles. The exercises will be performed in bed or sitting or standing as appropriate and will include activities to strengthen your trunk muscles and help you regain the ability to turn and sit up in bed, transfer from bed, sit to stand and walk. Each additional trunk training session will be for between 30 – 40 minutes, every week day, for at least 6 weeks, to complete the 16 hours training. The exercises will be steadily progressed during each session and over the course 6 weeks, through increasing repetitions and amount of work done by the trunk muscles. The exercises will be planned around your normal daily treatment given by your in-hospital or community care team, and will avoid disruptions to your on-going rehabilitation. If you are discharged from the hospital before we complete this planned exercise dose, we would continue them at your home or wherever you are discharged to. The additional exercises will be delivered by an experienced physiotherapist and a therapy assistant. Before you start the additional exercises, at the end of the training and at six months after stroke, we will assess the performance of your trunk

muscles, your ability to move about and ask you questions about your quality of life. These assessments involve the use of activities and questionnaires similar to those used by Physiotherapists to assess functioning during routine rehabilitation. We will also document your use of hospital services such as social support, General Practitioner (GP) and hospital visits throughout the study. The assessments at the end of the training and at 6 months will be conducted in your home environment or wherever you are discharged to. Additional information about the type of stroke and your pre-existing condition before the stroke will be collected from your medical notes and if you agree, your GP will be informed about your participation in the study. You will be involved in the study for no more than six months.

What to expect during the consent process

If you are interested in participating after today, you will be given at least 24 hours to decide your participation, ask questions and consult your clinical team before consenting to participate. After you have received satisfactory answers to your questions, you will be required to complete a consent form before you will be included in the study.

What are the possible benefits of taking part?

Participation in this study will give you the opportunity to receive an enhanced rehabilitation in terms of additional training of trunk muscles and mobility skills required for your activities of daily living. We are not certain if this will improve the outcome of your rehabilitation but evidence in those with a mixed ability in the trunk suggest it might.

What are the possible disadvantages and risks of taking part?

There is a possibility that this additional training can induce fatigue and muscle soreness in some individuals. However, we would be monitoring this and would pace your exercises according to your comfort levels.

What if something goes wrong?

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 [Dr Isaac Sorinola; Tel: 020 7848 8170; email: isaac.2.sorinola@kcl.ac.uk]. If you remain unhappy and wish to complain formally, you can do this through the Guy's and St Thomas' Patients Advice and Liaison Service (PALS) on 020 7188 8801, pals@gstt.nhs.uk. The PALS team are based in the main entrance on the ground floor at St Thomas' Hospital and on the ground floor at Guy's Hospital in the Tower Wing.

In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against Guy's and St Thomas' NHS Foundation Trust and/or King's College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time without having to give any reason. If you decide to withdraw from the study, this will not have any effect on your ongoing hospital rehabilitation or out-patient rehabilitation.

How will my information be kept confidential?

Only members of our research team (Dr Isaac Sorinola, Dr Claire White, Dr Caroline Burgess, Prof Tony Rudd, Mr Gareth Jones and the research assistants) will have access to your data. In addition, you will not be identifiable from the results of the work. You will be assigned a research number and your information will be referred to by using this number, not your name. There will only be one copy of the list matching numbers and names and this will be kept in a locked secured cabinet in the Chief investigator's office in King's College London. The procedures for handling, processing, storage and destruction of your data are compliant with the Data Protection Act 1998. This means that the data will be stored securely for 7 years before destruction.

What will happen to the results of this study?

The results of the study will be utilised to plan the next phase of the research work and support funding application. In addition, it will be used as part of published articles and presentations to scientists, clinicians and NHS policy makers. Participants will be invited at a later date to a meeting where the results of the study will be presented in lay language.

Who is organising and funding this study?

This study is sponsored by both King's College London and Guy's and St Thomas Foundation NHS Trust and funded by the National Institute of Health Research (NIHR) Research for Patient Benefit scheme.

How have patients and the public been involved in this study?

The research questions and aims of this study were derived through consultation with the South London Stroke Patient User Group. Members of this group would also be on the study steering committee and will be actively involved in the conduct of the study, analysis and dissemination.

Who has reviewed this study?

The study has been peer reviewed by independent external assessors of the scientific committee of the NIHR Research for Patient Benefit and approved for funding. It has also been approved by the Research and Development Unit of Guy's & St Thomas Foundation Hospital, the Research Design Service London, the senior staff of the Division of Health and Social Care Research, King's College London and the East of England - Essex Research Ethics Committee.

Further information and contact details:

Dr Isaac Sorinola
Academic Dept. of Physiotherapy and Health & Social Care Research Division,
Faculty of Life Sciences & Medicine, King's College London, Rm. 3.24 Shepherd's House,
SE1 1UL, UK

Version 2
Email: isaac.2.sorinola@kcl.ac.uk.