



**London South Bank
University**

Guy's and St Thomas'
NHS Foundation Trust **NHS**

INFORMATION SHEET FOR PARTICIPANTS

Study title: The Effect of Pause Phase Duration on Dynamic Stability During Sit-to-Stand-and-Walk: A Comparison Between Stroke and Healthy Individuals (Phase 1)

Invitation to participate

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Please ask us if there is anything that is not clear or if you would like more information. This study will be used for partial fulfilment of a PhD by Gareth Jones the research physiotherapist involved in the study from Kings College London. Please take time to decide whether or not you wish to take part.

Purpose of the study

We are interested in finding out how differently stroke patients execute everyday but complicated movements. In order to do this, it is important to compare stroke patients' performance with similarly aged people who have not had a stroke. We are particularly interested in movements from sitting to walking straight ahead and then stopping to turn off a switch. We think that by finding out how stroke patients execute these everyday movements compared to individuals who have not had a stroke, we will be able to measure recovery from stroke better and be able to see if newly designed rehabilitation programmes work better.

Why have I been chosen and do I have to take part?

We are looking for healthy aged individuals aged over 18 years, who are within 1 year of the date-of-birth, and are of similar height and weight of the stroke patients we have already recruited to this study.

It is up to you to decide whether or not to take part. If you decide to do so you will be given this information sheet to keep and be asked to sign a consent form. You are free to withdraw at any time, without the need to give any reasons.

What will happen if I take part?

If you are interested as a participant today, then you will be given this information sheet to read and consider. The researcher will also today arrange a time to telephone you tomorrow, or at another convenient time, to ask if you are still interested in participating. If you are then we will arrange a time for you to attend the gait laboratory at London Southbank University where the research is taking place.

Here the researcher will ask you to change into some gym clothing, take down some body measurements, record your name and date of birth, see how fast you walk, and ask you to take a few minutes to complete a health questionnaire. Then they will attach some small markers to your body. Then the researcher will ask you to sit on a stool, stand up, pause, and walk straight ahead to turn of the light at a switch in front of you.

This is described below in more detail. We will pre-arrange and pay for a taxi to transport you to and from your home address.

Your GP will be informed of your participation in this study by letter subject to your approval (respond “Y” to statement no. 8 of the consent form).

What do I have to do?

If you agree to take part, we will invite you to attend the gait laboratory at London South Bank University for a morning or afternoon session which will take up to a maximum of 1.5 hours.

When you arrive the investigator will measure your weight, height, the width of your shoulders, and your knee height in standing. You will then have a number of small spherical markers attached to points on your skin with sticking tape, and additionally lightweight plastic mounts with markers imbedded in them will be wrapped to your upper-arms, forearms, thighs and shins.

Your skin will need to be exposed for this and you will be barefoot – you will be asked to bring and wear suitable clothing, for example sports underwear/cycling shorts or similar, or we will provide this if you do not have any. There is a changing room available. You will then be asked to stand still while a 3-dimensional measurement system comprising 8 cameras records the position of the markers for 5-10 seconds. This might need to be repeated. Some of the markers will then be removed before the researcher will ask you to repeatedly stand up from sitting on a height adjustable stool and walk at a comfortable pace 5m forward in a straight line along a walkway, stop and operate a switch. The signal to commence the tasks will be a light source in front of you. There will be 4 force plates imbedded at the level of the walkway at the beginning and another longer one towards the end. You will be asked to lead with your non-dominant leg (the opposite side to the hand you write with). We will aim to capture 10 walks. The cameras will track your movement via the markers during these walks.

What will happen with the information collected?

The information we will collect as part of this study, if you agree to participate, is the following:

Questionnaire information collected during your visit which will include your name, date of birth, telephone number, a completed health questionnaire which will take you a few minutes to complete, physical measurements, and tracking data from the markers you will wear.

Your name, date of birth and telephone number will be stored securely on university password-protected computers or on an encrypted external storage device, and this information is for reference only – it will not be used directly in any other way. Other collected information will not include your name or other identifiable features, and will be analysed by either Gareth Jones at London Southbank University or Kings College London. The findings of the study will be circulated in published journal articles, conference presentations and grant reports, and will not include information on your identity or contact details

Disadvantages and risks of taking part

There will be no risks associated with this research. All analysed data will not include your name or other identifiable features ensuring complete confidentiality. Your identity will not be revealed to those outside the research team.

Your initial physical assessment and application/removal of markers has the potential to cause you mild temporary discomfort and/or inconvenience. The researcher is trained to undertake these tasks and is familiar with the local Code of Practice for Research Involving Human Participants. All markers will be attached to

your skin with hypoallergenic tape and you will be asked if you have any allergy or intolerance to sticking tape used before you are included in the study.

You will be required to wear suitable clothing to expose the markers attached to your body. Private changing facilities are available at the gait laboratory LSBU for your use. The gait laboratory is not situated on a pedestrian through-route, and is accessed only via a relevant security swipe-card – therefore, there is minimal risk of unscheduled visitors or observers being involved in your visit. There will always be two experienced researchers present and all care will be given to ensure your comfort, safety, and dignity at all times.

We understand that your visit to the laboratory will last up to a period of 1.5 hours. We will encourage you therefore to bring snacks to eat, fluids and any prescribed medications you need for the duration of the session. Necessary breaks will be offered to you in addition.

The benefits of taking part

In agreeing to participate, the benefits to you include helping us understand the best way to measure sitting-to-walk so we can understand the difficulties people have after stroke with this common everyday task. We will be able to provide copies of our final report of findings when it has been prepared and reviewed. The findings of this study will be disseminated in an examined PhD dissertation and on the discretion of the project supervisor potentially submitted for publication in peer-reviewed scientific journals.

What happens 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 [Gareth Jones on 02071885082, gareth.jones@gstt.nhs.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 and this is due to someone's negligence then you may have grounds for legal action for compensation against Guy's and St Thomas' NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Who has reviewed this study?

The Health Research Authority has approved the study on behalf of the NHS in England. (Copies of the approvals are available upon request).

Confidentiality

All information that is collected about you during the course of the research will be kept strictly confidential. Access to personal data obtained during data collection will be possible only by the research team (contact details are at the end of this sheet).

Further information and complaints

If you require further advice about this study at any time, or have any complaints you may contact your GP or Mr Gareth Jones who will do their best to address any of your concerns. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital reception and/or of the Hospital Trust Research and Development Office.

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