Newcastle Clinical Ageing Research Unit
Newcastle University
Campus for Ageing & Vitality
Newcastle upon Tyne
NE4 5PL

Telephone: 0191 208 1250
Fax: 0191 208 1251
www.ncl.ac.uk/crp

PARTICIPANT INFORMATION SHEET

The effect of tDCS on cortical and motor activity during walking in young and older adults: a pilot study

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The aim of this study is to investigate differences in brain activity upon application of non-invasive brain stimulation during walking between two groups; healthy older adults and healthy young adults. For healthy older adults walking becomes more difficult and may result in loss of balance and falls. Whilst completing daily activities, carrying out two tasks at once (dual-task) such as walking and talking, is crucial for effective functioning. Research suggests people with Parkinson's disease find it more difficult to walk when distracted by a dual-task, in comparison to healthy older adults. This is related to dysfunction of areas of the brain related to cognition and walking.

Currently, an invasive technique called deep brain stimulation (DBS) is used to treat Parkinson's disease (PD). DBS is linked to improved motor deficits through modulation of brain activity in some patients. The principle of brain stimulation is to restore clinical function by reversing abnormalities in brain activity and physiology caused by PD. Lower activation of motor regions of the brain have been observed in PD in comparison to healthy older adults. Brain stimulation of motor circuits through non-invasive means, such as transcranial direct current stimulation (tDCS), has potential in improving activation levels and subsequently improve motor function. Research indicates tDCS may improve the efficacy of rehabilitative interventions when combined with physical therapy. Greater understanding of the brain pathways/activity affected by stimulation and dual-task will help with development of individualised therapeutic interventions. Brain cortical activity plays an important role during

walking and is associated with cognition. Cognitive impairments such as attention or memory problems are common with ageing. Cognitive cortical activity can be monitored during walking using functional near infra-red spectroscopy (fNIRS), which is non-invasive and currently used within research.

We are interested in how attention and thought processes relate to problems of walking associated with ageing. Investigating cortical (brain) activity will help us to understand these problems during walking better and potentially lead to improved interventions.

We will identify two groups of adults 1) Healthy older adults, and 2) Healthy young adults within the Newcastle upon Tyne area. We will assess the participant brain cortical activity during walking on a treadmill under different conditions (such as; with distraction or with an auditory cue).

Why have I been chosen?

It is important for us to recruit several groups of participants; an older adult group, and a young adult group to assist us with the study.

You have been selected to be a participant in one of these groups. The groups will be tested in the same manner, which will allow us to compare findings between the groups. This will help us determine age-specific processes from other processes.

Do I have to take part?

It is up to you whether you decide to participate. If you do decide to participate you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part you are still free to withdraw from the study at any time and do not have to give a reason. This will not have any influence upon the treatment or standard of care that you receive in future.

What will happen to me if I take part?

This study will involve one visit that can be arranged at your convenience. The full assessment will take up to 3 hours, with rests as required. If you decide to take part you will be invited to undergo an assessment which will take place at the Institute of Neuroscience, Newcastle University. The assessments will be conducted by researchers at Newcastle University, all members of the Brain and Movement Research team.

The **first part** of the assessment will last up to 60 minutes and involves:

1. A review of your medical history, level of education, your occupation, activity levels and falls history.
2. Some simple questionnaires about how confident you feel with your balance and your mobility.
3. Straightforward tests of memory, language and problem-solving, which involve pencil and paper. There will be someone with you to assist at all times. Most people find these tests quite enjoyable!

The **second part** of the assessment involves tests of brain cortical activity and applying non-invasive brain stimulation during brief walking periods on a treadmill, lasting up to approximately 90 minutes. Regular breaks will be undertaken during this period. The total period of walking is 20 minutes.

The cortical activity during walking on a treadmill testing will involve:

1. Walking under different conditions; for example: completing verbal numeracy test.
2. You will wear a head-mounted combined functional near infra-red spectroscopy (fNIRS)/transcranial direct current stimulation (tDCS) device (equivalent to a swimming cap). Two small electrodes for the tDCS will be secured on to your head with two rubber straps. You may experience a mild tingling/itching sensation upon application of stimulation from the tDCS.

You will need to bring any glasses that you wear with you to the testing.

What are the possible disadvantages or risks of taking part?

There are no major disadvantages or risks in taking part in this study. tDCS uses low currents and does not require direct brain-electrode contact, meaning it can be used safely with no adverse effects. Side effects are limited to mild tingling/itching sensation, with a small risk of headache and fatigue. Additionally, the caps may be uncomfortable over time.

What are the possible benefits of taking part?

The benefit of taking part in this research is that it will increase our knowledge of cortical problems occurring during walking with ageing. We will be able to collect information about the frequency and nature of these problems and investigate their cause. This may aid in the development of new treatments or interventions for walking issues in older adults. Please note that there will be no direct benefit to you participating in this study. However, with your permission, we will inform your local doctor or relevant medical practitioner of any findings that may warrant further attention.

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

You can withdraw from the study at any time. All information collected is useful and may still be utilised. Your withdrawal would not affect the standard of care that you can expect to receive in the future.

If you have memory problems, which could make it difficult for you to tell us if you do not want to carry on. We will discuss this with you and your relative or carer (if applicable) before starting any tests. Should, in the event of you being unable to tell us yourself, your relative or carer express concerns about you carrying on, we will withdraw your participation in the study.

What if there is a problem?

This is an observational study involving assessment. Sometimes previously unrecognized medical issues may be identified during the assessment that may require further attention. In this instance the researcher who assesses you will take appropriate action. This will usually mean writing to your GP who can assess matters further.

If you have a concern about any aspect of this study, you should ask to speak to Dr. Annette Pantall who will answer your questions (contact number 0191 208 1247).

Who is the sponsor and data controller for this research?

Newcastle University is the sponsor for this study based in the United Kingdom. Newcastle University will be using information from you to undertake this study and will act as the data controller for this study. This means that Newcastle University is responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited, as Newcastle University need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, Newcastle University will

keep the information about you that has already been obtained. To safeguard your rights, the minimum personally identifiable information will be used. You can find out more about how Newcastle University uses your information by contacting their Data Protection Officer [rec-man@ncl.ac.uk].

Will my taking part in the study be kept confidential?

All data samples collected as part of this study are anonymised with participants being assigned a unique study number (e.g. OA1 or YA1). All electronically stored data (e.g. videos) will be named using the individuals study number to ensure confidentiality. Facial features will be recognisable from the video and/or photographs. A video and/or photographs help us to verify the data and if you agree, we may use it for presentations at conferences or seminars. However, this is not an essential aspect of the testing and if you would rather not have your video and/or photographs taken this is not a problem. The only information we will retain for our database will be the age and sex of participants and whether they are a patient. We will keep one hard copy of the assessment in the Clinical Ageing Research Unit. This is the only place where we store any personal details like names and addresses. This information is kept locked away and is only available to people directly running the study. These people will treat your information in the strictest confidence. Dr. Annette Pantall, the Principal Investigator of this study, is ultimately responsible for the protection of this information.

The results of any tests are kept strictly confidential. Our plan is to keep the test data for 5 years, after which it will be securely disposed of.

What will happen to the results of the research study?

Once we have results we will aim to publish them in peer reviewed scientific journals. We will also present the findings at international meetings. No participant-identifiable information will be included in any written or oral output from the study. If participants would like copies of any publications then they can contact the researchers involved to request them.

Participants in the study will be sent an annual newsletter that briefly details the progress of the study. Key findings will be outlined in a final newsletter at the end of the study. If participants express an interest we will provide specific feedback on results of the tests.

Who is organizing and funding the research?

Dr Annette Pantall (Principle investigator of this study), Dr Lisa Alcock and Aisha Islam will supervise the running of the study and will conduct the assessments, together with members of the CARU Research team.

Who has reviewed the study?

This study has been reviewed and approved by the Newcastle University research ethics committee. Newcastle University has agreed to provide indemnity insurance for the study.
We are trying to improve the quality of clinical and research standards. This is being achieved through 'clinical governance'. As part of this process, this study may be reviewed by a clinical governance team. Such a team would need to look at any information that you provide us with to make sure that the research was carried out in accordance with proper procedures.

Thank you for taking the time to read this. You may keep this information sheet.

Further Information

Contact for further specific information:

Dr Annette Pantall
Research Fellow
Clinical Ageing Research Unit
Newcastle University
Newcastle
NE4 5PL
Tel: 0191 208 1247 (direct)/ 0191 208 1250 (general line)
Fax: 0191 208 1251
Email: annette.pantall@ncl.ac.uk