

# Non-invasive brain stimulation to improve walking and brain activity in older adults

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<b>Registration date</b> 29/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/05/2022	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Difficulties in walking are common in older people. Treatments developed to improve walking include transcranial direct current stimulation (tDCS) which is a generally painless, non-invasive treatment. This study aims to investigate:

1. Does tDCS change brain activity in the areas associated with thinking (cognition) and motor activity?
2. Does tDCS changing walking patterns such as step time or step length?
3. Is there a difference in how tDCS affects younger and older people?

### Who can participate?

Healthy volunteers aged between 18-40 years and aged 60 years and over

### What does the study involve?

Firstly, the participants complete several questionnaires which include assessing fear of falling, balance confidence and mental function. A special cap with optic emitters and sensors (functional near-infrared spectroscopy) which measures brain activity is then placed on the participant's head. Small stimulating electrodes are also positioned within the cap. A small movement sensor (accelerometer) is placed on the lower back which records walking features. The participant walks on the treadmill for 10 minutes at their preferred walking speed. A very low current is then sent through the electrodes, which stimulates nerve cells involved with leg movement and planning movements. The tDCS is applied for 20 minutes whilst the participant is walking on a treadmill. The participant walks for another 10 minutes after the tDCS is applied.

### What are the possible benefits and risks of participating?

There are no direct benefits to the participant although this study will provide a better understanding of tDCS and its effect on walking. The risks of participating are that the treadmill walking may be tiring and the special cap may be uncomfortable to wear over a long period. This novel study will provide important information regarding the mechanism of tDCS.

### Where is the study run from?

Newcastle University (UK)

When is the study starting and how long is it expected to run for?  
July 2018 to July 2019

Who is funding the study?

1. Newcastle University (UK)
2. Reece Foundation (UK)
3. Brazilian Federal Agency for Support and Evaluation of Graduate Education (Brazil)
4. Barbour Foundation (UK)

Who is the main contact?

Dr Annette Pantall  
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## Contact information

### Type(s)

Scientific

### Contact name

Dr Annette Pantall

### ORCID ID

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

6770/2018

## Study information

### Scientific Title

The effect of transcranial direct current stimulation on complex treadmill walking and cortical activity: a pilot study

## Study objectives

Transcranial direct current stimulation (tDCS) combined with treadmill walking for 20 minutes:

1. Increases cortical activity (as measured by functional near-infrared spectroscopy) in the prefrontal region and primary motor region
2. Modifies gait parameters
3. Affects cortical and gait parameters differently depending on age

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 19/07/2018, Newcastle University Ethics Committee (Newcastle University, Newcastle upon Tyne, Tyne and Wear, NE1 7RU, UK; +44 (0) 191 208 6000; fmsethics@ncl.ac.uk ), ref: 6770 /2018

## Study design

Interventional single-centre double-blinded randomized study.

## Primary study design

Interventional

## Study type(s)

Other

## Health condition(s) or problem(s) studied

Age-related gait impairment

## Interventions

This study uses a double-blinded, randomised, sham-controlled design. Forty-four participants are recruited and assigned into two groups: healthy young adults (YA; n = 23) and healthy older adults (OA; n = 21). Prior to the experiment, OA and YA are randomly allocated to active tDCS intervention (active-OA and active-YA) or control sham tDCS intervention (sham-OA and sham-YA). Participants are randomised by creating vectors of alternating integers 1 (stim) and 2 (sham) and applying the MatLab randperm function to each of the vectors. This randomisation vector was created at the beginning of the study. Participants are then sequentially given a number of the randomised code which determines if they receive active or sham stimulation.

Participants perform a total of 20-min single-task treadmill walking (STW) at a self-selected speed combined with anodal tDCS. Only the experimenter that applied the tDCS is aware of the intervention allocation of the individual (active or sham) to ensure both the participant and other experimenters are blinded. The active group receives anodal tDCS over the M1 at Cz (over the vertex) and the left prefrontal cortex (PFC), between AF3 to Fp1 (9 cm anterior and 3 cm lateral to Cz), on the 10/20 EEG system. The cathode (5 x 5 cm<sup>2</sup>) is positioned over the right mastoid, contralateral to the left PFC. tDCS is delivered at 0.6 mA for 20-min with a ramp-up of 10 s, using a 3 x 3 cm<sup>2</sup> electrode. The current density is maintained at 0.067 mA/cm<sup>2</sup>, within the recommended safety limits (0.029 to 0.08 mA/cm<sup>2</sup>). In the sham stimulation, the tDCS montage is the same, but the current ramps down 10s after the beginning of stimulation. This montage provides a similar sensation of active stimulation but does not induce neurophysiological changes.

## Intervention Type

Device

## Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

tDCS stimulator (HDCstim, Newronika, Milan, Italy)

## Primary outcome(s)

Cortical activity is assessed using functional near-infrared spectroscopy which measures oxygenated haemoglobin levels (HbO<sub>2</sub>), from which cortical activity can be inferred. HbO<sub>2</sub> is recorded during the 5-minute pre-intervention treadmill walking, during the 20-minute treadmill walking with tDCS and during the 5-minute post-intervention treadmill walking.

## Key secondary outcome(s)

1. Gait is measured using an accelerometer (Axivity, Newcastle, UK) placed on the lower back during the 5-minute pre-intervention treadmill walking and 20 minutes later during the 5-minute post-intervention treadmill walking. Gait parameters are extracted from the accelerometry data using previously validated algorithms. Initial contact and final contact detection times are used to estimate the step and stance time. Step/stride length is determined from the initial contact events through the application of the inverted pendulum model.
2. Cognitive performance is measured with a cognitive vigilance task before and after the 20-minute tDCS intervention. This task involves the person listening to a sequence of odd or even numbers. The person then has to state how many odd or even numbers they heard. The performance is quantified by the absolute error (difference between the correct answer and the response given by the participant) and expressed as a percentage (0% indicates that there is no error)
3. Dual-task motor costs are calculated before and after the 20-minute tDCS intervention. Dual-task motor cost is the difference in a gait parameter (e.g step length) between the value of the parameter when single task walking compared to dual-task walking.
4. Global cognitive function is assessed with the Montreal Cognitive Assessment (MoCA) prior to the 20-minute tDCS intervention
5. Fear of falling is assessed with the Falls Efficacy Scale - International (FES-I) score prior to the 20-minute tDCS intervention
6. Muscle activity is recorded with electromyography (EMG) during the 5-minute pre-intervention treadmill walking, during the 20-minute treadmill walking with tDCS and during the 5-minute post-intervention treadmill walking. EMG electrodes are placed on the leg muscles tibialis anterior, soleus, lateral gastrocnemius and medial gastrocnemius.

## Completion date

18/07/2019

## Eligibility

### Key inclusion criteria

1. Young adults aged between 18-40 years and older adults aged ≥60 years
2. Able to walk unaided on a treadmill for 5 min
3. Good English language comprehension

### Participant type(s)

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

40 years

**Sex**

All

**Total final enrolment**

44

**Key exclusion criteria**

1. Adults aged <18 years and between 41-60 years
2. Not able to walk unaided for 5 min
3. Poor English language comprehension
4. Cognitive impairment (Montreal Cognitive Assessment [MoCA] score  $\leq 21$ )
5. Psychiatric co-morbidities
6. History of drug or alcohol abuse
7. Chronic musculoskeletal, cardiovascular or respiratory disease affecting gait
8. Implanted metal objects
9. A history of seizures or any contraindication to tDCS

**Date of first enrolment**

20/07/2018

**Date of final enrolment**

10/05/2019

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Newcastle University

Henry Wellcome Building

Faculty of Medical Sciences

Newcastle upon Tyne  
United Kingdom  
NE1 7RU

## Sponsor information

### Organisation

Newcastle University

### ROR

<https://ror.org/01kj2bm70>

## Funder(s)

### Funder type

University/education

### Funder Name

Newcastle University

### Alternative Name(s)

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Universities (academic only)

### Location

United Kingdom

### Funder Name

Reece Foundation

### Funder Name

Brazilian Federal Agency for Support and Evaluation of Graduate Education

### Funder Name

## Results and Publications

### Individual participant data (IPD) sharing plan

Participant level data is available on request and will be placed in the publicly available repository data.ncl (<https://data.ncl.ac.uk/>). The type of data stored will include processed HbO<sub>2</sub> data, gait parameters, EMG, cognitive scores and demographic data. Consent was obtained from participants for anonymised data to be shared. All data are anonymised with participants given the prefix OA or YA followed by a number. No birth dates are included.

### IPD sharing plan summary

Stored in publicly available repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		03/12/2021	24/05/2022	Yes	No
<a href="#">Participant information sheet</a>	version 1.0	01/08/2018	22/10/2021	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>			22/10/2021	No	No