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

Submission date	Recruitment status	[_] Prospectively registered
27/09/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/11/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/05/2022	Other	

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?
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Contact information

Type(s)
Scientific

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Additional identifiers

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

Primary study design
Interventional

Study design
Interventional single-centre double-blinded randomized study.

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^2) 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^2 electrode. The current density is maintained at 0.067 mA/cm^2, within the recommended safety limits (0.029 to 0.08 mA/cm^2). 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_2), from which cortical activity can be inferred. HbO_2 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 ≤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 Welcome 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
Barbour Foundation

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_2 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?
Results article		03/12/2021	24/05/2022	Yes	No
Participant information sheet	version 1.0	01/08/2018	22/10/2021	No	Yes
Protocol file			22/10/2021	No	No