Enhancing motor learning in healthy older adults through non-invasive brain stimulation

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43120

Source
ToetsingOnline

Brief title
Enhancing motor learning in elderly through non-invasive brain stimulation

Condition

- Other condition

Synonym
getting older, healthy ageing

Health condition

gezonde veroudering

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Twente
Source(s) of monetary or material Support: NWO ORA Plus

Intervention

Keyword: ageing, motor learning, tDCS

Outcome measures

Primary outcome

Participants will perform a sequence-learning task, performance on this task will provide the main outcome parameters. The participant uses a response box to learn to tap a 5-element sequence as many times as possible in a 3 minute time period. All right-hand fingers excluding the thumb are used. In total, 8 blocks of 3 minutes tapping are included. In the fixed-sequence blocks (Baseline Sequence, and practice blocks 1 to 5), a fixed sequence is displayed continuously on the computer screen. In the random-sequence blocks (1 block before and 1 block after the fixed-sequence blocks), a new random sequence is to be performed after every sequence performance.

The main study parameter will be the number of sequences performed correctly, relative to the baseline sequence block, during each practice block.

Secondary outcome

The secondary study parameter will be the number of random sequences performed correctly in the post-test random sequence block, relative to the baseline random sequence block.

Study description

Background summary

Transcranial direct current stimulation (tDCS) is a technique that can increase excitability of the cortex. It has been used in many studies, including young and older adults (YA and OA), to enhance cognitive performance. In the light of the current aging population, enhancing cognition in healthy OA is a promising direction of research. Unfortunately, results have not been consistent and differential findings between YA and OA are understood poorly. Accordingly, there has been a call to advance the field by taking a more systematic approach. Therefore, we aim to conduct a study that replicates an important existing result, namely, that tDCS can enhance motor (sequence) learning in OA. To better understand previous findings of differential results between age groups, we will extend the existing study with an extra learning condition that will allow us to tear apart contributions of tDCS to task-general and sequence-specific learning in OA and YA. Because higher age is often related to reduced dexterity, we expect a larger effect of tDCS on task-general learning in OA compared to YA.

Study objective

We focus on a previous study showing enhanced motor sequence learning performance in OA when coupled with active tDCS stimulation. In their study, Zimerman et al. (2013) found a facilitating effect of M1 anodal tDCS on sequence learning in OA, these effects were still present during retention tests. Surprisingly, they found no effect of atDCS on learning in YA and no learning at all in the OA sham control condition. The Zimerman et al. (2013) study warrants replication in order to: 1) confirm the important main result of facilitation of sequence learning in OA; 2) confirm the unexpected findings regarding the YA and sham conditions; and 3) to potentially extend these results by testing additional hypotheses. Specifically, an opportunity to extend on the previous findings is to include random sequences in the practice and retention sessions. This allows us to distinguish between tDCS contributions to task-general versus sequence-specific learning.

Study design

The study follows a two (Age Group: YA versus OA) * two (tDCS Condition: atDCS versus sham, within subjects) design. tDCS Conditions will be separated by at least 10 days and blinded to participants and experiment leader.

Intervention

We will treat participants with a Neuroelectrics Starstim tCS, a class IIa

device according to the classification in the Council Directive 93/42/CEE for medical devices. TDCS will be delivered through rubber electrodes housed in 25 cm2 saline-soaked sponges. In both stimulation conditions, the anode electrode will be placed above the hand area of the left primary motor cortex (C3 will be localized using the 10-20 EEG system); the cathode electrode will be placed on the right supraorbital region. Impedance is checked before and during stimulation to ensure good contact quality of the sponges with the scalp. The stimulation will be started at the onset of the practice phase (practice block 1) of the sequence-learning task. For both stimulation conditions, the current will be ramped up to 1 mA (0.04 mA / cm2) over 8 seconds. In the sham control stimulation condition, the current will be delivered for 30 seconds before being ramped down. In the stimulation condition, the current will be delivered for 20 minutes before being ramped down.

Study burden and risks

The burden and risks associated with the behavioural aspects (visiting the lab; administering questionnaires and computer task) of this study are low. The applied tDCS intervention is well tolerated and has generally been associated only with minor adverse effects in healthy humans, such as headache, moderate fatigue, nausea, and an itching sensation as well as skin irritation under the electrodes. Regarding tDCS, standardized protocols and considerable literature including clinical studies exists, and a recent review of 172 articles concludes that *tDCS is a safe technique when used in 1*2 sessions for healthy volunteers* (Brunoni et al., 2011). The participants will not have any direct personal benefit from participation; the main benefit is an increased fundamental understanding of the possibilities to enhance motor learning in different age groups. In the light of the current aging population, enhancing cognition in healthy OA is a highly relevant and promising direction of research. An example of a potential specific application of insights in the effects of tDCS on motor learning is for example improved re-learning of motor skills after stroke.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age 62 * 75 or 18 * 30 years
* Right-handed, to be confirmed by using the Edinburgh handedness inventory (Oldfield, 1971).
* Good vision (on 1 meter distance), glasses are allowed

Exclusion criteria

* History of skin diseases that could result in irritation of the skin underneath the electrodes
* History of epilepsy or a known case of epilepsy in a first degree relative
* Metallic implants in the brain
* Presence of cardiac pacemakers, implanted heart rhythm monitor, implanted defibrillator, cochlear implant or implanted brain electrodes
* Presence of severe or frequent headache
* Use of medication that alters the motor cortex excitability
* Use of medication that, according to the product information, can increase the chance of seizures.
* Use of any illegal drugs in the last month (relying on self-report)
* Pregnancy
* Had spinal surgery or have drains in their spinal cord or ventricles
* Other neurological disorders
* A history of cardiac conditions that interfere with physical load
* Severe depression
* A score on the Montreal Cognitive Assessment (MoCA) of 22 or lower, indicating mild

cognitive impairment (Nasreddine et al., 2005). This tool has been extensively validated (e.g., Freitas, Simões, Alves, & Santana, 2013). YA will not be administered this questionnaire. See appendices for full questionnaire.
* Severe motor problems or limitations in using the fingers or arms, chronic joint pain, arthritis or rheumatism

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-11-2016
Enrollment:	32
Type:	Actual

Medical products/devices used

Generic name:	transcranial direct current stimulation
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-10-2016
Application type:	First submission
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL58571.044.16