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Investigation of non-invasive brain stimulation and its associated placebo effects on visual memory

Submission date	Recruitment status	[_] Prospectively registered
07/02/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/02/2023	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/05/2024	Other	

Plain English summary of protocol

Background and study aims
The goal of this study is to determine the extent to which the benefits of non-invasive brain stimulation (NIBS) on visual memory performance among young non-disabled adults are due to the actual treatment effect versus the placebo effect. NIBS is a low-cost and low-risk method believed to improve various health outcomes such as cognition, pain, and motor function. However, the evidence for the reliable and valid impact of NIBS on these outcomes is inconsistent. The study aims to measure both the treatment and placebo effects of NIBS. This will improve our understanding of how much of the improvement in performance is driven by the treatment effect versus the placebo effect. Previous studies on NIBS do not typically record participant expectations for NIBS, making it challenging to conclude whether positive or null results are due to a lack of treatment effect or an imbalance in the placebo effect between groups.

Who can participate?
Adults aged 18 years and over who are right-handed and pass the screening questionnaire

What does the study involve?
Participants will be randomly allocated to one of three groups: an anodal tDCS group, a sham tDCS group and a no-tDCS control group. The intervention used in this study is non-invasive brain stimulation, specifically transcranial direct current stimulation, to be applied to the area of the scalp over the right parietal cortex of the brain.

What are the possible benefits and risks of participating?
There is no direct benefit to participants. Possible risks are minimal in regard to active brain stimulation. The primary side effects reported due to the use of non-invasive brain stimulation are scalp tingling and minor discomfort of the scalp.

Where is the study run from?
Arizona State University (USA)

When is the study starting and how long is it expected to run for?
January 2019 to May 2024

Who is funding the study?
1. Arizona State University Global Sport Institute (USA)
2. Arizona State University Graduate College JumpStart Program (USA)

Who is the main contact?
Dr Sydney Schaefer, sydney.schaefer@asu.edu

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
10.17605/OSF.IO/E7GW3 Subjects

Study information

Scientific Title
Evidence and sources of placebo effects in transcranial direct current stimulation during visuospatial working memory training

Acronym
TDCS PM

Study objectives
Hypothesis 1a: Anodal transcranial direct current stimulation (tDCS) on the right parietal lobe will improve the rate and amount of motor skill acquisition, as well as subsequent visuospatial performance post-stimulation, compared to sham tDCS.

Hypothesis 1b: Sham tDCS will improve the rate and amount of motor skill acquisition, as well as subsequent visuospatial performance post-stimulation, compared to no tDCS.

Hypothesis 2: Individuals with higher tDCS expectancy will demonstrate better rate and amount of motor skill acquisition, as well as better subsequent visuospatial performance, while controlling for stimulation type (anodal or sham).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/03/2019, Arizona State University Office of Research Integrity and Assurance (1151 S Forest Ave Tempe, AZ 85281, USA; +1 (0)480 965 6788; research.integrity@asu.edu), ref: STUDY00015526

Primary study design
Interventional

Study design
Randomized three-armed mixed within- and between-subjects design. For hypothesis 1a (effect of P4 tDCS), this study can be considered to have a double-blinded, sham-controlled design, with one within-subject factor of time and one between-subject factor of tDCS group (anodal vs sham). Both researchers and participants will be blinded to the stimulus conditions.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Modifications in working memory performance in young non-disabled adults

Interventions
Participants will be randomly assigned by simple randomization with stratification to one of three groups (arms): an anodal tDCS group, a sham tDCS group and a no-tDCS control group. There is one within-subject factor, which is time (pre-tDCS vs post-tDCS assessment on the mental rotation task), and one between-subject factor, which is the group (true/anodal tDCS, sham tDCS, and no-tDCS).

The intervention used in this study is non-invasive brain stimulation, specifically transcranial direct current stimulation, to be applied to the area of the scalp over the right parietal cortex of the brain.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Transcranial direct current stimulation

Primary outcome(s)
Visual memory performance is measured using the Corsi Block Tapping Task which is recorded once during the experiment

Key secondary outcome(s)
Placebo effects related to non-invasive brain stimulation recorded from an 8-point Likert scale are recorded pre- and post-visual memory practice during a single lab visit

Completion date
01/05/2024

Eligibility

Key inclusion criteria
1. At least 18 years old
2. Right-handed
3. Passed the screening questionnaire for tDCS studies (Thair, Holloway, Newport, & Smith, 2017)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
98

Key exclusion criteria
1. Mixed-handed or ambidextrous
2. Report any diagnosed current psychiatric condition, such as clinical depression or bipolar disorder

Date of first enrolment
03/03/2019

Date of final enrolment
29/03/2022

Locations

Countries of recruitment
United States of America

Study participating centre
Arizona State University
1151 S Forest Ave
Tempe
United States of America
85281

Sponsor information

Organisation
Arizona State University

ROR
https://ror.org/03efmqc40

Organisation
Arizona State University

ROR
https://ror.org/03efmqc40

Funder(s)

Funder type
University/education

Funder Name
Arizona State University Global Sport Institute

Alternative Name(s)
Arizona State, This Arizona State University, Territorial Normal School, Tempe Normal School of Arizona, Tempe Normal School, Tempe State Teachers College, Arizona State Teachers College, Arizona State College, ASU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location

United States of America

Funder Name
Arizona State University Graduate College JumpStart Program

Alternative Name(s)
Arizona State, This Arizona State University, Territorial Normal School, Tempe Normal School of Arizona, Tempe Normal School, Tempe State Teachers College, Arizona State Teachers College, Arizona State College, ASU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The online repository that contains all relevant data of this study is managed under this https://doi.org/10.5281/zenodo.7551889. Once the manuscript linked to these data is published the researchers shall make the repository open to all.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/04/2024	15/05/2024	Yes	No
Protocol file			15/05/2024	No	No