

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

<b>Submission date</b> 07/02/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 10/02/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/05/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## 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

### Contact name

Dr Sydney Schaefer

### ORCID ID

<https://orcid.org/0000-0002-6976-8419>

### Contact details

611 E Orange St

Tempe

United States of America

85281

+1 (0)480 727 6651

sydney.schaefer@asu.edu

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### 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

### **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.

### **Primary study design**

Interventional

### **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>

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Arizona State University

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# 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?
<a href="#">Results article</a>		20/04/2024	15/05/2024	Yes	No
<a href="#">Protocol file</a>			15/05/2024	No	No