

Informed Consent Form

Title The effects of High-definition transcranial direct current stimulation on cognitive bias among youth with social anxiety symptoms

NCT number NCT 07099521

Date April 3, 2024

Informed Consent Form

Dear Student,

Hello! I am the principal investigator of this study. Thank you very much for your willingness to participate in this research. Below, I will introduce the specific experimental content to you:

1. Research Title

The effects of High-definition transcranial direct current stimulation on cognitive bias among youth with social anxiety symptoms

2. Investigator Information and Contact Details

Principal Investigator: Yi Yu Phone Number: 13026197169 Email:2022023804@m.scnu.edu.cn

3. Research Purpose

This study employs repetitive high-definition transcranial direct current stimulation (HD-tDCS) targeting the left dorsolateral prefrontal cortex (left-DLPFC) to explore changes in individual cognitive processing bias before and after intervention.

4. Experimental Procedure

The entire experiment will last for 5 days and will be divided into four main stages: pre-experimental stage, pre-test stage, intervention stage, and post-test stage.

Pre-experimental Stage: Before participating in the experiment, you will complete a questionnaire. Based on the questionnaire responses, we will screen eligible participants and determine the final list for subsequent experiments. To protect your privacy, you will be assigned a code number and randomly divided into two groups—Experimental Group 1 and Experimental Group 2. On the first day of the experiment, you will be required to fill out a demographic information form and scales assessing mental disorders and cognitive status.

Pre-test Stage: You will complete three computer-based button-press experiments. These experiments will only measure your behavioral responses and will not involve any physiological measurements, ensuring no physiological harm to you. Experiment 1 will adopt the dot-probe task, Experiment 2 the free recall and recognition task, and Experiment 3 the word-sentence association paradigm. All paradigms are classic in the field of psychology, supported by theoretical foundations and previous research, ensuring their reliability.

Intervention Stage: You will receive HD-tDCS for 20 minutes, twice daily, with a 3-hour interval between sessions (2mA current intensity), for five consecutive days. According to the international 10/20 EEG electrode placement system and referencing previous studies, the anode center electrode will be placed at F3, targeting the left prefrontal cortex, while the four cathode return electrodes will be placed at Fz, Fp1, C3, and FT7.

Post-test Stage: On the last day of the intervention, you will complete scale assessments and three

experimental tasks again.

Throughout the experiment, students from the School of Psychology at South China Normal University will accompany and patiently guide you to ensure the smooth progress of the experiment and prevent any accidents.

5. Duration of the Experiment

The entire experiment will last for 5 days. The first and fifth days will require completion of scale assessments, three experimental tasks, and HD-tDCS intervention, taking approximately 1 hour and 30 minutes. The middle three days will only involve HD-tDCS intervention, taking about 40 minutes each day.

6. Explanation of High-Definition Transcranial Direct Current Stimulation Intervention

High-definition transcranial direct current stimulation (HD-tDCS) is an effective and promising non-invasive brain stimulation technique that applies a weak electrical current through electrodes on the scalp in a safe and tolerable manner, altering cortical neuronal excitability to achieve therapeutic effects in improving individual cognitive function. After decades of development and application, HD-tDCS has become well-established and does not cause harm to the human body, ensuring your safety during the experiment.

During HD-tDCS treatment, you may experience slight warmth, tingling, or itching sensations on the scalp. These are usually temporary, but if they persist or worsen, please immediately inform the investigator.

7. Experimental Benefits and Potential Risks

(1) Experimental Benefits

Upon completion of the tests, you will receive a participant fee of 280 RMB. Additionally, you will receive 10 free sessions of high-definition transcranial direct current stimulation (HD-tDCS) intervention, which may potentially improve cognitive function and mental symptoms.

(2) Potential Risks

- a. The experiment duration is relatively long, which may cause fatigue and boredom.
- b. As the experimental materials involve emotional stimuli, they may trigger adverse emotional reactions in you.
- c. The use of HD-tDCS as an intervention method during the experiment may cause mild discomfort (e.g., tingling, itching, and warmth).

(3) Risk Protection Measures

- a. You are required to sign this informed consent form before the experiment begins, and you have the right to terminate the experiment at any time during the process. Each experiment will be conducted in separate sessions to avoid prolonged durations that may cause fatigue and boredom, ensuring that you participate in the experiment while in a good mental state.
- b. During the experiment, a one-on-one investigator will be present to monitor your emotional

responses at all times. If you feel uncomfortable, you have the right to terminate the experiment immediately, and the investigator will provide necessary psychological counseling and adjustment. You may leave the laboratory only after ensuring that your emotions have recovered and stabilized.

c. Firstly, the target, intensity, and frequency of HD-tDCS are based on previous internationally peer-reviewed articles, ensuring a certain level of safety and reliability. You have the right to terminate the experiment at any time throughout the process. Additionally, after each intervention session, you will be required to fill out a feedback questionnaire, which will inquire about your perceived differences before and after treatment, any discomfort experienced, the specific type of discomfort (e.g., headache, fatigue), the intensity of discomfort, and its duration. If any abnormalities are detected, the investigator will immediately halt subsequent interventions and seek medical advice.

8. Rights and Obligations of Participants

(1) Rights

If you experience any physical discomfort or other adverse reactions caused by the experiment during the process, you have the right to notify the researchers and request to withdraw from the study at any time.

(2) Obligations

- a. Before the experiment begins, you must provide true and reliable information about your physical and mental condition to the investigator. Any deception may result in the researchers' right to terminate the experiment.
- b. During the formal experiment, you must carefully complete all experimental tasks as instructed by the researchers and follow their arrangements without engaging in any behaviors or activities unrelated to the experiment.
- c. If, owing to your non-adherence to the research protocol, any emergency situations arise or other serious adverse events for which you are responsible occur during your participation in the study, the researchers may terminate your continued participation in the study and have the right to withhold your payment.

9. Confidentiality Principle

If you decide to participate in this study, all your personal information and data collected during the experiment will be strictly confidential. Your materials and experimental data will only be accessible to researchers for review and extraction. When necessary, only upper-level management and members of the ethical committee will be allowed to access your information in accordance with regulations. When publishing the research findings, no personal information about any participant will be disclosed in the article. You must also adhere to the confidentiality principle regarding any confidential information related to this study and must not disclose certain information to third parties.

Informed Consent Statement

I have read this informed consent form and understand the purpose, content, and the rights and obligations of both parties involved in this study. I voluntarily agree to participate in this research.

Participant Signature: _____

Date: _____