

An Investigation of the Effect of 5 Consecutive Days of Bihemispheric tDCS on Speech Fluency in Individuals With Stuttering

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Protocol

In this study, a randomized double-blind, sham-controlled, parallel-group experimental research design was applied. The study included 36 adults, aged between 18 and 52 (Mdn=27.55), native Turkish speakers, right-handed dominant, with developmental stuttering and no speech and language problems other than stuttering, who were not currently receiving therapy. Individuals under 18 years of age, with a diagnosed brain lesion, with intracranial metal implantation, with any neurological or psychiatric disorder, using drugs and substances that may affect the central nervous system, and with a history of epilepsy/seizures were excluded. Participants who voluntarily agreed to participate in the study declared their willingness to participate in writing by filling out the Informed Voluntary Consent Form. The researcher assessed stuttering using the Stuttering Severity Instrument version 4 (SSI-4, Riley, 2009) and implemented the intervention. This study was approved by Istanbul Biruni University Non-Interventional Clinical Research Ethics Committee (2023/85-70). The study was registered at ClinicalTrials.gov (NCT06278233).

Randomization and masking

The researcher randomized participants to the sham and tDCS study arms using block randomization. Eight possible sequences were created by selecting block sizes of four and six and these were randomized. A unique 3-digit code was assigned per participant to conceal the allocation. The code was used to assign participants to tDCS or sham stimulation in the order of their presentation (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>). Blinding was achieved by masking the group assignment of the assessor and participants.

Procedure

After all volunteers who wanted to participate in the study were informed about the study, they filled out the Informed Voluntary Consent Form, Health Consent Form, Flinders Handedness Scale and eligible participants filled out the OASES form. Then, the participants were assigned to the tDCS and sham study groups according to the block randomization and continued their practices for five consecutive days according to this assignment. Nineteen participants received 20 minutes of 1-mA stimulation for five consecutive days, while speech fluency was temporarily facilitated using metronome-timed speech (one participant was only included in the daily graphs and daily analyses because he attended the intervention session for 4 days). The other 17 participants received the same speech fluency intervention with sham stimulation. Speech fluency during reading and speaking was assessed at baseline, before and after stimulation on each day of the 5-day intervention, and 1 week after the end of the 5-day intervention.

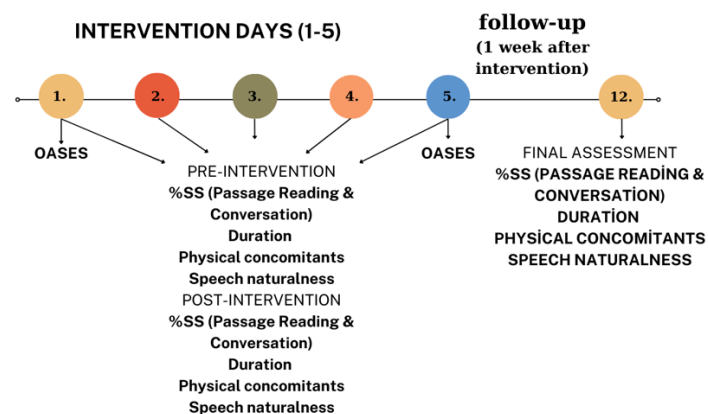


Figure 1: Experimental design. The metrics used for the primary outcome (% ss = percentage of stuttered syllables) and secondary outcomes (SSI-4, OASES) are shown in bold text.

For the assessment, after collecting recordings of reading and speech samples, skull measurements were made from nasion (Nz) toinion (In) and from left preacur point to right preacur point, then a standard 32-channel electroencephalography (EEG) coil (EASYCAP, GmbH, Hersching, Germany) was placed on the participants' heads to identify the stimulation sites, and electrode placement was performed with the help of a saline-soaked sponge.

tDCS intervention

In the tDCS study arm, participants received stimulation at 1 mA for 20 minutes during the fluency intervention. These are frequently used tDCS parameters and were chosen because they have been effective in previous tDCS intervention studies (Marangolo *et al.*, 2013; Allman *et al.*, 2016). The anode was placed on the left inferior frontal cortex (at the intersection of F7 and FC5) and the cathode was placed at the intersection of F8 and FC6. This montage has been used in other studies (Yada, Tomisato and Hashimoto, 2018; Karsan *et al.*, 2022). This electrode placement covers a region of functional deficit and white matter abnormality that has been identified in people with stuttering (Watkins *et al.*, 2008). The electrodes were placed in sponges soaked in saline and placed on the scalp. The same electrode placement was used in the sham stimulation study arm, during which the current was increased for 15 seconds, held at 1 mA for 15 seconds and decreased for 15 seconds at the beginning of the session.

No serious side effects were observed during the study and tDCS side effects were limited to the mild symptoms commonly reported in previous studies (e.g. itching and tingling sensation under the electrodes).

Fluency intervention (metronome-timed speech)

While teaching the participants to read with a metronome, the researcher first presented his own name and surname as a model, and then asked the participants to say their names and interests in accordance with the metronome tempo. Afterwards, the tDCS application was started and the relevant reading materials were shown on the computer screen used in the study. The participants were asked to read the visual materials on the screen in accordance with this metronome tempo by saying one syllable per metronome beat. When the stimulation period ended, the tDCS was terminated and then the post-implementation evaluation phase began. In this phase, the participants were asked to read the reading texts normally (without metronome beats) and chat about predetermined topics.

Reading materials

Each intervention session consisted of words and sentences paired in syllable count (gradually increasing in linguistic complexity from one-syllable words to five-word sentences for each session) and a written text of one of five well-known stories (Pinocchio, Beauty and the Beast, The Bremen Musicians, Rapunzel, Hansel and Gretel) with word counts ranging from 889 to 1239.

Materials used in evaluation sessions

For the speaking assessment, two of the three pre-determined conversation topics were selected based on the interests of the participants and conversations were held on these two topics. For the reading assessment, eleven reading passages from the Ministry of National Education's 2019-2020 curriculum were selected. One of these eleven passages was used in the reading assessment according to the sequence of the pre-defined assessment sessions. This ensured that each assessment session was unique and equally challenging.

Outcome measurements

Speech fluency and reading fluency were measured and assessed at baseline, before and after the intervention on each intervention day, and 1 week after the intervention using the percentage of syllables stuttered (%ss). The primary outcome measure was the overall change in fluency at the end of the 5-day intervention and 1 week later, but we measured how fluency was affected over the course of the intervention by including an additional assessment of change in fluency immediately after the intervention session on each of the 5-day intervention days. Repetitions, prolongations, syllable repetitions, tense pauses and pre-speech sound blocking were defined as moments of disfluency. For both reading and speaking measures, the first 300 syllables were used for analysis (syllable count ranged

from 139-490 syllables). An independent speech-language pathologist completed all disfluency counts. Inter-rater reliability was measured by comparing all speech samples from 7 randomly selected participants with counts completed independently by a second independent speech-language pathologist.

Statistical Analysis

Statistical analyses were performed in two steps. In the first step, the change from the initial / baseline measurements (Day 1 pre-intervention) to the post-intervention measurements on Day 5, as well as the change from the initial measurements to the final measurements performed on Day 12 of the tDCS and sham groups were compared. Within the scope of the second step analyses, the change in scores from the pre-intervention measurement to the post-intervention measurement was calculated for each treatment day (Days 1-5) and these change scores were compared between the two groups (tDCS and sham). Similar inferential statistical tests were used for the analyses described in the first and second steps. First, for all dependent variables, the Shapiro-Wilk test was used to examine whether the data were normally distributed. For the dependent variables that were significantly different from the normal distribution ($p < 0.05$), the Mann-Whitney-Wilcoxon test, a nonparametric test, was used to compare whether the median values of independent samples were different. For the dependent variables that were not significantly different from the normal distribution ($p > 0.05$), Fisher's F-test was first applied to examine whether the variances of the two groups (tDCS, sham) were homogeneous. If the variances of the groups were homogeneous, independent samples t-test (Student's t-test), one of the parametric tests, was used to compare whether the arithmetic mean values of the independent samples were different. If the variances of the groups were not homogeneous, Welch's t-test was used to compare whether the arithmetic mean values of the independent samples were different. All statistical analyses were performed on R version 4.1.2 (R Core Team, 2013).