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# Effect of Home-Based Transcranial Direct Current Stimulation on Cognitive Function in Patients with Mild Cognitive Impairment: A Two-Week Intervention

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**Purpose:** Repeated transcranial direct current stimulation (tDCS) is expected to have the potential to improve cognitive function in patients with mild cognitive impairment (MCI). We aimed to evaluate the efficacy and safety of at-home tDCS for elderly patients with MCI.

**Materials and Methods:** Patients aged 60–80 years, who maintained normal daily living but reported objective memory impairments, were enrolled. Active or sham stimulations were applied to the dorsal frontal cortex (left: anode; right: cathode) at home for 2 weeks. Changes in cognitive function were assessed using visual recognition tasks and the Mini-Mental State Exam (MMSE), and safety and efficacy were assessed using self-reports and a remote monitoring application.

**Results:** Of the 19 participants enrolled, 12 participants were included in the efficacy analysis. Response times and MMSE scores significantly improved after active stimulation compared to the sham stimulation; however, there were no significant differences in the proportion of correct responses. The mean compliance of the efficacy group was 97.5%±4.1%. Three participants experienced burns, but no permanent sequelae remained.

**Conclusion:** This preliminary result suggests that home-based tDCS may be a promising treatment option for MCI patients; however, it requires more attention and technological development to address safety concerns.

**Clinical Trial Registration:** Clinical Research Information Service (CRIS), KCT0002721

**Key Words:** Transcranial direct current stimulation, mild cognitive impairment, hospital-based home care services, crossover design, electric stimulation

## INTRODUCTION

Mild cognitive impairment (MCI) is a condition of decreased cognitive function that can be confirmed by neuropsychological tests. Patients with MCI may experience subjective discomfort; however, unlike dementia, MCI does not interfere with patient independence and daily functioning.[1,2] Although some cases of MCI may progress to dementia,[3] there are no proven treatments or conservative methods to improve cognitive function. Recently, transcranial direct current stimulation (tDCS), a non-invasive method of brain stimulation, has been proposed as a treatment for MCI.

The tDCS is a neuromodulation technique that controls nerve excitability by transmitting a small amount of current through

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an electrode patch on the scalp. Anodal stimulation increases cortical activity by bringing the resting potential closer to the threshold potential, while cathodal stimulation suppresses excitability by separating the resting potential from the threshold potential.[4] Under the hypothesis that control of brain activity affects brain functions, such as behavior, emotions, and information processing, several studies have been conducted on the effects of tDCS on depression, multiple sclerosis, and other central nervous system disorders.[5-7]

Previous clinical trials and experimental studies have reported the effects of tDCS on the functioning of various cognitive domains. One study showed that tDCS improves visuospatial working memory in healthy adults by stimulating the right prefrontal cortex.[8] Another study reported improvements in normal aging-related cognitive decline and reversal in pathological brain activity during tDCS stimulation.[9] Studies investigating the effects of tDCS and repeated transcranial magnetic stimulation in patients with Alzheimer's disease have also reported improvements in cognitive function.[10,11] Boggio, et al.[12] reported improved performance in a visual memory recognition task after tDCS stimulation of the dorsolateral prefrontal cortex (DLPFC) in patients with Alzheimer's disease.

Non-invasive neuromodulation techniques often require repeated application for efficacy and therefore need to be available to patients at home to serve as a realistic treatment modality.[13] tDCS is suitable for home use as it is relatively user-friendly, inexpensive, small,[14] and has no serious side effects reported.[15] Notably, the efficacy and safety of applying tDCS at home for diseases, such as depression, chronic pain, multiple sclerosis, tinnitus, and mild vascular dementia, have been investigated.[16-20] Recently, several studies have shown that tDCS is effective in improving cognitive function in patients with MCI. One study reported the effectiveness after at-home tDCS treatments for 6 months;[21] however, this period is too long for patients to wait for an effect. Another study that reported efficacy administered tDCS treatments for a short period of time, but not at home.[22] Therefore, it is necessary to evaluate the effects of tDCS administered at home for a relatively short period of time in order to use it as an actual treatment modality.

The present study investigated the effect of tDCS treatment on cognitive function in patients with MCI using a tDCS device developed for home-based self-application. We hypothesized that 2 weeks of repeated tDCS stimulation at home would improve cognitive function measured with visual recognition tasks and MMSE scores in patients with MCI. We also assessed the safety of self-administering tDCS at home for patients with MCI.

## MATERIALS AND METHODS

### Participants

We recruited outpatients who visited Gangnam Severance Hospital and Severance Hospital and had already been clinically diagnosed with MCI. The present study protocol was approved by the Ministry of Food and Drug Safety of South Korea and the Institutional Review Board of both hospitals (IRB approval number: 3-2017-0354), and written consent was obtained from all participants.

Patients aged between 60–80 years who had decreased cognitive function but maintained their independence in daily activities were selected as participants in this study. Cognitive impairment was determined using the Korean version of the Global Deterioration Scale (GDS; 2–3 points).[23] Dementia was determined using the Clinical Dementia Rating (score over 0.5 indicating dementia) and the Korean version of the MMSE for Dementia Screening (cut-off depending on age and education).[24] Independence in daily activities was determined according to the Seoul-Instrumental Activities of Daily Living score (<7 points).[25] Depressive symptoms were assessed according to the Korean version of the Geriatric Depression Scale (K-GDS; ≤8 points).[26] Finally, psychiatrists who were not involved in the patient's clinical care confirmed a diagnosis of mild neurocognitive disorder using the criteria of the 5th edition of the Diagnostic and Statistical Manual of Mental Disorders.

Participants with a history of dementia or use of cognitive enhancers (including donepezil, rivastigmine, galantamine, and memantine) were excluded. Maintenance therapy with fixed dose general medications and psychiatric medications other than cognitive enhancers was permitted. Those with alcohol use disorder, epilepsy, and problems associated with direct current stimulating electrodes (e.g., history of cerebrovascular surgery, dermatological problems, metal plates inserted into the cephalous, etc.) were excluded. Recruitment of participants started in March 2018 and ended in July 2019.

### Outcome measures

Cognitive improvement was assessed using visual recognition tasks similar to those described in previous studies in which tDCS was administered to patients with Alzheimer's disease.[10,12] Participants were required to memorize pictures displayed for 10 seconds on screens containing two, four, six, or eight pictures. After a 1-second interval, a specific stimulus was displayed, and participants were required to respond as quickly as possible and indicate whether it was a picture they had been shown earlier. Stimuli were presented electronically using the E-Prime 3.0 software (Psychology Software Tools, Pittsburgh, PA, USA) in a laptop with a 15-inch screen, and responses were recorded using the laptop's keyboard. The MMSE and standardized neuropsychological tests were administered using the Korean version of the Consortium to Establish a Registry for Alzheimer's Disease Neuropsychological assessment battery (CERAD-K).[27]

### Intervention

*tDCS stimulation protocol*

The electrodes were placed on the DLPFC (anode on F3 and


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cathode on F4) as described in previous studies.[10] Stimulations were self-administered by the participants for 30 minutes each day for 14 consecutive days. While the typical period of tDCS administration was reported to be 2 to 8 weeks in previous clinical trials, we opted in our study, home-based and having an exploratory purpose, for a 2-week stimulation period to minimize potential risks.[28]

During active stimulation, the current was increased for the first 30 seconds, maintained at 2 mA for 29 minutes, and then decreased for 30 seconds. The sham stimulation increased the current for 30 seconds and then decreased it for 30 seconds, remaining for 29 minutes with no current flow.[10,12,29] The circular electrode (67 mm in diameter and 22 mm in thickness) was used after inserting a disposable sponge into the patch supporter with saline solution. The electrode was inserted into a pre-selected hole in the cap that fit the head size, allowing it to be easily fixed in the correct position by the participant at home. More detailed protocols and figures are available in a previous article published by the current group.[30]

*Home-based tDCS device and safety strategy*

Home-based tDCS was provided only after three checklist-based training sessions using a training device and after the participants passed a test. The present study was conducted using a tDCS device (YDS-301N; Ybrain, Seongnam-si, South Korea) designed with functions necessary for home application, such as measuring and automatically stopping current output. The smartphone application included with the device detected its performance and sent the data to a server for remote monitoring by the investigator. When the device operation was complete, the self-assessment questionnaire for safety evaluation was used. In addition, 24-hour contact and remote support were provided via the same smartphone.

*Trial design and study schedule*

The present study was a randomized, double-blind, crossover clinical study. Participants were randomly allocated to the active-sham sequence group or the sham-active sequence group, and all underwent two 2-week treatment periods with a 2-week

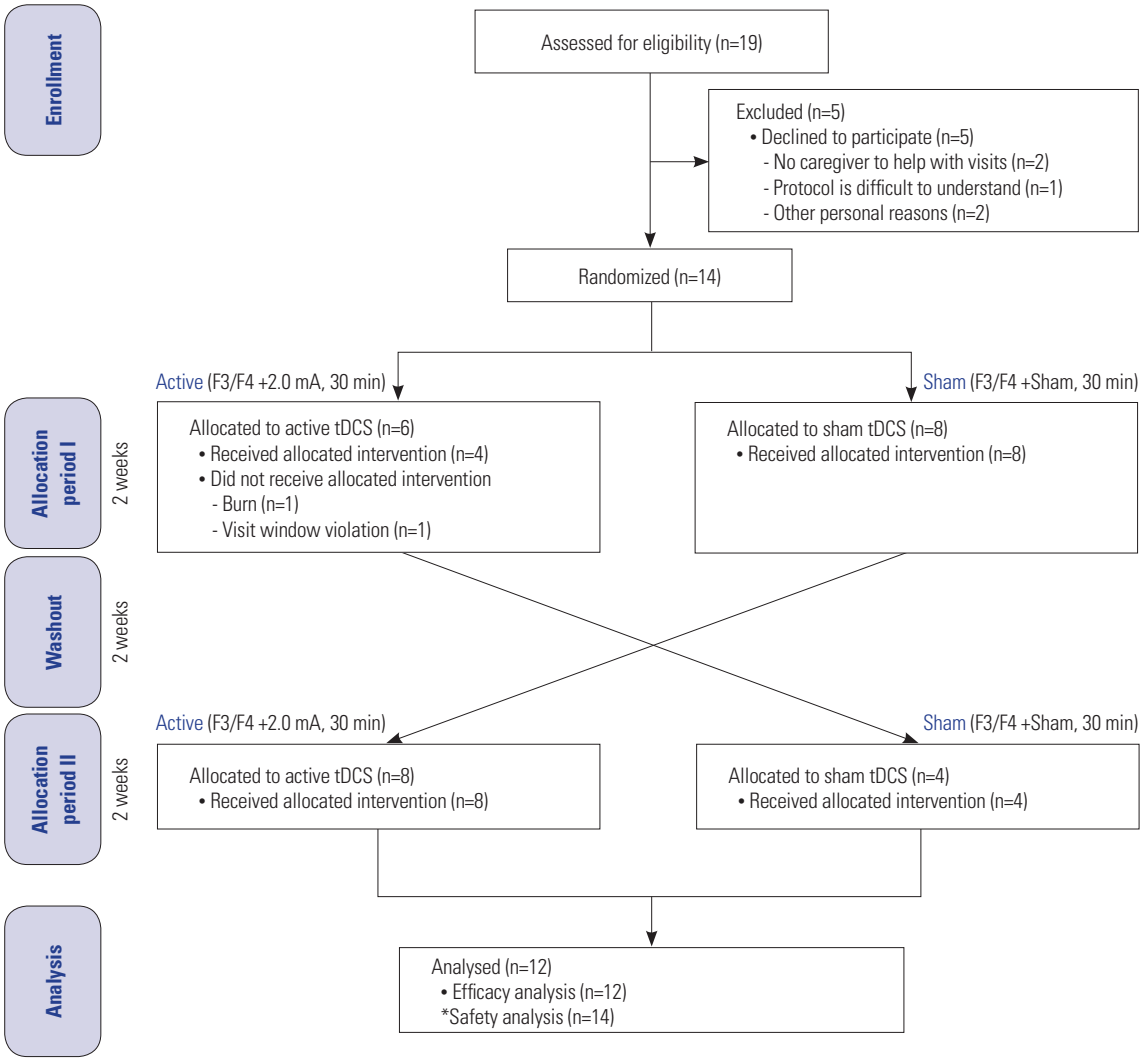


**Fig. 1.** Study design and method. tDCS, transcranial direct current stimulation.

washout period. Outcome measures were evaluated at the beginning and end of each treatment period, and side effects were evaluated daily using a smartphone application (Fig. 1) (Supplementary Table 1, only online).

### Statistical analysis

The sample size was calculated based on the sample used in a previous study.[12] To obtain at least 90% power (1-beta=0.9) at a significance level of 0.05 (α=0.05), the smallest sample size (considering a drop rate of 30%) was fixed at 20 patients (10 per group) using PASS 12 software (NCSS Statistical Software, Kaysville, UT, USA).

A Mann-Whitney U test for independent samples was performed to compare the demographic and clinical characteristics of participants who completed the study with those of participants who dropped out, including the efficacy assessment. *P*-values<0.05 were considered statistically significant.

For the efficacy assessment, the differences in correct response rates in the visual recognition task, as well as changes in the MMSE and each sub-item of CERAD-K before and after treatment, were calculated. The differences between active and sham setups were analyzed using a linear mixed model[31] to assess sequence effect, period effect, and treatment effect. The efficacy analysis included data from the participants who completed the intervention (treatment completion group), but the adverse events included the results of all participants (both treatment completion and dropout groups). All analyses were performed using SAS version 9.3 (SAS Institute Inc., Cary, NC, USA) software.

## RESULTS

A total of 19 participants were enrolled, and five withdrew from participation before starting the tDCS application. Of the remaining 14 patients, one dropped out due to side effects and one stopped participating for personal reasons. Finally, data from 12 participants were included in the efficacy analysis (Table 1). The participants included in the efficacy assessment (treatment completion group) had more years of education and higher MMSE scores compared to the dropout group, but the differences were not statistically significant (Table 2).

In the difference in response time before and after stimulation (after stimulation minus before stimulation), the mean of the active stimulation was -187.8 ms [95% confidence interval (CI): -295.50 to -80.15], which was significantly larger than that of the sham stimulation of 17.6 ms (95% CI: -89.79 to 125.50, $p$=0.013). There were no significant sequence or period effects ($p$=0.404, $p$=0.111, respectively) (Fig. 2). There was no significant difference in the percentage of correct responses (active: 1.042%; 95% CI: -4.610 to 6.693 vs. sham: 1.736%; 95% CI: -3.916 to 7.388, $p$=0.780) and no significant sequence or period effect ($p$=0.317, $p$=0.780, respectively). The improve-

**Table 1.** Demographic and Clinical Characteristics of Study Participants

| Participant | Sex | Age (years) | Education (years) | Current psychiatric diagnosis | Current psychiatric medication | Current Hx | Past Hx | CDR | GDS | MMSE-DS | S-IA | K-GDS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | F | 74 | 16 | Adjustment disorder | Escitalopram, quetiapine, trazodone | Diabetes mellitus | | 0.5 | 2 | 27 | 0 | 3 |
| 2 | F | 76 | 16 | | | | Colon cancer | 0.5 | 2 | 28 | 3 | 0 |
| 3 | F | 75 | 9 | | | | Hypertension | 0.5 | 2 | 27 | 0 | 3 |
| 4 | F | 71 | 9 | | | Hypertension, diabetes mellitus | | 0.5 | 2 | 25 | 0 | 4 |
| 5 | F | 75 | 15 | | | Hypertension | Arthritis | 0.5 | 3 | 25 | 6 | 4 |
| 6 | F | 71 | 12 | | Choline alfoscerate | Hypothyroidism, dyslipidemia | | 0.5 | 2 | 26 | 1 | 4 |
| 7 | F | 76 | 14 | | Choline alfoscerate | Osteoporosis | Glaucoma, cataract | 0.5 | 2 | 26 | 0 | 2 |
| 8 | F | 65 | 12 | | | | Osteoporosis | 0.5 | 2 | 27 | 0 | 1 |
| 9 | M | 68 | 18 | | | Hypertension | Hematologic cancer | 0.5 | 2 | 25 | 0 | 3 |
| 10 | F | 67 | 18 | | | | Transient global amnesia | 0.5 | 3 | 25 | 0 | 2 |
| 11 | M | 77 | 12 | | | | Thyroid cancer | 0.5 | 0 | 29 | 3 | 0 |
| 12 | F | 73 | 14 | | Choline alfoscerate | | | 0.5 | 2 | 24 | 4 | 0 |

GDS, Korean version of the Global Deterioration Scale; CDR, Clinical Dementia Rating; MMSE-DS, Korean version of the Mini-Mental State Exam for Dementia Screening; S-IA, Seoul-Instrumental Activities of Daily Living score; K-GDS, Korean version of the Geriatric Depression Scale; F, female; M, male; choline alfoscerate, L-alpha-glycerylphosphorylcholin.


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ment in MMSE scores was also significantly greater after active stimulation than after sham stimulation (active: 0.732; 95% CI: -0.388 to 1.852 vs. sham: -0.875; 95% CI: -1.995 to 0.245, $p$=0.047), and no significant effect of sequence or period effect was observed ($p$=0.843, $p$=0.882, respectively). There were no significant differences in the CERAD-K subscale measures.

The mean compliance of the efficacy assessment group was 97.5%±4.1%. There was no significant difference in compliance between the active-first treatment group (97.3±5.4%) and sham-first treatment group (97.5±3.7%). Three participants reported skin burns in the area of application. All burns occurred during active treatment. One of the participants discontinued treatment immediately after reporting the skin burn, whereas the other two reported them after completion of the protocol. Dermatological treatment was promptly administered, including ointment as prescribed by a dermatologist. Subsequent follow-up assessments revealed that none of these participants had permanent sequelae.

## DISCUSSION

Our current findings tentatively suggest that repeated administration of home-based tDCS over a 2-week period may hold promise as a potential treatment option for patients with MCI. Its convenience for at-home application over a 2-week period makes it a feasible option for widespread use in clinical settings. Particularly noteworthy was home-based tDCS's potential for alleviating symptoms during the early stages, especially in situations lacking standard and effective drug treatments for cognitive symptoms in MCI patients;[32] however, the technique requires further research and technological development to adequately address its safety concerns.

**Table 2.** Comparison of Clinical Features Between the Treatment Completion Group and Dropout Group

| | Treatment completion group (n=12) | Dropout group (n=7) | *p* value |
|---|---|---|---|
| Age (yr) | 72.33±3.94 | 71.57±5.09 | 0.650 |
| Education (yr) | 13.75±3.05 | 11.43±3.74 | 0.227 |
| CDR | 0.50±0 | 0.50±0 | >0.999 |
| GDS | 2.00±0.74 | 2.00±0 | 0.773 |
| MMSE-DS | 26.17±1.47 | 25.14±1.46 | 0.142 |
| S-IA | 1.17±2.04 | 0.71±1.11 | 0.967 |
| K-GDS | 2.00±2.13 | 2.14±1.68 | 0.711 |

GDS, Korean version of the Global Deterioration Scale; CDR, Clinical Dementia Rating; MMSE-DS, Korean version of the Mini-Mental State Exam for Dementia Screening; S-IA, Seoul-Instrumental Activities of Daily Living score; K-GDS, Korean version of the Geriatric Depression Scale.
Data are presented as mean±SD.

The current results showed that repeated application of tDCS to the DLPFC for 2 weeks improved the reaction time in the memory task, similar to the results of previous studies[10,12]; however, unlike in previous studies, there was no significant difference in the rate of correct responses. We suggest this is because the task used in our study was relatively easier than that used in previous studies. The improvement in MMSE score was consistent with the results of a previous study that reported similar improvements in cognitive function in patients with Alzheimer's disease.[33]

Unlike the MMSE score, the comprehensive neurocognitive assessment performed using the CERAD-K system did not show significant improvement in certain subdomains. The MMSE evaluates the overall cognitive function as one total score, whereas the CERAD-K individually evaluates specific areas of cognitive function and does not provide a total score. If the treatment affected different cognitive domains in different participants, our study would not be able to confirm significant improvement in specific cognitive domains due to the small sample size.[21] In addition, the 2-week period may be too short to assess the effects of tDCS treatment on the cognitive function of subdomains. Future studies with larger sample sizes and longer treatment periods are necessary to identify and evaluate such improvements.

Most of the participants who started treatment showed high compliance, indicating that even older adults who report cognitive impairments can regularly self-administer home-based tDCS without great difficulty. This suggests that the self-application of tDCS at home can be a useful treatment method in a

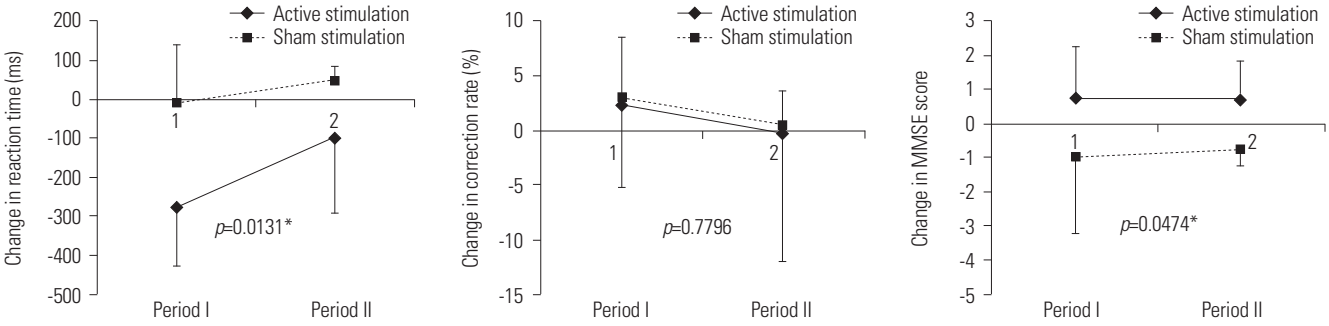


**Fig. 2.** Comparison of effects of transcranial direct current stimulation on cognitive function (active versus sham stimulation). Data are presented as estimated mean and standard error from linear mixed models. *Indicates statistical significance of treatment effect according to a linear mixed model at $p$<0.05. Period I: first treatment period before washout. Period II: second treatment period after washout. MMSE, Mini-Mental State Exam.

real clinical setting; however, a high percentage of participants quit before starting treatment. Therefore, overcoming the fear of using new electronic devices is important for the practical use of home-based tDCS.

In the present study, burns tended to occur more frequently than in previous studies.[15,34] Although permanent sequelae (such as scars) did not occur in any of the burn cases, this still indicates potential safety concerns for performing tDCS at home. Some possible reasons for the burns could be that the size of the electrode used in our study was relatively smaller and the current used was higher than in previous studies; however, another study using the same electrode settings reported no skin burns.[35] The burns may have also been due to differences in skin properties between younger adults and the elderly.[36] Even if the procedure is performed without problems in the hospital, the wrong method may be used during self-administration of tDCS at home, or there may be a difference in the assistance received from a caregiver. In future studies regarding the safety concerns of this technique, images of actual device wearing should be recorded on the smartphone to monitor safety and assess accuracy.

Although our study presents important findings on the effects of tDCS on MCI and the practicality of using tDCS at home, it had some limitations. First, although the crossover design required a relatively small number of participants and the results of this study were statistically significant, the dropout rate was higher than expected; therefore, large studies are needed to verify the clinical effectiveness and safety of this technique. Second, the long-term effect of tDCS on cognitive function could not be determined. Even if short-term treatment is effective, this may be another problem for practical use if it is to be applied continuously since it does not have a long-term effect. Although our results did not suggest long-term effects, studies assessing the long-term effects of tDCS are still rare and more need to be conducted. Third, we did not clearly assess the participants' ability to use a smartphone at the pre-treatment stage. Therefore, it is difficult to distinguish whether these participants quit due to personal reasons or because they could not use the smartphone due to low cognitive function.

In summary, the results of the current study suggest that home-based, self-administered tDCS may be an effective and realistic treatment for patients with MCI. Alternatively, we also revealed that the safety and usability of home-based tDCS should be improved in order for it to be used in clinical practice.

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