

Towards an Experimental Framework for Evaluating Effect of Home-Based tDCS on Cognitive Function of the Elderly with MCI: a Randomized, Double-Blinded, Cross-Over Study

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Extended Abstract

Recently, transcranial direct current stimulation (tDCS) that modulates brain activation by weak direct currents has received attention from clinical researchers. Despite the growth of interest in applying tDCS to actual clinical practice, geriatric patients in need of the treatment are more likely to feel burden of a visit to a medical institution and raise a concern over the safety of the tDCS device and its application on their skin and scalp, which might in turn prevent its adoption and employment in the home-based tDCS practice without any guidance or help of professionals or guardians. Therefore, the present study will not only examine the safety and effectiveness of a home-based tDCS system, but also determine whether the elderly with mild cognitive impairment (MCI) can apply tDCS at home by themselves and perform a cognitive and neuropsychological test battery for evaluating the clinical effect of home-based tDCS.

Twenty elderly participants, aged from 60 to 80 years, who complained about subjective memory impairment but general functions and daily life performance were maintained at some level. To filter out unqualified candidates, the following standardized battery and questionnaires will be employed: the Korean Version of Mini-Mental State Examination for Dementia Screening [1], the Seoul-Instrumental Activities of Daily living score [2], the Korean version of Geriatric Depression Scale [3], and the Korean version of Global Deterioration Scale [4] or Clinical Dementia Rating [5].

This study will be designed as a randomized, double-blinded, and cross-over trial that consists of active and sham stimulation conditions applied with 2mA on the dorsolateral prefrontal cortex (left – anode, right – cathode) in an random order, including a 2-week washout phase. Based on the previous studies [6-8], the threshold levels of 2mA current was determined. The daily application of the tDCS will be conducted for 2 weeks (a total of 14 sessions per condition). The duration of each session in the shame tDCS will be the same as the active tDCS for 30 min. In the sham treatment, the current is applied only for 1 min, and therefore, the strength of the current will be slowly increased to 2 mA and decreased to zero for 1 min. Zero amount of current is applied for remaining 29 min.

A tDCS device used in this study is designed to be suitable for independent home use and is composed of a docking station and miniaturized modules. Setup of stimulation cannot be modified at the module by the subject, as it is accessible with password via the station. In addition, the module contains skin-contact recognizing function. Therefore, the device automatically starts and stop stimulation when it recognizes the patch adhered to skin or detached form the skin during stimulation.

Safety and suitability will be evaluated via an application linked with tDCS device. This application detects applying tDCS and records self-inspection questionnaire for safety assessment after daily usage of tDCS. In addition, 24-hour contact information is provided to participants during the study. If any side effect would be suspected, the subject needs to visit healthcare institution immediately.

The present study will be carried out in the way that patients with MCI apply the compact tDCS developed for home use by themselves for relatively long-term period. Such attempt could investigate application of tDCS to become more realistic therapy. Furthermore, the elderly with declined cognitive function can use tDCS at their home by themselves, implying high possibility of safe use by patients with various diseases and at different age, which will be able to confirm future home-based use of tDCS.

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