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PROCEEDINGS #13. UPDATED SAFETY AND TOLERABILITY OF REMOTELY-SUPERVISED TRANSCRANIAL DIRECT CURRENT STIMULATION (RS-TDCS)

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Abstract

Transcranial direct current stimulation (tDCS) is a promising therapy with a growing number of applications. However, clinical studies to date have been limited by small sample sizes and few sessions studied. To increase enrollment and extend treatment, we developed a protocol for remotely-supervised or RS-tDCS to enable participants to receive treatment from home while monitored in real-time.1, 2 Here we present the findings of two studies in multiple sclerosis (MS), the first being an open label feasibility study with 1.5mA x 20 minutes and the second being a randomized, controlled clinical trial of active 2.0mA or sham x 20 minutes. In addition, we have extended the protocol for use in Parkinson's disease (PD), completing 10 open-label 2.0 mA sessions x 20 minutes. All sessions were performed using a dorsolateral prefrontal cortex montage (DLPFC) and were paired with cognitive training tasks. This study adds to previous safety evidence.3

Methods

Eligibility criteria were purposefully broad in both studies to assess the feasibility of a remote-supervision protocol . The criteria required that patients had a definite diagnosis of MS (all subtypes), were between the ages of 18-70, had no history of serious brain trauma, and were physically, visually, and cognitively competent enough to perform study procedures. Additonally, participants were required to enroll in the study with a healthcare proxy if their disability was greater than an Expanded Disability Status Scale (EDSS) Score of 6.5. Eligibility criteria for the Parkinson's Disease (PD) cohort was similar to the MS criteria, albeit with a larger age range for participation (30-89) and without the EDSS score requirement.
The RS-tDCS protocol included a baseline screening and tolerabilty test, followed by training in device operation. Participants were then sent home with a study kit that included a laptop computer and tDCS equipment. Each remote session was self-administered with guidance from a study technician, while constant supervision was maintained via videoconferencing. Extensive safety and stop criteria were followed to prevent any adverse events or misuse. The studies used the Soterix Mini-CT device that delivered a 20 minute session of a specific current "dose" or sham, based on a preprogrammed one-time use code that was provided by the study technician at each session.
Safety and tolerability were measured by assessing both experiences of minor adverse events and pain ratings. Following each session, participants were asked if they had experienced any adverse events, which were read aloud from a list of those most commonly reported. Pain ratings (using a visual analogue scale, 1-10) were measured before, during, and after each session. Any participants experiencing pain or adverse events above an intensity of seven were discontinued from the study as per study protocols.

Study 1

MS participants (n=26) were recruited between the dates of March 2015 and February 2016 at the Lourie Center for Pediatric MS at Stony Brook University. This trial was an open-label study and all participants knowingly received the active tDCS therapy. 1.5mA of tDCS therapy was administered for 20 minutes each day for 10 days.

Study 2

Participants with MS (n=15) were recruited between January 2016 and September 2016 at the MS Care Center at New York University Langone Medical Center. This study is an ongoing, actively recruiting, randomized, double-blinded, controlled clinical trial using RS-tDCS.
All MS patients were randomized to either the active condition (20 minutes of 2.0mA tDCS) or the sham condition. The sham condition served as the control in this study and aimed to deceive participants into believing they were receiving the 20 minutes of tDCS by ramping up at the first minute of the session and ramping down at the last minute of the session. All participants who received the sham condition were offered 10 sessions of 2.0mA open-label tDCS following completion of 20 sessions of sham.

Study 3

Participants with PD (n=4) were recruited between the dates of June 2016 and October 2016 at the Fresco Institute for Parkinson's and Movement Disorders at the New York University Langone Medical Center. Using the aforementioned remotely-supervised protocol established for MS, participants in the PD cohort received open-label 2.0 mA tDCS for 10 sessions to assess the feasibility and generalizability of the remotely-supervised protocol for this new cohort.

Results

Study 1

Patients with MS (n=26) were recruited and completed study procedures. Two patients were discontinued during the course of the study. The first of the two was discontinued due to personal obligations, and the second was discontinued due to extreme sensations of skin burning (8.5/10 on the analogue scale) without any physical burns.The burning sensation did not continue after termination of the session. Overall, 248 sessions were successfully completed with this cohort.

Study 2

Patients with MS (n=17) were recruited and completed study procedures. Only one participant was discontinued from the blinded active condition due to serious headaches at an intensity above 7. One participant who was originally assigned to the sham condition and who opted for the extended, open label sessions voluntarily withdrew due to resurgence of headaches (the headaches did not meet our criteria of discontinuing the patient). 147 sessions of the active 2.0 blinded condition were succesfully completed. 135 shammed sessions were successfully completed. 54 sessions of the open-label, extended sessions following sham were completed.

Study 3

Participants with PD (n=4) were recruited and completed study procedures. No participants voluntarily withdrew from this cohort nor were any discontinued. 40 sessions were successfully completed.
In total, 624 sessions have been completed using the RS-tDCS protocol. Three participants have been discontinued and one has voluntarily withdrew from the study. Participants who were discontinued due to adverse events found that they reverted to their baseline state when terminating the intervention.
The percent of adverse events experienced is presented below in Fig. 1. This Figure does not include information regarding the intensity or duration of the adverse events experienced. Instead, it reports the frequency of advese events experienced, which accounts for the high incidence rate of adverse events in the sham condition. Table 1 accounts for the intensity of the most commonly reported adverse events. The table also includes the number of adverse events reported relative to the number of total sessions. On average, an intensity above 3 was not reported for any of the most common adverse events in any stimulation condition.

Table 1
Average Intensity of commonly experienced adverse events

Session Condition	Total Sessions	Tingling (SD, n)	Itching (SD, n)	Burning Sensation (SD, n)
2.0 mA Blinded	147	1.6 (0.8, 73)	2.2 (0.9, 35)	2.3 (1.3, 46)
2.0mA Open Label	94	1.8 (1.1, 36)	2.3 (1.2, 5)	2.2 (1.3, 28)
1.5mA Open Label	248	2.5 (2.2, 158)	2.0 (1.6, 65)	3.1 (2.1, 64)
Sham	135	2.4 (1.4, 40)	1.7 (0.9, 13)	1.4 (1.1, 15)

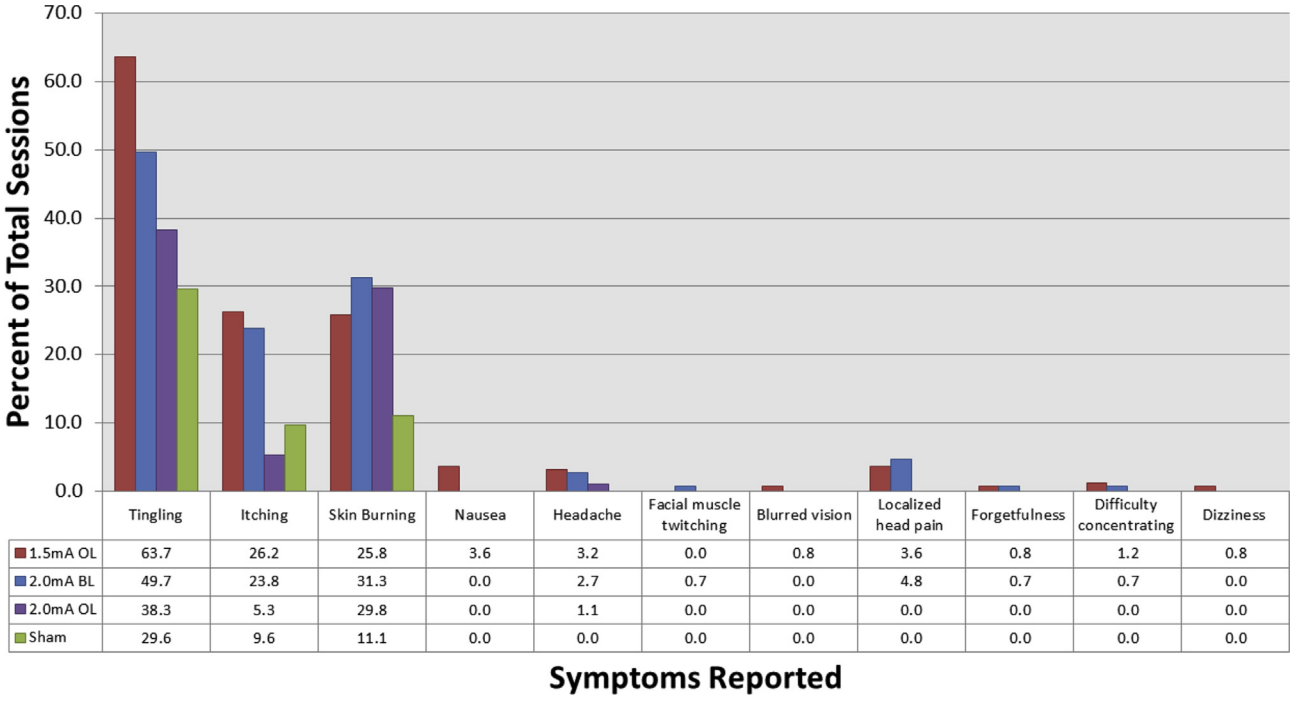

Fig. 1. Adverse events experienced with tDCS.

Discussion

The RS-tDCS protocol is safe and tolerable in both MS and PD participants, and continues to lead to high rates of compliance with treatment sessions. No serious adverse events have been reported. The most common side effects reported are skin tingling and itching.Of note, across conditions, the 1.5mA open label condition reported the highest rates of side effects. This may be accounted for by open-label treatment, where participants may have been more focused on potential effects of the stimulation. The 2.0mA open label condition may not be as comparable to the 1.5mA open label condition due to a smaller sample size in the 2.0mA condition.Overall, none of the adverse events were severe, with intensity below 3 on a visual analogue scale of 1-10. Both 1.5 and 2.0mA tDCS are safe and tolerable forms of treatment in both MS and PD, and may be generalizable for clinical study in a wide range of neurologic and psychiatric disorders.

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PROCEEDINGS #14. POSITIONAL ACCURACY OF SCALP ELECTRODES MOUNTED ON A READY-MADE BAND TARGETING MOTOR CORTEX

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1. Abstract

Proper electrode placement is an important aspect of effective transcranial electrical stimulation (tES). Traditional positioning methods rely on scalp measurements such as the 10-20 system, or physiological localization such as mapping of motor evoked potentials (MEPs) using transcranial magnetic stimulation (TMS). While effective, these methods can be laborious, and the relatively non-focal nature of tES due to spreading of current through the scalp, skull, and CSF suggests that faster or easier methods may achieve acceptably low error while facilitating research throughput.
The present paper presents a geometric analysis of a ready-made, one-size-fits-all flexible band design for targeting the primary motor cortex (M1) via a ready-made, non-custom flexible band design. Using established standards for head dimensions and head shape variability, we present data showing that the modelled design allows for consistent targeting of M1 over a wide range of head sizes and shapes.

2. Introduction

Transcranial electrical stimulation has been shown to modulate motor performance, both behaviorally and biologically [1-2]. While desirable