

Remotely-Supervised tDCS is Feasible: Results of a Pilot Study in Multiple Sclerosis (MS)

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Objective

To evaluate the feasibility of a remotely-supervised tDCS protocol for use in multiple sclerosis (MS).

Background

Transcranial direct current stimulation (tDCS) refers to the delivery of mild electrical stimulation and is thought to enhance cortical excitability. tDCS has potential clinical application for symptomatic management in MS. However, repeated sessions are necessary in order to adequately evaluate a therapeutic effect. It is not feasible for many individuals with MS to visit clinic for treatment on a daily basis, and clinic delivery is also associated with substantial cost.

Methods

A research protocol to remotely supervise self- or proxy-administration was developed for home delivery of tDCS using specially-designed equipment and a telemedicine platform tailored to deficits common in MS^{1,2}. Using a DLPFC montage, a dose of 1.5mA was applied for 20 minutes. The study targeted ten treatment sessions across two weeks for each participant enrolled. All participants were enrolled from the Stony Brook MS Comprehensive Care Center and medically screened by a study physician prior to the baseline visit. With the primary outcome of feasibility, all participants were enrolled in open label, active tDCS.

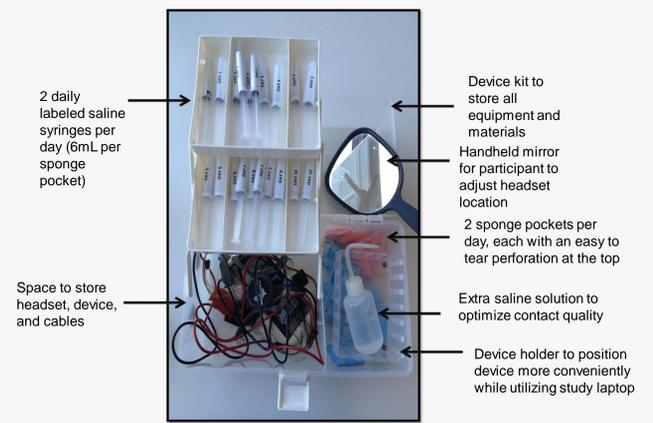


Figure 1. tDCS study kit

The baseline measures were collected in clinic followed by the presentation of the tDCS study kit (Figure 1), an instructional video (Figure 2) on the tDCS device, study laptop and daily study procedures. Additional instruction was provided to confirm understanding of each participant and/or proxy. The first self-guided tDCS session was then completed in clinic. On day two of the study, study technicians delivered the equipment to the participant's home, confirmed environmental suitability, and observed the second self guided session, providing training where necessary.

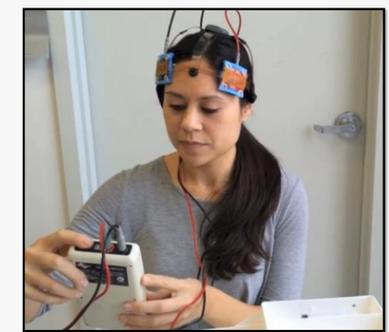


Figure 2. tDCS instructional video

Sessions 3-10 of the study were completed by the participant from home using remote-supervision software. Sessions were scheduled in advance during the baseline visit, and participants were monitored to determine if any predefined "stop" criteria were met (Figure 3). VSee, a telemedicine software, was used daily to confirm headset placement, collect daily inventories of pain, mood, fatigue, and any side effects. The communication software was also used to provide the daily, one-time use unlock code. In addition, TeamViewer software was installed to allow study technicians to troubleshoot any computer issues and to initiate the video conference on behalf of participants.

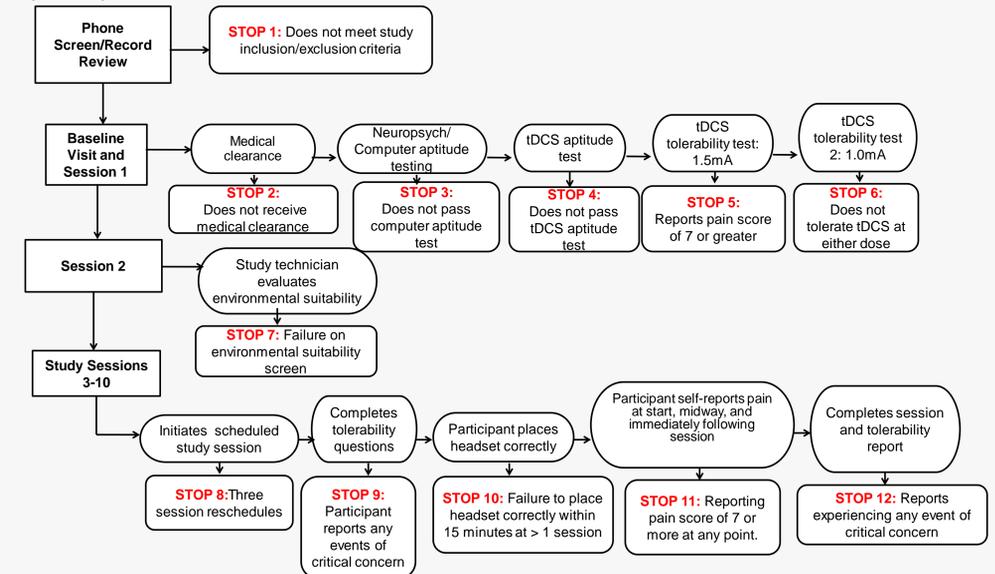


Figure 3. Study stop criteria flowchart

Results

Twenty participants (n=20), ages 30 to 69 years with a range of disability, Expanded Disability Status Scale or EDSS scores of 1.0 to 8.0 and subtype (n=6 RRMS, n=2 PPMS, and n=12 SPMS), were enrolled to test the feasibility of the methods. Protocol adherence exceeded what has been observed in studies with clinic-based treatment delivery³, with all but one participant (95%) completing at least eight of the ten sessions (Figure 4). Across a total of 192 supervised treatment sessions, no session required discontinuation and no adverse events were reported. The most common side effects were itching/tingling at the electrode site with no side effect exceeding an intensity of moderate (Figure 5). The study was met with strong patient interest and highly positive feedback.

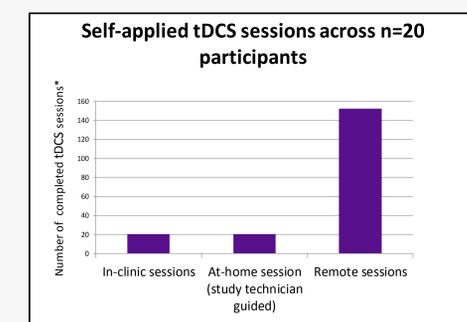


Figure 4. Study session completion by location

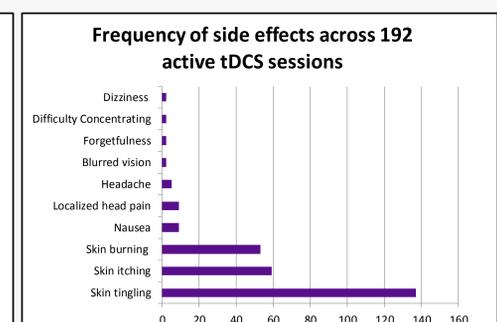


Figure 5. Side effect frequency across 192 tDCS sessions

Conclusions

- The remotely supervised methods proved to be an effective and well-tolerated means to provide access to patients of a range of disability, especially those with more advanced form of the disease (70% progressive).
- This method could be effective in supporting future clinical trials to determine optimal dosing, cumulative treatment effects, and the efficacy of tDCS in treating symptoms specific to MS.

References

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