Brain Stimulation 15 (2022) 385–387

Contents lists available at ScienceDirect

Brain Stimulation

journal homepage: http://www.journals.elsevier.com/brain-stimulation

Factors supporting availability of home-based Neuromodulation using remote supervision in middle-income countries; Brazil experience

Letter to the Editor

Noninvasive brain stimulation with transcranial direct current stimulation (tDCS) is a low-cost, safe, and deployable/battery powered [1] intervention. Growing evidence for efficacy for its use in a wide range of neurological and psychiatric disorders [2] supports its adoption into clinical management, including in middle-income countries such as Brazil. As tDCS can be safely and rigorously delivered (e.g., electrode montage, impedance, and current) to patients at home for treatment with remote supervision [3,4], its deployability is especially relevant for worldwide use. Chief among guidance for remote supervision of tDCS is ensuring close supervision and control over subject stimulation at home. In addition, tDCS can be easily paired with other telemedicine or digital-therapy administered interventions to enhance therapeutic outcomes. The COVID-19 pandemic has accelerated research and interest in home-based and remotely supervised tDCS [5]. Indeed, tDCS may have potential in treating COVID-19 related brain disorders and post-acute sequelae [6] (see Table 1).

Across its potential uses for neurological and psychiatric symptoms and conditions, there is an urgent need for further research. In addition, tDCS is increasingly gaining regulatory approval for use worldwide, and home-based use can be provided using telehealth delivery. However, the use of home-based medical devices presents complex challenges that vary according to the location of the intervention. On the one hand, people who live in rural areas frequently have restricted access to health care, due to locomotion and transportation issues [7], increasing the need for home-based treatment. On the other hand, limited broadband internet availability [8] can preclude home-based interventions that are designed to depend on high-quality digital connectivity and advanced devices (e.g., smart phones). As part of advancing the use of remote supervision to provide home-based tDCS, it is important to consider equitable access across nations and demographics. These considerations include aspects of technology device design and protocols for use with remote supervision.

These considerations are particularly relevant for middle-income countries such as Brazil, where the use of low-cost, scalable interventions for treating neurological and psychiatric disorders are highly desirable. In Brazil, and across the world, there is a soaring burden of central nervous system-related problems and multimorbidity between physical, neurological and psychiatric disorders. Notwithstanding the seminal and out-sized contribute of Brazilian science to tDCS [9], the deployment of home based in Brazil has been relatively halted – as comparing across high-income countries – despite the facts that the National Health Authority (ANVISA) in Brazil has already approved the use of tDCS devices from at least 5 companies including for motor and speech recovery after a stroke, depression, schizophrenia, and pain generated by fibromyalgia, that tele-health has been widely adopted during the COVID-19 pandemic, and that the presence of a public health system in Brazil (SUS) ensures capillarity of adopting tDCS and mobile Health techniques across the country.

We believe that such limited availability occurs due to several factors: (1) prices of internet data plans may further limit the access of some individuals compounded by tax policies [10] – in Brazil, most data plans are "pre-paid" and are composed by unlimited data access of some apps (usually social media ones) and low-internet speed for other apps or web browsing; (2) low accessibility to smartphones with capabilities to be coupled with tDCS; (3) low digital literacy, especially in older people, or those with lower socioeconomic status; (4) in the context of the public and private health systems, lack of reimbursement compared to pharmacotherapy; (5) regulatory barriers for the use of traditional tDCS that may disincentive the use of a novel technique of tDCS; (6) relatively low-cost of salary of health-care personnel who apply tDCS; (7) relatively limited knowledge of tDCS and portable tDCS by health providers in addition to challenges in training clinicians on the home-based tDCS.

Considering the opportunities represented by home-use tDCS systems in low-middle income country, these barriers to a more widespread tDCS adoption should be researched (e.g. in community based trials) and resolved, including through equitable tDCS device design. These future trials may also provide critical data to encourage governments to adopt this technique in the public sector, which may provide a top-down incentive to a more widespread use of this technique.

https://doi.org/10.1016/j.brs.2022.02.005

Table 1
Standard protocols for clinical trials utilizing home-based tDCS with remote supervision and either high or limited broadband internet connection. It is important to emphasize the remote supervision rubric is conceived to allow site/protocol/subject specific customization. It is therefore incumbent on the operator team to design how each of the seven Remote-Supervised elements are addressed, adopting a rigorous but least-burdensome approach.

Remote supervision of home-based tDCS: quality rubric [3]	High broadband internet connection	Limited broadband internet connection
(1) Training of staff in tDCS treatment and supervision;	- Smartphone or laptop or desktop video conference - Link of the conference recorded to be watched online - Online checklist to be consulted - One in-person training (more as deemed needed).	- Standard recorded training to be downloaded and watched any time - One in-person training (more as deemed needed) - Recurrently phone call or text message or e-mail to monitor the training procedures - Printed checklist with illustrative instructions.
(2) Assessment of the user's capability to participate in tDCS remotely (evaluation of tDCS aptitude: to follow the steps to operate the device, and place the headset with the electrodes after previous explanation)	- Smartphone or laptop or desktop video conference.	- In-person visit - Pictures of the tDCS gear after setting it up to show/send to the operator via e-mail/message-app.
(3) Training procedures and materials including assessments of the user and/or caregiver (continuous reevaluation). Aspects to consider for evaluating subject independence: A) Subject require staff assistance in placing headgear? B) Subject requires assistance in powering on the device? C) Subject requires operator assistance in establishing electrode contact quality? B) Subject requires assistance in activating the stimulation once provide the code?	- Smartphone or laptop or desktop video conference before, during and after session as deemed protocol/subject appropriate. Three options can include: 1) Live supervision through video conference every session (supervision for the entire duration of the session) 2) Daily contact through video conference before the session (visual check of the headset placement and clear the user for the session) 3) Live supervision through video conference for the first three sessions and evaluation of independence in operating the tDCS equipment.	- Weekly in-person visit (as needed – generally until subject reaches certified independence in operating tDCS equipment) - Phone calls or text message before and after every session - Pictures of the tDCS gear after setting it up to show/send to the operator.
(4) Strict dose control for each session; dose codes with time limit life; and use of tDCS device (turn it on and off)	- tDCS device connected to the internet - and/or Session codes provided by an operator in video conference - or Session codes provided by an online dedicated platform.	- Session codes provided by text or phone call - Inclusion of Proxy helper (caregiver or younger person).
(5) Simple and fail-safe electrode preparation techniques and tDCS headgear	- Headgear designed for reproducible and consistent electrode placement - Pre-saturated single use electrode.	- Headgear designed for reproducible and consistent electrode placement - Limited use electrode with simple instructions and illustrative materials for preparation.
(6) Monitoring adverse effects after each session	- Speech self-report through cellphone or laptop or desktop video conference - Self-report by text/audio message or e-mail - Self-report by an online dedicated platform.	- Self-report by text/audio message or e-mail - Notes in a diary.
(7) Quantify compliance Processes that even after subjects are certified to being home-tDCS there is a system to access ongoing compliance (such as an alert is improper set-up/use is suspected) or spot-checks on factors such as device preparation, electrode saturation/placement, stimulation protocol.	- Smartphone or laptop or desktop video conference - Device monitors performance (eg. session duration, impedance) and generates completion code, collected through dedicated chat or platform.	- Weekly in person visits (as needed) - Reports by phone call or text message before/after each session - Pictures of the tDCS gear after setting it up to show/send to the operator - Device monitors performance (eg. session duration, impedance) and generates completion code. Completion code generated by device relayed to operator by phone or text or diary (in which cases reviewed by operator on a schedule such as weekly).

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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2 February 2022
Available online 15 February 2022