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Supervised transcranial direct current stimulation (tDCS) at home: A guide for clinical research and practice

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ABSTRACT

Background: Transcranial direct current stimulation (tDCS) is a method of noninvasive neuromodulation and potential therapeutic tool to improve functioning and relieve symptoms across a range of central and peripheral nervous system conditions. Evidence suggests that the effects of tDCS are cumulative with consecutive daily applications needed to achieve clinically meaningful effects. Therefore, there is growing interest in delivering tDCS away from the clinic or research facility, usually at home.
Objective: To provide a comprehensive guide to operationalize safe and responsible use of tDCS in home settings for both investigative and clinical use.
Methods: Providing treatment at home can improve access and compliance by decreasing the burden of time and travel for patients and their caregivers, as well as to reach those in remote locations and/or living with more advanced disabilities.
Results: To date, methodological approaches for at-home tDCS delivery have varied. After implementing the first basic guidelines for at-home tDCS in clinical trials, this work describes a comprehensive guide for facilitating safe and responsible use of tDCS in home settings enabling access for repeated administration over time.
Conclusion: These guidelines provide a reference and standard for practice when employing the use of tDCS outside of the clinic setting.

Introduction

Transcranial direct current stimulation (tDCS) is a method of non-invasive neuromodulation that has been increasingly studied for its potential use as a clinical tool. An electrical current of low intensity is delivered from a device and passed through scalp electrodes targeting the brain region(s) of therapeutic interest. tDCS is typically conducted through two large (20–35 cm^2) saline-soaked sponge-electrodes or with a ring array to focalize current delivery [1,2].

There is no approved clinical indication for the use of tDCS in the U.S., and the level of evidence supporting the clinical use of tDCS varies across uses and conditions [3–28]. However, despite the growing number of studies, varied regulatory approvals internationally [29], and consensus on safety [1,30], definitive guidance for any effective therapeutic application remains yet to be established [22,24,31–36].

A major challenge to completing the necessary clinical studies is the number of treatments likely necessary to evaluate benefit and determine optimal dosing. Evidence from both basic and clinical studies suggest that the effects of tDCS can be cumulative, such that multiple daily or semi-daily applications are needed to achieve

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clinically meaningful effects [12,27,28]. These findings emphasize the benefit of extended tDCS protocols spanning weeks, months, or longer [28,37,38]. With this consideration, many studies may have used ineffective dosing of tDCS due to the real-world obstacle of requiring patients to repeatedly visit the clinic for treatments [63].

Providing tDCS treatment at home can decrease burdens for patients and their families by eliminating the need for travel to the medical or research facilities for every treatment session. Other advantages include relatively increased treatment compliance [39] and enhanced access to tDCS for patients who reside in geographically remote areas and/or live with physical or cognitive disabilities and/or chronic illness [38]. Our experience over the past several years evaluating tDCS for clinical benefit, both in controlled clinical trials [40–43] as well as in case studies [37,38], has confirmed the advantages of delivering treatment at home [63].

While most at-home tDCS approaches necessitate interactions between tDCS supervisors (the research or clinical team members) and a tDCS user (a study participant or a patient) with or without help of a lay assistant (such as a caregiver or family member serving as a co-participant in a research study or assisting a patient with daily activities), key elements that define the rigor of each approach are:

i) Level of training and remote assistance provided by the tDCS supervisor to the tDCS user and his/her lay assistant (if applicable);
ii) Suitability of procedures for accurate and replicable electrode placement at home;
iii) Monitoring of tDCS protocol adherence;
iv) Quality of the device (e.g. good manufacturing practices for quality assurance and functionalities allowing for dose control);
v) Safety monitoring and assessment of targeted outcomes;
vi) Ongoing adjustment of the above factors to the specific needs and/or limitations of the individual tDCS user.

Varying approaches to at-home use of tDCS have been described in the literature to date [39]. The most rigorous approaches to at-home tDCS include comprehensive clinical study protocols with high methodological control for high accuracy and reproducibility. For example, our groups have developed and implemented a protocol termed “Remotely Supervised” or RS-tDCS, which uses standardized procedures with real-time and ongoing supervision during each treatment session [37,40–46,62] with patient-tailored at-home tDCS [40,47–49].

Following the implementation of the initial basic recommendations and guidelines for at-home tDCS in clinical trials [50], the purpose of this work is to provide a comprehensive guide to operationalize safe and responsible use of tDCS in home settings. While our primary goal of at-home use is to facilitate clinical research, we acknowledge that clinical use varies across countries in terms of regulatory frameworks [29] and that there are clinicians who employ tDCS for off-label clinical use in the U.S. [22,24,25,51]. Therefore, we address tDCS home use in both investigative and clinical contexts.

Outside of the scope of this review is the unsupervised “do-it-yourself” or DIY approach to tDCS, where tDCS is self-administered by untrained individuals without formal training, often using devices that do not meet good manufacturing practices [52].

Although professional oversight is not mandated for the private use of publicly available tDCS devices, it is important to understand that adverse effects may result from uninformed or careless tDCS application (e.g., burns) along with unintended and unknown neuromodulatory effects, including the potential for undesired neurobehavioral outcomes. Further, from a research perspective, unsupervised and poorly informed tDCS home use has limited value for understanding and reproducing stimulation outcomes [53].

Below, we provide guiding considerations and recommendations for each of the eight core elements of at-home tDCS application described in the original guidelines. Each element is first described broadly, followed by considerations specific for research and clinical contexts. When tDCS is applied in research settings (regardless of the device’s FDA indication), the device use must be approved by an institutional review board (IRB) and subsequent procedures must strictly adhere to the IRB-approved protocol. Physicians may prescribe a device for off-label use [54], but all regulatory requirements (which differ in individual U.S. states and among countries) must be followed [31,52,55]. While clinicians are required to meet good practice standards, the scientific and methodologic rigor typical for controlled clinical trials may not be feasible in day-to-day clinical practice.

Considerations and recommendations for home use of tDCS in research and clinical contexts

Training for tDCS supervisors and tDCS users -Building competency in tDCS

Competency in tDCS is a core requirement for use of at-home tDCS in accordance with best practices. Competency is defined as “a combination of knowledge, skills and performance” or in other words “the ability to apply knowledge, skills and judgment in practice [56].” In the area of at-home tDCS, competency of both the tDCS supervisor, as well as the tDCS user (a study participant or a patient, Table 1) is essential.

Building competency in tDCS is a systematic process that involves gaining relevant knowledge, building skills for tDCS applications, and practicing the process of tDCS delivery in both practice and real-life settings. For tDCS supervisors, an initial tDCS training session can provide a useful starting point, but the overall competency building process requires a comprehensive, multi-level training program with high quality content that is free of commercial bias, has well-defined performance standards, and allows for objective evaluation of trainees’ performance. As of 2019, aside from multiple short courses of various quality and content, the first CME-accredited tDCS fellowship (New York City, 2015, 2016, 2017, 2018) represents an example of comprehensive education in tDCS under the reviewed by the American Medical Association (AMA). Additional courses are available, either in conjunction with scientific meetings or as stand-alone trainings, however these are typically not CME-accredited and often short in duration of training (i.e., one or two days). In general, tDCS competency training for tDCS supervisors (summarized in Table 2) should include knowledge of the following relevant background [57]:

- principles and mechanisms of tDCS;
- regulatory status (regionally applicable regulations or guidelines for research/clinical use);
- precautions for general safety;
- rationale and procedures for tDCS applications and participant-selection in various populations and settings;
- neurophysiological basis of tDCS effects;
- research and clinical protocol design, including approaches to sham-control;
- informed dose selection; and
- review of existing tDCS devices and their use.

The skill-building component of the comprehensive training process should also include:

- participant-screening procedures;
- safe, accurate and replicable electrode preparation and montage;
- activating/deactivating tDCS device;
- outcome monitoring; and
- mandatory record keeping.

The evaluation component of the training must allow for objective assessment of trainees' progress toward competency/mastery in the above-described elements. This can be achieved through a set of theoretical and practical tests concluded with an examination of trainees' preparedness to perform tDCS independently.

tDCS supervisors with established tDCS competency can provide training for the at-home user (e.g., a study participant or a patient). For tDCS users, an initial in-person training in the research facility or at-home with the tDCS supervisor can be used to familiarize the user with tDCS and the specific procedures that will be conducted in the home setting. The in-person training may be supplemented with instructional materials that use lay-language.

Research: Research personnel should have formal training and sufficient experience to administer stimulation to participants. For example, the RS-tDCS protocol has standardized training procedures that are taught to participants during a baseline study visit, requiring the participant to demonstrate competency prior to initiating tDCS applications. Once home, ongoing support for the participant is provided during subsequent training sessions via videoconferencing [40,47–49].

Clinical context: tDCS supervisors guiding at-home tDCS in clinical settings should, at a minimum, complete a training (preferably CME-accredited) assuring a clinician's competency in tDCS before they engage in prescribing and guiding at-home tDCS for therapeutic use. The clinician is also responsible for assuring proper training of both the tDCS supervisor and the tDCS user before beginning at-home tDCS treatments.

User selection and assessment of capability

User selection for at-home tDCS should follow general principles of user screening prior to tDCS application as described in detail in standard publications [1,30]. Further, the user selection procedure specifically for at-home tDCS should include consideration of the user's physical and cognitive capacity to operate the tDCS device safely and reliably. In addition, particularly in the psychiatric setting, the user's emotional capacity to operate independently outside of the in-clinic therapeutic setting should be considered, and how the remote supervision may influence the nature of the therapeutic relationship. The inclusion of both formal and informal caregivers to provide lay assistance with the tDCS application should be considered for users with substantial disability.

Research: The process of subject selection in research settings is highly standardized. The inclusion and exclusion criteria must be well defined and approved by the IRB.

Clinical context: Although the IRB oversight of patients' screening prior tDCS does not apply outside of research, it is the clinician's responsibility to educate themselves on conditions that would exclude the patient from at-home use on a precautionary basis (e.g., incapacity due to cognitive or physical impairment) [1]. Further, a well-defined replicable tDCS application protocol and workflow for clinical patient selection is needed.

Device and electrode preparation and placement

A significant best practice that must be upheld for administration of tDCS in home settings is correct electrode preparation and placement. Electrode preparation may entail application of saline to electrodes and/or cleaning the electrodes of any stimulation byproducts. Once electrodes are prepared for stimulation, accurate electrode placement is needed. Placement of the anode and cathode electrodes determines the electrical current flow through the brain. The placement is based on the targeted region of interest and deviations from a pre-defined location on the scalp may affect the outcomes of tDCS application.

The most commonly employed electrode montages in tDCS research are left anodal M1-SO (C3-right supraorbital region [Fp2]) montage and the bilateral frontal (F3–F4) montage. To date, high definition or HD-tDCS arrays have been used in laboratory settings only, but future at-home applications may incorporate this methodology as well. The placement of electrodes is typically based on measurement systems adapted from EEG (10–20 international system) but more sophisticated methods exist, such as MRI-informed electrode placement (e.g., neuro-navigated [58,59]). However, neither of those approaches are suitable for tDCS users at home and therefore provisions must be available to assure that at-home tDCS users have correctly aligned their electrodes to a predefined location. The placement of electrodes at home can be guided by visual and tactile aides. For example, a head strap can be used to hold the electrodes in place and visual markers can be used by a patient with a mirror to determine proper placement (Fig. 1A and B) [60]. Electrode preparation and placement completed by users at home may be verified by tDCS technicians through use of live videoconferencing.

Research: Across our collective experience using tDCS, we have found that simplified procedures for electrode preparation can greatly benefit participants who are unfamiliar with non-invasive brain stimulation or have cognitive or physical deficits. Researchers should consider the challenges their patient population may have when preparing tDCS at-home.

Clinical Context: In the absence of accepted guidelines for any clinical use at this time, and no approved use for any clinical indication in the USA, clinicians are encouraged to employ treatment decisions and stimulation parameters that are evidence-based, referring to the most recent published studies in the related field that specifically address the clinical problem(s) that they are targeting [24]. Use of novel montages or stimulation parameters for tDCS therapeutic use should be minimized without careful consideration, as outcomes can vary with alterations of the tDCS approach.

Dose control

Effective dose control is one of the most important aspects of at-home tDCS. A tDCS dose is constituted by multiple parameters, including intensity and duration of the current, number and size of the electrodes, and the electrode placement/target brain region.

Table 1
Definitions of Roles in At-Home Use of tDCS.

tDCS Supervisor: Staff members from the research or clinical team who will supervise the at-home delivery of tDCS.
tDCS User: The individual study participant or patient who will receive tDCS at home
Lay Assistant: An caregiver or family member who will assist the tDCS User at home

Table 2
Competencies in tDCS. There are core competencies that should be mastered by tDCS supervisors and users before commencement of at-home treatment.

1) Operating the tDCS device, including preparation of electrodes; electrode positioning and montage; activating/deactivating the device;
2) Recording and reporting outcomes pertaining to safety and efficacy
3) *Making informed decisions about tDCS dosing based on a review and evaluation of existing evidence;
4) *Making informed decisions about pairing tDCS with other therapies (pharmacological and behavioral), and potential modulators of tDCS effects;
5) *Training the user in tDCS delivery;
6) *Setting provisions for monitoring of outcomes – both the functional outcomes of interest and safety-related outcomes;
7) *Understanding and adhering to any regionally applicable regulations or guidelines for research/clinical use of tDCS.

Table 2. Competencies in tDCS [Items marked "*" indicate competencies that apply only to tDCS supervisors].

Stimulation devices should include safeguards to prevent delivery of an incorrect dose. Unlike pharmacological treatments that can be precisely measured, tDCS has no standardized markers of completion of the determined dose. Devices used for tDCS in home settings should allow for *controlled dose* for each stimulation session. This can be achieved via pre-programmed stimulation parameters in the device and electronic codes that unlock the pre-set stimulation parameters for specific treatment sessions, or via time-sensitive electronic lock that allows for tDCS application of prescribed dose in a pre-defined time window. For example, the time-sensitive lock may allow for delivering one 20-min stimulation at pre-defined intensity once a day any time between 6am and 6pm. Commonly used conventional tDCS doses include 20 or less minutes of stimulation, amperage intensities in the range of 1–2.5 mA delivered via two large (20–35 cm^2) electrodes. However, many exceptions to these conventions exist and investigators ought to consult the growing literature when designing new studies aimed at exploring clinical questions.

Research: Doses that are experimental (meaning that they have limited or no evidence of efficacy or safety), such as doses including high current intensities, should be reserved for research purposes and examined in laboratory settings prior to deployment to clinical trials in home settings.

Clinical context: Previously untested stimulation dosing parameters should be avoided for clinical use. However, a patient's individual dose may be titrated to adjust for the needs of a patient over time at the clinician's direction. For example, a long-term titrated dose schedule may consist of consecutive daily sessions followed by a pattern of less frequent application over time. Dosing and titration remain an open question in the use of tDCS with research needed to better guide clinical application.

Ongoing monitoring for procedural adherence and targeted outcomes

The extent to which at-home tDCS delivery is monitored depends upon the users or population involved, professional context of delivery (controlled research study vs clinical practice), and technological sophistication of the equipment (i.e., devices with dose control). Through the use of HIPAA compliant videoconferencing software such as VSee [61] and Zoom [49], tDCS operators can effectively instruct, correct, and aid users during each stimulation session. Both programs are examples of videoconferencing software that protects and encrypts all audio, video, and screen sharing data with the use of password protection for each encounter and conducted across protected networks, meeting the standards for HIPAA compliance. Real-time monitoring via videoconferencing also allows the operator to monitor procedural compliance and treatment tolerance over each stimulation session.

Both investigators and clinicians should track users' adherence to their assigned treatment schedule as this may affect the efficacy and overall treatment outcomes. As has been observed in clinical trials, tDCS is likely to have the greatest benefit when sessions are completed consecutively each day and users adhere closely to this schedule [19]. Treatment schedules of a lesser frequency, such as two or three sessions per week, may be insufficient for clinical benefit [7]. Devices that record stimulation activity may be advantageous, as the record can serve as a proxy measure of treatment adherence.

Assessment of treatment outcomes should be conducted at a priori determined check-in points to ascertain whether the user continues to benefit and respond to treatment. These assessments should include repeat administrations of a formally established and psychometrically valid measure of the symptoms or clinical problems that are being treated.

Research: In the research setting, at-home tDCS controlled trials can use real-time monitoring of participants to control for diversion from the protocol, inappropriate use, or other confounding factors. For example, the use of telemedicine platforms, such as

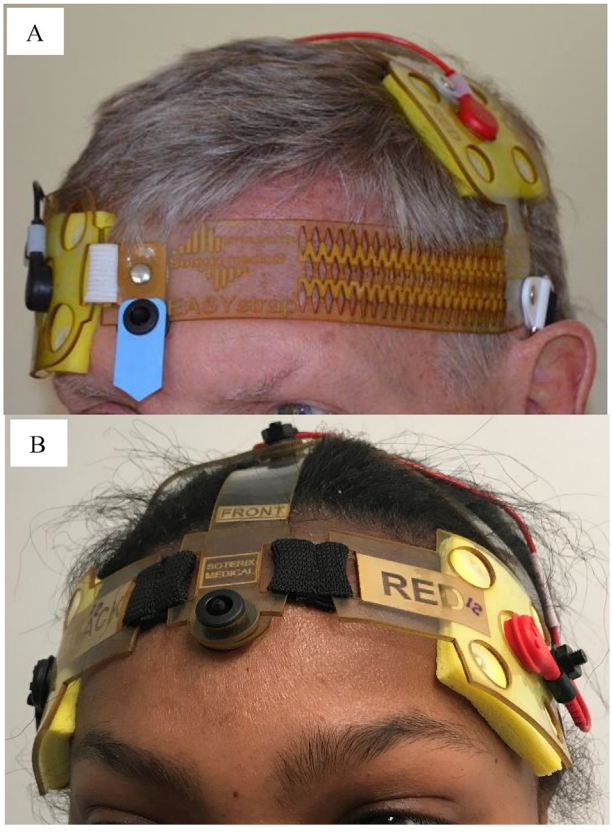

Fig. 1. A, B. A: tDCS headgear for the electrode M1-SO montage with the anode over the area of the motor cortex and the cathode over the contralateral supraorbital region. The headgear is size-fitted and has a center point (blue arrow) that supports accurate self-placement by user. The headgear does not require neuronavigational measurements and is suitable for use in home settings. B: The tDCS headgear for the bilateral front montage (F3 and F4). Similar to the M1-SO montage headgear, the headset is size-fitted and is suitable for use in home settings. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

videoconferencing, allow tDCS supervisors to verify if the user applies tDCS in accordance with good practices, or instruct participants, when necessary, to find quieter spaces, to redirect their attention towards the treatment and to address and resolve other interferences that may arise during treatment.

Clinical context: Ongoing monitoring at pre-determined time points is also important for the clinician to assure safe and appropriate use of tDCS at home, and to determine tDCS treatment outcomes. The timing and frequency of monitoring may vary, depending on a patient's adherence to the procedure and overall performance. Ongoing and objective assessment of targeted outcomes is an essential component to tDCS treatment; should assessments reveal a lack of clinical benefit for a patient, an informed discussion should be held with the patient to determine whether to continue treatment, alter stimulation dosage, or to discontinue tDCS treatment.

Ongoing evaluation for safety/adverse events

Tolerability of tDCS is constituted by multiple factors, including but not limited to the integrity and conductance of the skin, skull thickness, or *individual differences in pain threshold.* A tolerability test should be conducted prior to initiating tDCS in home settings. Should a user find the target tDCS dose intolerable, the dose may be attenuated (e.g., the amperage may be decreased in increments of 0.50 mA) for comfort.

Any reports of painful sensations should be recorded, with a pause of treatment and evaluation at pre-determined thresholds, as pain may reflect excessive irritation of the skin under the electrode or insufficient moisturizing of the electrode. This requires immediate attention of supervising personnel, and the dose should be adjusted if the report of pain or excessive unpleasant skin sensation under an electrode persists.

Supervising personnel should routinely inquire about any adverse events related to the treatment. Importantly, no serious adverse effects have been reported with at-home delivery of tDCS, as is comparable to in-clinic delivery of tDCS [30]. The authors' combined experience, which includes over 5000 tDCS sessions to date delivered using the RS-tDCS protocol 41,42,44–46,50,62, is evidence of the safety of tDCS, with no serious adverse events observed, including in the context of extended treatment schedules (up to 60 tDCS treatment sessions for an individual recipient [37,38]) and relatively high stimulation amperages (up to 2.5 mA). Of note, across the studies using the rRS-tDCS protocol, stimulation at conventional amperages (0.5–2.5 mA) has been well tolerated. While the safety of tDCS performed in accordance with good practices is well established, it is important to emphasize that all personnel involved in the treatment should follow good clinical practices in tDCS, and remain vigilant when dispensing tDCS to home settings.

Research: Adverse event monitoring and reporting is mandatory as per IRB regulatory requirements. Beyond good practice in research, collection of adverse event reports enables researchers to compare rates of stimulation side effects between home environments, patient populations, and stimulation parameters. Participants completing tDCS sessions at home should be prompted to report any adverse events that they may have experienced in the time since the previous tDCS session as well as during that day's stimulation session to capture any possible associated effects. Any report should be evaluated, followed, and documented until the event has stabilized or resolved.

Clinical context: For the clinician, it is recommended that tolerability be assessed initially in-person either during the training or familiarization with the procedure to determine the stimulation intensity. Based on the literature to date, dosing up to 2.0 mA is widely tolerated with few exceptions and serves as a starting point for titration of a tDCS dose. Doses can be attenuated if a patient finds the stimulation uncomfortable, too distracting, or painful.

Discontinuation of treatment

To ensure safety of the at-home tDCS user, explicitly defined stimulation stop criteria should be established. An example of an event that may necessitate discontinuation of a session may be excessive impedance between electrodes preventing safe conductance of the electrical current (which may be indicated with a measure of impedance on a tDCS device). Similarly, there may be events that warrant discontinuation of the treatment altogether such as strong adverse responses to a stimulation protocol (e.g., persisting pain) or poor treatment or procedural compliance.

Research: As per most IRB requirements, study protocols include specific pre-determined criteria for discontinuation of an intervention and removal of a participant from a study. Although some discontinuation criteria may pertain to administrative aspects, such as study closure, discontinuation criteria for tDCS study should emphasize protocol adherence and participant safety. Investigators may consider use of a stop criteria flowchart (Fig. 2), in which participants must meet all requirements (as determined by the investigator) before initiating stimulation.

Clinical context: Clinicians are encouraged to consider setting appropriate treatment-use guidelines for the patient as relevant, but initially more rigorous monitoring is encouraged. Ongoing and routine patient reports and check-ins should be maintained throughout the duration of use.

Environment/settings

To ensure that a user can perform the tDCS application at home, it is important to consider certain features of the home environment and setting of the stimulation session. An assessment of the home environment may be necessary. Considerations include access to adequate and clutter-free space for operation of the device, including the operation of any monitoring system (e.g., laptop computer) as well as rehabilitation equipment (e.g., cognitive or motor training), if applicable. Further, users should be instructed on appropriate storage of the tDCS equipment, keeping it in clean and dry space.

Research: A dose can constitute both the stimulation parameters as well as the ongoing activity that the participant is engaged in during the stimulation. For example, a rehabilitative activity paired with tDCS directly for therapy (e.g., cognitive or motor training) or other neutral activity (e.g., meditation, video viewing). At a minimum, to avoid interference during therapeutic activities, participants should be encouraged to complete treatment sessions in a safe, quiet, distraction-free setting.

Clinical context: Patients should also be encouraged to find a distraction free setting for their stimulation. Consideration for the activities or rehabilitation completed during the stimulation should be factored into a home setting evaluation.

Minimum device specifications

A tDCS device should meet a minimum standard of specifications for reliable and precise distribution of the stimulation. Features that are considered critical for a minimally sufficient device include impedance monitoring, medical grade equipment and materials, dosing assurance, user friendly interface, and safety features.

Measure of impedance

A measure of impedance is important to assure that the target current may be established between the two electrodes without causing skin irritation. If impedance is too great or it is not possible to safely conduct a current, then stimulation should be restricted by the device as a safety precaution. In situations of high resistance, maximum voltage should be defined and metered for devices to ensure safety.

Medical grade materials

Any tDCS device for use by patients should be vetted for safe and standardized human application. Medical grade materials should be used in the production of any stimulator device; materials include insulated wires, refined electrodes, and cleanable devices or electrodes.

Dosing assurance

A device should be able to maintain a constant output amperage despite variable skin and scalp conditions. Any device that is to be used remotely should have the functionality to be pre-programmed by study tDCS supervisors, clinician, or device company to match the dose specifications.

User-friendly interface

User-friendly features such as a large, digital LED screen that displays device options and stimulation status are useful for guiding patients of varying technical abilities. For instance, devices including a clear display for stimulation status, time remaining in a treatment session, and measures of impedance or contact quality can facilitate successful device operation. For devices with interactive displays, features such as simplified language and succinct instructions can improve the patient's experience. For devices that are analog or that lack a digital display, stimulation settings should be clearly marked as to their function and in order of use for correct stimulation dispersal.

Safety features

Basic safety features should be incorporated in all tDCS devices. Importantly, the device should allow for dose control, and there should be an easily identified "stop" feature that allows the user to terminate stimulation. Further, auditory signals, such as a beep indicating the end of stimulation session should be included as well. Safety precautions should be summarized in lay-language instructional materials and reviewed with the user prior dispensing the device to home.

Discussion

tDCS is a therapeutic approach that is under increasing investigation for its potential clinical applications. There are no verified tDCS protocols for clinical use at this time, and these guidelines are primarily targeted to inform and facilitate further clinical research. tDCS delivered at home can decrease the time and travel burden associated with attending the clinic or research institution for treatment and it has the potential to provide treatment access to those who would not be able to attend clinic routinely (e.g., those with illnesses that are more advanced and disabilities), while promoting treatment adherence and compliance. As other non-invasive low-intensity electrical stimulation methods (such as tACS) evolve, these guidelines may serve in the future as a guide-template for emerging neuromodulation technologies when reaching the stage of transition to clinical settings or remotely-supervised at-home applications.

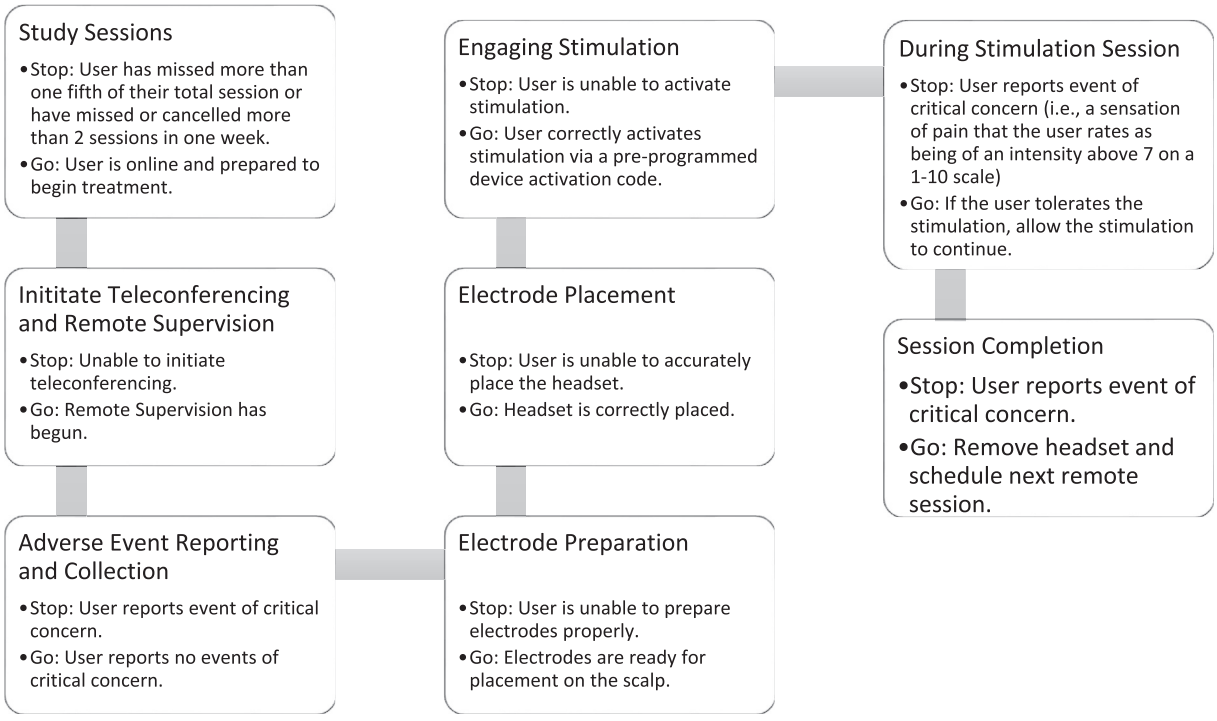

Fig. 2. Example of Study Stop Criteria: Rigorously defined stop/go criteria can clearly delineate procedures for reproducible delivery of at home tDCS.

Table 3
Summary considerations for at-home delivery of tDCS in accordance with good practices.

Element	Research	Clinical
Electrode Placement	Consult the literature and consider carefully how to best position the electrodes to achieve the desired effect.	Use electrode placement montages that have been shown to yield benefit towards the desired treatment outcome.
	Exploratory and experimental montages and electrode placement can be used but may yield unpredictable results.	Exercise caution when employing an electrode placement montage that has limited evidence of efficacy or tolerability.
Monitoring	Participants receiving tDCS remotely should be monitored for as many sessions as reasonable in order to assure that the experimental protocol is being followed precisely.	It is encouraged that the clinician check in with the patient periodically as warranted.
Tolerability	Adverse events must be recorded. Well-defined procedures should outline how to address typical and atypical reported adverse events. If a participant is unable to tolerate the pre-specified amperage of stimulation and the study design does not permit reduction of the dose, then the participant must be prevented from moving forward in the study.	A tolerable dose should be found for each clinical patient. 20 min of 2.0 mA tDCS is a typical starting point to assess tolerability and efficacy of the dose. The dose should be calibrated in regular increments if a participant cannot tolerate the stimulation dose.
Dose	Dose is optimized based on study hypothesis (brain target) and prior work in the literature.	Following conventional tDCS doses is encouraged but, ultimately, discretion (and ultimate responsibility) is left to clinicians when determining parameters of clinical treatment.
Training	Standardized training for both the patient and research staff should be required and outlined by the protocol.	Comprehensive training assuring clinician's competency in tDCS before he/she engages in prescribing and guiding tDCS for therapeutic use.
		Sufficient training for a user; assurance of competency to operate the tDCS equipment and to report outcomes.
Environment	Participants ought to complete treatment sessions in a distraction-free setting.	Patients should be encouraged to find a distraction-free setting to complete treatment sessions.
Evaluation	Specific research outcomes assessment should be conducted at time points decided a priori.	Regular, a priori assessment of efficacy is encouraged considering the experimental nature of the treatment.
Minimum Device Specifications		
➢ Device monitoring that blocks or moderates stimulation if impedance is too great to conduct a current as intended between the electrodes.		
➢ Medical grade materials should be used in the production of any device build that is used for research or clinicians.		
➢ Doses should be delivered by devices with precision and accuracy. Device should have a capacity for researchers and clinicians to pre-program and lock the dosage that will be delivered to users.		
➢ Safety features should be implemented into a device build to ensure that essential protections are provided to the patient. These include the ability to abort a session or limiting the device's ability to stimulate in situations of high resistance.		
➢ The device should be user friendly and intuitive as appropriate for patients with disability (i.e. those with limited vision or cognitive ability. Examples include large fonts and texts used on the device and clear indication as to how to abort stimulation sessions.		

Conclusion

This comprehensive guide (Table 3) provides recommendations for supervising at home use based on core elements to ensure safe and responsible use of tDCS.

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Declaration of competing interest

Authors Leigh Charvet, Michael Shaw, Adam Woods, and Helena Knotkova declare no conflicts of interest. The City University of New York (CUNY) has IP on a neurostimulation system and methods with Marom Bikson as inventor. Marom Bikson has equity in Soterix Medical Inc and serves as a consultant for Boston Scientific, GHK, and Mecta.

CRediT authorship contribution statement

Leigh E. Charvet: Conceptualization, Writing - original draft. **Michael T. Shaw:** Conceptualization, Writing - original draft. **Marom Bikson:** Conceptualization, Writing - original draft. **Adam J. Woods:** Conceptualization, Writing - original draft. **Helena Knotkova:** Conceptualization, Writing - original draft.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.brs.2020.02.011.

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