Transcranial electric stimulation in do-it-yourself applications

Background: Transcranial electric stimulation (tES), in particular transcranial direct current stimulation (tDCS), has emerged as a widely distributed research tool for influencing human brain function. Its simplicity and low cost has contributed substantially to its do-it-yourself (DIY) use for brain enhancement or even treatment of diseases in lay populations. *Here, we define DIY as self-application of tES without fully conforming to a verified efficacious protocol and/or using a device that has not been certified.* DIY-ers are either healthy subjects looking for neuroenhancement and/or patients (most frequently chronic pain, seasonal affective and generalized anxiety disorders, bipolar or schizophrenic patients) seeking treatment. Their primary goal is self-improvement or self-treatment on a self-observational basis.

- Three groups may be differentiated:
  1) The "hardcore" DIY group buying "kits", building and using the stimulator at home; sometimes even selling this home-made stimulator on the internet; posting available scientific knowledge on different internet pages and translating them into lay information (for example, http://www.reddit.com/r/tDCS, http://www.diytdcs.com; tdcsplacements.com)
  2) Home-users – buying a stimulator from the internet (or from a company) and using it at home without supervision;
  3) Patients having received a stimulator from a medical doctor, legally prescribed as an "off label-treatment" for home, without or with (initial) supervision

Estimating scientific risks and potential mechanisms for (self-) injury to the brain when using tES

- Scientific protocols have been developed to optimize parameters for influencing brain function, so as to selectively enhance or reduce brain excitability as most frequently indexed by transcranial magnetic stimulation (TMS) evoked motor evoked potentials (MEPs). These effects, in terms of enhancement, beneficial or detrimental, are strongly stimulation dose and time dependent. For example, too long anodal stimulation may reverse excitability increase into inhibition [1]. Doubling cathodal stimulation intensity may reverse inhibition into excitation [2]. With the exception of a single case report of a schizophrenic patient, the longest research use documented was 60 minutes; however, on the DIY websites a duration of several hours per day, for example, in order to learn a new language, is frequently seen. Unplanned results may occur from build-up of effects across multiple sessions or from influence on non-target areas. Long-term use bears a risk of structural change, which has not been evaluated in terms of neurogenesis, synaptogenesis, galvanotaxis, myelination, and possibly other factors.

- Most relevant in the context of claims of brain enhancement is a recent study showing a detrimental effect of a commercially available device sold for brain enhancement [3]. This is in line with published data on risk for interference with learning and memory (e.g. [4, 5])

- The risk in children, (for example, home-stimulation initiated by highly motivated parents) is almost not studied. The dose may well have to be attenuated due to lower skull thickness [6]. Thus, protocols of 2 mA intensity cause higher current flow intensity in children's brain than has been investigated and regarded to be safe in most protocols in the adult.

- Subjective benefits may be triggered by "suprathreshold" placebo effects and may be accompanied by initial "subthreshold" side effects. Long-term, repetitive stimulation may augment the side-effects due to maladaptive plasticity. While such long-term side effects are not necessarily different from those of oral compounds, since there is, for example, the risk of outgrowing of new abnormal nerve connections (galvanotaxis) there may be a new dimension of detrimental effects so far unknown in drug therapy.

Unsolved issues:

- Legal rules and considerations vary strongly dependent on country. When using tDCS devices, some countries (like Germany) limit purchase to CE certified devices for medical use according to the medical product law. Furthermore, only health professionals (listed under MPG(§3)) can apply these devices therapeutically. However, current medical device legislation does not cover the use of devices, such as tDCS, for cognitive enhancement outside legal patient care. For example in Germany, buying a stimulator from a company and using a stimulator legally prescribed as an "off label-treatment" for home requires additional supervision and formal device instruction by registered medical personnel. Other countries, like the USA, have much less restricted regulations (see, for example, [7]), nevertheless, the home-use is not regulated.

- Frequently, it is not clear if the stimulators should be or are classified as Medical Devices or Consumer Devices or General Wellness Devices. Accordingly, it is not clarified, how well home-users are protected from potential malfunctions. Only when devices are certified to CE mark according to medical product law or FDA QS standards are consumers protected by the company.

- Development of robust safety standards, determined by the dose, inclusion/exclusion criteria and other protocol issues: since no formal obligations exist for reporting side effects, not even a possibility to report them, detrimental effects may take a much longer time to be detected as compared with drug therapy.

Recommendation:

Necessary conditions: Given this situation, the IFCN recommends that for any use of tES in the treatment of a medical indication (at home or in the clinic) this should be done with a medical grade device or consumer device (CE mark) and under supervision of a medical provider and trained personnel. In the United States, devices having been approved for *Over-The-Counter* (*Non-Prescription*) by the governing regulatory agency may also be used by law.

Necessary and sufficient conditions: In medical applications, a necessary and sufficient condition is the use of protocols, which have demonstrated in peer-reviewed clinical trials to be both safe and efficacious. The manufacturer should have this information in the user manual, based on clinical evaluations. In non-medical applications, efficacy and safety should also be standard, including home-use. Many scientific investigations have shown both positive and negative results for circumscribed cognitive processes in special investigations. As many 'home-applied' protocols have not been formally tested, and many sensitive parameters have not been carefully reproduced, stimulation may switch positive into negative results.

Thus, the IFCN warns against the use of DIY devices and methods unless they have shown both efficacy and safety.

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