Regulating consumer use of transcranial direct current stimulation devices

Uncertainty about the safety of unsupervised use of technologies to enhance cognition, mood and behaviour warrants regulatory oversight

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Transcranial direct current stimulation (tDCS) is a non-invasive brain stimulation device that uses a small electrical current (~ 1–2 mA) between two or more electrodes placed on a person's scalp to manipulate neural activity. The current is not enough to cause brain cells to fire, but can change their readiness to fire, potentially influencing learning and cognition. There is considerable evidence that tDCS can modulate cortical excitability for brief periods (~ 30 min) after a single 20-minute application.[1]

The capacity to alter neural activity has raised considerable interest in whether tDCS can also enhance cognitive function (eg, memory, language and mathematical skills) in healthy individuals, as well as ameliorate symptoms in a growing number of medical conditions. Recent clinical trials suggest superiority of tDCS over placebo in the treatment of depression.[2] However, the use of tDCS for cognitive enhancement, particularly in healthy individuals, remains controversial. Meta-analyses suggest improvements in cognition are extremely subtle and limited to certain cognitive domains that are unlikely to provide meaningful enhancement.[1,3]

There are currently no reliable prevalence statistics for consumer use of tDCS, with many individuals constructing their own devices.[4] However, interest in tDCS devices to enhance cognition is expanding rapidly as the number of devices entering the market grows.[5] For example, the tDCS page on the forum Reddit regularly receives over 6000 hits a month and has 2700 subscribers.[6]

Despite limited evidence of improvements in cognition, these devices are being marketed to healthy consumers to enhance their memory, attention, language, mathematical skills, sporting and gaming performance.[7] It is therefore timely for clinicians, researchers and regulatory authorities to anticipate growing consumer interest in the use of such devices to prevent harms that may emerge from their use for enhancement purposes.

Safety concerns

tDCS has been shown to be safe when used in a supervised clinical or research environment under strict treatment protocols that dictate the location, duration and strength of stimulation.[8] However, when used incorrectly, tDCS can cause adverse side effects, such as itching or burning sensations under the electrodes, with several reports of skin lesions from electrode attachment, and negative mood changes in those with mood disorders (eg, mania and hypomania). Furthermore, unexpected adverse effects of tDCS have been reported, including increased anger and impaired cognition and memory.[9] There are several reasons to be cautious about promoting their use to consumers:

- individuals are able to use settings outside recommended safety limits;
- safety is well established for short periods of stimulation (eg, 20 min), but in longer periods of stimulation, including daily use over multiple weeks, it is less established;
- consumer products and homemade systems do not provide the same level of confidence that the stimulation is being administered as expected; and
- brain anatomy varies from one individual to another.

There may also be risks faced by children whose brains are still developing, particularly those with neurodevelopmental disorders, such as attention deficit/hyperactivity disorder, autism or schizophrenia.[10] With thinner skulls, the amount and frequency of stimulation applied to a child's brain could potentially have a much greater adverse effect.[11] This is particularly troubling given evidence that shows that home users of tDCS devices, such as children involved in online gaming, often use higher currents for extended periods of time.[6] The prolonged and unsupervised use of tDCS may also have unexpected effects on people with diagnosed or subsyndromal psychiatric disorders (eg, psychosis and depression). Thus, uncertainty about the long term safety of unsupervised tDCS use raises a number of ethical and regulatory questions.

Ethical concerns

The principles of liberty and respect for autonomy suggest that competent individuals should be free to enhance or manipulate themselves, provided that their actions do not harm others and that they are fully informed of the risks, which may often mean that new devices have been shown to be safe and effective. However, these devices may not be safe when used by untrained persons outside of recommended procedures. Emerging technologies to enhance cognition, mood and behaviour are often

promoted in the absence of robust scientific evidence of their ability to provide the meaningful benefits that they claim.[12] The inflated ability of emerging neurotechnologies such as tDCS to significantly enhance cognition, mood and performance in the scientific and mainstream media may undermine the ability of individuals to fully weigh up the risks and benefits of using them.

Neuroethicists have highlighted a number of additional ethical concerns regarding the use of consumer tDCS devices for non-therapeutic uses. These concerns include the impact of social coercion and the perceived need to keep up with electrically enhanced peers, particularly among anxious parents and the "worried well".[7] This anxiety may provide additional motivation to individuals to use tDCS devices outside the recommended safety limits. They also point to justice concerns about unequal access and benefits arising out of the use of the devices, particularly in competitive circumstances that provide a substantial financial or other personal benefit (eg, workplace, sporting arena, and competitive university entrance exams), which could amount to cheating.[12] Ethical debates often turn on whether there is something unique about technological interventions that act more directly on the brain. We, nevertheless, simply make the point that ongoing concerns about the long term safety of commercial tDCS devices, particularly when used by untrained individuals, warrant regulatory oversight in Australia.

Regulatory oversight

Consumer tDCS devices could be subject to a range of regulatory controls in the areas of medical devices, product safety and consumer law. For present purposes, we focus on whether it could (and indeed should) be subject to medical device regulation, as this is more suited to the adoption of a proactive approach to risk management.

In the absence of specific national regulation covering such devices, consumer tDCS devices would need to come within the legislative definition for medical devices under the *Therapeutic Goods Act 1989*. This definition requires that medical devices must have, as one of their intended purposes, "diagnosis, prevention, monitoring, treatment or alleviation of disease; compensation for an injury or disability; or modification … of a physiological process".[13] The intended purposes of medical devices are in large part influenced by manufacturers' representations. The extent of regulatory oversight by the national regulator, the Therapeutic Goods Administration, is determined by the risk classification assigned to the device.[13]

A broad interpretation of the existing definition of a medical device could potentially bring consumer tDCS devices within national medical regulation. This would primarily be on the grounds of the modification criterion, given the strongest evidence shows that tDCS modifies neural structure and function, including neuron firing, interconnectivity and neuroplasticity. The devices are also marketed as enhancing performance in a number of respects and could therefore be seen as suitable for treating conditions for which these devices have a therapeutic purpose.[3]

Recent developments in the United States and the European Union (EU) offer a way forward in the event that regulatory reform is needed. The US Food and Drug Administration has taken a proactive approach to examining risks associated with their use, notwithstanding ongoing debate over whether consumer tDCS devices come within the current regulatory definition of a medical device.[3] This has included convening a public workshop on the issue,[14] and publishing guidance confirming such devices should not be considered low risk "due to the risks to a user's safety from electrical stimulation".[15]

In the EU, the Medical Device Regulation (MDR) has recently come into force and will apply in full from 26 May 2020.[16] The medical purpose definition in the MDR is similar in many respects to the definition in the Australian medical device regulation. It continues to include a modification criterion, which has been expanded to cover modification of "the autonomy or of a physiological or pathological process or state".[16]

The MDR also now covers devices both with and without a medical purpose, when they are based on a similar technology.[16] A list of such products includes "equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain".[16] As a result, consumer tDCS devices will now be subject to EU regulation for the purposes of risk management and clinical evaluation regarding safety, where necessary. Given similarities in approach between the EU and Australian medical device regulations, we argue these devices should also now be subject to regulatory oversight in Australia.

Conclusion

Although there is widespread marketing and commercial sales of consumer tDCS devices in Australia, there is currently no national regulatory oversight of their safety or effectiveness by the Therapeutic Goods Administration. This is despite an emerging international consensus that there are safety concerns associated with their use, particularly for vulnerable groups such as children and those with mental illness and neurodevelopmental disorders. A proactive regulatory approach is both timely and appropriate. Recent EU developments offer a way forward in the event that national regulatory reform is considered necessary to ensure that these devices are subject to national medical device regulation.

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