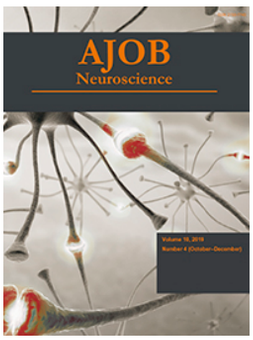

AJOB Neuroscience

ISSN: 2150-7740 (Print) 2150-7759 (Online) Journal homepage: https://www.tandfonline.com/loi/uabn20

Ethical and Regulatory Concerns About Direct-to-Consumer Brain Stimulation for Athletic Enhancement

Robert Martone & John Shook

To cite this article: Robert Martone & John Shook (2019) Ethical and Regulatory Concerns About Direct-to-Consumer Brain Stimulation for Athletic Enhancement, AJOB Neuroscience, 10:4, 191-193, DOI: 10.1080/21507740.2019.1665124

To link to this article: https://doi.org/10.1080/21507740.2019.1665124

Published online: 23 Oct 2019.

attention. Kreitmair's article is highly important for mapping out how new technologies *might* change perception of the self and one's surroundings (even if only temporarily). It is also important to note that this change would *not* be a potential by-product of the technology but would be the primary objective of the technology. For some people, neurological change will only be an interesting temporary adventure, but for others it might provide hope for a better life. When such life-changing technology is offered to consumers we should also consider this in detail for the supporting evidence (or lack thereof). Furthermore, if a DTC neurotechnology does prove to be efficacious we should then consider whether it should remain in the DTC market or be subject to medical regulation and *offered* within a medical context. For other forms of technology – that are not life changing - we should look at lessons learned from the longer and shorter histories of associated technologies and their regulation. These lessons should be used steer the market to protect the most vulnerable rather than try to address all forms of DTC neurotechnology and all forms of marketing this technology as if equally ethically important. ■

REFERENCES

Bell, S. K., J. C. Lucke, and W. D. Hall. 2012. Lessons for enhancement from the history of cocaine and amphetamine use. *AJOB Neuroscience* 3 (2): 24–29. doi: 10.1080/21507740.2012.663056.

Kreitmair, K. V. 2019. Dimensions of ethical direct-to-consumer neurotechnologies. *The American Journal of Bioethics Neuroscience* 10(4): 152–166.

Lucke, J. C., S. Bell, B. Partridge, and W. D. Hall. 2011. Deflating the neuroenhancement bubble. *AJOB Neuroscience* 2(4): 38–43. doi: 10.1080/21507740.2011.611122.

Outram, S. M. 2010. The use of methylphenidate among students: The future of enhancement? *Journal of Medical Ethics* 36(4): 198–202. doi: 10.1136/jme.2009.034421.

Simons, D. J., W. R. Boot, N. Charness, et al. 2016. Do "brain-training" programs work? *Psychological Science in the Public Interest* 17(3): 103–186. doi: 10.1177/1529100616661983.

Starr, R. R. 2015. Too little, too late: Ineffective regulation of dietary supplements in the United States. *American Journal of Public Health* 105 (3): 478–485. doi: 10.2105/AJPH.2014.302348.

Stohs, S. J., and H. G. Preuss. 2017. What health care professionals should know about the regulation and safety of dietary supplements. *Journal of the American College of Nutrition* 36(4): 306–309. doi: 10.1080/07315724.2016.1275065.

Wexler, A. 2019. Separating neuroethics from neurohype. *Nature Biotechnology* 37: 1–3. doi: 10.1038/s41587-019-0230-z.

Wexler, A., and P. B. Reiner. 2019. Oversight of direct-to-consumer neurotechnologies. *Science* 363(6424): 234–235. doi: 10.1126/science.aav0223.

Ethical and Regulatory Concerns About Direct-to-Consumer Brain Stimulation for Athletic Enhancement

Robert Martone, University at Buffalo
John Shook, University at Buffalo

We offer critical analyses and ethical concerns relating to direct-to-consumer (DTC) athletic enhancement in response to "Dimensions of Ethical Direct-to-Consumer Neurotechnologies" by Karola Kreitmair (2019). Transcranial electrical stimulation (tES) for physical enhancement is acquiring growing attention from professional athletes, the military, and the general public. Kreitmair rightly sees the need for an ethical framework to encompass a growing class of DTC neurotechnology products. This class of products deserves a level of strict scrutiny because these products are directed at altering the activity of the central nervous system.

Ethical concerns for short-term and long-term safety must be paramount, especially for DTC usage among members of the public, far above practical interests in measurable efficacy. Devices capable of altering brain function, whether in clinical or consumer settings, should be developed, tested, and marketed according to ethical practices. Consumers, no less than patients, deserve rigorous protections and ample information about these DTC devices in order to make informed decisions. Skeptical doubts and worried concerns about "brain doping" (Gazerani 2017; Lefaucheur 2019) may not abate public interest in accessing affordable short-cuts to physical enhancement.

Address correspondence to John Shook, Philosophy, University at Buffalo, 135 Park Hall, Buffalo, NY 14260716-432-75, USA. E-mail: jshook@pragmatism.org

Designing large clinical trials to focus on ascertaining the safety parameters and proper dosage for transcranial brain stimulation, and low-level tES in particular, has received relatively little attention to date. Consumers using tES devices as they like under uncontrolled conditions are hardly comparable to patients receiving uniform treatments under clinical care. Furthermore, noting how dozens of tES case studies have incidentally reported few serious harms occurring during clinical application (Bikson et al. 2018) is not an adequate substitute. (If such a substitution were reasonable, then the Food and Drug Administration [FDA] could discard most of the rigors of the Phase 1 stage.) As Kreitmair notes, many supporting claims for DTC tES devices are anecdotal, or take the form of manufacturer papers that have not undergone peer review. There is too little known about appropriate tES dosages, especially for usage outside of controlled clinical application. Hoping that "low levels" will be keeping everyone safe is just a hope (Bestmann and Walsh 2017).

Even less is understood about the real efficacy and reliability of tES for improving athletic capacities and skills. Experimental tests on athletic individuals can discern slight improvements to exercise performance, although much variability across individuals is the norm (Angius et al. 2018; Holgado et al. 2019; Huang et al. 2019; Kamali et al. 2019; Machado et al. 2019). Studies meeting high standards (large, randomized, blinded, placebo controlled) should carry the most weight. Conclusive scientific confirmations of improved athleticism from tES, showing both consistency of results from the same tES technique and reliability of results for many types of athletes, are still in the future (Colzato et al. 2017). Even if optimism about tES become warranted, we are not all athletes. How enhancements of exercise performance for elite athletes could transfer to exercise improvements for anyone else is largely speculative. To date, there has only been modest research into measurable whole-body results for non-athletes unfamiliar with arduous training regimens.

Should consumers be left to draw their own conclusions about how well tES devices may work for them without unwanted side-effects after prolonged use? The public receives little guidance from current government oversight or regulation. Kreitmair does not demand much more, basically claiming that these devices should not be subject to heightened regulatory scrutiny just because the FDA has declined to regulate them: DTC devices should not be evaluated "according to medical device criteria … because they are not regulated" (Kreitmair 2019, 155). This circular reasoning is a result of the author's struggle to cast a broad ethical framework over a narrowly defined group of devices that have (so far) escaped regulatory oversight.

Device classifications are not monolithic or unchanging. They may prove to be incorrect or in need of revision. Kreitmair brings up DTC genetic testing as an example where regulators developed an evolving understanding of oversight needs. In our view, many sorts of DTC neurotechnology devices, not excepting devices for athletic performance, should become candidates for research and regulatory scrutiny in a manner akin to medical devices. Kreitmair eventually concurs: "It is likely that some DTC neurotechnologies will ultimately require FDA oversight" (Kreitmair 2019, 162).

It might be thought that tES for athletic abilities, such as speed, strength, agility, and endurance, does not deserve a level of regulatory or ethical scrutiny as high as tES for cognitive operations. That neat distinction between "physical" and "mental" functioning lacks neurological or psychological warrant. Improved athleticism from tES could be partly or largely due to a variety of altered cognitive processes singly or in combination. Electrical stimulations of any brain areas are significantly interventional and carry both known and unknown risks. Letting the "buyer beware" could not be an adequate standard. Furthermore, risks from tES DTC products are taken not only by the purchasing consumer, but also by others in a household inappropriately accessing to a device, such as a child or a relative with a disqualifying medical condition.

Kreitmair offers "human flourishing" as the ultimate objective of DTC neurotechnology devices, a goal more broadly applicable than clinical efficacy. It is no coincidence that human flourishing is reminiscent of the FDA's "General Wellness" category of devices unattached to specific claims about treating diseases or health conditions. The promise of enhanced physical performance through tES is surely a route toward human flourishing. However, that flourishing cannot be reliably attained without proper attention to risk, efficacy, autonomy, and other important values. We assert that a DTC tES device's safety and efficacy are fundamental to any claim of transparency, safety, just distribution, and other ethical dimensions. Absent an adequate understanding of a tES device's effectiveness for trained athletes or casual consumers, it is impossible to determine acceptable risk levels, sufficient transparency regarding validation and effects, or equitable distribution or regulation.

We specifically urge that the dimension of autonomy should be elevated as its own priority. This is critical in the case of DTC tES for athletic performance enhancement, where there is only modest neuroscientific knowledge about neural architectures affected by these consumer devices. Kreitmair discusses autonomy within the context of transparency, taking the view that one's ability to act with autonomy would be impaired in the absence of transparency. And so it is. Yet transparency about vast ignorance is not an ideal way to make an "informed" patient or consumer, nor is it the most ethical way to respect the autonomy of vulnerable persons. Autonomy should be central to the capacity for consumer judgments about DTC tES devices.

Manufacturers can show respect for their customers by sharing more than anecdotal success stories. Heightened regulatory scrutiny should at least motivate manufacturers to cooperate with peer-reviewed studies in order to establish utility and risk profiles. Independent scientific interest to date has yielded limited results from generally underpowered studies. A

consensus strategy to address key unresolved questions could significantly advance the field, much as precompetitive consortia have led advances in other fields.

In summary, there is an enthusiastic and growing market for tES-aided athletic enhancement. The DTC market deserves stronger research and regulatory standards. Manufacturers of DTC tES devices should partner with athletic, research, and regulatory communities to promote the appropriate use of these neurotechnologies, and to ensure a robust continuity of empirical studies into the future consumer use of tES athletic enhancements.

COMPETING INTERESTS

The authors declare that they do not have any competing interests. ■

REFERENCES

Angius, L., A. Pascual-Leone, and E. Santarnecchi. 2018. Brain stimulation and physical performance. *Progress in Brain Research* 240: 317–339.

Bestmann, S., and V. Walsh. 2017. Transcranial electrical stimulation. *Current Biology*: *CB* 27(23): R1258–R1262. doi: 10.1016/j.cub.2017.11.001.

Bikson, Marom, Bhaskar Paneri, Andoni Mourdoukoutas, et al. 2018. Limited output transcranial electrical stimulation (LOTES-2017): Engineering principles, regulatory statutes, and industry standards for wellness, over-the-counter, or prescription devices with low risk. *Brain Stimulation* 11(1): 134–157. doi: 10.1016/j.brs.2017.10.012.

Colzato, Lorenza S., Michael A. Nitsche, and Armin Kibele. 2017. Noninvasive brain stimulation and neural entrainment enhance athletic performance–A review. *Journal of Cognitive Enhancement* 1(1): 73–79. doi: 10.1007/s41465-016-0003-2.

Gazerani, P. 2017. Performance enhancement by brain stimulation. *Journal of Sports Science & Medicine* 16(3): 438–439.

Holgado, D., M. A. Vadillo, and D. Sanabria. 2019. The effects of transcranial direct current stimulation on objective and subjective indexes of exercise performance: A systematic review and meta-analysis. *Brain Stimulation* 12(2): 242–250. doi: 10.1016/j.brs.2018.12.002.

Huang, L., Y. Deng, X. Zheng, and Y. Liu. 2019. Transcranial direct current stimulation with halo sport enhances repeated sprint cycling and cognitive performance. *Frontiers in Physiology* 10: 118. doi: 10.3389/fphys.2019.00118.

Kamali, A. M., Z. K. Saadi, S. S. Yahyavi, A. Zarifkar, H. Aligholi, and M. Nami. 2019. Transcranial direct current stimulation to enhance athletic performance outcome in experienced bodybuilders. *PLoS One* 14(8): e0220363. doi: 10.1371/journal.pone.0220363.

Kreitmair, K. 2019. Dimensions of ethical direct-to-consumer neurotechnologies. *AJOB Neuroscience* 10(4): 152–166.

Lefaucheur, J. P. 2019. Boosting physical exercise with cortical stimulation or brain doping using tDCS: Fact or myth? Neurophysiologie *Clinique* = *Clinical Neurophysiology* 49(2): 95–98. doi: 10.1016/j.neucli.2019.01.002.

Machado, Daniel G. d. S., Gozde Unal, Suellen M. Andrade, et al. 2019. Effect of transcranial direct current stimulation on exercise performance: A systematic review and meta-analysis. *Brain Stimulation* 12(3): 593–605. doi: 10.1016/j.brs.2018.12.227.

The Human Right to Science and Direct to Consumer Neurotechnologies

Sebastian Porsdam Mann, University of Copenhagen and University of Oxford
Maximilian Martin Schmid, A&BC Consulting

Kreitmair identifies seven dimensions "intended to provide guidance for consumers, developers, researchers, and ethicists to work towards ethical DTC neurotechnology" (Kreitmair 2019, 12). These are introduced as a "starting off point" for "further discussion." In this contribution, we introduce the human right of everyone to "enjoy the benefits of the progress of science and its applications" (Article 15(1)b International Covenant on Economic, Social and Cultural Rights [ICESCR] 1976) and argue that it provides a legally binding and morally weighty framework for the assessment of DTC neurotechnologies. Thus, compliance with the "right to science," or RtS, can serve as a useful additional dimension for ethical DTC neurotechnology.

The RtS originated in the United Nations' 1948 Universal Declaration of Human Rights, Article 27(2) of which states that "[everyone] has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits." As a declaration, the Universal Declaration at first

Address correspondence to Sebastian Porsdam Mann, PhD, Oxford Uehiro Centre for Practical Ethics, Suite 8, Littlegate House, St Ebbes Street, Oxford OX1 1PT, United Kingdom. Email: sebastian.porsdammann@philosophy.ox.ac.uk