BACKGROUND

What is neurofeedback?

Electroencephalography (EEG) neurofeedback is a type of biofeedback that records brain activity and displays it to users, aiming to teach them to control their brain functions. There are currently over 15,000 providers globally offering neurofeedback.

For what indications is it being offered?

Examples of clinical indications:

ADD/ADHD, epilepsy, addictions, anxiety, autism spectrum disorder, bipolar disorder, depression, PTSD and schizophrenia.¹

Examples of non-clinical indications:

Memory improvement and performance enhancement.¹

Is it effective?

Even though there has been extensive research on EEG neurofeedback, many of theses studies have been criticized for their lack of rigor. Importantly, many of these studies have been performed by neurofeedback providers, raising concerns about potential conflict of interest. Currently, the relatively few double-blind sham-controlled studies in this field indicate that neurofeedback provides no greater benefit than sham. As a result, it has been argued that its effects are due to placebo (i.e. individuals receive psychobiological benefits that stem from the overall therapeutic context rather than from the treatment itself.)²

The efficacy of EEG neurofeedback, therefore, remains contested, and, to-date, this technique is not recommended by any professional physician society.

OBJECTIVE

To examine the ethical implications of offering interventions that are no better than placebo both for clinical indications and for enhancement purposes.

Neurotherapy or Placebo? The Ethical Implications of Offering EEG Neurofeedback for Clinical Indications and Neuroenhancement

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ETHICAL ISSUES OF OFFERING PLACEBO AS THERAPY

Why can offering placebo in the clinical setting be ethically problematic?

- Without appropriate disclosure, the use of placebo as treatment can be problematic because: It involves some level of deception
- It can be paternalistic and challenges the autonomy of patients
- It can create issues of trust between physicians and patients

According to the American Medical Association, placebo may be used for treatment, among others, only upon obtaining the patient's general consent.³

Under which conditions can placebo therapies be ethically acceptable? Scholars have advocated for the use of open label placebo (i.e. being transparent about the use of placebo as a treatment) as a way to avoid misleading patients and to promote autonomous decision-making. In addition, it has been claimed that placebos can only be used if there is scientific evidence from randomized controlled trials that placebos have a significant benefit over no treatment/usual care.^{4,5}

ETHICS OF OFFERING NEUROFEEDBACK FOR CLINICAL INDICATIONS, IF NO BETTER THAN PLACEBO

- Informed decision-making: Providers often make unsupported or exaggerated claims regarding the efficacy of neurofeedback therapies, raising concerns about misleading advertising and informed consent processes.¹
- Vulnerable populations: These services often target individuals suffering from neuropsychological conditions, and parents of children suffering from certain disorders, who may be more prone to suffering psychological harm and more susceptible to unsupported claims.⁶
- **Potential opportunity cost** when neurofeedback is performed instead of well-established alternatives.
- Financial cost: Neurofeedback usually comes at a high financial cost (the total cost of treatment for up to 40 sessions may range from \$3,000-10,000, which is typically not covered by health insurance).
- Potential physical harm: Neurofeedback has a low risk of physical harms. However, there have been anecdotal cases of individuals experiencing adverse effects such as confusion, disorientation and ocular sensitivity after neurofeedback sessions.

ETHICS OF OFFERING NEUROFEEDBACK FOR ENHANCEMENT, IF NO BETTER THAN PLACEBO

Neurofeedback for enhancement purposes does not necessarily target vulnerable populations and concerns about opportunity costs are less pronounced when consumers are not suffering from a disease. However, concerns remain regarding misleading claims about the efficacy of this technique. While, in principle, regulatory standards for wellness claims are lower than those regarding health claims, the line between health and wellness is often blurry.

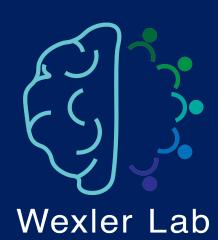
To-date there is a lack of clear scientific evidence supporting the efficiency of neurofeedback compared to sham. However, neurofeedback has been shown to have some positive effects for individuals for certain indications (e.g. ADHD/ADD)- even if those are due to placebo effect. Individuals can experience real benefit from placebo but offering of such therapies can only be ethical if transparency and informed consent requirements are met. More specifically:

- 2.1.4



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DISCUSSION

 Neurofeedback providers should avoid making unsupported claims about health and wellness.

• During the informed consent process, the following information needs to be disclosed to individuals:

- information about alternative options for treatment
- o concise explanation of the experimental nature of the therapy
- potential placebo effect

 More research is needed to establish the efficacy of neurofeedback above and beyond the placebo effect and/or to better understand the placebo mechanisms.²

REFERENCES

1. Wexler, A., Nagappan, A., Kopyto, D., & Choi, R. (2020).

Neuroenhancement for Sale: Assessing the Website Claims of Neurofeedback Providers in the USA. *Journal of Cognitive Enhancement*. 2. Thibault, R. T., & Raz, A. (2017). The psychology of neurofeedback: Clinical intervention even if applied placebo. American Psychologist. 3. American Medical Association (2006) Code of Medical Ethics Opinion

4. Blease, C., Colloca L., & Kaptchuk T. (2016) Are open-label placebos ethical? Informed consent and ethical equivocations. *Bioethics*. 5. Miller, F. G., & Colloca, L. (2009). The legitimacy of placebo treatments in clinical practice: evidence and ethics. The American Journal of Bioethics. 6. Nagappan, A., Kalokairinou L. & Wexler A. (2020) Ethical and Legal Considerations of Alternative Neurotherapies (under review).

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