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Neurofeedback as placebo: a case of unintentional deception?

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Abstract

The use of placebo in clinical practice has been the topic of extensive debate in the bioethics literature, with much scholarship focusing on concerns regarding deception. While considerations of placebo without deception have largely centred on open-label placebo, this paper considers a different kind of ethical quandary regarding placebo without an intent to deceive—one where the provider believes a treatment is effective due to a direct physiological mechanism, even though that belief may not be supported by rigorous scientific evidence. This is often the case with complementary and alternative medicine (CAM) techniques and also with some mainstream therapies that have not proven to be better than sham. Using one such CAM technique as a case study—electroencephalography (EEG) neurofeedback for attention-deficit/hyperactivity disorder (ADHD)—this paper explores the ethics of providing therapies that may have some beneficial effect, although one that is likely due to placebo effect. First, we provide background on EEG neurofeedback for ADHD and its evidence base, showing how it has proven to be equivalent to—but not better than—sham neurofeedback. Subsequently, we explore whether offering therapies that are claimed to work via specific physical pathways, but may actually work due to the placebo effect, constitute deception. We suggest that this practice may constitute unintentional deception regarding mechanism of action. Ultimately, we argue that providers have increased information provision obligations when offering treatments that diverge from standard of care and we make recommendations for mitigating unintentional deception.

INTRODUCTION

Electroencephalography (EEG) neurofeedback is a type of biofeedback that aims to teach users how to control the electrical activity from their brain by recording brain activity and providing real-time audio and/or video feedback.[1] Although more than 15000 providers globally[2] offer the therapy for numerous clinical indications, evidence for the effectiveness

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of EEG neurofeedback remains contested. The technique is not recommended by any professional physician society, and neurofeedback research has been widely criticised for its weak methodology and lack of rigour, as most studies have not used double-blinding and sham controls.[3–5] Studies employing rigorous experimental designs have mostly been conducted in the context of attention-deficit/hyperactivity disorder (ADHD) and have demonstrated that participants who received genuine neurofeedback display equivalent improvements to those of the sham group.[6 7]

Because neurofeedback appears to have some positive effect for ADHD—although one that is comparable to that observed in control groups—some scholars have argued that the benefits of neurofeedback are likely due to the placebo effect.[3–5 7 8] In other words, neurofeedback for ADHD may not work in the way providers claim (ie, through direct training of one's brain waves) but may be due to psychosocial or other non-specific factors, such as interacting with a provider, attempting to focus for regular periods of time, the overall therapeutic context[9] or other placebo mechanisms like classical conditioning.[10]

If neurofeedback is effective for ADHD due to a placebo effect, is it ethical for providers to offer it in clinical practice without describing it as such? Although the use of placebo in clinical practice has been the topic of extensive debate in the bioethics literature for several decades, much scholarship has focused on concerns regarding deception,[11–13] where a physician administers a certain treatment to a patient while withholding information about the nature of treatment in order to elicit the placebo effect. At issue in this scenario is the potential infringement of autonomy, as patients have been denied the opportunity to make an autonomous and informed decision about their healthcare management. Notably, the deception scenario in this literature often relies heavily on beliefs: the physician does not *believe* the therapy is effective beyond a placebo effect, yet she communicates a false belief to the patient about its effectiveness in order to elicit the placebo response.[14] Indeed, the American Medical Association defines placebo as 'a substance provided to a patient that the physician *believes* has no specific pharmacological effect on the condition being treated' (emphasis added).[15]

With regard to neurofeedback for ADHD, however, there seems to be no transmission of a false belief, as the provider likely believes that the treatment is effective due to brain training and feedback. Thus, in this scenario, there may be no intent to deceive on the part of the provider. In the bioethics literature, considerations of the administration of placebo without an intent to deceive have mostly centred on the context of open-label placebo, where both the provider and the patient believe that the therapy being provided has a psychosocial and not directly physiological mechanism of action.[16–18] But the neurofeedback case represents a different kind of ethical quandary regarding placebo without an intent to deceive, as in this case the provider *believes* a treatment is effective due to a direct physiological mechanism, even though that belief may not be supported by rigorous scientific evidence.

The neurofeedback scenario highlights the shortcomings of previous ethics literature regarding the administration of placebo in clinical practice. Specifically, most prior work on the ethical aspects of administering placebo in clinical practice has focused on scenarios where it is assumed that (a) there is a shared medical consensus about what constitutes

an effective treatment; (b) providers adhere to that shared consensus; and (c) there is a known mechanism of action for effective treatments. But as the case of neurofeedback exemplifies, the ethical considerations of administering a placebo treatment become more complex in grey areas where evidence is contested, where providers hold beliefs that are not supported by mainstream professional organisations and where a treatment may work due to psychosocial factors. To date, such borderline cases have remained relatively unexplored in the literature; one notable exception is Barnhill, who has called attention to cases where an individual physician's beliefs may be at odds with the general medical consensus.[14]

In this article, we use EEG neurofeedback for ADHD as a case study to consider the ethics of providing therapies which may have some benefit, although one that is likely due to a placebo effect. First, we provide background on EEG neurofeedback and research indicating that its efficacy for ADHD may be due to a placebo effect. Subsequently, we examine whether offering therapies that are claimed to work via specific physical pathways—but may in fact work due to the placebo effect—constitute a form of deception. We suggest that even without intent, this practice may constitute a form of unintentional deception with regard to mechanism of action. Ultimately, we argue that providers have increased information provision obligations—regarding the evidence base of the therapy and its mechanism of action—when offering treatments that have not proven to be better than placebo. This article aims to broaden the discussion regarding the ethics of placebo in clinical practice and to bring attention to the ethical implications of offering therapies that have not proven to be better than sham.

NEUROFEEDBACK AND PLACEBO

EEG neurofeedback began attracting attention in the late 1960s when Joe Kamiya, a researcher at the University of Chicago, published the results of an experiment indicating that participants could learn how to control the electrical brain activity using neurofeedback.[19 20] Since then, more than 3000 studies on neurofeedback have been published, and the therapy is offered as a treatment for a broad range of disorders such as ADHD, autism spectrum disorder and schizophrenia.[21] Neurofeedback for clinical indications is offered by professionals from various backgrounds including medical doctors, but the field is dominated by psychologists and social workers.[21] In this article, we refer to those offering neurofeedback as providers and to individuals receiving this therapy as clients, to reflect the terminology commonly used in this field.

A typical neurofeedback session lasts approximately 20–30 minutes and involves an individual wearing an electrode cap and playing a video game, watching a movie or listening to audio. As long as the individual produces the desired electrical activity, the video or audio continues at a normal pace. However, if the predetermined pattern is interrupted (eg, if the individual gets distracted), the video or audio slows down or stops until the electrical activity returns to the desired pattern. In this way, neurofeedback presumes that one can consciously influence the electrical activity of one's brain, which according to providers can thereby result in mental and behavioural improvements.[1 22] It has been reported that total cost of treatment of up to 40 EEG neurofeedback sessions may be between $4000 and $10 000,[22] and it is seldom covered by insurance.

Despite the proliferation of neurofeedback providers, the technique has remained controversial[23 24 25] for several reasons. First, many studies supporting the efficacy of neurofeedback (ie, its performance as compared with sham under the controlled conditions of a trial)[26] have been conducted by those who have significant financial and ideological interests in its commercialisation, raising concerns about conflicts of interest.[27] Second, EEG neurofeedback is currently advertised for some conditions, such as schizophrenia and Asperger's syndrome, for which there is a paucity of evidence.[21] Third, only a handful of neurofeedback studies have employed a double-blind or triple-blind, sham-controlled design.[7 28] In the context of neurofeedback, the sham intervention may take different forms, such as showing participants in the control group prerecorded encephalograms instead of live displays of the electrical activity from their brains.[29]

Among the studies that have used a double-blind or triple-blind, sham-controlled design, only one—a stroke rehabilitation study—found EEG neurofeedback to be superior to sham.[7 30] Most of the remaining studies that have employed double-blinding or triple-blinding and sham controls have been conducted for ADHD. The results of these studies indicate that both neurofeedback and sham groups show equivalent improvements, leading some scholars to suggest that neurofeedback may have some efficacy for ADHD—although due to placebo effect.[7 31–33]

Neurofeedback proponents, however, have criticised these studies and their conclusions, arguing that their results are overgeneralised. They have also questioned the appropriateness of randomised control trials (RCTs) and blinding for complex interventions like neurofeedback.[34–36] Notably, these critiques—of whether RCTs represent the most optimal design to capture the effects of certain complex interventions—are similar to those made by some proponents of complementary and alternative medicine (CAM) treatments. Walach, for example, has argued that RCTs place too much focus on demonstrating the efficacy of a technique above and beyond a sham control when in fact the control itself may be quite effective in real-world settings, although due to a non-specific effect.[37]

To date, the most carefully designed study of EEG neurofeedback for ADHD was made possible by the National Institute of Mental Health, which recently funded a longitudinal, multisite, placebo-controlled, double-blind randomised trial that was designed by experts in neurofeedback, ADHD and statistics.[38] The highly anticipated results, which were published last year, showed that both the neurofeedback and control groups demonstrated significant improvements in attention, and that neurofeedback was not superior to the control condition.[9] The authors concluded that the effects of neurofeedback for ADHD are 'best explained by other factors besides the specific effect of deliberate brain wave contingent reinforcement (eg, EMG biofeedback, supportive coaching, reinforced practice in exerting mental effort on a boring activity, nutritional and sleep hygiene counseling, and placebo response)'.[9]

Thus, with regard to EEG neurofeedback for ADHD, there appears to be evidence of benefits, but with a different mechanism of action than the one presented to clients. Though there are currently other well-established treatments for ADHD that have a high degree of effectiveness,[39] most of these treatments are pharmacological and may come with certain

side-effects.[40] In this regard, there is a case to be made about the conditional provision of neurofeedback to clients, as it is a non-invasive therapy with a low risk of side-effects. In the following section, we explore whether the provision of neurofeedback for ADHD is deceptive—and therefore, potentially ethically problematic—if its benefits are based on the placebo effect.

NEUROFEEDBACK AND DECEPTION

To assess whether providing neurofeedback for ADHD without disclosing its potential mechanism of action constitutes deception, it is worthwhile to review how the term deception is defined. One definition that appears in some criminal and civil legal codes involves demonstrating an intent to deceive; in other words, that there was a knowing and wilful effort to mislead.[41 42] In these cases, an individual holds a true belief but engages in an act of deliberately transmitting a false belief to another individual. This definition of deception, which focuses on wilful intent to mislead, is the kind of deception that is often discussed in the clinical ethics literature, including literature on the ethics of providing placebo.[43–45] Scholars in this field have discussed different types of deception, depending on whether it is manifested through actions, omissions or lying,[46 47] whether it is directed to patients, their families[48] or third parties,[49] and whether deception is benevolent or malevolent.[43 45] The common denominator in all these definitions is that deception is a knowing and deliberate act.

Is there a wilful intent to mislead in the context of those who provide neurofeedback for ADHD? While we do not have empirical evidence of providers' intentions—and thus cannot know for sure—two of us have spent a number of years studying neurofeedback as a sociological phenomenon. This has involved interviewing neurofeedback providers[50] and clients, examining provider websites,[21] reading neurofeedback articles, conducting digital ethnography on neurofeedback forums and attending a national neurofeedback conference. It is our impression that providers believe that they are offering an effective treatment, and one that works because individuals have the ability to train the electrical activity from their brains. In offering neurofeedback for ADHD to the general public, then, we do not consider it likely that providers are intentionally deceiving their clients.

Assuming that neurofeedback providers do not have an intent to deceive, do their actions constitute deception? In contrast to the earlier definitions of deception, other definitions and descriptions place an emphasis on the *outcome* of a deceitful action or omission (ie, creating a false belief) rather than on the *intent* of the deceiver.[51 52] For example, according to the Oxford English Dictionary, to deceive means to 'cause [someone] to believe what is false'.[52] In this definition, it is the result of an action, rather than the motive and knowledge of the deceiver, that is foregrounded. Following this definition, then, the intentions of neurofeedback providers may be irrelevant, as long as they result in an individual holding a false impression regarding a meaningful aspect of the therapy that could affect their decision making.

The next question, then, is whether there is any misrepresentation on the part of the neurofeedback provider likely to lead to a false belief on the part of the client. Clearly,

providing misleading information about the effectiveness of a therapy would constitute deception. But if clients are led to believe that neurofeedback works due to training one's electrical brain activity, but its effect is instead based on a placebo response, would that constitute deception? To help illustrate this case, it is useful to provide a hypothetical example outside of the neurofeedback context: if a healthcare provider were to tell a client that a magnetic bracelet would relieve pain by absorbing negative energy and toxins, believing that this is true—and if there were indeed studies showing that magnetic bracelets had some analgesic effect, although likely due to a placebo effect—would offering the magnetic bracelet for pain relief constitute deception?

Although in these cases, statements about the effectiveness of the therapy may not be outright false, the fact that the benefits may be based on a different mechanism (ie, placebo) than the one communicated may still create some level of deception. Two outspoken critics of neurofeedback have supported this view, stating in a recent paper that '(neurofeedback) entails a degree of deception—the putative mechanisms differ from the actual underlying mechanisms'.[7] Delving deeper into this argument, we consider deception to be an issue because, irrespective of their professional background, providers offering therapies for clinical indications are expected to have a reasonable understanding of the scientific underpinning and limitations of the therapies they are offering. This is in line with Macdonald and Gavura, who have argued that CAM providers may still be liable of wilful ignorance and 'culpably low epistemic standards', even if they do not intend to deceive their clients.[53] In this regard, providers need to take reasonable steps to ensure sufficient knowledge of their services[53] and have an ethical obligation to provide their clients with accurate and comprehensive information before the beginning of the treatment.[54–56]

In view of these obligations, despite the apparent lack of intention to deceive, we argue that misrepresenting the mechanism of action of a therapy is a secondary kind of deception, one that—in the case of neurofeedback—is likely unintentional. This is because information that may be crucial for individuals to make informed decisions about their healthcare management is being misrepresented or not adequately explained by providers. Considering the high cost of neurofeedback and the existence of effective alternatives for ADHD, information regarding the mechanism of action (and more specifically about the fact that benefits may be limited to placebo effects) may be essential for informed decision-making.[16 53]At the same time, the concept of unintentional deception should be limited to information that a reasonable person[57] would deem important to receive before deciding to pursue a given therapy and would not extend to trivial details about treatment, as this would set an untenable professional standard.

This kind of unintentional deception regarding mechanism of action is not unique to neurofeedback and also applies to other interventions where an individual is informed that the therapy is beneficial due to a presumed mechanism of action that might not hold up to scientific scrutiny. This is often the case with CAM therapies, such as acupuncture, that have demonstrated some level of effectiveness, although one where the mechanism of action and the role of the placebo effect is not well understood.[51 58] At the same time, unintentional deception may also apply in the context of mainstream medicine, for interventions for which efficacy beyond placebo has not been well-demonstrated (eg, the

use of certain antidepressants for the treatment of depression).[14 59 60] In these cases, just as in neurofeedback, we do not consider the deception involved to be ethically comparable to that of a deliberate intent to mislead. However, there is still an unintentional deception regarding mechanism of action, and as we argue in the next section, providers have an ethical responsibility to mitigate it by providing increased information to clients when offering therapies that have not be proven to be better than placebo.

MITIGATING UNINTENTIONAL DECEPTION IN NEUROFEEDBACK

There has been extensive discussion in the ethics literature regarding the information that must be disclosed to a patient before beginning a therapy. While there is no consensus regarding the types of information that should be provided during the informed consent process,[61–64] typically, physicians offering clinical treatments are expected to disclose the purpose and nature of the proposed treatment, its potential material risks and anticipated benefits, as well as reasonable alternatives and their respective risks and benefits.[56 65] The provision of information is usually proportionate to the risk of the therapy offered.[66] Explanation of the mechanism of action is not typically included in the information that should be disclosed to patients according to state laws, and ethicists have argued that such information is not essential for patients.[67]

However, when resorting to therapies that depart from the standard of care, it has been argued that physicians have an enhanced duty of information provision. For example, with regard to off-label uses of pharmaceuticals with uncertain net benefits, Largent *et al* have argued that physicians should provide an ‘augmented therapeutic consent’,[68] in which the uncertainties regarding the risks and benefits of the treatment are communicated to patients in greater detail than a routine therapeutic consent.[68] Others have contended that physicians have an ethical responsibility to disclose the off-label nature of the treatment[69 70] even though such disclosure is not legally required, at least in the USA.[68] In addition, Barnhill has argued that when providers offer treatments that according to the consensus view of the medical community are placebo, they must inform their patients of this consensus.[14]

Similarly, in the context of CAM, scholars have underlined the need for a rigorous informed consent process that goes beyond the typical requirements in the clinical setting.[71 72] Along these lines, in the USA, state laws and regulations concerning the provision of CAM require that providers of such therapies disclose specific information regarding the limitations and uncertainties of the proposed courses of treatment, as well as their training. In Florida, for example, CAM providers must disclose their education, experience and credentials relevant to the therapies provided.[73] Notably, in some states, such as Texas and California, providers must disclose information about the therapeutic basis of the treatment and (in the case of Texas) its purported mechanism of action.[74 75]

The arguments in favour of enhanced disclosure indicate that information that may be considered non-essential for patients in the context of established treatments acquires new significance in the context of therapies that depart from the standard of care. This is because certain assumptions that tend to hold true for the former (eg, that there is a sound scientific basis and proven efficacy) cannot always be taken for granted in the context of the latter. As

a result, providing further information about these aspects ensures that individuals are not misled.

In this regard, we argue that those who provide neurofeedback for ADHD—and more broadly, therapies that may work due to placebo effect—have an obligation to provide an enhanced level of information during consultations with their clients. In this context, and in line with Thibault *et al*[7 40] who have called for the non-deceptive provision of neurofeedback services, we consider that neurofeedback providers should inform their clients about the mechanism of action and the possibility of placebo effect, despite the treatment being low risk.

The provision of additional information—specifically regarding mechanism of action and the possibility of a placebo effect—will ensure that clients can make informed decisions about their healthcare management. These disclosures are important for promoting autonomy, as limitations related to the effectiveness of a therapy may be crucial for individuals' decision making. Enhanced disclosure is also important in terms of maintaining trust: as Barnhill has argued, if an individual is led to believe that a treatment works due to specific effects but later discovers that it may work due to a placebo effect, they may lose trust in their provider, or even in the medical profession as a whole.[14] As such, in order to promote autonomy and maintain trust in providers, enhanced disclosure should apply to treatments for which the efficacy is likely based on placebo effect. This should be the case both for CAM treatments (eg, acupuncture) and treatments provided in mainstream healthcare settings for which efficacy beyond placebo has not been well-demonstrated (eg, certain antidepressants).

We note that our argument regarding enhanced disclosure does not extend to therapies of proven efficacy, even if their mechanism of action is not well-understood. Uncertainty regarding the mechanism of action of a therapy is not uncommon—especially in the field of psychiatry—and is not in itself ethically problematic. For example, there are certain therapies, such as deep-brain stimulation, which have conclusively proven to be more effective than placebo, despite their mechanism of action not being well-understood.[76] We consider that for such therapies of established efficacy enhanced disclosure is not necessary, as it is unlikely that information about their mechanism of action could affect the individuals' perception of risks and benefits and play a role in their decision making.

Disclosing the possibility of placebo effect is in line with the work of several scholars who have advocated for the use of open-label placebo (ie, being transparent about the use of placebo as a treatment) as a way to avoid misleading individuals and to promote autonomous decision-making.[11 77] Our call for enhanced disclosure requirements for treatments that are not proven to be better than sham is based on the assumption that such disclosure will not negatively affect therapeutic benefits to individuals. This assumption is supported by research indicating that deception may not be necessary in order to elicit placebo effects.[16–18] However, it is important to highlight that existing research supporting the efficacy of open-label placebo focuses on pharmacological interventions. There is a need for further research exploring whether enhanced disclosure requirements for therapies like neurofeedback, that require the active involvement of an individual, could result in

nocebo effects,[78 79] and whether lowering the expectations of individuals could reduce the effectiveness of the treatment.

CONCLUSION

In this paper, using EEG neurofeedback for ADHD as a case study, we have argued that the provision of therapies that may be effective due to the placebo effect—such as neurofeedback for ADHD—raises unique ethical issues. In particular, when the effects of a therapy are based on a mechanism of action other than the one communicated to a client, this may be deceptive, even if unintentional. This is because in the context of these therapies, information about the mechanism of action may be essential for clients to make informed decisions about their healthcare. In order to promote the ethical provision of these therapies, we have argued that providers should disclose additional information to clients—such as the mechanism of action of the therapies, and the possibility of the placebo effect—that would permit them to make informed decisions.

This argument builds on existing ethics literature according to which providers of CAM and off-label therapies have enhanced disclosure obligation towards their clients compared with informed consent requirements for scientifically well-established treatments. In this regard, we consider that these obligations should extend to treatments that have not proven to be better than placebo and their mechanism of action is not well understood. While we acknowledge that rectifying unintentional deception would be challenging, as in some cases it will require providers to contradict their own beliefs, we consider that this article can contribute to a broader dialogue within the ethics community regarding the ethical provision of therapies that divert from medical consensus.

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Data availability statement

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