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MINI-REVIEW

Mind-Reading or Misleading? Assessing Direct-to-Consumer Electroencephalography (EEG) Devices Marketed for Wellness and Their Ethical and Regulatory Implications

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Abstract
The market for direct-to-consumer brain health products—including brain-training games, neurostimulation devices, and consumer electroencephalography (EEG) devices—is expected to top $3 billion by 2020. While many direct-to-consumer neurotechnology products have come under scrutiny from scientists and regulators, one set of products—consumer EEG devices—have largely escaped scholarly and regulatory critique. While these products do not present overt safety risks, by claiming to provide individuals with "snapshots" of their own mental states, they present a subtle, and arguably more complex, set of ethical issues. In addition, consumer EEG companies often explicitly or implicitly rely on studies conducted in the field of neurofeedback, a domain in which almost all adequately controlled studies point to little more than an interesting placebo effect. This paper presents an initial critique of consumer EEG devices, focusing only on devices that are marketed directly to consumers for improving their well-being. We categorize the behavioral and wellness-related marketing claims made by consumer EEG companies, analyze the evidence base for such claims, and argue that the ethical and legal issues wrought by these devices deserve greater attention.

Keywords Direct-to-consumer neurotechnology · Electroencephalography · EEG · Cognitive enhancement · Brain health · Neurofeedback · Neuroethics · Regulation of neurotechnology

Introduction

The market for direct-to-consumer brain health products—including brain-training games, neurostimulation devices, and consumer electroencephalography (EEG) devices—is expected to top $3 billion by 2020 (SharpBrains 2018). Many direct-to-consumer products sold for cognitive enhancement have come under scrutiny, both from scientists and regulators. For example, the effectiveness of computer-based brain-training games has repeatedly been called into question by researchers (Simons et al. 2016), and the Federal Trade Commission has taken action against a number of companies marketing brain enhancement software (FTC 2015, 2016). In addition, direct-to-consumer neurostimulation products have been the subject of much debate in the bioethics and neuroscience literature (Fitz and Reiner 2015; Steenbergen et al. 2016; Wexler 2016) and have been discussed at numerous meetings held by regulators and medical organizations in recent years.

Consumer-grade EEG devices marketed to the general public for wellness, however, have largely escaped scholarly and regulatory critique. Historically, EEG has been mostly relegated to the research lab, to better understand cognitive functions, and to clinical contexts, where it is used to inform decision-making related to seizures, brain death, and sleep. In

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addition, EEG has been used for a technique called neurofeedback, where individuals attempt to self-regulate their brainwaves and in turn alter their behavior (Thibault et al. 2015). Less commonly, EEG has been used by lay individuals, to translate brain signals into musical or artistic output (Christopher et al. 2014).

The marketing of consumer-grade EEG devices to the general public represents a new and distinct chapter for this neurotechnology. The earliest consumer-grade EEG devices—inspired by the EEG systems used in research, but stripped to the elements necessary to record some degree of brain activity—appeared on the market roughly a decade ago, and were initially marketed for "thought control" of either real-world or virtual objects. In recent years, new companies have entered the consumer EEG market, often running crowdfunding campaigns for their devices. Collectively, these companies have raised more than $7 million via outlets such as Kickstarter and Indiegogo (Roy 2017). Currently, consumer EEG devices range in price from approximately $99 to $799, and can be purchased online from company websites and via retailers such as Amazon. At least one consumer EEG device, Muse, is sold in-stores at the electronics retailer Best Buy.

Since 2013, the marketing claims made by consumer EEG companies have undergone a steady shift from thought control to promises of "brain enhancement" and "cognitive wellness." In addition, many companies now imply that their device can provide an accurate snapshot of a user's brain state (e.g., engagement, arousal, and attention). Some companies advertise that consumer EEG devices can improve physical performance and even cure medical conditions.

Consumer EEG devices differ from other direct-to-consumer brain enhancement products in several ways. While they do not present overt safety risks (in contrast to the skin burns that may result from consumer neurostimulation devices, see Wexler 2018), by claiming to provide individuals with "snapshots" of their own mental states, they present a subtle, and arguably more complex, set of ethical issues. In addition, compared to other direct-to-consumer neurotechnology products, when consumer EEG companies focus on wellness applications, they implicitly rely on the field of neurofeedback—a technique that has failed to gain widespread acceptance after 60 years of research and where almost all adequately controlled studies point to little more than an interesting placebo effect (Thibault and Raz 2017; Schönenberg et al. 2017). For these reasons, consumer EEG devices marketed for wellness deserve more scrutiny than they have received. Here, we categorize the behavioral and wellness-related marketing claims made by consumer EEG companies, analyze the evidence base for such claims, and argue that ethical and legal issues raised by these devices deserve greater attention.

Marketing Claims Made by Consumer EEG Companies

We identified companies marketing consumer EEG devices based on keyword searches ("consumer EEG," "home EEG," "EEG neurotechnology," and "EEG wearable"). Companies were included in the study if (a) they were marketing EEG devices to individual consumers for personal use; (b) their device was immediately available for purchase on the company's website as of January 2018; or (c) they had received funding from individuals via a crowdfunding campaign, as such funding was indicative of a consumer transaction (albeit a future-oriented one). Companies marketing EEG devices solely for use in neurofeedback clinics or primarily for scientific or neuromarketing research (e.g., EMOTIV EPOC) were excluded, as were companies primarily marketing EEG hardware or parts (e.g., OpenBCI).

To categorize the claims made by consumer EEG companies, we developed coding categories iteratively based on reviews of companies' websites and/or crowdfunding pages. We focused only on claims that related to whether a consumer EEG device can help improve aspects of behavior, mental states, or well-being. We attributed a categorical claim (i.e., "improves meditation") to a company if there was text, image, or video on the company's website and/or crowdfunding page that explicitly supported the claim. In only one case was a company's hardware product (Neurosky's Mindwave device) clearly distinct from the third-party apps sold for use with the device. However, because (a) Neurosky markets its device primarily for use with apps; (b) the apps are clearly listed, hosted, and promoted on the Neurosky website itself; and (c) the apps do not work with any other consumer EEG device, we attributed both the claims made by the company and the apps to a single entity (Neurosky Mindwave). Both authors independently coded the claims; initial inter-rater reliability was 97.2% and following discussion agreement was 100%.

In total, 18 companies met our inclusion criteria. As shown in Table 1, the greatest number of claims made by consumer EEG companies was related to improving concentration, relaxation, meditation, and sleep (see supplementary material for detailed tabulation). Beyond claims regarding well-being, five companies claimed their device could allow individuals to control virtual or real-world objects via brainwaves and four claimed to promote lucid dreaming. In addition, a number of companies made medical claims, some more explicitly than others. For example, Neurosky's website features over 100 third-party apps, some of which make explicit medical claims about treating ADHD and chronic pain. Other companies merely allude to their product's medical benefits (e.g., Neuroplus highlights media coverage about how the device ameliorates the symptoms of ADHD). Still others, like Versus and Mindset, do not emphasize medical benefits, but reference scientific literature regarding how neurofeedback can be used to treat a variety of clinical

Table 1 Number of direct-to consumer EEG devices, out of the 18 included in our dataset, making claims relating to improving behavior, mental states, or well-being

	n
Improves focus/concentration	12
Reduces stress & promotes relaxation	12
Improves meditation	9
Improves sleep	9
Optimizes cognitive performance	8
Improves athletic performance	9
Optimizes learning	5
Improves memory	3

Devices included in our dataset include Aurora Dreamband from iWinks LLC, Aware from United Sciences, Dreem from Rythm, Insight from EMOTIV, FocusBand from T 2 Green Pty Ltd., iBand+ from Arenar, Kokoon from Kokoon Technology Limited, Mindball from Interactive Productline, MindWave from NeuroSky, Mindset from Mindset, Melomind from myBrain Technologies, Muse from InteraXon, SenzeBand from Neeuro, Neuroon Open from Inteliclinic, Neuroplus from NeuroPlus, Inc., Sleep Shepherd from Sleep Shepherd, Super Brain II from REX, and Versus by NeuroTherapeutics

indications. Thus, due to ambiguity in terms of what could be interpreted as a medical claim, Table 1 focuses only on non-medical claims related to well-being.

Assessing the Evidence

In this paper, we focus on assessing the evidence for the wellness-related claims shown in Table 1. Although the marketing approaches taken by consumer EEG companies differed in tone, they all relied on the assumption that observing one's own brainwaves can improve well-being in relation to concentration, stress, performance, and other behaviors. However, for consumer EEG to improve well-being beyond the benefits derived from placebo effects, at least three assumptions would need to hold true. First, the device would need to validly and reliably record the brain signals that companies claim to measure. Second, the measured brain signal would need to accurately reflect a given behavior or mental state. Third, providing individuals with their brainwave data would need to help them alter a behavior or mental state. Here, we analyze the evidence base for each of these three assumptions.

The Device Validly Records Brain Activity

If consumer EEG devices were substantially equivalent to research-grade EEG systems, it could be comfortably assumed that they measure brainwaves. However, consumer EEG devices differ from research systems in many regards. Their hardware generally includes only a few electrodes compared to the 32–128 commonly used in research; they utilize dry rather than wet electrodes, which have greater impedances and noise levels (Mathewson et al. 2017); and they employ passive rather than active electrodes, which are not designed to amplify the EEG signal at the site of acquisition before transmitting it through the wires. Their software for online artifact removal and source localization—two complex tasks that companies and an open source EEG community have been working on for decades—generally differs from the tried-and-tested programs commonly used in research. In the context of consumer EEG, moreover, there is no experienced technician to ensure low impedance, remove sweat from the scalp, minimize muscle and eye artifacts, and avoid contamination from electrical appliances. These differences may compound, resulting in considerably different outputs from consumer and research-grade devices. Notably, many consumer EEG devices employ only a few electrodes placed directly over facial muscles (forehead and temporalis) that can contaminate the EEG signal with muscle activity orders of magnitude greater than brainwaves (Whitham et al. 2007). Thus, before accepting that a consumer EEG device validly records brain activity, data from a given device would need to be compared to that from a method known to validly record brainwaves—for example, a research-grade EEG system.

To attempt to validate consumer EEG devices, researchers could either (a) simultaneously record from a consumer and research-grade device; (b) compare recordings from consumer and research-grade devices taken at different times; or (c) run a standard EEG protocol with the consumer device and examine whether the results reflect established findings. Of the 18 devices assessed, we could identify only one company that took the first approach and simultaneously recorded from two EEG systems. The company found that recordings from its device, Versus, correlated highly with those taken with a five-sensor wet-electrode system (Wyckoff et al. 2015). In another study, researchers utilized the second approach, and found that the two consumer EEG devices tested—Mindwave and Muse—were susceptible to artifacts, and the latter showed poor test-retest reliability (Ratti et al. 2017). At least one company used the third approach, and collaborated with academic researchers to show that its device, Muse, can identify age-related changes in the EEG that are partially consistent with the literature (Hashemi et al. 2016). However, appended to that study are comments from one reviewer who criticized the lack of validation of the analysis protocols, and recommended that even the revised version not be published. A second study conducted by academic researchers showed that Muse could detect event-related potentials (Krigolson et al. 2017); however, it is unclear how well these results would translate to consumer use, as the authors found that data quality was only "sufficient" after research assistants had become experienced in setting up participants with the Muse headset.

For the remaining 15 devices, after browsing through the company websites and using online search engines, we were unable to identify any publicly available research that tested validity via one of the methods outlined above. We acknowledge that such evidence may be proprietary. However, without this data, the public has little reason to believe that most consumer EEG devices validly and reliably record brain activity.

Brainwaves Derived from EEG Accurately Reflect Certain Behaviors or Mental States

Scientists can leverage EEG data in at least two ways to attempt to identify mental states and behaviors: by using pre-specified bandwidths or applying machine learning algorithms. The first and historically more common approach parcels EEG data into five bandwidths—delta, theta, alpha, beta, gamma—and can generally provide the information necessary to distinguish between two widely diverging states, such as sleep and wakefulness. On the one hand, these bandwidths were defined almost a hundred years ago and continue to effectively serve as a tool for analyzing brain data across a range of disciplines including neurobiology, medicine, and research on cognition. On the other hand, in the consumer EEG context, these bandwidths seem to be employed in the overly simplistic manner commonly used in neurofeedback practice—where the amplitude of certain bandwidths not only correlates with, but is assumed to drive a particular behavior or mental state (e.g., increasing the amplitude of one's alpha waves will cause a meditative state). This belief rests on a shaky foundation (Thibault and Raz 2017). For one, while expert meditators may have high levels of alpha activity, individuals can also achieve a meditative state while producing little alpha activity, and high amplitude alpha waves can also be produced when individuals are anxious (Beyerstein 1990). Thus, alpha amplitude remains unconvincing as a marker for meditation. In a similar manner, neurofeedback practitioners often attempt to increase beta activity (~13–30 Hz) because a number of studies correlate this frequency with heightened attention. And yet, beta amplitude also correlates with alcoholism (Rangaswamy et al. 2002) and poor attention in children with ADHD (Ogrim et al. 2012). Moreover, some of the most robust neurofeedback studies show that attention can improve substantially (Cohen's $d = 1.5$) without any significant change in underlying EEG activity (Schönenberg et al. 2017). Behavior can also remain objectively unchanged when individuals nonetheless learn to increase a pre-specified bandwidth of brain activity (Schabus et al. 2017). Thus, most mental states and behaviors cannot be clearly inferred by parceling brainwaves into standard frequency bins. Although sleep can be inferred from EEG data, it remains unclear how gaining access to this data can help improve sleep.

Increasingly, researchers are turning to the second approach and using machine learning to derive mental and behavioral states from EEG data. In the general EEG literature, this method has shown moderate success at identifying more specific states than is possible using only pre-specified bandwidths (e.g., distinguishing workload intensities and vigilance levels). With regard to consumer EEG, we identified a number of studies that applied machine learning to data collected with Muse and Mindwave. Some of these experiments, for example, could identify better than chance alone, lapses in attention (Armanfard et al. 2016) and whether individuals were watching "emotional" versus "logical" videos (Bashivan et al. 2015). Even when consumer EEG devices successfully distinguish between mental states, however, they likely do so based on the electrical activity produced by facial muscles, which contaminates the EEG signal. When individuals are resting, their muscle activity can continue to produce high-frequency electrical signals 10–200 times greater in amplitude than brainwaves (Whitham et al. 2007). These signals can dominate parts of the EEG recording and are difficult to remove even from data collected with research-grade EEG systems. Thus, it remains unlikely that consumer EEG devices—which utilize fewer electrodes and simpler components—would rely primarily on brain activity to distinguish mental states. With these considerations in mind, consumer EEG devices nonetheless maintain the potential to one day serve as drowsiness detectors (even if relying on data from muscles), for example, to alert drivers when they appear fatigued. Beyond drowsiness, there is currently little evidence to suggest that these devices, regardless of the methods used, can track the brain signatures associated with other consumer EEG promises such as optimal performance and improved learning or memory capacity.

Providing Individuals with EEG Brainwave Data Can Help Them Improve the Behavior or Mental State in Question

Rather than conducting research, the majority of consumer EEG companies implicitly or explicitly rely on findings from the neurofeedback literature. This reliance remains problematic because not only do consumer-grade and research-grade devices differ substantially, but the neurofeedback literature itself is hardly convincing. Of over 3000 publications claiming that neurofeedback using EEG can improve attention, cognitive performance, insomnia, and a range of other behaviors, only 11 experiments employ a double-blind and leverage a sham-control group (e.g., who receive data from a previously recorded participant; Thibault and Raz 2017). Ten of these studies demonstrate equivalence between sham and genuine neurofeedback. Thus, the use of consumer EEG largely rests on a body of literature that has yet to establish the benefit of receiving genuine brainwave data.

Participants in neurofeedback studies likely improve their behavior not because they viewed their brain activity, but

because of salient psychosocial influences (e.g., placebo effects: Kirsch et al. 2016) and the benefits of cognitive training in general. Indeed, participants in the neurofeedback context interact with practitioners over multiple sessions (Margo 1999), are immersed in a clinical environment with flashy technology (Ali et al. 2014; Olson et al. 2016), and receive an expensive treatment (Waber et al. 2008). These influences likely increase expectation and motivation, which in turn alter the behavior or mental state in question (Nichols and Maner 2008). Moreover, because consumer EEG companies target behaviors and mental states that are highly amenable to psychological factors (see Table 1), placebo effects likely play a large role (Wampold et al. 2005). In some experiments, these psychosocial influences are large enough to match the efficacy of standard-of-care treatments (e.g., Fuchs et al. 2003). If participants in neurofeedback studies are indeed improving due to psychosocial and cognitive mechanisms, it is far from clear that these same effects would replicate in the consumer context (without the clinical setting, expert treatment, etc.).

If consumer EEG devices do indeed help improve aspects of well-being, data would be needed from studies using consumer devices. At least three consumer EEG companies have conducted such studies. One experiment showed that when individuals used Muse rather than participate in 10 minutes of online high school math lessons, they improved reaction time on a Stroop task (Bhayee et al. 2016). Based on the substantial difference between the experimental groups alongside the impossibility of a double-blind design, placebo effects may explain the findings. Another device, Versus, has a few in-house case studies and at least one peer-reviewed experiment (Sherlin et al. 2012) on sports performance—none employed a control group and independent replication is lacking. Finally, NeuroPlus has one non-peer-reviewed in-house experiment with a control group that received no treatment. While this study suggests that their device improves attention, due to the weak research design, it may have been that psychosocial influences drove the improvement. Although these companies may be commended for publicly sharing research conducted with their own devices, the experimental designs conflate EEG effects with placebo responses. Taken together, there is little evidence to support the marketing claims of consumer EEG companies regarding altering mental states and behavior.

Ethical and Regulatory Issues

The fact that many companies are marketing products for health and well-being based on less-than-rigorous science is not in itself novel. Consumer EEG devices, however, are unique among products on the direct-to-consumer brain improvement market in that the benefits are claimed to come from providing information to individuals about their own brain states. In other words, while dietary supplements, brain-training games, and neurostimulation devices are all marketed to improve health or cognition, none of them claim to be doing so by measuring or tracking one's mental state. Consumer EEG companies, on the other hand, claim to provide snapshots of mental states (e.g., concentration, vigilance, arousal) by "reading" electrical activity captured from the scalp—and it is the reading and interpretation of that activity that is claimed to lead to behavioral improvement.

Thus, in some ways, consumer EEG devices may raise more ethically troublesome issues than other direct-to-consumer neurotechnologies, as their promoters make claims not only of behavioral improvement but also of a kind of "diagnostic" of one's mental state. Unlike other consumer products that measure aspects of physical conditions and performance—such as heart rate monitors, pedometers, and scales—consumer EEG "diagnostics" remain fuzzy: companies claim that their devices measure particular brain signals (that they may be hardly measuring), that may or may not correlate with, or be predictive of, a certain mental state.

Providing individuals with information about their mental states is not without consequence, as it may affect their behavior in unexpected ways. One parallel can be found in direct-to-consumer genetic tests—another consumer product that occasionally relies on tenuous scientific findings to provide individuals with information about themselves. In extreme cases, genetic information has caused people to change religions or donate millions to a particular population (Heine 2017). While consumer EEG devices are a less extreme example—they do not claim to provide information about one's core identity—these devices may lead individuals to modify their behavior to align with their supposed interpretation of their brain activity. For example, if individuals receive ongoing feedback from a consumer EEG device that they are stressed (even if they are not), they may enact a stressed mindset to align with this interpretation of their mental state—or they may simply become stressed by this information.

Despite the general lack of scientific rigor in the domain of consumer EEG devices, to our knowledge, no regulatory enforcement action has been taken against these companies. In the USA, where the majority of consumer EEG companies are located, products that make medical claims are considered medical devices and regulated by the Food and Drug Administration (FDA). Thus, consumer EEG products making explicit (and even implied) medical claims—such as treating ADHD or chronic pain—without prior FDA approval would be in violation of federal law. The vast majority of consumer EEG products, however, only make claims relating to "general wellness" (see Table 1), which according to FDA includes claims relating to physical fitness, stress management, mental acuity, learning capacity, and sleep management (Food and Drug Administration 2016). In a 2016 guidance, the FDA stated that it would exercise enforcement discretion (i.e., it would not enforce regulations) for "low risk devices" marketed for "general

wellness purposes" (Food and Drug Administration 2016). This clarification in FDA oversight appears to shift the federal regulatory burden for consumer EEG devices from the FDA to the Federal Trade Commission (FTC), which has the authority to take action for "unfair or deceptive" business practices. While the FTC has taken action against several companies manufacturing brain-training games, it has not filed complaints against consumer EEG device manufacturers.

Conclusion and Recommendations

On the one hand, the development of inexpensive EEG technology allows researchers to conduct neuroscience studies in real-world settings. On the other hand, the mushrooming of the consumer EEG market presents reasons to be wary; as we outlined, there is little reason to believe that most consumer EEG devices validly and reliably record brain activity, and it remains unclear whether most devices accurately reflect the mental states that companies claim to index. Perhaps most importantly, the neurofeedback literature that consumer EEG companies who are focused on wellness rest upon is shaky at best, and has recently come under scrutiny in both scientific journals (Schabus et al. 2017; Schönenberg et al. 2017; Thibault et al. 2017; Thibault and Raz 2016) and the mainstream media (Boser 2017; Fink et al. 2017).

In light of our findings, we recommend that companies marketing consumer EEG devices substantiate their claims with adequate evidence to pass standard scientific scrutiny (e.g., employ robust controls, provide a description of their analyses and results, and ideally, engage in peer-review). We further recommend that the authorities who regulate advertising take note of the unsubstantiated claims that continue to pervade the rapidly expanding consumer EEG market. Currently, consumers are left to themselves to evaluate the veracity of neuroscientific claims—a task in which very few are well-trained. We hope this initial critique of consumer EEG devices serves to encourage robust and open research practices while also alerting scientists and regulators to the issues raised by the rapidly expanding market for direct-to-consumer neurotechnologies.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

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