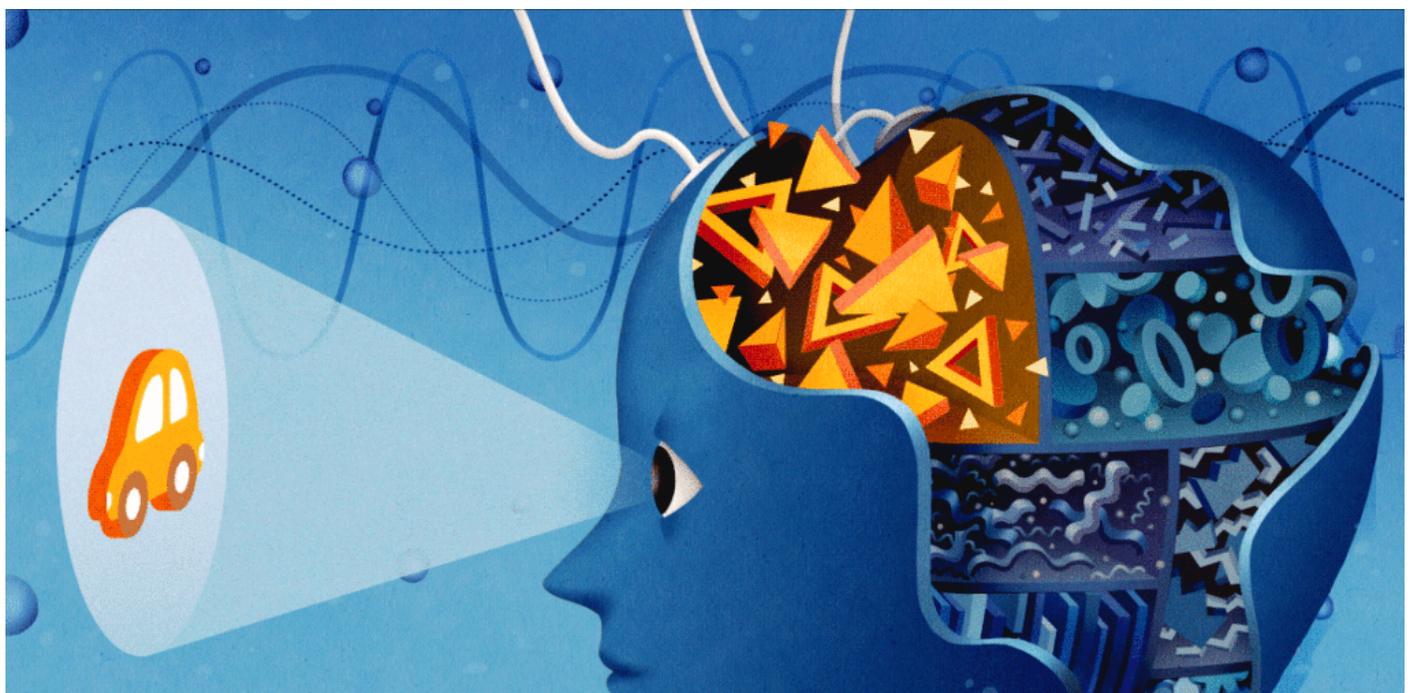


NEWS

# Despite dearth of data, firms sell brain training as autism antidote

BY HANNAH FURFARO

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On the website of the company Neurocore, an illustration of an anthropomorphized human brain, complete with hopeful eyes and a wide smile, is pumping iron. “A stronger brain makes anything possible,” says the tagline next to the cheery brain.

This concept — body-building for the brain — is the premise behind the Michigan-based company’s popular therapy. Known as neurofeedback, the therapy is based on the idea that by monitoring and adjusting electromagnetic signals, or waves, emanating from the brain, people can improve their mood, for example, or alleviate a headache.

Neurocore offers its therapy for, among other conditions, attention deficit hyperactivity disorder

(ADHD), depression, stress, anxiety — and autism. The notion is that people with autism can learn to recalibrate their aberrant brain rhythms.

There's no solid evidence that neurofeedback works as a treatment for autism. Most studies of neurofeedback have significant flaws. Still, its lofty promises spell big business: Apart from Neurocore, there are hundreds of centers offering neurofeedback as a therapy in the United States and elsewhere. (The brain-training market, which includes neurofeedback, is worth an estimated \$2 billion worldwide.)

The therapy has been available for decades, but drew intense scrutiny this past year because Neurocore is financially backed by billionaire **Betsy DeVos**, the U.S. Secretary of Education. DeVos and her family have invested millions in the company, and she is a former member of the company's board. DeVos did not respond to several requests for comment.

An investigation by *Spectrum* has shown that U.S. federal agencies with oversight in this area have not taken any action against Neurocore or other companies, even after several consumer complaints. This is despite the fact that there are **nearly 100 instances** in which Neurocore claims its technique can alleviate certain conditions.

"I have grave concerns about the marketing of these programs to families of children with autism spectrum disorder or ADHD or any other disorders at this point, because they're not well-established treatments," says **Joseph Raiker**, director of the Program for Attention, Learning and Memory at Florida International University in Miami.

The therapy's recent popularity has also prompted the National Institutes of Health to look at it more closely. The agency spent just \$7.9 million on neurofeedback research between 1997 and 2009. Since then, however, it has funneled about \$53 million to 168 studies on the approach, including clinical trials for autism, ADHD and obsessive-compulsive disorder.

So far, the only moderately promising results for autism come from small studies. For example, the results of one trial, published in February, involved 10 children with autism and 7 controls, but no placebo group<sup>1</sup>. Another study, published in September, involved 17 people with autism and 10 controls<sup>2</sup>.

## Real-time readout:

The idea that people might be able to control their brain waves dates back to the late 1960s, when neurobiologist **Barry Sterman** tested the idea in cats. Sterman monitored cats' brain waves using a technique called electroencephalography (EEG). Using food as a reward, he trained the animals to activate a certain brain frequency at will.

In the 1970s, individual practitioners first used the therapy on themselves and then on clients; the

first neurofeedback clinic opened in 1973<sup>3</sup>. In 1978, Sterman reported that six of eight people with **epilepsy** showed a **significant decline in seizures** after three months. In the mid-1990s, commercial companies began marketing neurofeedback devices to consumers and therapists. They promised to improve cognitive performance or offered drug-free relief from depression, migraines and the like.

A few years later, studies hinted that a band of 8- to 13-hertz brain waves called **the mu rhythm** may be abnormal in some people with autism<sup>4</sup>. Because the mu rhythm is linked to a circuit involved in social imitation, the researchers suggested that irregularities in this rhythm lead to the social challenges in people with autism. Some companies and practitioners began offering neurofeedback for autism.

Brian Perez was about 10 when a family friend mentioned neurofeedback. Perez has autism, and throughout his childhood, he had frequent emotional outbursts at school and at home. His parents tried various treatments to help him, but nothing worked. On the family friend's recommendation, his parents enrolled him in neurofeedback training twice each week. It eased his behavior so well that they continued the sessions.

Now 26, Perez attends college and works part-time, says his mother, Lisa. She says the therapy placed an enormous financial burden on the family, and is not convinced it is responsible for his achievements. "Did it cure anything? No," she says. "But he's not ready to give it up."

Perez still attends weekly training sessions at the **Brain Healing Center** in Coral Springs, Florida, which cost \$175 per session; his insurance doesn't cover the treatment. (Neurocore's costs are comparable: A 30-pack of sessions at the company costs nearly \$2,000.)

During each session, Perez watches a computer screen while electrodes attached to his scalp pick up the collective electrical activity in his brain. His therapist, Gerald Gluck, tailors the type of game or visual task Perez will see, and compares Perez's EEG to a database of control scans to determine which rhythms need to be changed.

Once Gluck chooses the brain waves Perez should try to alter, Perez concentrates on the visual task at hand. For example, in the 'green dot' task, a green dot appears on the screen, and a bell rings when Perez successfully manipulates a brain wave. He can choose to see EEG feedback of his brain waves on a separate screen or learn to concentrate without that visual reminder.

The real-time visual and audio feedback is supposed to teach Perez to adjust his brain waves in real-world contexts — say, to help him improve his memory.

(At Neurocore, too, therapists measure and compare the clients' baseline brain frequencies with a "normative database," says **Elyse Kemmerer White**, chief science officer at the company. "When we find differences in activity, we can personally address those changes by bringing up some

frequencies that may not have enough power and trying to lower frequencies that have too much power.”)

On the Brain Healing Center’s website, a list of frequently asked questions includes the question: “Are the results permanent?” The answer: “In most cases of ADD/ADHD, learning disorders, brain injury, yes.”

More than two years ago, Gluck told Perez that his EEG readings show he no longer has autism. (EEG scans are not part of the generally accepted diagnostic criteria for autism.)

“It’s a very big claim,” Perez says. Still, he says, neurofeedback helped him overcome social awkwardness and continues to help improve his memory and organizational skills. “I feel like it has helped me significantly, and I do use the word significantly. But I still think it needs more research.”

Gluck says he has treated more than 100 people with autism since around 2000. Up to 90 percent of the people he treats substantially improve, he says, and some can decrease the amounts of medication they take. “Traditional medicine has very little to offer, for the most part” in treating autism, Gluck says.

## Little oversight:

In the U.S., at least two government agencies have regulatory authority over companies that offer neurofeedback. The U.S. Food and Drug Administration (FDA) polices medical devices, although it exempts devices (including those used for neurofeedback, such as EEG machines) when they are used for relaxation training or other non-medical applications. The Federal Trade Commission (FTC) enforces rules that prohibit deceptive advertisements of treatments not covered by the FDA.

An analysis by *Spectrum* of FDA records shows the agency has issued warning letters to neurofeedback and biofeedback device manufacturers at seven companies. In 2012, for example, it **warned a California-based manufacturer** called **EEG Info** about “violations,” including claims that its device can be used as a ‘therapeutic application’ for autism and other conditions. But the agency has never recalled a neurofeedback device or prohibited its production.

Information obtained from a Freedom of Information Act request filed by *Spectrum* shows that the FTC has received at least seven consumer complaints since 2006 about companies that manufacture neurofeedback devices or offer the therapy. One person complained about unwanted solicitations in the mail from Neurocore. Another said she developed “pre-seizure/post-concussion symptoms that lasted for five months” after using a neurofeedback device sold by a company called the **Clear Mind Center**. She also said that the “company does not provide sufficient training of equipment allowing unlicensed techs to run [it],” according to the FTC’s records. But the agency has not required Neurocore and other companies to refund consumers or otherwise compensate for any damage or inconvenience. An FTC spokesperson confirmed this analysis.

In August, the National Advertising Division (NAD), the Better Business Bureau's investigative arm, asked Neurocore to **voluntarily cease advertising** its services as treatments. A spokesperson for the NAD says the organization scrutinized Neurocore's advertising as part of its routine monitoring of advertisements for new products and ones that target vulnerable populations.

In its **17-page recommendation**, the NAD took particular issue with **Neurocore's claims** that neurofeedback decreases the severity of autism features by 25 percent.

## Careful claims:

Before September, Neurocore's website cited a study reporting a 26 percent **decrease in "reported symptoms"** on an autism evaluation checklist. It also cited another study that "noted improvements in executive functioning, thought to be a central concern in autism." Both sentences have since been deleted from the website.

"Although we believe we were clear this was a third-party study and not a Neurocore study, we decided to remove it to avoid any confusion," **Mark Murrison**, Neurocore's chief executive officer, told *Spectrum* about the removal of the 26 percent statistic. "We are very careful to not make claims specifically about autism itself," he says. "We have always stated we treat the symptoms of autism — which include a high co-occurrence of anxiety, mood and attention issues."

The NAD's censure has no legal teeth. [Still, Neurocore appealed the recommendation to the National Advertising Review Board (NARB), which is affiliated with the Council of Better Business Bureaus.]

"The public has a right to receive accurate and truthful information about the alternatives to chemical treatments for these conditions, and we have provided it," [Murrison] says.

[But on 20 June, the NARB affirmed the NAD's recommendation that Neurocore cannot support several of its claims. For instance, the NARB determined Neurocore should stop claiming its treatment leads to a 25 percent reduction in autism features. The panel also said Neurocore should take down YouTube testimonials claiming the treatment reduces or eliminates the need for medications used to treat attention deficit hyperactivity disorder, depression and other conditions.]

In a statement, Neurocore said it would comply with the NARB's recommendations.]

Even though the company advertises its services for people with autism, most people who visit Neurocore do not have the condition, company officials say.

When *Spectrum* asked what the company would tell a parent about the effectiveness of the therapy for autism, Kemmerer White said, "Good question," and deferred the reply to **Nick Bolhuis**, Neurocore's director of clinical operations. "The body of research needs to continue to grow in the

field of neurofeedback as it specifically relates to [autism],” Bolhuis said.

Neurocore’s website is **less tentative**, stating, “Neurocore can help with autism.”

## Long road:

From a basic-research perspective, there is, in fact, much to learn about neurofeedback, other researchers say.

“It’s definitely an area of growth and an area of great promise,” says **Ralph-Axel Müller**, professor of psychology at San Diego State University and co-investigator on the February study on autism. “But how can we specifically target certain brain abnormalities in a given individual child with [autism]? That’s still a big challenge.”

In the meantime, although neurofeedback is unlikely to be harmful, it can waste parents’ time, energy and money. Families may forgo proven treatments to spend their resources on neurofeedback, says **Kevin Pelphrey**, director of the Autism and Neurodevelopmental Disorders Institute at George Washington University in Washington, D.C. “There’s so many of these kinds of brain-training small companies, or even quite large companies, that charge people for unproven technologies,” Pelphrey says. “And they’re really giving science a very bad name.”

If anything, neurofeedback should be used in combination with behavioral treatments, Pelphrey says. “If we want to [use neurofeedback to] help people respond to other evidence-based treatment, I think that we’re close,” he says.

Meanwhile, Neurocore has **changed some of the wording** on its website. As of late September, the company had removed statements about the efficacy of neurofeedback for autism. For example, the statement, “There is currently no cure for autism, but the symptoms can greatly improve through Neurocore’s proven, natural autism treatment program,” was removed. Another statement, “In some cases, children’s medication may be able to be reduced,” was also removed.

And the company is continuing to pursue its own research on the treatment: Its website now advertises a clinical trial for older adults with memory concerns.

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