The ADHD brain retrained

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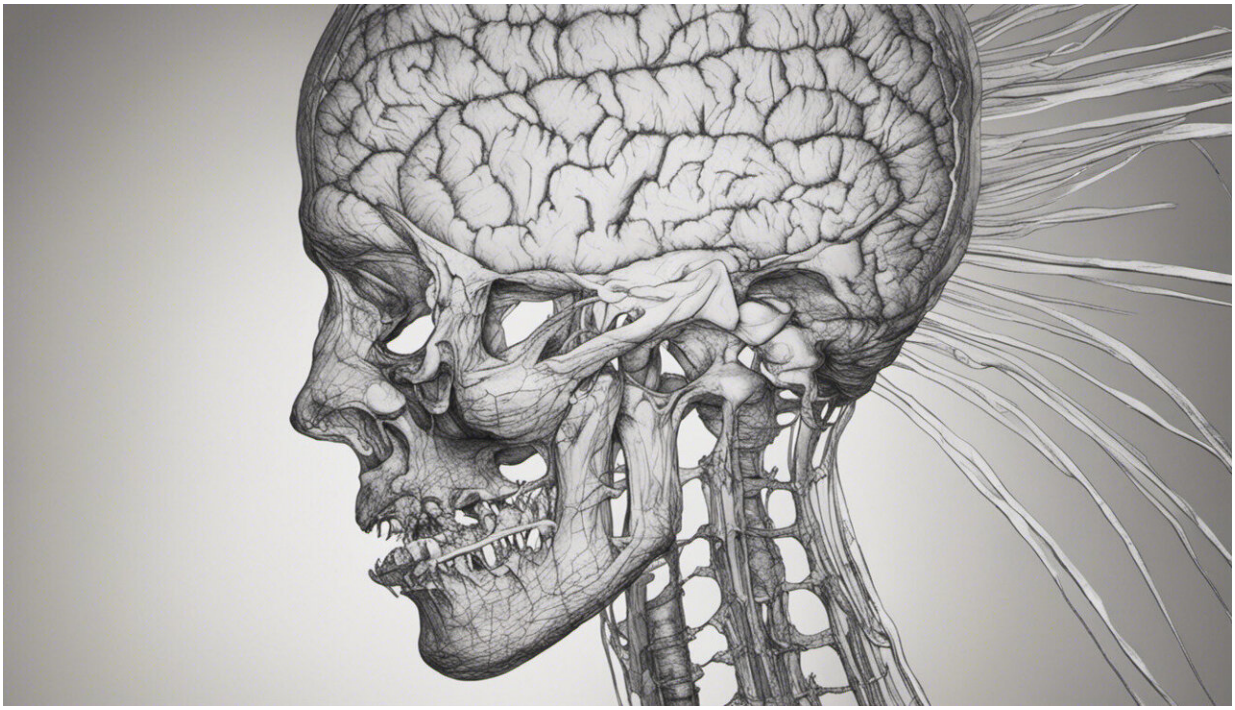

Credit: AI-generated image (disclaimer)

The cost of attention deficit hyperactivity disorder (ADHD) can be as high as EUR 7,000 per patient per year in the United Kingdom and some 4 million children suffer from the disorder in Europe. NEWROFEED has developed a personalised, drug-free treatment for home use based on neurofeedback.

ADHD is a chronic debilitating disorder usually diagnosed during

childhood. It negatively impacts many aspects of young patients' lives including academic achievements, social skills and perception of self-worth. It's not surprising then that this can lead to strained parent-child relationships.

The most common treatment for ADHD is a form of psychoactive medication, which in many cases is methylphenidate (MPH), an amphetamine. While these drugs do have a positive impact, leading to short-term adaptation of the child's behaviour, they have significant side effects, impacting sleep, appetite and sometimes the personality of the child through affective blunting (reduction in emotional response), and reduced creativity.

Personalised neurofeedback therapy

The EU-funded NEWROFEED project has developed a "safe alternative with a superior benefit / risk ratio for patients, who are not willing to take drugs due to severe adverse events," informs Dr. Michel du Peloux, project coordinator and chief executive officer of Mensia Technologies who developed the device. NEWROFEED implemented the non-inferiority study to demonstrate that the medical device Mensia Koala would be non-inferior to the reference drug treating ADHD for children aged 7 to 13 years old.

As du Peloux explains, "There is a need for innovative, drug-free treatments for ADHD. We believe there is an alternative: neurofeedback, a methodology to 'rewire' the brain that was conceptualised in France as early as the 1960s and later developed in the US from the 1960s onwards." The technique is self-paced and uses electroencephalography (EEG) signals from the brain to help the patient train brain functions and normalise activity to a healthy range.

Robust and user-friendly enough for home use

NEWROFEED took advantage of advances in research for the deployment of neurofeedback as a large-scale treatment for ADHD. This has helped eliminate problems with heterogeneous methodologies and technical implementations in existing trials as well as lack of standardised implementation for automated neurofeedback delivery. Recent breakthroughs in real-time software and hardware design and function have also enabled the fully automated device to be user-friendly and robust enough after minimal training for home use.

"We now have gold standard European clinical proof that Mensia Kola is an effective and safe therapy for sub groups of ADHD patients," affirms Dr. du Peloux "with the outstanding benefit of 'at home' brain training." The personalised neurofeedback protocols can be delivered on the affordable, user-friendly device to optimise training at home under remote medical supervision. The final release of SMR neuromarkers will supply evidence of this.

Technical and organisational challenges

The amplifier of the system exhibited classical defaults in the prototype. "However, more resources and formation of a specific task force allowed us to gain high level expected quality for our exclusive device after some months of testing," explains Dr. du Peloux.

For delay challenges, there were heavy constraints on fostering rapid enrolment in five countries. However, Dr. du Peloux has over 30 years' experience in management positions in the pharmaceutical, medical device and healthcare world. "My expertise and the whole team's efforts across five countries served to overcome problems with enrolment and resulted in better communication by establishing new selection centre in

countries," he emphasises.

Commercial success planned to expand

Funding from the EU's Horizon 2020 programme means that the Mensia Koala neurofeedback device has been on the French market since March 2018. Mensia Technologies plan expansion into the rest of Europe by 2019-2020. Registration via the FDA for introduction into the United States is also on the schedule. "We will make it a success!" declares Dr. du Peloux.

Dr. Du Peloux goes as far as claiming that EU funding has been instrumental in making sure this key milestone of large scale clinical trial sponsorship will enable thousands of families to access the first worldwide digital therapeutics validated in Europe to treat ADHD.

Provided by CORDIS

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