Neurofeedback, sham neurofeedback, and cognitive-behavioural group therapy in adults with attention-deficit hyperactivity disorder: a triple-blind, randomised, controlled trial

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Summary

Background Many studies suggest that electroencephalographic (EEG) neurofeedback might be beneficial in the treatment of attention-deficit hyperactivity disorder (ADHD). However, numbers of well controlled studies are low and neurofeedback techniques are regarded as highly controversial. The present trial examined the efficacy (compared with sham neurofeedback) and efficiency (compared with meta-cognitive therapy) of a standard EEG neurofeedback protocol in adults with ADHD.

Methods We did a concurrent, triple-blind, randomised, controlled trial using authorised deception in adults with ADHD from one centre (University of Tübingen) in Tübingen, Germany. Participants were eligible if they fulfilled the DSM-IV-TR criteria for ADHD, were aged between 18 years and 60 years, and had no or stable use of medication for at least 2 months with no intention to change. We excluded participants who had comorbid schizophrenia or schizoaffective disorder, bipolar disorder, borderline personality disorder, epilepsy, or traumatic brain injury; substance abuse or dependence; or current or planned other psychological treatment. Those eligible were randomly assigned to three groups: a neurofeedback group which received 30 verum θ-to-β neurofeedback sessions over 15 weeks, a sham neurofeedback group which received 15 sham followed by 15 verum θ-to-β neurofeedback sessions over 15 weeks, or a meta-cognitive group therapy group which received 12 sessions over 12 weeks. Participants were assigned equally to one of the three interventions through a computerised minimisation randomisation procedure stratified by sex, age, and baseline symptom severity of ADHD. Participants were masked as to whether they were receiving neurofeedback or sham neurofeedback, but those receiving meta-cognitive therapy were aware of their treatment. Clinical assessors (ie, those assessing outcomes) and research staff who did the neurofeedback training were masked to participants’ randomisation status only for neurofeedback sessions.

Findings Between Feb 1, 2013, and Dec 1, 2015, 761 people were assessed for eligibility. 656 (86%) were excluded and assessed before treatment, at midtreatment (after 8 weeks), after treatment (after 16 weeks), and 6 months later. All individuals with at least one observation after randomisation were included in the analyses. This trial is registered with ClinicalTrials.gov, number NCT01883765.

Interpretation Our findings suggest that neurofeedback training is not superior to a sham condition or group psychotherapy. All three treatments were equivalently effective in reducing ADHD symptoms. This first randomised, sham-controlled trial did not show any specific effects of neurofeedback on ADHD symptoms in adults.

Funding German Research Foundation.
Research in context

Evidence before this study
Attention-deficit hyperactivity disorder (ADHD) is a prevalent childhood disorder that is often maintained throughout development and persists into adulthood, leading to substantial problems in daily functioning. Although pharmacotherapy is considered the first-line treatment for ADHD at all ages (at least for severe cases), non-pharmacological therapies might be equally effective without the risk of drug side-effects. Some studies have shown that electroencephalographic (EEG) neurofeedback improves parent-rated ADHD symptoms in children and adolescents. However, adequate and well controlled studies to support its use are scarce, particularly in adults. We searched PubMed with the search terms “ADHD”, “neurofeedback”, “adults,” and “clinical trial” for articles published in English between Oct 1, 2010, and March 31, 2017. This search identified two feasibility studies that investigated the effects of neurofeedback when compared with either no intervention or a sham control in small groups of students prone to ADHD. Although the first study of neurofeedback versus no intervention reported beneficial effects, the second study of neurofeedback versus sham control found no advantage of neurofeedback. The PubMed search additionally identified one randomised controlled trial. This trial showed that, compared with waiting-list control, neurofeedback promoted improvement of self-reported ADHD symptoms but did not show transfer of learning to a computerised assessment of executive functions.

Added value of this study
In this first randomised, adequately controlled, triple-blind investigation of neurofeedback for the treatment of adults with ADHD, we found no superior efficacy of neurofeedback to sham neurofeedback or meta-cognitive therapy in the treatment of ADHD symptoms. Furthermore, targeted EEG bands (θ:β) remained unaffected by neurofeedback training, and clinical improvements were unrelated to the EEG θ-to-β power ratios across assessments in all treatment conditions.

Implications of all the available evidence
This study adds to first evidence from other studies that investigated the effects of neurofeedback in children with ADHD or other clinical disorders and observed no advantage for neurofeedback when compared with sham treatments. Our results suggest that although neurofeedback training is effective in reducing ADHD symptoms it neither outperforms sham neurofeedback nor group psychotherapy. As such, neurofeedback cannot be recommended as an efficient approach in the treatment of adults with ADHD.

become the first-line treatment for ADHD at all ages (at least for severe cases), studies of long-term efficacy and safety are scarce. Moreover, a substantial percentage of adult patients do not benefit from medication; report profound, although often manageable, side-effects; or express reservations about use of medication. Consequently, a strong demand exists for alternative or adjunct non-pharmacological approaches. Although little research has been done, some of the first studies have yielded encouraging results for the efficacy of cognitive-behavioural therapies (CBTs). For instance, findings suggest that meta-cognitive therapy, a 12 session group-administered intervention designed to enhance time management, organisation, and planning, provides significant benefits to adult patients in terms of reduced inattention and secondary improvements in comorbid symptoms of anxiety and depression.

A large body of evidence suggests that electroencephalographic (EEG) neurofeedback training might be a promising therapeutic method with lasting effects and minimal-to-no side-effects. EEG neurofeedback is based on the assumption that deviant brain activity patterns can be voluntarily modulated by operant learning strategies and that normalisation of brain activity will then translate into improved cognitive and behavioural functioning in individuals with ADHD. Clinicians typically use a training protocol that aims to increase EEG fast-wave activity (primarily in the β range), while suppressing slow-wave activity (primarily in the θ range). Although 30 or more sessions are usually done, evidence exists that significant improvement can also be indicated within fewer than 15 sessions. Several studies have reported impressive efficacy (eg, Cohen’s d >0.8) of neurofeedback protocols in children and adolescents with ADHD, and some studies reported equal or even superior efficacy of neurofeedback compared with medication or CBT. However, other investigators have expressed scepticism about these results and emphasised the need for more scientifically rigorous studies. To date, the main shortcomings of the existing studies include the scarcity of randomised and well controlled trials, non-blinded participants and raters, and the absence of objective neuropsychological or electrophysiological data. Thus, although considerable clinical evidence for positive effects of neurofeedback training in ADHD exists, proof is inadequate that training results are due to active treatment elements. In fact, evidence suggests that neurofeedback in the treatment of children with ADHD is not superior to a sham treatment.

We designed this trial to investigate the efficacy (as compared with sham neurofeedback) and efficiency (as compared with an approved short-term group CBT programme) of standard neurofeedback training in the treatment of adults with ADHD. By using the term efficacy, we refer to the capacity of a therapy to induce intended changes. By contrast, efficiency is achieved by applying cost-effective and time-effective care procedures with the fewest inputs. We postulated that verum neurofeedback, but not sham neurofeedback, is effective
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