Lancet Psychiatry. 2017 Sep;4(9):673-684. doi: 10.1016/S2215-0366(17)30291-2. Epub 2017 Aug 9.

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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Abstract

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 and sham neurofeedback. The primary outcome was symptom score on the Conners' adult ADHD rating scale, 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.

FINDINGS:

Between Feb 1, 2013, and Dec 1, 2015, 761 people were assessed for eligibility. 656 (86%) were excluded and 118 (15%) were eligible for participation in this study. Eligible participants were randomly assigned to neurofeedback (38 [32%]), sham neurofeedback (39 [33%]), or meta-cognitive therapy (41 [35%]). 37 (97%) individuals for neurofeedback, 38 (97%) for sham neurofeedback, and 38 (93%) for meta-cognitive therapy were included in analyses. Self-reported ADHD symptoms decreased substantially for all treatment groups (B=-2·58 [95% CI -3·48 to -1·68]; p<0·0001) between pretreatment and the end of 6 month follow-up, independent of treatment condition (neurofeedback vs sham neurofeedback B=-0·89 [95% CI -2·14 to 0·37], p=0·168; neurofeedback vs meta-cognitive therapy -0·30 [-1·55 to 0·95], p=0·639). No treatment-related or trial-related serious adverse events were reported.

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.