The efficacy of LENS neurofeedback treatment for ADHD

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Primary Objective: The present study aims to test the efficacy of treatment of patients with ADHD, using LENS neurofeedback.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON33274

Source
ToetsingOnline

Brief title
LENS neurofeedback treatment for ADHD

Condition

- Cognitive and attention disorders and disturbances

Synonym
Attention Deficit Hyperactivity Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,PsyQ Eindhoven

Intervention

Keyword: ADHD, LENS neurofeedback, RCT

Outcome measures

Primary outcome

Changes in ADHD symptom level: clinical response defined as a decrease of at

least 2 points on the self-reported ADHD rating scale.

Secondary outcome

1. symptom levels of depression and anxiety (SCL-90 subscale scores)

2. global level of mental and physical functioning (SCL-90 total score)

3. sustained attention capacity: Bourdon-Wiersma task

4. inihibitory control: SSRT (inhibitory performance, response speed,

individual response variability, and response accuracy; (Logan, Cowan et al.

1984)

5. medication use (agent, dosage)

Study description

Background summary

Convergent data from neuroimaging, neuropsychological, genetics, and neurochemical studies have implicated fronto-striatal network abnormalities (lateral prefrontal cortex, dorsal anterior cingulate cortex (ACC), caudate nucleus, and putamen) as likely contributing to the pathophysiology of ADHD (Bush, Valera et al. 2005). Deficient behavioral inhibition (BI) processes are considered a core feature of ADHD (Alderson, Rapport et al. 2007). BI processes are usually assessed using go- no go paradigms, such as the stop-signal task (Lubar and Lubar 1984). Relative to typically developing children, children with ADHD were found to reveal significantly slower mean reaction time (MRT), greater reaction time variability (SDRT), and slower stop-signal reaction time (SSRT). Stop-signal reaction time differences are viewed to reflect a more generalized deficit in attention/cognitive processing rather than behavioral inhibition (Alderson, Rapport et al. 2008).
Preliminary evidence is emerging that neurofeedback training can help to improve behavioral and cognitive functioning of individuals with ADHD.
Lubar and Lubar (Lubar and Lubar 1984) treated six children with ADHD with

neurofeedback and academic treatment. The training consisted of two sessions per week for 10 to 27 months, with a gradual phase-out. Feedback was provided for either increasing 12- to 15-Hz sensorimotor rhythm (SMR) or 16- to 20-Hz beta activity. Inhibit circuits were employed for blocking the SMR or beta when gross movement, excessive EMG, or theta (4-8 Hz) activity was present. Treatment combined biofeedback with academic training, including reading, arithmetic, and spatial tasks to improve attention. All children showed increased SMR or beta and decreased slow EEG and EMG activity. Changes could be seen in their power spectra after training in terms of increased beta and decreased slow activity. All six children demonstrated considerable improvement in their schoolwork in terms of grades or achievement test scores. Using fMRI recordings, Levesque and colleagues (Levesque, Beauregard et al. 2006) found that neurofeedback training (NFT) normalized functioning of the ACC, an essential brain structure for the regulation of attention and behavior. The training, employing the Lubar protocol (Lubar and Lubar 1984) during 40 (60-minute) sessions over 13 weeks, was divided in two phases (20 sessions in each phase): in the first phase, subjects were trained to enhance the amplitude of the sensorimotor rhythm (12-15 Hz) and decrease the amplitude of theta activity (4-7 Hz); in the second phase, subjects learned to inhibit the amplitude of their theta waves (4-7 Hz) and increase the amplitude of their beta-1 waves (15-18 Hz).

Monastra et al. (Monastra, Monastra et al. 2002) investigated 100 children, ages 6-19, with ADHD, either inattentive or combined types. All of the patients participated in a 1-year, multimodal, outpatient program that included Ritalin, parent counseling, and academic support at school. Fifty-one of the participants also received EEG biofeedback therapy. Significant improvement was noted on the Test of Variables of Attention and the Attention Deficit Disorders Evaluation Scale when participants were tested while using Ritalin. However, only those who had received EEG biofeedback sustained these gains when tested without Ritalin. The results of a Quantitative Electroencephalographic Scanning Process revealed significant reduction in cortical slowing only in patients who had received EEG biofeedback.

Classical neurofeedback such as employed by Lubar and Lubar (1984) and Levesque et al. (2006) employs basic principles of biofeedback. Patients receive immediate feedback of the electrical activity of (parts of) their brain, that allows them to learn how to regulate their mental condition. Neurofeedback training is aimed at teaching trainees a method of self-regulation. The learning process is governed by the laws of operant conditioning. When the characteristics of the EEG-signals match the desired EEG profile, reward is delivered. Through a trial-and-error process, although not necessarily at a conscious level of processing, the trainee develops strategies to modify his or her EEG to maximize reward, and thus learns to self-regulate brain functioning to match the desired EEG-parameters.

In the present study, we aim to investigate the effects of the Low Energy Neurofeedback System (LENS) on ADHD-patients. Instead of displaying information on a computer screen to assist the patient in conditioning brainwave patterns, the LENS, developed by Ochs (2006), uses weak electromagnetic signals as a

carrier wave for the feedback to assist in reorganizing brain physiology, administered at a positive offset frequency from the person*s own dominant EEG frequency. Although the feedback remains invisible for the person who is being treated and the subject remains passive throughout the treatment procedure, clinical evidence supports the efficacy of the LENS across a spectrum of conditions.
Preliminary evidence of the clinical efficacy of the LENS treatment for several disorders, that involve the central nervous system, has been published. Among others, patients with traumatic brain injury (N = 12; age 21 - 53 years) have been investigated. Time since injury ranged from 36 months to 21 years. Comparison of two groups receiving, respectively, direct LENS treatment (25 sessions) and waiting list, indicated improvement after treatment for participants* reports of depression, fatigue, and other symptoms, as well as for some measures of cognitive functioning. Most participants experienced meaningful improvement in occupational and social functioning (Schoenberger, Shiflett et al. 2001). The efficacy of the LENS method in the treatment of fibromyalgia patients has received preliminary support (Mueller, Donaldson et al. 2001) when combined with physical therapy for the pain symptoms. Thirty patients who met the 1990 American College of Rheumatology criteria for fibromyalgia syndrome (FS) were included in a prospective study. Patients were initially treated with the LENS neurofeedback (called electroencephalograph (EEG)-driven stimulation by the latter authors) until they reported noticeable improvements in mental clarity, mood, and sleep. Self-reported pain, then, having changed from vaguely diffuse to more specifically localized, was treated with modest amounts of physically oriented therapies. Pre- to posttreatment and extended follow-up comparisons of psychological and physical functioning indices, specific FS symptom ratings, and EEG activity revealed statistically significant improvements, that were attributed to the neurofeedback treatment. The present study is, to the best of our knowledge, the first to investigate the efficacy of LENS neurofeedback treatment for individuals with ADHD.

Study objective

Primary Objective: The present study aims to test the efficacy of treatment of patients with ADHD, using LENS neurofeedback.

Study design

A prospective, randomized (waiting list and placebo) controlled trial with between-groups and within-subject comparisons using repeated measures.

Intervention

The duration of the neurofeedback treatment is 10 weeks. Participants receive 20 treatment sessions of 30 minutes, including EEG preparation. The treatment is performed using the LENS Biofeedback system, implemented on a laptop

computer.
Brain potentials are recorded using one solid silver electrode which is placed on the scull at the Fz position in accordance with the international 10-20 system and two electrodes at, respectively, the left ear lobe (reference electrode) and the right ear lobe (ground). The impedance is checked and kept below 5 k*. The skin is lightly abraded using scrubbing gel.
The sampling rate is 256 Hz. The frequency range of the recorded brain activity is 0-60 Hz.
In each 30-minute treatment session, after electrode placement, the patient is seated in an ordinary armchair. No specific instructions are given.
The feedback algorithm of the LENS determines the feedback frequency by adding the continuously changing dominant (peak) EEG frequency and an offset value. The latter is a changeable but fixed variable. Most feedback is delivered at a 1% duty cycle, meaning that, at a feedback frequency of 1 Hz, the actual duration of the feedback pulse is .01 seconds; at a feedback frequency of 30 Hz, the actual duration of the feedback pulse is .003 seconds. Radiated signal levels from the LENS are: during feedback 1*10-22 Watts/cm2; during baseline: 1*10-25 Watts/cm2.

LENS and placebo treatment are delivered as follows:
1. A LENS practitioner who is not involved with the participants in the study creates a LENS High Efficiency (HE) map as well as Least Stimulation maps for each participant in the study.
2. The maps are subsequently used by the therapist for this patient when assigned to the LENS and placebo condition.
3. The LENS and placebo groups have different sets of software, although the screens are identical. There is no readout or traces of the EEG on the screens of either group. As a result, the therapist remains blinded for which software set is used.
4. The direct LENS treatment group uses the HE applications; the placebo group uses the Least Stimulation applications.

Study burden and risks

It is possible that patients with ADHD may not benefit from this neurofeedback treatment. There is no indication from previous studies of LENS neurofeedback or from the treatment outcome literature regarding ADHD that LENS neurofeedback might result in further increase of ADHD complaints. In controlled studies of efficacy of neurofeedback treatment of children with ADHD, no adverse events or short- or long-term risks were noted (Fox, Tharp et al. 2005), nor were any adverse events or side effects noted in other neurofeedback studies. If any sign of deterioration of the participants* condition is detected, neurofeedback treatment will immediately be terminated, and alternative treatment will be offered.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 40, k. 3.738
6200 MD Maastricht
NL
Scientific
Universiteit Maastricht

Universiteitssingel 40, k. 3.738
6200 MD Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Ambulatory patients with ADHD (ADHD rating scale > 6/9).

Exclusion criteria

Comorbidity on Axis 1 or 2 of DSM-IV-TR; relevant neurological disease, e.g., epilepsy; relevant neurovascular disease, e.g., status after CVA, migraine. Concurrent pharmacological treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2009
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	06-07-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL26789.068.09