The efficacy of neurofeedback treatment of burnout

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The present study aims to initiate the testing of a new, curative, person-directed, approach of patients with burnout, that uses neurofeedback, also called EEG (electroencephalogram)-biofeedback.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Adjustment disorders (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON30742

Source
ToetsingOnline

Brief title
Neurofeedback treatment of burnout

Condition

- Adjustment disorders (incl subtypes)

Synonym
burnout, occupational stress symptoms

Research involving
Human

Sponsors and support

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

Intervention

Keyword: burnout, neurofeedback

Outcome measures

Primary outcome

Level of burnout complaints (Utrechtse BurnOut Schaal; Schaufeli, 1995)

Level of (mental and physical) complaints (SCL-90; Arrindell & Ettema, 1986)

Secondary outcome

Score on the BAP-scale (well-being)

Study description

Background summary

Burnout is defined as ** a syndrome of emotional exhaustion, depersonalisation, and reduced personal accomplishment* and is considered a pathological response pattern to occupational stress.
Professional health care for patients with burnout comprises preventive as well as curative care. In curative care for burnout patients, we can distinguish interventions aiming at improving occupational conditions, e.g., the reduction of stressors at the work place, and person-directed interventions aimed at recovery and reinforcement of the patient's psychological resilience. Allthough the literature holds several descriptions of interventions in the treatment of burnout, a recent Cochrane Systematic Review makes clear that empirical research into the efficacy of these interventions is scarce. The available controlled studies, moreover, provide only very limited support for both person-directed and work-directed approaches of burnout.
Neurofeedback 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 on 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.

Study objective

The present study aims to initiate the testing of a new, curative, person-directed, approach of patients with burnout, that uses neurofeedback, also called EEG (electroencephalogram)-biofeedback.

Study design

A pilot study with within-subject comparisons with repeated measures, without experimental controls.
Measurements:
1. pre-treatment
2. process measurement during treatment
3. post-treatment
4. follow-up after 6 weeks
5. follow-up after 12 weeks

Intervention

Neurofeedback protocol:
The duration of the neurofeedback training is 10 weeks. Participants receive 20 training sessions of 60 minutes, including EEG preparation. The training is performed using the NeuroCARE Pro Biofeedback system, implemented on a laptop computer. Brain potentials are recorded with two AgCl electrodes which are placed on the scull (at C3 and C4, in accordance with the international 10-20 system) and two electrodes at, respectively, the upper rim the right ear cup (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 feedback is given by interrupting (during 150 ms) the sound that accompanies the viewing of a pleasant video movie, preselected by the participant. The participants do not receive specific instructions during the training.
The sampling rate is 256 Hz. Artifacts caused by eye or gross body movements are corrected using an active wavelet-base de-noising routine. The frequency range of the recorded brain activity is 0-60 Hz. The Neurocare Pro program uses time-frequency filtering with the help of adaptive Gabor transformations. For each of the 16 targets, the signal intensity traversing outside (either below of above) the zone of variability surrounding the current value of that signal, will be sufficient to interrupt the ongoing audio-visual stream. The size of the target is recalculated dynamically and is also modified by the trainer. Targets are CVB's (current value boxen): 0-2.5 Hz, 2.5-6.5 Hz, 8-13 Hz, 15-18 Hz, 20-23 Hz, 23-38 Hz, 33-37 Hz, 38-42 Hz, recorded over the left and right hemisfere.

Study burden and risks

Neurofeedback treatment for burnout complaints is integral to the regular mental health care program of institutions for mental health care in The Netherlands. The treatment that is administered in this study comprises the standard number of treatment sessions. The duration of the sessions conform to standard practice. The treatment methodology conform to standard practice.
The extra burden associated with participation encompasses completion of two questionnaires (UBOS, SCL-90) after treatment termination, and at follow-up assessment after 6 and 12 weeks. Questionnaires are sent by mail to the participants. They are requested to return these by mail in a prestamped and addressed envelope.
In the clinical nor in the scientific literature any side effects, adverse events or safety risks from the neurofeecback training have thus fare been reported.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

UBOS-score > 2,21

Exclusion criteria

comorbidity on Axis 1 or 2 of DSM-IV-TR
concurrent pharmacological treatment for burnout or other mental disorders
relevant neurological disease, e.g., epilepsy
relevant neurovascular disease, e.g., status after CVA, migraine

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	8
Type:	Actual

Medical products/devices used

Generic name:	Neurofeedback-system;with ProComp 2 hardware interface;and with Neurocare Pro software
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-06-2007
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	NL15247.068.07