Biofeedback breathing regulation during exposure in patients with PTSD

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric disorders
Study type	Interventional

Summary

ID

NL-OMON32976

Source
ToetsingOnline

Brief title
Biofeedback during exposure

Condition

- Psychiatric disorders

Synonym
PTSD and stress disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Ipse Movet

Intervention

Keyword: breathing biofeedback, exposure, PTSD

Outcome measures

Primary outcome

The acute effects of additive biofeedback will be assessed by measuring change in: breathing frequency, heart rate (HR), heart rate variability (HRV), saliva cortisol levels during exposure sessions, and the change on the Subjective Units of Distress (SUDS) during the sessions as well as the change on the Impact of Event Scale-Revised (IES-R) from session to session. Secondary parameters are anxiety and depression rates on the Hospital Anxiety and Depression scale (HADS) from baseline to 1 week post-treatment.

Secondary outcome

not applicable.

Study description

Background summary

Posttraumatic Stress Disorder (PTSD) has a major health and economic burden on patients, their relatives and society as a whole. It is therefore important to have optimal treatment available for this disorder. Trauma focused cognitive behavioural therapy (TF-CBT) has been found to be the most effective psychotherapeutic treatment, with imaginal exposure as its key ingredient. Nevertheless, not every patient fully recovers with TF-CBT and often several exposure sessions are needed to reduce the PTSD symptoms. Based on recent pilot-studies showing that biofeedback induces changes in the parasympathetic nervous system and reduces anxiety and depression rates, we expect biofeedback to be a good complementary component to imaginal exposure conducted during TF-CBT treatment. We hypothesize that it induces acute changes in psycho physiological arousal and subjective distress and accordingly fastens the reduction of the core PTSD symptoms and accompanying anxiety and depression

symptoms.

Study objective

The main objective of this study is to assess whether treatment of PTSD with TF-CBT can be more effective and efficient by adding breathing biofeedback to the exposure sessions. We hypothesize that adding breathing biofeedback to exposure in TF-CBT produces acute changes in physiological reactivity (e.g., increase in heart rate variability (HRV)) and fastens the reduction of PTSD-symptom levels compared to exposure in a TF-CBT condition without any adjunctive intervention. Secondary, we assess and compare the reduction of anxiety and depression scores of both TF-CBT conditions (TF-CBT + biofeedback vs. TF-CBT alone).

Study design

In this pilot study a comparison between PTSD patients (N = 20) randomised to either regular TF-CBT treatment (N = 10) or TF-CBT treatment with and adjunct of breathing biofeedback during exposure (N = 10) will be made. All patients (N = 20) will receive all elements of TF-CBT treatment including the main element of imaginary exposure. The PTSD patients in the TF-CBT + biofeedback condition will receive one extra session for biofeedback training. In all subsequent exposure sessions they will conduct breathing biofeedback as well as during imaginal exposure in home work assignments.

Intervention

Patients will be randomized to regular TF-CBT (n = 10) or to TF-CBT + biofeedback (n = 10). The latter group will receive breathing biofeedback during all exposure sessions within the TF-CBT treatment. During exposure sessions, physiological parameters, immediate subjective distress levels and PTSD symptom levels will be obtained in both conditions.

Study burden and risks

The burden and risks associated with participation in this study is reasonable. Participants receive trauma focused behavioural therapy (TF-CBT), which is considered to be the most effective treatment for PTSD and breathing biofeedback is not an invasive procedure.

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

CAPS score of * 50
Male and female, aged 18 years and above
Written informed consent
Eligible for exposure therapy
Right handed

Exclusion criteria

Suicidal risk
Presence of any of the following DSM IV diagnoses, at present or in the past: psychotic disorder incl. schizophrenia, a bipolar disorder, depression with psychotic features, a panic disorder with or without agoraphobia or excessive substance related disorder over the past 6 months
Primary diagnosis of severe depressive disorder
Presence of primary or co-morbid personality disorder
An organic disorder
Taking any psychotropic medications at present

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-01-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL29279.018.09