ChIP-Studie: Changing Interpretations in PTSD

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20517

Source
Nationaal Trial Register

Brief title
ChIP (Changing Interpretations in PTSD)

Health condition

Posttraumatic Stress Disorder (PTSD)
Posttraumatische Stress Stoornis (PTSS)

Sponsors and support

Primary sponsor: Pro Persona/ Overwaal, Centre for Anxiety Disorders
Tarweweg 2, 6534 AM Nijmegen
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

1.
Appraisal Index (pre to post training). The "Appraisal Index" measures positive interpretation style in PTSD patients. It is calculated by summing up the number of PTSD-related appraisals

in response to an open-ended ambiguous sentence task. A higher score on this "Appraisal Index" represents a more dysfunctional, PTSD-related interpretation style.

2.
Post Traumatic Cognition Inventory (PTCI, pre to post training).

Secondary outcome

1.
Interpretation bias as assessed with the Word Sentence Association Paradigm (WSAP).

2.
Posttraumatic Stress Symptom Scale, Self Report (PSS-SR) (Foa, et al., 1993).

3.
Frequency and amount of distress provoked by the most important, trauma-related re-experience in the preceding week

4.
Trauma characteristics:
Negative Life Events and Trauma Questionnaire (NLETQ).

5.
Trauma-related psychopathology:
Health Status as measured with EuroQol (EQ-5d).
Depression as measured by Beck Depression Inventory (BDI).

6.
Personality:
Symptoms of borderline personality disorder, as measured by the Borderline Personality Disorder Checklist (BPD).
Self-compassion as measured by a short-form version of the Self-Compassion Scale Short Form (SCS-SF)
Explicit self-esteem, as assessed with the Rosenberg Self-Esteem Scale (RSES)

7.
Implicit measures:
Implicit self-esteem as assessed with an Implicit Association Test (IAT).
Implicit trauma-identification as assessed with an Implicit Association Test (IAT).

8.
The development of "Appraisal Index" and "Frequency/amount of distress of most important re-experience": Assessment before/after each training session.

9.
The influence of CBM-app training on course of PTSD over a six months follow-up period.

10.

Success of treatment as usual following the study.

Study description

Background summary

In this randomized clinical trial, we want to examine whether a CBM training aimed at inducing positive appraisal style (positive CBM-app) can alter dysfunctional appraisal styles in PTSD patients. We will investigate the effects of CBM-app training on PTSD related dysfunctional cognitions and PTSD symptoms.

Country of Recruitment: The Netherlands

Study objective

We hypothesize that an appraisal- specific, computerized CBM training (referred to as CBM-app) can induce positive appraisal styles in a sample of PTSD patients. We expect that, compared to participants who receive a neutral training, those who receive positive CBM-app training will show less PTSD related dysfunctional cognitions/symptoms post training.

Study design

Primary outcome measures:
1. Appraisal Index (pre to post training).
2. PTCI (pre to post training).

Secondary outcome measures:
1. WSAP (pre to post).
2. PSS-SR (pre to post).
3. Frequency/Distress re-experience (pre to post).
4. Trauma characteristics (pre).
5. Trauma-related psychopathology (pre to post).
6. Personality (pre).
7. Implicit measures (pre).
8. Development of Appraisal Index (before and
after each training session). Development of
Frequency/ amount of distress of most
important re-experience (before each training
session)
9. Outcomes on 1 month and 6 month follow up:
Appraisal Index, PTCI, PSS-SR,
Frequency/Distress re-experience,
EQ-5d, BDI
10. Success of treatment as usual (follow up)

Intervention

Interpretation bias modification (CBM-app):
This training comprises processing a series of reappraisal-related scripted vignettes (40 sentences per training session, 4 training sessions in total) that appear to participants as a sentence completion task. Each sentence comprises one to-be-completed word fragment, such that the meaning of the sentence remains ambiguous until the final word fragment is resolved.

Positive training group:
The word fragments produce an outcome consistent with positive (re) appraisal by assigning a positive meaning to the sentence.

Neutral training group:
The word fragments produce an outcome consistent with ambiguous (re) appraisal, as the meaning of the sentence will remain ambiguous.

Contacts

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Eligibility criteria

Inclusion criteria

1. Between 18 en 70 years of age
2. Diagnosis of PTSD (structured interview MINI)
3. Self reported PTSD symptoms (PSS-SR > 20)

4. History of interpersonal trauma
5. Internet access and desktop computer

Exclusion criteria

1. Psychosis or delusion disorders (current/past)
2. Suicidality
3. Mental retardation
4. Substance/alcohol abuse or dependence
5. Insufficient ability to speak and write Dutch

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2014
Enrollment:	146
Type:	Actual

Ethics review

Positive opinion

Date:	21-01-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38718
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4269
NTR-old	NTR4405
CCMO	NL45594.091.13
OMON	NL-OMON38718

Study results