ChIP-Studie: Changing Interpretations in PTSD

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20517

Bron
Nationaal Trial Register

Verkorte titel
ChIP (Changing Interpretations in PTSD)

Aandoening

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

Ondersteuning

Primaire sponsor: Pro Persona/ Overwaal, Centre for Anxiety Disorders
Tarweweg 2, 6534 AM Nijmegen
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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The Netherlands

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-02-2014
Aantal proefpersonen:	146

Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	21-01-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38718
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten