Treatment of PTSD due to chronic interpersonal violence in

early childhood: which treatment works best?

Gepubliceerd: 26-09-2014 Laatst bijgewerkt: 18-08-2022

This study focuses on PTSD due to repeated and prolonged interpersonal abuse in childhood (eg sexual and / or physical abuse) within the immediate environment. By using a Randomized controlled design, we examine whether Imaginary Exposure is more...

Ethische beoordeling Positief advies **Status** Werving gestart

Type aandoening -

Onderzoekstype Interventie onderzoek

Samenvatting

ID

NL-OMON25931

Bron

Nationaal Trial Register

Verkorte titel

PTSD in early childhood

Aandoening

PTSD childhoodtrauma Exposure Rescripting

Ondersteuning

Primaire sponsor: Psychotherapy & Movement

https://pm-psychotherapieamsterdam.nl

Overige ondersteuning: Psychotherapy & Movement

https://pm-psychotherapieamsterdam.nl

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome measure is severity of PTSD symptoms, as assessed with the Post-Traumatic Stress Diagnostic Scale PDS (self-report) (Foa, Riggs, Dancu, & Rothbaum, 1993; Arntz, 1993), Dutch version.

Toelichting onderzoek

Achtergrond van het onderzoek

Meta-analyses show that Trauma-Focused Cognitive Behavioral, Imaginary Exposure and Eye Movement Desensitization-Reprocessing are the most effective psychological treatments for posttraumatic stress disorder (PTSD) (Bisson et al, 2007; Bradley, Greene, Russ, Dutra & West, 2005; Cloitre, 2009; Seidler & Wagner, 2006). These relatively short treatments (9-12 sessions of 90 minutes) results in a considerable reduction of PTSD symptoms in 40-70% of patients. However, the vast majority of research has been conducted on PTSD following a single traumatic event. Research examining the application of these two protocols to PTSD as a result of repeated and prolonged interpersonal abuse in childhood (eg sexual and / or physical abuse) within the immediate environment is scant. Whether Imaginary Exposure should be regarded a 'golden standard treatment' in this patient group is unknown, en thus, research examining the effectiveness of Imaginary Exposure in this patient group is needed. Moreover, a novel treatment called 'Imaginary Rescripting' may more actively intervene in key processes that play a role in the development of PTSD such as dysfunctional based schedules and tonic immobility (TI). Hence, it may be more effective as compared to Imaginary Exposure.

This study focuses on PTSD due to repeated and prolonged interpersonal abuse in childhood (eg sexual and / or physical abuse) within the immediate environment. By using a Randomized controlled design, we examine whether Imaginary Exposure is more effective as compared to a waitinglist with regard to severity of PTSD symptoms, and whether Imaginaire Rescripting is more effective as compared to Imaginary Exposure.

Doel van het onderzoek

This study focuses on PTSD due to repeated and prolonged interpersonal abuse in childhood

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(eg sexual and / or physical abuse) within the immediate environment. By using a Randomized controlled design, we examine whether Imaginary Exposure is more effective as compared to a waitinglist with regard to severity of PTSD symptoms, and whether Imaginaire Rescripting is more effective as compared to Imaginary Exposure.

Primary hypotheses:

We expect that in this patient group with repeated and prolonged interpersonal abuse in childhood within the immediate environment, Imaginary Exposure will be more effective as compared to a waiting list condition.

Moreover, we expect that Imaginary Rescripting is more effective as compared to Imaginary exposure, based on the hypothesis that Imaginary Rescripting more actively intervenes in key pathological processes in PTSD.

Secondary hypotheses:

- We expect that ImRes is less heavy for patients as compared to IE, thus expecting drop-outs to be lower in the ImRes group as compared to the IE group
- We expect that for those with a higher 'Tonic Immobility Score', ImRes is more effective as compared to IE, because ImRes directly focuses on TI.
- We expect that for those with higer dissociation scores, ImRes is more effective.
- We expect that emotion-regulation will improve more in the ImRes group as compared to the IE group, as ImRes not only focuses on fear but also explicitly on other emotions.
- We expect self-image to improve more in the ImRes condition as compared to the IE condition, as this intervention focuses more explicitly on the UCS/UCR representation.

Onderzoeksopzet

- Measurement 1: After inclusion, so at the start of treatment
- Measurement 2: After 11 weeks (ending therapy)
- Measurement 3: At follow-up, 6 months after measurement 2

Onderzoeksproduct en/of interventie

This study is a randomized controlled trial with three conditions, i.e. Waiting list (WL), Imaginary Exposure (IE), Imaginary Rescripting (ImRes).

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Treatment duration is 11 weeks, during the first 5 weeks 2 sessions of 90 minutes each will be provided, followed by 6 weeks of one 90 minute session.

In the treatment conditions, homework of maximum 1 hr per week is given.

No sessions for the waitinglist will be provided.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 1. Meeting DSM-IV criteria for PTSD
- 2. Comorbidity with depression, anxiety disorder, ADHD, dissociative disorder, reactive psychotic disorder, alcohol/drugs consumption, borderline personality disorder and cluster C personality disorder are included.
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- 3. Having experienced repeated or chronic interpersonal trauma before age of 16 (e.g. sexual, physical or emotional abuse) by one or more perpetrators for example (foster-/step-) parents, elder brother, sister, uncle, aunt, nephew, niece, friend of parents, someone from the neighbourhood, school, sport, institution, church and give minimal two examples. Age difference is 5 years with the perpetrator.
- 4. At least 18 years of age till 85 years old.
- 5. Sufficient fluency in Dutch to complete treatment and research protocol
- 6. Participants using antidepressant medication are required to be a stable dose for at least 3 months before the beginning of the treatment and remain on this dose throughout the treatment. The same applies for benzodiazepinens with a maximum of 30 mg oxazepam equivalents.
- 7. Signed informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 1. Other psychiatric treatments
- 2. Schizophrenia, active suicidality, dissociative identity disorder, mentally retarded
- 3. No fixed residence, major financial problems, , no aid figure, problems with justice and law, current sexual and physical abuse
- 4. Use of other psychotropic drugs than antidepressants and benzodiazepines.
- 5. Insufficient fluency in Dutch

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel: Parallel

Toewijzing: Gerandomiseerd

Blindering: Open / niet geblindeerd

Controle: Actieve controle groep

Deelname

Nederland

Status: Werving gestart

(Verwachte) startdatum: 23-06-2015

Aantal proefpersonen: 173

Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 26-09-2014

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register ID

NTR-new NL4665 NTR-old NTR4817

Ander register - : -

Resultaten

Samenvatting i	resultaten
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Not yet.