PTSD as a result of chronic interpersonal violence in early childhood; Imaginal Exposure vs Imagery Rescripting vs Body Focused Rescripting.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26598

Source
NTR

Brief title
PTSD in early childhood

Health condition

The research aims to 2 new forms of treatment for patients with comorbid PTSD as a result of multiple and repeated abuse in childhood to assess and compare Imaginary Exposure. The expectation is that these new forms of treatment will lead to a better end-state functioning, less dropout and a higher valuation for feasibility of therapists. The expectation is that Body Focused Rescripting superior to Imaginary Rescripting.
Hypotheses treatment study (1): Effects 1. We expect treatment effects on the primary outcome measures in the ranking IE

Sponsors and support

Primary sponsor: PSYQ Haaglanden
Carel Reinierszkade 197
2593 HR Den Haag
Nederland
Tel: 088 3573900

Email: psychotrauma-onderzoek@psyq.nl
Source(s) of monetary or material Support: PSYQ (Parnassia groep) is the main sponsor of this study.

Intervention

Outcome measures

Primary outcome

1. Anger Expression Scale (AEQ);

2. State-Trait Anger Inventory (ZAV);

3. Guilt scale (Kubany);

4. Shame scale (Smucker);

5. Grief / consolation / happiness scale.

Secondary outcome

1. Symptom levels/clinical problems typically associated with PTSD following early onset chronic interpersonal trauma,
namely (a) the PTSD symptom severity , assessed with the Clincan-administerd PTSD scale (Caps; Blake et al., 1995) and the Post Traumatic Diagnostic Scale (PDS; Foa, Cahman, Jaycox & Perry, 1997)'

2. Symptom levels of Depression assessed with the Beck Depression Inventory (BDI II, Beck, Rush, Shaw & Emery,
1079);

3. Emotion Regulation Difficulties, assessed with the Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer,2004);

4. Self-image (Self-Ideal Discrepancy) (MSGO-Revised, W. Van Beek, 2009;

5. Brief Symptom Inventory (de Beurs));

6. Variables shown to be involved in the maintenance of PTSD that be expected to be rreduced as a consequence of
succesful teratment, namely:

A. Negative trauma related appraisals, assesed with the Posttraumatic Cognitions Inventory (PTCI: van Emmerik,
Schoorl, Kamphuis & Emmelkamp, 2006);

B. SMI modi List (web version).

7. Predictors:

A. Dissociation trait (DIS-Q): Vanderlinden, Van Dyck, Vandereycken, Vertommen;

B. Tonic immobility scale: Original version of Forsyth, Marx, Fuse, Heidt & Gallup, 2000, Dutch translation, Van Minnen &
Hagenaars, 2009. 12 items on a 6 point scale with responses consistently possible an experience in which patients
were
unwanted persuaded or forced into sexual activity without consent.

8. HVR (heart rate variability);

9. Personality disorders SCID-II;

10. Questionnaire for the therapeutic relationship: Working Alliance Inventory, patient version (WAI-P);

11. Questionnaire for therapists: Working Alliance Inventory, therapists version (WAI-T).

Study description

Background summary

Meta-analyzes show that Trauma-Focused Cognitive Behavioral, Imaginary Exposure and Eye Movement
Desensitization-Reprocessing 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). In 40-70% of the patients indicate that relatively short treatment (9-12 sessions of 90 minutes) to considerable reduction of PTSD symptoms. The vast majority of research has been conducted on PTSD following follwing a single traumatic event in childhood .
There is still little research on the application of this protocols to PTSD as a result of repeated and prolonged interpersonal
abuse in childhood (eg sexual and / or physical abuse) within the immediate environment. The question arises whether "new" forms of treatment such as Imaginary Rescripting and Body Focused Rescripting that more active intervention on key processes that play a role in the development of PTSD as dysfunctional based schedules and tonic immobility (TI) effective a proven effective form of treatment as imaginal exposure (IE). In this study, therefore the effectiveness of three treatments for chronic PTSD after interpersonal trauma in childhood investigated, namely (1) imaginal exposure, (2)

Imaginary Rescripting and (3) Body Focused Rescripting.

Study objective

Objective of the study:

The research aims to 2 new forms of treatment for patients with comorbid PTSD as a result of multiple and repeated abuse in childhood to assess and compare Imaginary Exposure. The expectation is that these new forms of treatment will lead to a better end-state functioning, less dropout and a higher valuation for feasibility of therapists. The expectation is that Body Focused Rescripting superior to Imaginary Rescripting.

Hypotheses treatment study (1):

Effects 1. We expect treatment effects on the primary outcome measures in the ranking IE A. In Rescripting therapies is influenced not only the fear but also anger, guilt, shame and sadness;

B. Because context dependence is less (UCS revaluation);

C. Because active intervention is essential processes in development of PTSD, such as TI;

D. Body Focused Rescripting better effects than ImRes because ImRes will initially focus on the explicit memory, while
patients with TI and dissociation possibly better results expected if one focuses on implicit memory. The context of the
UCS / UCR would be better represented if the traumatic event is not in vitro (imaginary) but in vivo depicts. The newly
learned response to the UCS representation is not directly aimed at expressing the blocked emotion (emotional
processing), but had to be aware of sensoromotor components (sensorimotor processing) such as perception of
sensory and physiological sensations of fixed action tendencies and defensive postures focus more on implicit than
explicit memory (Ogden, Minton & Pain, 2006).

2. Dropout. We expect that the IE condition the dropout % higher than in the latter treatments because BFRes ImRes
and less stress.

3. Preferences of therapists. It is expected that therapists 'new' treatments find more workable and less heavy for the
patient seem to be. Hypothesized predictors of treatment success (2): There will be investigated predictors of treatment success. The hypotheses to be tested, we formulate based on the most recent empirical findings. If predictors are included: severity axis II

(borderline symptoms and avoidant
symptoms), TI (TI-self-report and TI as discrepancy between low physiological and subjective anxiety), dissociation,
alcohol and drug use, severity of trauma, therapeutic relationship and HRV . We expect that patients with high TI and high dissociation score a better effect on the ImRes condition and even more in the BFRes condition than the IE condition. In the patients with a low dissociation TI and low score will be the difference between the conditions are less severe.

Generates motor (tonic) immobility post-traumatic complications? Serious sexual abuse involving penetration increases the likelihood of experiencing motor (tonic) immobility (Heidt et al., 2005)? Is motor (tonic) immobility one aspect of peritraumatic dissociation (Hagenaars, et al, 2009)? What correlation is there between motor (tonic) immobilititeit, peritraumatic dissociation, PTSD, anxiety and depressive (Heidt et al., 2005)?

Study design

The waiting period of 5 weeks of ring forms include the control group. Patients are randomized to 1 of 3 treatments assigned.

Two sessions of 90 minutes per week for 6 weeks last 4 weeks 1 time per week. Total 16 seats plus Homework 2 times per week (max. 1 hour).

Duration of treatment 11 weeks.
Homework: • IE / ImRes / BF Res: listening to the tape of the session 2 times a week Exposure in vivo is in all conditions outside the study protocol. 52 patients per condition.

Measurement 1 after inclusion, measuring 2 to start treatment after 5 weeks of Measurement 3, Measurement 4 after
10 weeks (termination therapy) and follow-up after 3 months (Measure 5) and 12 months (Measure 6). In all conditions
of the research will end a break of 3 months be inserted after assessing whether the therapy according to TAU
(treatment as usual) should be prosecuted. During the pause, the handler if necessary by phone. As further
improvements after termination of the protocol are expected, a pause of 3 months at comparable RCTs are necessary.

Intervention

In this study the effectiveness of three treatments for chronic PTSD after interpersonal trauma in childhood will be investigated, namely (1) imaginal exposure (IE), (2) Imaginary Rescripting (ImRes) and (3) Body Focused Rescripting (BFR es).

Study design:

This study is a multicenter randomized 3-group trial.

3 conditions: IE, ImRes, BFRes. The waiting period of 5 weeks of ring forms include the control group. Patients are randomized to 1 of 3 treatments assigned. Two sessions of 90 minutes per week for 6 weeks last 4 weeks 1 time per week. Total 16 seats plus homework 2 times per week (max. 1 hour).

Duration of treatment 11 weeks.

Homework: IE / ImRes / BF Res: listening to the tape of the session 2 times a week.
Exposure in vivo is in all conditions outside the study protocol.

52 patients per condition.

Measurement 1 after inclusion, measuring 2 to start treatment after 5 weeks of Measurement 3, Measurement 4 after
10 weeks (termination therapy) and follow-up after 3 months (Measure 5) and 12 months (Measure 6).

In all conditions of the research will end a break of 3 months be inserted after assessing whether the therapy according to TAU (treatment as usual) should be prosecuted. During the pause, the handler if necessary by phone. As further
improvements after termination of the protocol are expected, a pause of 3 months at comparable RCTs are necessary.

Background of the study:

Meta-analyzes show that Trauma-Focused Cognitive Behavioral, Imaginary Exposure and Eye Movement
Desensitization-Reprocessing 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). In 40-70% of the patients indicate that relatively short treatment (9-12 sessions of 90 minutes) to considerable reduction of PTSD symptoms. The vast majority of research has been conducted on PTSD following follwing a single traumatic event in childhood .
There is still little research on the application of this protocols to PTSD as a result of repeated and prolonged interpersonal
abuse in childhood (eg sexual and / or physical abuse) within the immediate environment. The question arises whether "new" forms of treatment such as Imaginary Rescripting and Body Focused Rescripting that more active intervention on key processes that play a role in the development of PTSD as dysfunctional based schedules and tonic immobility (TI) effective

a proven effective form of treatment as imaginal exposure (IE). In this study, therefore the effectiveness of three treatments for chronic PTSD after interpersonal trauma in childhood investigated, namely (1) imaginal exposure, (2)
Imaginary Rescripting and (3) Body Focused Rescripting.

Contacts

Public
P.M. Jong, de
Psychotherapy & Moment
drs. P.M. de Jong & M.T.C van Hemert
Sarphatistraat 27a
Amsterdam 1018 EV
The Netherlands
0031 (0) 20- 528 52 31
Scientific
P.M. Jong, de
Psychotherapy & Moment
drs. P.M. de Jong & M.T.C van Hemert
Sarphatistraat 27a
Amsterdam 1018 EV
The Netherlands
0031 (0) 20- 528 52 31

Eligibility criteria

Inclusion criteria

PTSD patients from mainstream mental health. The sample consists of 156 patients with a primary diagnosis of PTSD and comorbid disorders reported to various
treatment programs PsyQ Psychotrauma and Personality Problems The Hague, Rotterdam and Spijkenisse. The
various Psychotrauma treatment programs are mainly patients with a primary diagnosis of PTSD, is also expected that
around 50% of patients at intake to meet the inclusion criteria (total inflow Indoor 1, 5 years).
Participants are victims of
repeated or chronic interpersonal trauma in childhood (eg sexual or physical abuse) at an age younger than 16 years.
Participants are 18 years or older.

Exclusion criteria

1. Psychiatric problems that may interfere with the study participation or that require more intensive care than can
be offered in the present study , including dementia, psychotic symptoms, depression with suicidal ideation, full blown borderline personality disorder, substance dependence, dissociative identity disorder IV no fixed residence, major financial problems, no aid figure, problems with police and law, current abuse;

2. Current use of tranquillizers;

3. On as IV no fixed residence, major financial problems, no aid figure, problems with police and law, current abuse.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-03-2013
Enrollment:	156
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-02-2013
Application type:	First submission

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
NTR-new	NL3702
NTR-old	NTR3872
CCMO	NL42151.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Not yet. The first general publication will be coming in april.