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

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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…

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

Summary

ID

NL-OMON36992

Source
ToetsingOnline

Brief title
PTSD : Exposure vs Rescripting

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
Posttraumatic stress disorder; psychological consequences of early childhood trauma

Health condition

comorbide depressie en persoonlijkheidsproblematiek

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Childhoodtrauma, Exposure, PTSD, Rescripting

Outcome measures

Primary outcome

The main dependent variables are:

The non-fear emotions, guilt, shame, anger and sadness to 4 composite measures

constructed by the

Primary outcome measures are.

• Anger Expression Scale (AEQ)

• State-Trait Anger Inventory (ZAV)

• Guilt scale (Kubany)

• Shame scale (Smucker)

• Grief / consolation / happiness scale

plus PTSD score en state trait anxiety inventory

Secondary outcome

Secundary study parameters are:

(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)

(b) Symptom levels of Depression assessed with the Beck Depression Inventory

(BDI II, Beck, Rush, Shaw & Emery,

1079)

(c) Emotion Regulation Difficulties, assessed with the Difficulties in Emotion

Regulation Scale (DERS; Gratz & Roemer,2004)o

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

(e) Brief Symptom Inventory (de Beurs))

(2) 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)

(3) Predictors:

• Dissociation trait (DIS-Q): Vanderlinden, Van Dyck, Vandereycken, Vertommen

• 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.

• HVR (heart rate variability)

• Personality disorders SCID-II

• Questionnaire for the therapeutic relationship: Working Alliance Inventory,

patient version (WAI-P)

• 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

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 • In Rescripting therapies is influenced not only the fear but also anger, guilt, shame and sadness,
• because context dependence is less (UCS revaluation)
• because active intervention is essential processes in development of PTSD, such as TI
• 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 theUCS / 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.

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.

Intervention

Standard protocol interventions that have been in the mental health care but not used in RCT investigated.

Study burden and risks

In all the three conditions, participants will receive bona fide treatments for PTSD. Content, intensity and duration of the
treatment are comparable to usual clinical care for this group within PsyQ Psychotrauma departments. In order to study
the effects of the treatment participants will be asked to fill in a number of questionairres and complete interview before
treatment, at mid treatment, at post treatment and at 3-and 12 - months follow-up. The benefit for individual participants
concern the fact that they receive a bona fide teratment for their condition and that this treatment will be provided by
experienced therapists who will receive additional supervision for the cases treated within the project.On a more
general level, the study addresses a highly relevant topic, which has a date been under researched. The study has the
potential to greatly improve knowledge about the efficacy of treatments for PTSD with chronic traumatization in early

childhood.

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

1. Meeting DSM-IV criteria for PTSD
2. Having experienced repeated or chronic interpersonal trauma before age of 16 (e.g.sexual or fysical abuse)
3. At least 18 years of age
4. Having sufficient fluency in Dutch to complete treatment and research protocol
5. Participants using prescribed anti-depressant medication are required to be on a stable dose for at least 2 weeks before the beginning of the treatment and remain on this dose throughout the treatment.

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
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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2013
Enrollment:	156
Type:	Actual

Ethics review

Approved WMO

Date:	07-02-2013
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	NL40781.018.12