PTSD as a result of interpersonal violence in the primary support group in childhood: Imaginairy Exposure versus Imaginairy Rescripting versus. Drama Rescripting

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The research aims to review and compare imaginairy exposure to new forms of treatment for patients with comorbid PTSD due to multiple and repeated abuse in childhood within the primary support group. It is expected that these new forms of treatment...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36329

Source
ToetsingOnline

Brief title
PTSD and Rescripting

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
Post-traumatic stress disorder / Childhood traumas

Health condition

PTSS

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: Effect study, Interpersonal violence, PTSD

Outcome measures

Primary outcome

Self report questionnaires:

The non-fear emotions guilt, shame, anger and sorrow will be constructed to 4

composite measures that will serve as the primary outcome measures.

* Anger Expression Scale (AEQ)

* Self-expression and control questionnaire (ZECV)

* State-Trait Anger Inventory (ZAV)

* Guilt scale Kubany (translated version see annex)

* Shame scale Smucker (translated version see annex)

* Grief (Poms, Lobbestael)

Secondary outcome

Secondary outcomes

* PDS: Severity and frequency of PTSD is measured with the Dutch version of the

PSS-SR (Foa, Riggs, Dancu, & Rothbaum, 1993; Arntz, 1993). This contains 17

items that correspond to the DSM IV PTSD symptoms, each rated on a 0-3 point

scale.

* Dutch translation of the Clinician-Administered PTSD Scale (CAPS-DX)

* PTCI: Dysfunctional trauma-related cognitions measured by the Posttraumatic Cognitions Inventory (Foa, Ehlers, Clark, Tolin & Orsillo, 1999, Van Emmerik, Schoorl, Kamphuis & Emmelkamp, 2006)

* Symptom BSI (The Fair)

* Difficulties in Emotion Regulation Scale (MANAGERS) translated version (Gratz and Roemer, 2004).

* SMI mode List (web version)

* Self-image (Self-Ideal Discrepancy) (MSGO-revised, W. Van Beek, 2009)

Assessment of emotion activation, dissociation and habituation per session:

* SUD scores: are determined every 10 minutes during the session

* Dissociation rating scale at the beginning and end of the session

* PDS

* Emotion Scale: per emotion a 10 point scale

*

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 possible responses during an experience in which patients were persuaded or forced into unwanted sexual activity without consent.

* HVR (heart rate variability)

* Personality disorders SCID-2

* Questionnaire for the therapeutic relationship: Working Alliance Inventory,

patient version (WAI-P), therapists version (WAI-T)

Study description

Background summary

Meta-analyses show that Trauma Focused Cognitive behavioral therapy, imaginal 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). 40-70% of patients show that relatively short treatments (9-12 sessions of 90 minutes) lead to significant reductions in PTSD symptoms. There is as yet little research on the use of these protocols in PTSD cases as a result of prolonged interpersonal abuse in childhood within the primary support group. The question arises whether new forms of treatment, with a more active intervention in key processes that play a role in the development of PTSD * like dysfunctional basic schemas and tonic immobility (TI), are more effective than a proven effective form of treatment like Imaginal Exposure (IE).

Study objective

The research aims to review and compare imaginairy exposure to new forms of treatment for patients with comorbid PTSD due to multiple and repeated abuse in childhood within the primary support group. It is expected that these new forms of treatment will lead to a better end-state functioning, less dropout and a greater appreciation for practicality of therapists.

Study design

This study is a multicenter randomized 3-group trial.
3 conditions: IE, ImRes, DramaRes. The normal waiting list is the control group, randomization will be applied at clinics where there is no waiting list.
Two sessions of 90 minutes per week for 6 weeks, last 4 weeks once a week.
Total 16 sessions plus daily homework.
Duration of treatment 10 weeks.
Homework:
* IE: listen to recording of the session 2 times a week
* ImRes: listen to recording of the session 2 times a week.
* DramaRes: Exercise at home and recording 2 times.i
Exposure in vivo falls outside the trial in all conditions.
55 patients in each condition.
Measurement 6 after 2 weeks measurement 3 after 10 weeks (therapy end) and follow-up after 3 months (measurement 4), 12 months (measurement 5). Preferably the waiting list condition no treatment to offer, if not possible, a supportive

contact. After the 3d measurement (after 10 weeks) this condition will be offered one of the three treatments. After the trial the remaining conditions will be assessed to see if the treatment can be paused or if it should be continued as TAU.
Per session, several measurements (see outcomes).
Measurement 1 IE Measurement 2 follow up IE
Measurement 3, 4, 5
Measurement 1 ImRes Measurement 2 follow up ImRes
Measurement 3, 4, 5
Measurement 1 DramaRes Measurement 2 follow up DramaRes Measurement 3, 4, 5

Intervention

Regular interventions from protocol operations that are in use in Mental Health Care institutions but have as yet not been researched in RCT.

Study burden and risks

Not applicable

Contacts

Public
Parnassia Bavo Groep (Den Haag)

Sarphatistraat 27 A
1018EV Amsterdam
Nederland
Scientific
Parnassia Bavo Groep (Den Haag)

Sarphatistraat 27 A
1018EV Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Principal Diagnosis PTSD according to DSM-IV criteria.
2. Comorbid disorder on axis I and axis II
3. Interpersonal abuse (sexual, physical or mental abuse) within the primary support group in childhood before age 16. Age difference with the perpetrator is at least 5 years.

Exclusion criteria

1. Psychosis, severe depression with suicidal behavior, dissociative identity disorder, mental retardation.
2. On axis IV: no fixed residence, major financial problems, no aid figure, problems with police and law, current abuse, continuous abuse.
3. Medication (SSRIs) should be set before joining the trial. Preferably no use of benzodiazepines. No interim medication change.

Study design

Design

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

Recruitment

NL
Recruitment status: Will not start

Enrollment:	165
Type:	Anticipated

Ethics review

Not approved

Date:	28-03-2011
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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	NL33167.097.10