Het effect van sessiefrekwentie op de behandeling van PTSS t.g.v. trauma's uit de kindertijd.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25041

Source
NTR

Brief title
IREM-Freq

Health condition

PTSD due to trauma(s) that took place before the age of 16.

PTSS t.g.v. van trauma's die plaatsvonden in de kindertijd, voor de leeftijd van 16 jaar.

Sponsors and support

Primary sponsor: University of Amsterdam, Netherlands;University of Western Australia, Australia;University of Munich, Germany;University of Münster, Germany;University of Lübeck, Germany;Hunter New England Mental Health Service, Newcastle, Australia;Sexual Assault Resource Centre, Perth, Australia; PsyQ Amsterdam, Beverwijk, the Netherlands;GGZ Oost-Brabant, Helmond, the Netherlands;GGZ Noord-Holland Noord, Heerhugowaard, the Netherlands;Sinai Center, Amstelveen, the Netherlands; ABATE, Enkhuizen, the Netherlands
Source(s) of monetary or material Support: Initiators

Intervention

Outcome measures

Primary outcome

CAPS-5 total severity score, assessed at 24 weeks after start of treatment

Secondary outcome

1. Self-reported PTSD-symptoms are assessed with the PCL, at every assessment as well as at start of every session (Weathers et al., 2013). The time frame in the instruction of the PCL will be changed from “in the past month” to “in the past week”. Seven items are added to the PCL to assess shame, anger, guilt, disgust, sadness, anxiety and happiness (see Arntz et al., 2007). Therapists can use these ratings to steer the treatment.

2. Depression will be assessed with the BDI-II (Beck, Steer, & Brown, 1996; Van der Does, 2002), a 21-item self-report instrument assessing depressive symptoms during the last two weeks.

3. PTSD-related cognitions: the PTCI, a self-report instrument, is used to assess trauma related cognitions (Foa et al, 1999).

4. Guilt and Shame will be assessed with a new instrument developed on the basis of the PFQ2 & ASGS, with 8 items to assess how often the participant experienced feelings of guilt amd shame (Harder & Zalma, 1990).

5. Anger will be assessed with the Self-Expression and Control Scale (SECS) (van Elderen et al., 1996, 1997; Dutch: Zelfexpressie en –controle vragenlijst, ZECV; van Elderen et al., 1995), and with the hostility subscale of the Symptom Checklist-90-Revised (SCL-90, Arrindel & Ettema, 1986; Derogatis, 2010).

6. General, social and societal functioning will be assessed with the WHODAS, taken by the research assistant who is blind for condition (WHO, 2000; 2001).

7. Learned Helplessness is assessed with the DAQ (Kleim et al., 2011).

8. Happiness is assessed with the 1-item happiness question validated in more than 30 countries (Veenhoven, 2011)

9. Dissociative experiences will be assessed with the Dissociative Experiences Scale Taxon (DES-T; Waller, Putnam, & Carlson, 1996)

10. Medication use will be monitored during treatment and at each assessment.

11. Vividness, valence and encapsulated belief(s) will be assessed by having the participants rate these aspects on 0-100% scales immediately after shortly imagining their memory of the index trauma (cf. van den Hout & Engelhard, 2012; Engelhard et al., 2011; Wild et al., 2007;

Kwon et al, 2013).

Study description

Background summary

This international randomized clinical trial (RCT) investigates the effects of frequency of treatment sessions of Imagery Rescripting (ImRs) and EMDR as treatments of PTSD due to childhood trauma. Participants are randomized to ImRs or EMDR (both 12 sessions), either twice a week, or once a week a session (2x2 design). The primary outcome is change in PTSD severity as assessed with the CAPS-5. Various secondary measures are assessed, including guilt, shame, and anger. Factors that might explain an effect of session frequency are investigated both among patients and therapists. We will also develop an index that predicts which patient is better off with what treatment, frequency, or treatment-frequency combination (personalized medicine). There are 11 participating sites, 2 Australian, 3 German, and 6 Dutch sites (2 of the academic network PsyQ-UvA; 1 of GGZ Oost-Brabant; 1 of GGZ-NHN; 1 of Sinaï Centrum; 1 of ABATE). Total minimum N = 220, possibly N=280.

Senior researchers:

Arnoud Arntz (UvA); Thomas Ehring (LMU, München); Eva Fassbinder (UKSH, Lübeck); Chris Lee (UWA, Perth); Nexh Morina (WWU, Münster)

Note that ethical approval has been obtained from the ethical committee of the University of Amsterdam for the Dutch sites. German and Australian sites are in the process of obtaining ethical approval from local ethical committees.

Study objective

1. A frequency of two sessions per week is more effective than a frequency of one session per week.

2. Treatment type (EMDR vs.) ImRs moderates the frequency effect.

3. The frequency effect is mediated by memory, relationships and motivational facors in both patient and therapist.

Study design

baseline

6-8 weeks (i.e., post resp. halfway treatment for high resp. low frequency arms)

12-16 weeks (i.e., post treatment for low frequency)

24 weeks

52 weeks

there might be an additional pre-wait assessment if natural waitlist is > 5 weeks at the participating site.

Intervention

EMDR, 12 sessions, delivered once a week

EMDR, 12 sessions, delivered twice a week

ImRs, 12 sessions, delivered once a week

ImRs, 12 sessions, delivered twice a week

Contacts

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Eligibility criteria

Inclusion criteria

- PTSD as defined by the DSM-5, assessed with the SCID-5-CV or SCID-5-RV and the CAPS.

- PTSD as main complaint

- Duration of PTSD > 3 months.

- Index trauma happened before the age of 16

- patient agrees that index trauma is focus of treatment

- If a recent trauma occurred: recent trauma happened more than 6 months ago

- Age between 18 and 70

- Ability to understand, read, write and speak country's language. In German and Dutch sites the English language is also possible, if the site has research assistants and therapists of both conditions that are sufficiently fluent in English.

Exclusion criteria

- Acute PTSD

- DSM-5 substance use disorder, severity level moderate or severe (defined by 4 or more symptoms). (After 6 weeks of abstinence participation is possible).

- Use of benzodiazepine (patients are motivated to stop benzodiazepine use in order to follow treatment protocol) (After 2 weeks of abstinence participation is possible)

- Comorbid psychotic disorder

- DSM-5 Bipolar disorder, type 1 (current or past)

- Acute suicide risk

- IQ < 80

- Serious neurological problems like dementia

- Scheduled to begin another form of PTSD treatment

- PTSD focused therapy within the past 3 months. If patients are in treatment for PTSD, there should be a 3-months treatment free period before they can participate in the study. PTSD-

focused treatment includes emotion-regulation treatments for PTSD like STAIR and other PTSD-focused treatments, but not general supportive treatments.

- Patients should not start with any form of psychological treatment or medication during screening or during the study's treatment or waitlist period. Medication should be on a stable level for 3 months, if not stopped. (Non-PTSD focused supportive treatment may be continued during wait and screening, but not during the study treatment and study post-treatment follow-up period (i.e., up to the 24 weeks assessment).

- Not able to plan 12 sessions of 90 minutes within 6 to 8 weeks (time in between the sessions needs to be at least 2 days), or 12 sessions within 12 to 16 weeks (time in between sessions needs to be at least 6 days and on the average a week or longer).

COVID-19 related ad hoc exclusion of participants that could not be seen face-to-face during all their treatment sessions. The research into factors explaining the possible superiority of the twice-a-week treatment require face-to-face treatment because of the pre-session assessment procedures of patients and therapists. The (temporary) closure of mental health institutes in Australia, Germany, and the Netherlands, has lead the study board to take this decision. Moreover, because of excluding these participants, and the slowing down of recruitment during the pandemic, the stop date has been provisionally extended with at least a year.

Because of capacity problems 3 PsyQ sites did not start participation, only the Amsterdam and Beverwijk PsyQ sites participate. To compensate, the ABATE mental health institute joined the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2018

Enrollment:	220
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
requests can be submitted by researchers with an appropriate research question and statistical analysis plan, with guarantees of privacy regulations and not interfering with publication plans of the study baord.

Ethics review

Not applicable
Application type: Not applicable

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	NL6965
NTR-old	NTR7153
Other	Ethics Review Board (FMG-UvA) University of Amsterdam : 2017-CP-8638

Study results

Summary results

none.