PT-STRESS study: a two-phase randomized study aimed at predicting and coping with non-response in the treatment of PTSD; the latter by alternating recommended trauma-focused treatments (EMDR/T-CBT), or by switching to interpersonal therapy (IPT).

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The aim of the current study is to increase understanding of the effectiveness and efficiency of psychological treatment for patients with PTSD and to better personalize differential therapeutics.Key questions:1. Which generic predictors of...

Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON53245

Source
ToetsingOnline

Brief title
PT-STRESS study

Condition

- Anxiety disorders and symptoms

Synonym
posttraumatic stress disorder, PTSD, trauma

Research involving
Human

Sponsors and support

Primary sponsor: Dimence (Deventer)
Source(s) of monetary or material Support: Financiering door de instelling;Dimence

Intervention

Keyword: IPT, non-response, PTSD, trauma

Outcome measures

Primary outcome

The primary outcome measure for treatment effectiveness in both phases is PTSD symptom reduction measured with the PTSD Checklist for the DSM-5 (PCL-5; Boeschoten, Bakker, Jongedijk, & Olff, 2014). The PCL-5 is administered at baseline and repeated weekly. The week 8 assessment serves as the endpoint of phase 1 and the start measurement of phase 2. The PCL-5 is also administered weekly in phase 2.

Secondary outcome

Secondary outcome measures are the CAPS-5, ITV, HADS, MHC-SF and PNEP.
In addition, we shall measure variables to investigate generic predictors of treatment success and specific moderators. Based on the literature, it appears that the following variables may affect outcome. Further, we have added several instruments to match those that Wibbelink et al. (2021) use in their research in order to be able to collaborate in future data analyses (PAI analysis).

* Demographic variables: age, gender, education, employment, marital status, ethnicity/race, medication use, treatment history.

* Mini-SCAN, LEC-5, CTQ-SF, ECR-RS, SCL-90 hostility subscale, BEAQ, IAPT,

PTCI, TRGI, TRSI, WAV-12 and an expectancy rating for both patients and

therapists.

Study description

Background summary

The symptoms of posttraumatic stress disorder (PTSD) follow exposure to a traumatic event and are accompanied by significant functional limitations. PTSD is very common: a multinational study shows a lifetime prevalence of 3.9%. Effective treatment options exist for people with PTSD, with Eye Movement Desensitization and Reprocessing (EMDR) and (imaginary) Exposure (a specific form of trauma-focused Cognitive Behavioral Therapy, T-CBT) both listed as first-choice interventions in the Dutch standard of care for psychotrauma and stressor related disorders. Our impression is that of the various proven effective forms of treatment, these specific forms of trauma-focused treatment are also used in the Netherlands. About 40% of patients with PTSD do not benefit sufficiently from either of the aforementioned guideline treatments and about 18% of patients do not complete a trauma-focused treatment (treatment dropout). Knowledge about general predictors of treatment success in psychotherapy is limited, making it currently impossible to predict which patient will or will not benefit from which specific psychotherapeutic treatment (i.e., EMDR vs. Trauma-oriented CBT). Little scientific knowledge exists about optimal follow-up treatment when patients insufficiently benefit from their initial treatment. Nevertheless, based on the experiences of the consulted expert group, the national standard of care for psychotrauma and stress-related disorders recommends that a switch be considered in that case between EMDR and T-CBT as trauma-oriented forms of psychotherapy. For patients who drop out (e.g. from inability to tolerate exposure to traumatic memories) or do not benefit from exposure therapies, an alternative is to switch not to another proven effective trauma-focused intervention, but to a non-trauma-focused intervention. A suitable non-trauma-focused treatment is Interpersonal Psychotherapy (IPT; Markowitz, 2021). Previous research suggests that IPT can be an effective first-line treatment option, but the effectiveness of IPT as a second treatment step for people with PTSD who have not responded to a trauma-focused psychotherapy has never been investigated. We hypothesize that IPT will yield greater symptom reduction and less dropout for patients with PTSD who do not respond to a course of trauma-focused psychotherapy compared to switching to another trauma-focused therapy.

Study objective

The aim of the current study is to increase understanding of the effectiveness

and efficiency of psychological treatment for patients with PTSD and to better personalize differential therapeutics.

Key questions:
1. Which generic predictors of treatment success influence treatment outcome of patients with PTSD who receive the three psychotherapeutic treatments investigated in this study (regardless of the type of treatment)?
2. Which specific moderators can be identified among the different psychotherapies (EMDR, CBT; and IPT in the second phase)?
3. In patients with PTSD, does offering another proven effective form of trauma-focused psychotherapy (T-CBT after EMDR, or EMDR after T-CBT) improve PTSD symptoms following insufficient response to a first proven trauma-focused treatment?
4. Is switching from a trauma-focused therapy to a non-trauma-focused treatment (IPT) a more effective strategy for dealing with non-response to a first proven effective psychotherapeutic treatment compared to switching to another trauma-focused therapy?
5. When treating patients with PTSD, are there differences in tolerance of the method (looking at patient experiences of undesirable effects and negative events as a result of the treatment) and differences in dropout rate among T-CBT, EMDR and IPT?

Secondary goals:
- Investigating the extent to which therapist allegiance to a specific therapy method affects outcomes;
- Investigating whether the quality of therapy implementation or the treatment integrity (*adherence/ competence*) affects treatment outcomes;
- Investigating how much the quality of the therapeutic alliance influences outcomes.

Study design

The study is a randomized controlled trial (RCT) conducted in two phases. Its aim is to compare two different proven effective trauma-focused, guideline-recommended treatments (EMDR and T-CBT) for patients with PTSD to one another and with a non-trauma-focused psychotherapy (IPT) and to investigate possible predictors and moderators for treatment success. Patients with PTSD will first be randomized to T-CBT or EMDR in the first treatment phase. After this first phase of treatment, non-responders are re-randomized for a second phase of treatment. They receive either the alternative phase 1 trauma-focused psychotherapy or IPT as non-trauma-focused therapy for PTSD.

Intervention

Half of initially non-responsive patients will be treated with the non-trauma-focused intervention interpersonal therapy (IPT) in phase 2 of the

study. The first and second phases will offer the
trauma-focused treatments Exposure (a specific form of T-CBT) and EMDR.
- Interpersonal Psychotherapy (IPT) does not target the memories of a traumatic event but the interpersonal consequences of trauma, seeking to improve affective and interpersonal functioning that PTSD symptoms have disrupted (Bleiberg & Markowitz, 2019). PTSD following a traumatic life event produces social withdrawal and a blunted, inhibited emotional life, disrupting interpersonal functioning. IPT helps benumbed patients recognize and tolerate their feelings so they can use them to handle their social environment, determine who is trustworthy, and mobilize protective social supports. IPT addresses patient emotions and their relationship to interpersonal interactions. As patients recognize their feelings, the therapist helps patients to name, normalize, and use their feelings rather than seeing them as an additional threat.
- In exposure, as a specific form of trauma-focused CBT, patients directly confront traumatic memories and cues and learn to expose themselves to terrifying but not in fact dangerous stimuli to achieve habituation or extinction. The current study will use a protocol-based treatment of Cognitive Behavioral Therapy for PTSD that includes imaginal and in vivo exposure (Van Minnen & Arntz, 2017).
- In EMDR, patients are distracted from the traumatic memories by a dual attention task, usually using eye movements. This study will use a protocolled EMDR treatment for PTSD (De Jongh & Ten Broeke, 2019).

Study burden and risks

Major adverse events are not expected as these have not been documented in previous studies (Hoppen, Lindemann, & Morina, 2022). The greatest burden on subjects is completing the questionnaires necessary to answer the primary research questions. In phase 1, this totals approximately 10.5 hours (with baseline measurement the most extensive and subsequent weekly measurements); for patients treated for an additional 8 weeks in phase 2, completing the questionnaires takes approximately another 6 hours. A patient participating in both treatment phases therefore spends a total of approximately 16.5 hours completing assessments. Patients taking medication must be stably prescribed prior to the study, then continued during the study as advised by the doctor and preferably not changed, unless necessary due to a crisis or serious side effects. Patients receive treatment sessions twice a week, which is relatively frequent compared to usual treatment, but research shows that dropout is lower with twice weekly sessions (Levinson et al., 2022). Study participation further assures patients that the treatments they receive are performed as intended by the therapy developer because therapists receive supervision and checks are made to ensure treatment integrity.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Adults between the ages of 18 and 65 who were classified at intake with a primary diagnosis of PTSD (based on the DSM-5 criteria).
- Adults who are willing to participate in the research (informed consent).

Exclusion criteria

- Insufficient mastery of the Dutch language.
- Patients who cannot follow the treatment protocol (for example due to long-term absence) are excluded from the study.
- Patients who use medication that is not stable. If properly adjusted to the last prescribed medication, the medication is continued as advised by the doctor and preferably not changed during the treatment, unless necessary due to

side effects, crisis, et cetera.
- Patients who have already received a proven effective form of trauma-focused treatment for PTSD earlier in the past year (of a sufficiently long duration according to the guidelines of the standard of care and sufficiently well implemented to be effective).
- Patients with severe suicidality, which requires acute intervention and the structural addition of additional treatment interventions (such as hospitalization).
- Patients with a (mild) intellectual disability.
- Patients with a serious addiction as a comorbid problem.
- Patients with an acute mania or a psychotic state.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2023
Enrollment:	442
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-11-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL84095.042.23