Cost-Effectiveness of Intensive Trauma-Focused Treatment versus Spaced Trauma-Focused Treatment as First-Line Treatment for Post-Traumatic Stress Disorder in Adults With Multiple Trauma Exposure: Randomized Controlled Trial

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The primary aim of the study is to determine the effectiveness and cost-effectiveness of I-TFT versus S-TFT as a first-line treatment for PTSD in people with multiple traumas. Hypotheses are: (1) I-TFT is non-inferior to S-TFT in terms of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56960

Source
ToetsingOnline

Brief title
FLIP-IT study (First-Line Intervention for PTSD - Intensive Treatment)

Condition

- Other condition

Synonym
Posttraumatic stress disorder, PTSD

Health condition

psychische stoornissen, t.w. posttraumatische stressstoornis

Research involving
Human

Sponsors and support

Primary sponsor: ARQ Centrum'45 (Diemen), onderdeel van ARQ Nationaal Psychotrauma Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cost-effectiveness, Massed treatment, Posttraumatic stress disorder, Randomized controlled trial

Outcome measures

Primary outcome

The primary clinical outcome parameter is the difference in response pattern in terms of PTSD symptom severity on the clinical interview (CAPS-5) from baseline to endpoints between experimental and control conditions. Main outcome parameters for cost-effectiveness are the difference in health-related quality of life (EQ-5D-5L) and costs from a societal perspective (TiC-P) from baseline to endpoints between the experimental and control group.

Secondary outcome

Symptom complexity (defined as dissociative symptoms, moral injury, complex PTSD symptoms, and comorbid personality traits), comorbidity (depression, anxiety), verbal memory, experiential avoidance, and social support.

Study description

Background summary

Intensive trauma-focused therapy (I-TFT) is as effective as but shows faster results than regular weekly trauma-focused therapy (S-TFT). However, according to clinical guidelines, it should only be implemented as a third-line treatment for PTSD. This RCT has been set up to determine if it is more cost-effective to implement I-TFT as a first-line treatment as compared to regular weekly treatment.

Study objective

The primary aim of the study is to determine the effectiveness and cost-effectiveness of I-TFT versus S-TFT as a first-line treatment for PTSD in people with multiple traumas. Hypotheses are: (1) I-TFT is non-inferior to S-TFT in terms of effectiveness (PTSD reduction), (2) I-TFT is superior to S-TFT in terms of cost-effectiveness.

Study design

Randomized controlled, single-blind, trial with two equal-sized treatment arms (I-TFT and S-TFT) and pre-, post and follow-up (at 6 and 9 months from baseline) measurements.

Intervention

The experimental group receives I-TFT, consisting of 2 50-min preparatory sessions; 5 days of I-TFT (60-min Prolonged Exposure + 60-min Eye Movement Desensitization & Reprocessing therapy) within two weeks; and 2 50-min follow-up sessions. The control group receives S-TFT consisting of 16 weekly, 50-min evidence-based S-TFT sessions (Prolonged Exposure, Eye Movement Desensitization & Reprocessing therapy, Brief Eclectic Psychotherapy for PTSD, Narrative Exposure Therapy, or Imagery Rescripting). Both conditions have a total treatment duration of 800 minutes.

Study burden and risks

In regular trauma-focused therapy the risk for adverse events and worsening of symptoms is generally low. Studies into I-TFT have shown the risk for dropout and adverse events to be comparable to, or lower than, S-TFT. The combination of prolonged exposure therapy and EMDR therapy in intensive format as applied in this study has also demonstrated comparable low risk of dropout and adverse events in large uncontrolled studies. In the assessments and treatment sessions (I-TFT and S-TFT), patients can experience it as burdensome to discuss their traumatic experiences and PTSD symptoms. These are short-term effects and usually decrease when the patient benefits from treatment. The five research assessments during the study require time investment (around 10 hours, excluding travel time) from the participants, but this is spread out over the 9 months of the study. All in all, we estimate the risks of participation in the

study to be minimal and the additional burden reasonable.

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) 18 years or older;
(2) PTSD diagnosis according to DSM-5 (CAPS-5);
(3) PTSD diagnosis based on >= 2 potentially traumatic events (PTEs);
(4) no prior treatment for PTSD (or less than 8 sessions);
(5) employed (working or on sick leave for <= two years).

Exclusion criteria

(1) current psychotic disorder, severe alcohol or substance use disorder, high suicidal intent (MINI-S for DSM-5) with a concrete suicide plan; severe aggressive behavior that poses danger for others;
(2) insufficient command of the Dutch language to be able to complete the assessments.

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:	Recruiting
Start date (anticipated):	18-11-2024
Enrollment:	186
Type:	Actual

Ethics review

Approved WMO

Date:	20-08-2024
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
Other	LTR nummer volgt na goedkeuring studie
CCMO	NL86057.018.24