Treatment of PTSD and Addiction

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27175

Source
Nationaal Trial Register

Brief title
TOPA

Health condition

Co-occurring posttraumatic stress disorder and substance use disorder

Sponsors and support

Primary sponsor: Arkin, Department of Research, Amsterdam, the Netherlands; University of Amsterdam, the Netherlands.
Source(s) of monetary or material Support: Stichting tot Steun VCVGZ

Intervention

Outcome measures

Primary outcome

Severity of PTSD symptoms as measured with the Clinician Administered PTSD Scale for DSM 5 (CAPS-5).

Secondary outcome

Measured by therapist:

- Completion of PTSD treatment (yes/no);
- Completion of SUD treatment (yes/no);

Measured during assessments:
- Psychological distress (Brief Symptom Inventory (BSI));
- Alcohol and drug use problems (Alcohol Use Disorder Identification Test (AUDIT) and Drug Use Disorder Identification Test (DUDIT));
- Substance use (MATE-Q-nl module 1);
- Interpersonal problems (Inventory of Interpersonal Problems (IIP-32));
- Emotion dysregulation (Difficulties in Emotion Regulation Scale (DERS));
- Trauma-related guilt (Trauma Related Guilt Inventory (TRGI));
- Trauma-related shame (Trauma Related Shame Inventory (TRSI));
- Internalised and externalised anger, and anger control (Zelf Expressie en Controle Vragenlijst (ZECV));
- (Recent) victimization and (recent) perpetration (LEC-5 with minor extension);
- Impulsivity and working memory, measured with neurocognitive tasks.

Measured at start of each therapy session:
- PTSD symptoms (PTSD checklist for DSM-5 (PCL-5);
- Substance use in the past days.

Economic evaluation:
An economic evaluation will be conducted alongside the randomized trial and will be performed according to the intention-to-treat principle. We will evaluate the relationship between costs, as measured with the Treatment Inventory of Costs in Patients with psychiatric disorders (TiC-P) – and health outcomes of treatments. We will perform both a cost-effectiveness analysis with PTSD symptoms as effect measure and a cost-utility analysis using QALYs, based on the EuroQol 5D (EQ-5D-5L).

Study description

Background summary

Posttraumatic stress disorder (PTSD) and substance use disorder (SUD) often co-occur. This study is a randomized controlled trial in patients with co-occurring PTSD/SUD who will receive PTSD-treatment as an add-on to regular SUD treatment.

The primary objectives are to:
1). Compare effectiveness of Prolonged Exposure therapy (PE), Eye Movement Desensitization and Reprocessing (EMDR), and Imagery Rescripting (ImRs) as add-on to regular SUD treatment with SUD treatment only in reducing PTSD symptoms in patients with co-occurring PTSD/SUD.
2). Compare effectiveness of simultaneous SUD/PTSD treatment with sequential SUD/PTSD treatment in reducing PTSD symptoms in patients with co-occurring PTSD/SUD.
3). Explore differential effectiveness between active treatments (PE vs EMDR; PE vs ImRs;

EMDR vs ImRs) in reducing PTSD symptoms in patients with co-occurring PTSD/SUD.

Study participants will be patients (18 years of age or older) who applied for treatment of a substance use disorder at Jellinek Amsterdam or Utrecht, for whom treatment of co-occurring PTSD is indicated. Participants will be allocated to PE-simultaneous, EMDR-simultaneous, ImRs-simultaneous, PE-sequential, EMDR-sequential, or ImRs-sequential. All PTSD treatments will consist of 12 sessions, conducted twice a week. The primary outcome measure is severity of PTSD symptoms, as measured with the Clinician Administered PTSD Scale for DSM-5 (CAPS-5). Various secondary outcome measures will be assessed, including treatment completion, substance use, psychological distress, interpersonal problems, emotion dysregulation, guilt, shame, and anger. An economic evaluation will be conducted alongside the randomized trial. The intended sample size is 205 participants.

Senior researchers:
Arnoud Arntz (UvA); Marleen de Waal (Arkin/Jellinek); Anna Goudriaan (AMC/Arkin); Loes Marquenie (Jellinek).

Study objective

1). We expect that at 3-month follow-up, all trauma-focused therapies will have led to a stronger reduction of PTSD symptoms than the SUD treatment only condition
2). We expect a greater reduction of PTSD symptoms in the simultaneous treatment condition compared to the sequential treatment condition at 6 and 9 months follow-up.

Study design

Baseline
3-month follow-up
6-month follow-up
9-month follow-up

Intervention

All participants will receive regular SUD treatment plus either one of the following PTSD interventions:
Prolonged Exposure, 12 sessions, twice a week;
Eye Movement Desensitization and Reprocessing, 12 sessions, twice a week;
Imagery Rescripting, 12 sessions, twice a week.

For all participants, regular SUD treatment will start shortly after baseline assessment.
Participants randomized to simultaneous SUD/PTSD treatment will receive PTSD treatment between baseline and 3-month follow-up.
Participants randomized to sequential SUD/PTSD treatment will receive PTSD treatment between 3-month and 6-month follow-up.

Contacts

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Eligibility criteria

Inclusion criteria

- age 18 years or older;
- substance use disorder(s) according to the Diagnostic and Statistical Manual of Mental Disorders 5 criteria (DSM-5), with the primary diagnosis involving one of the following substances: alcohol, cannabis, cocaine (snorting), amphetamines, benzodiazepines, opioids;
- posttraumatic stress disorder according to the DSM-5 criteria;
- sufficient understanding of the Dutch language.

Exclusion criteria

- acute psychotic disorder;
- mental retardation or cognitive impairment (IQ<70);
- current physical or sexual abuse or death threats;
- current acute suicidal behavior;
- life threatening self-mutilation;
- homelessness;
- involvement in a compensation case or legal procedures concerning admission or stay in the Netherlands;
- involvement in legal procedures regarding the index trauma;
- engagement in any other current PTSD treatment.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2019
Enrollment:	205
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-07-2019
Application type:	First submission

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	NL7885
Other	METC AMC : 2019_068#B2019478

Study results