Treatment of PTSD and Addiction

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27175

Bron
Nationaal Trial Register

Verkorte titel
TOPA

Aandoening

Co-occurring posttraumatic stress disorder and substance use disorder

Ondersteuning

Primaire sponsor: Arkin, Department of Research, Amsterdam, the Netherlands; University of Amsterdam, the Netherlands.
Overige ondersteuning: Stichting tot Steun VCVGZ

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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

9-month follow-up

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Arkin
Marleen de Waal

0031205905895

Wetenschappelijk

Arkin
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2019
Aantal proefpersonen:	205
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-07-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7885
Ander register	METC AMC : 2019_068#B2019478

Resultaten