

PROBEL; Prognostics in the Treatment Evaluation of the National System for Veterans' Care

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We hypothesize that combining PD, NP and PP factors will have a larger contribution in predicting treatment outcome than using predictors within a single domain.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29049

Bron

Nationaal Trial Register

Verkorte titel

PROBEL

Aandoening

Posttraumatische Stresstoornis, Posttraumatic Stress Disorder

Ondersteuning

Primaire sponsor: Stichting Centrum '45 partner in ARQ National Psychotrauma Center, Diemen/Oegstgeest, the Netherlands

Overige ondersteuning: Ministry of Defense

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is change in PTSD symptom severity during the first year of treatment. We will develop a prognostic model that predicts treatment outcome based on PD (such as, stigma, shame, and guilt), NP (executive functions and verbal memory), and PP (the stress- and immune system) factors collected before starting and after a year of treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Veterans with posttraumatic stress disorder (PTSD) benefit less from psychotherapy than non-military populations. Identification of predictors of treatment outcome may provide insights to guide treatment selection and develop personalized treatment strategies with more benefit in the future. We expect that a prognostic approach that extends regular diagnostic assessment with measurement of candidate predictors across multiple domains: psychodiagnostic (PD), neuropsychological (NP), and psychophysiological (PP), will have a higher prognostic value than using predictors within a single domain.

Doel van het onderzoek

We hypothesize that combining PD, NP and PP factors will have a larger contribution in predicting treatment outcome than using predictors within a single domain.

Onderzoeksopzet

This is a prospective observational cohort study in which patients will be assessed at three time points.

All patients will be assessed before the start of treatment (T1) and follow-up assessments will be completed after 6 (T2) and 12 months (T3).

Onderzoeksproduct en/of interventie

This is an observational study with a naturalistic design. Treatment will be provided according to standard clinical care. At the five participating centers patients will receive conventional evidence-based trauma-focused psychotherapy. Treatment will consist of eye movement desensitization reprocessing (EMDR), brief eclectic psychotherapy (BEP), narrative exposure therapy (NET), and cognitive behavioral therapy (CBT). These interventions will be delivered in outpatient, day treatment or inpatient settings.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Soldiers and veterans who participated in a military deployment, who meet the diagnostic DSM-5 criteria for PTSD or subthreshold PTSD. Further inclusion criteria are age between 18 and 65 years and having a treatment indication for trauma-focused psychotherapy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Acute suicidality and severe psychiatric co-morbidity that would impede undergoing trauma-focused therapy.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 01-02-2020

Aantal proefpersonen: 260

Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49653

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8202
CCMO	NL70282.058.19
OMON	NL-OMON49653

Resultaten