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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29049

Source
Nationaal Trial Register

Brief title
PROBEL

Health condition

Posttraumatische Stressstoornis, Posttraumatic Stress Disorder

Sponsors and support

Primary sponsor: Stichting Centrum '45 partner in ARQ National Psychotrauma Center, Diemen/Oegstgeest, the Netherlands
Source(s) of monetary or material Support: Ministry of Defense

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The secondary outcome measures are change during the first year of treatment in depressive symptoms severity and level of daily functioning.

Study description

Background summary

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.

Study objective

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.

Study design

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).

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2020
Enrollment:	260
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 49653
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results