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

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The primary objective of this project is to investigate whether using prognostic factors from the PD, NP and PP domain will lead to a better prediction of treatment outcome in veterans with PTSD. Our secondary objective is to investigate whether the...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49653

Source
ToetsingOnline

Brief title
PROBEL

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
posttraumatic stress disorder

Health condition

psychische stoornissen: Trauma- en stressorgerelateerde stoornissen, posttraumatische stress stoornis

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Centrum 45 (Oegstgeest)
Source(s) of monetary or material Support: Het project wordt gefinancierd via Dienstencentrum Personele Zorg (DCPZ);Divisie Personeel en Organisatie Defensie (DPOD) van het ministerie van Defensie. Postadres: Postbus 90004;3509 AA Utrecht; E-mail: secretariaat.dcpz@mindef.nl.

Intervention

Keyword: Posttraumatic stress disorder, Prognosis, Treatment outcome, Veterans

Outcome measures

Primary outcome

The primary outcome measure is change during the first year of treatment in PTSD symptom severity (between T1 and T3). 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 during the study.

Secondary outcome

The secondary outcome measures are change during the first year of treatment in depressive symptoms severity and level of daily functioning (between T1 and T3).

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. We expect that a prognostic approach that extends regular diagnostic assessment with an assessment of 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

The primary objective of this project is to investigate whether using prognostic factors from the PD, NP and PP domain will lead to a better prediction of treatment outcome in veterans with PTSD. Our secondary objective is to investigate whether the change in PD, NP, and PP factors is related to treatment outcome in veterans with PTSD.

Study design

In this observational cohort study, we will prospectively examine predictors of treatment outcome in veterans with PTSD. To this end, some additional measurements will be performed besides regular clinical assessments. This concerns the assessment of candidate predictors in three clinically relevant domains: PD, NP, and PP. 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). This will be a multicenter study performed at treatment centers of the National System for Veterans* Care (Dutch: LZV).

Study burden and risks

The burden associated with participation in this study is limited and the risk is negligible. In this observational study, three additional assessments will take place parallel to regular diagnostic assessment and treatment. The total time of the three assessments (T1, T2, and T3) is about 8 h. Two assessments (T1 and T3) will measure prognostic factors in all three domains: PD, NP, and PP. The intermediate assessment (T2) consists of a short set of online questionnaires. The PD measurements consist of structured interviews and several online questionnaires. The NP examination consists of neuropsychological tests. The PP measurements will include a physical examination, a blood pressure assessment, monitoring of heart rate, a blood sample, and a hair sample. In addition, we will ask participants to perform a dexamethasone suppression test at home, which involves taking 5 salivary samples on the first day, ingestion of 0,25 mg dexamethasone in the evening and 4 salivary samples the next day. Dexamethasone is given in a physiological dose of which no side effects are expected. The burden associated with participating primarily concerns time to perform the additional measurements and patients can experience it as confronting to talk about their traumatic experiences and symptoms in structured interviews. Patients do not directly benefit from participating in the current study. However, patients will be able to receive a personal report with results of the additional assessments. This study will provide knowledge about the contribution of various clinically relevant factors to treatment outcome. This knowledge could contribute to more focused

treatment, is relevant to develop personalized treatment strategies, and better treatment outcomes for veterans with PTSD. Given the purpose and relevance of the study, the burden and risk associated with participation are acceptable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Soldiers and veterans who participated in a military deployment and meet diagnostic DSM-5 criteria for PTSD or subthreshold PTSD. Further inclusion criteria are age between 18 and 65 years and indicated to receive trauma-focused psychotherapy.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: acute suicidality and severe psychiatric co-morbidity. For the subjects that will undergo the dexamethason supression test more exclusion criteria are: allergy to one of the ingredients of dexamethasone and (intended) pregnancy or breastfeeding.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-06-2021
Enrollment:	22
Type:	Actual

Ethics review

Approved WMO Date:	10-07-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-01-2021
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	25-03-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29049
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL70282.058.19
Other	PROBEL NL8202

Study results

Date completed: 13-05-2024

Summary results
Trial ended prematurely