The effectiveness of an intensive clinical trauma treatment for older adults with Complex PTSD.

Gepubliceerd: 05-10-2021 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON28114

Bron
NTR

Verkorte titel
ITACO

Aandoening

Complex trauma, Personality disorder, Posttraumatic Stress Disorder

Ondersteuning

Primaire sponsor: Not applicable
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

(1) Believability of negative and positive cognitions, (2) PTSD symptoms.

Toelichting onderzoek

Achtergrond van het onderzoek

In the 11th edition of the International Classification of Diseases (ICD-11) complex Post traumatic Stress Disorder (cPTSD) was added as a formal disorder. Similar to post traumatic stress disorder (PTSD), cPTSD includes re-experiencing the traumatic event, avoidance of trauma-related stimuli and hyperarousal. Additionally, three symptom clusters have been defined for cPTSD: affect dysregulation, negative self-concept and disturbances in interpersonal relationships. These symptom clusters are thought to represent disturbances in self-organization (DSO). Since the treatment methods developed for the treatment of PTSD do not include specific interventions targeting the DSO symptom cluster, there has been debate about the approach that should be taken regarding treatment for cPTSD. Some suggest that a phase-based approach is required (i.e., starting with a stabilization phase before focusing on trauma confrontation and processing). However, others suggest that there is insufficient evidence to warrant the inclusion of a stabilization phase, and this may even have a detrimental effect on the patient's treatment process. Although more research is needed to clarify which approach is recommended, there is a growing consensus that treatment of cPTSD requires more than the standard interventions used for the treatment of PTSD. This view is also supported by a recent meta-analysis which showed an increased treatment effect when using a combined treatment program (comprising trauma focused techniques- and personality-focused treatment techniques such as CBT and dialectical behavior therapy (DBT)) in comparison to trauma-focused interventions alone. At present, there is little research available as to what specific psychological treatments should be combined for optimal treatment of cPTSD. Moreover, the research presented above has focused on (younger) adult patients (65 years and younger). To our knowledge, little is known about the treatment of PTSD in older adults, let alone older adults with cPTSD.

Drawing on previous findings, we hypothesize that elderly patients with cPTSD will benefit from an intensive, clinical, trauma-focused treatment. Furthermore, we hypothesize that adding a supplementary treatment intervention, integrally targeting the DSO symptom clusters, will increase the treatment effect. Therefore, the present study will focus on assessing the effectiveness of a combined treatment protocol, comprising an intensive multi-method (trauma-focused) inpatient treatment and a subsequent short (DSO-focused) outpatient treatment program for elderly patients with cPTSD. The inpatient part of the treatment program will comprise daily trauma treatment (EMDR or a combination of IM and EMDR), as well as psychoeducation, art therapy and a physical activity program. The following outpatient treatment program will comprise two conditions. Participants will either receive treatment as usual (TAU) or a short treatment program with interventions from schema-focused therapy (SFT) specifically aimed at DSO symptoms of cPTSD. In the present study, both the immediate effect of the intensive trauma-focused treatment and the effect of subsequent SFT-based treatment or TAU will be investigated.

Doel van het onderzoek

We hypothesize that elderly patients with cPTSD will benefit from an intensive, clinical, trauma-focused treatment (i.e. reduction of trauma symptoms). Furthermore, we hypothesize that adding a supplementary treatment intervention, integrally targeting the DSO symptom clusters, will increase the treatment effect.

Onderzoeksopzet

Primary outcomes: (1) VAS negative and positive cognitions are measured daily during baseline and clinical trauma treatment, twice per week during the outpatient treatment phase and once at follow-up; (2) PCL-5 measured once per week during baseline and treatment phases and once at follow-up.
Secondary outcomes: (1) YSQ and SMI and (2) BSI. Both 1 and 2 are measured at the start of the baseline phase, at the beginning and end of the outpatient treatment phase, and at follow-up.

Onderzoeksproduct en/of interventie

Intensive clinical traumatreatment and schema-focused therapy.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

The inclusion criteria for participation in the research study will be (1) age of 65 years or older and (2) diagnosis of cPTSD based on the International Trauma Questionnaire (see “instruments” for more detailed information). Patients are required to have sufficient Dutch language proficiency, in order to be able to complete the various instruments and participate in the therapy program.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with comorbid mental disorders that can interfere with the treatment program (e.g., major cognitive disorders, substance abuse disorders, major depressive disorders and psychotic disorders) will be excluded from participation in the present study. Lastly, patients with somatic disorders that interfere with the continuity of the therapy program will be excluded from participation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-10-2021
Aantal proefpersonen:	10
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:	05-10-2021
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	NL9809
Ander register	METC Zuyderland : METCZ20210128

Resultaten