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

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON28114

**Source**
NTR

**Brief title**
ITACO

**Health condition**

Complex trauma, Personality disorder, Posttraumatic Stress Disorder

### Sponsors and support

**Primary sponsor:** Not applicable
**Source(s) of monetary or material Support:** Not applicable

### Intervention

### Outcome measures

**Primary outcome**

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

**Secondary outcome**

(1) Presence of schema's and modes, (2) level of psychopathology.

# Study description

**Background summary**

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.

### Study objective

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.

### Study design

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.

### Intervention

Intensive clinical traumatreatment and schema-focused therapy.

## Contacts

**Public**
Mondriaan GGZ
Kelly Brandts

0631106157
**Scientific**
Mondriaan GGZ
Kelly Brandts

0631106157

## Eligibility criteria

### Inclusion criteria

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.

### Exclusion criteria

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.

## Study design

### Design

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 05-10-2021 |
| Enrollment: | 10 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

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|---|---|
| Date: | 05-10-2021 |

Application type: First submission

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL9809 |
| Other | METC Zuyderland : METCZ20210128 |

# Study results