

# **Narratieve Exposure Therapie voor posttraumatische stressstoornis geassocieerd met herhaald interpersoonlijk geweld bij patiënten met Ernstige Psychische Aandoeningen: een gemengde methoden onderzoek**

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The primary aim of this study is to evaluate NET in SMI patients with comorbid PTSD associated with repeated interpersonal trauma whether: a) the PTSD symptoms changes and b) changes occur in the present SMI symptoms, care needs, quality of life,...

|                             |                          |
|-----------------------------|--------------------------|
| <b>Ethische beoordeling</b> | Positief advies          |
| <b>Status</b>               | Werving nog niet gestart |
| <b>Type aandoening</b>      | -                        |
| <b>Onderzoekstype</b>       | Interventie onderzoek    |

## **Samenvatting**

### **ID**

NL-OMON24662

### **Bron**

NTR

### **Verkorte titel**

NET for PTSD in SMI-patients

### **Aandoening**

physical abuse, sexual abuse, PTSD, Narrative Exposure Therapy (NET), severe mental illness (SMI) Flexible Assertive Community Treatment (FACT), intervention study, indepth interviews, repeated measures, mixed methods

Lichamelijke mishandeling, seksueel geweld, PTSS, Narratieve Exposure Therapie (NET), Ernstige Psychische Aandoeningen (EPA), FACT, diepte interviews, herhaalde metingen, gemengde methoden

## Ondersteuning

**Primaire sponsor:** Radboud university medical center

Afdeling IQ healthcare

Geert Grootplein 21

6525 EZ Nijmegen

Postbus 9101

6500 HB Nijmegen

**Overige ondersteuning:** GGNet

Vordenseweg 12

7231PA Warnsveld

Also: Institution where the study is carried out.

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Quantitative outcomes: <br>

1a) existence and 1b) severity of dissociative symptoms (DES); 2a) existence and 2b) severity of PTSD (CAPS-5); <br>

Qualitative outcomes:<br>

Participants' experiences with NET, perceived influencing factors for success or failure of NET.

Sensitizing concepts are: experiences with NET during treatment and in daily life, experienced changes in symptoms, care needs, quality of life, daily life functioning, and possible influencing factors for success or failure.

## Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale: In the Netherlands, SMI patients receive Flexible Assertive Community Treatment (FACT) provided by multidisciplinary community mental health teams. In GGNet, FACT-teams are trained in screening for traumatic experiences and PTSD symptoms to improve the treatment of SMI patients with comorbid PTSD. SMI patients with comorbid PTSD are offered evidence based trauma focused treatment like Eye Movement Desensitization Reprocessing (EMDR) or Prolonged Exposure (PE), according to the international PTSD guidelines. For patients with (comorbid) PTSD associated with repeated interpersonal trauma there is a large amount of evidence for the effectiveness of Narrative Exposure Therapy (NET) within various patient groups. NET has not been specifically studied in SMI patients. Since 2012, our FACT-teams offer NET to SMI patients with PTSD associated with repeated interpersonal trauma. All NET treatments are monitored according to the treatment protocol. This trauma specific

monitoring is combined with the routine outcome monitoring (ROM), which is common practice in mental health care and based on Dutch performance indicators for SMI.

**Objective:** The primary aim of this feasibility study is to evaluate NET in SMI patients with comorbid PTSD associated with repeated interpersonal trauma whether: a) the PTSD symptoms changes and b) changes occur in the present SMI symptoms, care needs, quality of life, and care consumption. The second aim is to gain insight in patients' experiences with the NET and to identify perceived determinants of treatment results in terms of symptom changes, care needs, and quality of life.

**Study design:** This feasibility cohort study is a mixed methods convergent design. The quantitative method consists of a repeated measures design and the qualitative method consists of a Grounded Theory design with semi-structured in-depth interviews.

**Study population:** Adult (21 to 65 years) SMI patients (n=25) with comorbid PTSD associated with repeated interpersonal trauma, receiving FACT and referred for NET by their psychiatrist. Participants are independently living outpatients and do not receive involuntary treatment following Mental Health Law.

**Intervention (if applicable):** the Narrative Exposure Therapy (NET) is offered to the patients of this study population. All patients included will receive the NET according to the guidelines by their psychologist or nurse practitioner.

**Main study parameters/endpoints:**

**Quantitative:** There will be eight main study parameters: 1a) existence and 1b) severity of dissociative symptoms (DES); 2a) existence and 2b) severity of PTSD (CAPS-5); 3) care needs (CAN); 4) psychiatric symptoms (HoNOS); 5) Quality of life (MANSA); and 6) care consumption. These outcomes will be analysed using Mixed models to estimate the difference in means between pretest and posttest, taken into account the repeated measures.

**Qualitative:** Experiences with NET, identified relevant themes and determinants for success or failure.

The integration of the quantitative and qualitative results will be focused on interpreting how the qualitative results enhance the understanding of the quantitative outcomes.

**Nature and extent of the burden and risks associated with participation, benefit and group relatedness:**

The semi-structured interview takes up to 60 minutes and is conducted three months after NET. At this stage patients are less vulnerable and most of them function better. The interview is not aimed at the traumatic experiences but is focused on the treatment experience and the treatment effect on symptoms and daily life functioning. Moreover, patients are accustomed by the therapy to talk about their experiences in general.

## **Doe~~l~~ van het onderzoek**

The primary aim of this study is to evaluate NET in SMI patients with comorbid PTSD associated with repeated interpersonal trauma whether: a) the PTSD symptoms changes and b) changes occur in the present SMI symptoms, care needs, quality of life, and care consumption. The second aim is to gain insight in patients' experiences with the NET and to identify perceived determinants of treatment results in terms of symptom changes, care needs, and quality of life.

## **Onderzoeksopzet**

T0 before intervention

T1 one month after finalizing intervention

T2 seven months follow up

Interview: three months after finalizing intervention

## **Onderzoeksproduct en/of interventie**

Narrative Exposure Therapy

## **Contactpersonen**

### **Publiek**

GGNet, poli complex trauma,

M.W. Mauritz  
Kruisbergseweg 29

Doetinchem 7009 BL  
The Netherlands  
Tel 088-9334656

### **Wetenschappelijk**

GGNet, poli complex trauma,

M.W. Mauritz

Kruisbergseweg 29

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Adult SMI patients with one of the following primary diagnoses: schizophrenia, schizoaffective, bipolar, or major depressive disorder(verified by M.I.N.I. plus) or personality disorder (verified with SCID-II) and
2. a history of repeated interpersonal trauma (emotional, physical and/or sexual abuse) according LEC-5 and
3. comorbid PTSD according CAPS-5 and
4. a GAF-score < 60 during > two years and
5. receiving FACT

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- (1) a high suicidality score on the M.I.N.I.-plus and/or a recent suicide attempt; (2) a current manic period; (3) the existence of dissociative identity disorder; (4) the existence of a antisocial personality disorder, (5) severe alcohol or drug dependence (likely to interfere with attendance as assessed by the M.I.N.I-plus and routine outcome monitoring); (6) severe intellectual impairment (estimated IQ < 70) or; (7) insufficient competency in the Dutch language ,  
(8) The provision of other trauma focused treatment in the past year, and (9) the provision of involuntary treatment following Mental Health Law.

## Onderzoeksopzet

## Opzet

|                  |                         |
|------------------|-------------------------|
| Type:            | Interventie onderzoek   |
| 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: | 15-03-2016               |
| Aantal proefpersonen:   | 25                       |
| Type:                   | Verwachte startdatum     |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 18-02-2016       |
| 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  | NL5608 |

**Register ID**

NTR-old NTR5714

Ander register CMO Arnhem-Nijmegen nr 2015.1843 : Protocol ID NL53222.091.15

## Resultaten

### **Samenvatting resultaten**

Mauritz, M.W., Sande, R. van de, Goossens, P.J.J., Draijer, N., Achterberg, T. van (2014). Phase-Based Treatment of a Complex Severely Mentally Ill Case Involving Complex Posttraumatic Stress Disorder and Psychosis Related to Dandy Walker Syndrome. *Journal of Trauma & Dissociation*, 15, 5, 588-606.

<br><br>

Mauritz, M.W., Goossens, P.J.J., Draijer, N., Achterberg, T. van (2013). Prevalence of interpersonal trauma exposure and trauma related disorders in severe mental illness (review). *European Journal of Psychotraumatology*, 4, <http://dx.doi.org/10.3402/ejpt.v4i0.19985>.