

# Narrative Exposure Therapy for Posttraumatic Stress Disorder associated with repeated interpersonal trauma in patients with Severe Mental Illness: a mixed methods convergent design

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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 change following NET and (b) changes occur in the present SMI symptoms, care needs,...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON42436

### Source

ToetsingOnline

### Brief title

NET for PTSD in SMI-patients

### Condition

- Other condition
- Anxiety disorders and symptoms

### Synonym

posttraumatic stress disorder (PTSD)

### Health condition

schizofrenie en andere psychotische stoornissen, bipolaire stoornis, depressie,

persoonlijkheidsstoornis

## **Research involving**

Human

## **Sponsors and support**

**Primary sponsor:** Radboud Universitair Medisch Centrum

**Source(s) of monetary or material Support:** GGNet

## **Intervention**

**Keyword:** Mixed methods, Narrative Exposure Therapy (NET), Posttraumatic Stress Disorder (PTSD), Severe Mental Illness (SMI)

## **Outcome measures**

### **Primary outcome**

Quantitative parameters and outcomes:

The existence of PTSD before and after providing NET according to CAPS-5

Changes in: severity of PTSD and dissociative symptoms after providing NET according to CAPS-5 and DES.

Changes in: primary disorder symptoms according to HoNOS, care needs according to CAN, quality of life according to MANSA, and care consumption in minutes before, during, and after NET treatment (retrieved from the electronic record).

### **Secondary outcome**

Qualitative parameters and outcomes:

The semi-structured interview is based on a topic list and will focus on the experience of NET and its meaning for the participants. The interview also will pay attention to the effect of NET in terms of changes in: symptoms, daily functioning, care needs and perceived quality of life.

Topic list:

The themes are derived from the following sensitizing concepts: (1) experiences with NET, changes in: (2) symptoms, (3) care needs, (4) perceived quality of life, and (5) influencing factors and meaning.

Experiences during NET

- Therapeutic relationship
- Lifeline
- Narration
- Exposure
- Effects in daily life

Symptoms before, during and after NET

PTSD

- Intrusion symptoms
- Avoidance
- Negative alterations in cognitions and mood
- Alterations in arousal and reactivity
- Depersonalization and derealisation (dissociative subtype)

Existing SMI

- Primary symptoms of psychotic, bipolar, depressive or personality disorder

Changes in care needs

- decreased care needs (which areas of life)
- persisting care needs (which areas of life)

#### Changes in quality of life

- perceived quality of life (which aspects)
- effects on daily life functioning

#### Influencing factors and meaning

- success
- failure
- significance for perceived daily life functioning
- significance for meaningfulness

## Study description

### Background summary

Interpersonal trauma exposure and trauma related symptoms are often overlooked in the treatment of severely mentally ill patients even though prevalence rates for both are high. As shown in recent research, repeated interpersonal trauma and Posttraumatic Stress Disorder (PTSD) have a negative influence on the course of the present severe mental illness (SMI).

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, treated in the FACT teams, are offered evidence based trauma focused treatment like Eye Movement Desensitization Reprocessing (EMDR) or Prolonged Exposure (PE), according to the international PTSD guidelines. Several studies have shown that these exposure based trauma focused therapies (i.e. EMDR and PE) are effective in SMI patients and well tolerated. 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. To our knowledge this is the first study which aims to evaluate the outpatient practice of providing NET to SMI patients with comorbid PTSD associated with repeated interpersonal trauma and receiving FACT.

## **Study objective**

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 change following NET 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 treatment and to identify influencing factors on treatment results in terms of symptom changes, care needs, and quality of life.

## **Study design**

Quantitative and qualitative methods are combined in this mixed methods convergent design.

The quantitative method consists of a pretest-posttest design and will be carried out among adult (21 to 65 years) SMI patients with one of the following primary diagnoses: schizophrenia spectrum disorder; bipolar disorder, major depression, or personality disorder and co-morbid PTSD associated with repeated interpersonal trauma. We will include consenting participants (N=25) receiving continuous FACT from one mental health center. These participants are independently living outpatients and referred by their psychiatrist for the NET according to the guidelines. Participants do not receive involuntary treatment following Mental Health Law. The qualitative method consists of a Grounded Theory design with semi-structured in-depth interviews.

Data collection: Quantitative data will be collected from the electronic patient records on three occasions: one week (T0) prior to NET, one month (T1) after NET and at six months (T6) follow up. On the first occasion the following instruments are used for trauma specific measurements: (1) the LEC-5 to verify the trauma history, (2) the CAPS-5 to verify the existence and severity of PTSD, (3) the DES to verify the existence and severity of dissociative symptoms. At T1 and T6 CAPS-5 and DES are administered again. For Routine Outcome Monitoring (ROM) the following instruments are used and combined at T0, T1 and T2: (1) the HoNOS to measure psychiatric symptoms, (2) the CAN to

measure care needs, and (3) the MANSA) to measure the experienced quality of life. At T0 the M.I.N.I. - plus (or the SCID-II in case of a personality disorder) will be used to verify the current chart diagnosis of the primary existing SMI. This is in line with the current practice whereby existing diagnoses are re-assessed every two years. Care consumption in minutes will be calculated based on the electronic record for the following period: three months before NET, during NET and during six months follow up. Qualitative data collection will be performed on one occasion: semi-structured in-depth interviews are held two months after providing the NET treatment and four months before follow up measures following a convergent design. All participants will be interviewed about their experiences with the NET treatment and its effect on their daily life based on a topic list.

**Analysis:** quantitative analysis: The results from post-treatment and follow up measurements will be compared with pretest measures using paired t-tests. Qualitative analysis: The interviews will be analyzed by the grounded theory method to identify relevant themes in how patients experience this treatment and create meaning in daily life functioning. Integrative analysis: Integration of both quantitative and qualitative results will be focused on the influencing factors on treatment results in terms of reducing symptoms, care needs, care consumption, and in improving quality of life.

**Discussion:** To our knowledge, this is the first evaluation of NET for PTSD in SMI patients receiving FACT.

### **Study burden and risks**

The semi-structured interview takes up to 60 minutes and is conducted two months after NET treatment. 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. The risk of worsening of symptoms or suicidality as a result of the interview, is therefore estimated as low.

## **Contacts**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

(1) SMI outpatients who receive NET and have one of the following primary diagnoses: schizophrenia (295.90), schizoaffective disorder (295.70), bipolar disorder type I (296.40-46 or 296.50-56), type II (296.89), major depressive disorder (296.20-26 or 296.30-36) according to M.I.N.I.-plus or personality disorder (301.xx) according SCID-II, and each has a GAF-score < 60 during  $\geq$  two years.

### **Exclusion criteria**

(1) The provision of other trauma focused treatment in the past year, (2) the existence of a antisocial personality disorder, (3) the existence of a dissociative disorder, or (4) the provision of involuntary treatment following Mental Health Law.

## **Study design**

## Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

## Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 22-04-2016

Enrollment: 25

Type: Actual

## Ethics review

Approved WMO

Date: 28-12-2015

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 08-06-2017

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

## 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
CCMO	NL53222.091.15