

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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24662

Source

NTR

Brief title

NET for PTSD in SMI-patients

Health condition

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

Sponsors and support

Primary sponsor: Radboud university medical center

Afdeling IQ healthcare
Geert Grooteplein 21
6525 EZ Nijmegen
Postbus 9101
6500 HB Nijmegen

Source(s) of monetary or material Support: GGNet

Vordenseweg 12
7231PA Warnsveld

Also: Institution where the study is carried out.

Intervention

Outcome measures

Primary outcome

Quantitative outcomes:

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

Qualitative outcomes:

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.

Secondary outcome

Quantitative outcomes:

3) care needs (CAN); 4) psychiatric symptoms (HoNOS); 5) Quality of life (MANSA); and 6) care consumption.

Study description

Background summary

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.

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 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

T0 before intervention

T1 one month after finalizing intervention

T2 seven months follow up

Interview: three months after finalizing intervention

Intervention

Narratieve Exposure Therapy

Contacts

Public

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Eligibility criteria

Inclusion criteria

1. Adult SMI patients with one of the following primary diagnoses: schizophrenia, schizo-affective, 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

Exclusion criteria

- (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.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	15-03-2016
Enrollment:	25
Type:	Anticipated

Ethics review

Positive opinion	
Date:	18-02-2016
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 NL5608

Register ID

NTR-old NTR5714

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

Study results

Summary results

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.

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>.