Mechanisms of recovery and empowerment study

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Study (i) - NET: Observational treatment study Primary Objective:1A. To establish if emotion regulation and perceived daily stress have changed after NET treatment in responders (i.e. significant reduction in PTSD symptoms) and in non-responders (i....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON52970

Source
ToetsingOnline

Brief title
MORE study

Condition

- Anxiety disorders and symptoms

Synonym
post traumatische stress stoornis, psychotrauma

Research involving
Human

Sponsors and support

Primary sponsor: ARQ Nationaal Psychotrauma Centrum
Source(s) of monetary or material Support: Door de uitvoerende instelling zelf: ARQ Nationaal Psychotrauma centrum;een anoniem fonds en de Universiteit van Utrecht.

Intervention

Keyword: Narrative Exposure Treatment, Processes of Change, Refugees/Asylumseekers, Victims of human trafficking, Victims of sexual violence

Outcome measures

Primary outcome

Study (i): Main study parameters are mood, PTSD symptoms, perceived daily

stress and emotion regulation before, after and during treatment.

Study (ii): Main study parameters are emotion regulation, bodily awareness,

self esteem and self-efficacy before, during and after treatment.

Secondary outcome

Post-traumatic stress and personal recovery.

Study description

Background summary

Displaced Victims of Interpersonal Violence (DVIVs) are often challenged by past traumatic experiences and invalidating daily stressors. These daily stressors are risk factors for developing and maintaining psychopathology, mainly a post traumatic stress disorder (PTSD). Furthermore, the combination of past traumatic experiences and social daily stressors increases the risk of (sexual) revictimization. Meanwhile psychological treatments, targeting PTSD, are less effective in DVIVs compared to other populations.
The MORE study is designed to explore if perceived daily stress and emotion regulation are altered during trauma-focussed psychotherapy (i.e. Narrative Exposure Therapy; NET), and how they interact with changes in psychopathology during NET (study i NET). Expected is that non-response in PTSD symptoms goes along with non-response in perceived daily stress and emotion regulation. For responders on PTSD symptoms we expect significant response on emotion regulation and perceived daily stress. Expected is that PTSD response precedes responses in perceived daily stress and emotion regulation for treatment responders. Furthermore a treatment module specifically tailored to address prominent issues for the population (i.e. increased risk of (sexual) revictimisation by PreVic (study ii) will be evaluated. Foreseen is that the treatment will have a beneficial effect on emotion regulation, bodily

awareness, self esteem en self-efficacy (PreVic).

Study objective

Study (i) - NET: Observational treatment study
Primary Objective:

1A. To establish if emotion regulation and perceived daily stress have changed after NET treatment in responders (i.e. significant reduction in PTSD symptoms) and in non-responders (i.e. no significant reduction in PTSD symptoms).
1B. To establish if changes in perceived daily stress, emotion regulation and psychopathology during the course of NET are different in responders than in non-responders.

Secondary Objectives
2. To establish if victims of childhood trauma are underrepresented in treatment responders (i.e. significant reductions in PTSD symptoms).
3. To establish if personal recovery has changed after NET.
4. To establish if changes in emotion regulation, perceived daily stress and personal recovery after NET persist at 6 weeks follow-up.

Study (ii) Potential effects of PreVic
Primary Objective:
1. To establish if emotion regulation, bodily awareness, self esteem and self-efficacy change during PreVic.
Secondary Objective:
2. To establish if PreVic can be considered a feasible and acceptable therapy by both patients and therapists.

Study design

Study (i):
The NET study will entail an observational treatment design in which repeated weekly measurement will be added to Narrative Exposure Therapy.
Study (ii):
The PreVic study will follow a case series design in which repeated assessments will be conducted before, during and after treatment.

Study burden and risks

The MORE study containts 2 sub-studies:

Study NET (i): Participants will follow NET, which is an evidence based therapy for DVIVs. A couple adaptations to regular treatment procedure are made. Questionnaires will be administered before (T0), after (T1) treatment and at 6 weeks follow up (T2), partly overlapping the routine outcome monitoring. Also

brief assessments will take place before every therapy session. All questionnaires together this will take a maximum of 325 minutes without interpreter and a maximum of 395 minutes with interpreter. Furthermore participants are excluded from other therapies during NET, and until the follow-up measurement (T2) after NET. Exceptions are made for pharmacotherapy and crisis consultation during treatment, during waitlist and between T1 and T2 psychoeducation is additionally allowed. It is unlikely that participation in this study will be counterproductive and we consider the burden of the study reasonable.

Study PreVic (ii): Participants will follow treatment as indicated. Additional questionnaires will be administered weekly during treatment, as well as before treatment (T0), after treatment (T1) and at 4 weeks follow-up (T2). For the PreVic study assessments will take maximum 250 minutes without and maximum 325 minutes with interpreter. During inclusion period participants are excluded from other treatments, except pharmacotherapy and crisis consultation during treatment and between T1 and T2 psychoeducation is additionally allowed. It is unlikely that participation in this study will be counterproductive and we consider the burden of the study reasonable.

Routine Outcome Monitoring (ROM): For all studies a total of 45 minutes (without interpreter)/60 minutes (with interpreter) questionnaire administration time coincides the routine outcome measurement (ROM). ROM is a standard treatment procedure that all patients undergo, independent of research participation.

Contacts

Public
ARQ Nationaal Psychotrauma Centrum

Nienoord 13
Diemen 1112XE
NL
Scientific
ARQ Nationaal Psychotrauma Centrum

Nienoord 13
Diemen 1112XE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

For the NET study
• Aged 18 years or older
• Displaced Victims of Interpersonal Violence (DVIVs)
• PTSD as primary diagnosis established during a clinical interview
• Indicated for trauma focused treatment
• Informed consent
• Cognitively able to give consent to participate in the study

For the PreVic study:
• Aged 18 years or older
• Displaced victims of interpersonal violence (DVIVs) subcategory: victim of sexual exploitation and/or sexual violence
• Treatment indication for PreVic
• Informed consent
• Cognitively able to give consent to participate in the study

Exclusion criteria

For all studies:
• Acute crisis or acute suicidality
• Substance abuse
• Acute psychosis

For the NET study:
• Recent (less than 6 months ago) completed trauma-focused treatment

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):	30-03-2018
Enrollment:	82
Type:	Actual

Ethics review

Approved WMO

Date:	22-01-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	15-04-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	09-09-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	26-04-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	30-11-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-04-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL61808.058.17