Early Intervention with Eye Movement Desensitization and Reprocessing to reduce PTSD symptom severity: A randomized controlled trial in recent rape victims.

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Objective: To examine the efficacy of two sessions of Early EMDR therapy between day 14 and day 28 post-rape on the reduction of PTSD (symptoms) at 12 weeks post-rape. The main research question is:Do victims of rape report significantly less PTSD...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON49388

Source
ToetsingOnline

Brief title
Early EMDR to reduce PTSD symptom severity: A RCT in recent rape victims

Condition

- Anxiety disorders and symptoms

Synonym
Traumatization Fear

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Innovatiefonds Zorgverzekeraars;Stichting Achmea Slachtoffer en Samenleving;Vereniging EMDR Nederland;EMDR Research Foundation

Intervention

Keyword: EMDR, PTSD, Rape, RCT

Outcome measures

Primary outcome

The primary outcome is the participants* level of PTSD symptom severity.

Secondary outcome

Secondary measures include the degree of dissociation, memory representation, vividness and emotional intensity of the images during recall in the Early EMDR condition and the participants* level of comorbid psychopathology, with special attention to depression and sexual problems.

Study description

Background summary

After experiencing rape, the risk of developing post traumatic stress disorder (PTSD) is high, with rates up to 40% three months post-rape (Möller, Bäckström, Torbjörn, Söndergaard & Helström, 2014; Rothbaum et al., 1992). As PTSD constitutes a major individual, societal and economic burden (Thielen et al., 2016; Olff et al., 2005), the prevention of PTSD gained much attention in recent decades. However, at present, there is no clear evidence-based preventive intervention for acutely traumatized individuals (Rose et al., 2002; Sijbrandij et al., 2006; Qi, Gevonden & Shalev, 2016). Clinical guidelines and expert consensus mainly suggest what not to do in the acute aftermath of trauma (NICE, 2005). At the same time, there is an urgent call for new initiatives in early interventions for trauma survivors, especially for incorporating existing evidence-based techniques into preventive interventions. In this study, we will investigate whether Eye Movement Desensitization and Reprocessing (EMDR) therapy at an early stage after rape can be efficacious in reducing PTSD

symptoms. As far as we know, our study will be the first to investigate the efficacy of EMDR as a preventive intervention for acute rape victims using an randomize controlled trial. If the intervention proves effective, it may be broadly applicable in clinical practice. The study will also enhance knowledge with regard to acute psychological relief and the aftercare of rape victims.

Study objective

Objective: To examine the efficacy of two sessions of Early EMDR therapy between day 14 and day 28 post-rape on the reduction of PTSD (symptoms) at 12 weeks post-rape.

The main research question is:
Do victims of rape report significantly less PTSD symptoms at 12-weeks follow up, after two sessions of Early EMDR therapy compared to TAU?

Study design

The proposed study is a randomized controlled trial allocating subjects within 7 days post-rape, to either two sessions of Early EMDR Therapy or Treatment As Usual (TAU) in the time period 2-4 weeks post-rape, including a pre-treatment assessment at 2 weeks post-rape and post-treatment assessments at 4, 8 and 12 weeks post-rape. The participants will be assessed with regard to PTSD (symptomatology), degree of dissociation, memory representation, sexual problems, image vividness and emotional intensity during recall of these images in the studied intervention, and comorbid psychopathology. The assessments have a quantitative (structured interview and questionnaires) nature.

Intervention

The studied intervention is EMDR versus Treatment As Usual (TAU; i.e. Watchful Waiting).

Study burden and risks

Study participation is not expected to form a risk for the participants as EMDR therapy poses minimal strain on participants. There may be some participants in whom the assessment questions can activate traumatic memories, but clinical experiences, and previous research indicates that it is highly unlikely that participants will experience psychological difficulties other than transient emotional reactions.
All of the assessments can be completed at the participant*s home environment. All questionnaires can be filled out online (via Research Online for Researchers), and the researcher will go to the patient for the clinical interview. If preferred or deemed necessary, the pre- and post-treatment assessments can also be completed at one of the three sites. All participants

will be offered further treatment after the final assessment.

Contacts

Public
Universitair Medisch Centrum Utrecht

Lundlaan 6
Utrecht 3508AB
NL
Scientific
Universitair Medisch Centrum Utrecht

Lundlaan 6
Utrecht 3508AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet the following criteria:
- Present within 7 days post-rape at the Rape Centers in Utrecht, Leiden, Hoofddorp or Almere.

Exclusion criteria

- Age < 16
- Assault without penetration
- Cognitive disability
- Acute psychosis
- Insufficient knowledge of the Dutch language
- Current intoxication
- Severe alcohol/drug abuse (substance treatment a priority)
- Acute suicidal ideation
- Current treatment (ad admittance) for PTSD

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2018
Enrollment:	34
Type:	Actual

Ethics review

Approved WMO

Date:	01-02-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	10-07-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-02-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL60551.041.17

Study results

Date completed:	11-02-2020
Actual enrolment:	57