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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Victims of rape report significantly less PTSD symptoms at 4-,8- and 12-weeks follow up, after two sessions of Early EMDR therapy compared to TAU.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19897

Bron
NTR

Verkorte titel
Early EMDR

Aandoening

Rape, Sexual Assault, PTSD, EMDR, RCT, Early Intervention

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: Stichting Achmea Slachtoffer & Samenleving (SASS), Innovatiefonds Zorgverzekeraars, EMDR Europe, Vereniging EMDR Nederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

PTSD symptoms at 12 weeks, as measured with the CAPS(-CA)

Toelichting onderzoek

Achtergrond van het onderzoek

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, aftercare of rape victims, and the possible mediating role of cognitive memory processing between experiences of dissociation and PTSD.

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 4, 8 and 12 weeks post-rape. The main research question is: 1. Do victims of rape report significantly less PTSD symptoms at 4-,8- and 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, 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.

Study population: Subjects are victims (age ≥16 years) of rape, who present themselves

within 7 days post-rape at the Rape Centers at Leiden, Utrecht, Hoofddorp and Almere.

Primary study parameters/outcome of the study: The primary outcome is the participants' level of PTSD symptom severity.

Secondary study parameters/outcome of the study:

Secondary measures include the degree of dissociation, 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.

Doel van het onderzoek

Victims of rape report significantly less PTSD symptoms at 4-,8- and 12-weeks follow up, after two sessions of Early EMDR therapy compared to TAU.

Onderzoeksopzet

2, 4, 8 and 12 weeks post-rape

Onderzoeksproduct en/of interventie

EMDR

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2018
Aantal proefpersonen:	37
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-10-2017
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	NL6586
NTR-old	NTR6760
Ander register	NL60551.041.17 : ABR 60551

Resultaten