

Eye Movement Desensitization and Reprocessing treatment in pregnant women with Posttraumatic Stress Disorder after previous childbirth

No registrations found.

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

Summary

ID

NL-OMON20013

Source

Nationaal Trial Register

Brief title

EMDR_PTSD

Health condition

Pregnancy, posttraumatic stress disorder, childbirth, PTSD, trauma, EMDR, eye movement desensitization and reprocessing, postpartum

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis

Source(s) of monetary or material Support: Vereniging EMDR Nederland

Intervention

Outcome measures

Primary outcome

Severity of PTSD

Secondary outcome

Obstetrical and neonatal complications, percentage of PTSD diagnoses, percentage caesarean sections, subjective childbirth experience, health care costs.

Study description

Background summary

After childbirth, 1-3% of women will develop a posttraumatic stress disorder (PTSD). Many women will become pregnant again and experience severe anxiety associated with pregnancy and childbirth. Our objective is to assess efficacy and safety of EMDR treatment for pregnant women with PTSD after childbirth. After screening 1667-5000 multiparae, 50 pregnant women with PTSD will be randomized between care-as-usual or 3 sessions of 90 minutes EMDR.

Study objective

In follow up measurements compared to pre-treatment measurement

- 1) WITHIN the treatment group there is a decline in the severity of PTSD symptoms and percentage of PTSD diagnoses;
- 2) BETWEEN treatment group and care-as-usual group there is more reduction in PTSD symptom severity, a lower percentage of PTSD diagnoses, fewer caesarean sections, a more positive childbirth experience, and lower health care costs in the treatment group;
- 3) EMDR does not lead to more obstetrical or neonatal complications.

Study design

Data will be collected at several timepoints:

- Screening (gestational age 8-20 weeks)
- T0:Pre-assessment (circa 20 weeks gestational age)
- In between sessions (every two weeks for care as usual)
- T1: Post-treatment antepartum (30-32 weeks gestational age)

-T2: Post-treatment postpartum (2-3months postpartum)

Intervention

Care-as-usual group: care-as-usual is defined as standard care during pregnancy, with routine obstetrical checks. Assuming good clinical care, anxious pregnant women and those with traumatic delivery experiences will receive more counseling compared to not-anxious pregnant women, but will (probably) not be referred for EMDR.

Eye Movement Desensitization and Reprocessing (EMDR) group: EMDR is a psychological intervention that was developed for the treatment of traumatic memories. It is internationally recognized as a first choice therapy for treating posttraumatic stress disorder. EMDR is conducted according to the Dutch translation of the basic EMDR protocol 2015, and is provided in 3 sessions of 90 minutes. Eye movements were applied as the distracting stimulus.

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Eligibility criteria

Inclusion criteria

Multiparae with a gestational age of 8-20 weeks, who master the Dutch language

Exclusion criteria

<18 years old,

current psychological treatment

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-04-2015
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion	
Date:	30-03-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47330
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4886
NTR-old	NTR5123
CCMO	NL49304.100.14
OMON	NL-OMON47330

Study results