PERCEIVE: Postpartum EaRly EMDR-therapy InterVention: A randomized controlled trial in women with traumatic birth experience

No registrations found.

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

Summary

ID

NL-OMON20758

Source
NTR

Brief title
Early EMDR

Health condition

Traumatic birth experience, TBE, posttraumatic stress disorder, PTSD, childbirth, delivery, trauma, eye movement desensitization and reprocessing, EMDR

Sponsors and support

Primary sponsor: Onze Lieve Vrouwen Gasthuis
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

PTSD (symptoms)

Secondary outcome

Quality of Life, FoC, mother-infant boding and breastfeeding

Study description

Background summary

Up to 43% of women perceive giving birth as traumatic. This may lead to (symptoms) of PTSD, fear of childbirth, mother-infant bonding problems, depression, problems with breastfeeding and a lower quality of life. Our objective is to determine the effectiveness of early intervention EMDR in reducing (symptoms of) PTSD in women after a traumatic birth experience. Women eligble for the study will be randomized between 'care-as-usual' or 2 sessions of 60 minutes EMDR therapy 14-36 days postpartum.

Study objective

1. Women who receive early intervention EMDR will have less PTSD (symptoms) than those allocated in the care-as-usual group.

2. Early intervention EMDR will have a positive effect on Quality of Life, Fear of Childbirth, depressive symptoms, mother-infant bonding and breastfeeding as compared to care-as-usual.

Study design

- Screening (8-10 postpartum)

- T0: Pre-assessment (14 days postpartum)

- T1: Post-treatment assessment + interview (36 days postpartum)

Intervention

Eye Movement Desensitization and Reprocessing (EMDR) group: patients in the intervention group will receive two sessions of Early EMDR therapy consisting of sixty minutes each between 14 and 36 days after delivery. Session will be provided by a certified EMDR therapist.

Care-as-usual group (CAU): patients will receive care as provided currently, which means no treatment for their traumatic birth experience. If patients in the CAU group wish to receive treatment, they will be referred to a professional who will assess their eligibility and may then

do so after the last measurement (six weeks postpartum).

Contacts

Public
OLVG
Dr. M.G van Pampus

+3120 599 38 94
Scientific
OLVG
Dr. M.G van Pampus

+3120 599 38 94

Eligibility criteria

Inclusion criteria

Women with a traumatic birth experience no more than two weeks prior to randomization, both medical of by a primary care midwife in the hospital or at home, who master Dutch language.

Exclusion criteria

Age <18 years, birth trauma related to previous birth, current/recent psychologic treatment or diagnosis or recent suicide attempt.

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):	01-09-2020
Enrollment:	216
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-08-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54443
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8843
CCMO	NL73231.100.20
OMON	NL-OMON54443

Study results