

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

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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...

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

Samenvatting

ID

NL-OMON20758

Bron

NTR

Verkorte titel

Early EMDR

Aandoening

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

Ondersteuning

Primaire sponsor: Onze Lieve Vrouwen Gasthuis

Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

PTSD (symptoms)

Toelichting onderzoek

Achtergrond van het onderzoek

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 eligible for the study will be randomized between 'care-as-usual' or 2 sessions of 60 minutes EMDR therapy 14-36 days postpartum.

Doel van het onderzoek

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.

Onderzoeksopzet

- Screening (8-10 postpartum)
- T0: Pre-assessment (14 days postpartum)
- T1: Post-treatment assessment + interview (36 days postpartum)

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	216
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	21-08-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54443
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten