EMDR in pregnant women with Fear of Childbirth

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational non invasive

Summary

ID

NL-OMON47031

Source
ToetsingOnline

Brief title
EMDR in pregnant women with Fear of Childbirth

Condition

- Pregnancy, labour, delivery and postpartum conditions
- Anxiety disorders and symptoms

Synonym
Fear of Childbirth

Research involving
Human

Sponsors and support

Primary sponsor: Verloskunde/Gynaecologie
Source(s) of monetary or material Support: Vereniging EMDR Nederland

Intervention

Keyword: childbirth, EMDR, Fear of Childbirth, pregnancy

Outcome measures

Primary outcome

Primary outcome measurement is severity of FoC-symptoms

Secondary outcome

Secundary outcome measurements are the amount of caesarean sections, Healthcare costs, subjective delivery experience, and the percentage of obstetrical complications.

Study description

Background summary

In 7.5% of pregnant women, there is a pathological fear of childbirth: Fear of Childbirth (FoC). In these women, the fear of childbirth can lead to terminating pregnancy, avoiding pregnancy, or demanding a primary caesarean section. FoC is associated with a higher risk of premature birth or emergency caesarean section, a six times higher chance of getting a post-traumatic stress disorder after childbirth and possibly a longer duration of labor .
Some studies show a positive effect of individual psychotherapy, psycho-education and group learning relaxation techniques. For specific phobias in general, cognitive behavioral therapy with exposure (in vivo) is the treatment of choice. Research shows that Eye Movement Desensitization and Reprocessing (EMDR) is also effective for specific phobias. We expect EMDR may also be effective for FoC. Thereby, in some phobias, including FoC, it can be very difficult to apply exposure in vivo.

Study objective

Main objectieve of this study is if EMDR is an effective treatment for women with FoC. Our hypotheses are that in follow-up measurement compared to the pretreatment-measurement 1) WITHIN the treatment group there will be a decrease in the severity of the FoC symptoms, and 2) BETWEEN the treatment group and care-as-usual group there will be less severe FoC symptoms, less caesarean sections, lower health care costs, and a more positive birth experience. Last

hypothesis is 3) that following EMDR does not lead to more obstetric complications, especially preterm birth. Since we provide results regarding both efficacy and safety, our main objective thus can be answered.

Study design

The procedure of this randomized controlled trial (RCT) is as follows. At a gestational age of approximately 8-20 weeks screening takes place among all pregnant women. When their sum score on the WDEQ-A * 85, FoC is diagnosed and they are invited to a clinical interview. Afterwards, they are randomized between two groups:
- the treatment group. These women will be offered EMDR (up to 3 sessions) in addition to standard antenatal care during pregnancy
- the control group. These women receive the standard antenatal care.

In both groups, 60 participants will be allocated. There will be a maximum of six treatment sessions, after which the post-treatment antepartum measurement will be conducted (T1). 2-3 months postpartum the post treatment postpartum measurement will be conducted(T2). The outcome assessors of T1 and T2 are blinded to participants group assignment.

Study burden and risks

Participants are asked at least once to complete a short screening questionnaire during (one of their) first visits to a midwife of gynaecologist. For the majority of the women (those who scored below cut-off) this will be the only effort: no treatment or other measurements will follow. The screening questionnaire includes questions about psychological well-being, and fits into the context of the visit to the midwife/gynaecologist where already an anamnesis is conducted.
If scored above cut-off, two clinical interviews will follow, a weekly/after each session written questionnaire. After childbirth there will be one last written questionnaire.
Aborting the questionnaire, or deciding not to hand in is possible. Data are anonymised. There are no known risks of EMDR treatment during pregnancy.

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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Pregnant women with a gestational age of circa 8-20 weeks, who mastered the Dutch language

Exclusion criteria

<18 years old
Current psychological treatment
Intermediate or high suicide risk (based upon MINI interview)
Severe psychotic disorder, such as schizophrenia or current psychosis (based upon MINI-interview)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2015
Enrollment:	1600
Type:	Actual

Ethics review

Approved WMO Date:	18-11-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-05-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-04-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-10-2018
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23809
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL49305.100.14
OMON	NL-OMON23809