The effect of EMDR in women with a traumatic childbirth experience who don*t meet criteria for PTSD

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We want to evaluatie wether or not support and assistance in processing this trauma through the use of EMDR, a proven therapy for PTSD, could be of use for women without an official diagnosis, but with significant residual complaints.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON48428

Source
ToetsingOnline

Brief title
EMDR after a traumatic childbirth

Condition

- Anxiety disorders and symptoms

Synonym
stress, traumatic symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: EMDR, PTSD, traumatic childbirth

Outcome measures

Primary outcome

Psychological complaints.

Has there been psychiatric treatment? If yes, which institute, diagnosis and

duration of treatment.

Secondary outcome

Scores on the questionnaires

Time off work.

Study description

Background summary

Around 10-15% of women who give birth in the Netherlands each year (which is around 170.000 women in total) recall their birth as a traumatic experience. Only 1-3% of the entire group fulfills the criteria for a Post Traumatic Stress Disorder (PTSD). The others do not qualify for an official psychiatric diagnosis, but frequently have complaints, like flashbacks, nightmares, hyperarousal (fear), postponing a new pregnancy, being unable to view photos of the birth, etc. Except for the standard pospartum check-up, there is no aftercare for these women.
If these women are not provided with help in processing this birth trauma, this may lead to other psychological issues, such as disorders of fear and depression, but also to problems bonding with the child, being unable to resume work (burn-out), and problems with the relationship with the partner.

Study objective

We want to evaluatie wether or not support and assistance in processing this trauma through the use of EMDR, a proven therapy for PTSD, could be of use for women without an official diagnosis, but with significant residual complaints.

Study design

This study concerns women who, during a check-up by telephone after 3 weeks (and/or a check-up in person after 6 weeks), indicate that they experienced the birth as unpleasant or traumatic. Both check-ups are already part of standard practice. These women are asked if they are willing to get information about a study in the Radboudumc bij there gynaecologist. The gynaecologist will inform the patient and gives the patient the informend consent. If they agree, they will receive a call from Nicole van Voorst, to make an appointment and tot fill in the 2 questionnaires (see earlier) with them.
If the women fall into the category suitable for this study, they will, , be randomised allocated to either the EMDR group or the control group.

All women will be asked to fill out several questionnaires screening for the problems mentioned above at times T=0, 3 months, 6 months and 12 months. This concerns a explorative study, for which we will include women during one year in a single center (the Radboudumc).

Intervention

EMDR (1-3 sessions).

Study burden and risks

Because there is no treatment for these women in the regular situation, there is no risk in not getting the treatment if they end up in the control group. There is even a benefit, because the will be followed for over a year and we will give them medical and psychological advise if necesecarry over the year. We also will inform the family doctor that the patient is in this trail. An EMDR treatment can cause short term emotions during the EMDR session, however, without treatment those emotions will also be present because you work with the subjective unit of distress (SUD) in the present time. Not treated, the emotions will stay longer and probably be much stronger. At the end of an EMDR session the SUD is lower then at the start, as a result of the effect of the EMDR. This means that there will be a direct relief of tension after the EMDR session. The most common side effect of EMDR is tiredness in the first 24 hours after treatment. After 24 hours there will be contact with the psychologist, by email to check how the first day went. If there is a reason to contact the patient by phone, or to make an appointment this will be done and adequate interventions will be made.
Since there is currently no treatment offered to these women, the treatment group is certainly no worse off, and possibly better, than the control group.
It will take participants 4 times approximately 20 minutes to fill out the questionnaires and 2 hours of interview,

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

A traumatic childbirth experience, and a score on the PCL-5 questionnaire of <33, and on the PPQ questionnaire of >/<=19.
A sufficient knowledge of the Dutch language.
Age >/<= 18 years.

Exclusion criteria

No traumatic childbirth experience, of a traumatic childbirth experience, but a score on the PCL-5 questionnaire of >33, or on the PPQ questionnaire of <19.
Insufficient knowledge of the Dutch language.

Age < 18 years

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-09-2019
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	17-07-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-12-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL69127.091.19