Validating and realising a clinically tested A-EMDR application for postpartum traumas

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Ethical review	Approved WMO
Status	Pending
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON56920

Source
ToetsingOnline

Brief title
A-EMDR application for postpartum traumas

Condition

- Pregnancy, labour, delivery and postpartum conditions
- Psychiatric disorders NEC

Synonym
(1) postpartum trauma; (2) negative or traumatic feelings after childbirth

Research involving
Human

Sponsors and support

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

Regionale Ontwikkeling (EFRO)

Intervention

Keyword: A-EMDR, Postpartum post-traumatic stress disorder

Outcome measures

Primary outcome

Structured interviews and questionnaires will be conducted to collect qualitative data on the feasibility of the intervention, including insights into the process, advantages and disadvantages, and patients' experiences of the application.

Secondary outcome

Additional questionnaires are administered on comorbid symptoms (depressive symptoms (IDS) and anxiety symptoms (STAI), general functioning (OQ-45), and quality of life (WHODAS). This will allow us to investigate whether specific subgroups may influence feasibility and whether these scores change clinically. Furthermore, the trial will examine the extent to which traumatic events evoke no or significantly reduced emotional reactions in the patient, as measured by the PTSD Checklist (PCL-5), allowing for a conservative assessment of efficacy.

Study description

Background summary

A significant percentage (9-21%) (Stramrood et al., 2011) of births are experienced as traumatic, with 3.2-4% leading to post-traumatic stress disorder (PTSD) in young mothers, and up to 18.5% in those with additional risk factors (Grekin & O*Hara, 2014). Postnatal PTSD has negative consequences for both mother and child, impacting attachment (mother-child bonding), breastfeeding and future pregnancies (Kopmeiners et al., 2023). Moreover, it significantly

increases the risk of postpartum depression (20-75%) which prolonged negative effects on mother and the newborn (Dutch Society for Obstetrics & Gynaecology, 2019). Early and effective treatment is therefore essential. Research shows that the standard treatment, Eye Movement Desensitization and Reprocessing (EMDR), is effective (Dutch Society for Obstetrics & Gynaecology, 2019), but unfortunately has limited availability and is difficult to combine with young motherhood, resulting in long waiting times. E-health solutions can address this gap by providing effective treatment with a low-barrier of entry.

Study objective

The main objectives are to investigate whether our product is suitable for the target group, to identify barriers to wider implementation in mainstream care, and to gather patient experience and feedback. We want to know if patients perceive the added value of our treatment and how we can improve it. The trial will also provide insight into early efficacy, an estimate of the number of treatment sessions required, feasibility within specific subgroups, and preliminary insights into clinical changes in comorbid symptoms, overall functioning, and quality of life.

Study design

Interventional Single-Arm Clinical Feasibility Study

Intervention

The intervention consists of a maximum of 4 EMDR sessions of 45 minutes each using an e-Health intervention based on traditional EMDR. The sessions take place over a period of 3 weeks, with a 1-week interval between sessions. On non-response, conventional EMDR will be offered to participants.

Study burden and risks

In this study, there will be a potential benefit to participants as a result of the EMDR therapy. The therapy can elicit short-term emotions during the sessions as part of the therapeutic process. However, these emotions would also be present if left untreated due to the subjective unit of distress (SUD) being addressed in the present moment. If left untreated, the emotions may persist for a longer duration and potentially intensify. The goal of an EMDR session is to achieve a lower SUD score at the end compared to the beginning, as a result of the treatment*s effectiveness.

Participants will take part in a maximum of four 45-minute EMDR sessions and complete questionnaires three times, each taking approximately 20 minutes. Additionally, 30 minutes will be required for intake, 30 minutes for closing,

and 15 minutes for follow-up.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Women (>=18 years) who have recently given birth at Radboudumc or are currently in care at Radboudumc's POP clinic, and who have a negative or traumatic childbirth experience within the first +-6 to 12 weeks postpartum.

Exclusion criteria

Current or past psychotic disorder

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2024
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	autonomous EMDR application
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	24-07-2024
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	14-10-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL85436.000.24