Postpartum Early EMDR Therapy Intervention (PERCEIVE) Study for Women After a Traumatic Birth Experience: Study Protocol for a Randomized Controlled Trial

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Study protocol

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Abstract

Background. Up to 43% of women perceive giving birth as traumatic which may result in the development of posttraumatic stress disorder (PTSD) or related symptoms. Negative and traumatic childbirth experiences can also lead to fear of childbirth, avoiding or negatively influencing a subsequent pregnancy, mother-infant bonding problems, problems with breastfeeding, depression and reduced quality of life. For PTSD in general, eye movement desensitization and reprocessing (EMDR) therapy has proven to be effective. However, little is known about the preventive effects of early intervention EMDR therapy in women after a traumatic birth experience. The purpose of this study is to determine the effectiveness of early intervention EMDR therapy in preventing PTSD and reducing PTSD symptoms in women with a traumatic birth experience.

Methods. The PERCEIVE-study is a randomized controlled trial. Women suffering from the consequences of a traumatic birth experience will be randomly allocated at maximum 14 days postpartum to either EMDR therapy or “care-as-usual”. Patients in the EMDR condition receive two sessions of therapy between fourteen (T0) and thirty-five days postpartum. All participants will be assessed at T0, and at nine weeks postpartum (T1). At T1 all participants will undergo a CAPS-interview about the presence and severity of PTSD symptoms. The primary outcome measure is severity of PTSD symptoms, whereas the secondary outcomes pertain to fear of childbirth, mother-infant bonding, breastfeeding, depression and quality of life. The study will be conducted at a large city hospital and at several midwifery practices in Amsterdam, the Netherlands.

Discussion. It is to be expected that the results of this study will provide more insight about the safety and effectiveness of early intervention EMDR therapy in the prevention and reduction of PTSD (symptoms) in women with a traumatic birth experience.

Trial registration. Trial register. NL73231.000.20. Registered on August 21, 2020. https://www.trialregister.nl/trial/8843

Background

Up to 43% of women perceive giving birth to a child as traumatic which may result in post-traumatic stress disorder (PTSD) or related symptoms.[1] According to recent meta-analyses 3-4% of all women develop PTSD following childbirth while up to 33% of women experience symptoms of PTSD.[2,3,4,5] Risk factors for a traumatic birth experience are diverse. Prevalence of traumatic birth experiences has been found to be higher among women with unexpected interventions during labour and delivery, such as unplanned caesarean section or vacuum assisted delivery.[4,6] However, medically uncomplicated deliveries might also be perceived as traumatic. [4,6,7,8,9] A Dutch retrospective survey analysing the perception of over 2000 women with a self-reported traumatic birth experience showed that lack, or loss, of control (54.6%), and fear of baby's health or life (49.9%), followed by high intensity of pain or physical

discomfort (47.4%) attributed significantly to the traumatic aspect of this experience.[10] Other risk factors include a history of psychiatric illness, previous trauma, fear of childbirth (FoC) and preeclampsia.[3,6]

According to the Dutch Society of Obstetrics and Gynaecology (NVOG, 2019) guidelines on birth related PTSD (symptoms) and the National Institute for Health and Care Excellence (NICE) treatment guidelines (2014) a traumatic birth experience is defined as 'the (subjective) experience and interpretation of a woman with or without satisfying diagnostic criteria of the Diagnostic and Statistical Manual of Mental Disorder (DSM-) 5 for PTSD' (NVOG, 2019, p. 14).[11,12] DSM-5 criteria include symptoms of re-experiencing, avoidance and numbing, negative cognitions and mood and hyperarousal. Symptoms may resolve naturally, but in some cases may lead to a chronic mental health condition.[13] To meet the diagnostic criteria for PTSD, symptoms must last more than one month and result in significant dysfunction. However, due to similarity with physiological symptoms associated with a major life event, such as becoming a parent, PTSD (symptoms) are often not well recognized. Additionally, PTSD can be confused with postpartum depression because of a diagnostic overlap in symptoms such as negative cognitions, and co-occurrence of both disorders.[13]

Besides PTSD, exposure to a negative or traumatic childbirth frequently results in fear of childbirth, avoiding a subsequent pregnancy, reduced quality of life (QoL), problems with breastfeeding and depression.[6,14,15,16,17]Also, a birth-related trauma causing distress during a subsequent pregnancy has been found to be related to both maternal and fetal negative outcomes, such as avoiding prenatal care, demanding a planned caesarean section, and preterm birth.[18,19,20,21] Furthermore, traumatic birth experiences may negatively influence the mother-infant bonding with studies showing that children from parents with PTSD express a more avoidant attachment style, caused by feelings of rejection and anger towards the infant.[22,23] Mother-infant bonding and early attachment proves essential for the infants future self-esteem and resilience, emotion regulation and their ability to form close relationships.[24,25] Conversely, studies have shown that the presence of PTSD in parents is associated with the development of psychopathology and higher rates of anxiety and behavioural problems in their offspring.[14,26] Moreover, it may impair infant cognitive development of the infant.[27] To this end, it is conceivable that preventing PTSD, or alleviating PTSD symptoms, reduces the likelihood of mother infant bonding difficulties, thereby exerting a positive effect on both the mother and a 'butterfly effect' on the infant to create a healthier adult in later life.[25] Hence, research that would identify a short-term and cost-effective postpartum intervention is important.

Regarding the treatment of PTSD in general, meta-analyses and treatment guidelines recommend eye movement desensitization and reprocessing (EMDR) therapy as one of the first-line therapies for this mental health condition.[9,28,29,30] Additionally, encouraging results have been reported with early EMDR interventions after traumatic events to reduce PTSD related symptoms.[31] However, a recent review on EMDR therapy studies concluded that 'research is needed to evaluate prevention of PTSD, with clinician-administered diagnostic measures (e.g., CAPS-5) administered to treated and nontreated individuals' (p. 245). [32] Recently, am uncontroled pilot study in which EMDR therapy was used as an early intervention

among 37 women reporting a traumatic birth experience showed a significant reduction in the proportion of women with PTSD symptoms six weeks postpartum after one session of EMDR therapy compared to no treatment (79% EMDR vs. 40% no treatment).[33] This encouraging result calls for replication through a randomized controlled trial.[34,] Finally, it is important to note that data on the safety of early interventions following recent trauma, particularly regarding exposure to adverse birth events, are limited.[3536]

Methods And Design

Aim

The main purpose of the study is to determine the safety and effectiveness of “early intervention EMDR” in preventing PTSD or reducing symptoms of PTSD at nine weeks postpartum in women with a traumatic birth experience, and to compare these results with care as usual in women who experienced their delivery as a traumatic event. Safety is defined as the absence of any adverse events, such as increased suicidal ideation, serious self-injurious behaviour or crisis contacts for any of the aforementioned reasons.[37] It is hypothesized that early intervention EMDR therapy is safe and that women who receive early intervention EMDR will report significantly less PTSD (symptoms) nine weeks after the delivery compared to women who receive no treatment. Further, our secondary objectives are to determine the effects of early intervention EMDR therapy on fear of childbirth (FoC), quality of life (QoL), mother-infant bonding (MIB), breastfeeding and depression. It is hypothesized that early intervention EMDR will significantly increase the success of breastfeeding, improve MIB and QoL, reduce FoC and prevent or reduce depressive symptoms as compared to care-as-usual.

Study design

The PERCEIVE study will use a randomized controlled experimental design. A total of 216 women with traumatic birth experience will be recruited within 14 days postpartum and randomized to either the early EMDR intervention or “care as usual” (CAU). Patients in the early EMDR group will receive two sessions of EMDR therapy between 14 and 35 days postpartum. Patients in the CAU will receive no treatment but will receive two telephone calls during the study period. The two groups will be compared on a number of outcome variables before (T0 = 2 weeks) and post-treatment (T1 = 9 weeks; see Figures 1 and2). Women will be recruited in a large hospital and several first line midwifery practices in the Amsterdam area, the Netherlands. We expect the study duration will encompass two years from start inclusions to end inclusions. The study protocol is approved by The Medical Research Ethics Committee of the OLVG Hospital and registered with trialregister.nl (reference no. NL73231.000.20)

Patients

Inclusion criteria

Women less than 14 days postpartum who report a traumatic birth experience will be asked to participate in this study. Medical deliveries as well as women who had a delivery supervised by a primary care

midwife from community midwifery practices in Amsterdam will be included. Furthermore, they must master the Dutch language.

Exclusion criteria

Exclusion criteria include age less than 18 years old, birth trauma related to a previous birth, recent diagnosis of a psychiatric disorder, recent or current worsening of symptoms of a previously diagnosed psychiatric disorder requiring treatment, or a recent history of a suicide attempt; that is, less than three months prior to the beginning of the study.

Procedures and interventions

When women agree to participate, they will receive a home visit from the researchers to ensure women acknowledged the information and to fill out an informed consent. After screening and providing informed consent, participants will be randomly allocated to either the EMDR therapy or the 'care-as-usual' (CAU) condition within 14 days postpartum (see Figure 1). Randomization will be on a 1:1 basis by block randomization with random block sized of two, four or six by an independent computer program Castor EDC. After completing the first assessments (T0) participants will be informed in which group they have been randomized.

The EMDR therapy group

Participants in the EMDR therapy condition will receive two treatment sessions between 14 and 35 days postpartum, consisting of 60 minutes each.[38] The EMDR therapy sessions will be conducted in an out-hospital clinic by trained psychologists who have completed both the basic and advanced EMDR therapy training course accredited by the Dutch National EMDR Association (www.emdr.nl) and have at least one year of experience with providing EMDR therapy. When the participant or therapist is not able to be physically present because of the COVID-19 epidemic, therapy sessions may, by exception, be conducted digitally.
The essence of EMDR therapy is that the therapist aims to reduce the vividness and emotionality of trauma memories by asking the patient to recall the trauma memory while simultaneously making eye movements.[3940] The EMDR therapy will implemented with the use of rapid deployment of sets of eye movements offered by fingers or using a light bar.[36] In case of any adverse events during the study period, the EMDR therapist will report this to the researcher and set up an individual plan with regards to the wishes' and needs of the participant.

The CAU group

The CAU group will receive care as provided currently which means no treatment for their traumatic birth experience. However, participants in this group will receive two telephone calls between fourteen and thirty-five days postpartum to monitor the course of symptoms regarding their traumatic birth experience. These conversations will be conducted by the researcher. When symptoms worsen significantly during

the study period, women will be referred to their general practitioner. He or she can then refer the patient to a psychologist or psychiatrist when needed. When a participant is stable, but wishes to receive EMDR treatment she will be asked to wait for treatment until nine weeks postpartum.

Assessments

Screening

After giving birth all maternity women will receive a flyer with information about the study, regardless the type of delivery or the presence of birth complications. Eight to ten days postpartum all women will be asked the following question: 'How did you experience the delivery of your baby?' Depending on the place of the delivery this question will be asked either by the researcher or by their own midwife. Women will be considered eligible for the study if the answer includes the word "trauma" or "traumatic", or when the patient indicates to suffer from symptoms appropriate to PTSD.

Safety

Safety of early intervention EMDR will be monitored by the therapist. The occurrence of any adverse events, such as increased suicidal ideation, serious self-injurious behaviour or contacts with healthcare providers in case of mental health crisis will be reported to the researcher. Safety of participants in the CAU group will be monitored by the researchers. Based on regular phone calls it will be estimated whether extra interventions regarding their psychological symptoms are indicated.

Effectiveness

Other outcome variables will be assessed using multiple questionnaires. After randomization, but prior to the treatment (T0), both groups will receive the PTSD checklist for DSM-5 (PCL-5), World Health Organization Quality of Life Questionnaire-BREF (WHOQOL-BREF), Postpartum Binding Questionnaire (PBQ), Wijma Delivery Expectancy/Experience Questionnaire version B (W-DEQ B), Early Postpartum Depression Scale (EPDS) and questions on breastfeeding (see Figures 1 and 2). While the experiences of the women are leading in this study, the results of patients' questionnaire scores will not influence the inclusion and randomization process. Questionnaires will be send through Castor with an unique ID code. If participants do not have access to a computer, the questionnaires will be provided on paper with a return envelope.

Nine weeks postpartum (T1) each participant in both groups will undergo a CAPS-5 interview and receives the same questionnaires as at T0. The CAPS interview will be conducted by an independent person who is blinded to the randomization and who has received official training in assessment of the CAPS as to not bias the results. The CAPS version regarding symptoms in the last month will be used.

Instruments

The following measurement instruments will be used:

Posttraumatic Stress Disorder Checklist (PCL-5) [41]

The PCL-5 is a 20-item self-report questionnaire corresponding to the symptoms in the DSM-5 (APA,2010) and are rated from 0 (not at all) to 4 (extremely). Total symptom severity scores ranging from 0 to 80 can be obtained by summing the scores for each of the 20 items. A total score ≥31 has been found suggestive for a probable PTSD in the English version.[42] Additionally, symptom clusters following the different DSM-V criteria can be analysed separately.[43] A previous study found strong internal consistency, test-retest reliability, convergent validity and discriminant validity of the PCL-5 reported clinically significant change on a DSM–IV version of PCL to be 10 points.[44,45] For the PCL-5, this clinically significant change has not been set yet.

Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) .[46]

PTSD diagnosis as well as PTSD symptom severity will be assessed by using the Dutch version of the Clinician Administered PTSD Scale for DSM-5.[43,47] The CAPS-5 is a structured clinical interview that enables standardized DSM-5 PTSD diagnosis based on symptom severity scores. The interview consist of 20 questions regarding PTSD symptom severity (B-E items), and several questions concerning other DSM-V criteria. PTSD diagnosis can be made by following the DSM-5 diagnostic rule, which requires: the A criterion (exposure to (imminent) dead, severe injury or sexual violence); ≥1 B item (questions 1-5); ≥1 C item (questions 6-7); ≥2 D items (questions 8-14), ≥2 E items (questions 15-20), the F criterion (duration ≥1 month), G criterion (causing significant suffering or disability) and H criterion (symptoms are nog caused by another somatic condition or substance use). Questions regarding the B-E criteria are rated from 0 ('absent') to 4 ('disabling'). Symptoms rated ≥2 are included in the calculation for the diagnosis. To assess whether criterion A was met during birth we will use specific questions according to the work of Alcorn et al. The exact questions are: (1) 'Did you feel that your life or your baby's life was threatened during or after birth?' (2) 'Did you think that you or your baby might die?' (3) 'Did you experience an actual injury or threat of serious injury around the time of birth?' (4) 'Did your baby experience an actual injury or threat of serious injury around the time or birth?'.[1] High validity and reliability of the CAPS-5 have been found.[43,48]

World Health Organization Quality of Life assessment (WHOQOL-BREF)[49]

Quality of life is measured by using the Dutch version of the WHOQOL-BREF. It contains 26 items covering four domains: physical health, psychological health, social relationships and environment. Domain scores can be transformed to a score ranging from 0 to 100 with higher scores reflecting better quality of life. There is no cut-off point to demonstrate better or worse quality of life in this particular population. It has been validated for this specific population.[50]

Postpartum Bonding Questionnaire (PBQ) [51]

Mother to infant bonding is assessed by using the PBQ It consists of 25 statements, each followed by a six-point Likert scale ranging from “Always”(0) to “Never”(5) with a range of 0-125 with higher scores reflecting a problematic mother-to-infant bond. Good validity and reliability of the Dutch version of the PBQ have been found.[52] To analyse the effects of PTSD symptom severity on the PBQ, only the total score will be used since later validation studies have not been able to replicate its factor structure. A score of 26 or higher is suggesting for some kind of bonding disorder, whereas a score of 40 or higher indicates severe bonding disorders.[53]

Wijma Delivery Experience Questionnaire version B (W-DEQ B) [54]

The W-DEQ B is used to measure postpartum fear of childbirth. The W-DEQ is a 33-item self-report questionnaire assessing FoC during pregnancy (version A), and after delivery (version B) in terms of the woman’s cognitive appraisal of childbirth. It was designed as a monofactorial scale, all 33 items being scored on a six-point scale leading to a sum score between 0 and 165, with higher score equalling more FoC.)[50] High reliability and promising validity of the W-DEQ B has been found.[54]

Edinburgh Postnatal Depression Scale (EPDS) [55,56]

The Dutch version of the EPDS is a self-reporting questionnaire designed to assess pregnancy and post-partum depression; it is composed of 10 items scored on a four-point Likert scale. Higher scores reflect a greater level of depression severity with a cut-off score of ≥13 to screen positive for depression.[56.] The Dutch version of EPDS is a widely used measure with good psychometric characteristics.[51]

Breastfeeding

Women will be asked whether they had the intention to breastfeed, and whether they currently breastfeed or not using ‘yes’ or ‘no questions.

Sample size calculation

Based on a mean difference between two treatment arms of at least 10 points on the PCL-5 scale and a standard deviation of 20, 86 patients are needed for this study to be included in each arm. Considering up to 20% loss to follow-up, 108 patients need to be included per treatment arm. We consider this sample size calculation to be conservative; the mean and difference estimates used were based on previous studies with PCL-5 score as primary endpoint. [57,58] The calculation was performed in PASS v11 using an alpha of 0.05 and a power of 90.3%.

Data management

Privacy of participants will be guaranteed by assigning a different number to each participant

starting with 1 for the first patient who is included in the study. All gathered data from the participants will be stored under this number. The data being gathered consists of paper questionnaires and digital

data. The key between the participant's code and the data

will be stored by the researchers in a file which is secured with a password on a memory stick with a security code. The memory stick will be stored in an locked closet, in a locked room.The data from the questionnaires are gathered using a secured, encrypted connection (https) and are stored in an online, password protected, secured database that is only accessible by the researchers via Castor EDC. Data will be exported into separate SPSS to be used for statistical analyses.

Interview data on paper will be stored in a locked closet, in a locked room under the participant number, and only the researchers have access to the key. At the end of the study, data will be inserted in the same SPSS file as the electronic data for analyses.

Data will be kept for 15 years in accordance with national guidelines. We will submit modifications to this protocol to the approving ethical committee, the institutional review board, participants, and investigators.

Due to the minimal risks of the early intervention EMDR and the short time span of the intervention, a data monitoring committee is deemed unnecessary.

Statistical analysis

Primary study parameters

For the CAPS-5, an independent t-test will be performed to compare symptom severity scores between groups at T1. If the assumption of normality is violated, a Mann-Whitney U test will be performed. A linear mixed model analysis will determine the difference between the intervention group and standard group in changes in PTSD symptom severity as measured by the PCL-5 measured at inclusion and at follow up (T0 and T1). Mixed linear model analyses will be performed to take into account that measurements within the same individual are correlated. Mean scores of the PCL-5 will be modelled as a function of the intervention condition (EMDR therapy, standard), time of measurement (T0 – screening, T1 Follow-up), the baseline PCL-5 score, and the interaction between time and intervention. Per protocol analyses and intention-to-treat analyses will test the main effect of treatment condition, the main effect of time, and the interaction effect. The assumptions of normality, homogeneity of variances, and sphericity will be tested prior to interpreting the results. Furthermore, adverse events will be reported and Chi-square tests will be done to test differences between the intervention and the control group.

Secondary study parameters

Independent sample t-test will be used to assess the differences on the PBQ, W-DEQ B, WHOL-QOL and EPDS between groups on a continuous scale. Also, a Chi-square test will be conducted to compare frequencies of moderate (26-40) and severe bonding disorders (40 or higher) on the PBQ, and using a cut-off score on the W-DEQ B of 85 or higher to indicate FoC. Linear mixed models analyses will determine the difference between the intervention group and CAU group in scores on PBQ, W-DEQ B, WHOQOL-BREF and EPDS at inclusion and at follow up (T0 and T1). A multiple linear regression analyses will be

performed to determine the relation between PTSD symptom severity and score on the PBQ, W-DEQ B, EPDS and WHOQOL-BREF between groups and within group and will be adjusted for baseline characteristics such as age, previous psychologic/psychiatric problems, socio-economic status, parity and mode of delivery.

Other study parameters

Descriptive statistics will be used to evaluate demographic and clinical baseline characteristics of the arms of the trial. Chi square tests and F-tests (ANOVA's) will be used to compare demographic and clinical characteristics between the groups and characteristics of subjects who did not complete the intervention or follow up with those of the completers. Also, breastfeeding differences between groups will be analyzed using Chi-square tests.

Interrater reliability and treatment fidelity

Patients, therapists and researchers will not be blinded due to the nature of the study. Assessment of the CAPS-5 interview will be conducted by an independent trained clinical interviewer, who is not aware of the randomization result. The therapists are independent of the research team and work at different sites outside the hospital. Patients in the EMDR therapy group will be randomly and equally distributed among therapists. All EMDR sessions will be recorded on video, and randomly rated for treatment fidelity. During the entire study duration group supervision every two to three months is obligatory for all therapists. After each first session with a new patient, a case conceptualization will be sent for supervision including: the story of the traumatic event, with a hierarchy of the most relevant traumatic moments (targets) regarding to the current impairment. Deviations from protocol will be noted and reported. If known, therapists register when a patient terminates the study and the reason for stopping. Furthermore, they inform the PI about it as soon as possible. Women who withdraw from treatment will be invited to fill in the previously mentioned questionnaires and the CAPS interview.

Dissemination and implementation

After completion of the study, the results will be submitted for publication to peer-reviewed scientific journals. Furthermore, results will be shared at national and international conferences, in Dutch or international publications, and possibly used for education and training purposes.

Discussion

The PERCEIVE-study will be the first randomized controlled trial that examines safety and effectiveness of early EMDR therapy in preventing or reducing PTSD (symptoms) in women with a traumatic birth experience. We consider this of great importance given the major impact of PTSD (symptoms) on both mother and infant found in the literature. [14, 15, 16, 17] The processing of having experienced an impactful event in relation to the birth of a child is expected to positively influence the women's' and infants' quality of life in longer term.

The study has several strengths. Firstly, the randomized controlled design eliminates bias in treatment assignment. All women who report having experienced giving birth as traumatic, despite the type of delivery or presence of complications and PTSD symptom severity at baseline will be included and randomized. Hereby the preventive effect of early intervention EMDR, as will be assessed in this study, may be generalized in all women reporting a traumatic birth experience. Another strength of this study is that PTSD (symptoms) will be assessed using a clinical interview, which will be conducted by an independent assessor four weeks after the last EMDR therapy session to reliably determine the presence of PTSD. To this end it is important to note that this is the first protocol using the CAPS-5 interview in this specific population, which will add importance to the study, particularly when compared to past research which mainly used self-reporting questionnaires. Clearly, we need to test whether our assumptions are supported, but we consider it as an advantage that our treatment protocol consists of only two treatment sessions which make it easy to implement in existing care systems. Another advantage is that the study uses a broad variety of secondary outcome measures including fear of childbirth, mother-infant bonding, quality of life, breastfeeding and depression.

Yet, some limitations of the present study should also be noted. First, due to the nature of the study patients and researchers cannot be blinded. To limit potential bias, women will be informed in which group they are elongated after finishing the first pre-treatment assessments, and the clinical interview will be conducted by an independent person. Secondly, since there is no current protocol for women experiencing traumatic childbirth, 'usual care' might differ individually. Therefore, a compromise has been made to give all women in the CAU group an expectative policy. They will receive two telephone calls during the study to monitor their symptom severity. When symptoms worsen significantly during the study period, the women in the CAU group will be referred to their general practitioner. Another limitation of the study protocol is the definition of the A-criterion in the DSM-V for PTSD diagnosis. Not al women reporting a traumatic birth experience will be exposed to (imminent) dead, severe injury or sexual violence during the delivery, which may cause difference in PTSD diagnoses based on the course of the delivery rather than the effect of early intervention EMDR therapy itself. To limit this bias, specific questions focused on childbirth related PTSD are added to the A-criterion. Finally, because of the COVID-19 epidemic patients as well as therapist will be at risk of being quarantined during the study period. Given the short time span in which therapy sessions have to be conducted it is decided to exceptionally allow therapy sessions to take place digitally in these cases. Although little is known about the effectiveness of online EMDR therapy for PTSD yet, it is expected that effects may be similar to real life EMDR therapy.[59]

If early EMDR therapy proves to be effective in preventing or reducing PTSD (symptoms) after a traumatic birth experience, this would provide a strong argument for standard screening of women for traumatic experiences after giving birth and to refer them for treatment in an early phase after the delivery.

List Of Abbreviations

CAPS-5 Clinician-Administered PTSD Scale for DSM-5

CAU Care-as-usual

DSM Diagnostic and Statistical Manual of Mental Disorders

EMDR Eye Movement Desensitization and Reprocessing

EPDS Edinburgh Postnatal Depression Scale

FOC Fear of childbirth

MIB Mother infant bonding

PBQ Postpartum Bonding Questionnaire

PCL-5 The PTSD Checklist for DSM-5

PTSD Posttraumatic stress disorder

QOL Quality of life

TBE Traumatic birth experience

W-DEQ B Wijma Delivery Experience Questionnaire version B

WHOQOL-B World Health Organization Quality of Life assessment

Declarations

Declarations

Trial status

Protocol version 1, dating 01-01-2021. Screening and recruitment started on 11 September 2020 and will continue to approximately the end of 2022.

Ethical approval and consent to participate

The study was approved by The Medical Research Ethics Committee of the OLVG Hospital, and is registered as NL7323100020. Written, informed consent to participate will be obtained from all participants.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interest

The authors declare that they have no competing interests.

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Authors' contribution

All authors have made substantial contributions to the concept of this study. KD and YH drafted the paper under supervision of MP. All authors were involved in critically revising the manuscript, and accept the final manuscript.

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Figures

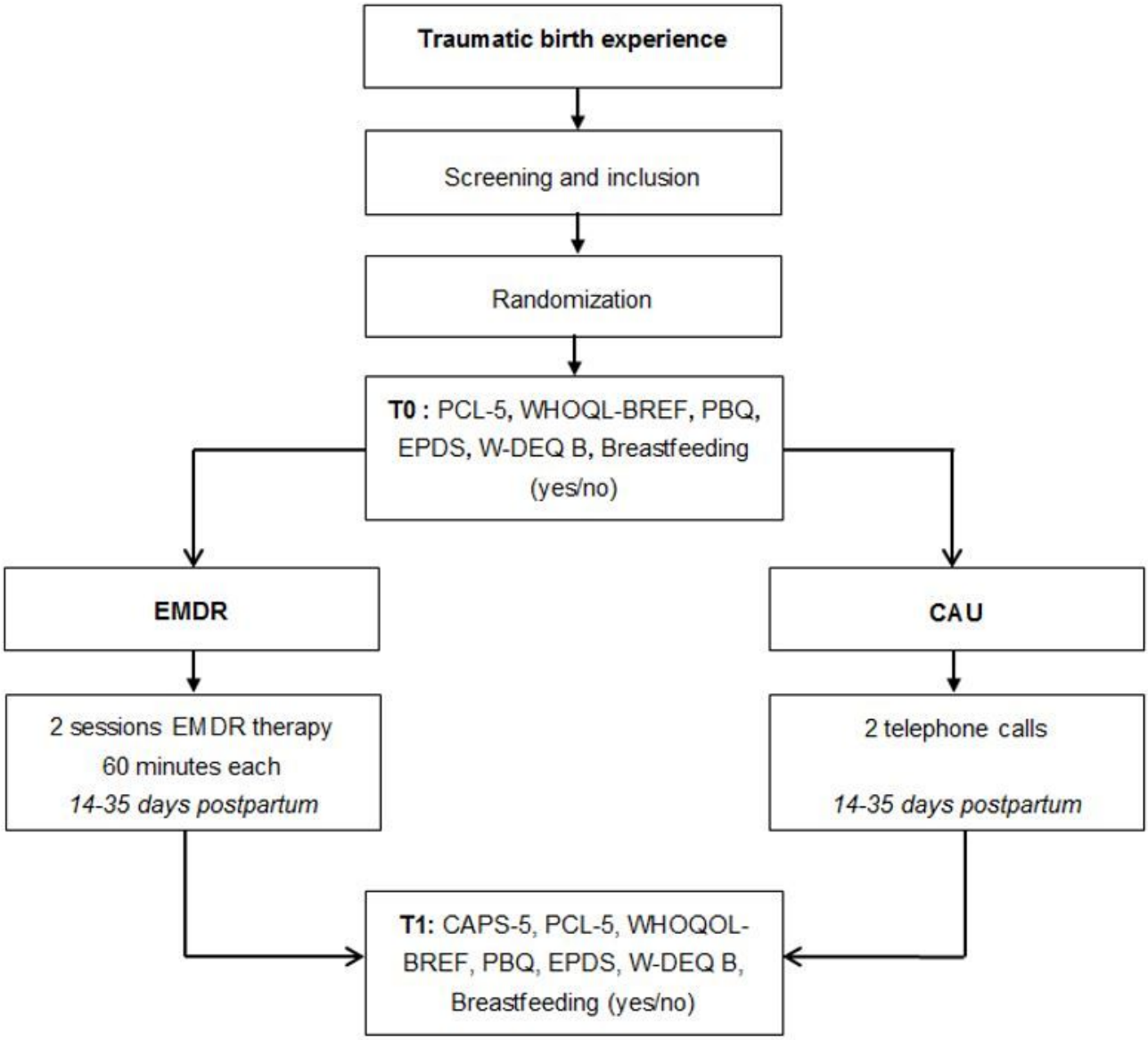

Figure 1

Trial flow chart showing treatment conditions and measurements. PCL-5, Posttraumatic Stress Disorder Checklist; CAPS-5, Clinician-Administered PTSD Scale for DSM-5; EPDS, Early Postpartum Depression Scale; PBQ, Postpartum Binding Questionnaire; W-DEQ B, Wijma Delivery Experience Questionnaire version B; WHOQOL-BREF, World Health Organization Quality of Life assessment. T, time point

	STUDY PERIOD		
	Enrolment	Post-allocation	
TIMEPOINT		*T0*	*T1*
ENROLMENT			
Screening	X		
Informed consent	X		
Allocation	X		
INTERVENTIONS:			
EMDR		←	→
CAU		←	→
ASSESSMENTS			
PCL-5		X	X
CAPS-5			X
W-DEQ B		X	X
EPDS		X	X
PBQ		X	X
WHOQOL-BREF		X	X
Breastfeeding (yes/no)		X	X

Figure 2

Enrolment and assessments over time.

Supplementary Files

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