Early psychological interventions for prevention and treatment of post-traumatic stress disorder (PTSD) and post-traumatic stress symptoms in post-partum women: a systematic review and meta-analysis protocol

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Early psychological interventions for prevention and treatment of post-traumatic stress disorder (PTSD) and post-traumatic stress symptoms in postpartum women: a systematic review and meta-analysis protocol

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ABSTRACT

Background: One in 10 women experience post-traumatic stress disorder (PTSD) at four to six weeks following birth, with rates of 15.7 per cent in high-risk populations. PTSD is highly comorbid with other mental health conditions, and an expanding evidence base has identified that symptoms of PTSD and accompanying comorbidities have a detrimental effect on women, infants and the family system.

Objectives: This protocol will guide a systematic literature review and meta-analysis that aims to estimate the effect of early interventions on PTSD and post-traumatic stress symptoms in women following a traumatic birth. The protocol follows the PICOS framework.

Methods: There will be no limitation on the geographical location in which the studies are conducted. The population of interest are pregnant and postpartum women who have experienced a traumatic birth. Experimental interventions include any early psychological intervention delivered within three months of a traumatic birth experience as secondary prevention, or before birth as primary prevention. Usual care or any active intervention will be included as comparator interventions. The primary outcome is post-traumatic stress disorder or post-traumatic stress symptoms. Randomised controlled trials (RCTs) or pilot studies will be included in the review.

Results: Eleven electronic databases will be searched, data will be extracted, and meta-analysis will be conducted in Review Manager 5. Heterogeneity between studies will be measured by the I^2 test and Chi-squared test. Risk of bias assessments will be conducted in accordance with the criteria outlined in the Cochrane Handbook for Systematic Reviews of interventions. Strength of evidence will be evaluated by the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) approach. Five reviewers will discuss study selection, data extraction and quality assessment. Results will be synthesised to formative narrative summary if there is insufficient data to conduct meta-analysis.

Conclusions: This protocol explains the methodology of a systematic literature review and meta-analysis of early psychological interventions in preventing PTSD and traumatic stress symptoms in women following a traumatic birth. Protocol development has been informed by the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols guidance (PRISMA-P).

Keywords: perinatal trauma, early intervention, psychological intervention, post-traumatic stress disorder, PTSD, birth, trauma, midwifery, review, protocol, Evidence Based Midwifery

Introduction

Post-traumatic stress disorder (PTSD) and symptoms of PTSD are experienced by 3.1 to 15.7 per cent of women following birth (Grekin & O'Hara 2014). PTSD and associated comorbid mental health disorders, including depression, are associated with a multitude of negative effects on mother–infant attachment as well as quality of life, physical health and family system (Fenech & Thomson 2014).

Early interventions are delivered in the early time period following a traumatic event. Previous systematic reviews have assessed the effectiveness of midwifery debriefing, suggesting that this form of early intervention is unhelpful in the days and weeks following birth (Bastos et al 2015, National Institute for Health and Care Excellence (NICE) 2014, 2016). NICE (2014, 2016) recommends Trauma Focused Cognitive Behavioural Therapy (TF-CBT), Narrative Exposure Therapy (NET) and Prolonged Exposure Therapy (PET) in the first four weeks following a traumatic birth, and Eye Movement Desensitisation and Reprocessing (EMDR) after four weeks; including a more definitive recommendation against treatment that involves reliving the experience as this could be harmful.

The International Society for Traumatic Stress Studies (ISTSS 2018) recommends early clinical treatment of PTSD symptoms in adults with multiple session TF-CBT and EMDR. Other Cochrane reviews have concluded that early universal psychological interventions, offered to all those who have witnessed or experienced a traumatic event, cannot be recommended to clinical practice (Roberts et al 2019a). Early psychological interventions including early EMDR intervention, trauma-focused cognitive-behavioural therapy (CBT-T) and cognitive therapy without exposure are effective in reducing PTSD symptoms in populations who have clinical presentation of PTSD (Roberts et al 2019b).

Ayers et al (2007) additionally found CBT to be an effective treatment for postpartum PTSD. Paradoxically, Gough & Giannouli (2020) reported therapists' sense of limitation by the emphasis placed on CBT while working with birth trauma, highlighting each case as unique. Early EMDR interventions have been specifically designed for treating populations in the days and weeks following exposure to a traumatic event or cumulative series of events (Shapiro & Laub 2008, Jarero et al 2016, Shapiro & Maxfield 2019) and may be particularly suitable for early prevention of PTSD and treatment of traumatic stress symptoms in women following a traumatic birth experience, with no exposure, or reliving of the event.

Rationale

The nature of PTSD and associated symptomology of shame, fear and avoidance, deter women from seeking treatment (Ford 2019). Given the multifinality of trauma, negative effects of PTSD, symptoms thereof, and accompanying comorbidities in women following traumatic birthing experiences (Ayers et al 2006, Fenech & Thomson 2014); it is important that a systematic review of the evidence is conducted on the effectiveness of early psychological interventions in reducing PTSD and PTSD symptoms in this population.

Objectives

This protocol has been developed in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines (Moher et al 2015). The research question was guided by the PICOS framework (Richardson et al 1995) and was implemented to ensure a 'well-built clinical question' for evidence-based medicine. The PICOS framework focuses on, patient, intervention, outcome, and study design of specific interest as follows:

- Population — pregnant and postpartum women who have experienced a traumatic birth
- Intervention — any early psychological intervention delivered within three months of a traumatic birth experience as secondary prevention, or before birth as primary prevention
- Comparator — usual care or any active intervention
- Outcome — post-traumatic stress disorder or post-traumatic stress symptoms
- Study design — randomised control trial or pilot study.

The objectives of this review are to:

- Estimate the effect of early interventions on PTSD and post-traumatic stress symptoms in women following a traumatic birth.
- Estimate the effect of intervention type.

Methods

Eligibility criteria

Types of study to be included

Any randomised or cluster randomised or pilot study that includes an early intervention targeting traumatic stress symptoms and prevention of PTSD in women during the perinatal period. Sample size, language, or publication status will not be used as an inclusion criterion and there will be no date limitations.

Participant characteristics

Studies that include adult women over the age of 18 years will be eligible for inclusion. Women who had a full term or pre-term traumatic birth experience, even if the birth was obstetrically straightforward; as assessed by reporting the birth as psychologically

traumatic, or experiencing an emergency caesarean, instrumental birth (vacuum or forceps), severe perineal tear, or postpartum haemorrhage. Pregnant women will be included for primary prevention or postpartum for secondary prevention (that is, up to three months).

Diagnosis

There will be no restriction on diagnosis or comorbidity at the time period when the early intervention was administered. This includes sub-clinical symptom scores of PTSD assessed by validated clinician or self-report psychometric tests such as, but not limited to, the PCL-5, IES-R. Assessment by Diagnostic and Statistical Manual of Mental Disorders; DSM-III, DSM-III-R, DSM-IV, DSM-V (American Psychiatric Association), International Classification of Diseases; ICD-9, ICD-10 or ICD-11 (World Health Organization) diagnostic criteria for PTSD and Criterion A qualifying as experience of a psychologically traumatic birth will be included.

We will focus on studies that report participants as experiencing a physically or psychologically traumatic birth during screening and symptoms of PTSD on outcome according to both self-report and clinician-administered measures of PTSD and chronic stress as stipulated by the Diagnostic and Statistical Manual of Mental Disorders; DSM-III, DSM-III-R, DSM-IV, or DSM-V (American Psychiatric Association) and the International Classification of Diseases; ICD-9, ICD-10 or ICD-11 (World Health Organization).

Exclusion criteria

The following studies will be excluded from this review: systematic reviews, meta-analysis, case-series and case reports, qualitative outcome measure only, studies focusing on effectiveness of religious or spiritual interventions and interventions that focused on parenting skills as the primary outcome. Interventions designed for abuse-related post-traumatic stress symptoms. Solely dismantling studies will not be included. There will be no restriction on the setting in which the intervention took place.

Condition being studied

Post-traumatic stress disorder experienced by women following a traumatic birth experience.

Types of intervention

Experimental interventions

Any experimental non-pharmaceutical intervention designed to prevent, reduce or treat symptoms of PTSD delivered by one or more health care professionals or layperson, during the perinatal period as a primary or secondary early intervention beginning no later than three months after the traumatic event will be eligible for inclusion.

Intervention categories could include but are not limited to any of the following:

- Any psychological intervention including trauma-focused cognitive behavioural therapy (TF-CBT) and EMDR, TF-CBT predominantly utilised trauma-focused cognitive, behavioural, or cognitive-behavioural techniques. Individual exposure therapy and prolonged exposure as well as early group-based interventions.
- Non-trauma-focused early interventions, including CBT and internet-based cognitive behavioural therapy (iCBT), addressing symptoms of PTSD not including treatment of PTSD symptoms through a trauma-focused or exposure-based therapy.
- Any online interventions and those that targeted expanding knowledge through psychoeducation, resilience, communication and on improving regulation, coping and stabilisation skills. This category includes midwifery-led debriefing, birth after thoughts, and counselling facilitated during the perinatal period.

Comparator interventions

Control interventions that include care-as-usual, waiting-list control, minimal or placebo condition are eligible for inclusion. Any alternative trauma-focused, or non-trauma-focused early psychological or biopsychological intervention will also be included in the search criteria.

Primary outcomes

1. Severity of post-traumatic stress symptoms using a validated psychometric measure of PTSD (continuous)
2. Diagnosis of PTSD as measured by clinician-administered diagnostic interview such as the CAPS-5 (Dichotomous).

Search strategy

The keywords in the search strategy will be used to carry out systematic searches in the following databases: AMED (Allied and Complementary Medicine Database) Embase, PsycInfo, MEDLINE, CINAHL, ProQuest PILOTS, ProQuest Dissertations, Cochrane Central Register of Controlled Trials (CENTRAL), The World Health Organization International Clinical Trials Registry Platform, ClinicalTrials.gov and the ISRCTN registry.

Keywords

Population

1. (perinatal OR postnatal OR antenatal OR prenatal OR pre-natal OR ante-natal OR peri-natal OR birth OR childbirth OR parturition OR postpartum OR caesarean OR caesarean OR haemorrhage OR assisted

delivery OR vacuum delivery OR perineal tear OR stillbirth OR stillborn OR forceps OR instrumental delivery).af.

Intervention & comparison

2. (EMDR OR (eye movement desensiti#ation and reprocessing) OR CBT OR cognitive behavio?ral therapy OR iCBT OR online intervention OR telehealth OR exposure OR counselling OR counseling OR therapy OR psychoeducation OR early intervention OR group intervention OR Psychological OR Psychotherapy OR debriefing OR birth afterthoughts OR midwifery led intervention OR rewind OR TF?CBT OR CPT OR cognitive processing therapy OR stabili#ation OR treatment as usual OR care as usual OR cau).af.

Outcome

3. (Post?Traumatic Stress Disorder OR PTSD).af.

Study design

4. (RCT or randomi#ed control* trial or protocol or pilot or clinical trial).af.

Searching other resources

Reference lists of identified studies, along with related review articles, policy documents, clinical guidelines, articles published by relevant charities and management guidelines will be hand-searched.

Internet searches of known websites, conference proceedings and discussion will be conducted as follows:

European Society for Traumatic Stress Studies (https://www.estss.org)

International Society for Traumatic Stress Studies (http://www.istss.org)

United Kingdom Psychological Trauma Society (http://www.ukpts.co.uk)

Birth Trauma Association UK (https://www.birthtraumaassociation.org.uk/)

Prevention and Treatment of Traumatic Childbirth (PATTCh) http://pattch.org/)

National Institute for Health and Care Excellence (www.NICE.org.uk)

Maternal Mental Health Alliance (www.maternalmentalhealthalliance.org)

Royal College of Obstetricians and Gynaecologists (https://www.rcog.org.uk/)

Royal College of Psychiatrists (https://www.rcpsych.ac.uk/)

Royal College of Midwives (https://www.rcm.org.uk/).

Selection of studies

Titles and abstracts of all studies will be screened. Study protocols will be retained and saved in a separate protocol folder for cross-referencing during the final review analysis. If an abstract describes an RCT or pilot study, the review author will independently read the full paper to assess whether the study meets the inclusion and exclusion criteria. After independently reading the screened full text articles, the multidisciplinary team of review authors will then discuss screening outcomes and ensure agreement on inclusion and exclusion of papers. Authors of eligible papers will be contacted for English translation if necessary.

Data extraction and management

Following screening of inclusion and exclusion criteria, data from each trial will be entered into a table format and data extracted into Review Manager 5 (Cochrane Collaboration 2014). Extracted information will include: detail of the trauma categorical specificity of traumatic event, primary or secondary prevention, timing of the intervention, the randomisation process, the interventions used, drop-out rates, reasons for drop out, fidelity to intervention, description and theoretical basis of intervention, dosage, timing, detail on facilitator, ethical approval and PTSD outcome data, including dichotomous incidence rates of PTSD, and continuous means and standard deviations in comparator and control groups as assessed at reported time points. Intention to treat, per protocol t-tests and results of analysis of variance (ANOVA) will be recorded in data extraction tables.

Assessment of risk of bias in included studies

Risk of Bias will be assessed in accordance with the criteria outlined in the Cochrane Handbook for Systematic Reviews of interventions (Higgins et al 2011).

Criteria for risk of bias assessment will be as follows:

1. Random sequence generation
2. Allocation concealment
3. Blinding of outcome assessment
4. Incomplete outcome data
5. Selective outcome reporting
6. Other bias (including imbalances in baseline statistics, early termination, researcher conflict of interests and allegiance).

Bias will be assessed as high, uncertain, or low risk. The risk of bias judgements will be taken into account in the final consideration of treatment effect. Studies with high risk of bias will be marked down by 1.

Data synthesis and measures of treatment effect

Meta-analysis on continuous and dichotomous outcomes will be performed dependent on assessment of risk of bias and sufficient data by intervention category and follow up.

Continuous outcomes will be analysed using mean difference (MD) in scales assessing for PTSD. The standardised mean difference (SMD) will be used as the summary statistic in meta-analysis as it is expected that studies will measure PTSD using differing psychometric scales. A fixed effects model will be used if different studies are estimating the same treatment effect (Higgins et al 2011). Tests for subgroup differences will be based on random-effects models in order to guard against high risk of false-positive results when comparing subgroups in a fixed-effect model.

Dichotomous data will be managed with the risk ratio (RR) as the main categorical outcome measure. All outcomes will be presented using 95% confidence intervals (CI). Rules for interpreting SMDs (or 'Cohen's effect sizes') will be guided by Cohen (1988) as <0.40=small, 0.40 to 0.70=moderate, >0.70=large.

If data is unavailable for calculation of meta-analysis, results will be synthesised to formative narrative summary. Funnel plots testing for publication bias across studies will be performed if more than 10 studies are identified as eligible for inclusion and sufficient data are available.

Dealing with missing data

Intention to treat data will be reported in the results. When mean (M) and standard deviations (SD) are missing, these will be calculated with other quantitative data available within the paper, including CIs, t statistics and p values. When imputation is not possible, the paper will not be included in analysis and will be reported on as a single study.

Assessment of heterogeneity

The presence and extent of between study variation will be assessed before making a decision to conduct a meta-analysis. Studies will be assessed qualitatively for clinical and methodological heterogeneity in terms of the variability in participant populations, interventions, study design outcomes and methodological rigour. An explorative study of forest plots will be assessed for possible statistical variability between intervention effects. Heterogeneity between studies will be measured by the I^2 test and Chi-squared test ($P < 0.10$). An I^2 of less than 30% will be considered to indicate that statistical heterogeneity might not be important; an I^2 of 30% to 60% to indicate moderate heterogeneity; an I^2 of 50% to 90% to indicate substantial heterogeneity and an I^2 greater than 75% to indicate considerable heterogeneity.

The strength of the body of evidence and outcomes will be evaluated by the GRADE approach (Guyatt et al 2011, Guyatt et al 2013, Langendam et al 2013). The GRADE guidelines framework will assess the quality of evidence in terms of study limitations, inconsistency/unexplained heterogeneity, indirectness of the available evidence, imprecision of effect estimates. Assessments will be made by researchers, independently followed by discussion and agreement as a team. High, moderate and low specifiers will be applied to each comparison as an indication of the confidence that the effect estimate will remain unchanged as a result of further research.

Discussion

This systematic review protocol has been developed to include all psychological interventions delivered to women in the early period following a traumatic childbirth experience. It is recognised that some unpublished studies may be extracted, and, in this case, study authors will be contacted for further information. If study authors are unresponsive or cannot be contacted, the study will be excluded from the review.

The inclusion of studies in English may lead to an overestimation of effects, as it has been reported that studies that have been published in English are more likely to have reported significant results in favour of the intervention (Egger et al 1997). Including only studies in the English language may be considered to introduce cultural bias. This is accounted for in the eligibility criteria for selected studies, where language is not used as a criterion for inclusion.

The review aims to include validation from a subject matter librarian on database searches. Where feasible, raw scores will be translated to standardised means for continuous and risk ratio for dichotomous variables to allow comparability across studies. If meta-analysis is not appropriate, results will be reported qualitatively, along with the overall GRADE quality of evidence for PTSD as the main outcome of interest.

No ethical approval was required for this review protocol, considering the investigation of secondary data and previous studies conducted on this topic. Our ethical consideration has been predominantly focused on the mother–infant dyad. Mild sub-clinical post-traumatic stress symptoms, including avoidance and numbness, are an expected stress response to a traumatic incident. It remains apparent that in some cases, this stress response may negatively impact upon the mother–infant dyad, maternal bonding, quality of life and wellbeing of the mother and family unit (Fenech & Thomson 2014). A peritraumatic response to a traumatic event may act as protective mechanism for women in the short term but, if symptoms as a result of such experiences remain unresolved, delayed onset of the disorder may occur (Utzon-Frank

et al 2014). It is for this reason that investigation of effective intervention for prevention is the focus of this review in this context.

Conclusion

The proposed systematic literature review will be the first to assess early interventions in the prevention and treatment of PTSD and PTSD symptoms in postpartum women who have had a traumatic birth experience. Results may provide insight into the clinical effectiveness of psychological interventions administered during the antenatal period as primary prevention, or within twelve weeks of a traumatic birth experience as secondary prevention. Early intervention is particularly important in this stage in a woman's life cycle as women may be more vulnerable to the effects of experiencing trauma, including mental health symptoms of post-traumatic stress, anxiety, depression, and physical symptoms of pain and fibromyalgia. Equally important is the dyadic bond between mother and infant that can be negatively impacted by mental health symptoms, and familial stressors (Grekin & O'Hara 2014).

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Patient consent for publication

Not required.

Provenance and peer review

Not commissioned, externally peer reviewed.

PROSPERO registration number

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