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BMJ Open Effectiveness of trauma-focused psychological therapies compared to usual postnatal care for treating post-traumatic stress symptoms in women following traumatic birth: a systematic review protocol

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ABSTRACT

Introduction: Maternal mental health has been largely neglected in the literature. Women, however, may be vulnerable to developing post-traumatic stress symptoms or post-traumatic stress disorder (PTSD), following traumatic birth. In turn, this may affect their capacity for child rearing and ability to form a secure bond with their baby and impact on the wider family. Trauma-focused psychological therapies (TFPT) are widely regarded as effective and acceptable interventions for PTSD in general and clinical populations. Relatively little is known about the effectiveness of TFPT for women postpartum who have post-traumatic stress symptoms.

Methods and analysis: We will conduct a review to assess the effectiveness of TFPT, compared with usual postpartum care, as a treatment for post-traumatic stress symptoms or PTSD for women following traumatic birth. Using a priori search criteria, we will search for randomised controlled trials (RCT) in four databases: Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, PsycINFO and OpenGrey. We will use search terms that relate to the population, TFPT and comparators. Screening of search results and data extraction will be undertaken by two reviewers, independently. Risk of bias will be assessed in RCTs which meet the review criteria. Data will be analysed using the following methods, as appropriate: narrative synthesis; meta-analysis; subgroup analysis and meta-regression.

Dissemination and ethics: As this work comprises a synthesis of existing studies, ethical approvals are not required. Results will be disseminated at conferences and in publications.

INTRODUCTION

Maternal mental health remains relatively underexplored despite the potential long-term impact and consequences for women,

Strengths and limitations of this study

- Using a comprehensive literature search and synthesis, this systematic review will provide the best evidence available regarding the effectiveness of trauma-focused psychological therapies for women who have suffered a traumatic birth experience.
- The systematic review protocol was developed and published prior to conducting the review to avoid reporting bias.
- There may be some issues related to data (incorrect reporting, missing or insufficient data), but we will contact the original researchers to ask for the clarification, if necessary.

their babies and the wider family network.^{1–4} A recent confidential enquiry into maternal deaths and morbidity in the UK and Ireland⁵ reported that mental health problems remain one of the leading causes of maternal death: from 2009 to 2013, 23% of deaths in women postpartum (ranging from 6 weeks to 1 year after pregnancy) were attributed to either suicide or accidental death (eg, following substance misuse). The most common maternal mental health problem diagnosed during the postnatal period is depression.⁶ It has been suggested, however, that the term ‘postnatal depression’ is overused in clinical practice as a label for any mental illness occurring postnatally.⁷

It is increasingly recognised that a traumatic birth can result in post-traumatic stress symptoms (ie, symptoms that fall below the diagnostic threshold), or post-traumatic stress disorder (PTSD).^{8,9} PTSD is a severe and debilitating mental health disorder that an individual may develop in response to

experiencing or witnessing a highly traumatic event.¹⁰ For some women, giving birth can be a frightening, anxiety-provoking and traumatic experience. Perceptions of childbirth as traumatic arise when a woman believes that there is a serious or significant threat to her own life (eg, anticipated or unexpected obstetric complications, emergency caesarean section) or the life of her baby (eg, premature labour, still-birth).^{11 12} PTSD symptoms that may occur in women after a traumatic birth include intrusive thoughts and images about the traumatic event (eg, seeing severe blood loss, being rushed to hospital); avoidance of stimuli associated with the traumatic event (eg, avoiding attending hospital appointments or sharing birth experiences with others; avoiding the baby who is a reminder of the trauma); blunting of affect (eg, low mood); negative thoughts and beliefs about the self, others or the world (eg, 'I am going to die', 'I am not a good mother'); dissociative states and emotional dysregulation. PTSD symptoms can typically impede aspects of daily functioning, including social relationships and ability to find and sustain employment.

It is estimated that the proportion of women who suffer post-traumatic stress symptoms following 'normal' childbirth is about 3–6% at around 6 weeks postpartum, decreasing to about 1.5% at 6 months postpartum.¹³ Prevalence rates appear to be higher for at-risk groups (eg, women who have experienced obstetric complications, emergency caesarean sections, premature births or stillbirths) and are estimated to be up to 44% within 2 years postpartum.¹⁴ However, prevalence estimates vary widely, perhaps due to differences in study designs, sampling frames, sample sizes, diagnostic criteria employed and measurement instruments.^{14–16} It is anticipated that the number of women who experience traumatic births is likely to rise, due to increasingly complex medical needs of women who become pregnant when older or obese.^{17–20} There is, therefore, an urgent need to consider how best to support women who suffer from post-traumatic stress symptoms during the postnatal period.

Description of the intervention

Systematic reviews have consistently concluded that trauma-focused psychological therapies (TFPT) are effective treatments for PTSD in general population groups. These include different modes of exposure therapy such as narrative exposure therapy (NET), trauma-focused cognitive-behavioural therapy (TFCBT) and eye-movement desensitisation and reprocessing (EMDR).^{21–23} All TFPT share some core treatment principles, in particular, an emphasis on supporting patients to make sense of and process memories of trauma, and cognitions and attributions relating to traumatic events.^{24–26} EMDR²⁷ and CBT, in particular, are recommended by NICE guidance on PTSD for children and adults who have experienced a single traumatic event.²³

How the intervention might work

Exposure therapy typically involves asking the individual to relive the trauma, either in their imagination or by writing (in NET) a trauma narrative to create a detailed account of the event. The individual is then asked repeatedly to revisit or read the narrative in order to become habituated to the post-traumatic stress symptoms that are generated.^{24 28} TFCBT involves helping individuals to make sense of their experiences, identify ways or patterns of thinking that are negative, recognise thoughts and beliefs about the self, others or the world that are associated with the traumatic event, and finally, note behavioural or coping responses which may be helpful in the short term, yet perpetuate anxiety in the longer term. Individuals are encouraged to develop new ways of thinking about and appraising traumatic events.²⁹ EMDR involves supporting individuals to identify and then focus on a traumatic image (eg, finding oneself with heavy bleeding), an associated thought (eg, 'My baby and I are going to die'), the emotion (eg, extreme fear) and physical sensations, while receiving bilateral stimulation, most commonly in the form of eye movements.²⁷

Importance of the review

Although TFPT are effective and acceptable as treatments for PTSD in general and clinical populations, postpartum women are typically excluded from research studies, so the clinical utility of these interventions is yet to be established.² There is currently no systematic review that synthesises evidence regarding the effectiveness of TFPT for women who have suffered a traumatic birth. A Cochrane review of psychosocial and psychological interventions (eg, CBT) for postnatal depression does exist,^{30 31} but PTSD and trauma symptoms are not included as outcomes of interest. It is quite possible that PTSD following childbirth differs from PTSD that occurs in other contexts.³² Unlike typical stressors that contribute to PTSD, such as abuse, assault, torture and war, childbirth is by and large deemed to be a positive event, while also concurrently seeming traumatic for some women. The implication is that women's needs may be misunderstood.³³ Behaviours indicative of PTSD, such as social withdrawal and avoidance, may be misattributed to needing to care for a baby, when in fact this is as a consequence of PTSD. It is also evident that for some women caring for a baby continues to be a reminder of traumatic experiences, which may in turn mediate the propensity for developing strong bonds and secure attachments between mother and child. Overall, it is likely to be clinically important to take account of the postnatal context when planning and delivering TFPT.

OBJECTIVES

The primary objective of this systematic review is to assess the effectiveness of TFPT, compared with usual

postpartum care for PTSD or post-traumatic stress symptoms in women following traumatic birth.

Secondary objectives are to examine the effectiveness of these psychological interventions for common comorbid symptoms including depression, anxiety or distress, as well as any adverse effects including an increase in PTSD symptoms or death.

METHOD AND ANALYSIS

Inclusion/exclusion criteria

Population

Women experiencing post-traumatic stress symptoms and/or the impact of these following traumatic birth, who meet PTSD diagnostic threshold, or who have subthreshold symptoms. Diagnostic assessment could be made according to self-report, such as via a questionnaire (eg, PTSD Symptom Scale—Self Report version (PSS-SR)³⁴), or via a clinician-administered assessment (eg, Structured Clinical Interview for DSM-IV (SCID)^{35 36}; Clinician-administered PTSD Scale (CAPS)³⁷). There is no restriction on age, nationality or birth mode.

Intervention

TFPT added to usual (standard) postnatal care to reduce symptoms of PTSD. Psychological interventions that will be included in this review are as follows:

1. *Exposure therapy*: Any individual therapy which involves guiding the individual to relive and process the trauma memory through creating a narrative using formats such as writing or audio-recording. During therapy, the patient will revisit the narrative repeatedly in order to habituate or develop tolerance of trauma symptoms.
2. *Trauma-focused cognitive-behavioural therapy (TFCBT)*: Any psychological therapy that predominantly employs trauma-focused cognitive, behavioural or cognitive-behavioural techniques and that aim to support individuals to identify unhelpful thoughts or thinking styles, and behaviours, and develop new ways of thinking about or coping with trauma. Examples of therapies within this category are cognitive therapy,²⁹ cognitive processing therapy³⁸ and prolonged exposure.³⁹
3. *EMDR*: A structured protocol-driven trauma-focused therapy, which relies on an adaptive information process model of PTSD.⁴⁰ EMDR comprises eight elements, including recall of images, thoughts, emotions and bodily sensations associated with traumatic events, while receiving bilateral stimulation.
4. Any other psychological intervention that does not fit the above categories, but clearly describes the theoretical underpinning and is intended to target trauma symptoms and related distress in postpartum females.

Comparators

1. Standard postnatal care (which denotes the usual postnatal care provided within the first 6 weeks post-birth in settings which do not routinely offer TFPT).

2. Standard postnatal care, plus any non-specific supportive counselling or 'attention control' (eg, befriending) provided by primary care/postnatal follow-up.

Types of outcome measures

Primary outcome

Recovery (dichotomous outcomes) from, or reduction (continuous outcomes) in PTSD or trauma symptoms as measured by validated scales, for example, PSS-SR,³⁴ CAPS,³⁷ Impact of Events Scale (IES).⁴¹ Scores of continuous outcome measures reported, such as PSS-SR and CAPS, will be converted to indicate recovery or not from PTSD according to well-established cut-off scores (eg, cut-off scores for the PSS-SR, the CAPS and the IES are 14, 40 and 19) or as described by the study authors.

Secondary outcomes

- Recovery (dichotomous outcomes) from, or reduction (continuous outcomes) in depressive symptoms as measured by validated scales, for example, Edinburgh Postnatal Depression Scale (EPDS),⁴² Beck Depression Inventory (BDI),⁴³ State of Anxiety and Depression (SAD).⁴⁴
- Recovery (dichotomous outcomes) from, or reduction (continuous outcomes) in anxiety symptoms as measured by validated scales, for example, Beck Anxiety Inventory (BAI),⁴⁵ Hospital Anxiety and Depression Scale.⁴⁶
- Well-being or quality of life, for example, Short Form-36 (SF-36).⁴⁷
- Adverse events or effects, for example, increased PTSD or trauma symptom severity, death.

Timing of outcome measurements

Timing of outcome measurements will be grouped into three periods of time:

- Short term: up to 6 months post-intervention;
- Medium term: between 6 and 12 months post-intervention
- Long term: over 12 months post-intervention.

Types of studies

We will include all randomised controlled trials (RCTs), cluster RCTs, quasi-randomised trials (such as trials which allocate study participants according to day of the week), and RCTs that comprise a cross-over methodology that compare TFPT for PTSD symptoms in women following traumatic birth with usual postpartum care. Study populations which comprise non-postpartum individuals will be included if the subset of data specific to the women are published or obtainable from the paper/trialists. There will be no restriction based on the study sample size, language, study setting or publication status.

Data sources and search strategy

We will carry out systematic searches in the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, PsycINFO and OpenGrey using a search

strategy developed in consultation with an information specialist at the academic institution where the first reviewer (MF) is based (table 1). To maximise search sensitivity, we will use index terms (eg, Medical Subject Heading: MeSH) and free-text terms referring to population (eg, 'pregnancy', 'postnatal') and interventions (eg, 'Cognitive Therapy', 'Eye Movement Desensitisation Reprocessing') without terms referring to outcomes. No restrictions on date, language or publication status will be applied to the searches. The electronic searches will be supplemented by a hand search of the reference lists of all included studies. The citations we retrieve from the searches will be imported into the reference management software package EndNote X7.

Data collection and analysis

Selection of studies

Two reviewers will independently screen titles and abstracts of all potential studies identified through the

search strategy, and they will code them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. The two reviewers will then independently read the full text of the studies retrieved to determine whether trials meet the inclusion criteria or to record reasons for excluding ineligible studies. A third author will undertake a random check of 10% of results at each stage. Any disagreements will be resolved through discussion or, if required, through consultation with other review authors. The process of the study selection will be outlined in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram and 'characteristics of excluded studies' table.

Data extraction and management

Two review authors will independently extract data using a data extraction form designed for this review which include details about study eligibility; sample frame and size; participant characteristics; diagnosis and diagnostic

Table 1 Searching strategy (MEDLINE)

Population	AND	Intervention	AND	Study design*
exp Pregnancy/ OR		exp Cognitive Therapy/ OR		exp Clinical Trial/ OR
exp Pregnancy Outcome/ OR		CBT.mp. OR		exp Clinical Trial, phase I/ OR
exp Delivery, Obstetric/ OR		exp Eye Movement Desensitization Reprocessing/ OR		exp Clinical Trial, phase II/ OR
exp Parturition/ OR		EMDR OR		exp Clinical Trial, phase III/ OR
birth.mp OR		exp Behavior Therapy/ OR		exp Clinical Trial, phase IV/ OR
childbirth.mp OR		Behaviour* therapy.mp OR		exp Controlled Clinical Trial/ OR
exp Postnatal Care/ OR		exp Psychotherapy/ OR		exp Randomized Controlled Trial/ OR
postnatal.mp OR		psychological.mp OR		exp Random Allocation/ OR
exp Postpartum Period/ OR		exp Psychological Techniques/ OR		randomised.mp OR
postpartum.mp OR		exp Psychology, Experimental/ OR		trial.mp OR
exp Maternal Health Services/ OR		Trauma focused.mp		RCT.mp
exp Infant, Newborn/ OR				
exp Caesarean Section/ OR				
caesarean OR				
exp Stillbirth/ exp Intensive Care, Neonatal/ OR				
exp Intensive Care Units, Neonatal/				

*Search will be performed initially with sets of terms referring to population and interventions. The terms referring to study design may be added if necessary to increase search specificity.

criteria used; nature, timing and duration of intervention; number and frequency of sessions; professional background of trial therapists; outcomes (primary and secondary measures); statistical analyses; duration of follow-up and attrition. Attempts will be made to obtain missing and/or unpublished details, by contacting study authors. This process will involve contacting trialists for independent data sets of postnatal women, if they are included in trials that also include other trauma victims.

Risk of bias assessment

Two review authors will independently assess the risk of bias of all included studies, using the approach recommended in the *Cochrane Handbook for Systematic Review of Interventions*.⁴⁸ The Cochrane's risk-of-bias tool addresses six specific domains: (1) sequence allocation for randomisation; (2) allocation concealment; (3) blinding of personnel and assessors; (4) incomplete outcome data; (5) selective reporting and (6) any other notable risks of bias. For each item, one of the following three judgements will be made: 'low risk' of bias (plausible bias—unlikely to seriously alter the results), 'high risk' of bias (plausible bias that seriously weakens confidence in the results) or 'unclear risk' of bias (plausible bias that raises some doubt about the results) when insufficient information was reported to permit judgement. The process for reaching judgments will be described in the risk-of-bias tables to ensure transparency.

Summary assessments of risk of bias

The overall quality of the evidence for each outcome will be assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.^{48 49} The overall quality of evidence for each outcome will be assigned to one of four levels—high, moderate, low or very low—according to factors including within-study risk of bias (methodological quality), directness of evidence, heterogeneity, precision of effect estimates and risk of publication bias.^{48 49}

Measures of treatment effect

For dichotomous outcomes, such as the presence of PTSD, depression or anxiety, the Mantel-Haenszel method for computing the pooled risk ratio (RR) with 95% CIs will be used. For continuous data, and where different scales have been used, the standardised mean difference (SMD) and 95% CI will be calculated to indicate the direction and consistency of effect. The weighted mean difference (WMD) and 95% CI will be calculated where all outcomes were measured using the same scale in the same way.

Multiplicity and unit of analysis issues

If a study reports data for more than one outcome or time-point, analyses will be conducted separately for each outcome/time-point (short, medium, long term). For trials with multiple arms of treatment in a study, the appropriateness of combining data to create a single

pair-wise comparison will be considered if therapies are sufficiently similar. Alternatively, data from the arms of the trial which fit closest to the review objectives will be used. Where studies have adopted a cross-over design, only outcome data from the first randomisation period will be included. If cluster-randomised trials are identified, sample sizes will be adjusted using an estimate of the intracluster correlation coefficient (ICC) from the trial or from a study of a similar population, based on statistical advice.

Dealing with missing data

Dealing with missing data may include imputing outcomes for the missing participants to facilitate an intention-to-treat (ITT) analysis.⁴⁸ This may involve a sensitivity analysis by imputing outcomes for the missing participants with the most optimistic and the most pessimistic scenarios and then comparing the results of these two analyses. The sensitivity analysis may also be conducted to facilitate comparisons of the ITT with imputations from 'available case analysis' (ie, analyse data with participants whose outcomes are known).⁴⁸ If these analyses yield similar results in the same direction of the effects of the treatment (indicating participants with missing outcomes are safely excluded), the results of available case analysis will be used for meta-analysis. The impact of including these studies in the overall assessment of treatment effect (summary effect) will be further assessed with additional sensitivity analysis comparing the results of meta-analyses with and without trials which are rated as high risk bias due to missing data (see Sensitivity analysis).

Assessment of reporting biases

When sufficient studies are available (n=10 or more), we will construct funnel plots and scrutinised them for signs of asymmetry.⁴⁸

Data synthesis

Random effects meta-analyses will be performed which will produce the average effect size of the intervention across studies, allowing for differences in the treatment effect from study to study. Random effects meta-analyses is a conservative option and more appropriate for this study than a fixed-effect model (which assumes that there is one true effect), because the populations and settings are likely to be slightly different, therefore the effects are likely to be slightly different. However, if there are only few studies (two to four studies), it may be inadequate to accurately estimate of the width of the distribution of intervention effects.^{48 50} In this case, a fixed-effect analysis will be performed. Then, the results obtained from these two methods random effects and fixed-effect models will be compared to seek potential bias and heterogeneity. Analyses will be conducted by a statistician (ESWN) using a statistical software, STATA V.14.

Heterogeneity

Heterogeneity will be assessed within each comparison. In the instance of clinical heterogeneity (eg, variation in study settings, intervention modality), we will conduct subgroup analyses. Alternatively, if there is methodological heterogeneity (eg, variation in study designs, outcome measures or risk of bias), we will perform sensitivity analyses, where data are available. If there is significant heterogeneity between studies, extracted data will be synthesised into a narrative summary.

Where meta-analyses are performed, tests of statistical heterogeneity will be carried out using I^2 and χ^2 statistics,⁴⁸ as well as visual inspection of the forest plots. If heterogeneity is identified (eg, the I^2 is >30%, and the p value is <0.10 in the χ^2 test for heterogeneity or different direction of the effects), prespecified subgroup analysis and meta-regression analyses will be conducted to identify important determinants of heterogeneity when sufficient data are available.

Subgroup analysis and meta-regression

If possible, subgroup analyses will be undertaken as follows:

1. Study setting (high-income vs middle-income vs low-income countries).
2. Delivery mode of the intervention which shares the same theoretical modality (eg, face-to-face vs web-based TFCBT).

Meta-regression analysis

1. Intervention frequency (eg, number of sessions).
2. Methodological heterogeneity of trial (eg, ways of dealing with missing data, whether effect estimates from 'per-protocol' analyses differ compared with 'ITT' analyses).

Sensitivity analysis

Sensitivity analyses will be conducted to assess the effects of quality of trial methodology by comparing the results of meta-analyses with and without trials that are judged to have a high risk of bias for one or more of the domains of random sequence generation, allocation concealment, blinding of outcome assessment or incomplete outcome.

A sensitivity analysis will also be conducted to examine potential bias caused by missing data, by comparing results from different methods of dealing with missing data (eg, available case analysis, ITT analysis using imputation of outcomes, assuming that all missing participants had positive outcome or that all missing participant had negative outcomes). Results of sensitivity will be reported in a summary of findings table.

Ethics and dissemination

Ethical approval is not required to conduct systematic reviews. The protocol was registered in PROSPERO (CRD42016043897). The findings of the review will be presented at relevant national and international conferences and submitted to a peer-reviewed journal.

DISCUSSION

There is a lack of acknowledgement that women postpartum may be at risk of developing symptoms of trauma or PTSD. This means that their mental health needs likely remain undetected and unmet and, importantly, symptoms may impact on childcare and rearing. Women are not routinely included in studies investigating the effectiveness of psychological interventions for PTSD, and therefore we know little about whether these interventions are effective and acceptable to this population. We believe that this systematic review will be a valuable contribution to improving women's mental health and well-being following childbirth.

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