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Research Article

The Effectiveness of Psychosocial, Psychological, and Psychoeducational Interventions for Women to Reduce Perinatal Depression in Low- and Middle-Income Countries: A Systematic Review and Meta-Analysis PROTOCOL

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Abstract

Background: The most common mental health condition that affects perinatal women and mothers worldwide is depression. Systematic reviews have been done to assess psychosocial, psychological, and psychoeducational interventions for depression during the perinatal period. However, most of them only include high income countries. The aim of this systematic review and meta-analysis is to synthesize and evaluate all the available evidence related to the effectiveness of these interventions of perinatal women with depressive symptoms in low- and middle-income countries. Methods and analysis: A systematic review and meta-analysis is going to be conducted on the basis of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols 2020 statement. Randomized controlled studies will be identified through PubMed, CINAHL, Web of Science, PsycINFO, Scopus, Cochrane Register of Controlled Trial, ClinicalTrials.gov and revise through grey literature. Bridging searches will be also conducted through the competition of the review and articles meeting inclusion criteria will be added. Results will, where possible, be synthesized in statistical meta-analysis using Review Manager 5.4. Effect sizes expressed as odds ratio for categorical data and Standardized Mean Differences (SMD) for continuous data. The risk of bias is going to be assessed by The Cochrane Collaboration risk of bias tool. The standard χ^2 and I^2 tests will be used to quantify the amount of statistical heterogeneity. Sensitivity and subgroup analyses will be performed as well. Publication bias will be checked with funnel plots. Assuming included studies in the systematic review will be carried out with very different populations or types of interventions random effects model will be more conservative.

Introduction

Approximately 11.9% women in the perinatal period are disturbed by depression [1]. Perinatal period is often defined as the time between conception and up to one year postpartum [2]. The Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5) defines perinatal depression as a major depressive episode with peri-partum onset, i.e., symptom onset during pregnancy or in the four weeks following delivery [3] but other definitions on perinatal depression described it as an episode of depression occurring up to 1 year after delivery [4]. Although variation exists between settings, an estimated 16% of women are affected by depression in pregnancy and 20% in the postnatal period [5].

Perinatal depression syndromes are associated with pregnancy or the postpartum period which includes significant mental and behavioural changes e.g., such as difficulty of concentrating, feelings of guilt, hopelessness, thoughts of self-harm or suicide, changes in appetite, insomnia, unrest, and reduced energy [6]. From an economic point of view, the lifetime costs of maternal mental health disorders alone to both mother and child have been estimated at $112,299 and $51,622, separately [7]. Therefore, the prevention and early intervention is important not only because of the wellbeing of mother, child, and the whole family but also because of the economic resources worldwide [8]. Most maternal depression in Low and Middle-Income Countries (LAMICs) remains undetected and untreated [5]. Metanalysis by Gelaye's et al., showed that antepartum and postpartum depression in LAMICs were highly prevalent affective about one out of four and one in five women, respectively. This is due to several social and environmental conditions including the higher prevalence of poverty, early child abuse, and interpersonal violence in these nations [9].

Some research suggests that perinatal women with depression are inclined to choose psychotherapy interventions above pharmacological therapy due to the potential adverse effects of the medical treatments and because psychotherapy gives the chance to express their feelings during psychotherapy [10]. Furthermore, there are additional complications during pregnancy and breastfeeding, and women often find it difficult to accept medication during this time [5]. The World Health Organization, recommended in 2016 that psychological interventions should be the first line treatment for pregnant and breast-feeding women with moderate-severe depression (World Health Organization. Mental Health Gap Action Programme & World Health Organization, n.d.). Therefore, psychosocial, psychological and psychoeducation

approaches are more appropriate. Systematic reviews have been done to assess these treatments for depression during the perinatal period. However, most of them only include High Income Countries (HIC) [12-14]. Despite the positive results in HICs, it is well acknowledged that interventions used to treat mental illness in HICs may not always be applicable for the needs of LAMICs [15].

Yet very few systematic reviews have targeted LAMICs. Rahman's systematic review indicated that interventions – primarily psychoeducation, psychosocial and psychological interventions – proved more advantageous than standard care for both mothers and child (16); however, some of the included studies lacked baseline depression screenings for women to be included in the studies, which makes the results more ambiguous. Moreover, the last studies were included in 2012 and since then, some RCTs have been performed [17-20]. Gajaria & Ravindran conducted a systematic review in 2018 were qualitative investigations and case reports were included and no meta-analysis was conducted [15]. Barbui, et al., published in 2020 an umbrella review of the efficacy of psychosocial interventions for mental health outcomes in LAMICs, however, the only systematic review related to postpartum depression was the one published by Rahman et al. [16,21].

Poor mental health during the perinatal period is not uncommon and it has significant repercussions on the well-being of mothers and their children [22]. To our knowledge, no clinical practice recommendation has been made for nurses, midwifes or health workers related to reduce perinatal depression and anxiety symptoms in women from low- and middle-income countries in which are the effectiveness of psychosocial, psychological, or psychoeducational interventions. The aim of this systematic review and meta-analysis is to synthesize and evaluate all the available evidence related to the effectiveness of psychosocial, psychological, and psychoeducational interventions of perinatal women with depressive symptoms in low- and middle-income countries compare to routine care.

The research question is what is the effectiveness of psychosocial, psychological, and psychoeducational interventions in improving depressive symptoms among perinatal from low- and middle-income countries?

Methods

This is a protocol for a systematic review and meta-analysis of the literature on the basis of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols 2020 statement [23]. The protocol of this systematic review is published in PROSPERO (CRD42023453042)

Eligibility Criteria

The inclusion and exclusion criteria of the studies (Table 1) are defined based on the Participants, Interventions, Comparator, Outcomes, and Study type framework (PICOS) schema [24].

	Inclusion Criteria	**Exclusion Criteria**
Topic	Papers evaluating psychosocial, psychological, and psychoeducational interventions in which outcomes intend to improve depression in women during perinatal period	Papers evaluation other therapies
Setting	Low- and middle-income countries and upper middle-income countries	High-income countries
Types of studies/ designs	Individual RCT Cluster RCT	All the other type of studies which are not RCT
Type of publications	Any papers published	
Language	English, Spanish or French	Other than the ones described in inclusion criteria

Table 1: Inclusion and exclusion criteria.

Participants

The participants will be women in perinatal period (pregnancy and postpartum up to 1 year) who have been screen positive or have a diagnose of depressive symptoms before being involved in the study. Depression must be diagnosed or screen positive by any of the following criteria at baseline: diagnosed according the diagnostic and statistical manual of mental disorders (DSM-IV or DSM-V) by a mental health specialist or a screened with positive depression symptoms by a trained health worker with the following validated scales or self-reported depression items 1) Edinburg Postnatal Depression Scale (EPDS), 2) Hamilton Rating Scale for Depression (HRSD), 3) Postpartum Depression Scale (PPDS), 4) Major Depression Inventory (MDI), 5) Beck Depression Inventory (BDI), 6) Inventory to Diagnose Depression (IDD), 6)Centre of Epidemiological Studies Depression Scale (CES-D), 7) Zung Self rating depression scale (SDS), 8) Patient Health Questionaire-9 (PHQ-9) among other validated and self-reported questionaries' and scales. Studies that include non-depressed and depressed perinatal women in the same study will be include if they report the information separately. Women to whom the intervention is delivered before delivery, a report of the outcome after delivery is needed, if not the study will be excluded.

Studies will be excluded if women included in the trials suffer from serious diseases such as heart, lung, kidney, hypertension, autoimmune system illness or hypertension or complications during pregnancy and delivery as preeclampsia, antepartum haemorrhage, gestational diabetes, or complications in the parturient or infant threaten of abortion, preterm labour, or foetal mal formation. Moreover, if they suffer other stress factors after delivery related to infant complications which require a time in the Neonatal Intensive Care Unit (NICO) they will be excluded as well.

Type of interventions

Studies which delivered a psychosocial, psychoeducational, and psychological interventions are going to be included, the overall interventions that are going to be included are: 1) problem solving 2) behavioural activation 3) cognitive behavioural therapy 4) interpersonal therapy 5) education in depression and symptomology 6) and therapeutic support along with other interventions considered inside these interventions' categories.

Usually more than one type of interventions is given in real practice, as well as pharmacotherapy. In those studies where patients are taking antidepressants while during the intervention are going to be also included but not when the intervention consists exclusively in pharmacotherapy delivery or pharmacotherapy education.

Those studies in which other family members are include they can be included in the systematic review if there is any outcome assessing depression in women during perinatal period.

Comparators

The comparator intervention for this systematic review is going to be: 1) Enhance Usual Care (EUC) including all services normally available in the clinics, including antidepressants, medical consultations, external referral for other speciality treatment or medical consultations 2) no intervention and 3) in the studies

conducted after 2010, enhanced usual depression care (EUDC) based on the Mental health Gap Active Programme (MhGAP) which aims at scaling up services for mental health in low- and middle-income countries, are going to be included as active control (11). If in the clinics any type of psychosocial, psychological, or psychoeducational intervention is delivered as part of usual care, they are going to be excluded only if the health workers in the clinic have been given any type of training in these interventions except studies which they take MhGAP as an active control since it is part of the intervention itself.

Outcomes measures

Primary outcome

Outcomes assessment ≤6 months post-delivery of psychosocial, psychological, and psychoeducational interventions are associated with changes with depression or depression symptoms in perinatal women. We hypothesized the identified outcomes will include changes in scales and self-reported measures as Edinburg Postnatal Depression Scale (EPDS), Hamilton Rating Scale for Depression (HRSD), Postpartum Depression Scale (PPDS), Major Depression Inventory (MDI), Beck Depression Inventory (BDI), Inventory to Diagnose Depression (IDD), Centre of Epidemiological Studies Depression Scale (CES-D) and Zung Self rating depression scale (SDS).

If more than one assessment is made during this period, we are going to choose the result closer to 6 months postpartum.

Secondary outcomes

Outcomes in 1) Depression assessment >6 months post-delivery of psychosocial, psychological, and psychoeducational interventions are associated with changes with depression or depression symptoms in perinatal women following the same scales presented before, 2) anxiety: Beck Anxiety Inventory (BAI), Generalized Anxiety Disorder 7-item scale (GAD-7); 3) quality of life in any validated scale: Penn State Worry Questionnaire (PSWQ), the Quality of Life Scale (Flanagan, 1978) (QOLS), McGill Quality of Life Questionnaire — Expanded (Cohen et al., 2019) (MQOL), Health-Related Quality of Life Questionnaire (CDC, 2000) (HRQOL), World Health Organization Quality of Life Instrument (WHO, 2012) (QOL). Also, satisfaction of the programme from the participants if reported and adverse effects outcomes: suicide attempts, hospitalization required related to perinatal depression or anxiety etc. For outcomes 2, 3 and 4 the best time point assessment is going to be considered at 6 months, if not, the closest to this time point.

Study design

Eligible studies include RCTs as well as cluster RCTs methodology and protocols, feasible or pilot studies with available data following these study designs. Quasi experimental RCTs will be excluded, as were one group pre-test post-test, case reports, qualitative studies, and conference abstracts.

Those studies with poor report or low quality understood are going to be excluded even though they match all the other criteria. They will be considered as poor report if they have high risk of bias considering they have more than three high risk of bias items or four concerns in risk of bias assessment.

Setting and language

There are no restrictions in the study publication date, but only studies published in English, Spanish and French are going to be eligible.

Information Sources

A systematic search of the following electronic databases will be conducted in PubMed, CINAHL, Web of Science, PsycINFO, and Scopus. We will search for unpublished completed or ongoing trials in the Cochrane Register of Controlled Trial (CENTRAL) and Clinicaltrials.gov and revise through Google Scholar. In addition, reference lists of articles of interest and citations of the included articles will be screened for additional eligible published studies. Medical Subject Headings (MeSH) terms and keywords are going to be use related to prenatal depression and anxiety in women from LAMICs. The search is going to be conducted in April 2023. However, we will screen and include studies published till the systematic review is completed.

Search strategies and terms are going to be developed in collaboration with a health science librarian (LL). The search strategy follows PICOS format with the following concepts: prenatal or postpartum period, depression and/or anxiety, psychoeducation or psychoeducation or psychological interventions, low- and-middle-income countries and RCTs.

Search strategy

The search strategy will contain the terms pregnancy, postpartum, psychosocial, psychoeducation, psychological, depression and developing countries with other MeSH and terms combined with Booleans operators OR, AND, NOT. Firstly, it is going to be conducted in PubMed and after at the other databases adapting the first one.

Selection process

The study selection process will be conducted by two reviewers independently (MB and JR) after duplicate elimination. In the first phase the two reviewers will screen in duplicate separately the titles and abstracts. Only those studies who have been agreed to screen full text will be screen in the second phase after agreement.

In the second phase we will review full articles and the determination of eligibility will be based on inclusion and exclusion criteria, reviewed by the two reviewers again. The rationale of exclusion criteria will be reported for each study excluded.

Disagreements in the different phases are going to be discussed and if no consensus is reached between the two reviews, a third independent reviewer will resolve the disagreements (ML). If necessary, authors from the possible eligible studies are going to be contacted to resolve any question that might have an impact in the eligibility process.

The PRISMA flow diagram 2020 will be used to present the overall search and selection process [23].

Data collection process

Data is going to be extracted using a customised data extraction form purposefully designed for this systematic review. The following information will be extracted: authors, publication year, country, target population, inclusion and exclusion criteria, sample size, outcome points assessments, intervention and sessions detailed, control and characteristics detailed and efficacy of interventions mainly.

Study risk of bias assessment

The risk of bias is going to be assessed by The Cochrane Collaboration risk of bias tool (RoB 2) [25] from the included studies by two team members independently (MB and JR).

This tool assesses the risk of bias in the following domains: 1) bias arising from the randomization process 2) bias due to deviation from intended interventions 3) bias due to missing outcome data 4) bias in the measurement of the outcome 5) bias in the selection of the reported result.

Therefore, the overall risk-of-bias judgment will be judged as low risk of bias, some concerns or high risk of bias depending on the individual domains previously assessed. In case of disagreements a third reviewer (ML) is going to be consulted. If additional information from the original authors is needed, authors are going to be corresponded.

Meta-analysis

Results will, where possible, be synthesized in statistical meta-analysis using Review Manager 5.4. Effect sizes expressed as odds ratio for categorical data and Standardized Mean Differences (SMD) for continuous data, and their 95% confidence intervals will be calculated for the analysis. When SMD is not provided, if data is available it is going to be calculated.

Clinical and methodological heterogeneity of studies will be assessed by comparing study designs, participant characteristics, interventions, and outcomes. The standard Chi2 and I2 tests will be used to quantify the amount of statistical heterogeneity. We assume that studies included in the systematic review will be carried out with very different populations or types of interventions, for this reason random effects model will be more conservative.

The results will be displayed as forest plots. To manage potential sources of heterogeneity, subgroup analysis will be planned considering:

- Start of the intervention (before/after delivery)

- Number of sessions (<15 sessions/ ≥15 sessions)

- Delivery mode (face to face/ internet based/ telephone base)

- Providers (peers or non-health workers/ trained health workers/ experienced mental health providers)

- Different interventions (psychosocial/psychological/ psychoeducational)

Sensitivity analysis will be performed excluding studies with high risk of bias, anti-depressive medication studies and outliers. We will consider high risk of bias articles, those ones that has two high risk of bias or more, or one high risk of bias plus one or more concerned risk of bias. We will consider outliers, those ones where confidence interval does not overlap the other ones.

Where statistical pooling is not possible due to clinical, methodological, or statistical heterogeneity, the findings will be presented in narrative form including tables and figures to support the data presentation where appropriate.

Certainty assessment

The overall certainty is going to be assessed with The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach for grading the certainty of evidence [26] and a summary of findings will be created using GRADEPro GDT [27]. The Summary of findings will present the following information where appropriate: absolute risks for the treatment for the treatment and control, estimates of relative risk, and a ranking of the quality of the evidence based on the risk of bias, directness, heterogeneity, precision, and risk of publication bias of the review results.

Ethics and dissemination: The ethical assessment is not required.

PROSPERO registration number: (CRD42023453042).

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