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Effectiveness of psychological, psychoeducational and psychosocial interventions to prevent postpartum depression in adolescent and adult mothers: study protocol for a systematic review and meta-analysis of randomised controlled trials

Carmen Martín-Gómez [1], Patricia Moreno-Peral [2,3], Juan A Bellón [2,3,4,5], Sonia Conejo Cerón [2,3], Henar Campos-Paino [2,3], Irene Gómez-Gómez [1], Alina Rigabert [1,6], Isabel Benítez [1], Emma Motrico [1,2]

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For numbered affiliations see end of article.

Correspondence to
Dr Patricia Moreno-Peral; predictmalaga@hotmail.com

ABSTRACT

Introduction The prevalence of postpartum depression (PPD) is 17%, and the incidence is 12% worldwide. Adverse consequences for mothers and babies have been associated with this disease. To assess the effectiveness of psychological, psychoeducational and psychosocial interventions in preventing PPD, a systematic review and meta-analysis (SR/MA) will be conducted.

Methods and analysis A SR/MA will be performed following the indications of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Studies will be identified through MEDLINE (Ovid and PubMed), PsycINFO, Web of Science, Scopus, CINAHL, Cochrane Central Register of Controlled Trials, OpenGrey, Australian New Zealand Clinical Trial Registry, ClinicalTrials.gov and evidencebasedtherapy.org from inception until 31 January 2020. Bridging searches will be also conducted until the review is completed. The selection criteria will be as follows: (1) subjects will be pregnant females or females who have given birth in the last 12 months and who were non-depressive at baseline; (2) psychological, psychoeducational and psychosocial interventions; (3) comparator will be usual care, attention control, waiting list or no intervention; (4) outcomes will be specific results on PPD; and (5) the design of the studies will be randomised controlled trials. No restrictions regarding the year of publication, the setting of the intervention or the language of publication will be considered. Pooled standardised mean differences and 95% CIs will be calculated. The risk of bias of the studies will be assessed through the Cochrane Collaboration risk of bias tool. Heterogeneity between the studies will be determined by the I^2 and Cochran's Q statistics. Sensitivity and subgroup analyses will also be performed. Publication bias will be checked with funnel plots and Egger's test. Heterogeneity will be explored by random-effects meta-regression analysis.

Ethics and dissemination The ethical assessment was not required. The results will be presented at conferences and disseminated through publications.

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Strengths and limitations of this study

- This systematic review and meta-analysis (SR/MA) of randomised controlled trials (RCT) will assess the effectiveness of psychological, psychoeducational and psychosocial interventions in preventing postpartum depression (PPD).
- This SR/MA will include results on PPD throughout the whole period considered 'postpartum period', up to 12 months after delivery.
- In this study, we will analyse which variables can explain the heterogeneity in the results.
- This study will include only RCTs that have been performed with psychological, psychoeducational and/or psychosocial interventions.
- This study will conform to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement to achieve high scientific quality.

INTRODUCTION

Postpartum depression (PPD) is one of the most common postnatal complications following childbirth.[1] PPD shares the same diagnostic criteria for major depressive disorders, with an onset specifier of within 4 weeks after delivery according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-V)[2] or within approximately 6 weeks after delivery according to International Classification of Diseases 11th Revision.[3] Despite

these criteria, empirical research and reviews consider the 'postpartum period' to be from the first hours after delivery to 1 year after childbirth.[4–7] The most common symptoms of PPD are fatigue, sadness, difficulty concentrating, lack of interest in the baby, feelings of being a bad mother, fear of harming the baby or oneself and a loss of interest or pleasure in life.[8] PPD also increases the risk of later depression in the mother.[9] Furthermore, in extreme cases, it can also lead to suicidal ideation, attempted suicide or suicide.[10] Moreover, PPD affects the health of children and is associated with an increased risk of their psychological and developmental disturbances.[8] Globally, depression is considered a major public health issue that is twice as common in women during childbearing ages than in men.[11] The burden of disease in terms of years lived with disability attributable to major depression is increasing, ranking third in the world in high-income countries.[12] Two recent systematic reviews and meta-analyses (SR/MA) have shown that although it varies by nation, the global prevalence of PPD is approximately 17%, and the incidence is 12%.[13 14]

Early psychosocial or pharmacological treatments are recommended to reduce the prevalence of PPD, improve the health conditions of females and their families and reduce costs.[15 16] While there are effective treatments for PPD,[17 18] treatments alone are not sufficient to minimise the development, intensity and duration of maternal depressive symptoms and their potential impact on an infant.[8] An additional way to reduce the burden of PPD is to lower the incidence of new cases, which can be achieved through prevention.[19] The majority of preventive interventions for depression available are based on psychological, psychoeducational or psychosocial approaches.[20]

The prevention of PPD is attracting increasingly more interest. In support of PPD prevention, there are a multitude of randomised controlled trials (RCTs) as well as some SRs/MAs that have addressed this topic. To date, six SRs/MAs on the effectiveness of interventions that prevent PPD, including psychological, psychoeducational and/or psychosocial strategies, have been published.[20–25] However, there are some differences between these previous SRs/MAs and this work. First, the majority of the previous SRs/MAs included females with a diagnosis of depression at the beginning of the intervention[22–25] or only excluded the trials in which more than 50%[20] of the females were depressed at baseline. Second, two studies focused on specific kind of psychological interventions, such as family therapeutic interventions and self-help psychological interventions.[24 25] Finally, one of the SRs/MAs only included studies conducted in countries ranked as having 'very high' human development according to the WHO.[20] Additionally, new RCTs on interventions for the prevention of PPD have been recently published. Therefore, robust evidence synthesis that follows methodologically rigorous processes to systematically identify psychological, psychoeducational and psychosocial interventions and analyse their effectiveness could be considered beneficial in promoting interventions for the prevention of PPD.

Given the aforementioned reasons, the goal of this study is to conduct an SR/MA of RCTs assessing the effectiveness of psychological, psychoeducational and psychosocial interventions in preventing PPD in females during the first postpartum year.

METHODS AND ANALYSIS

This is a protocol for an SR/MA whose design has followed the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols 2015 statement.[26] The protocol of the study was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 29 October 2018 and was last updated on 4 September 2019.

Eligibility criteria

The inclusion and exclusion criteria of the studies (see table 1) were defined based on the participants, interventions, comparator, outcome and study design (PICOS) schema.[27] The objective was to determine the effectiveness of psychological, psychoeducational and psychosocial interventions in preventing PPD.

Participants

The participants will be adolescents and adult mothers who had given birth in the previous 12 months. Since some interventions may begin before delivery, pregnant women will also be included when the study reports a measure of PPD after delivery. Studies that included females with a diagnosis of depression will not be considered in this SR/MA in order to distinguish the programmes designed to prevent PPD from other possible kinds of interventions. To this end, depression will be required to have been discarded through any of the following criteria at baseline: diagnosis by a mental health specialist, validated scales with standard cut-off points (eg, Patient Health Questionnaire-9 or Edinburgh Postnatal Depression Scale) or standardised interviews (eg, Structured Clinical Interview for DSM Disorder or Composite International Diagnostic Interview). Studies that include depressed and non-depressed females at baseline will also be included if they provide separate results for the non-depressed participants. If necessary, the authors will be asked for this information. Studies with a subset of females with a history of depression will be included. It is not required that psychiatric disorders other than depression have been ruled out at baseline.

Type of interventions

Studies will be eligible based on the inclusion of psychological, psychoeducational or psychosocial interventions. In this context, psychological interventions are those focused on changing the thoughts and behaviours of an individual (eg, cognitive–behavioural therapy, interpersonal psychotherapy and psychological debriefing).[21] Psychoeducational interventions aim to inform females

Table 1 Inclusion and exclusion criteria

Criteria	Inclusion criteria	Exclusion criteria
Population	Adolescents and adult mothers* who had given birth in the previous 12 months and were not depressed at baseline.	Other populations.
Intervention	Psychological, psychoeducational and psychosocial interventions.	Any other type of intervention such as a pharmacological intervention, acupuncture, aromatherapy or a similar intervention.
Comparator	No intervention, usual care, waiting list and attention control.	Any type of intervention with available evidence of its effectiveness in preventing depression.
Outcome	Prevention of postpartum depression (incidence and/or reduction of symptoms).	Different outcomes or trials in which the effects on postpartum depression and other diseases are provided together.
Study design	Randomised controlled trials.	Other designs.
Language	All languages.	None.
Setting	All settings.	None.

*Pregnant females will be included when the study reports a measure of depression after delivery.

regarding PPD without engaging them in an active intervention that has been designed to change their behaviours or moods (eg, informative sessions and the distribution of fact sheets).[22] The goal of psychosocial interventions is to promote changes through certain links with the social environment (eg, home visits, telephone support, group interventions and interventions in which the woman's partner has been included in the session).[21 28] The above-mentioned definitions are based on previous SRs/MAs. Despite this differentiation, psychological, psychoeducational and psychosocial interventions usually overlap in real practice. Interventions carried out before and/or after delivery will be included. Furthermore, studies in which the interventions are focused on couples and/or other family members in addition to the females themselves will be included.

Comparators

The comparator in eligible studies will be any of the following: usual care, attention control (which is based on any type of intervention for which there is no available evidence about its effectiveness in preventing PPD) or waiting list. Studies where the control group does not participate in any type of intervention but undergoes the same assessments as the intervention group will also be included.

Outcome

Studies will be included when they report the incidence of new cases of PPD and/or the reduction of postpartum depressive symptoms during the first postpartum year as a primary or secondary outcome. It will be required that outcomes were measured by validated scales or standardised interviews. If more than one scale was used to measure PPD in the same study, the following action will be taken: a hierarchy will be developed, and the instrument most used across all the studies will be selected. Otherwise, if the instruments used in one study do not have a high frequency of use, it will be selected the best validated instrument for the country and setting in which the study was conducted. This method allows all studies, regardless of the instrument used to measure the outcome, to be included in the meta-analysis, for the sake of optimal power and representativeness.[29] When a study provides results of PPD and other diseases together (eg, anxiety), the authors will be contacted to request these data separately. If the authors do not have this information or they do not reply to the query, the study will be excluded.

Study design

Studies will be eligible when they are original and use a quantitative RCT methodology, including cluster RCT methodology. Other kinds of design such as cross-over trials or quasirandomised trials will be excluded from this SR/MA. RCTs will be included because they are a reference standard for clinical trials; they provide more evidence on causality than other types of studies do.[30] Characteristics such as sample size, study duration and the number of treatment sessions have no limitations and will be described in the qualitative analysis. The blinding also does not have limitation, but it will be assessed through the Cochrane Collaboration risk of bias tool.

Setting and language

No limits will be imposed on the study publication language or publication date.

Information resources and search strategy

A literature search will be systematically conducted by using the following electronic databases: MEDLINE (through Ovid and PubMed), PsycINFO, Web of Science, Scopus, CINAHL, Cochrane Central Register of Controlled Trials, OpenGrey (System for Information on Grey Literature in Europe), Australian New Zealand Clinical Trial Registry, ClinicalTrials.gov and evidencebasedtherapy.org. This

search will be performed using Medical Subject Headings and keywords related to RCTs, prevention and PPD. The online supplementary file shows PubMed's search strategy, as the search will be developed first in PubMed. Then, the search will be adapted to the rest of the above-mentioned databases, always following the PICOS format. In addition, PROSPERO will be searched for similar ongoing or recently completed systematic reviews. Furthermore, to ensure literature saturation, recent SRs/MAs in the field will be hand-searched, and their reference lists will be reviewed, as well as the references from the RCTs included in this SR/MA. Moreover, authors from studies meeting the inclusion criteria and experts in the field will be contacted to identify additional relevant studies missing in our search. No restrictions on the language or setting will be implemented. It is expected that the time frame of the search will extend from inception to 31 January 2020. Bridging searches will also be conducted to capture literature until the review is completed.

Study selection

The whole study selection process will be conducted independently by two researchers. This process will be performed in the following consecutive phases: After duplicate records are eliminated, the titles and abstracts of all studies will be reviewed. Studies that do not meet the inclusion criteria will be excluded. Full-text articles from the remaining records will then be screened to assess eligibility. Disagreements will be discussed until a consensus is reached between the two reviewers, or, if necessary, a third independent reviewer will resolve the disagreement. Additional information will be sought from the corresponding author to resolve any questions about eligibility. The kappa index[31] will be calculated to assess the level of agreement between the studies.

Data extraction

A purposefully designed data extraction sheet will be completed independently by two reviewers to display the most relevant characteristics of each study. Discrepancies will be resolved by a consensus between the two reviewers or by a third independent reviewer. Regarding the qualitative data that will be collected, it will include author/year and country, target population characteristics (whether the females are nulliparous or multiparous, whether they are adolescents or adults, whether the intervention is aimed explicitly at females who belong to a specific ethnic minority and whether they have a history of depression), session details for the intervention group (type of prevention, type of intervention, orientation, setting and provider, intervention duration (number of sessions and estimated contact hours, frequency of sessions), whether there were prenatal or postnatal sessions as well as whether there were other people participating in the intervention, such as fathers or any other relative), sample size (control/intervention) and type of control group. Furthermore, the exclusion criteria regarding the depressive females at baseline and validated instruments used (cut-off if a scale was used), prevention depression outcomes and validated instruments used (cut-off if a scale was used) and follow-up information provided by the RCTs will be collected.

Risk of bias

The Cochrane Collaboration risk of bias tool[27] will be used to assess the quality of the studies included. This tool allows the quality of the studies to be measured by six criteria: (1) random sequence generation, (2) allocation concealment, (3) blinding of the participants and clinicians, (4) blinding of the outcome assessments, (5) incomplete reporting of the outcome data, and (6) selective reporting of the data. In all items, 0 points are assigned for low risk of bias, 1 point is assigned for unclear risk and 2 points are assigned for high risk. Therefore, the risk of bias score will range from 12 to 0. The quality ratings will be checked by two reviewers, and disagreements will be resolved through discussion and consultation with a third independent reviewer. The inter-rater reliability will be rated using intraclass correlation coefficients.[31] The authors from the original articles will be contacted if additional information is required.

Assessment of publication bias

To assess the publication bias, a funnel plot will be examined. Following the approach proposed by Duval and Tweedie,[32] the number of studies that are missing from the funnel plot will be estimated, if any. The effect size after the imputation of these missing studies will be estimated by the trim-and-fill method. Begg and Mazumdar's test[33] and Egger's test[34] will also be performed.

Meta-analysis

Quantitative data from each study will be extracted and inserted into an Excel sheet by two independent reviewers. Statistical analyses will be carried out by using the Comprehensive Meta-Analysis (CMA) software package V.2.2.021 and STATA Release V.14.2.

Standardised mean differences (SMD) and 95% CIs will be used to calculate the effect sizes, as we expect that most of the RCTs included in our meta-analysis will have reported the differences in symptoms of PPD. For studies that only report the incidence of PPD, CMA will be used to obtain the equivalent SMD. The first postintervention measure that was assessed after delivery and reported in the study will be the measure used for the effect size analyses. The effect size will be interpreted by Cohen's proposal: 0.20 corresponds to a small effect size, 0.50 corresponds to a medium effect size and 0.80 corresponds to a large effect size.[35] A random effects model will be selected under the assumption that studies included in the meta-analysis have been carried out with heterogeneous populations.[27] When studies report multiple intervention groups, they will be recorded as different groups, and the effect sizes will be calculated separately for each intervention and control group. We will inflate the SEs

of nested comparisons in the same RCT by following the suggestions of Cates.[36]

Heterogeneity of the effect sizes will be estimated through forest plots, the Cochran's Q statistic and its p value. Heterogeneity will also be tested by the I^2 statistic, which can quantify the heterogeneity ranging from 0% (no heterogeneity) to 100% (the differences between the effect sizes can completely be explained by chance alone), and the interpretations of the percentages are as follows: 0%–40% indicates potentially unimportant heterogeneity, 30%–60% indicates moderate heterogeneity, 50%–90% indicates substantial heterogeneity and 75%–100% indicates considerable heterogeneity.[27]

Sensitivity analyses will be performed using a fixed effects model and a Hedges' g. RCTs from the analysis will be excluded when they have a high risk of bias (a score of 6 points or more) or elicit a large increase in heterogeneity. Furthermore, sensitivity analyses will be performed regarding the average of all follow-ups reported in the studies.

To explore the heterogeneity across studies, subgroup analysis will be performed using a mixed effects model according to the following variables: previous deliveries (eg, primiparous only vs primiparous and multiparous), history of depression (females without history of depression only vs females with and without history of depression), risk level (females with specific risk factors vs general population), age (adolescents vs adolescents and adults), ethnicity (intervention aims to females from a specific ethnic group vs not) and intervention timing (pre partum only vs pre partum and post partum vs post partum only).

Meta-regressions will be conducted to explain the between-trial heterogeneity. Prior to the data being included in meta-regression analysis, normality of the distribution will be confirmed by skewness and kurtosis normality tests,[37] and the pertinent transformations will be performed to obtain approximately normal data distributions when necessary. Risk of bias and sample size will be included in the meta-regression models, and the models will be adjusted for these factors; sample size only will be included if publication bias is detected. Of the covariables considered for subgroup analysis, those with a significance level of $p<0.15$ and those that were not removed from the model due to collinearity will also be included in meta-regression models. CIs and SEs will be calculated using the Knapp and Hartung method.[38] P values will be calculated using the Higgins and Thompson[39] permutation test, taking into account multiplicity adjustments, if necessary. A plot of the standardised shrunken residuals will be used to test goodness of fit in the meta-regression models.

Quality of evidence

To determine whether the estimated effect size is reliable, the Grading of Recommendations Assessment, Development and Evaluation[40] system will be used. This system helps to evaluate the quality of evidence in the domains of risk of bias, consistency, directness, precision and publication bias through four categories: high, moderate, low and very low.

Patient and public involvement

No patients or public are involved.

Ethics and dissemination

Due to the characteristics of this study, the ethical assessment was not required. The results from this SR/MA will be presented at international conferences related to this field and disseminated through peer-review publications.

DISCUSSION

This SR/MA will assess the effectiveness of psychological, psychoeducational and psychosocial interventions in preventing PPD. This study will summarise qualitative and quantitative evidence on this topic and will provide an overview of the current body of knowledge on PPD. A meta-analysis will be performed, and a statistical integration of the results will be used to compute common effect sizes and significance. The effect size, robustness and quality of evidence obtained in this meta-analysis will help determine whether psychological, psychoeducational and psychosocial interventions can prevent PPD or postpartum depressive symptoms. It is expected that the results found in this study can contribute towards improving the prevention of PPD and can be incorporated into perinatal mental health guidelines.

Author affiliations
[1]Department of Psychology, Universidad Loyola Andalucia, Dos Hermanas (Sevilla), Spain
[2]Prevention and Health Promotion Research Network (redIAPP), ISCIII, Madrid, Spain
[3]Instituto de Investigación Biomédica de Málaga (IBIMA)., Málaga, Spain
[4]El Palo Health Centre, Adalusian Health Service (SAS), Málaga, Spain
[5]Department of Public Health and Psychiatry, University of Málaga (UMA), Málaga, Spain
[6]Fundación Andaluza Beturia para la Investigación en Salud (FABIS), Huelva, Spain

Twitter Carmen Martín-Gómez @cArmen_MaRgO and Alina Rigabert @AlinaHep

Contributors CMG is the guarantor of the study. EM and CMG designed the study, and PMP, JAB, SCC, HCP, IGG, AR and IB collaborated on the design. CMG and EM drafted the protocol, and PMP and JAB revised the manuscript. CMG, SCC and HCP will independently screen the potential studies, extract the data, assess the risk of bias and complete the data synthesis. CMG, JAB and PMP will perform the data analyses. CMG, PMP, JAB, SCC, HCP, IGG, AR, IB and EM read, provided feedback, discussed and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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ORCID iDs
Carmen Martín-Gómez http://orcid.org/0000-0003-0748-2762
Patricia Moreno-Peral http://orcid.org/0000-0003-4130-9090
Juan A Bellón http://orcid.org/0000-0002-4268-4979
Sonia Conejo Cerón http://orcid.org/0000-0002-1357-2281
Henar Campos-Paino http://orcid.org/0000-0002-0563-3080
Irene Gómez-Gómez http://orcid.org/0000-0001-8014-6955
Alina Rigabert http://orcid.org/0000-0003-2121-7623
Isabel Benítez http://orcid.org/0000-0002-0141-0816
Emma Motrico http://orcid.org/0000-0002-0720-567X

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