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Effectiveness of web-based and mobile-based psychological interventions to prevent perinatal depression: Study protocol for a systematic review and meta-analysis of randomized controlled trials

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ABSTRACT

Introduction: Perinatal depression is one of the most common complications during pregnancy and one year following childbirth. A negative impact on the mental and physical health of women, their children, partners, or significant others has been associated with this disease. Web-based and Mobile-based psychological interventions can reduce the burden of the disease through prevention of new cases of depression. It is crucial to know the effectiveness of these interventions to implement them around the globe. This systematic review and meta-analysis aims to assess the effectiveness of Web-based and Mobile-based psychological interventions to prevent depression during the perinatal period.

Method and analysis: A systematic review and meta-analysis will adhere to the PRISMA guidelines. Studies will be identified through MEDLINE, PsycINFO, Web of Science, Scopus, CINAHL, CENTRAL, Opengrey, Australian New Zealand Clinical Trial Registry, National Institute for Mental Health Research at the Australian National University, clinicaltrial.gov, beacon.anu.edu.au, and evidencebasedpsychotherapies.org from inception until 31 March 2021. We will also search the reference lists provided in relevant studies and reviews. The selection criteria will be as follows: 1) pregnant women or women who have given birth in the last 12 months and who were non-depressive at baseline; 2) Web-based and Mobile-Based psychological interventions; 3) comparators will be usual care, attention control, waiting list or no intervention; 4) outcomes will be the incidence of new cases of perinatal depression and/or the reduction of depressive symptoms as measured by validated instruments; and 5) the design of the studies will be randomized controlled trials. No restrictions regarding the year or language of publication will be considered. Pooled standardized mean differences and 95% confidence intervals will be calculated. The risk of bias of the studies will be assessed through the Cochrane Collaboration risk of bias 2.0 tool. Heterogeneity and publication bias will be estimated. Sensitivity and sub-group analyses will also be conducted. Random effects meta-regression will be performed.

Ethics and dissemination: As a systematic review, ethical approval is not required. The results from this study will be presented at international conferences and disseminated through peer-reviewed publications. Patients and the public will be involved in the dissemination plans.

PROSPERO registration number: 230,089 (submitted).

1. Introduction

Perinatal depression (PND) is one of the most common complications occurring during pregnancy and one year following childbirth (Howard and Khalifeh, 2020). PND may be broadly defined as a non-psychotic depressive episode of mild to major severity occurring during

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pregnancy or in the first year after childbirth (Gavin et al., 2005; Gelaye et al., 2016). It is estimated to have an average prevalence of 12% (Woody et al., 2017), but the prevalence rates of depression among pregnant and postpartum women have been increasing during the COVID-19 pandemic, to 31% and 22%, respectively (Yan et al., 2020). When left untreated, PND carries a negative impact on the mental and physical health of women, their children, partners or significant others (Rao et al., 2019; Slomian et al., 2019). PND is also one of the leading causes of death for women during pregnancy and the year after giving birth (Martini et al., 2019; Orsolini et al., 2016; Esscher et al., 2016). Furthermore, PND brings a strong economic burden to society, which far outweighs the cost of providing appropriate services (Bauer et al., 2014).

Although numerous treatment options for PND are effective (NCCMH, 2018; Yonkers et al., 2009), not all depressed women receive appropriate diagnosis and treatment (Howard and Khalifeh, 2020; Vesga-López et al., 2008). Moreover, treatment alone is not sufficient to eliminate the disease burden imposed by PND. Decreasing this burden will be very difficult unless the incidence of new cases is reduced, and this is only possible through prevention (Cuijpers et al., 2012). There is robust evidence from systematic reviews and meta-analyses that psychological interventions are effective to prevent depression (Bellón et al., 2015) and perinatal depression (Curry et al., 2019). Cognitive behavioral therapy and interpersonal therapy are recommended, but other theoretical frameworks are promising (such as mindfulness-based approaches). More evidence about their effectiveness is needed (Curry et al., 2019; Shi and MacBeth, 2017).

Web-based and Mobile-based psychological interventions are attracting increasingly more interest for prevention of depression. Compared to face-to-face interventions, they are particularly accessible, sustainable, and provide low-cost scalable opportunities (Andersson and Titov, 2014; Christensen and Griffiths, 2002). Furthermore, women during the perinatal period are frequent users of the internet and social media, search for information on the internet about perinatal and postnatal topics (Sayakhot and Carolan-Olah, 2016), and are interested in mental health apps (Osma et al., 2016). Additionally, psychiatrists and psychologists have considered this kind of intervention delivery useful for preventing maternal depression (Sprenger et al., 2017).

Recent systematic reviews and meta-analyses showed that Web-based and Mobile-based psychological interventions are effective to prevent depression in the general population (Rigabert et al., 2020; Deady et al., 2017; Stratton et al., 2017; Sander et al., 2016), but the evidence is scarce concerning the prevention of perinatal depression. To date, eight systematic reviews aimed at overviewing Web-based and Mobile-based interventions during the perinatal period (Dosani et al., 2020; Hussain-Shamsy et al., 2020; Roman et al., 2020; Zhou et al., 2020; Ashford et al., 2016; Lau et al., 2017; Van Den Heuvel et al., 2018; Loughnan et al., 2019; Lee et al., 2016) have been published. However, their focus was not on prevention studies (studies on treatment interventions are also included); all types of interventions were included (such as healthy lifestyles and smoking cessation) and were restricted to the postpartum period. Furthermore, to date, new studies (Barrera et al., 2015; Chan et al., 2019; Haga et al., 2019; Le et al., 2020; Kelman et al., 2018; Fonseca et al., 2019) and study protocols (Nishi et al., 2020; Jones et al., 2013; Witteveen et al., 2020; Sun et al., 2019; Pilkington et al., 2017) on PND prevention through Web-based and Mobile-based psychological interventions have recently been published. Therefore, a systematic review of the effectiveness of Web-based and Mobile-based psychological interventions to prevent depression during the perinatal period is needed.

Given the aforementioned reasons, we aim to conduct a systematic review and meta-analysis of randomized controlled trials (RCTs) assessing the effectiveness of Web-based and Mobile-Based psychological interventions for preventing PND. This study is part of the Action Cost Riseup-PPD 'Research Innovation and Sustainable Pan-European Network in Peripartum Depression Disorder' (CA-18138) founded by the Horizon 2020 Framework Programme of the European Union (Fonseca et al., 2020).

2. Methods and analysis

This protocol study has followed PRISMA-P (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols 2015 Statement) (Moher et al., 2016) and will adhere to PRISMA (Moher et al., 2009) guidelines. The study has been registered in the International Prospective Register of Systematic Reviews (PROSPERO) on 20 January 2021, study protocol registration number: 230089 (submitted).

2.1. Eligibility criteria

The inclusion and exclusion criteria of the studies (see Table 1) were defined based on the Population, Intervention, Comparison, Outcome, Study Design (PICO-S) model (Higgins and Green, 2011). The rationale for our inclusion criteria is to have a broad and comprehensive assessment of Web-based and Mobile-Based psychological interventions for the prevention of PND.

2.2. Participants

The participants will be restricted to women during the perinatal period (from pregnancy to one year after childbirth). Studies that included women with depression will not be considered to ensure selection of preventive interventions (interventions that occur before the onset of a depressive disorder). To this end, we will include only studies that excluded at baseline depressed women or that provided separate results for non-depressed women at baseline, by using a standardized interview (e.g., Composite International Diagnostic Interview or MINI International Neuropsychiatry Interview) or validated self-reports with standard cut-off points (e.g., Patient Health Questionnaire-9 or Edinburgh Postnatal Depression Scale). As cut-off points of validated screening tools differs among countries and populations (Cox, 2019), the standard cut-offs points used by each study to exclude depressed participants must correspond to that obtained in a validation for the country and setting where the study was conducted. If this information is not provided or there is no information about separate results for non-depressed women, the authors will be contacted to request this data.

2.3. Type of interventions

Studies will be eligible based on Web-based and Mobile-based psychological interventions, defined as any therapeutic psychoeducational, psychosocial, or psychotherapeutic treatment with the stated aim of

Table 1
Inclusion and exclusion criteria.

Criteria	Inclusion criteria	Exclusion criteria
Population	Pregnant women and mothers who have given birth in the previous 12 months and were not depressed at baseline.	Other populations.
Intervention	Web-based and Mobile-based psychological interventions delivered entirely via the internet, mobile devices, or tablet computers, or blended.	Any other type of intervention and interventions including only face-to-face interventions will be excluded.
Comparator	The comparators will be usual care, attention control, waiting list or no intervention.	Other comparators.
Outcome	Prevention of perinatal depression (incidence and/or reduction of symptoms).	Other outcomes.
Study design	Randomized controlled trials.	Other designs.
Language	All languages.	None.
Setting	All settings.	None.

improving mental health delivered via the internet, mobile devices or tablet computers (Eysenbach and CONSORT-EHEALTH Group, 2011; Ebert et al., 2017). Web-based and Mobile-based interventions that are combined with face-to-face intervention (blended interventions) will be also included.

2.4. Comparators

Eligible comparators will be usual care (the routine care received by patients for prevention depression in everyday health practice), attention control, waiting list or no intervention.

2.5. Outcome

We will only include RCTs in which the primary or secondary outcome is the incidence of new cases of perinatal depression and/or the reduction of perinatal depressive symptoms measured by standardized interviews or validated symptom scales. If more than one scale was used to assess depression in the same study, the instrument most used across all the studies will be selected. If the instruments used in one study do not have a high frequency of use, the best validated instrument for the country and setting in which the study was conducted will be chosen. This procedure will permit us to select the best depression measure for the sake of optimal power and representativeness (Cuijpers, 2016). If the RCTs reported measures of perinatal depression and other disease together (e.g. anxiety), the authors will be contacted to request data separately. Only the depression data will be considered in our analyses.

2.6. Study design

RCTs will be the only study design selected because they represent the gold standard for evaluating health care interventions (Campbell et al., 2012). Cluster, hybrid implementation-effectiveness, pragmatic and pilot RCTs will be also included. Other kinds of designs such as cross-over trials or quasi-randomized trials will be excluded from this systematic review and meta-analysis.

Setting, language and publication date.

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

2.7. Information resources and search strategy

Relevant studies will be identified through a search in the following electronic databases: MEDLINE (through Ovid and PubMed), PsycINFO, Web of Science, Scopus, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), Opengrey (System for Information on Grey Literature in Europe), Australian New Zealand Clinical Trial Registry, National Institute for Mental Health Research at the Australian National University, and clinicaltrial.gov. This search strategy will be supplemented with hand searching of reference lists of articles and other relevant systematic reviews and meta-analyses on this topic. In addition, experts in the field and authors of the selected studies will be contacted and asked to complete the list of included publications. In addition, two academic websites comprising electronic databases will be also explored, “Beacon 2.0” (https://beacon.anu.edu.au) and “Psychotherapy, randomized controlled and comparative trials” (http://www.evidencebasedpsychotherapies.org/).

Search strategies will be developed using keywords and text words related to the perinatal period, web-based and mobile-based interventions, depression, prevention, and RCTs. They have been piloted in PubMed then will be adapted to the other databases. The databases will be searched separately by two reviewers. The Appendix A provides the PubMed search strategy, as the search has been developed first in PubMed following the PICOS model. Then, the search will be adapted to the rest of the abovementioned databases, always following the PICOS model. It is expected that the time frame of the search will extend from inception to 31 March 2021.

2.8. Study selection

The whole study selection process will be conducted independently by two researchers using Rayyan (Qatar Computing Research Institute, Hamad bin Khalifa University), a Web-based platform designed for data management for systematic reviews (Ouzzani et al., 2016). Two stages of screening for article selection will be conducted. In the first stage, after duplicate records are eliminated, the titles and abstracts of all the studies will be reviewed. Studies that do not meet the inclusion criteria will be excluded. In the second stage, full-text articles from the remaining records will then be screened to assess eligibility. Any disagreements will be discussed and resolved by consensus or by a third independent reviewer, if necessary. Additional information will be sought from the corresponding author to resolve any questions about study eligibility. Inter-agreement of the total selection will be assessed by the Kappa index (Fleiss et al., 2013). The reasons for the exclusion of studies will be reported in the characteristics of excluded studies tables.

2.9. Data extraction

After study selection, two independent reviewers will extract the most relevant characteristics from the original studies using a purposefully designed data extraction sheet. Discrepancies will be resolved by consensus between the two reviewers or by a third independent reviewer. We will also contact authors to obtain incomplete or unclear information, where appropriate. A priori author/year and country; target population characteristics (whether women are nulliparous or multiparous, whether they are adolescents or adults, whether the intervention is aimed explicitly at women who belong to a specific ethnic minority, and whether they have a previous history of depression); type of prevention (universal, selective, indicated); exclusion criteria of depression at baseline and validated instruments used (cut-off if a scale was used); inclusion criteria to participate; sample (control/intervention); conditions; intervention orientation and intervention details in both experimental and control groups (e.g. number of sessions); guidance (guided, unguided); outcome measure of prevention of depression; and evaluations during all follow-ups provided from the RCTs.

2.10. Risk of bias

The quality of the articles will be assessed using the risk of bias criteria proposed by the Cochrane Collaboration tool (RoB), version 2.0 (Eldridge et al., 2020). Hence, we will be able to distinguish between studies which appeared to give a reliable estimate concerning the review question and those studies where there appears to be a strong possibility that bias has been introduced. Each eligible study will be evaluated by two independent reviewers. Any disagreements will be discussed with the involvement of a third reviewer until consensus is reached. The authors of the original articles will be contacted if additional information is required.

2.11. Assessment of publication bias

Publication bias will be assessed by inspecting the funnel plot of the primary outcome measure and by Duval and Tweedie's trim-and-fill approach (Duval and Tweedie, 2000). This procedure generates an estimate of the effect size after adjusting for publication bias. Begg and Mazumdar's test (Begg and Mazumdar, 1994) and Egger's test (Egger et al., 1997) will also be performed.

2.12. Meta-analysis

At least two independent reviewers will extract quantitative data

from each study. We will present data from eligible studies in an evidence table and summarise using descriptive statistics. If studies are missing data needed to calculate the effect size, the authors will be contacted. If no response is received, the study will not be included in the statistical analyses. Comprehensive Meta-Analysis (CMA) software package, V.2.2.021 and STATA-Release V.14.2 will be used for the statistical analyses. CMA will also be used to convert the different data formats into a comparable format.

Effect sizes will be calculated using standardized mean differences (SMDs) and 95% confidence intervals (CIs), as we expect that most of the RCTs included in our meta-analysis will have reported the differences in symptoms of perinatal depression. The first post-intervention measure assessed and reported in the study will be the primary outcome of our meta-analysis. Cohen's effect size interpretation will be used: an SMD of 0.2 indicates a small effect size; 0.5, a medium effect size; and 0.8, a large effect size (Cohen, 1989). Under the assumption that studies included in the meta-analysis have been carried out with heterogeneous populations, a random effects model will be selected (Higgins and Green, n.d.). For multiple-arm trials, the pairwise difference between each arm and the control will be reported, and the effect sizes will be calculated separately for each arm and the control. To correct the fact that the control arm will be counted more than once, we will inflate the standard errors (SEs) of nested comparisons in the same RCT by following the suggestions of Cates (Cates, 2015).

Heterogeneity between the results will be assessed using forest plots, Cochran's Q test and its *p* value, and quantified with the I-squared statistic. According to the I-squared statistic, heterogeneity will be considered as follows: unimportant heterogeneity (0%–40%), moderate heterogeneity (30%–60%), substantial heterogeneity (50%–90%) and considerable heterogeneity (75%–100%) (Higgins and Green, n.d.).

We will perform sensitivity analyses to reflect the extent to which the meta-analytical results and conclusions may be altered as a result of changes in analytical approach. Sensitivity analyses will be performed using a fixed effects model and a Hedges' g. A sensitivity analysis will be performed excluding RCTs when these have a high risk of bias or cause the largest increase in heterogeneity. In addition, sensitivity analyses will be carried out with the average of all follow-ups reported in the studies.

A priori, we will perform subgroup analysis using a mixed-effects model according to the following variables: parity (e.g. primiparous only versus primiparous and multiparous), age (adolescents versus adolescents and adults), previous history of depression (women without previous history of depression only versus women with and without history of depression), type of prevention (indicated, selective, or universal), intervention orientation (Cognitive Behavioral Therapy vs. other), intervention guidance (guided vs. unguided), number of sessions, level of usability or adherence (if it was measured), and intervention timing.

Meta-regressions will be conducted. The normality of the distribution of the variables will be confirmed by skewness and kurtosis normality tests prior to inclusion in meta-regression analysis (D'Agostino et al., 1990), and 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 variables. However, sample size will only be included if publication bias is detected. Of the covariables considered for sub-group analysis, those with *p* values less than 0.15 and those that were not removed from the model due to collinearity will be included in the meta-regression models. CIs and SEs will be calculated using the Knapp and Hartung method (Knapp and Hartung, 2003). *P* values will be calculated using the Higgins and Thompson (Higgins and Thompson, 2004) permutation test, taking into account multiplicity adjustments, if necessary. We will use a plot of standardized shrunken residuals to test goodness of fit in the meta-regression models.

2.13. Quality of evidence

We will follow the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group methodology for assessing the quality of the evidence (Balshem et al., 2011). We will consider the domains of risk of bias, consistency, directness, precision, and publication bias through four categories: high, moderate, low, and very low.

2.14. Patient and public involvement

Patients and/or the public will not be involved in the design, conduct and reporting of this study. However, scientific, professionals and user's organizations will be contacted for the dissemination plans of this research.

3. Ethics and dissemination

Due to the characteristics of this study, ethical assessment was not required. The results of this systematic review and meta-analysis will be presented at international conferences related to this field and disseminated through peer-reviewed publications.

4. Discussion

There is a public health need to know the effectiveness of Web-based and Mobile-based psychological interventions for the prevention of PND around the globe. Due to both the burden of the disease (higher in developing countries) and to the fact that these types of interventions can be shared globally and easily scaled-up, evidence resulting from this study can contribute to the reduction of mental health disparities worldwide. Furthermore, these kinds of interventions need not be interrupted at times like the present, where due to the Covid-19 pandemic, face-to-face psychological interventions have been reduced or cancelled.

This systematic review and meta-analysis aims to address this gap in the literature and will summarise evidence-based research which examines the effectiveness of Web-based and Mobile-based psychological interventions to prevent PND worldwide and possible factors that may influence their effectiveness. Recommendations will be made to inform future research priorities. These results will be useful to relevant academic and practitioner communities, key stakeholders such as policy- and decision-makers, pregnant and postpartum women, and their families.

Author contributions

EM is the guarantor. EM designed the study, and the other authors collaborated on the design. EM and SC-C drafted the protocol, and PM, CM-G, IG-G and AF revised the manuscript. EM, CM-G and IG-G will independently screen the potential studies, extract the data, assess the risk of bias and complete the data synthesis. PM-P and SC-C will perform the data analyses. EM and AF will draft the final manuscript of this SR/MA. All authors read, provided feedback, discussed, and approved the final protocol manuscript.

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Patient consent

Not required.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Search strategy in PubMed

PICOS	Population	((((((((((postpartum[Title/Abstract]) OR postnatal[Title/Abstract]) OR puerperal[Title/Abstract]) OR perinatal[Title/Abstract]) OR prenatal[Title/Abstract]) OR antenatal[Title/Abstract]) OR intrapartum[Title/Abstract]) OR pregnancy[Title/Abstract]) OR "pregnancy"[MeSH Terms]) OR "pregnant women"[Title/Abstract]) OR "pregnant women"[MeSH Terms]) OR matern*[Title/Abstract] OR "postpartum"[tw] OR "post-partum"[tw] OR "post partum"[tw] OR "puerperium"[tw] OR "Perinatal care"[Mesh] OR "perinat*"[tw] OR "postnat*"[tw] OR "maternal"[tw] OR "Prenatal Care"[Mesh] OR "prenatal"[tw] OR "Prenatal education"[Mesh] OR "antenatal" OR "Puerperal Disorders"[Mesh])
	Intervention	("internet"[MeSH Terms] OR "internet"[All Fields] OR web-based OR technology intervention OR "telemedicine"[MeSH Terms] OR "telemedicine"[All Fields] OR "ehealth"[All Fields] OR online OR "social networking"[MeSH Terms] OR ("social"[All Fields] AND "networking"[All Fields]) OR "social networking"[All Fields] OR computer* OR interactive OR "software"[MeSH Terms] OR "software"[All Fields]) OR ("mobile health"[tw] OR "mhealth"[tw] OR "ehealth"[tw] OR "m-health"[tw] OR "e-health"[tw] OR "mcare"[tw] OR "Computers, Handheld"[Mesh] OR "cell phones"[tw] OR "cell phone"[TW] OR "cellular phone"[tw] OR "cellular phones"[tw] OR "cellular telephone"[tw] OR "cellular telephones"[tw] OR "mobile phone"[tw] OR "mobile phones"[tw] OR "mobile telephone"[tw] OR "mobile telephones"[tw] OR "iphone"[tw] OR "ipad"[tw] OR "cellphone"[tw] OR "cellphones"[tw] OR "pda"[tw] OR "personal digital assistant"[tw] OR "blackberry"[tw] OR "android"[tw] OR "smartphone"[tw] OR "smartphones"[tw] OR "smart phone"[tw] OR "smart phones"[tw] OR "tablet"[tw] OR "handheld computer"[tw] OR "apps"[tw] OR "mobile application"[tw] OR "mobile applications"[tw] OR "mobile communication"[tw] OR "mobile technology"[tw] OR "mobile games"[tw])
	Comparator	No restriction
	Outcome	("depressive disorder"[MeSH Terms] OR "depressive disorder" [All Fields] OR depress* OR "depression"[MeSH Terms] OR "anxiety"[MeSH Terms] OR "anxiety"[All Fields] OR "mental health"[MeSH Terms] OR "mental health"[All Fields] OR "mental disorders"[MeSH Terms] OR "mental disorder"[All Fields]) AND prevent*
	Study design	(randomized controlled trial[Publication Type]) OR (trial[Title/Abstract])

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