


BMJ Open Changes in perinatal mental healthcare during the COVID-19 pandemic: a protocol for a collaborative research study between the COST actions RISEUP-PPD and DEVOTION

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ABSTRACT

Introduction Significant changes in routine maternity care have been introduced globally in response to the COVID-19 pandemic to reduce infection risk, but also due to lack of medical facilities, staff shortages and the unpredictable nature of the disease. However, it is yet to be established if specialised perinatal mental health (PMH) services have been similarly affected. As a Task Force in PMH and COVID-19 pandemic within Riseup-PPD COST Action, this study aims to identify changes in PMH practices, policies and protocols during the COVID-19 pandemic in Europe.

Methods and analysis An online survey of experts in the PMH who are members of the COST Action 'Riseup-PPD' and the COST Action "DEVOTION" across 36 European countries will be conducted. A questionnaire on changes in PMH care practices during the COVID-19 Pandemic will be administered. It consists of open-ended questions, checklists and ratings on a 7-point scale addressing seven domains of interest in terms of PMH: (1) policies, guidelines and protocols; (2) PMH care practices at a national level; (3) evidence of best practice; (4) barriers to usual care; (5) resources invested; (6) benefits of investment in the policies and (7) short-term and long-term expectations of the policies. Data will be collected using Qualtrics. Descriptive statistics will be reported and differences between countries will be examined using the χ^2 statistic or Student's t-test.

Ethics and dissemination Ethical approval was obtained from The Ethics Committee for Research in Life and Health Sciences of the University of Minho (Portugal) to undertake an anonymous online survey. The findings will be disseminated to professional audience through peer-review publication and presentations and shared widely with stakeholders, policy-makers and service user groups. A position paper will be developed to influence policy-making at a European level to alleviate the adversities caused by COVID-19.

Trial registration number NCT04779775.

INTRODUCTION

COVID-19 is an infectious disease caused by SARS-CoV-2 that has triggered a worldwide

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study will identify changes in perinatal mental health care practices, policies and protocols during the COVID-19 pandemic in Europe.
- ⇒ Existing practices implemented to minimise the negative impact of COVID-19 on PMH across the various stages of the COVID-19 pandemic will be synthesised.
- ⇒ Key experts in perinatal mental health across 35 European countries will be represented.
- ⇒ The selection of key experts will be restricted to European countries only.
- ⇒ Only members of the two COST Action programmes will be invited as experts.

pandemic since the breakout from Wuhan, China in December 2019.¹ It has infected more than 71.5 million people, causing 1.6 million of deaths up to mid of December 2020.²

Initial cases of COVID-19 during pregnancy detected in China suggested that pregnant women are at no higher risk for infection than the general population.³ However, more recent studies paint a different picture. Pregnant women, due to their altered immune system are at higher risk for COVID-19.⁴ The WHO have highlighted that older age, being overweight and being diagnosed with comorbid medical conditions are risk factors for severe COVID-19 in pregnant women.⁵ Although with a very low prevalence (3.2%), vertical transmission of COVID-19 from mother to the fetus is possible, as reported in a recent systematic review including 936 neonates.⁶ However, although there are increased risks of complications in pregnancy associated with COVID-19 such as miscarriage (2%), intrauterine growth restriction (10%) and preterm birth (39%), the

pathophysiological mechanisms involved are yet to be understood. Data from a cohort study of 384816 adults from England found that maternal smoking during pregnancy was positively associated with COVID-19 infection, while on the other hand, breast feeding had a significant relationship with lower risk of COVID-19 infection rates in adults.⁷ Oxytocin has been shown to have anti-inflammatory function in COVID-19.^{8 9} These findings highlight the need to better the inequalities and differences associated with varying rates of infection, and on the other hand, that practices regarding support a mother's exposure to oxytocin such as breastfeeding and skin to skin contact should be supported.

As a response to the pandemic, routine care was altered in an effort to reduce the transmission of the virus to women, their babies and staff. For example, one of the changes implemented in some countries was that partners were no longer permitted access to outpatient antenatal visits and routine ultrasound screening, while restrictions were also implemented in their visitation right to accompany their partner during labour or support their partner and baby in the early days after delivery.^{10 11} Across Europe, antenatal classes have ceased or have been transferred to an online format, antenatal regular check-ups are somewhat reduced or offered via telephone, the presence of the supporting person during childbirth is often not allowed in a maternity ward, visits of the father and other family members to the hospital after delivery are reduced or restricted, newborns of infected mothers are sometimes separated, home visits of a midwife after birth and breastfeeding support are also reduced.^{12 13} Although official and national guidelines for perinatal health in general or infected mothers/newborns may be available,^{5 14 15} practices have been changing constantly, some of which may not be evidence based (eg, separation of women from their babies, preventing skin-to-skin contact and breast feeding) or are in contradiction with the recommendations for respectful maternity care (eg, exclusion of birth companions).¹⁶⁻¹⁸ Along with these changes, there are general restrictions, such as distancing from others, restricted socialising and restricted movement, which may be necessary but can impose substantial psychological distress.¹⁹⁻²¹

Perinatal mental health (PMH) is defined as the biopsychosocial well-being during the pregnancy, childbirth and post partum. PMH problems can occur anytime during pregnancy or within the first postpartum year, with depression and anxiety as the most common.²² A global pandemic, natural disasters and man-made tragedies can all have an adverse effect on mental health in the general population.^{23 24} After the public announcement of COVID-19 in China, pregnant women reported significantly higher rates of depressive symptoms, as well as thoughts of self-harm, than before the public declaration.²⁵ One in three pregnant women reported self-isolating due to fear of COVID-19 infection.²⁶ The high impact of COVID-19 on maternal mental health during pregnancy and postpartum has been evident in different

countries worldwide.^{20 27} A recent systematic review of 81 mental health studies of pregnant and postpartum women found elevated levels of common mental health symptoms, such as depression, anxiety and trauma-related symptoms, among pregnant or postpartum women during the COVID-19 pandemic compared with before the onset of the pandemic.²⁸ Similar findings were reported in another review of 17 studies assessing the impact of the pandemic only in pregnancy.²⁹

Even though the adverse impact of the pandemic on PMH is increasingly recognised, good practices in PMH during the COVID-19 pandemic are yet to be explored. Furthermore, if they are to be sustained, we also need to understand how they are incorporated into national policies, guidelines, protocols and official documents across European countries during the COVID-19 pandemic. This has important clinical implications and can be used to inform policy-makers at both the national and the European level—with the ultimate goal of providing support for women in the peripartum period and promote an optimal experience for mothers and their families during childbirth and postpartum in particularly challenging situations like a global pandemic.

With this task in mind, a special task force within the COST Action CA18138 Research Innovation and Sustainable Pan-European Network in Peripartum Depression Disorder (Riseup-PPD) was formed, in collaboration with the COST Action PMH and Birth-Related Trauma: Maximising best practice and optimal outcomes-DEVOTION. The Task force is titled 'PMH and COVID-19 pandemic' and was established with the aim to investigate the best practices, policies and guidelines to help alleviate the negative consequences of COVID-19 on women's mental health.³⁰

A recent review pointed out emerging issues in the prevention, diagnosis and treatment of peripartum depression,³¹ which are highlighted even more with the ongoing pandemic. The Task Force has already addressed the deleterious impact of COVID-19 on PMH, the risk factors for mental health vulnerability during the current pandemic and highlighted good psychological practices in PMH during the COVID-19 pandemic.³² The latter refers to providing adequate information about the COVID-19 pandemic and the impact on the psychological reaction of emotional distress, screening for psychological problems, facilitating social support and offering e-resources for psychological support, promotion of positive coping strategies, prolonged skin-to-skin contact and exclusive breast feeding. The Task Force pointed out that research on good practices in PMH in the time of COVID-19 pandemic should: (1) capture the wide range of psychological distress presentations, focusing on depression and anxiety; (2) look into complex roles of physical distancing and social isolation due to epidemiological measures; (3) take into account the barriers in seeking help augmented by the pandemic that may be overcome by new e-health services; (4) investigate changes in perinatal healthcare practices and factors

that may alleviate them; and finally, (5) boost the efforts for further development and validation of specific PMH assessment tools.³²

The main aim of this study is to identify changes implemented in PMH care due to the COVID-19 pandemic in seven domains of interest: (1) policies, guidelines, protocols and documents; (2) PMH care practices at a national level; (3) evidence of best practice; (4) barriers to usual care; (5) resources invested; (6) benefits of investment in the policies and (7) short-term and long-term expectations of the policies.

METHODS AND ANALYSIS

Study design

A cross-sectional survey will be conducted.

Participants

The participants will be experts in PMH who are members of the COST Action Riseup-PPD and the COST Action DEVOTION. The COST members are researchers in applied sciences and clinicians (ie, clinical psychologists, clinical social workers, general practitioners, midwives, nurses, obstetrician/gynaecologists, paediatricians, psychiatrists, psychotherapists), as well as researchers from other backgrounds (eg, neuroscience, biology, epigenetics, biomedical engineer, mathematics, statistics, architecture, social sciences) and key stakeholders (eg, health economists, politicians, decision-makers, representatives from peer-support groups and service users). The main aim of the Riseup-PPD is to gather a multidisciplinary network of researchers to collect and promote evidence-based knowledge on prevention, assessment, and treatment of peripartum depression. DEVOTION is a pan-European multidisciplinary network of birth trauma researchers working towards an ideal universal standard of care to prevent and minimise birth trauma and optimise birth experiences.

Taken together, both COST Actions include representatives from 35 European COST countries (Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and UK), one cooperating member (Israel) and four international partner countries (Australia, Brazil, Canada and the USA).

For the current study, only members of the 35 European countries will be eligible to participate. Three members per country will be invited to participate in the survey. In COST countries where there is high representation of members (eg, Portugal), the members with the highest number of years of expertise in the field of PMH will be contacted.

Instruments

Demographic and expertise background questionnaire

The demographic and expertise background questionnaire will comprise questions on the area of specialisation (ie, clinical psychologists, clinical social workers, general practitioners, midwives, nurses, obstetrician/gynaecologists, paediatricians, psychiatrists, psychotherapists) academic degree, institutional affiliation and position, years of experience and years working in perinatal care and/or PMH (each with categories: up to 1 year, 2–5 years, 5–10 years, more than 10 years), current employer (check all that apply: public, private, birth centre, hospital, home birth, primary care service, academic/research, counselling office, non-governmental organisation, other), number of patients/clients per year per institution and personally, gender, age and country.

Questionnaire on changes in PMH care practices during the COVID-19 pandemic

A questionnaire for the consultation of experts was developed by the research group of the Task Force 'PMH and COVID-19 pandemic' for the purpose of this study, based on the previous questionnaire for experts on mental health used in Europe.³³ The questionnaire includes 30 questions with specific references to the change of policies, protocols and practices regarding PMH during COVID-19 pandemic. It consists of 16 yes/no questions, 18 open-ended questions, 4 checklist questions and 2 items with response ratings on a 7-point scale (1=not adequate to 7=excellent).

The topic areas covered seven domains of interest in terms of PMH: (1) policies, guidelines and protocols (exemplary item: Since the COVID-19 outbreak, have the main policies, guidelines or protocols regarding PMH changed in your country? with yes/no answer format); (2) PMH care practices at a national level (exemplary item: Please describe changes to mental healthcare practices since the COVID-19 outbreak in your country.); (3) evidence of best practice (exemplary item: In your view, what are the best practices that have been implemented for treating PMH during COVID-19 outbreak in your country? Please, describe.); (4) barriers to usual care (exemplary item: Since the COVID-19 outbreak in your country, have there been any barriers to usual care in terms of PMH? with yes/no answer format); (5) resources invested (exemplary item: Have sufficient resources (financial or otherwise) been invested into these specific policies, protocols, and guidelines regarding PMH & COVID-19 in your country? with 7-point scale from 1-strongly disagree to 7-strongly agree); (6) benefits of investment in the policies (exemplary item: What are the expected economic and social benefits of investments in these policies, protocols, and guidelines on PMH & COVID-19? as an open-ended question with four provided categories for answer: economic benefits, social benefits, individual benefit for patients, and individual benefit for healthcare practitioners); and (7) short- and long-term expectations of the policies (exemplary item: What are

the short- and long-term expectations of the policies, protocols, and guidelines you have described, regarding PMH and COVID-19? As an open-ended question with two provided categories for answer: short-term and long-term expectations).

Guidelines are defined as systematically developed recommendations to assist in practitioner and patient decision making about treatments for clinical conditions.³⁴ Protocols are a comprehensive set of criteria outlining the management steps for a single clinical condition.³⁵ Documents are defined as official records that provide information or evidence. Finally, Best Practice is defined as a technique or methodology that through experience and research has proven reliably to lead to the desired result.³⁶

The survey was written in English and a pilot study with three experts in PMH was conducted. Questions for pilot are presented in online supplemental table A1. Amendments to the questionnaire were made accordingly which included rewording questions to elicit appropriate responses. The questionnaire for key experts can be found in online supplemental file 1.

Procedure

A link to the online survey hosted in Qualtrics will be sent by email to members from both COST Action RISEUP-PPD and COST Action Devotion. Experts will be asked to complete the online questionnaire in English. First, they will read an electronic consent form presenting an overview of the study aims, content of the questions asked, potential risks and benefits, and ethical aspects of the study (ie, voluntary participation, confidentiality and secure storage of the data, and absence of any type of compensation). At the bottom of the form, they will be asked to confirm eligibility criteria (members of either COST Actions) and to provide their consent to participate in the study. Participants who do not meet the predefined inclusion criteria will be directed to a message thanking them for their interest and informing them of the required eligibility criteria for participation in the study. The questionnaires are estimated to take approximately 15–20 min to complete.

Data analysis

Survey data will be manually checked for accuracy and consistency before analysis. All analyses will be conducted using records without missing values. Descriptive data analyses were performed to report frequencies and percentages for categorical data and means and SD for continuous variables. Two authors will code all answers to the open-ended questions independently. Inter-rater reliability will be calculated by Cohen's kappa coefficient and all discrepancies will be discussed until consensus is reached. If needed, a third author will be consulted to resolve any disagreements between the raters.

Differences between countries will be examined using the χ^2 statistic or Student's t-test. Size effects will be presented following the interpretation proposed by

Cramer's V and Cohen's d for the effect size as follows: 0–0.19, negligible; 0.20–0.49, small; 0.50–0.79, medium; 0.80 and over, high (Cohen, 1988). All p values will be two sided and considered significant below 0.05. SPSS V.26.0 statistical software will be used for these analyses.

Patient and public involvement

No patients or public are involved.

Ethics and dissemination

Ethical principles by the Declaration of Helsinki will be followed in this study. The ethical approval was obtained from The Ethics Committee for Research in Life and Health Sciences (CEICVS) of the University of Minho, Portugal (No. CEICVS 045/2020). One link in English will be shared to all participants and the University of Minho will set up the questionnaire in the Qualtrics. Data will be collected anonymously, and participants will be informed that IP addresses or any other identifier will not be collected. Before entering the study, each participant will give informed consent (see online supplemental file 1). The confidentiality of all data will be secured according to European legislation detailed at Regulation (EU) 2019/679 of the European Parliament and the Council of 27 April 2016 on the protection of persons concerning the processing of personal data, as well as the transfer of said data.

The findings from this study will be disseminated as papers published in peer-reviewed journals, presented at national and international conferences, and most importantly, its results will be used inform policy-makers and have an impact on the changes in PMH care on a national and European level.

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Contributors EM, AMM and SNR designed the study idea and made a questionnaire. SNR led the pilot study and drafted the protocol manuscript. EM, AMM, AG-Á, EV and JL revised it. SNR, EM and EV developed the analysis plan for the data. All authors reviewed the manuscript critically and suggested revisions, and gave the final approval before the submission.

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