Jan 11, 2021

Anxiety of pregnant women in time of catastrophic events, including COVID-19 pandemic – a systematic review and metanalysis protocol.

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1 Works for me dx.doi.org/10.17504/protocols.io.bq9zmz76

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ABSTRACT

Introduction. The article presents a rapid systematic review protocol. The aim is to assess the current studies about the influence of exposure to a natural disaster or catastrophic event on the prevalence of anxiety among pregnant women worldwide. We hope that this knowledge will provide better understanding of the current situation related to the COVID-19 pandemic. There are more than 30 million coronavirus infection cases worldwide, and many countries have declared states of a natural disaster. Therefore, we believe that experiences from previous natural disasters on maternal anxiety could be an important lesson for planning intervention in this group of patients.

Methods and Analysis. For the purpose of this systematic review the following databases will be screened Pubmed / MEDLINE, Web of Science, Cochrane Library, EMBASE, Google Scholar. This literature review will compare the prevalence of anxiety among pregnant women during a catastrophic event including and pregnant women with pregnancy studied in a naturally stable setting. Exposure to natural disasters or other catastrophic events onmaternalanxiety. The risk of bias will be assessed independently during the data extraction process by at least two researchers using the Newcastle-Ottawa Scale.

Ethics and Dissemination. A manuscript will be prepared for submission to a peer-reviewed journal. The current protocol is made using PRISMA-P guidelines and were registered in PROSPERO with ID-number: CRD42020178944.

DOI

dx.doi.org/10.17504/protocols.io.bq9zmz76

PROTOCOL CITATION

Stepan Feduniw, Jan Modzelewski, Dorota Sys, Sebastian Kwiatkowski, Anna Kajdy 2021. Anxiety of pregnant women in time of catastrophic events, including COVID-19 pandemic – a systematic review and metanalysis protocol.. **protocols.io**
https://dx.doi.org/10.17504/protocols.io.bq9zmz76

KEYWORDS

Perinatal anxiety, Maternal anxiety, Pregnancy, Catastrophic event, Natural disasters, COVID-19

CREATED

Jan 08, 2021

LAST MODIFIED

Jan 11, 2021

OWNERSHIP HISTORY

Jan 08, 2021 Dorota Sys Centre of Postgraduate Medical Education

Jan 08, 2021 Stepan Feduniw Lazarski University, Faculty of Medicine

PROTOCOL INTEGER ID

46105

GUIDELINES

Anxiety of pregnant women in time of catastrophic events, including COVID-19 pandemic – a systematic review and metanalysis protocol.

Based on the PRISMA-P guidelines.

A	B	C	D
Reporting Item			Page Number
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	NA
Update	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	6
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	10
Contribution	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA
Sources	#5a	Indicate sources of financial or other support for the review	10
Sponsor	#5b	Provide name for the review funder and / or sponsor	NA
Role of sponsor	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), funder if any, in developing the protocol	NA
Rationale	#6	Describe the rationale for the review in the context of what is already known	2-3
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	3-5
Information	#9	Describe all intended information sources (such as electronic sources;databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	4
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	4

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Study records	#11a	Describe the mechanism(s) that will be used to manage data management records and data throughout the review	5-6
Study records	#11b	State the process that will be used for selecting studies (such selection process as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	5-6
Study records	#11c	Describe planned method of extracting data from reports data collection (such as piloting forms, done independently, in duplicate), any process processes for obtaining and confirming data from investigators	5-6
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	3-6
Outcomes and prioritization	#13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6
Risk of bias in individual studies	#14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	5-6
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	5-6
Data synthesis	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ)	NA
Data synthesis	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	NA
Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	5-6
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	5-6
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	5-6

PRISMA-P guidelines for *"Anxiety of pregnant women in time of catastrophic events, including COVID-19 pandemic – a systematic review and metanalysis protocol."*

This checklist was completed on 10. September 2020 using http://www.goodreports.org/,a tool made by the EQUATOR Network in collaboration with Penelope.ai.

ABSTRACT

Introduction. The article presents a rapid systematic review protocol. The aim is to assess the current studies about the influence of exposure to a natural disaster or catastrophic event on the prevalence of anxiety among pregnant women worldwide. We hope that this knowledge will provide better understanding of the current situation related to the COVID-19 pandemic. There are more than 30 million coronavirus infection cases worldwide, and many countries have declared states of a natural disaster. Therefore, we believe that experiences from previous natural disasters on maternal anxiety could be an important lesson for planning intervention in this group of patients.

Methods and Analysis. For the purpose of this systematic review the following databases will be screened Pubmed / MEDLINE, Web of Science, Cochrane Library, EMBASE, Google Scholar. This literature review will compare the prevalence of anxiety among pregnant women during a catastrophic event including and pregnant women with pregnancy studied in a naturally stable setting. Exposure to natural disasters or other catastrophic

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Ethics and Dissemination. A manuscript will be prepared for submission to a peer-reviewed journal. The current protocol is made using PRISMA-P guidelines and were registered in PROSPERO with ID-number: CRD42020178944.

INTRODUCTION

1 The perinatal period is often a time of maternal emotional distress related to the pregnancy itself. Women are concerned with fetal wellbeing and labor outcome. Besides the pregnancy itself, there are several risk factors correlated with a higher prevalence of anxiety[1]. Risk factors of anxiety include adverse childhood events (overprotective or harsh parenting, maltreatment, and physical punishment). Parental history of mental disorders and low socioeconomic status are also described as increasing the risk of anxiety[1–3].

One of the adverse influences on the mental health of pregnant women could be insecurity related to catastrophic events or the occurrence of a natural disaster. A catastrophic event is defined as a disaster or accident which takes place within a designated area, or is caused by an act of terrorism or war, and results in the deaths of six or more persons within 30 days after onset of such an event, regardless of the cause, that causes damage to property of significant severity and magnitude[4]. Examples of natural catastrophic events are natural disasters, like floods, fires, earthquakes, droughts, tsunamis and epidemics[4]. Human-made catastrophic events are wars, explosions of factories, nuclear reactors, acts of terrorisms. All these events may aggravate the economic state of individuals, regions, and countries and specific restrictions of transport, housing, job loss, and hunger[5].

The current COVID-19 pandemic is also an example of a natural disaster. The health burden is enormous, with more than 30 million cases worldwide, almost one milliondeaths, and more than 60 thousand patients in a critical state[6]. The restrictions related to social distancing have put a strain individuals, families, societies, and countries. Many aspects of daily life have been affected, resulting in stress, anxiety, and depression.

Anxiety is a feeling of worry, nervousness, or unease about something with an uncertain outcome, and it can co-exist or lead to depression[7]. The feeling of insecurity about any catastrophic event, including the COVID-19 pandemic, may lead to generalized anxiety disorder[2]. The available literature shows that pregnancy is especially prone to anxiety[7,8]. Furthermore, the prevalence of antenatal anxiety varies from 15 to 23%[9], when worldwide, only 3-5% of the population suffers from anxiety symptoms[3].

The relationship between anxiety and insecurity of pregnant women is highly probable[10]. Mental health has a crucial effect on maternal wellbeing and fetal development[11]. Therefore, it is necessary to look for early diagnosis and possible interventions in patients affected by the pandemic.

We hope that analyzing previous natural disasters will help us better understand this relationship and plan studies and interventions among pregnant women affected by the COVID-19 pandemic worldwide.

Aim of the study: To investigate the impact of anxiety on mental health in a population of pregnant women exposed to catastrophic events compared to healthy pregnant women without such exposure.

Review Question

-***How stress and insecurity related to the natural disaster impacted the anxiety of pregnant women?***

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A	B	C	D
Population	**Intervention**	**Comparison**	**Outcome**
Pregnant women	Exposure to natural disaster or another catastrophic event	Pregnant women, in time without catastrophic events	Assessment of the anxiety of pregnant women and their attitude to the problematic situation

Table 1. Review question.

METHODS

2 Study selection

Searching databases

- Pubmed / MEDLINE,
- Web of Science,
- Cochrane Library,
- EMBASE,
- Google Scholar.

Search strategy

The results will be assessed manually without using any Search software. The general search phrase is shown in Table 2. Search engine options will be used to limit the search to title and abstract, languages restricted to English, German or Polish, no publication time limits.

A
(pregnant OR pregnancy OR partum OR prepartum OR prenatal OR gestation OR partus OR prelabour OR maternal) AND ("catastrophic event" OR epidemic OR pandemic OR COVID-19 OR SARS-COV 2 OR "natural disaster" OR cataclysm OR explosion OR flood OR fire OR earthquake OR tsunami OR war OR "economic state" OR job loss OR hunger OR drought OR bomb) AND (anxiety OR mental)

Table 2. Search strategy.

Inclusion criteria

Types of studies:

All types of evaluative study designs are eligible for inclusion, including grey literature. Studies will not be selected based on methodological quality.

Types of participants

This literature review will compare the prevalence of anxiety among pregnant women during a catastrophic event and pregnant women with pregnancy studied in a naturally stable setting.

Types of exposure:

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Exposure to natural disasters or other catastrophic events onmaternalanxiety.

Types of outcome measures:

Assessment of anxiety of pregnant women during a catastrophic event. We expect that different scales to measure anxiety will be used. Therefore, a direct comparison will not be possible. Only a few used scales were evaluated for use in the pregnant women population by ICD-10 (10th revision of the International Statistical Classification of Diseases and Related Health Problems)[12] or DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition)[13,14] guidelines. Regarding the method of anxiety evaluation, only studies using STAI (State-Trait Anxiety Inventory), GAD-2/7 (Generalised Anxiety Disorder scale)[15,16], EPDS (Edinburgh Postnatal Depression Scale – Anxiety subscale)[17], HADS (Hospital Anxiety and Depression Scale) – Anxiety subscale[18], BMWS (Brief Measure of Worry Severity)[19], CWS (Cambridge Worry Scale)[20], W-DEQ – Version A (Wijma Delivery Expectancy/Experience Questionnaire)[21], PRAQ-R (Pregnancy-Related Anxiety Questionnaire-Revised)[22] would be included into the study[9]. The results published based on these studies will be assessed according to DSM-5 criteria and ICD-10 criteria. The effects of maternal anxiety will be divided into four groups: 0-none, 1-mild, 2 – moderate, and 3- severe anxiety.

Exclusion criteria

Editorials, newspaper articles, and other forms of popular media will be excluded. Failure to meet any one of the above eligibility criteria will result in exclusion from the review, and an independent reviewer will resolve any apparent discrepancies resulting from the selection process. The main reason for exclusion will be incorrect anxiety measurement. The number of excluded studies (including reasons for exclusion for those excluded following review of the full text) will be recorded at each stage.

Patient and Public Involvement:

No patients involved

ASSESSMENT OF RISK OF BIAS AND DATA EXTRACTION

3 The risk of bias will be assessed independently during the data extraction process by at least two researchers using the Newcastle-Ottawa Scale. The third reviewer will determine any differences. Data on the prevalence and severity of anxiety will be extracted.

Each study will be assessed and compared in three aspects:

- The selection of the study group and the control group
- The comparability of the groups
- The detection of the exposure

A study will reach one star for each signaling question. The questions will be divided into three categories: Selection, Comparability, and Exposure/Outcome. Out of 9 possible stars, reaching 7 or more will be evaluated as a high-quality study.

Studies will be divided into three categories: low risk of bias, unclear bias, and high risk of bias. The following characteristics will be evaluated:

- Random sequence generation (selection bias)
- Allocation concealment (selection bias)
- Incomplete results (attrition bias)
- Selective reporting (reporting bias)
- Other biases

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HETEROGENEITY AND REPORTING BIAS

4 In case of severe methodological, clinical, or statistical heterogeneity, pooled results will not be reported. We will identify heterogeneity by both visual inspections of forest plots and statistical methods. Reporting bias will be determined by using funnel plots.

ETHICS & DISSEMINATION

5 A manuscript will be prepared for submission to a peer-reviewed journal. The current protocol is made using PRISMA-P guidelines and were registered in PROSPERO with ID-number: CRD42020178944.

RESULTS

6 The authors suggest that the present study would lead to a better understanding of anxiety related to catastrophic events during pregnancy. Appropriate recommendations for the perinatal period are needed to improve maternal and neonatal outcomes.

DISCUSSION

7 Nowadays, the mental health of pregnant women is an important aspect of perinatal care. Medical care providers' primary interest is maternal depression, but perinatal anxiety is also a significant health problem that could lead to adverse outcomes during pregnancy and depression. The COVID-19 pandemic may have a profound impact on mental health worldwide[23]. Crucial seems to be the fact that attention on the mental health of pregnant women is in the center of doctors' discussions. Since the beginning of the pandemic state worldwide (March 2020), several studies have been published. In the last four months, considerable attention is paid to the general mental health of the population. Pregnant women seem to be more attached to anxiety and the present situation seems to make it worth it. The reason for that fact is double worry because they self and the unborn fetuses. In September 2020, there are 15 studies about the influence of COVID-19 on pregnant women's mental health worldwide. The researches from Poland[24], Hong Kong[24], Iran[25,26], China[27–29], Turkey[30,31], India[32], Canada[33], Israel[34,35], UK[36], Qatarare[37], Ireland[37,38]. Moreover, Japan[39] is studying anxiety among pregnant women during the COVID-19 pandemic. The worldwide interests of the current situation highlight the need for this systematic review. Comparing present COVID-related studies between each other and to other catastrophic events would customize the perinatal medical care.

CONCLUSION

8 We hope that analyzing previous natural disasters will help us better understand this relationship and plan studies and interventions among pregnant women affected by the COVID-19 pandemic.

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OTHER INFORMATION

10 **Authors' contributions: SF:** Conceptualization, Investigation, Methodology, Project Administration; Writing – Original Draft Preparation **JM**: Conceptualization, Investigation, Methodology, Writing – Original Draft Preparation; **DS**: Conceptualization, Investigation, Project Administration, Writing – Original Draft Preparation; **SK:** Conceptualization, Investigation, Methodology, Writing – Review & Editing; **AK:** Conceptualization, Investigation, Methodology, Supervision, Writing – Review & Editing

Funding: This study has received no funding.

Competing interests statement: None

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