

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	An International Survey on Fear and Childbirth Experience in Pregnancy and the Postpartum Period during the COVID-19 Pandemic: Study Protocol
AUTHORS	Lok, Kris Yuet-Wan; Ko, Rachel Wai Tung; Fan, Heidi; Wong, Janet Y.H.; Choi, Edmond; Shek, Noel Wan Man; NGAN, Hextan; Tarrant, Marie; Li, Junyan; Huang, Yi-yan; Ouyang, Yan-Qiong; Fong, Daniel Yee Tak

VERSION 1 – REVIEW

REVIEWER	Nomura, Roseli M. Y. Univ Sao Paulo, Gynecology and Obstetrics
REVIEW RETURNED	15-Mar-2021

GENERAL COMMENTS	<p>Thank you for the opportunity to read this study protocol. Fear and childbirth experience is a relevant issue that can have a major impact on the mental health of pregnant women during the COVID-19 pandemic.</p> <p>Abstract: The authors inform that the study will recruit pregnant women and new mothers. The inclusion criteria should be better specified. Include the gestational age or trimester to be recruited and the criteria for defining what will be considered 'new mothers'. Inform how many and which questionnaires will be applied.</p> <p>Main text Background: This section presents the main concerns related to the effects of public health measures imposed due to the COVID-19 pandemic. The experience of childbirth and fear of the pandemic is a relevant issue that can have a major impact on the mental health of women.</p> <p>Methods The authors described the inclusion criteria for this online survey. The period of pregnancy and postpartum is a period that usually causes stress in a woman's life, even outside a pandemic. How will it be possible to differentiate fear related to a previous mental health problem and not due to the COVID-19 pandemic? Do the authors consider whether the payment for participation can influence the results? How to avoid bias? In the proposed online survey, is the participant allowed to view all forms before signing the online consent form? Is it possible for the participant to know the extent of the research and if there are any questions that she dislikes? In outcome measures, the authors report three main results, however, four are listed. Please clarify.</p>
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	<p>Is the proposed fear scale an instrument validated in each language and culture? Is the Childbirth Experience Questionnaire validated in each language and culture, mainly in Chinese? Please clarify. The authors reported that it was translated into traditional and simplified Chinese. Could the authors provide more details about this process?</p> <p>The two countries where the study is planned to be carried out have huge territories. How can the authors guarantee that the surveys collected will represent pregnant women and new mothers across the country, and not a regional view with a higher prevalence of COVID-19 or with greater severity?</p> <p>This online survey is quite interesting. However, I have some concerns. There are limitations in the methodology. I doubt if the results really represent the fear of the population investigated, as we have the bias that more affected women may be more interested in participating.</p>
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REVIEWER	Dahlen, Hannah Western Sydney University, School of Nursing and Midwifery
REVIEW RETURNED	16-May-2021

GENERAL COMMENTS	<p>It is unclear as to the dates of the study and when to will commence or if it has commenced or even concluded. No dates are given which is needed for BMJ Open protocols</p> <p>If about to commence then one wonders about whether this is now too late</p> <p>The title is very cumbersome and needs re-writing</p> <p>The paper needs a very good edit as lots of grammatical issues. ie page 2 "It is a multi-country study involving two countries including China and Canada which targets to recruit 1000 pregnant women and new mothers" and "All collected data may be limited to represent participants with a very low level of digital literacy and low socioeconomic status" I won't go any further as it needs a very good edit.</p> <p>This is now old data and needs updating "As of 4 January 2021, over 85 million confirmed cases have been recorded globally"..... This aim is not accurate as only assessing two countries. "To assess the childbirth experiences of new mothers under COVID-19 globally"</p> <p>The explanation of the sample size calculation is very hard to follow and confusing. for example this makes no sense "To allow incomplete questionnaires, we shall target 500 pregnant women and 500 individual who have recently given birth in Hong Kong and other participating countries." You say China and Canada and then Hong Kong is mentioned. Is Hong Kong also included and is it only Hong Kong and not China?</p> <p>More explanation of what this means is needed: "Individuals who do not meet the inclusion criteria, or due to psychological or physical reasons, will be excluded." You are measuring mental</p>
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	<p>health symptoms but here you are excluding for 'psychological reasons'</p> <p>Are all the questions forced?</p> <p>There is not enough detail to fulfil the criteria needed to recommend this protocol for publication in its current state</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer #1:

Abstract

R1-1: The authors inform that the study will recruit pregnant women and new mothers. The inclusion criteria should be better specified. Include the gestational age or trimester to be recruited and the criteria for defining what will be considered 'new mothers'. Inform how many and which questionnaires will be applied.

A: We include all the pregnant participants at the time of data collection, and new mothers were defined as women who gave birth since 2020. This has been clarified. (P.2 Line 12-13)

Methods

R1-2: The authors described the inclusion criteria for this online survey. The period of pregnancy and postpartum is a period that usually causes stress in a woman's life, even outside a pandemic. How will it be possible to differentiate fear related to a previous mental health problem and not due to the COVID-19 pandemic?

A: We are sorry that we do not have the data on the stress level of pregnant women and new mothers before the COVID-19 pandemic. We have questions asking the participants about their previous health histories and whether they received any psychiatric treatment before pregnancy and at the time of data collection. We will adjust the mental health status in the data analysis to understand the level of fear about COVID-19 infection.

R1-3: Do the authors consider whether the payment for participation can influence the results? How to avoid bias?

A: We thank the reviewer for the comments and suggestions. We understand that the payment for participation can influence the results. However, the incentive was HK\$50 (US\$6.5) which was minimal. Therefore, we used coupons as incentives to encourage participation in the study. When we analyze the data, we will also compare the participants' sociodemographic characteristics with the general population to avoid bias.

R1-4: In the proposed online survey, is the participant allowed to view all forms before signing the online consent form? Is it possible for the participant to know the extent of the research and if there are any questions that she dislikes?

A: The study has been reviewed and approved by the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (UW 20-490). (P.11 Line 28-29). We have provided adequate details of the study before obtaining consent from the participants. Participants can choose to withdraw from the study any time. (P.12 Line 5)

R1-5: In outcome measures, the authors report three main results, however, four are listed. Please clarify.

A: This has been amended. (P.7 Line 16)

R1-6: Is the proposed fear scale an instrument validated in each language and culture?

A: We are sorry for the confusion. We have added the details of the fear scale. (P.7 Line 27-29).

R1-7: Is the Childbirth Experience Questionnaire validated in each language and culture, mainly in Chinese? Please clarify. The authors reported that it was translated into traditional and simplified Chinese. Could the authors provide more details about this process?

A: The Childbirth Experience Questionnaire was translated into traditional Chinese. It will be validated in this study. The paper that reported the translation and validation of the Childbirth Experience Questionnaire has been submitted for publication and is under review.

R1-8: The two countries where the study is planned to be carried out have huge territories. How can the authors guarantee that the surveys collected will represent pregnant women and new mothers across the country, and not a regional view with a higher prevalence of COVID-19 or with greater severity?

A: Limited generalizability is one of the limitations of our study. We cannot guarantee that we can recruit women from every province. We have tried to distribute the questionnaires on different social platforms to reach participants from diverse geographical locations. The participants in China and Canada stated the provinces they live in, which will allow us to examine the association between the number of cases and the proposed outcomes. (P.11 Line 6-9)

R1-9: This online survey is quite interesting. However, I have some concerns. There are limitations in the methodology. I doubt if the results really represent the fear of the population investigated, as we have the bias that more affected women may be more interested in participating.

A: Due to the COVID-19 pandemic, we could not recruit the participants in hospitals or clinics. An online questionnaire is a necessary and effective way of collecting data during the pandemic. We have addressed this as our limitations. (P.3 Line 8-10; P.11 Line 2-6)

Reviewer #2:

R2-1: It is unclear as to the dates of the study and when it will commence or if it has commenced or even concluded. No dates are given which is needed for BMJ Open protocols. If about to commence then one wonders about whether this is now too late

A: When we submit our paper to the journal, we were at the start of collecting data in China and Canada, and the data collection was in progress at that time in Hong Kong. As of 10th July 2021, the data collection procedure in Hong Kong and Canada has been completed, and the data collection is in progress in China.

R2-2: The title is very cumbersome and needs re-writing

A: The title has been changed. (P.1 Line 2-3)

R2-3: The paper needs a very good edit as lots of grammatical issues. i.e. page 2 "It is a multi-country study involving two countries including China and Canada which targets to recruit 1000 pregnant women and new mothers" and "All collected data may be limited to represent participants with a very low level of digital literacy and low socioeconomic status" I won't go any further as it needs a very good edit.

A: The paper has been edited, and the sentences have been modified. (P.3)

R2-4: This is now old data and needs updating "As of 4 January 2021, over 85 million confirmed cases have been recorded globally".....

A: This has been updated. (P.4 Line 4 to 7)

R2-5: This aim is not accurate as only assessing two countries. "To assess the childbirth experiences of new mothers under COVID-19 globally"

A: This has been amended. (P.6 Line 2)

R2-6: The explanation of the sample size calculation is very hard to follow and confusing. for example this makes no sense "To allow incomplete questionnaires, we shall target 500 pregnant women and 500 individual who have recently given birth in Hong Kong and other participating countries." You say China and Canada and then Hong Kong is mentioned. Is Hong Kong also included and is it only Hong

Kong and not China?

A: We are sorry for the confusion caused. This has been amended. (P.6 Line 12-17)

R2-7: More explanation of what this means is needed: "Individuals who do not meet the inclusion criteria, or due to psychological or physical reasons, will be excluded." You are measuring mental health symptoms but here you are excluding for 'psychological reasons'

A: We did not include women who were psychologically or physically unable to communicate. However, they were not likely to join our study as we used an online survey to collect data. Therefore, this has been removed to prevent confusion. We did not exclude participants who had psychological problems if they can answer the questionnaire. (P.6 Line 20-24)

R2-8: Are all the questions forced?

A: All questions are forced to ensure completion of the questionnaire and prevent missing data.

VERSION 2 – REVIEW

REVIEWER	Nomura, Roseli M. Y. Univ Sao Paulo, Gynecology and Obstetrics
REVIEW RETURNED	23-Jul-2021

GENERAL COMMENTS	Thank you for the opportunity to read the revised version of this manuscript. I am happy to recommend acceptance this study protocol. I think the authors have adequately addressed the reviewers' comments and suggestions. They justified the main concerns and presented explanations about the strategies planned for this study. The selection and recruitment methods were clarified. The concerns about the instrument's validation were explained, allowing the use for this study. The challenges for on line questionnaires were pointed. The sample size calculation was clarified.
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REVIEWER	Dahlen, Hannah Western Sydney University, School of Nursing and Midwifery
REVIEW RETURNED	22-Jul-2021

GENERAL COMMENTS	Thanks for addressing my concerns.
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