PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	The psychological wellbeing of women at high risk of spontaneous preterm birth cared for in a specialised preterm birth clinic: a prospective longitudinal cohort study
AUTHORS	Dawes, Lisa; Waugh, Jason J.S.; Lee, Arier; Groom, KM

VERSION 1 – REVIEW

REVIEWER	Andree Kurniawan Pelita Harapan University, Internal medicine
REVIEW RETURNED	13-Oct-2021

GENERAL COMMENTS	The authors have done longitudinal study to evaluate relation between at risk of spontaneous preterm birth with psychological wellbeing. My comments are 1. The results were suspected anxiety or depression, high risk of anxiety or depression. Not diagnosed of anxiety and depression based on clinical criteria. Should be mentioned well in the results and also in the discusison 2. In the introduction have been mentioned that " Meta-analyses show that antenatal depression is associated with a modestly increased risk of preterm birth and fetal growth restriction, and decreased rates of breastfeeding initiation" so what was the novelty of this study? and the clinical question should be clear in the introduction 3. It was not cohort study, because there was no control . This may appropriate as characteristic of health care quality of life women who came to pre term clinic who had at risk of anxiety and depression 4. In the table 2 was no clear, what was the set 1,2,3 . were it follow up? 5. How do you do mixed model? without control. 6. After revised the results, the discussion should be also revised. Discuss the descriptive of at risk mental health problem and quality of life in preterm women who came to clinic. Compare the results with others studies

REVIEWER	Maggie Redshaw NPEU, Department of Population Health
REVIEW RETURNED	13-Nov-2021

GENERAL COMMENTS	This is well written describing a useful study of women's mental health and wellbeing in the context of possible preterm birth and previously experienced PTB or difficulties associated with pregnancy losses or cervical surgery. Specialist preterm birth clinics have developed and the quality of the evidence supporting their provision has been less than adequate. As a complex intervention their value and the associated difficulties in describing what is provided and their impact is well illustrated in this paper.

	The study design and analysis is appropriate, However, in the discussion section on limitations, the authors rightly discuss the relatively small sample size and the theoretical need for a comparison group, though there is probably little motivation to design a study which directly compares centres with and without such a clinic in operation. Building on the other study referred to (O'Brien et al, 2010), using qualitative methods, carried out alongside such a quantitative study may well provide more information about exactly how such clinic provision works, in a psychological sense, for women in such a situation. A minor point relates to the EPDS which essentially measures symptoms of depression, though the authors do emphasise that the EPDS and the STAI are screening, rather than diagnostic measures. The conclusion to the paper emphasises that 'Women at increased risk of spontaneous preterm birth have high rates of anxiety in early pregnancy' while it would be more appropriate to say that these women are more likely to have higher levels of anxiety, given that less than 40% screened positive on the STAI.

VERSION 1 – AUTHOR RESPONSE

Reviewer One's Comment	**Authors' Response**
1. The results were suspected anxiety or depression, high risk of anxiety or depression. Not diagnosed of anxiety and depression based on clinical criteria. Should be mentioned well in the results and also in the discussion.	We agree that this is an important distinction. We have defined this in the results section, (first paragraph of page 10). We have also discussed this, including the limitations in the discussion (fourth paragraph of page 18). Reviewer Two has stated that the authors "do emphasise that the EPDS and the STAI are screening, rather than diagnostic measures".
2. In the introduction have been mentioned that " Meta-analyses show that antenatal depression is associated with a modestly increased risk of preterm birth and fetal growth restriction, and decreased rates of breastfeeding initiation" so what was the novelty of this study? And the clinical question should be clear in the introduction.	Previous studies, including the meta-analyses referred to here, have assessed the consequences of antenatal depression. The reason for our reference to these meta-analyses was to demonstrate the impact of antenatal depression on other pregnancy conditions. Our study had a different clinical question, it was designed "*to assess rates of anxiety, depression and health-related quality of life in pregnant women at high risk of spontaneous preterm birth who are cared for in a preterm birth clinic"*. The study aim is stated in the last paragraph of the introduction (page 5).
3. It was not cohort study, because there was no control. This may appropriate as characteristic of health care quality of life women who came to pre term clinic who had at risk of anxiety and depression.	A cohort study is defined as a longitudinal study that that follows participants over a period of time in which the participants have a particular condition. Cohort studies do not require a control or comparator group.

	We can confirm this is a cohort study as reported. The language used in the rest of the reviewer's question is unclear and so we are unable to respond further.
4. In the table 2 was no clear, what was the set 1,2,3. Were it follow up?	The 'set' refer to the set of questionnaires. This is defined in the methods section (paragraph 2, page 6) – *"Participants completed three sets of questionnaires: prior to their first clinic appointment (baseline, Set 1), after their second appointment (usually 2-3 weeks later, Set 2), and after their last appointment (usually at 23-24 weeks of gestation, Set 3)."* We have now added an additional footnote to Table 2 to remind readers of this.
5. How do you do mixed model? Without control.	Mixed models for repeated measures analysis is a standard method for analysing data that are not independent. One example of such data is longitudinal data when observations are repeatedly collected over time on a subject, such as this study. Mixed models allow the correlation of observations from the same subject to be modelled effectively. The use of mixed models for repeated measures analysis do not require a control group or comparator.
6. After revised the results, the discussion should be also revised. Discuss the descriptive of at risk mental health problem and quality of life in preterm women who came to clinic. Compare the results with others studies.	We have stated in the first line of the discussion that *"this is the first study to assess the psychological wellbeing of women receiving care in a specialised preterm birth clinic."* This limits the comparison to other studies. We have, however, compared the rates of anxiety and depression in pregnancy (both in the whole population and in high risk pregnancies) in paragraph 2 of the discussion, page 17.
Reviewer Two's Comment	**Authors' Response**
This is well written describing a useful study of women's mental health and wellbeing in the context of possible preterm birth and previously experienced PTB or difficulties associated with pregnancy losses or cervical surgery. Specialist preterm birth clinics have developed and the quality of the evidence supporting their provision has been less than adequate. As a complex intervention their value and the associated difficulties in describing what is provided and their impact is well illustrated in this paper.	No changes required.
The study design and analysis is appropriate, However, in the discussion section on limitations, the authors rightly discuss the	No changes required.

relatively small sample size and the theoretical need for a comparison group, though there is probably little motivation to design a study which directly compares centres with and without such a clinic in operation.	
Building on the other study referred to (O'Brien et al, 2010), using qualitative methods, carried out alongside such a quantitative study may well provide more information about exactly how such clinic provision works, in a psychological sense, for women in such a situation.	We agree that the use of qualitative methods to assess which elements of a preterm birth clinic improve psychological wellbeing is important. This was the rationale of including free-text responses in the study-specific questionnaire and performing thematic analysis on responses. There is scope for further dedicated studies in this area.
A minor point relates to the EPDS which essentially measures symptoms of depression, though the authors do emphasise that the EPDS and the STAI are screening, rather than diagnostic measures.	We acknowledge that a limitation of the study is the use of screening tests rather than diagnostic tests for anxiety and depression. We have discussed this, along with the rationale for their use and the validity of these tools in the fourth paragraph on page 18.
The conclusion to the paper emphasises that 'Women at increased risk of spontaneous preterm birth have high rates of anxiety in early pregnancy' while it would be more appropriate to say that these women are more likely to have higher levels of anxiety, given that less than 40% screened positive on the STAI.	This has been changed (first paragraph of the conclusion, page 19).

VERSION 2 – REVIEW

REVIEWER	Andree Kurniawan Pelita Harapan University, Internal medicine
REVIEW RETURNED	16-Dec-2021

GENERAL COMMENTS	The author have done beautiful work and written appropriately.