PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Hope for the best …but expect the worst: A qualitative study to explore how women with recurrent miscarriage experience the early waiting period of a new pregnancy
AUTHORS	Bailey, Sarah; Boivin, Jacky; Cheong, Ying; Kitson-Reynolds, Ellen; Bailey, Christopher; Macklon, Nick

VERSION 1 - REVIEW

REVIEWER	Sarah Meaney National Perinatal Epidemiology Centre, Ireland
REVIEW RETURNED	19-Feb-2019

GENERAL COMMENTS	Thank you for giving me the opportunity to review this manuscript. This is an important and well written paper that I believe will add greatly to the literature. Before it can be accepted for publication there are a few things which would need to be clarified and/or modified. Introduction. In your first paragraph you have given the definition of recurrent miscarriage (three or more consecutive losses) and you also mention the recent guidance from ESHRE. It might be worth a mention that in that guidance ESHRE have proposed to change this definition (although not all members agreed) to now define RM as two or more consecutive losses. This would mean that it will affect up to about 5% of those who are trying to conceive (ref Rai & Regan, (2009) Recurrent miscarriage. The Lancet) The statement beginning on Line 45 could be supported with a reference? Is it the Hutti et al 2015 reference from the end of the paragraph? If so I would just reference twice for clarity for the reader. I am not sure there is a need to refer to the early stages of pregnancy as the waiting stages. This makes sense in relation to your findings, however I do not think it necessary to refer to it in the introduction. From reading your paper it suggests that it is up to 6/7 weeks when they can have a scan but for others it might mean getting to 13 weeks when the risk of loss drops etc. this is emphasised by yourself in theme 3 whereby the women refer to attain personal milestones in the first trimester of pregnancy or even beyond the first trimester. You also have waiting period in inverted commas in some sentences and others not, adding a little

	bit to the confusion with no clear definition of what the “waiting period” is. Methodology: I have concerns that the two aims presented here do not marry well here. I can appreciate how you can explore women’s subjective experiences of the study intervention as well as their experience of a subsequent pregnancy following recurrent miscarriage. However I do not know if you have the scope within this paper to present the results in relation their experience of the research methods used in the randomised controlled trial (RCT) for feasibility purposes. This is highlighted by the fact that the topic guide and data collection were focused on “their perceptions and experiences of the waiting period of a new pregnancy”. There is little to no reference to the RCT made in paper, only a comment in the discussion. No reference to the trail or the intervention itself is made in the results section and the discussion only mentions that the RCT will be reported on elsewhere. I believe it is important to update your aims to reflect that which was collected and is now being presented in this paper more accurately. In the abstract and the analysis section you refer to a thematic network approach, to the best of my knowledge this means that you employ thematic analysis and then when presenting your data you organise it utilising this network approach. You have given a good description of it here, but I do wonder given the purpose of employing such a tool would it be of benefit to include the global theme identified and perhaps present the structure of a thematic network in a figure to illustrate the patterns between your basic themes and organisational themes more clearly? Figure 3 is a beginning but a web like map would be more appropriate given your methodology. You do not introduce the global theme until the discussion, this could perhaps be incorporated into the results or at least initially introduced into the results section? Results: Very well written with a good level of detail and interpretation. I suggest you need to put in titles for your tables/boxes. I think that theme 7, which is referred to in detail in the discussion could be developed a little further given that it was noted as a recurrent theme in the discussion With your results there is no clarity as to who was given the intervention or not. Did those who receive the intervention fair better or not. Did they still report the same experiences of emotional turmoil stress and anxiety? How did they find that the intervention help with this? Any differences at all with the control group? Or even those who experienced another miscarriage in this pregnancy versus those who continued in pregnancy. I feel this should have been explored more given the aims set out in the paper. Discussion: There are a few findings which are not fully explored in your results and these include commentary on how women felt relief following another miscarriage as they felt better able to cope with miscarriage (Line 35 of the discussion). This is really interesting

	finding and really important and needs to be explored more and presented in the results section. There are more strengths and limitations to these data. The PPI is a strength. The design being nested into an RCT is a limitation. These should be discussed a little further.

REVIEWER	Dr Susan Edwards Australia
REVIEW RETURNED	09-Mar-2019

GENERAL COMMENTS	Thank you for the opportunity to review this research paper. This article raises significant issues regarding the care of women experiencing recurrent miscarriage and is unquestionably important for women worldwide. The emotional and psychological consequence of miscarriage can be varied and for many women life altering. Improving the care of women who suffer miscarriage is a universal goal for healthcare providers. This research moves a step closer to meeting this goal by exploring the lived experience of women with recurrent miscarriage. The title reflects the content of the paper and the abstract is concise and well written. The introduction provides a good overview of what is known about recurrent miscarriage as well as identifying gaps in current literature. The paper clearly outlines the purpose of the study with a well-defined population group. The study design needs to summarise the research design and include why it was chosen and how it relates to the research question. Additionally, an explanation needs to be added as to why it yielded the best results for this research. Also, the PRCI would be best explained in the introduction alongside the information provided on page 4 – lines 5-12. Overall this research brings to light the experiences of women who suffer recurrent miscarriage and how they hope for the best… but expect the worst. Minor Edits Page 3 Line 12 - A definition of recurrent miscarriage has been provided but it would be good to add a definition of miscarriage. Page 3 Line 33 – This is a long sentence. I suggest adding a full stop after miscarriage. Page 3 Line 59 – What services are currently offered to women with recurrent miscarriage (or miscarriage) in the UK? Is counselling support available? Page 3 Line 50 – Suggest adding author/s e.g. One study by Hutti et al. 14 … Page 9 Line 23 – missing word "…that sharing the news of their pregnancy in the early stages pregnancy would tempt fate" suggest reworking or add early stages 'of' pregnancy would tempt fate…. Page 10 Line 59 – Consider changing 'Whilst' to While – (for an international audience). The use of whilst is used a number of times throughout the paper. Page 11 Line 37 – This sentence is too long resulting in loss of meaning and flow of the sentence. I suggest breaking this sentence into two. Page 11 Line 59 – The word 'losses' remove 'es' to 'repeated pregnancy loss'. Page 12 Line 31 – Remove additional word 'responses'. Page 15 Line 35 - Please ensure that you follow the BMJ Open referencing guidelines e.g. et al. needs to be in italics.

VERSION 1 – AUTHOR RESPONSE

Response to Reviewer 1

Thank you for your review of our paper. We have answered each of your points below:

Thank you for giving me the opportunity to review this manuscript. This is an important and well written paper that I believe will add greatly to the literature. Before it can be accepted for publication there are a few things which would need to be clarified and/or modified.

Introduction

In your first paragraph you have given the definition of recurrent miscarriage (three or more consecutive losses) and you also mention the recent guidance from ESHRE. It might be worth a mention that in that guidance ESHRE have proposed to change this definition (although not all members agreed) to now define RM as two or more consecutive losses. This would mean that it will affect up to about 5% of those who are trying to conceive (ref Rai & Regan, (2009) Recurrent miscarriage. The Lancet)

The definition of RM from ESHRE's recent guidance has now been included in this paragraph. (Page 3 Line 25)

The statement beginning on Line 45 could be supported with a reference? Is it the Hutti et al 2015 reference from the end of the paragraph? If so I would just reference twice for clarity for the reader.

The manuscript has been adjusted accordingly and a further reference added. (Page 4 Line 34)

I am not sure there is a need to refer to the early stages of pregnancy as the waiting stages. This makes sense in relation to your findings, however I do not think it necessary to refer to it in the introduction. From reading your paper it suggests that it is up to 6/7 weeks when they can have a scan but for others it might mean getting to 13 weeks when the risk of loss drops etc. this is emphasised by yourself in theme 3 whereby the women refer to attain personal milestones in the first trimester of pregnancy or even beyond the first trimester. You also have waiting period in inverted commas in some sentences and others not, adding a little bit to the confusion with no clear definition of what the "waiting period" is.

We very much appreciate this comment and have added in a section highlighting and clarifying why we refer to the early stages of a new pregnancy as the waiting period, giving a clear definition and have removed any inverted commas to avoid any confusion. (Page 4 Line 3)

Methodology:

I have concerns that the two aims presented here do not marry well here. I can appreciate how you can explore women's subjective experiences of the study intervention as well as their experience of a subsequent pregnancy following recurrent miscarriage. However I do not know if you have the scope within this paper to present the results in relation their experience of the research methods used in the randomised controlled trial (RCT) for feasibility purposes. This is highlighted by the fact that the topic guide and data collection were focused on "their perceptions and experiences of the waiting period of a new pregnancy". There is little to no reference to the RCT made in paper, only a comment in the discussion. No reference to the trail or the intervention itself is made in the results section and the discussion only mentions that the RCT will be reported on elsewhere. I believe it is important to update your aims to reflect that which was collected and is now being presented in this paper more accurately.

Thank you for raising this point. We agree that given the background, design and methodology of the associated RCT has been published elsewhere, and that the findings of the presented qualitative study do not require interpretation in the context of that study, it is sufficient to refer the reader to our earlier publication detailing the feasibility RCT. We have therefore reduced the degree of reference to the RCT as suggested

In the abstract and the analysis section you refer to a thematic network approach, to the best of my knowledge this means that you employ thematic analysis and then when presenting your data you organise it utilising this network approach. You have given a good description of it here, but I do wonder given the purpose of employing such a tool would it be of benefit to include the global theme identified and perhaps present the structure of a thematic network in a figure to illustrate the patterns between your basic themes and organisational themes more clearly? Figure 3 is a beginning but a web like map would be more appropriate given your methodology.

A figure illustrating the structure of a thematic network has been included.

You do not introduce the global theme until the discussion, this could perhaps be incorporated into the results or at least initially introduced into the results section?

The concept of the global theme, 'Hope for the best, but expect the worst' has been introduced at the beginning of the results section. (Page 6 Line 51)

Results:

Very well written with a good level of detail and interpretation.

I suggest you need to put in titles for your tables/boxes.

Thank you. Titles / box headings have been inserted

I think that theme 7, which is referred to in detail in the discussion could be developed a little further given that it was noted as a recurrent theme in the discussion

The reviewer makes an interesting point and the findings from Theme 7, 'Need for professional affirmation' have been developed (Page 12)

With your results there is no clarity as to who was given the intervention or not. Did those who receive the intervention fair better or not. Did they still report the same experiences of emotional turmoil stress and anxiety? How did they find that the intervention help with this? Any differences at all with the control group? Or even those who experienced another miscarriage in this pregnancy versus those who continued in pregnancy. I feel this should have been explored more given the aims set out in the paper.

A paragraph has now been included making clear that the broad themes and experiences presented in the results section are representative of both groups in the RCT, those who received the intervention and those who did not.

Discussion:

There are a few findings which are not fully explored in your results and these include commentary on how women felt relief following another miscarriage as they felt better able to cope with miscarriage (Line 35 of the discussion). This is really interesting finding and really important and needs to be explored more and presented in the results section.

We appreciate the reviewers comment and have explored the issue of uncertainty and coping more in the results section under organising theme 1 – 'Turmoil of emotions.'

There are more strengths and limitations to these data. The PPI is a strength. The design being nested into an RCT is a limitation. These should be discussed a little further.

We agree that the supportive and robust PPI involvement in this study helped to ensure the design of the study was centred on the patient's perspective and that the fact that the qualitative study was nested within the RCT feasibility study may have been a limitation. These factors have been detailed in the Discussion.

Response to Reviewer 2:

Thank you for your comments. Our answers to your points are as follows.

The study design needs to summarise the research design and include why it was chosen and how it relates to the research question. Additionally, an explanation needs to be added as to why it yielded the best results for this research. Also, the PRCI would be best explained in the introduction alongside the information provided on page 4 – lines 5-12.

Thank you for your comments. The reader has now been referred to our earlier publication that describes the intervention and the RCT study design in detail. Reference to the thesis has also been added. Information has been included summarising why a qualitative approach was utilised and added to the 'Design' section of this paper.

Minor Edits

Page 3 Line 12 - A definition of recurrent miscarriage has been provided but it would be good to add a definition of miscarriage.

A definition of miscarriage has been added to the introduction.

Page 3 Line 33 – This is a long sentence. I suggest adding a full stop after miscarriage.

Thank you. This has been amended

Page 3 Line 59 – What services are currently offered to women with recurrent miscarriage (or miscarriage) in the UK? Is counselling support available?

We have clarified that support for women with recurrent miscarriage during the early stages of a new pregnancy is usually limited and added an additional sentence to the potential reasons for this lack of support (Page 4 Line 48)

Page 3 Line 50 – Suggest adding author/s e.g. One study by Hutti et al. 14

Thank you. This has been amended

Page 9 Line 23 – missing word "…that sharing the news of their pregnancy in the early stages pregnancy would tempt fate" suggest reworking or add early stages 'of' pregnancy would tempt fate….

Thank you. This has been amended

Page 10 Line 59 – Consider changing 'Whilst' to While – (for an international audience). The use of whilst is used a number of times throughout the paper.

Thank you. This has been amended

Page 11 Line 37 – This sentence is too long resulting in loss of meaning and flow of the sentence. I suggest breaking this sentence into two.

Thank you. This has been amended

Page 11 Line 59 – The word 'losses' remove 'es' to 'repeated pregnancy loss'.

Thank you. This has been amended

Page 12 Line 31 – Remove additional word 'responses'.

Thank you. This has been amended

Page 15 Line 35 - Please ensure that you follow the BMJ Open referencing guidelines e.g. et al. needs to be in italics.

BMJ open referencing guidelines adhered to and 'et al' now in italics

VERSION 2 – REVIEW

REVIEWER	Sarah Meaney National Perinatal Epidemiology Centre, University College Cork, Ireland
REVIEW RETURNED	24-Apr-2019

GENERAL COMMENTS	I am satisfied that the authors have sufficiently dealt with my comments.