

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Life after loss Protocol for a Danish longitudinal follow-up study unfolding life and grief after the death of a child during pregnancy from gestational week 14, during birth or in the first 4 weeks of life
AUTHORS	Hvidtjørn, Dorte; Prinds, Christina; Bliddal, Mette; Henriksen, Tine; Cacciatore, Joanne; O'Connor, Maja

VERSION 1 – REVIEW

REVIEWER	Denise Defey School of Medicine, University of Uruguay, Uruguay
REVIEW RETURNED	12-Jun-2018

GENERAL COMMENTS	<p>This is a relevant piece of research which should improve its response rate to grant the validity of its outcome, specially as concerns fathers (since gender difference is one of the targets) and considering that non-responders may represent some of the most severe cases. Attached is a paper which reached parents directly by phone and reached a very high response rate of those they could trace and contact. Parents felt cared for and provided very rich spontaneous comments which, if recorded, can provide illuminating material for the discussion of results and for further papers using qualitative methodology as is suggested here. Non responders should be clearly described as to their sociodemographic profile, gender, type of loss and date contacted (24 to 60 days is an extended time span in the bereavement process). Even though it is too late to include this in the study design, the categories of "complicated grief" and "absence of grief" should be included in the literature review. Sociodemographic information should make it explicit whether participants are native Danish or immigrants. Upon analyzing the resulting data, stillbirths and TOPFA should each be clearly separated in the results because of specific features of the loss in each (dead fetus inside mother's body, parents' decision vs natural event, respectively). Some complementary qualitative information (as that suggested above) should enrich results providing subjective descriptions for the data provided, which could be included in the "Discussion" section.</p>
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REVIEWER	Ying-Fen Tseng Chung Hwa University of Medical Technology, Taiwan
REVIEW RETURNED	12-Jul-2018

GENERAL COMMENTS	<ol style="list-style-type: none">1. This protocol helps to fully explore the lost experience of couples who have experienced perinatal death in Denmark.2. It is recommended to clearly define the perinatal loss in the introduction part, and the subsequent text can avoid duplication.
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	<p>3. For a cohort study, the abstract of proposal should clearly state the three time points of the measurement.</p> <p>4. If the authors can draw a theoretical framework, the concept and rationale of the proposal should be more clearly presented.</p> <p>5. The reliability and validity of the scales are not stated in the part of methodology, and the number of items in some scales are inconsistent with Table 1. In addition, there are many scales and items used for each measurement, it is feared that the subject will be tired and the reliability and validity will be affected.</p> <p>6. The proposal does not describe the plan for statistical analysis.</p> <p>7. Did not mention the problems that this proposal may encounter and the strategies that are expected to be resolved.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Denise Defey

Institution and Country: School of Medicine, University of Uruguay, Uruguay

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

This is a relevant piece of research which should improve its response rate to grant the validity of its outcome, specially as concerns fathers (since gender difference is one of the targets) and considering that non-responders may represent some of the most severe cases.

As stated on page 10 in the methods section, each questionnaire is followed by reminders, the first one after 3 weeks and the second one after 6 weeks. Due to an initial low response rate, we further introduced a verbal reminder and our response rate has improved over the years.

As regards fathers, we can see in our data, that the response rate for fathers has also improved since the beginning of the data collection, but it is still considerably lower than the response rate for mothers. We are aware of this when inviting the parents to participate in the study, stressing the importance of the contribution from both mothers and fathers.

As regards the severity of the cases participating, we can of course not know how the non-responders are coping, but we will be able to tell if responders are representative of the population of bereaved parents regarding age, parity, gestational age at birth and age at death, whether the loss was TOPFA, miscarriage, stillbirth or death post partum, and whether the participant wanted to take part in a bereavement support group.

Attached is a paper which reached parents directly by phone and reached a very high response rate of those they could trace and contact. Parents felt cared for and provided very rich spontaneous comments which, if recorded, can provide illuminating material for the discussion of results and for further papers using qualitative methodology as is suggested here.

Thank you very much for bringing our attention to this study, which we have read with interest. We also agree, that using a qualitative methodology can enrich a study considerably and whenever possible, data from this survey will be combined with qualitative data in mixed method studies.

Non responders should be clearly described as to their sociodemographic profile, gender, type of loss and date contacted (24 to 60 days is an extended time span in the bereavement process).

As described on page 10 in the methods section, there are dissimilarities in the way we recruit the parents in the different regions of Denmark. In one part, the region of Southern Denmark (representing 20% of the population in Denmark), we have additional information on non-responders: mother/partner, age, date contacted, parity, gestational age at birth and age at death, whether the

loss was TOPFA, miscarriage, stillbirth or death post partum, and whether the participant wanted to take part in a bereavement support group. We will describe the non-responders/responders according to these variables. Unfortunately, we do not have information on socio-demographic profile and we do not have permission to provide this from registers. This information has been added in the data analysis section on page 15.

Even though it is too late to include this in the study design, the categories of "complicated grief" and "absence of grief" should be included in the literature review.

Complicated grief and absence of grief are encompassed in the criteria for the new diagnosis termed Prolonged Grief Disorder (PGD), defined by The World Health Organization, and we have therefore chosen to use this terminology (please see the introduction on page 3).

Sociodemographic information should make it explicit whether participants are native Danish or immigrants.

Unfortunately, we do not have information about the participants' country of birth, but the immigration rate in Denmark is very low, around 10 % of the Danish population are immigrants or descendants.

Upon analyzing the resulting data, stillbirths and TOPFA should each be clearly separated in the results because of specific features of the loss in each (dead fetus inside mother's body, parents' decision vs natural event, respectively).

Yes, we highly agree with the reviewer, the specific features of the loss are important to assess separately and the results will be analyzed according to the circumstances surrounding the death of the baby. This is now describes in the statistical analysis plan on page 15-16.

Some complementary qualitative information (as that suggested above) should enrich results providing subjective descriptions for the data provided, which could be included in the "Discussion" section.

Please, see our answer above.

Reviewer: 2

Reviewer Name: Ying-Fen Tseng

Institution and Country: Chung Hwa University of Medical Technology, Taiwan

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

1. This protocol helps to fully explore the lost experience of couples who have experienced perinatal death in Denmark.
2. It is recommended to clearly define the perinatal loss in the introduction part, and the subsequent text can avoid duplication. Thank you for directing our attention to this, a sentence defining perinatal loss is now included in the introduction, page 4.
3. For a cohort study, the abstract of proposal should clearly state the three time points of the measurement. Yes, of course, the specific time-points are now clearly stated in the abstract, page 2.
4. If the authors can draw a theoretical framework, the concept and rationale of the proposal should be more clearly presented. Our theoretical framework, or perhaps in this study better characterized as our hypothesis, is that "a longer period of intense grief may be the normal response for parents grieving after the death of a baby" (page 2-3) and this has now been stated more clearly in the

introduction. The theoretical framework behind the construction of the questionnaire is described in a specific section on pages 6-8.

5. The reliability and validity of the scales are not stated in the part of methodology, and the number of items in some scales is inconsistent with Table 1. In addition, there are many scales and items used for each measurement, it is feared that the subject will be tired and the reliability and validity will be affected. The reliability and validity of the scales are now stated in the methods section, pages 12-13.

The numbers in the text and in the table are now corrected.

We carefully chose the scales included to obtain plentiful information. Most participants, who open the survey, also answer all the questions. Of course, they still might get tired completing the questionnaire and this issue will be mentioned in the discussion in the papers to come.

6. The proposal does not describe the plan for statistical analysis. A section about plan for statistical analysis is now added, page 15.

7. Did not mention the problems that this proposal may encounter and the strategies that are expected to be resolved. The strength and limitation section on page two is now expanded, more clearly addressing the problems we may encounter in this study.

VERSION 2 – REVIEW

REVIEWER	Denise Defey School of Medicine, University of Uruguay
REVIEW RETURNED	16-Sep-2018

GENERAL COMMENTS	The authors have made the suggested corrections.
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REVIEWER	Ying-Fen Tseng Chung Hwa University of Medical Technology, Taiwan
REVIEW RETURNED	06-Oct-2018

GENERAL COMMENTS	In addition to worrying that the number of questionnaires is heavy on the case, my opinion is that the proposal has been revised to a feasible stage.
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