Author's response to reviews

Title: Parent distress reactions following a serious illness or injury in their child: A protocol paper for The Take a Breath Cohort Study

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Author's response to reviews: see over
Dear Dr Anna Clark,

Thank you for reviewing our manuscript, titled ‘Parent distress reactions following a serious illness or injury in their child: A protocol paper for The Take a Breath Cohort Study’ (MS: 1694460292146059).

We also thank you for allowing us an opportunity to respond to the comments of the reviewers. Responses are outlined below, and all changes are highlighted within the manuscript.

**Reviewer 1:**

Reviewer 1 appropriately noted that attrition at Time point 4 was high, which may threaten the validity of the findings.

We agree that this is the case and is a common issue in longitudinal studies. For this study, the high attrition reflects both the complexity of recruitment (involving 4 different hospital departments within the acute admission/diagnosis period) and the challenges in following up families whose children have been very unwell and at follow-ups are quite diverse in the extent to which they have ongoing treatment and health concerns. This attrition will be acknowledged in future reports of the study findings and a variety of methods will be employed to determine the extent to which this may introduce bias and/or limit the generalisability of findings. As one of the first studies internationally to collect longitudinal data on parent outcomes across different child illness groups, following an acute hospital admission, the study provides unique data which that, despite this limitation, will provide unique insight into parental experiences.

1. Purpose of a protocol: Strictly speaking I would not expect a protocol to present data – my understanding is that usually a protocol is published ahead of data collection.

Reviewer 1 is correct that data collection has been completed. Given the study complexity and the unique design (recruitment and collection of data across different illness groups), we believe that it is important to publish the study protocol as a basis for the series of planned cross-sectional and longitudinal analyses that are forthcoming. We agree that data are not commonly presented in protocol papers, however given that data are available to present, we believe it is important to provide these and that their inclusion will add to the level of interest for the reader.

2. Fig 3: It might be easier to follow this diagram if you distinguish more clearly between ‘eligible’ and ‘approached’. Lack of participation in the approached group is a different thing to being impossible to contact in the first place – different strategies needed to remedy in future research.

We agree with the reviewer’s comments. In the second box of the figure, the group labelled ‘Declined to participate’ was changed to ‘Eligible but not recruited’. This clarifies the number in the sample that was eligible but not recruited due to declining vs. not being able to be approached (missed, not approved, moved). The next box provides information on those that were eligible and approached and consented.

3. Layout: I am not clear why some sub-headings are underlined/in capitals/italicised/indented. Please consider making the structure of the manuscript clearer in this respect.

Apologies. We have now made the formatting and layout of all headings and subheadings consistent throughout the manuscript.
4. Reviewer 1 questioned the collapsing of the Neurology group and the PICU group into a single ‘mixed’ illness group, due to a low response rate from the Neurology group. They also suggested removing the Neurology group altogether.

We did consider this idea presented by Reviewer 1, however there were reasons why we decided to amalgamate the groups instead. Firstly, most of those within the Neurology group were initially admitted through PICU, and actually also satisfied the eligibility criteria for inclusion into the PICU group. Secondly, although we agree with Reviewer 1 that we adversely impact the response rate of the PICU group and the overall study by not excluding the Neurology group, we prefer to openly report the recruitment numbers across all departments, rather than remove one group just to improve response rates.

5. Reviewer 1 also suggested the inclusion of some particular recent references.

As suggested, the research of Le Brocque and colleagues was added in the first and fourth paragraphs of the Introduction, and the research of Colville and Pierce was added to the first, fifth and seventh paragraphs of the Introduction.

**Reviewer 2:**

**Major compulsory revisions:** None

**Minor revisions:**

1. Please provide examples of what was classified as a "major trauma" for parents in the exclusion criteria.

This has been added to page 9.

2. A brief description of how covariates will be assessed and included in relevant analyses seems important.

We plan to screen potential covariates using univariate analyses. Should these variables be significantly associated with outcomes (at the less stringent level p<0.1), they will be adjusted for in further analyses. The end of first paragraph of the “Data Analysis” section on page 13 has been modified to include this information.

3. The authors briefly mention power analyses in the data analysis section. The authors are encouraged to provide a priori power analyses for each relevant aim.

We have modified the Data Analysis paragraph, providing more clarity regarding analyses and power (sample size). Power calculations have been included for Aims 2 and 3. However, as Aim 4 is exploratory in nature, it would be illogical to calculate power and sample size. We do expect the path analysis model to be adequately powered with the sample of 240, and have clarified that this analysis is “exploratory” in text.
4. Figure 1 was somewhat confusing since it includes targets for intervention which is beyond what the authors are targeting in this study. It is recommended that the authors mention in the text or remove the intervention wording from Figure 1.

Rather than altering the original model, the targets for intervention associated with each stage of the model is now mentioned within the text (see page 6). This clarifies all aspects of the model presented, as suggested by Reviewer 2.

5. Figure 2 could be easily misinterpreted given the arrows in the diagram. It is recommended that the authors include IVs in the first box, mediators/moderators in the second box, and then outcomes in the final box, similar to the models they are testing. Currently, one could interpret that the moderators were IVs if they happened to take a look at the figure quickly.

Thank you for raising this issue, which was an error. The title of the first box in the Figure has now been correctly changed to ‘Predictors’ rather than moderators.