Author’s response to reviews

Title: Uncovering the emotional aspects of working on a clinical trial work: a qualitative study of the experiences and views of staff involved in a type 1 diabetes trial

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Author’s response to reviews: see over
Thank you very much for sending our paper out to review. We are very pleased to see that, on balance, the reviewers like the paper and we are very grateful indeed for their helpful and constructive comments. We hope you will agree that we have strengthened the manuscript in light of these. Below, we list our responses to the individual points raised by the reviewers and highlight the changes to the manuscript we have made. We would be very happy to make further revisions if required. Thank you again.

Editorial requests:
1. Please include a Methods section before the Results section (all research papers should have Background, Methods, Results, Discussion and Conclusion sections). Please note that ethical approval and consent statements should be in the Methods section.

Response: both of these have been done.

Reviewer’s report
Title: Uncovering emotion work in clinical trials: a qualitative study of the experiences and views of staff involved in a type 1 diabetes trial
Version: 2 Date: 31 August 2014
Reviewer: Mary Dixon-Woods

Reviewer’s report:
1. Is the question posed by the authors new and well defined? The authors argue that qualitative research is important alongside clinical trials. While I don’t disagree with this, I would suggest that it should not be the opening gambit for the paper. It is important that the paper focuses in on the substantive research question rather than making a claim for the value of a particular research methodology.

The question of staff experiences of trial “work” is an important one but as currently described in the paper refers more to a general field of study rather than a well-formulated research question with defined terms. The authors need to clarify the question they wish to address more precisely. For instance, there may be many different roles for staff on a trial - from those involved in recruitment to those involved in design and those involved in delivery of interventions. Their experiences are likely to be heterogeneous, and it is also likely that, say, the experience of the Chief Investigator may be very different from that of a research nurse. The authors should acknowledge this more clearly in their introduction, by way of more explicitly defining the specific research question.

The Introductory section would also be clearer with a more detailed discussion of the concept of emotional work/emotional labour and its potential value in exploring issues of trial work. At present most of this material is currently found in the Discussion.

Response: Many thanks indeed for these extremely helpful suggestions. In light of these and similar feedback from one of the other reviewers we have completely
redrafted the introduction in order to make the paper’s aims much clearer as well as making changes to the abstract. We have also added a section on emotional labour to the introduction and made clearer its potential relevance to trial work. In the discussion, we reflect on the potential limitations of having only interviewed educators (rather than, say, doctors). However, as we also make clearer in the revised manuscript, it was these particular staff members who led recruitment and were responsible for delivering the trial interventions. Hence, educators were most pertinent and important people to interview in our particular study.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?

The sub-heading of the Methods section seems to have been mis-labelled. Most of the Methods are in a section labelled “Results”. This section is reasonably clearly report but would benefit from a couple of introductory sentences to explain the study design.

The authors say that they analysed the data thematically, but they do not provide any reference for the method used. This is an important weakness as it is not clear whether the analysis was informed by any prior framework (as is often a feature of framework analysis) or whether the categories of analysis were grounded solely in the data themselves (as in some variants of grounded theory). The authors should give a reference for the concept of theoretical saturation, which they draw on without using the term explicitly.

Response: We apologise for having mistakenly mislabelled our methods section as results. This error has been corrected. We have added a section to the start of the methods explaining our study design and we have provided a clearer explication of our analytical approach together with references to relevant literature.

3. Are the data sound and well controlled?

The findings section would be clearer with a paragraph at the beginning to orientate the reader to the main categories of findings.

This section is actually rather hard to follow without in-depth knowledge of the trial itself. The authors need to avoid assuming any prior knowledge on the part of the reader.

Response: We have added a paragraph to the start of the findings to offer better sign-posting for the reader. We have also provided more detail regarding the roles undertaken by the trial staff we interviewed (educators) to help make the findings easier to follow (for instance, we have made it clearer that these staff members undertook trial work alongside routine clinical work). We have also slightly expanded the description of the trial earlier on in the paper and added reference to the trial protocol paper which has now been published.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?

I am not sure about data deposition but reporting seems to be fine. I think they could explain a little more clearly that the research question in some senses appears to have been conceived post-hoc, after the data were collected.

Response: We have addressed this point by redrafting our introduction.
5. Are the discussion and conclusions well balanced and adequately supported by the data?
The Discussion and conclusions are fine, and actually this section is perhaps the best part of the paper. It's a little long and the authors might consider shortening a bit, and perhaps putting a summary their recommendations into a box so that the implications of the study are clear. They should also acknowledge more clearly the need to evaluate their recommendations, not just to work out whether they are effective but also to assess the costs involved.

Response: We have looked at the discussions of similar papers published in Trials and our discussion appears to be of an average length. Given this, and the fact that Prof Dixon-Woods considers our discussion to be the best part of the paper, we have decided to maintain its present length. We would be happy to put a summary into a box if the editor would like us to do this. We have not done this as yet as we are not sure if this would be in kilter with the journal's house-style. In the revised text, we have acknowledged more clearly the need to evaluate our recommendations for effectiveness and cost effectiveness. Thank you for this suggestion.

7. Is the writing acceptable?
It's a bit clunky, with some very long and not always terribly grammatical sentences, but it is acceptable.

Response: We have redrafted the manuscript in some places in light of this observation.

Reviewer's report
Title: Uncovering emotion work in clinical trials: a qualitative study of the experiences and views of staff involved in a type 1 diabetes trial
Version: 2
Date: 26 August 2014
Reviewer: Jenny L. Donovan

Reviewer's report:
This is a well-written and interesting paper in an important area. It represents a very good use of qualitative research methods, and these are well described, along with a clear presentation of the findings and discussion. The views of recruitment staff have not been much heard in the published literature, and this paper raises important, interesting and original issues that need to be aired and further discussed.

Major compulsory revisions
It would be helpful if the authors:
1. Included the actual topic guide as a figure
2. Included a little more on the strengths and limitations of the study in the discussion. They have acknowledged the single trial, but should also acknowledge the focus of this paper on nurses’ experiences (both as a strength and limitation), the relatively small sample (balanced by with clear and consistent findings), and the reliance on interviews only.

Response: Thank you for these helpful suggestions. As the revised manuscript makes clearer, it was not our original aim to look at emotional labour and emotional
issues arising for staff during the trial; rather, these issues emerged from the data. As we specify in the revised manuscript, the study was originally developed to aid interpretation of trial findings, inform recommendations for rollout of the treatments investigated (MDI vs insulin pumps) and to suggest ways to support future staff. For this reason, a lot of the questions on the topic guide are not relevant to the material reported in the paper. Hence, we are concerned that, if we were to include the actual topic guide in its entirety, this could cause readers confusion. For this reason, we have only outlined the topics explored in the interviews which are relevant to the data and findings presented in our paper. We have put these into a Figure in line with Prof Donovan’s suggestion and, in the Figure, we have provided more detail about the areas we explored than was described in the original manuscript.

With regards to the second point, we have expanded our discussion of our study’s strengths and limitations, in line with Prof Donovan’s helpful suggestions.

Minor essential revisions
The paper is well written and presented. I could find only one typo: ‘Donovan’ not ‘Donnovan’.

Response: We have corrected this error.

Discretionary revisions
There are several potential revisions that the authors might like to consider:

1. The authors are not quite right that emotion in the context of recruitment to trials has not previously been reported or recognised. This does not negate their paper in any way, including its conclusions, but it would be helpful if their work could be integrated with the other papers and if they could remove the ‘erstwhile unrecognised and unreported’ phrase in the abstract. The paper by Taylor et al (Soc Sci Med 1992; 35: 217-24) was probably the first in the field. Although the authors were unaware, two other papers were also being published as they submitted their manuscript – and both of these raise and discuss the issue of emotion in relation to recruitment to trials: Donovan JL et al, Clear obstacles…. Trials 2014, 15:5, and Donovan JL et al, The intellectual …. Journal of Clinical Epi 2014; 67(8): 912-20. These papers raise similar, but not identical issues in relation to emotion in recruitment, and so it would be helpful if the authors would consider their findings and particularly identify the complementary and original findings in this submitted paper. Of particular interest in this submitted paper are the emotions arising from the nurses’ roles (complementary) and from the consequences of the delivery of the allocation (original). There are also several other original features in this submitted manuscript that can be identified (e.g. the importance of a continuing clinical relationship after the trial has finished).

Response: As Prof Donovan correctly suggests, we were unaware of her two newly published papers at the time we submitted the manuscript. Having read these papers we were left in no doubt of their importance and relevance and, hence, we have worked them into the revised manuscript, and described how our own paper builds on, complements and advances their findings. Far from being discouraged that
others are also writing about the emotional aspects of trial work, we believe we have produced a stronger manuscript by virtue of being able to refer to the two studies first authored by Prof Donovan. Interestingly, the other paper to which Prof Donovan refers (Taylor et al) involves a study undertaken with physicians before they delivered the trial. Hence, arguably this paper doesn’t chart the emotional elements arising from trial work as such; also the paper is centrally concerned with anticipated ethical conflicts rather than with emotional impacts. Nonetheless it is an excellent and ground-breaking paper and, hence, we have added it to our overview of the key literature in our introduction.

2. It would be helpful if the authors reported on the socio-demographic details of those interviewed – age, sex, length of service/experience clinically and in trials, whether they were directly employed by and for the trial – if they have the information available, and whether any of those factors seem to have any influence on responses.

Response: We have added some of the details suggested e.g. that all the educators were female; that they worked part time on the trial alongside routine clinical work; and their years of clinical/diabetes experience. We agree that these data are relevant to interpreting our findings (and also to reflecting on our study limitations). Unfortunately we did not collect socio-demographic data, but we do think that demographic data are less important than the other data we have been able to present.

3. The finding of the emotional work required after the receipt of the allocation, and particularly when this led to upset or anger, is particularly interesting and original. In the discussion, it might be worth raising the issue about how fully informed patients were, and how patient preferences were dealt with, particularly as not receiving the pump appeared to cause most distress. There is research by Mills N et al in Trials and JCE about this issue. If the authors have data from patient interviews about this, could this be presented here, or reference made to it if published elsewhere.

Response: In an earlier section of the paper (where we introduce the REPOSE trial) we describe the mechanisms which were put in place by the trial team to help ensure informed consent was gained. We do also specify that, to meet the trial’s inclusion criteria, patients could not have a stated preference for one treatment over the other. We have also expanded the findings slightly to make it clearer that, on some occasions, staff felt patients deliberately kept their treatment preferences to themselves until after they were randomized. Unfortunately, we do not have published patient data which we can cross-reference in our discussion. Other members of the REPOSE team are currently analysing the interviews with patients for a separate paper.

4. The terms ‘emotion work’ and ‘emotion labour’ are easily accepted and understood by social scientists. However, they may be less accessible to trialists, and the authors might like to consider whether these concepts could be expressed differently, particularly in the title, abstract and conclusions. It is important that this work is considered further by trialists.
Response: We have made the paper more accessible to trialists by adding a clear and succinct definition of emotional labour (and how the concept emerged) at the end of our introduction. We have also changed the title and reworded the abstract and other parts of the text to further increase the paper's accessibility and avoid use of terminology which might initially alienate some readers.

**Level of interest:** An article of importance in its field  
**Quality of written English:** Acceptable  
**Statistical review:** No, the manuscript does not need to be seen by a statistician.  
**Declaration of competing interests:**  
I declare that I have no financial competing interests.  
I have published papers that are complementary to this submission
Reviewer's report
Title: Uncovering emotion work in clinical trials: a qualitative study of the experiences and views of staff involved in a type 1 diabetes trial
Version: 2
Date: 17 August 2014
Reviewer: anna wolters

Reviewer's report:
Major Compulsory Revisions
1. It is not clear to me what the question is. The topic announced after the literature review is emotional labour/impact, but the fact that this topic uncovered itself during the interviews is in itself not a convincing justification. Its relevance might be enhanced by re-writing the introduction and quickly work towards emotion/randomization and, consequently, a clear research question. The two references [23, 24] seem the most relevant. These re-appear in the Discussion. I think the paper would gain depth if that part of the Discussion (more or less from ‘Like the “emotional labour” uncovered by…’ to ‘…pragmatic and realistic approaches to be developed) were taken as a starting point in the section Background. The present literature review insufficiently delves into the topic. A relevant author on emotion and other aspects of trial work is Jill Fisher, eg her book Medical Research for Hire.

Response: As indicated in our response to Prof Dixon-Woods above, we have totally redrafted our introduction and rewritten parts of our abstract in order to make the paper's aim and intended contribution much clearer. We have also expanded the coverage of the literature in the introduction, including adding in two references to Fisher's publications, as well as the two papers published by Donovan et al. (see above) which came out after we first submitted our manuscript. In doing so, we believe we have set the scene for our own work more strongly and convincingly.

2. ‘Findings': All its sub-sections show the pattern of a para introducing a topic that is illustrated with a quote, a new topic with a quote etc. But what’s the point? It might help to conclude these separate paras, and to add conclusions to each sub-section.

Response: Starting a subsection or topic with a quote from a participant is a fairly standard and entirely legitimate way of presenting qualitative data, not least because we refer back to the quote in our analysis, tease the key points out of it, and connect these points to other findings. We are concerned that, were we to add conclusions to separate paragraphs and subsections, this would make the paper needlessly long and very repetitive. However, we hope that by adding an introductory paragraph at the start of the findings (see above) which signposts all of the key findings we go on to report, we have now made this part of the manuscript much easier to navigate.

3. ‘Practical aspects': How does this sub-section contribute to the analysis of the emotion topic? What is the sub-question? What is the conclusion? I do understand its role in the narrative, although similar content has been described in the literature that was referred to earlier (in Studies of staff experiences) and
although the starting quote and the first lines of next sub-section (Emotional aspects) tell the same story.

Response: We have described practical aspects of working on the trial in order to be able to show that these had an emotional impact on staff. While the former is not a novel finding, the latter is; hence, our reason for reporting it. With regards to what the conclusion is – in the discussion we do suggest that a potential way to address the emotional elements of trial work is to tackle the practical aspects of trial work which cause staff stress and worry (although we go on to make the point that this could potentially be an expensive option). To address the final point raised by Ms Wolters, we have edited the quote at the end of the section on ‘Practical aspects of trial work’ to avoid any overlap with the data presented at the start of the section on ‘Emotional aspects of trial work’.

4. ‘Emotional aspects’: in line with the above comment, the empirics are well described (yet might be more succinct), but the urgency is missing because of lacking links between paras and of lacking conclusions.

Response: See our response to point 2 above. We also hope the addition of the introductory paragraph at the start of the findings section will help to address Ms Wolters' concern, together with our decision to completely redraft the manuscript’s introduction.

5. Since the Findings mainly show that staff experiences a problem, but less what makes the problem relevant, the Discussion and Conclusion as well seem to lack a bit of depth. The concept of emotion work in nursing and midwifery is taken to be applicable to the clinical trial situation. I think, however, that there are important differences that can and should be highlighted in making analytic use of the Findings. A concept of emotion work in trials (in adapting eg the work of ‘James and others’) would be a most welcome contribution to the growing body of work on trial co-ordination. You do have the material to work on that.

Response: We do apologise, but we are not entirely sure that we understand what Ms Wolters is suggesting/asking us to do. As far as we can tell, the first part of her comment relates to an earlier concern both she and Prof Dixon-Woods raised about the paper lacking a clear aim (and, hence, potentially lacking clear relevance to the trials literature). We hope, therefore, that by completely rewriting the introduction and making clearer what our manuscript is attempting to achieve we have satisfactorily addressed this concern. With regards to the second point, we have taken the concept of emotional work in nursing and midwifery to be applicable to the trial situation as this is where our own findings and data led us (i.e. after uncovering the emotional elements of trial work in our data we found no major differences between our findings and those reported in the nursing and midwifery literatures when these literatures are brought together). Hence a key aim of our paper is to bring the concept of emotional labour, which is well-recognised in nursing and midwifery
literatures, into the trials literature (again, we make this aim clearer in our redrafted manuscript). Contrary to what Ms Wolters appears to be suggesting in her final point, we do make recommendations for offering better (emotional) support to staff which are tailored and specific to those involved in trial research.

6. There seems to be too little distance between the problems experienced by the interviewees and what the authors do with it. It looks as if the problems and desires of staff are simply taken over in the recommendations. Little difference has been made between emotionally challenging issues in every nursing/midwifery and trial staff stuff. The appeal for a psychologist and one to one support therefore does not feel as being to the point. As a whole, the recommendations need more convincing arguments. It is of course possible that a re-analysis of the material leads to a different conclusion and to different (or no) recommendations.

Response: While we do use some of staff members’ own suggestions as the basis for some of our recommendations, we do also caveat these recommendations in the revised manuscript by suggesting that they should be subjected to future evaluation (see also our response to Prof Dixon-Woods above). In addition, we also make recommendations, drawing upon learning from the nursing/midwifery and other literatures, which were not explicitly identified by staff. In general we were a bit surprised by Ms Wolters’ concern above (and in point 5) as the other two reviewers (who are highly experienced and eminently well-respected qualitative researchers in the trials field) made very favourable comments about the paper and, more specifically, its discussion and recommendations.

7. The topic of emotion work was given attention in earlier trial literature. The title and abstract make too strong a claim.

Response: We have redrafted the abstract and changed the title to lessen the strengths of our claims.

Minor Essential Revisions
8. ‘Data coll & analysis’ : What was the role of the other four authors?

Response: The contribution of the other four authors is clearly stated in the section at the end of the paper titled ‘Authors contributions’.