**Author’s response to reviews**

**Title:** Optimising the acceptability and feasibility of novel complex interventions: an iterative, person-based approach to developing the UK Morita Therapy outpatient protocol

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**Author’s response to reviews:**

Dear Editor-in-Chief,

PAFS-D-16-00059

We thank the reviewers for their comments on our methodology manuscript entitled ‘Optimising the acceptability and feasibility of novel complex interventions: an iterative, person-based approach to developing the UK Morita Therapy outpatient protocol’. We are pleased to respond.

1. It feels very long and I think it would benefit from restructuring such that all the methods are together followed by the Results. It reads as three disconnected studies rather than an iterative integrated approach based on the MRC framework. I also think that in some places the writing could be condensed more/written more tightly to reduce overall word length. Whilst overall English is good some sentences need rewording for clarity.

We agree with the Reviewer’s comments and have edited the structure of our manuscript to present all research questions, methods and results together in turn, as suggested. Furthermore, the writing has been amended throughout the manuscript in order to improve clarity and reduce length, and the presentation of qualitative results in particular has been condensed. The overall length of the main manuscript has been reduced by approximately 13% / 700 words. We feel that further reduction in the word count would detract from the transparency of the approach, and believe the manuscript now holds together as a cohesive presentation of one integrated iterative approach.
2. Reviewer #1: I am afraid that, despite the authors’ claims, there is nothing novel here, as currently articulated in the paper. It feels as though the MRC guidance has been well followed but this is but one of many examples of that. It is good practice but not anything new.

Review #2: It would benefit, however, from highlighting whether this is indeed a novel approach (and if so how) or, rather, whether it is applying good practice in intervention development from one type of complex intervention to a different type of complex intervention (e.g. to the broad area of mental health / therapy or the adaptation of therapy for clinical depression and GAD, ...).

We thank the Reviewers for their comments. We agree that whilst our approach is not novel, our paper demonstrates best practice in intervention development. We believe additional value is gained through the specific application of our approach to the cross-cultural adaptation of an intervention, in which balancing optimisation of the approach for a UK population and adherence to the essence of the original approach was key. Furthermore, we believe we make a novel contribution to a field which is rarely reported in detail by presenting our approach to intervention development in a transparent and replicable manner. We have clarified these messages within our abstract (background/ conclusions), background (final paragraph) and discussion (first paragraph/ implications and conclusions section).

3. There are also some small inconsistencies across the paper- for example it is unclear to what extent the 4th stage included development and/or delivery of the training, and how the findings informed training. Thinking of the systematic approach to developing training, there should be agreed learning objectives based on a needs assessment (which has by implication been done albeit on a very sample) and then thinking of the best way for people to learn about these objectives and potentially be assessed on them. For a subsequent stage of a feasibility study, fidelity to the intervention (which would be dependent to some extent on the quality of the training), would be key.

We agree that this aspect of our process was unclear. Our intention was not to develop a comprehensive therapist training programme, which was developed following good practice with a focus on skills-based learning, and is outside the scope of this manuscript. Rather, our intention was to understand how we might tailor the content and focus of our therapist training programme in response to the specific issues our interviewees identified. We understand that this intention was not clearly articulated in our original manuscript and, to rectify this, have rephrased our stage four research question, and other references to the therapist training programme, to stress the importance of tailoring, as opposed to developing, a therapist training programme.
We are assessing therapist fidelity to the protocol within our feasibility study and, as noted in our discussion, will integrate this data with qualitative data on intervention acceptability and quantitative data on patient adherence to treatment in order to understand this relationship and, in turn, assess the need for further amendments to our therapy protocol.

4. As a small point there also should be consistency in use of terms feasibility and pilot which appear to be used interchangeably.

We have amended all such references to read ‘feasibility study’.

5. It would benefit from the addition of a Box to clearly explain Morita Therapy - many readers will not be aware of its key principles and practices and this may help understand some of the findings presented. Some sentences are quite unclear - particular in the findings sections - and a Box that readers can refer back to may help with this.

We agree that this would be helpful and have added Table 1 (key principles and practices of Morita Therapy) to communicate both the fundamental features of the approach, and all aspects of the approach referred to within the results section, to ensure clarity.

6. I think Table 3 would be better split the each half appearing in the part of the manuscript for the relevant section.

We have done this as advised.

7. It would probably make sense to refer to the therapist participants in Stage 3 as 'therapists', not participants.

We have done this as advised.

8. The objective and some of the aims/research questions would be better if not written in the plural personal pronoun, for example To develop a deliverable and acceptable Morita Therapy outpatient protocol for a UK clinical population?

We have amended the phrasing of our objective and research questions in line with this.
Thank you for the opportunity to revise our manuscript for Pilot and Feasibility Studies. We look forward to your editorial decision and stand ready to respond to any further issues raised should this be required.

Yours faithfully

Holly Sugg

PhD Student