Author’s response to reviews

Title: Delivering an Optimised Behavioural Intervention (OBI) to people with low back pain with high psychological risk; results and lessons learnt from a feasibility randomised controlled trial of Contextual Cognitive Behavioural Therapy (CCBT) vs. Physiotherapy

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Author’s response to reviews: see over
To the editor,

We thank the editor and the reviewers for providing such positive and constructive feedback, and have addressed each comment as follows:

Reviewer 1:
This manuscript presents the results of a feasibility study of a randomized clinical trial of high-quality Contextual Cognitive Behavioral Therapy (CCBT) vs. physiotherapy in the treatment of chronic low back pain patients who are deemed to be at high psychological risk. The main aims of the study were to demonstrate the feasibility of the protocol; secondary aims were to descriptively evaluate outcomes.

This study was very well-conceived, strongly justified with respect to the literature and to theory and very well-executed. Its contribution to the literature is very substantial, especially as it provides support for and a basis for a larger randomized trial. The manuscript is very well-written. The authors provide a very clear record of their activities in conducting the trial; many of the points raised would be very helpful to readers intending to conduct similar trials. The discussion of strengths and limitations is clear and appropriate.

Response: We thank the reviewer for this positive appraisal of our work and its implications.

I have only two minor essential revisions which take the form of requests for elaboration on two points:

1. On page 8, the authors state: “Credibility and acceptability scores were summarised by group. To assess credibility, mean scores and 95% confidence intervals were calculated overall and by randomised group for the first two questions of the Borkovec and Nau expectation and satisfaction questionnaire [35] (details in table 2).”

My concern relates to the nature of the informed consent process, specifically about what was told to the subjects who, as the authors admit, were originally referred for and, therefore, expecting to receive, physiotherapy. I can appreciate that this presented some challenges to the authors in creating a consent form with the optimal balance of information for the subjects to, on the one hand, make an informed decision to participate (i.e., elect to be randomized rather than just receive the treatment they expected), but, on the other hand, not influence the subject too much in respect of the credibility evaluation.

So, my questions are: when was the credibility assessment done? What had been told to subjects about the two interventions at that time? In other words, how prepared were subjects to give an appropriate response to the 2 questions: in the CCBT group – what did they know about this “alternative” form of treatment?; in physiotherapy group, were their opinions motivated by the fact that this was what they were originally referred for?

Response: This is a very astute observation, and indeed, an aspect that we strived to address in the study. We provided structured wording to ensure that all participants received exactly the same information. The information that all patients had received at the stage of providing credibility data were as follows:

a) On the information sheet: If you are having the behavioural treatment, CCBT you will need to come for a meeting with a psychologist (who specialises in helping people in pain) once a week for up to 8 weeks.
b) Assessing physiotherapist: ‘There are several interventions for your type of pain, and currently it is not known which of them is most effective. Two of them are physiotherapy and a talking therapy called Contextual Cognitive Behavioural Therapy- CCBT. “Behavioural” means the treatment is aimed at training you in skills and in changing behaviour patterns to improve your health and daily activities. Both treatments are known to be safe and are already used in some hospitals.’

c) Pre randomisation, by the researcher consenting participants: ‘ccbt involves a psychologist talking to patients about their back pain including their thoughts and feelings about pain. This is to help them understand how to make changes to their thoughts and behaviour and to lead a fuller life.’

The qualitative interviews suggest that patients understood that CCBT would be a talk-based therapy, but little else. IN reference to physiotherapy, we can only guess at patients motivation for providing high ratings for credibility, but it stands to reason that these would be effected by their referral.

We have added the information to patients in the manuscript under the method section.

2. In the Discussion, the authors might wish to consider how these factors may have influenced the results they obtained (slightly lower credibility scores in the CCBT group).

Response: We have now added the following in the first paragraph of the discussion: “In this study, credibility ratings were a little lower for CCBT than for physiotherapy as usual. A full trial that provided a combination of physiotherapy and CCBT against physiotherapy alone would probably achieve more equal ratings of credibility.”

3. The authors report that almost about half of the subjects had left school by age 16. This seems to be a very high percentage when compared to other studies and to the demographics of low back pain. This seems likely to have had an impact on the way they viewed the treatments “cognitively”, that is for credibility and acceptance. I think the authors should elaborate on this in the Discussion.

Response: We thank the reviewer for this observation and have now added the following to the discussion:

“Finally, around half of the participants in the current study reported leaving school before age 16. This might have impacted on their ability to grasp and use some of the more cognitive content of the CCBT intervention. We note, however, that the experiential nature of the CCBT approach would be more suitable than other interventions that rely more heavily on intellectual and verbal input.”
Reviewer 2:
1) METHODS: Eligibility criteria, line 4: the authors should specify also in the text that the TSK was used in 17 items (not only in the table 3).

Response: We have added this in the text.
2) DATA COLLECTION line 4: RDQ. In the world is known as RMDQ

Response: we have changed this in the text.
3) ANALYSES line 18: could be more complete by adding the initials of the two researchers.

Response: We have added the initials in the text.
4) The readers do not know the Borkovec & Nau modified questions. Can you include them? Was it a numeric scale?

Response: The full items are presented in table 2, and flagged in the analysis section, which also describes the response mode- a 10 point likert scale.

Reviewer 3
Major Compulsory Revisions
1. The title needs to better reflect the aim of this particular study. If you read the title it looks like that it is an RCT whereas it is a feasibility study of how to randomize. Is that what you are trying to say?

Response: We defined the trial according to the methodology, which is a feasibility study using a randomised controlled design to compare two interventions. The alternative to this description could be the use of the term Phase II trial, but we believe this is confusing to the readers. We do not see a problem in including the term RCT, as data from this feasibility study could potentially be included in larger meta-analytic studied. Should we drop the terms randomised and controlled from the title we would misleading readers into thinking that this is an uncontrolled study. The Medical Research Council’s framework refers to studies such as this as exploratory trials, and the aims (which match ours) are to be “used to consider variants of the intervention and their possible effects on outcomes in order as clearly as possible to define the intervention in a main trial; be used as a test of feasibility of key components of a larger main trial, such as recruitment, randomisation, measurement of outcome and so on. Additionally it may provide unique evidence of intervention effects for the purposes of calculating the power of a main larger trial”.

2. The abstract and more specifically the results need to be more stringent reflecting the findings and the level of statistics reported. To write: “average scores suggested that CCBT increases acceptance more than physiotherapy (increase of 7.9 versus 5.1) and change in disability and pain from baseline to 6 months were greater in the CCBT group than in the physiotherapy group” just based on point estimates since this can be considered as an overstatement.

Response: We were careful to state that no inferential tests could be carried out. We have now amended the abstract wording to:
“Numbers were too small for formal analysis. Although average scores for acceptance were higher in the CCBT group than in the group attending physiotherapy (increase of 7.9 versus 5.1) and change in disability and pain from baseline to 6
months were greater in the CCBT group than in the physiotherapy group, these findings should be interpreted with caution.”

We also removed the sentence: ‘There was a suggestion that CCBT may be better in the long term’.

3. Please, specify what physiotherapeutic aims and treatment where delivered. To write physiotherapy was delivered as usual will compare to write “psychology delivered as usual”. Furthermore, to state that physiotherapy “included at least 60% exercise” compares to write psychology “included at least 60% of exposure”.

Response: We have added the following in the methods section:

“Physiotherapy was delivered as usual within services, with the stipulation that it included at least 60% exercise and comprised group sessions (in total not exceeding 8 sessions), with an allowance of up to 3 individual sessions at the start of treatment if required. This was a pragmatic trial, and physiotherapy reflected the variability within the service. The general goal of physiotherapy was to encourage re-activation. We monitored the content through self-report by the physiotherapists in short forms and observation sessions by a physiotherapist expert (AM) to ensure fidelity. However the exact content of the physiotherapy sessions could vary between therapists and patients, as is typical in the real world.”

4. Please, report CI in the tables and results

We have added the adjusted mean scores, with 95% CI to the results for credibility ratings. However we have left the acceptability and credibility table with raw data scores (table 2) as questions 3-5 could not be adjusted for baseline scores (these are only asked post intervention). We have amended table 3 to include 95% CI.