Author’s response to reviews

Title: Clinical and economic outcomes of remotely delivered cognitive behaviour therapy versus treatment as usual for repeat unscheduled care users with severe health anxiety: a multi-centre randomised controlled trial

Authors:

Richard Morriss (richard.morriss@nottingham.ac.uk)
Shireen Patel (Shireen.Patel@nottingham.ac.uk)
Sam Malins (Sam.Malins@nottingham.ac.uk)
Boliang Guo (boliang.guo@nottingham.ac.uk)
Fred Higton (fridcartoons@gmail.com)
Marilyn James (marilyn.james@nottingham.ac.uk)
Mengjun Wu (Mengjun.Wu@nottingham.ac.uk)
Paula Brown (paula.brown@nihr.ac.uk)
Naomi Boycott (naomicope02@gmail.com)
Catherine Kaylor-Hughes (catherine.kaylor-hughes@nottingham.ac.uk)
Martin Morris (martin.morris@leicspart.nhs.uk)
Emma Rowley (emma.rowley@nottingham.ac.uk)
Jayne Simpson (jayne.simpson@nottshc.nhs.uk)
David Smart (david.smart@nhs.net)
Michelle Stubley (shelly.stubley@nottingham.ac.uk)
Joe Kai (joe.kai@nottingham.ac.uk)
Helen Tyrer (h.tyrer@imperial.ac.uk)

Version: 1 Date: 23 Nov 2018

Author’s response to reviews:
Dear Dr Munoz,

BMED-D-18-01471

Clinical and economic outcomes of remotely delivered cognitive behaviour therapy versus treatment as usual for repeat unscheduled care users with severe health anxiety: a multi-centre randomised controlled trial.

Thank you for asking us to revise this submission to BMC Medicine. We would like to thank the reviewers for some further improvements to the manuscript. We would like to respond to the reviewers’ comments point by point as follows:

Reviewer 1.

1. “The presentation of the qualitative arm of the study, in both methods and results, is too brief to be useful in its current form. It should either be expanded or removed from this manuscript; I suggest the latter, given that a further paper on this is planned”.

We have removed the qualitative data from the manuscript and will separately submit this data for publication. The removed text on the tracked manuscript is on page 12, lines 265-270, and on page 13 lines 310-314.

2. “The requirement of only 2 unscheduled appointments in 12 months does appear low, as the authors note, and some justification of this would be helpful. While it has the benefits of simplicity and inclusivity, it also has potential disadvantages, principally that it tends to over-represents younger women who are in general more likely to attend more frequently: see Dowrick CF, et al Br J Gen Pract. 2000; 50:361-5.”

We have added a sentence in our discussion on page 17 of the tracked changes manuscript lines 405 to 407 (page 16 lines 391-393 clean manuscript) under limitations acknowledging that by not having separate thresholds for the repeat same day utilisation of males and females (citing Dowrick et al 2000 as an additional reference as suggested by reviewer 1 – this is now reference 40 in the reference list), we may have recruited more women. If we had used a higher threshold for repeat utilisation of same day care, we would have recruited a similar proportion of females to males because the mean use of repeat same day utilisation of services in the sample was much higher than the minimum. We have added this point to the manuscript on page 17 of the tracked changes manuscript (lines 409-410) and page 16 (lines 395-396) of the clean manuscript.
3. “Patient recruitment and follow-up were both problematic, but (as the authors note in the discussion) this is not untypical of studies involving this particularly complex and vulnerable group of patients. It would be helpful to flesh out in the text the reasons for drop out at recruitment stage, as noted in Figure 1; e.g. is there information on why 163 people declined to participate, or 135 were uncontactable? Regarding follow-up, it is apparent and understandable that a concerted effort was made by the research team to achieve maximal follow-up (72%) at the primary end point of 6 months; however the discussion of study limitations should include acknowledgement of much lower rates at the other three time points, and possible implications of this”.

We do not have any other systematically collected data on the reasons why 163 people declined to participate or 135 were uncontactable. Our ethics approval did not allow us to do anything more than to politely ask people for reasons for not taking part in the study and we respected their right not to tell us if they did not wish to. In our qualitative data we have some information from a few non-participants who consented to interviews to obtain more information on non-participation but this is a small proportion of the total number. We intend to publish a qualitative paper focused on engagement and non-engagement with the trial and the intervention separately. We will provide what information we have from these interviews and also interviews from the health professionals who referred them in that paper. We did not have the resources to check whether we had the right contact details for those who we could not contact compared to patient records.

We have added a sentence on page 17 lines 422 to 424 of the tracked changes version of the manuscript (page 17 lines 408-410 of the clean manuscript) acknowledging less precision in the estimates of the treatment effect at 3, 9 and 12 months than at 6 months because of lower follow ups at 3, 9 and 12 months.

4. “The suggestion that results may be sustainable (page 17) is not based on direct evidence so would be better removed”.

As requested, the suggestion that the effects of the intervention may be sustainable has been removed (page 16 lines 386-389 of the tracked changes version of the manuscript).

5. “There is a typo in the abstract, Results paragraph: '12 with months'.”

The typo in the abstract “12 with months” has been corrected (see page 2, line 42 of tracked change and clean versions of the manuscript).
1. “I had a query regarding the outcomes at the 3-month follow-up assessment. The results in Table 2 suggest that there were very minimal differences between the RCBT group and TAU group at 3-months follow-up, which is surprising given other studies of remote internet treatment show large differences at the 3-month time-point (e.g., Hedman et al. studies of internet CBT for Illness Anxiety Disorder and Somatic Symptom Disorder). While it is difficult to compare across health care contexts and different CBT interventions, it raises interesting questions about the key drivers of the improvements (In both groups). What, if any, intervention was delivered at, or after the 3-month follow-up assessment? Were additional referrals made to non-responders of the RCBT group? Why do you see different patterns of results after that time-point, and is it possible that the superior effects in the RCBT group at 6-months were due to other concurrent treatments? It would be useful to consider an explanation for those findings in the discussion”.

Point 2 below discusses additional psychological treatment in both groups giving more specific data. Other psychological treatment is unlikely to explain why we were unable to show a difference in outcome at 3 months but were able to do so at 6 months. There was only a small amount of psychological treatment in the treatment as usual care and most of this occurred later than 3 months.

We believe that the reason we are unable to show a difference in outcome at 3 months but at later time points is because in this sample, participants had not received an explanation of health anxiety until they met the research team who explained the consent to participants of both groups as part of obtaining written and oral informed consent. There was a large mean drop of 6 points in both treatment groups from baseline to 3 months. Other studies recruited participants who were already diagnosed with health anxiety and did not receive such an explanation. We have given this explanation in the limitations part of the discussion (on page 18 lines 429-438 of the tracked changes manuscript and on page 17 lines 415-424 of the clean manuscript).

2. “What did the TAU group entail? What proportion of the participants in the TAU group sought and received additional psychological treatment services through IAPT or other psychological/psychiatric services? Have the authors considered that additional psychological treatment within existing health services contributed to the gains made in both groups?”

Table 3 outlines the contacts participants had with services in usual care. We have had added a sentence in the results page to explain that 8 (10.2%) participants had 2 or more sessions of psychological treatment in the treatment as usual group and two (2.6%) participants in the RCBT group after 6 months (page 13, lines 296 to 297 tracked changes manuscript; page 13, lines 290-291 clean manuscript).
3. “There is variability in the literature regarding the use of the 14-item and 18-item Short Health Anxiety Inventory (SHAI). It would be useful if it was made clearer throughout that the primary outcome measure was the 14-item SHAI”.

As the referee suggests we have replaced HAI with SHAI throughout the manuscript to indicate that we used the 14-item version of the Health Anxiety Inventory. We have made this clear for the first time on page 5 line 108 on tracked changes manuscript, again on page 9 line 209, lines 254, 283, 303, 433, 469 (abbreviations), Figure 1, Table 1, Table 2 and in additional tables. Please let us know if we have failed to spot any other changes we need to make on this point; it is easy to miss.

4. “Given the qualitative data was not presented in this study for both groups, it would be useful to omit it, or include the qualitative data for both groups (not just the TAU group)”.

We have removed the qualitative data (same point as referee 1 point 1).

5. “The authors make the conclusion (p15) that the higher rates of recruitment compared to previous studies were due to recruitment methods/non-stigmatising explanation. However, it is highly possible that the higher rates of recruitment were due to the accessibility and convenience of the intervention.”

We agree that high recruitment rates to the study may be related to increased accessibility and convenience of the intervention (page 17, lines 397-399 in tracked changes manuscript; page 16 lines 383-385 in clean manuscript). It is an important point to make.

We did not find any further editorial comments to address. We hope the paper is now suitable for publication in BMC Medicine.

Yours sincerely

Richard Morriss
Professor of Psychiatry and Community Mental Health
University of Nottingham