Author’s response to reviews

Title: A psychosocial intervention for the management of functional dysphonia: complex intervention development and pilot randomised trial.

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Author’s response to reviews:

Response to reviewers:

Dear Andrew

First of all thank you to you and the reviewers for the time and attention you have given to the paper. We have revised it according to their comments. I will reprint their suggestions below and detail how we have responded.

Reviewer 1.

(1) can the authors please state explicitly whether a full trial will follow on from their pilot study, and if so whether the same clinical settings would be used.

We have specified in the conclusion how this study, and a related study training speech and language therapists in cognitive behavioural therapy to treat head and neck cancer patients, will both be used to design a larger study.

(2) It is a little unclear how the participants are recruited. As it stands my understanding is that once at the clinic during their scheduled appointment, the therapist would introduce the study. Are the patients at this point given information sheet to take away and given time to make informed decision regarding consent? Or are they asked to consent there and then?

We have specified under the new “inclusion/exclusion criteria” section.
(3) How long are the 6-8 fortnightly sessions? Was acceptability of their duration tested?

We have specified in sections “Interventions: usual care” and Interventions: CBT” that these were of approximately one hour.

Reviewer 2:

(I) no mention is made of the number of therapists (although there are same therapists in both arms). Also no mention is made of the number patients within each therapist. These are important parameters, so the authors what to pursue a large RCT, when computing the therapist effect.

We have now made it clear throughout, from the abstract on, that one therapist delivered both treatments.

(II) the outcomes are briefly mentioned in the objectives of the pilot RCT. However, there is no mention of what may be primary outcome and what are the secondary outcomes.

We have added an additional objective under the section “acceptability and feasibility objectives”

(III) page 21: lines 22-42 - there needs to be consistency in reporting the results - the mean and 95% CI are preferred for pilot/feasibility studies

To align with this and the next reviewers comments on reporting pre and post measures we have now revised the “clinical utility” section to present pre- and post-treatment scores. In line with recommendations for treating pilot/feasibility data, we have not reported change scores but rather given the mean baseline and pre-treatment means with their standard deviation.

Reviewer 3:

* The abstract is approximately 50 words over limit, please revise

This is now under 400 words

* Please review the Pilot and Feasibility Journal submission guidelines for reference formatting (https://pilotfeasibilitystudies.biomedcentral.com/submission-guidelines/preparing-your-manuscript/research)

Now numbered references

* Consider changing "treatment as usual" to "usual care" or "standard of care"

Done
* Consider changing "fortnight" to "biweekly" or "every 2 weeks"
  Done

* Please review grammar and use of singular and plurals within the text
  Done

Specific Comments:

Abstract:

* Considering changing "broadly cognitive behavioural model" to "a broad cognitive behavioural model" (line 34)
  Deleted

* Remove term "significantly" in the sentence "On pre-post measures of voice and quality of life, patients in both treatment arms improved significantly" (lines 16-18)
  Done

Background:

* Suggest removing "and confused" from first sentence of the background
  Done

* Please add a reference for the sentence, "For many medically unexplained conditions, the current treatment of choice is cognitive behavioural therapy…”
  Done

* Suggest removing "therefore" on line 56, page 4
  Done

* Consider changing "In her recent review" to "In a recent review…” (line 27, page 5)
  Done

* When using the acronym "MRC" for the first time, write it out in full
  Done
Methods:

* Avoid the use of pronouns in text, when mentioning a person involved in the study, state the title of the individual with the initials in brackets, i.e. "Next, a SLT to be trained to deliver the CBT intervention (TM) was interviewed to establish individual training needs, learning style, normal practice in the management of functional dysphonia and to establish a protocol for how emotional issues were to be dealt with in the usual care arm of the RCT"

Reworded throughout accordingly

* Consider rewording the Stage 2: Feasibility section to read, "A further set of patient interviews were conducted with greater attention to factors highlighted in the initial intervention development stages. These interviews confirmed the findings on perfectionism, fatigue, disordered activity, rest and sleep. Furthermore, the interviews supported the feasibility of addressing these concerns with patients through the development of a shared multi-factorial understanding of their condition. The insights gained from Stage I were used to further refine the model, the training of the SLT, and the design and conduct of the pilot RCT."

Reworded as suggested

* Objectives 2 and 3 are not well defined through described measurements, please provide further information on how both of these objectives were assessed or if these objectives reflect acceptability and feasibility of the intervention to the SLT, please consider combining objectives 2 and 3 into the following, "To assess the feasibility and acceptability of the CBT intervention to a SLT by evaluating the ability to integrate CBT training into clinical practice and by evaluating the amount and nature of supervision required to embed the CB intervention in usual care"

Reworded in line with suggestions, and details of how assessed added to “results” section

* You allude to measuring clinical utility of the CBT intervention however this is not outlined as an objective

Extra objective added to Objectives section.

* Revise heading to "Inclusion/Exclusion Criteria" or alternatively, remove the heading put inclusion/exclusion criteria under the subheading of "Participants"

Done

* Consider revising the sentence, "Assessment and formulation were universal to all patients in the CBT treatment arm of the trial." (lines 53-55, page 11)

Done

* How were nonsuitability and attrition factored into the sample size to provide a total sample of 74? It appears that the sample size was based on the number of patients available after
ineligibility and refusal of consent rather than determined a priori, please clarify if this was the case. If a formal sample size calculation was not conducted, please state this

    This has been clarified.

* A CONSORT extension for pilot and feasibility studies was published on October 24, 2016. Please see the following link for the publication by Eldridge S, et al. and revise the first paragraph of the Results section on page 15: http://www.bmj.com/content/355/bmj.i5239

    New reference added and section reworded.

Results

* What would be considered feasible before moving to a larger RCT? You discuss acceptability and feasibility as objectives however do not provide any information as to what would constitute "acceptable" or "feasible". Please provide acceptability and feasibility criteria for success of the pilot study

    The criteria for feasibility added to start of results section

* You mention that 1 patient was excluded because he/she was <18 years however the inclusion criteria state that patients would be considered for randomization if they were >16 years, please clarify

    Inclusion was 18 or over, corrected in text.

* Rather than "contamination" consider using the term "co-intervention"

    Used former term throughout and minimised used of latter.

* Is it possible to report the questionnaire results at for each group at baseline and follow-up including mean differences? Consider using table format

    In line with reviewer two and three we have now reported key pre- and post-treatment measures in clinical utility section. As the main emphasis of this paper is feasibility, we have not included a table of results but rather indicated how measures do demonstrate sensitivity to change.

* When assessing acceptability of the intervention, was patient feedback taken into consideration?

    Not directly, this is now discussed under limitations.
* You discuss how drop outs were similar between groups (6 vs 7), were reasons collected for drop outs? Additionally, the flow chart indicates there were 4 drop outs per group, please explain the discrepancy compared to the written results on page 16.

We have corrected this discrepancy as the original flow diagram reflected both missing data and treatment drop out. For the purpose of this paper, we now report solely on the latter as an indicator of patient acceptability.

* Please comment on lost to follow-up in each group as this was not similar between the 2 study arms (6 vs 1). Do you think this has an effect on feasibility of the intervention? Particularly since lost to follow-up occurred in a higher number of participants in the CBT group. This information should be included in the results.

Revised section of discussion “As indicated by recruitment and drop out” now discusses this.

* Arguably, there was 67.6% completion in the CBT group and 78.4% at 6 months, please comment on this and how it may impact the feasibility and acceptability of the intervention.

As above, this is now discussed in section “As indicated by recruitment and drop out”

Discussion

* Are you able to elaborate on the point about participants with higher VPQ scores tended to drop out of the SLT arm and those with lower depression, fatigue and anxiety scores tended to drop out of the CBT arm? The discussion surrounding this point appears incomplete and would benefit from further insight into why this might have occurred.

We have expanded this discussion in section “As indicated by recruitment and drop out”.

* The first paragraph under "As indicated by treatment fidelity and protocol violations" is unclear and awkwardly worded, please revise.

This whole paragraph has been re-written and clarified.

* Refrain from generalizing the acceptability of the intervention to other clinicians as it has only been tested in a single SLT. A generalization is likely premature at this stage.

We have made it clear that it only applies to one therapist.

* Please highlight the limitations of the study in its own subsection.

New section added.

Conclusion
You have outlined an intervention that you discuss as both acceptable and feasible to provide, will a main RCT be considered to determine treatment effects of the CBT intervention?

We have indicated the direction of our current work is to do a more generic CBT training for SLTs to intervene in a variety of conditions.

All changes have been conserved in “track changes” mode within the re-submitted manuscript.