Reviewer’s report

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

Version: 0 Date: 01 Aug 2017

Reviewer: Theresa Aves

Reviewer’s report:

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

Summary:

In this pilot trial, patients with functional dysphonia were randomized to receive either standard voice therapy or standard voice therapy plus cognitive behavioural therapy in a 1:1 allocation. The authors described the stages of development of the intervention prior to conducting the pilot trial. The objectives of the pilot trial included acceptability and feasibility of the intervention to both participants and the SLT. Through the evaluation of recruitment, retention, participant questionnaires, time and supervision assessment and content analysis, the authors determined that the CBT intervention was both feasible and acceptable. Limitations of the research included the challenges faced by the SLT to provide standard voice therapy after learning and administering CBT, emotional distress from study participants dominating voice therapy sessions, and a gradient of distress where some patients may benefit from a CBT approach more than others. While the feasibility and acceptability may have been met, there was no discussion about moving forward to a larger RCT to measure intervention treatment effects.

General Comments:

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

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

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

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

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

Specific Comments:
Abstract:

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

* 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)

Background:

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

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

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

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

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

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

* 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."

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

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

* 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)

* 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

* 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

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

* 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

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

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

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

* 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

* 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
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.

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.

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

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.

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

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?

Level of interest
Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?
3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal