Reviewer’s report

Title: Lee Silverman Voice Treatment versus standard speech and language therapy versus control in Parkinson’s disease: a pilot randomised controlled trial (PD COMM pilot)

Version: 2 Date: 24 Sep 2017

Reviewer: Angela Halpern

Reviewer's report:

Thank you for your additional comments and continued discussion. From the author's comments, and from looking at the manuscript, it appears that the extensive recommendations for revision provided in the previous two reviews were not incorporated, and that the authors do not agree that it is necessary to add additional information to the discussion to address the topics/concerns raised. Therefore, unfortunately the decision to reject the article for publication still remains.

As the authors have stated, it appears that a circular discussion has been ongoing, thus, the comments here will be provided as an overall summary, rather than a point by point discussion.

My comments in the previous two cycles of reviews, citing the importance of including additional information in the paper, have been based on over 17 years of vast experience with patients with Parkinson disease (PD) as well as the literature on PD, and my experience as a part of a research team focused on voice and speech research with people with PD. This team has been funded by the National Institutes of Health for 20 years. This team has included career statisticians as well as internationally recognized researchers. The recommendations provided have been in regards to the considerations learned from this team when conducting voice/speech research with this PD population.

Based on the experience our team has had with multiple publications, when writing an article it is the responsibility of authors and reviewers to describe any possible confounds to a study, and clearly state all methods in order to ensure that the reader is provided with the proper tools and information in which to accurately ascertain and interpret the data.

The key elements raised previously are listed below:

1. The issue of decreased sensory awareness and the impact this can have on the self-perception of voice and speech for people with PD has been extensively described in the literature ((Sapir et al., 2011; Ramig et al., 2011; Ho et al., 2000; Kwan and Whitehill, 2011; Mollaei et al., 2013; Arnold et al., 2013; Kompoliti, 2000; Sapir 2014; Liu 2012; Houde, et al., 2004; Cucci et al., 2010) and in my previous review comments.
This is a fundamental problem in PD and has been shown to limit an individual's ability to self-rate their speech/voice. It is common for people with PD to deny they have a problem with speech/voice, when objective data and professional assessment demonstrate they do have a problem with speech/voice.

In light of this, why then would it be concluded that a self-rating scale (especially without reference or discussion of these issues in the paper) be chosen as the single primary outcome variable for a larger study?

As stated by Coster (2013): "The best design and most rigorously executed procedures cannot make up for a poorly chosen measure. Important knowledge about the impact of the intervention may be lost because the selected measure was unable to capture it or, even worse, distorted the true results".

Information regarding the confounds of using a measure of self-perception as a primary outcome variable should have been included in the discussion.

Furthermore, a correction to the author's comments, the Jacobson article does not report reliability or validity data on PD specifically. Thus, while the Jacobson article has published reliability data, this is not specifically with people with PD. Therefore, and especially in light of the issues with self-perception in this population (which makes application of perceptual measures different than with other populations), reliability results from the Jacobson study cannot be generalized to the PD population.

A single primary outcome variable with no validity or reliability data on the population of study places the outcomes of this research in question.

The current study would have been an opportunity to evaluate intra-subject reliability of VHI in PD, but this was not done.

The VHI has indeed been included in research publications with people with PD led by the Ramig team. When it has been a part of the Ramig led studies, the VHI was not used as a primary outcome measure, research results also included quantifiable acoustic measures, the VHI was given two times at the time points of measurement, and finally, information regarding the issues of a sensory mismatch in PD and the potential influence of these issues of self-perception on interpretation of the results was provided. All of which are points that were raised previously by this reviewer, and should have been provided by the authors, as information important for interpretation.

Please be clear, that the recommendations made by this reviewer are not points raised because of post treatment results that might go one way or another, these same cautions would be raised if the VHI was being used only as a descriptive baseline measure.
2. To make the reader aware of the impact that including data from a subject who didn't actually receive a particular treatment can have on the results. The reader who may not be familiar with ITT needs to be provided with an explanation that while this statistical measure was applied, X number of people didn't actually receive LSVT LOUD because they didn't complete the full 16 sessions. Readers may not be aware that LSVT LOUD treatment is not just considered LSVT LOUD because of the exercises that are conducted, but it is a combination of the exercises that are completed with the intensity of a specific protocol (4 times a week for 4 weeks, one hour sessions). If this is not discussed, it would be similar to using ITT to report on the results of X number of people who were randomized to a swallow exercise group, but then not providing an explanation that X individuals who were included in the final results never actually received the specified swallow treatments. So, the point again is that an explanation needed to be provided to elucidate the reader and help them understand the results, regardless of if the results supported or didn't support the hypothesis.

3. Finally, as stated previously, reporting on post baseline correlations for the entire sample of individuals with PD is not valid because it is confounded by treatment group effects. For post measures, when stratifying by group, correlations between outcome measures for an entire sample are meaningless.

It would only be correct to do these entire sample correlations for baseline assessments, which would not yet be confounded by treatment group. Thus, these results are misleading and should not be included as currently reported. In order to accurately represent the results, the correlations should have been reported by group.

Thus, while the research question is an important one, for all of these reasons stated above, unfortunately, in its current form, conclusions cannot be drawn and the manuscript should not be published.

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Yes. Non-financial interests include a preference for the LSVT LOUD as a treatment technique. Financial interests include receiving an employee salary, lecture honorarium and travel reimbursement from LSVT Global. During active research, my COI was approved by University of Colorado-Boulder.

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