Reviewer’s report

Title: ReaDySpeech for people with dysarthria after stroke: protocol for a feasibility randomised controlled trial

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Reviewer: Sarah Dean

Reviewer’s report:

Pilot and Feasibility Studies

ReaDySpeech for people with dysarthria after stroke: protocol for a feasibility randomised controlled trial

Thank you for inviting me to review this article which is very well written and presented. It is clearly structured and covers most, if not all, of the issues I would expect to see in a protocol for this type of study. This study is important because we lack research in this area despite the number of people affected and the devastating impact this condition can have for people with dysarthria and their carers and families. It is excellent to see that these researchers are working towards addressing a large gap in the evidence base for treatments for people with dysarthria after stroke.

Title. This covers the topic adequately.

Abstract. This conveys the main points of the protocol and matches the main text.

Main Text

Most of my points are queries for further detail, and you may have an extended protocol which covers these issues. If so I would signpost such an extended protocol or add in the detail into this main text (if you agree with my suggestions).

Inclusion criteria number 4 - does the 'likely to benefit from speech rehabilitation' need to be operationalised a bit more? If you are running your study over several centres (and even more centres for a definitive trial) you will need to be able to guide the therapists as to what exactly this means, otherwise (for example) some may be more 'lenient' than others in determining who is eligible - if you have too many participants with mild dysarthria you may not see an effect of your intervention (ceiling effects).

Exclusion criteria: similar to the above point - how are you assessing the exclusion criterion number 2: significant 'co-existing communication, cognitive, hearing or visual problems’?
Number 3 - is this needed? Surely if they were deemed stable /well in the inclusion criteria then they cannot be unwell/ unstable……or is there a time lapse that you are considering here? i.e. they become unwell after screening? Perhaps this needs to be clarified.

Line 121 screening log - this is an excellent idea and will be very useful for planning your larger study.

Page 8 Identification paragraph: I was not clear when you were checking for exclusions in this process; nor was I clear how the processes worked in terms of the different settings - are the screening, consent and baseline assessments the same for hospital and home settings?

Page 8 randomisation:

How will the treating therapist inform the participant of their allocation (I am particularly interested in how this is done for people who have been discharged from hospital).

Minimisation variables - did you consider having any others? I agree time since stroke is an important one to include, what about severity? (and if so how would you assess this - for stroke overall or just for the dysarthria?); what about gender and age? Do you need to consider these for your definitive study? Depending on your sample size you could have at least one more variable so it would be useful to consider which are the most important for achieving balance in your main trial.

Page 9 Blinding (and page 12 assessment of blinding). I suggest adding that the researcher will also report any instances of un-blinding not just what they guess at the end (just in case there are some things you can alter in the definitive trial regarding how you explain the importance of assessor blinding to patients / families and therapists). Given you cannot blind at other levels this is going to be really important quality indicator in your main trial.

Sample size justification: this section seems very appropriate to me although I was surprised that there was no mention of outcome measure variance. See more on this later.

Page 10 line 177. I would like to know more about how you are collecting adherence data and then assessing what constitutes the right amount of adherence.

Page 11 Outcome measures: examination of change scores is appropriate although I would suggest looking at more than just sensitivity - e.g. check for ceiling and floor effects, possibly (if you have enough complete case data sets) also look at variance to help you estimate future sample sizes.

Page 12 and 13 Data analysis: On line 227 it states analysis will be descriptive - I agree. Yet later, line 242 you state analysis will use an intention to treat principle - do you mean this is the intention for the definitive trial? (I would agree); if not I am confused as doing this for your current study does not make sense / is not congruent with your earlier statement.
Line 236, I was not sure if you were expecting your groups to be balanced at baseline - it seems highly unlikely given your small sample size and I would suggest it is only the minimisation variable that should be balanced. The degree of balance will also need to be expressed proportionally given your 2:1 randomisation ratio - do you intend to repeat this in your definitive trial? (it has implications for the statisticians). It might be worth asking participants in the interviews whether they found signing up to the study more attractive because of the increased chance of getting the 'active' treatment as this could impact on your decision about whether to continue with this design.

Figure 1: do you need to differentiate those at screening who meet inclusion criteria but were subsequently assessed as having exclusion criteria?

Minor points

Line 101 and line 137: use of number 4, when later you use the written form 'four' - suggest stick to the latter version consistently throughout article.

SPIRIT checklist:

1) Some of the page numbers are not congruent e.g. auditing details are on earlier page than that given in the checklist - it maybe just how it prints out but it does make it harder to check!

2) I did not spot any details about promoting retention yet the checklist says this is covered on page 13.

3) You could add more - in your main text - about your outcome measures known reliability and validity, as stipulated by the checklist. Similarly have you considered which of your measures might be candidate primary outcomes versus secondary outcomes? The checklist advises this specification although it could be an additional objective for the study?

Summary

Overall this is a really good protocol, it has been well presented and it was interesting to read. I suggest it will become an important step in taking this intervention development and evaluation forward. I wish the authors well with their future research endeavours.

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

An article of importance in its field

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

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