Author's response to reviews

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

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Author’s response to reviews:

Reporting

I wasn't clear how much time might elapse between a participant being identified for screening, and starting on the treatment. Might they have already received a period of usual care before commencing treatment within the study? Now clarified line 130

Since the face-to-face interviews with participants are being conducted by the primary researcher, and since the interviews involve open questions, some justification of the use of written records rather than audio-recordings that could be independently analysed would be helpful.

Yes have now clarified on line 190.

The interviews could also be used as an opportunity to ask the participant about their usual care, to triangulate with therapist records and check whether any additional care/support has been received.

Yes this was carried out now clarified line 195.

Some more detail would be helpful on how fidelity and adherence are assessed for the ReaDySpeech intervention, and how usual care will be described. Is there a coding framework for each group? The descriptions in the appendix would be starting points for such coding frameworks.

We didn't use a coding framework as feasibility trial but helpful suggestion for future trial. We have now given more detail around fidelity and adherence lines 179-185.
Given that usual care will vary between individuals (and across therapists), a reliable method for fully describing what happened and how treatment varied within each group could be important when accounting for differences in outcomes in the phase 3 trial.

Yes helpful point, as feasibility we weren't clear what treatment would be offered but a reliable method will be needed for phase 3.

Also, it is not clear how the ReaDySpeech programme itself provides adherence data. For instance, how does the programme monitor adherence?; does it depend on participant report?

Not participant report but recorded by the software - now described line 184.

Methodological issues

I recognise that these need not necessarily be addressed in the paper itself but offer them for consideration.

Does the identification of participants by the treating therapists open the door to a form of selection bias? This could be addressed in the analyses, particularly of the reasons therapists record for exclusion, and I could imagine time since stroke might influence therapists' judgement.

Yes this is a valid point and one we will need to address in a future trial.

Given the short duration of the treatment, might recruitment and retention rates be improved by offering the intervention to those allocated to the control group once outcome measurements have been completed?

Yes agreed and will be considered if recruitment and retention problematic.

Reviewer #2:

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.
Thank you for comments.

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).

As a feasibility trial we intentionally kept this broad as we didn't know what issues we would come up against with eligibility but agree for a phase 3 trial this would need to be much clearer.

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'?

For this feasibility trial this was therapist opinion but agree for phase 3 this may impact on recruitment and will need to be carefully considered during the recruitment process.

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.

Agreed duplication and now deleted.

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;

Ok this is described on line 125 & 128.
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?

Clarified and included line 121.

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).

Yes useful comment, we chose sites that worked across acute and community for this. Now included in line 137

We will need to think about this transition in future trials.

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.

Yes agree that we need to consider other variables to achieve balance in the main trial. As feasibility this seemed reasonable but yes something to consider for main trial depending on what this study shows.

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.

Yes agreed now amended line 148.

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.

Thanks for this, as feasibility no specification of the 'right amount' but have tried to clarify adherence on line 179 to 181.

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.

To consider this when planning future trial for estimating 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.

Yes agreed, this was related to the change scores for outcome measures, but agree it is confusing and now removed.

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).

Yes thank you helpful comment. This 2:1 is purely for this feasibility trial and balance likely to be affected.

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.

Yes we do ask about the randomisation process and what this means to them in terms of recruitment and retention line 193.

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

We didn't think necessary as if screened and randomised but later excluded these people would still be part of the analysis process.

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. Thank-you yes amended accordingly.

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!
Apologies, carried out again and double checked for any inconsistencies.

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

Yes agreed as feasibility this is now n/a.

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?

Yes thanks for this and will consider for future trial. This was really looking at feasibility of carrying out the measures but will consider which might be most likely to be primary for a bigger trial.

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.

Many thanks for comments.

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Editor's comments: Thank you submitting for this well-written protocol. I have just a few comments:

1) p12, line 186: "ii) Their" should be "ii) their" (remove capital T) - yes amended

2) p13 line 211: Assessment of blinding - should this be clarified to state that the researcher's allocation guess will be checked against the randomised allocation record once trial follow up in complete and/or the database is locked? - yes included line 221

3) p13 line 220: Although a data monitoring committee was not deemed necessary for this trial, was there a trial steering committee that provided oversight? - No independent trial steering committee for this study, my supervisory team were the trial management group.

4) p13 line 224: Please could you explain the sentence "Following completion of the outcome measures and prior to the un-blinding of the randomisation the database will be shared with a co-investigator for the study to co-ordinate locking and access to the database." - Now clarified as part of line 221 and that line now removed.

5) p14 line 232: replace comma with "and": ie CONSORT *and* SPIRIT checklist - yes done
6) As pointed out by both reviewers, please could you specify exactly how adherence will be assessed/calculated/reported? - yes helpful and have now included more detail about this.