Author’s response to reviews

Title: Extra upper limb practice after stroke: a feasibility study

Authors:

Emma Schneider (e.schneider@alfred.org.au)
Louise Ada (Louise.Ada@sydney.edu.au)
Natasha Lannin (n.lannin@latrobe.edu.au)

Version: 1 Date: 10 Aug 2019

Author’s response to reviews:

We have provided a response to the reviewer and editor comments in a word document. We also provide a response below.

Response to Reviewer #1:

1. In the Background section the authors have added the words “the amount of” to reflect that the intervention consists of more time spent on the same rehabilitation techniques. The sentence now reads: “One review investigated how much extra rehabilitation was required to produce a benefit and found that a 240% increase in the amount of usual rehabilitation was needed to ensure that the extra rehabilitation improved activity (10).”

2. As this is a Phase I study it does not have a control arm since the purpose of a Phase I study is feasibility and safety. A Phase II study will be justified if there is some potential for an effect (ie, the mean difference over time is of a worthwhile magnitude). Also, see the response to comment 8.

3. 95% confidence intervals are presented in the manuscript to inform the decision, amongst other factors, whether or not to recommend a confirmatory trial.

4. Feasibility of the intervention is first in the list of primary questions. This is later defined in the Method section as “Feasibility of the study involved examining recruitment, intervention (adherence, efficiency, acceptability, and safety) and measurement.” Feasibility of recruitment was considered as a percentage of all of those screened. The sentence has been reworded to make this clear: “Feasibility of recruitment was determined by calculating the number of eligible and consenting participants from the population of adults who were admitted to the inpatient rehabilitation unit with stroke and an upper limb activity limitation.”
5. We have rewritten the intervention results to clarify how the authors calculated the number of possible sessions. The first sentence now reads: “Removing the 77 sessions missed due to early discharge of seven participants from the study, there were a possible 403 sessions.”

We direct the reviewers to the limitations paragraph of the discussion for the answers to the questions posed: “Second, the high rate of early discharge; participants completed the extra upper limb practice program for a mean of 3 weeks, delivered over a mean of 20 session. This suggests that future trials may need to consider how to support participants to continue with the program at home after discharge.”

6. In this Phase I Study the feasibility of the intervention was determined by examining adherence, efficiency, acceptability, and safety. Feasibility of the intervention was explored in the discussion and the amount of time spent on extra upper limb practice is presented.

7. One of the feasibility questions was to determine the adherence to the intervention. In exploring the feasibility of the intervention in the discussion, the timing of the intervention was presented as factor affecting adherence. This finding will be critical to the design of a Phase II trial and we have therefore retained this sentence in the discussion.

8. The sentence now reads “The change observed in the clinical outcomes suggests a promising improvement in upper limb activity and grip strength above what might normally be expected (34).”

9. We have reworded ‘benefit’ to ‘clinical outcomes’.

10. The amount of usual practice of 25 minutes relates to the findings of the Schneider et al systematic review.

11. We have reworded the clinical section to clarify that the ability to grasp and release was quantified by the number of blocks moved in 60 seconds and then transferred to a rate of performance (blocks/s).

12. We have replaced ‘and’ with ‘or’.

13. We have added ‘by the multidisciplinary rehabilitation team’ into the intervention section on page 6 to give context to the results. The sentence now reads: “Amount of practice and session duration was tracked and recorded by the participant with assistance from the therapist using a stop watch and paper diary.”
14. We have removed ‘Length of stay until discharge’ from Table 1.

15. We have corrected this line to read ‘one (5%) had’.

16. The description “and reference values for healthy adults” has been added to the description of Table 3.

Response to Reviewer #2:

1. The sentence has been changed to “The challenge now is to determine a feasible way to provide a large amount of extra practice taking into account staff and resource constraints”.

2. The sentence has been changed “This model of delivery, however, is not an efficient way to increase the amount of usual rehabilitation in an inpatient rehabilitation service”.

3. We have amended the intervention description as follows: “The amount of support was gradually reduced once the participant could follow the self-directed programs.” … “Participants were encouraged to complete the required amount of daily practice but could choose to practice for greater or less than 60 minutes per session. Amount of practice and session duration was tracked and recorded by the participant with assistance from the therapist using a stop watch and paper diary.”

4. We have identified this limitation in the discussion: “participants completed the extra upper limb practice program for a mean of 3 weeks, delivered over a mean of 20 session.”

5. A reference for the AbleX is provided.

6. We have amended the intervention description as follows: “The amount of support was gradually reduced once the participant could follow the self-directed programs.” … “Participants were encouraged to complete the required amount of daily practice but could choose to practice for greater or less than 60 minutes per session. Amount of practice and session duration was tracked and recorded by the participant with assistance from the therapist using a stop watch and paper diary.”

7. The dose of usual upper limb rehabilitation reported was only what was scheduled on the participant’s weekly timetable. We acknowledge that this may not be the actual amount of upper
limb intervention delivered. We therefore refer to the amount of usual care as ‘scheduled’ and not delivered. In the intervention section the authors have added the words ‘by the multidisciplinary rehabilitation team’ to clarify that the usual care rehabilitation time was recoded from the participant’s weekly timetable to provide context to the results.

8. The sentence has been changed to “Feasibility of recruitment was determined by calculating the proportion of eligible and consenting participants from the population of adults who were admitted to the inpatient rehabilitation unit with stroke and an upper limb activity limitation.”

9. The grammatical error has been corrected and the sentence now reads “The participants were told not to continue the test if they had not completed the test (placed and removed all 9 pegs) in 120 seconds (31).”

10. We thank the reviewer for their comments.

11. The procedures for the collection of baseline demographics has been added to the method section: “Age, sex, time since stroke (days), side of hemiplegia, living situation, education, cognition (Mini Mental Status Examination) (29), unilateral special neglect (Albert’s Line Cancellation Test) (30), loss of sensation (light touch), spasticity (Tardieu Scale Quality of Muscle Reaction) (31), contracture (range of motion at the wrist and elbow), complexity of rehabilitation needs (Rehabilitation Complexity Scale - Extended) (32), and ability to pick up a cup unaided were collected at baseline to describe the sample.”
Table 1 now reads “Spasticity (Tardieu Scale Quality of Muscle Reaction, 0-5), mean SD).

12. The p-values have been removed from the manuscript as per Review 1, comment 3.

13. The description “and reference values for a healthy adult” has been added to the description of Table 3.

14. Because the mean difference in clinical outcomes over time is more than might be expected, we have concluded later in the discussion that a Phase II trial is warranted.

15. The timing of the intervention is an observation, rather than a data-supported comment. One of the feasibility questions was to determine the adherence to the intervention. In exploring the feasibility of the intervention in the discussion, the timing of the intervention was presented as factor affecting adherence. This finding will be critical to the design of a Phase II trial and we have therefore retained this sentence in the discussion.
16. The Schneider et al paper is now referenced in the appropriate style.

17. The reference is supplied.

18. The sentence has been changed to reflect the authors recommendation for a future study to include strategies for the intervention to continue after discharge. The sentence now reads “This suggests that future trials may need to consider how to support participants to continue with the program at home after discharge.”

19. The sentence “Fourth, the use of assessors who were aware of the study aims may have led to bias estimates of the magnitude of clinical outcomes” has been included in the limitations paragraph of the discussion.