PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Community-based Rehabilitation Training after stroke: protocol of a pilot randomised controlled trial (ReTrain)
AUTHORS	Dean, Sarah; Poltawski, Leon; Forster, Anne; Taylor, Rod; Spencer, Anne; James, Martin; Allison, Rhoda; Stevens, Shirley; Norris, Meriel; Shepherd, Anthony; Calitri, Raff

VERSION 1 – REVIEW

REVIEWER	Nicola Saywell, lecturer Auckland University of Technology, Auckland New Zealand
REVIEW RETURNED	17-May-2016

GENERAL COMMENTS	I think this is an excellent protocol, very clear and with enough detail to be able to see that the design is appropriate to answer the question. I only have a couple of minor questions, detailed in the attached document. I was particularly impressed with way the intervention is responsive to end-users but still strongly evidence-based. Can I suggest adding 'time to administer' to Table 1. Given that travel may represent a significant out-of-pocket expense, is there the possibility of offering travel cost reimbursement of any sort, to avoid cost being a barrier to participation? Page 9-line 23 “teach adapted…” should read “teaching adapted or compensatory strategies and providing (or the provision of) targeted strength training” I was not entirely sure whether peer-support was included but my impression was that the ‘discussion of issues and education’ was generally between a single participant and a trainer. Given that you have a group of participants meeting for 3 months, I wonder if incorporating an activity which allows participants to share their experiences of increasing mobility with the wider group could act as a motivator. I see that this happens in sessions 23-25 but would it be helpful to initiate it earlier?

REVIEWER	Heidi Janssen University of Newcastle Australia
REVIEW RETURNED	23-May-2016

GENERAL COMMENTS	Sample size and Figure 1.

	The patient flow figure needs to be made clearer or updated- in sample siae it states 24 per group will be recruited but in the figure it indicates only 8 per group will be recruited . Intervention: not clear how long the twice weekly sessions are- dose of exercise in mins and intensity? Hence- not easily reproduced. What does a typical session look like or is composed of? Everything else is very clear though.

REVIEWER	Helen Rodgers Newcastle University, UK I hold grants with one of the authors. Professor Anne Forster.
REVIEW RETURNED	27-May-2016

GENERAL COMMENTS	This paper describes a protocol for a feasibility study of community based training after stroke. The detailed protocol for the study has been reproduced verbatim in the submitted paper. The protocol contains detail that is not needed for a scientific paper. The paper could be made more concise. Some information is given several times within the paper e.g. aspects of data collection. It would be helpful to go through the paper to ensure that information is provided only once and some of the day to day detail removed. . The terms feasibility and pilot study are used interchangeably throughout the document and sometimes together. http://www.nihr.ac.uk/CCF/RfPB/FAQs/Feasibility_and_pilot_studies.pdf. It would be helpful for the authors to clarify whether they are undertaking a pilot study or a feasibility study as they are not the same. It would be helpful to have a separate paragraph about the success criteria for the feasibility study i.e. what parameters need to be met to proceed to a multi-centre study. The introduction is clearly written and builds upon work already undertaken in the area by the authors. It would be helpful to have a description of the theoretical basis for the intervention and the key essential components and evidence underpinning them. The most up to date source of statistics re stoke are in The Stroke Association, State of the nation. Stroke statistics. 2016. The Nation Stroke Strategy is for England not UK. The aims are clearly stated. I am surprised that there is no aims relating to the safety of the intervention or adherence to the intervention. Data is being collected about carer burden but is not mentioned in the aims. Similarly there is no information about carer recruitment and consent. Figure 1 - target recruitment is 48 yet according to figure 1 the sample size is 16. I gather that this is because the programme will delivered 3 times. The figure should be amended to reflect the full study. My main concern is about the potential time between different parts of the study . What is the time between baseline visit, and recruitment, recruitment and randomisation, and randomisation and start of the intervention? The protocol states that some participants will have to wait to undertake the intervention and indeed this could be 5 months according to the study timetable. Will all participants have completed the intervention by the 25 week outcome assessment?

	The strengths and weaknesses of the study should relate to the design of the feasibility study e.g point 4 relates to a larger study.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1
1.1 Can I suggest adding 'time to administer' to Table 1.
We have added ‘time to administer’ to Table 1 (please see pages 13-14 of the marked manuscript).

1.2 Given that travel may represent a significant out-of-pocket expense, is there the possibility of offering travel cost reimbursement of any sort, to avoid cost being a barrier to participation?
This is an excellent point. We do offer individuals support with travel expenses. It was not clear in the manuscript. We have now clarified this in the “participant recruitment” section on page 8 by including the following:
“To help mitigate the potential problem of excluding those who do not live close to a venue, reasonable travel costs (for example, mileage claims, local bus and train journeys, and specialised wheelchair taxis) to and from the training venue will be offered to all participants.”

1.3 Page 9-line 23 “teach adapted…” should read “teaching adapted or compensatory strategies and providing (or the provision of) targeted strength training”
Thank you. We have amended the sentence on page 9 so that it now reads: “teaching adapted or compensatory strategies….”

1.4 I was not entirely sure whether peer-support was included but my impression was that the ‘discussion of issues and education’ was generally between a single participant and a trainer. Given that you have a group of participants meeting for 3 months, I wonder if incorporating an activity which allows participants to share their experiences of increasing mobility with the wider group could act as a motivator. I see that this happens in sessions 23-25 but would it be helpful to initiate it earlier?

The reviewer makes a good point and we have not been explicit about the role of peer support. Although there is not a prescribed format within the group sessions for the exchange of experiences, we do believe that peer support may naturally develop. The ‘discussion of issues and education’ occurs at the end of each group session (sessions 2-21). Individuals are welcome to share their experiences during this period of the session and indeed they are free to talk to each other throughout the training session. Through regular session attendance individuals are likely to foster a sense of group attachment and therefore gain some form of peer support. Individuals may therefore be developing peer support quite early in the intervention (as quickly as session 2).

We have made the role of peer support explicit when we refer to the ‘discussion of issues and education’ component of the intervention in Figure 2 by adding the following: “…which includes sharing experiences so that participants might generate a sense of group peer support”.

Reviewer 2
2.1 Sample size and Figure 1.
The patient flow figure needs to be made clearer or updated- in sample size it states 24 per group will be recruited but in the figure it indicates only 8 per group will be recruited.

Thank you for pointing this out. We presented the flow figure to represent an individual cohort. This was confusing and so we have amended Figure 1 to reflect the full study.

2.2 Intervention:

not clear how long the twice weekly sessions are- dose of exercise in mins and intensity? Hence- not easily reproduced.

Figure 2 indicates that the twice weekly group sessions should last 90 minutes. To make this clearer, we have also added this information on page 9.

There are purposely no recommendations of intensity of exercise as this will very much depend on individual abilities. Trainers will tailor the programme type and adjust intensity of activity to suit individuals' capabilities and needs.

2.3
Intervention: What does a typical session look like or is composed of?
A typical session has been described in Figure 2. We reproduce that text here:
Sessions are structured so that one trainer can provide 1:1 coaching while the other supervises group activities. Group activities typically comprise a warm-up including brisk aerobic and range of movement exercises, a circuit of functional strengthening exercises, balance and coordination activities where appropriate, pair-work with the trainer, such as seated or standing wrestling, practice of functional mobility tasks, discussion of issues and education. 1:1 consultations include checking and setting of home-based activities, review and progression of goals, development of compensational strategies, practice of functional tasks with feedback and individual problem-solving, and progressing level of difficulty and complexity of tasks.

To make it clearer what a typical session looks like we have added a signpost to Figure 2 in the main text: "A more thorough description of the intervention can be seen in Figure 2 " (see page 10).

Reviewer 3
3.1 The detailed protocol for the study has been reproduced verbatim in the submitted paper. The protocol contains detail that is not needed for a scientific paper. The paper could be made more concise. Some information is given several times within the paper e.g. aspects of data collection. It would be helpful to go through the paper to ensure that information is provided only once and some of the day to day detail removed.

Thank you for spotting that the uploaded protocol is the same as the manuscript, this is an error in our uploading that we have now corrected.

We suggest it is important that the detail remains because this is a protocol paper that maps out the intervention and specifies our approach to management and delivery of the research. We do however accept and agree that there is repetition in the manuscript. We have removed 4 paragraphs from the "participant recruitment" section across pages 7 and 8. This information is retained in the "assessment and outcomes section" of the manuscript.

3.2 The terms feasibility and pilot study are used interchangeably throughout the document and sometimes together. http://www.nihr.ac.uk/CCF/RfPB/FAQs/Feasibility_and_pilot_studies.pdf. It would be helpful for the authors to clarify whether they are undertaking a pilot study or a feasibility study as they are not the same.
Thank you for providing the guidelines outlining the components of feasibility and pilot trials. To clarify we are undertaking a pilot RCT as a standalone external pilot however many of our objectives focus on the feasibility and acceptability of different aspects of an RCT (such as recruitment, randomisation, allocation concealment and outcome assessment blinding procedures) as well as the intervention.

To aid this clarification we have removed from the manuscript all occurrences where the term 'feasibility study' has been used (see page 3). We also checked that the work is only described as a

'pilot study or pilot trial/ pilot RCT'.

3.3 It would be helpful to have a separate paragraph about the success criteria for the feasibility study i.e. what parameters need to be met to proceed to a multi-centre study.
We agree. It would be very helpful to have specific progression criteria. However at the time of designing the study and writing the protocol we decided against pre-determining such criteria and instead plan to report to our study objectives, seeking advice from our trial management group (TMG), service user group (SUG), and trial steering committee (TSC) on whether to proceed to a definitive trial.

We have outlined these plans in the manuscript by stating: "We will report to our objectives and hold meetings with our TSC, TMG and SUG to discuss whether we have a sufficient case to apply for funds to run a definitive RCT of ReTrain" (page 20).

3.4 It would be helpful to have a description of the theoretical basis for the intervention and the key essential components and evidence underpinning them.
Yes we agree that a description of the theoretical and / or evidence base of the intervention would be helpful and thank the reviewer for asking us to provide some more detail. We are however mindful that doing this in great detail for all components of this complex intervention would be an extensive piece of work – for example the theory and evidence underpinning the physiology of exercise and training for muscle strengthening would be by itself a large undertaking; similarly the psychology of exercise based rehabilitation, e.g. goal setting, action planning; likewise the principles of the ARNI approach and so on. Instead we believe a theoretical framework within which the key essential components of the intervention can be mapped is a more parsimonious way to describe the overall intervention, and this is indeed how the trainer manual was constructed.

We have therefore added a short paragraph explaining this mapping (see page 10): "The ReTrain Trainer and Intervention Delivery manuals were designed using an overarching theoretical framework that enabled existing evidence based components (from the physiology of exercise training, Behaviour Change Techniques [34] and stroke rehabilitation guidelines) to be mapped together with the as yet un-researched ARNI principles and techniques. The theoretical framework is known as the Information-Motivation-Behavioural Skills model [35] and enables intervention mapping to take place [36]. This mapping process will be developed and refined as part of the work for this study and will specify the essential resources, activities and behaviours of both trainers and clients that must be present in sessions and across the programme."
New refs are:
34. Michie S, Richardson M, Johnston M, et al. The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions. Ann Behav Med. 2013; 46(1): 81-95

35. Fisher JD, Fisher WA, Williams SS, Malloy TE. Empirical Tests of an Information-Motivation-Behavioral Skills Model of AIDS-Preventive Behavior With Gay Men and Heterosexual University Students. Health Psych. 1994;13(3):238-50.

36. Bartholomew LK. Planning health promotion programs: an intervention mapping approach. San Francisco: Jossey-Bass; 2006.

3.5 The most up to date source of statistics re stoke are in The Stroke Association, State of the nation. Stroke statistics. 2016. The Nation Stroke Strategy is for England not UK.
Thank you for this update. At the time of writing our protocol this was not available and so we do not feel it is appropriate to update the manuscript.

Thank you for bringing to our attention the reporting error regarding the Nation Stroke Strategy. We have modified our text so that it now states that the figures are for 'England' rather than 'UK' (page 4).

3.6 I am surprised that there are no aims relating to the safety of the intervention or adherence to the intervention.

Thank you for raising these important issues.

Re safety of the intervention:
We have made it clearer in the manuscript that safety data are being collected by amending aim 4 (page 5) so it now reads: "…(4) assess outcome measurement burden for participants to confirm that data can be collected (including safety data), measures will be completed and to inform selection of primary and secondary measures for the definitive trial…"

Re adherence to the intervention
Our aim to examine adherence is embedded in the process evaluation work where we will be looking at the acceptability of the intervention to participants and trainers. We have made this explicit amending aim (5) (see page 5) which now reads: "…(5) rehearse process evaluation methods for the definitive trial, including assessment of intervention fidelity (i.e. adherence to the intervention manual by participants and trainers);…"

3.7 Data is being collected about carer burden but is not mentioned in the aims. Similarly there is no information about carer recruitment and consent.

Carer burden data are being collected to inform our health economic analysis. We've amended aim 6 (see page 5) to now read: "… (6) evaluate resource use, including carer support, and costs associated with intervention delivery, assess the feasibility of collecting health and social service resource use and explore the relative strengths of measures uses to calculate health related quality of life (QALYs) and provide an economic evaluation framework for the definitive trial.

We never planned to explicitly recruit carers to the trial. We plan to accommodate those who support participants during various activities of the study. As such, when carers complete the carer index questionnaire we took their decision to do this as constituting consent; and this was approved by the ethics review. However, carers (when present) will consent to video recordings and qualitative interviews, and this consent will be explicitly recorded at the beginning of these discrete activities.

3.8 Figure 1 - target recruitment is 48 yet according to figure 1 the sample size is 16. I gather that this is because the programme will delivered 3 times. The figure should be amended to reflect the full study.

Please see response to 2.1

3.9 My main concern is about the potential time between different parts of the study. What is the time between baseline visit, and recruitment, recruitment and randomisation, and randomisation and start of the intervention? The protocol states that some participants will have to wait to undertake the intervention and indeed this could be 5 months according to the study timetable. Will all participants have completed the intervention by the 25 week outcome assessment?

We share your concerns about the potential time between different parts of the study. We are looking at these timescales as part of the pilot RCT to see whether we can successfully recruit, randomise, collect data etc. within a sensible and acceptable timeframe.

We can clarify that everyone will have completed the intervention by week 25 outcome assessment. Nobody will wait as long as 5 months to undertake the intervention as we will be running overlapping cohorts.

We can see that our timeline gives the wrong impression about potential wait time for participants. We packaged participant identification, screening, consent and baseline assessments under the heading of 'recruitment'. Consent is expected to occur no earlier than 2 months prior to randomisation. We have added the following additional text to the 'study timeline' section (see page 16) for clarification: "months 0-9 recruitment: including participant identification (0-9 months), screening (2-9 months), consent and baseline assessments (3-9 months)…"

3.10 The strengths and weaknesses of the study should relate to the design of the feasibility study e.g. point 4 relates to a larger study.
Thank you for pointing this out to us. We are happy to remove the weakness outlined in bullet point 4 of the strengths and weakness section (page 3).

VERSION 2 – REVIEW

REVIEWER	Nicola Saywell Auckland University of Technology. Auckland New Zealand
REVIEW RETURNED	11-Jul-2016

GENERAL COMMENTS	Thank you, you have addressed the few questions I had from my initial review. I think this is a really interesting project and look forward to reading the results in due course.

REVIEWER	Heidi Janssen Hunter Medical Research Institute, Newcastle
REVIEW RETURNED	26-Jul-2016

GENERAL COMMENTS	READY TO GO