Author’s response to reviews

Title: Regaining Confidence after Stroke (RCAS): a feasibility randomised controlled trial (RCT)

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Reviewer/Editor reports:

Reviewer #1: Manuscript title: Regaining Confidence after Stroke (RCAS): a feasibility randomised controlled trial (RCT)

Overall: The paper reads well overall and is relevant. I do have a number of comments which hopefully will improve content.

Abstract: What were the more specific objectives besides "evaluate feasibility"? Please add info on eligibility criteria of participants.

The objectives have been amended: see Abstract background

We have clarified that it is feasibility of screening for eligibility that was assessed.

"Carers were invited to attend some…” be more specific, how many, a maximum?

We have added that carers were invited to attend three of the sessions. See abstract methods

Specify what outcome was used to 'examine fidelity'.
We have added the fidelity of the intervention to the objectives and: Sessions were video recorded. A six item checklist was developed from the manual content. And each item was rated as met, partially met, and not met. Fidelity was assumed if >75% of the criteria were met in a session. (Abstract) details Page 3 line 27/28 of reviewed manuscript.

Interviews were conducted... using open-ended questions?

We have added: Semi Structured interviews were conducted using open-ended questions. See: Abstract methods.

In the results, when reporting a mean, add SD, specify if allocation was random or not; for mean number of sessions, add denominator and SD.

These have been amended. See abstract. Results

In the conclusion, results or outcomes support the feasibility - and how was feasibility defined?

We have amended the conclusions to indicate that the results support the feasibility of conducting a trial to evaluate the RCAS course feasibility defined in the Abstract background.

Introduction:

P2, line 48-51: I would recommend to make sure the course i.e the intervention is described sufficiently and follows the TIDER http://www.equator-network.org/reporting-guidelines/tidier/; this course is anchored in which theory/approach/framework? Therefore, mood and confidence are the primary outcomes?

We have attached a copy of the Tidier checklist. The intervention is described in more detail in the introduction and methods sections.

How can these be measured, with what tools that are the most able to detect change over time?

The justification for the choice of measures has been added to the methods with bullet points for clarity.
P3, line 22: screening should come before recruitment - we screen for eligibility first, then recruit, get consent etc.

We had to recruit and consent potential participants before they could be screened for eligibility. The criteria required the administration of assessments that were not part of usual clinical care. We therefore needed participants consent before we could screen them. This has not been changed.

Line 27-28: need to define what is meant here by fidelity?

A definition of fidelity has been added to the introduction section. P3

Line 32-33: why using post in an era of internet and use or offer also online collection?

In our experience most participants prefer postal assessment of outcomes. This is especially the case for those with stroke, most of whom are elderly, and many have cognitive problems. We could have compared return rates by giving them the choice between postal and online outcome assessments, but we did not do this. A comment has been added to the discussion to indicate that this might be done in future studies. Discussion section.

P4, line 36: not sure I understand what is meant by this (Discharged from all other rehabilitation therapies) as it is a comparison between usual care versus usual care + RCAS?

We have clarified that this is discharge from NHS rehabilitation services. Usual care at this stage would include support from charities, such as the Stroke Association and social services support. This is mentioned in the description of usual care Methods section under the heading Control and intervention group

P5, line 19: how were those outcomes chosen? what are their characteristics, especially regarding ability to detect change?

More detail has been added to the methods to the methods justify the choice of outcomes

Line 54-57: "selected sessions" more precisely 3 x/11 sessions?

This has been amended to three sessions.
P6, line 35-38: was this information collected for both groups?

We have clarified that this was collected for both groups.

Line 44: 'sufficient participants' i.e. a minimum of 8? Page 8

In the methods with aim for a minimum of eight, however in two groups the minimum was six, this has been discussed in the discussion section.

P8, line 49-50: add a Figure to illustrate the study process. After allocation, need to wait to recruit enough to form a group, how long can that take, does this mean that 3 months after allocation may not be the same time post intervention completed, RCAS course?

Because of time delays to forming groups and starting groups not all participants would have completed intervention at the time of the 3 month follow up but all had completed the intervention by 6 months. As the timing of follow up had to be in relation to randomisation to ensure equivalent timing in the two groups, there is no end of intervention assessment.

We have indicated that the mean time between randomisation and starting a group was 37.5 days (SD 21.5, range 6-80).

Line 57-58: 'participants' add n=? 13

This has been added.

P9 line 3: 'A topic guide was used….' how was it developed and what the topics were, please, provide examples?

A topic guide, was developed from the literature and revised by steering group members, expert stroke rehabilitation researchers, clinicians and a stroke champion.

Participants were asked:

Tell me about what you thought about the Regaining Confidence after Stroke Course?

The aim was to illicit in-depth date and to use minimum prompts so as not to lead participants, and to allow open responses. Prompts were used to guide participants if needed. Topics explored included, any positive content, negative content, potential changes to content/study processes, effect on mood, confidence, social identity and the importance of social context.
P12, line 25-26: need to add full length of abbreviations as a legend of the Table.

Added full name in the table

P13, line 47-48: unclear to the reader why sessions # 4-5 and 7 are missing from the table.

More information has been added

P 15 line 28-29: How can the response rate be not complete as I understood these were collected by a research assistant at the time of getting consent?

The missing data in the baseline questionnaires was because a few questionnaire booklets were completed by participants independently of the researcher, or the researcher had missed items in error. The missing responses were not detected until the point of data analysis.

P 15: for the format of the Table, I find it easier to read when data are presented as n (%) instead as two columns, one for n and another one for %.

This is a matter of style and different formats are used. We leave it to the editor to decide if this needs to be changed

P16, line 2: typo error. Deleted in

Line 5-8: what would be targeted sample size needed to have sufficient power in an effectiveness trial? What would be the primary outcome and secondary outcomes based on these results in an effectiveness trial?

We have added the number needed in a definitive trial

P19, line 25: can you present facilitators as well or 'factors' influencing?

Facilitators

Group cohesion and peer support was described as being a factor in motivating stroke survivors to attend and return to the group sessions. Feeling part of something as opposed to feeling isolated helped members feel they were giving as well as receiving. Easy accessibility of a community venue facilitated attendance. The knowledge of stroke demonstrated by the group
leader was considered an essential skill. Natural ability to facilitate a group was observed and encouraged participation in the sessions. Articulating not wanting the course to end, suggested participants found the experience acceptable.

P20, line 28-34: did you get any 'benefit' on outcomes besides qualitative comments? How can we state that a shorter course would not reduce benefits?

Qualitative findings suggested that evaluating a shorter course that would reduce costs may be appropriate. However we do have the evidence to conclude if a shorter course would not reduce benefit. Shortening the course to six sessions would need to be explored prior to an evaluation of effectiveness.

P26, line 28: 'comparison' what does this mean? p value? for what test comparing what?

This has been deleted

Editor's comments

1) Please report 95% CIs for all estimates of feasibility;

These have been added

1) The analysis plan includes the description of the use of Mann Whitney U test to compare groups with the justification of this use based on small sample size. Please note that non-parametric methods should be based on non-Normality assumptions rather than sample size. Typically, they tend to have less statistical power than their parametric counterparts.

However, in this case, since the goal is not to assess statistical significance, please provide estimates of the comparisons with 95% CIs without any p-values on all secondary outcomes.

The comparison between groups has been removed

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