PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Does perturbation-based balance training prevent falls among individuals with chronic stroke? A randomized controlled trial.
AUTHORS	Mansfield, Avril; Aqui, Anthony; Danells, Cynthia; Knorr, Svetlana; Centen, Andrew; DePaul, Vincent; Schinkel-Ivy, Alison; Brooks, Dina; Inness, Elizabeth; Mochizuki, George

VERSION 1 – REVIEW

REVIEWER	Zehuai Wen Guangdong Provincial Hospital of Chinese Medicine, Guangzhou University of Chinese Medicine, Guangzhou, China
REVIEW RETURNED	21-Feb-2018

GENERAL COMMENTS	The statistical analysis was complied mainly with the trial protocol and their mention of statistical analysis in the protocol. However,there are still some things not clearly stated. 1.Please reference CONSORT statement and use the CONSORT checklist to check the reporting, especially for reporting the part of statistical analysis. 2.For baseline data, it is therefore proposed to report the descriptions only. In the Table 1, it is not necessary to do statistical inference tests by Wilcoxon-Mann-Whitney test or Fisher exact test. 3.Please state the definition of ITT and per-protocol analysis populations. 4.For the primary outcome, it is necessary to report the details of falls analysis, including compliance with ITT principles, negative binomial regression or logistic regression used, co-variables and how missing data are handled. It is suggested to use a table or figure to show the results. 5.In the statistical analysis section, author mentioned that 'the variables were not normally distributed we conducted analysis of co-variance (ANCOVA)'. However, ANCOVA method also requires variables to be normal distribution. 6.In the Table 4, there were some numbers should be carefully checked. The total number of 'Cause of fall', 'Motor activity at the time of the fall', 'Where did the fall occur', or 'Using an assistive device' in the control group was not equal to 64. Why?

REVIEWER	Dr. Kyoung Kim Daegu University, Department of Physical Therapy, South Korea
REVIEW RETURNED	26-Feb-2018

GENERAL COMMENTS	I think this paper is very creative and interesting for stroke patients This paper is organized well.

REVIEWER	GOZDE IYIGUN

	EASTERN MEDITERRANEAN UNIVERSITY HEALTH SCIENCES FACULTY PHYSIOTHERAPY AND REHABILITATION DEPARTMENT, TURKISH REPUBLIC OF NORTHERN CYPRUS
REVIEW RETURNED	05-Mar-2018

| **GENERAL COMMENTS** | Line 88: Authors may mention about the connection between falling and physical activity, and social integration since these parameters are being included as a secondary outcomes.

Line 116: "receiving physiotherapy or supervised exercise targeting balance and mobility". It might be specified as "recently" receiving or "received in the last.. days"

Line 348: Authors may include the importance of using booster sessions.

Line 355: Authors may discuss why there was not any difference on ABC, TUG and BBS.

Lime 365: Authors may mention that while the experimental group receives reactive balance training the control group receives proactive balance training and may discuss the findings more according to the nature of the difference in therapy protocols.

Line 380: About the fall characteristics the authors did not discuss the findings "line 306: Falls in control participants were more likely to occur during transfers than falls in PBT participants, whereas falls in PBT participants were more likely to occur during reaching/bending than falls in control participants".

Line 400: Does this really important to mention about the limitations for the administration of PASIPD ? If so the authors may only give these in a few sentence.

Line 420: It is known that though being more effective at preventing falls, reactive balance training is not used in clinical practice often due to the feasibility of proactive balance training, so does it worth for the clinicians to use ? The authors may mention in the clinical implications about why to use? |
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| **REVIEWER** | David Colquhoun
UCL, UK |
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| **REVIEW RETURNED** | 09-May-2018 |

| **GENERAL COMMENTS** | This seems to be a well-conducted study of a topic of clinical importance, it should be published. Tha fact that the outcome is that PBT does not reduce falls to any detectable extent is unfortunate, but it's a valuable contribution to knowledge that could save much effort and money. I have only three suggestions for minor changes.

(1) It would help the reader if a brief description of how "reactive balance control" is measured. It should perhaps also be pointed out that it's a surrogate outcome. What matters is falls.

(2) That being the case, the conclusion that "these results suggest that PBT may be a useful addition to existing balance training post-stroke" seems to me to be unduly optimistic.

(3) The term "statistical significance" has had much well-deserved |
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	criticism from statisticians for 50 years or more. Recently this has been noticed by biologists. I'd suggest that what matters is the false positive risk (always bigger then the p value). Others have suggested different solutions to the problem of p values..

VERSION 1 – AUTHOR RESPONSE

REVIEWER 1

Comment

The statistical analysis was complied mainly with the trial protocol and their mention of statistical analysis in the protocol. However,there are still some things not clearly stated.
1.Please reference CONSORT statement and use the CONSORT checklist to check the reporting, especially for reporting the part of statistical analysis.

> **Response**
> The manuscript was prepared using the CONSORT and TIDIER checklists; we have added reference to these checklists in the paper. The checklists were uploaded with the original submission; we apologize if these checklists were not passed to reviewers.

Comment

2.For baseline data, it is therefore proposed to report the descriptions only. In the Table 1, it is not necessary to do statistical inference tests by Wilcoxon-Mann-Whitney test or Fisher exact test.

> **Response**
> In compliance with our original protocol, we tested for differences between groups on several prognostic factors that would be expected to be related to increased risk of falling. Had the groups differed on these baseline variables, we would have added them as covariates to the analysis.

Comment

3.Please state the definition of ITT and per-protocol analysis populations.

> **Response**
> Intent-to-treat analysis included "all participants with some falls monitoring data" (Page 12, Lines 222-223). Per-protocol analysis included "only those participants who attended at least 10/12 of the initial training sessions and 1 booster session" (Page 12, Lines 226-228).

Comment

4.For the primary outcome, it is necessary to report the details of falls analysis, including compliance with ITT principles, negative binomial regression or logistic regression used, co-variables and how missing data are handled. It is suggested to use a table or figure to show the results.

> **Response**
> We have moved the falls data to Table 2, as suggested. Other Table numbers have been adjusted accordingly.

Comment

5.In the statistical analysis section, author mentioned that 'the variables were not normally distributed we conducted analysis of co-variance (ANCOVA)'. However, ANCOVA method also requires variables to be normal distribution.

> **Response**
> Rank-transforming the data essentially turns a parametric test into a non-parametric test. We have added a reference to support use of this technique to analyse non-normally distributed data (Page 12, Line 234).

Comment

6.In the Table 4, there were some numbers should be carefully checked. The total number of 'Cause of fall', 'Motor activity at the time of the fall', 'Where did the fall occur', or 'Using an assistive device' in the control group was not equal to 64. Why?

Response
We apologize for these typographic errors. We have corrected these errors in the Table.

REVIEWER 2

Comment
I think this paper is very creative and interesting for stroke patients This paper is organized well.

Response
We thank the reviewer for this positive comment.

REVIEWER 3

Comment
Line 88: Authors may mention about the connection between falling and physical activity, and social integration since these parameters are being included as a secondary outcomes.

Response
The connection between falls, physical activity, and social participation is made on Page 6, Lines 71-72.

Comment
Line 116: "receiving physiotherapy or supervised exercise targeting balance and mobility". It might be specified as "recently" receiving or "received in the last.. days"

Response
We have clarified that participants could not have been receiving physiotherapy or supervised exercise for balance/mobility at the time of the study (Page 8, Line 118).

Comment
Line 348: Authors may include the importance of using booster sessions.

Response
We have added further details about how the booster training sessions may benefit participants (Page 17, Lines 347-349).

Comment
Line 355: Authors may discuss why there was not any difference on ABC, TUG and BBS.

Response
We have added further discussion on this point (Pages 17-18, Lines 353-360).

Comment
Lime 365: Authors may mention that while the experimental group receives reactive balance training the control group receives proactive balance training and may discuss the findings more according to the nature of the difference in therapy protocols.

Response
We have added further clarification regarding the difference between the two programs (Page 18, Line 359-360).

Comment
Line 380: About the fall characteristics the authors did not discuss the findings "line 306: Falls in control participants were more likely to occur during transfers than falls in PBT participants, whereas falls in PBT participants were more likely to occur during reaching/bending than falls in control participants".

Response

We have added further clarification on this point (Page 19, Lines 396-399).

Comment

Line 400: Does this really important to mention about the limitations for the administration of PASIPD ? If so the authors may only give these in a few sentence.

Response

We believe this is an important point to raise, as we are not aware of any previous study that compared methods of administration of physical activity questionnaires, and other investigators may assume that similar scores will be obtained with in-person versus telephone administration, as we did. While BMJ Open does not have a word/page limit and there is no imperative to reduce the length of the paper, we have attempted to shorten this section.

Comment

Line 420: It is known that though being more effective at preventing falls, reactive balance training is not used in clinical practice often due to the feasibility of proactive balance training, so does it worth for the clinicians to use ? The authors may mention in the clinical implications about why to use?

Response

We respectfully disagree with the reviewer's assumption that PBT is not used in clinical practice. Although we are unaware of any published data reporting on the use of PBT in clinical practice, our own survey study in progress suggests that 60-70% of Canadian physiotherapists and kinesiologists who treat clients for balance problems have used PBT. We have clarified that the specific program developed for the purpose of the current study would be relatively easily implemented in clinical practice (Page 21, Lines 436-437).

REVIEWER 4

Comment

This seems to be a well-conducted study of a topic of clinical importance, it should be published. Tha fact that the outcome is that PBT does not reduce falls to any detectable extent is unfortunate, but it's a valuable contribution to knowledge that could save much effort and money. I have only three suggestions for minor changes.
(1) It would help the reader if a brief description of how "reactive balance control" is measured. It should perhaps also be pointed out that it's a surrogate outcome. What matters is falls.

Response

We have clarified in the Introduction section that reactive balance control is the "ability to react quickly after losing balance" (Page 6, Lines 80-81). Additionally, we have clarified that the reactive sub-scale of the mini-BEST was used to measure reactive balance control (Page 11, Lines 196-197). The reactive sub-scale is not a surrogate outcome for falls, but rather a measure that provides useful information about balance control.

Comment

(2) That being the case, the conclusion that "these results suggest that PBT may be a useful addition to existing balance training post-stroke" seems to me to be unduly optimistic.

Response

We have clarified in this section that our conclusion is based on the observed improvements in balance and mobility with PBT, and sustained improvements in reactive balance control 12-months post-training, combined with results from previous studies showing reduced fall rates following PBT, and that PBT is the only intervention shown to improve reactive balance control (Page 21, Lines 431-435).

Comment

(3) The term "statistical significance" has had much well-deserved criticism from statisticians for 50 years or more. Recently this has been noticed by biologists. I'd suggest that what matters is the false

positive risk (always bigger then the p value). Others have suggested different solutions to the problem of p values..

Response

Thank you for the comment. We would argue that, notwithstanding the criticism of the p-value and agreement that there are other factors more important than 'statistical significance', we are choosing to align with the report conventions in the field of rehabilitation and our original analysis plan. Thus, we base our data interpretation on p-values. We have added further context regarding clinical interpretation of statistically significant differences (Page 18, Lines 364-369).

VERSION 2 – REVIEW

REVIEWER	Zehuai Wen Guangdong Provincial Hospital of Chinese Medicine, Guangzhou University of Chinese Medicine, Guangzhou 510120, China
REVIEW RETURNED	11-Jun-2018

GENERAL COMMENTS	The author has responded to all my comments, except in table 1 of the baseline characteristics report. However, the author intends to report, also does not matter.