Reviewer’s report

Title: The effectiveness and cost-effectiveness of strength and balance Exergames to reduce falls risk for people aged 55 years and older in UK assisted living facilities: A multi-centre, cluster randomised controlled trial

Version: 1 Date: 05 Nov 2018

Reviewer: Lars Oddson

Reviewer's report:

This is a well-written manuscript that addresses the effectiveness and cost-effectiveness of an exercise intervention in the elderly population using technology to engage the participants and improve adherence. The technology, termed Exergames, includes real-time motion tracking of the participant using the Microsoft Kinect motion sensor during various games that have been designed to help motivate performance of various exercises that are intended to improve strength and balance. Using a multi-center cluster randomized control study design, the study compares the use the Exergame technology to a control group encouraged to perform a set of home exercises based on the OTAGO strength and balance program. This type of work is important and relevant to the field.

There is some concern that changes in the primary outcome (Berg Balance Score, BBS) are overstated and it is not currently clear whether they are clinically meaningful based on within-subject Minimal Detectable Changes reported in the literature of the BBS. The reported between-group change in BBS is based on a small decrease in the control group and a small increase in the intervention group following the training period. This needs to be further discussed in the manuscript. Furthermore, effect sizes are currently not reported, which is required under CONSORT standards. Please see additional comments below.

Specific Comments:

Line 57-61: It is stated that 56 participants were allocated to the intervention and 50 to the control condition and on Line 60 that Intention-to-treat analysis was applied on 49 in the intervention and 43 controls. However, since intention-to-treat analysis means that all subjects allocated to a certain group should be included in the analysis, this statement becomes confusing in the abstract although it is clarified in the Methods section that a sensitivity analysis using multiple imputation was conducted. Please rephrase.

Line 114-118: Long sentence, please break up for readability.
Line 134: Please use past tense consistently.
Line 134: "suite" should be "a suite".
Line 134: Replace "have been" with "were".
Line 141: Add hypothesis here or on Line 145.
The statement regarding "sufficient communal space" being >3m² appears inconsistent with information provided in Image 1 where required space appears to be >8-10m². Please clarify/revise accordingly.

Please clarify "Acute illness" whether only at time of enrollment or also during the study?

Was "Mental capacity" assessed using some form of scale and or simply decided by a "trained healthcare professional" and was this only for the purpose of understanding informed consent or understanding the games?

"Recent fracture or surgery in past 6 months" appears to include the following exclusion criteria "Orthopaedic surgery in the past six months", so duplication not needed.

Use of "6" or "six"; please be consistent throughout and follow norms.

Was any "Wheelchair use" an exclusion or subjects who were completely wheelchair dependent?

How were "Peripheral neuropathy or other uncontrolled....." assessed?

"Current use of gaming technology to exercise" was an exclusion criterion. Were subjects involved in regular forms of exercises allowed to participate?

Spell out "GP".

This section would benefit from a simple table to illustrate and compare the two interventions and make it easier for the reader to contrast what the two groups experienced.

This section appears to be background information and not current Methods.

"is" should be "was".

The section starting with "In an earlier feasibility study....." partly duplicates previous information in Methods. Some of this information would be more relevant in the Background section. Please revise and/or remove as relevant.

Clarify ".....were posted monthly". Were calendars mailed to the investigators?

Please clarify why sample size estimation was based on the Minimal Detectable Change of 8 points (according to reference #68, Conradsson et al. 2007) when results interpretation and discussion refers to a different study (#80, which appears to be the incorrect article by Donoghue, see comments below) that reports an MDC of 5 in the BBS?

It is not clearly stated what statistical procedure was used to compare pre- and post-data. Also, what statistical software was used?

Sentence appears incomplete and/or ends abruptly. End of parenthesis beginning on line 281 is missing. Please clarify/revise.

Where reported differences statistically significant?

Quantify "Several".

Throughout Results: Please report effect sizes as described under the 2010 CONSORT standards. See 17a. Outcomes and estimation.

Were falls reported pre-intervention?
Line 379: The last sentence, "This would represent....", reflects interpretation of the data and should be moved to Discussion.

Line 392-398: It would be helpful to the reader to indicate the various costs and associated probabilities mentioned in this section directly in the figure. Simply add lines pointing to the curve.

Line 407-408: This sentence represents interpretation of the data and should be moved to Discussion.

Discussion

Line 418-423: The difference in change between the groups reported in this trial (6.2 points "adjusted difference") was due to a small decrease in BBS in the control group and a small BBS increase in the intervention group. Please clarify (in Methods) how this "adjustment" was made. The information provided below Table 2 is insufficient.

Comparing the reported "adjusted" between-group difference of 6.2 with the within-subject MDC of 5 (or 8) required to be 95% confident that a true change in functional balance as measured with BBS has occurred as a result of an intervention, appears to overstate the results of the study. The mean (presumably "raw")]?) BBS values reported in Table 2 indicate a similar magnitude mean increase (2.6 points) and decrease (3.0 points) for the intervention and control groups, respectively. Consequently, on average the MDC of 5 (or 8) points increase in BBS was not achieved. How many subjects in the two groups achieved a BBS change of 5 or more? Please address this concern in the discussion.

Line 419: The reference #80, Donoghue et al. 2017 is incorrect for the statement made regarding "….clinically important change .....". It should be Donoghue & Stokes 2009.

Line 422: Please confirm that reference #78 is correct for the statement made.

Line 432: Clarify "traditional costs"; is it for the Otago program, regular physical therapy?

Table 1: One subject in the Exergame group was "Registered blind". Please explain how the subject was able to participate.

Appendix 1: The appendix should illustrate, name and describe the various exercises but not indicate that exercises have a specific effect unless there is a reference that supports the statement. The current study as presented in this manuscript was not designed to answer questions regarding effects of any specific exercises. Therefore, statements such as e.g. "Can improve balance and reduce the risk of falls" for the Sit to Stand exercise etc. should either be taken out, revised or be associated with a reference that has shown the statement is valid. For example, it would be ok to state "This exercise targets strength and balance during sit to stand activities", but not suggest any improvement unless such evidence is available. The wording "Can improve...." in this context is hypothetical and should be removed. The following exercise descriptions currently contain such statements that need to be revised:

Sit to Stand
Squats
Hip Frontal Flexion
Elbow Flexion
Full Body Turn
General - Shoulder
Hip Abduction
Knee Flexion
Shoulder Abduction

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

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