Author's response to reviews

Title: Feasibility, safety, acceptability and functional outcomes of playing Nintendo Wii Fit PlusTM for frail elderly: Study protocol for a feasibility trial

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Author’s response to reviews:

Reviewer #1:

First, we would like to thank you for your meticulous review. We believe it is necessary to hone our job. Below we have answered all questions asked.

1. Questioning: “Its an interesting study, and of value, but it is unclear at what status the study is currently at. If it is at fase II then I would suggest to add information on this, or make it clear that this is about fase I. There is info that suggest fase II is the current, but the main text is written as if this is not the case”

Answer: Thank you for your comment and question. We have rewritten the article by joining the phrases into one to facilitate understanding of the study (page 6).

2. Questioning: “The paper needs some revision of the language and there seems to be some problems with the references. Some are referenced not with numbers, but with naming, and some seems to be wrongly places e.g. reference for number 31 on page 10, which I believe should be 30 instead, but others could be there as well). Also the use of abbreviation should be used all the way through and not just some times (e.g. NWFP)”.
3. Questioning: “There is a lack of review of literature within the field. There are other studies looking at some of the same things. In this regards I would consider if you are working with VR or indeed Exergames/interactive games. In the last part there are starting to be quite some studies done”.

Answer: Thank you for your question. We performed a review of the literature and have rewritten the background (page 4). In addition we agree with your comment and have changed the term “virtual reality” to “interactive video games”.

4. Questioning: It would greatly increase the value of the paper and the readability if there was a better description of the actual training the participants are going to do (maybe a picture of some kind as well).

Answer: Thank you for your question. We agree with your comment that this increases the value of the paper, so we have added the description of the games (page 8).

Reviewer #2:

First, we would like to thank you for your meticulous review. We believe it is necessary to hone our job. Below we have answered all questions asked.

1. Questioning: The report is primarily focused on the protocol for the pilot study involving five participants (which is called Phase 1), yet it goes on to also include some information about the definitive randomised controlled trial (RCT)(which I am guessing is what they mean by Phase 2, but this is not clear) even though the sample size for this larger study has not been given. It is also possible that I am muddled in my understanding of their pilot trial.

Answer: Thank you for your question. We have rewritten the article by joining the phases into one to facilitate understanding of the study (page 6). We agree with your suggestions and this change will help the understanding of the protocol.

2. Questioning: “The authors state there are few studies evaluating the use of virtual reality in this population, citing three studies, but they do not really offer much by way of a synthesis of the evidence from these three studies and what the limitations or gaps in the evidence might be. It is this sort of information that would really help provide the platform for saying why your study is needed so I would urge you to provide this in your background section.

Answer: Thank you for your comment. We performed a review of the literature and have rewritten the background (page 4). In addition we have described the gaps in the literature (page 5).
3. Questioning: “Various details of the study protocol are given (participants, assessments, phase one details, phase 2 details etc) however in many places there is a lack of clarity for example: the patient population is a mix of pre-frail and frail (so how is this assessed? how many of each were in the pilot? will you stratify in the main trial to account for these clinical differences?)

Answer: Thank you for your comment. We agree with you and have better described the stratification of the patients (section allocation - page 11) which we believe is necessary according to the frail population.

4. Questioning: “how will you assess for no neurological or orthopaedic diseases? (is it realistic to expect frail elderly to have no orthopaedic problems - I presume this is part of the feasibility work although as this only involved 5 participants it might be hard to obtain meaningful estimates of orthopaedic disease prevalence)”.

Answer: Thank you for your comment. We agree with you and have rewritten the exclusion criteria (page 6). We will select individuals who have the “capacity to maintain a standing position and walk independently” regardless of whether or not they present orthopedic problems.

5. Questioning: “Furthermore there seems to be (page 6 line 34 onwards) details about what I would call 'acceptability' (of the intervention) rather than feasibility, so this needs clarifying”.

Answer: Thank you for your comment. We agree with you and have clarified the use of the terms. We have used the term 'acceptability' as suggested (page 9).

6. Questioning: “Checking for the incidence of falls up to 30 days later seems a very short time for a follow-up as your sample may not fall very often anyway, so seeing a reduction in falls after only 30 days seems very optimistic”.

Answer: Thank you for your comment. We agree with you and have removed the outcome falls from the text. We decided that it would be better to withdraw this outcome as we will not be able to access these patients over a long period in order to perform this evaluation. In subsequent studies we will be better structuring the methods for carrying out this evaluation.

7. Questioning: “Finally the discussion section seems to repeat much of what has already been covered”.

Answer: Thank you for your comment. We have rewritten and summarized the discussion section.

8. Questioning: “Unfortunately there are numerous problems throughout the manuscript with regards to the clarity of the writing and the choice of key words and terminology, e.g. incorrect use of the term physiotherapy / physical therapy”.

Answer: Thank you for your suggestion. We have reviewed the text and adjusted the abbreviations.
9. Questioning: “The authors do provide a SPIRIT check list and it appears complete but cross checking some of the checklist items with the manuscript shows that a number of elements are missing from the manuscript e.g. governance arrangements, data management etc.”

Answer: Thank you for your question. We performed a review of the SPIRIT checklist and found a roules that we solved.

10. Questioning: “I would urge the authors to seek further support in translating their work into English as this could make a substantial difference and may help clarify some of the concerns I have raised.

Answer: Thank you for your suggestion. We agree with your comment and have received support in the translations.

11. Commentary: Please do keep your line of research going, it is based on a good idea and I am sure you will learn a lot about conducting clinical trials by running this feasibility study.

Answer: Thank you for your commentary.

Editor comments:

First, we would like to thank you for your meticulous review. We believe it is necessary to hone our job. Below we have answered all questions asked.

1. Questioning: “I am concerned that you are planning to estimate the control success rate on a pilot study consisting of only 5 participants, as this number of participants will not provide an accurate estimate of this control rate. The sample size section also needs to be clarified, in particular whether the sample size will be determined based on a between-group or within-group analysis; it currently suggests that the sample size will be based on a within-patient change (between pre- and post-intervention)”.

Answer: Thank you for your comment. We agree with you and have rewritten the methods and the number of patients recruited in the study (page 10).

2. Questioning: “The authors would benefit from noting that analysis from a pilot study should focus on estimation (eg confidence intervals) rather than hypothesis testing; any proposed hypothesis tests should be purely exploratory rather than definitive”.

Answer: Thank you for your comment. We agree with you and have rewritten the section simple size.

3. Questioning: “The authors should further describe how they will assess feasibility in order to assess the primary hypothesis ("1. The Nintendo Wii Fit Plus will be feasibility and safety to frail elderly", which needs to be reworded to state that this intervention is feasible and safe to use in a frail elderly population)”.
Answer: Thank you for your comment. We agree with you and have rewritten the hypothesis section (page 13).