

Exergames improve balance and reduce fear of falling in women with fibromyalgia: Randomised controlled trial (#15079)

Overall, the manuscript describes an RCT aimed at determining the efficacy of a VR intervention on balance and fear of falling in women with fibromyalgia. I thank the authors for the effort and work an RCT demands as well as for the innovative application of exergames, widely used in other populations, in patients with fibromyalgia. Although at first sight results seem promising, there are a large number of concerns that make me doubt of whether the manuscript is acceptable in its current form. First, paragraphs in the introduction need to be rearranged and some rewritten in order to lead the reader towards the need of an RCT for the purpose mentioned above. Second, it does not seem clear to me why using TUG as a measure of balance. Third, most of the discussion and conclusions are based on the fear of falling which is only one of the measures, not even the primary, that were found to be significantly improved after interventions. Finally, I am not aware of the use of VAS for assessment of fear of falling and no citations are found in the manuscript.

A more detailed revision of the whole manuscript can be found below for each of the subsections.

Abstract

1. Results should have p-values
2. Discussion as written is a conclusion

Introduction

Overall, this section needs work in constructing the elements leading to hypothesis to be tested. It needs clarification on key concepts used in this and following sections such as physical function and balance. It is not clear how and why balance is relevant and how exergames can improve it in WwFM.

1. Line 43. Are stiffness or poor physical fitness used as synonyms or similar terms? If so, please explain, if not please rephrase sentence.
2. Line 47-49: I suggest merging both sentences as they read redundant.
3. Line 50: Please elaborate on the differences in response. This sentence reads too isolated and well connected to the rest of the paragraph.
4. Line 53. To my knowledge there is no evidence of direct link between impaired balance and fear of falling.
5. Line 56 and 57. Sentences need reference
6. Line 58. Sentence is not well connected to the rest of the paragraph, please explain how this is relevant for physical function, pain, QoL or balance.
7. Lines 59-62. In here authors criticise previous research, consider a new paragraph. Last sentence: "However.....; however..." , please revise.
8. Lines 63-65. I believe that each therapy effect should be followed by the outcome measure used, hence, these can be later used in the discussion but also to clarify readers as to what aspect/definition of balance you will be considering throughout the manuscript.
9. Line 67: "therefore, more motivating and enjoyable alternatives are required"... there is no reference for this sentence and does not seem as a logical conclusion led from previous sentences.

10. Line 69: merge with following sentence. I suggest not using “new” or “novel” as exergames have been out there for a while already. Perhaps emphasize in the novelty of using them in WwFM.
11. Line 70: “.....and the benefits of non-immersive virtual reality” should be followed by “...such as”
12. Line 72-74: please rephrase as sentence is not clear
13. Line 74. Again, the link with previous sentence is not clear.
14. Line 75: there is no clear rationale leading to the need of an RCT to explore exergames effect on WwFM. Also it is not clear the effect on what (it is only in the last sentence), and why would you expect it.

Materials and methods section

1. Inclusion criteria D: how do you measure it? how is that relevant?
2. Is there no exclusion criteria?
3. What is the standard health care received by these patients in where the study was conducted? Did all patients receive similar care in EG and CG?
4. Sample size calculation was performed using the FMQ and then TUG results from previous studies, however, the second seems to be more appropriate considering outcome measures and aim of the study.
5. Paragraph 147-153. It looks odd starting with “in summary” when later sentences still describe the system/game. Furthermore it is not clear if this is author’s conclusion or that draw by the authors’ of previous research.
6. Although the games are described in terms of the therapeutic reasoning, there is no description of how the system works (i.e. Motion, force, wireless, remote control, etc). There is also no description of what type of feedback is provided in each game (i.e. Scores, time)

Primary outcome

1. I am concerned of using the TUG as a measure of balance, mainly due to the fact that this test was developed as a test of “basic functional mobility”, which although includes balance is not specific for this system. I would expect a much more in deep justification for using this test.

Secondary outcome

1. There are no references for the Fear of Falling and CTSIB measures/tests.
2. Is fear of falling a continuous or discrete measure (i.e. 0-100 or 0:1:100)?
3. In regards to the FR test, how many trials did the WwFM perform? Did you use mean or best performance? Why not normalizing to participant’s height? What was the feet position for the FR (may largely affect results)?

Data analysis

4. Line 182: P should be *p*. The sentence is not clear; do you want to focus your discussion on this interaction?
5. Line 185-186: there is no reference for this stratification or the measure (comment above)
6. Paragraph 188-191: I would obviate this paragraph since it does not add much information to the manuscript.

Results

Overall I suggest revising the use of P throughout the paper (should be *p*) and make significant and non-significant differences explicit.

1. Sentence in Line 204 should be merged to that in 199
2. Overall this paragraph should explicit that is talking about compliance with the treatment
3. Paragraph 218-221 are these results significant?
4. Paragraph 206-210 are these results significant?
5. Line 212: at baseline or post-intervention?

Discussion

1. I suggest focusing discussion on the main variable first and not the FoF.
2. Line 224: for the treatment of balance?
3. Line 225: Can authors prove that exercises were “enjoyable”?
4. Lines 229-230: please rewrite, are you trying to say a that “ FoF impedes normal Daily life activities”?
5. Lines 232-233: So FM have FoF therefore are inactive and then overweight? I think conclusions based on the intervention effect on FoF are a bit overstated.
6. Lines 239-240: are authors trying to say that the measures are rater-dependant? This has not been mentioned anywhere else in the manuscript are argues against its use as a valid measure.
7. Line 245. Are author trying to say that from all CTSIB measures “eyes closed on an unstable surface” was the one that improved the most? It cannot be easily understood form what is written, please check.
8. Lines 244-247: please explain indexes here or in the methods as naïve audience may not understand the meaning of these numbers.
9. Lines 247: the following sentence is completely overstated (to the point of outrageous): “Therefore, the improvement in balance in terms of standing with eyes closed on an unstable surface may be equivalent to more than 10 years of balance aging.”. How can 10 years be calculated? Is there any linear relationship between balance scores and age? Are FM patients getting younger balance-wise?
10. Line 252: again FoF when main outcome measure is TUG

Conclusions

Overall I suggest rewriting the conclusions based on current findings.

1. Conclusion should be based on the primary outcome first
2. This conclusion cannot be draw from current results:

“These results, along with high adherence (only one participant abandoned the intervention), indicate that exergames may be a relevant alternative form of rehabilitation therapy aimed at maintaining or increasing the benefits of non-VR-based physical exercise.

3. Line 272: relevant or feasible?

Tables

Please highlight significant differences