Author’s response to reviews

Title: Effects of 3 months of short sessions of controlled whole body vibrations on the risk of falls among nursing home residents

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Author’s response to reviews: see over
Dear Editor,

Please find below my responses to the reviewer Michael Schwenk.

**Abstract**

1. Reviewer: I wonder if the authors can say 30 Hz intensity? Is the frequency related to the intensity of vibration training? Should author’s rater state 30 Hz frequency?
   Authors: We agree with the reviewer and we have made this amendment.

2. Reviewer: Authors cannot state that the Tinetti test showed an improvement if there was no significance. Better state: Tinetti score increased....
   Authors: The reviewer is right. This modification has been done in our abstract.

3. Reviewer : Author should state that gait was assessed under both single and dual task conditions
   Authors: This information has been added in the abstract.

4. Reviewer: Authors might use the term ‘fatigue’ instead of ‘tiredness’
   Authors: We have replaced the term “tiredness” by the term “fatigue” in our abstract and also in the introduction.

**Introduction**

5. Reviewer: Author’s state: “Physical activity is not an optimal solution given the time it requires and the physical condition of patients. Indeed, tiredness, lack of motivation, low compliance, and even injuries can be observed in the majority of patients”. I guess this perception of exercise training is a little biased and very much in favor of vibration training. In fact, there are several well designed studies which demonstrate that exercise training can successfully performed in nursing home residents, even in those with dementia, and no adverse effects occurred (e.g. Rolland, Y., F. Pillard, et al. (2007). "Exercise program for nursing home residents with Alzheimer’s disease: a 1-year randomized, controlled trial." J Am Geriatr Soc 55(2): 158-165). I agree with the authors that lack of motivation etc. can be a barrier for exercise training in selected nursing home patients and body vibration might be an alternative. But I disagree that exercise training (if conducted to guidelines for elderly) causes injuries in the majority of patients as stated by the authors. Also, the risk and benefits of body vibration training are discussed controversially in the elderly (e.g. Risks and benefits of whole body vibration training in older people. Age Ageing. 2009 May;38(3):254-5). Also, there are a lot of exclusion criteria for vibration training (e.g. prosthetic hips) substantially limiting the feasibility of this training in nursing home residents. Authors state at the end of the introduction that body vibration studies found high drop outs. This might be due to adverse events and thus, is contradictory to their initial statements.
   Author: This is an important point. We have changed our introduction by pointing out
that numerous studies showed beneficial aspects of physical activity on falls. Whole Body Vibration could however give a playful aspect to physical activity and therefore, be an alternative to physical activity. For nursing home residents who do not want to practice exercises, this type of “passive” activity could be an effective alternative for them. However, because of the many exclusion criteria to whole body vibration this therapy is not accessible to everyone. Moreover, as the reviewer said, it is important to add that the balance risk-benefits of the therapy is still discussed in the literature (Risks and benefits of whole body vibration training in older people. Age Ageing. 2009 May;38(3):254-5).

6. Reviewer: It is not clear which aspects of Vibrosphere are novel. The vibration? The oscillation? Gallileo oscillates as well. Other plates also involve both muscular and proprioceptive work. This is not a novel part but has been stated as novel by the authors. Authors should be more specific and highlight the innovation of the vibration system used

Authors: We agree with the reviewers, the specification was not clear. In fact, due to the instability of its spherical base, the Vibropshere® will activate the sensory organs (eye sensors, vestibular sensors, cutaneous sensors). Thanks to this characteristic, this device provides a supplementary effect on the balance. We have clarified our statement and we also have added a picture of the Vibrosphère (Figure 1).

7. Reviewer: Author’s hypothesize a greater reduction of the risk of falls compared to other studies but do not give any references of other studies. Also, they compare their vibration training with a control group. I guess there hypothesis is that the vibration training reduces fall risk compare to control group. Please clarify.

Authors: The reviewer is right. We have modified the hypothesis from “with the hypothesis of a greater reduction of the risk of falls in our study than in order studies” to “with the hypothesis of a reduction of the risk of falls in the treated group compared to the control group”.

8. Reviewer: Author’s “... decided to expose our population to a smaller vibration period than usually observed in other studies...” . Please state which other studies and what exposure has been used in this studies.

Authors: Other studies exposed their population up to 18 minutes / week. In our study, patients were exposed to only 3 minutes 45 seconds each week by sessions of only 15 seconds. These 15 seconds sessions are shorter than the minimum of 30 seconds used in other studies. One study (Changes in balance, functional performance and fall risk following Whole-Body-Vibration training and vitamin D supplementation in institutionalized elderly women. A 6 month randomized controlled trial. Gait and Posture. 2011) performed sessions of 15 seconds but the protocol was progressive up to sessions of 60 seconds at the end of the study. We have discussed this aspect in the discussion section.

Methods

9. Reviewer: Please give more details of the sample size calculation. Which effect size has been assumed? Based on which study?

Authors: The sample size calculation was based on the results of the study of a
previous study (Bruyère et al. (2005)). Indeed this study has the same objective than ours, was performed in the same region in Belgium (Liège) and institutionalised people was also the target population. They found a significant difference in the Tinetti test between the treated and the control group of 5.9 points with a variance of 6.1. Therefore, we fixed $\Delta^2$ (difference between treated and control group) = 34.8, $\alpha = 0.05$ and $\beta = 0.1$. The total of this calculation gives $n = 23$ ; 23 patients in the treated group and 23 patients in the control group = 46 patients in total.

Assuming a dropout rate of about 8% (Cheung, 2007), the study sample had to consist of at least 50 patients, 25 patients in the WBV group and 25 in the control group.

10. Reviewer: Author’s state that training period was six month. However, the tile and abstract says 3 month. This is confusing.
Author: This was a mistake. We thank the reviewer for noticing it. The training period lasted three months.We have made the correction.

11. Reviewer: Was the knee flexion angle specified?
Authors: No, just a knee flexion like skiing. There are no recommendations in the literature. It has been added in the text.

12. Reviewer: Authors stated that the plate also oscillates. Was this oscillation standardized?
Authors: Yes it was. We have reformulated this sentence.

13. Reviewer: What does “A low density cushion, 10 cm thick, was placed under the platform to facilitate the training” mean?
Authors: Because of the spherical base of the vibration device, four cushions of various density and thickness can be placed under the platform to decrease the difficulty. Given the physical health of our population, we decided to place the cushion with the lowest density and the highest thickness (10 cm) to facilitate the training as much as possible. This clarification has been added to the Methods section.

14. Reviewer: How many persons supervised each patient?
Authors: Each training sessions was supervised by one of the four supervisors. This specification has been added to the Methods section.

15. Reviewer: Did patient receive support during training, e.g. bar?
Authors: The device was placed in front of wall-bars present to reassure patients in case of imbalance. However, patients were asked not to hold onto these wall-bars during the training. This comment has been added to the Methods section.

16. Reviewer: Where did patients train? Did patients come to the training by themselves or were picked up from the rooms by the trainers?
Authors: Some patients came to the training room by themselves, but for most of them, supervisors had to pick them up from their room to the training room. This comment has been added to the Methods section and also
discussed in the Discussion section.

17. Reviewer: Locometrix: In the abstract author’s state that a 10 seconds test was performed. In the methods they say that patients walked 3 times 20 meters. This is confusing.
   Authors: We agree about the confusion aspect. In fact, patients had to walk 3 times a distance of 20 meters but parameters were just analysed during a sample of 10 seconds of stabilized walk recorded during each 20-meter distance.

18. Reviewer: Parameters of the Locometrix are hard to understand: e.g. what is the symmetry of the left and right half step on the cranio-caudal axis? What is a half step? Is the Locometerix a validated system? Please give a reference.
   Authors: We agree with the reviewer, those aspects are hard to understand. We have modified this part of the Methods section to develop more these aspects.

19. Reviewer: How was walking speed timed?
   Authors: By means of a chronometer. This specification has been added to the Methods section.

20. Reviewer: What does “this regression was tested with a student’s t-test” mean?
   Authors: It was a mistake. We have deleted the sentence.

21. Reviewer: Did patients give written informed consent?
   Authors: Yes, this information was available at the last line of the “participants” paragraph.

22. Reviewer: Several medical complications occurred in the intervention group. Where these complications related to the intervention, e.g. hip pain, fracture? It is essential to give reasons for the adverse events.
   Authors: This is of course an important point. Indeed, 4 subjects dropped-out for medical reasons and it is important to explain these reasons. Among the dropped-out, we recorded 2 hip pains who seemed to be related to the training, 1 fracture of the malleolus unrelated to the study and 1 hospitalisation for total hip replacement unrelated to the study.
   This specification has been added to the Results section.

23. Reviewer: Table 2: please state abbreviations. Parameters of Locometrix analysis are unclear e.g. what does u.a. mean?
   Author: It is an arbitrary unit. We have made a mistake; the abbreviation is “a.u.” or “arb. unit.” We have made the amendment in our manuscript. We also described the other abbreviations.

24. Reviewer: Table 3: Please give values. What does gait increase mean? Velocity? What does “total” mean
   Authors: These are values of the Tinetti test. This test is assessed on a total of 28 points, 16 points for assessing the balance of the patients and 12 points for
assessing the gait of the patients. This test is used to detect abnormalities of balance or gait. Our table has been modified.

25. Reviewer: How were falls recorded?
Authors: Falls were recorded by the nurses in the nursing homes. Falls were defined as “unintentionally coming to rest on the ground, floor, or other lower level.” Nurses completed the fall record with the date, time, and circumstances of the falls. They also noted consequences of the fall. We have added a paragraph on how the falls were recorded in the Methods section.

Results

26. Reviewer: It looks like the randomization was biased since groups significantly differed in several parameters. Are there any explanations for this, e.g. BMI, cognition?
Authors: The reviewer is right; groups significantly differ for sex, BMI and MMSE. However, by means of a logistic regression, we verified the global homogeneity of our population (all baseline variables together, in the same model) and the result of this logistic regression showed a β not significant. This means that, globally, our population is homogenous.
Moreover, even if some variables significantly differ between groups, we adjusted all of our analysis for these variables.

27. Reviewer: Why did authors only report baseline values of the Locmoetrix but no pre-post outcomes?
Authors: We have added a table with the Locometrix® results.

Discussion

28. Reviewer: Improvement in TUG might be related to the increased physical activity (walking to the training sessions) in patients in the intervention group. Control group patients might have had less physical activity.
Authors: This is an important point. We thank the reviewer for noticing it. We have now discussed this aspect at the end of our discussion.

29. Reviewer: What does “the Vibrosphere has not been uses efficiently” mean?
Authors: We have reformulated the sentence as follow: “The Vibrosphere® has not been used optimally during the study because patients held themselves onto wall-bars during the training, which may have decreased the proprioceptive work and thus the expected balance effects of the training.”
We hope this new sentence clarifies the point.

30. Reviewer: Why did authors place the cushion?
Authors: Four mats with different degrees of cushioning can be placed under the platform to decrease the level of difficulty. We decided to take the thickest cushion
because of the physical characteristics of our population. Vibrosphere® is really unstable and so, this thick cushion facilitates the training.

This specification and clarification has now been added in the Methods section.

31. Reviewer: The word “indeed” is used frequently, but is not necessary.
Authors: We thank the reviewer for this remark. We have deleted some of them.

32. Reviewer: If the Tinetti was high (22 points), why did patients than need support during training? Was it intended to training without support?
Authors: It was necessary because of the instability of the device. It is a hemisphere and it requires a lot of balance research, which is not easy for all nursing home residents. Moreover, 22 points is a mean result. Thus, some patients had results under this score. This is the reason why we offered assistance during the training. For the standardization of the protocol, we decided to give assistance to all patients.

33. Reviewer: The discussion can be shortened. E.g. authors repeat that statement of short duration of exposure several times.
Authors: We agree with the reviewer. We have deleted this repeated statement.

34. Reviewer: Result of adherence should be moved to the results chapter.
Authors: We thank the reviewer for this pertinent remark. We have made amendments accordingly.
Dear Editor,

Please find below my responses to the reviewer Borje Rehn.

Reviewer: Basically, I find the idea valid, i.e. to use “passive” strength training for persons not able to participate in regular regimes. As there is an association between impaired muscle function and falls among elderly, and as the elderly population increases, there has to be tailored interventions to prevent the decline. Research has also shown that vibration can have an effect on muscle function and balance on sedentary persons. The strength of this study, which the authors declare, is the prospective randomized design that also had enough participants on a low drop-out rate. Unfortunately, there was no effect shown which could perhaps be attributed to the low exposure.

1. Reviewer: I’m uncertain if this really was a controlled session of whole body vibrations and about the low exposure - choose another title!

Author: We have reformulated the title by “Effects of 3 months of short sessions of controlled whole body vibration on the risk of falls among nursing home residents”.

2. Reviewer: The section on power analysis is not understandable, needs more information.

Authors: We thank the reviewer for this remark. The sample size calculation was based on the results of a previous study (Bruyère et al. (2005)). Indeed this study had the same objective than ours, was performed in the same region in Belgium (Liège) and institutionalised people was also the target population. They found a significant difference in the Tinetti test between the treated and the control group of 5.9 points with a variance of 6.1. Therefore, we fixed $\Delta^2$ (difference between treated and control group) = 34.8, $\alpha = 0.05$ and $\beta = 0.1$. The total of this calculation gives $n = 23$ ; 23 patients in the treated group and 23 patients in the control group = 46 patients in total.

Assuming a drop-out rate of about 8% (Cheung, 2007), the study sample had to consist of at least 50 patients, 25 patients in the WBV group and 25 in the control group.

This paragraph has now been added in the appropriate section.

3. Reviewer: How was the randomization done?

Authors: We performed the randomisation by blocks of four with a computer-generated randomisation procedure. An identification number and a randomisation number were created for each participant. This specification has now been added to the Methods section.

4. Reviewer: I think the authors though did not pinpoint the target group adequately. Not everyone in a home resident is tired, have lack of motivation or low compliance. In fact, there has been research showing that elderly can take part in vigorous physical exercises, even those with dementia. Nevertheless, some may have various types of movement disorders or lack of motivation (doesn’t everyone?) that will prevent them
from taking part in more active types of physical training. I think that part should be written more carefully.

Author: This is an important point. We have modified our introduction by pointing out that numerous studies showed beneficial aspects of physical activity on falls. Whole Body Vibration could however give a playful aspect to physical activity and therefore, be an alternative to physical activity. For nursing home residents who do not want to practice exercises, this type of “passive” activity could be an effective alternative for them. However, because of the many contraindications to whole body vibration this therapy is not accessible to everyone. Moreover, it is important to add that the balance risk-benefits of the therapy is still discussed in the literature (Risks and benefits of whole body vibration training in older people. Age Ageing. 2009 May;38(3):254-5).

5. Reviewer: The physiological rationale for the dose of vibration is not clear (MCR) at all and I believe that is a major limitation, also just using one intensity. Moreover, the explanation of exposure is insufficient (MCR). The authors should present also the amplitude, the waveform, and the arm posture. What about shoes?

Authors: We fully agree with the reviewer and we have added information about the amplitude, the waveform, and the shoes in the Methods section. Regarding the physiological rationale for the dose of vibration and the utilisation of only one intensity there are actually, to our knowledge, no strict recommendations. Indeed, in the literature, we can observe that studies presented various protocols of exposure with various results according to these parameters. Further researches are still needed to examine the appropriate dose for such an application of WBV.

6. Reviewer: There is a bias introduced with having the supervisors involved as authors, however, this may not have any serious impact.

Authors: We understand the reviewer’s comment. However, thanks to the two locations, the investigators who conducted the assessments in one nursing home supervised patients from the other nursing home so that they would not know to which group the patient, they were assessing, belonged. Therefore, we think that no bias has been introduced in this way. We have modified the manuscript to clarify this point.

7. Reviewer: How was the analysis blinded?

Authors: As explained above, thanks to the two locations, the investigators who conducted the assessments in one nursing home supervised patients from the other nursing home so that they would not know to which group the patient, they were assessing, belonged.

8. Reviewer: How was falls defined and recorded? I think this is the main outcome, the other instruments just give an idea of the risk.

Authors: Falls were recorded by the nurses in the nursing homes. Falls were defined as “unintentionally coming to rest on the ground, floor, or other lower level.” Nurses completed the fall record with the date, time, and circumstances of the falls. They also noted consequences of the fall.
We have added a paragraph on how falls were recorded in the Methods section. The purpose of the study is to assess the impact of the training on the risk of falls, assessed mainly by the Tinetti test. The statistical power has been calculated based on results of the Tinetti test and therefore this study has not enough statistical power to assess the impact of the training on the number of falls. It has been exhaustively discussed.

9. Reviewer: The results from the quantitative walking analysis are not readily explained.

Authors: We have added a table with le Locometrix® results.