Author’s response to reviews

Title: Dual-task training with progression from variable- to fixed-priority instructions versus dual-task training with variable-priority on gait speed in community-dwelling older adults: A protocol for a randomized controlled trial

Authors:

Francis Trombini-Souza (francis.trombini@upe.br)
Marcelo Nascimento (marcelo.nascimento@univasf.edu.br)
Tarcísio Alves da Silva (tarcisio.silva@upe.br)
Rodrigo de Araújo (rodrigo.cappato@upe.br)
Mônica Perracini (monica.perracini@unicid.edu.br)
Isabel Sacco (icnsacco@usp.br)

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Author’s response to reviews:

To: Tovah Honor Aronin
The Editor-in-Chief
BMC Geriatrics

Original paper title: “Dual-task training with progression from variable- to fixed-priority instructions versus dual-task training with variable-priority on gait speed in community-dwelling older adults: A protocol for a randomized controlled trial Variable- and fixed-priority dual-task for older adults”

First, we would like to thank the Editor for the opportunity for resubmitting the manuscript in its revised form. If we have not yet been clear enough in our answers and arguments in this response letter, as well as throughout the manuscript, we would like to have a new opportunity to better address your questions or comments. First, we bring back the reviewers’ comments, which are shown in bold and italic and, subsequently, we provide our answer. In the text, we have highlighted green all the changes we have made to this new version.

Thank you in advance.
With best regards,
Professor Francis Trombini-Souza

Editor's comments

1. Please expand and clarify the Background of your manuscript to better explain the justification for the intervention and control trainings that you will be using in the study.
Authors’ answer: We thank the Editor for highlighting this issue and giving us the opportunity to better clarify this point in our manuscript. This part has been adjusted as follows: “Based on this rationale, in
the first 12 weeks of training, both groups will be trained with dual-task activities exclusively under variable-priority instructions so that they can better learn and retain the motor and cognitive gains provided by this type of dual-task training, as already shown in the literature[12]. Over the next 12 weeks, only the participants in the control group will continue to evolve into the dual-priority variable task training. The experimental group will receive an exclusively dual-task training with fixed-priority, to better mimic most of the functional activities of daily living. To our knowledge, no research to date has attempted to prove this rationale.”

2. Please consider whether this should be considered a superiority trial and revise accordingly if so. Authors’ answer: The manuscript refers to a superiority trial. This information was added and revised in the manuscript.

3. Please include a summary of the secondary outcomes in the text, for instance as "Secondary outcomes will measure gait variables, functional balance tests, reactions time, [etc.] to be measured at all time points." Authors’ answer: This part has been adjusted as follows: “Gait variables, functional mobility, and balance tests, reactions time, confidence and fear of falls, quality of life, depression symptoms and fall episodes are the secondary outcomes and will be assessed at all the time points. These secondary outcomes presented in Table 3 were chosen because they represent the functional, biomechanical, and quality of life aspects of patients at risk for falls.”

4. There are a few rows of Table 3 with no indication of time points. Please correct. Authors’ answer: We thank the Editor for pointing it out. All the time points were filled in the new table according to the SPIRIT timeline model.

5. Please provide further details in the Statistical analysis section. Authors’ answer: After some discussions with the other authors and extensive literature search, we judged more appropriate and robust to adjust the statistical analysis methods of this clinical study. The appropriateness of this section was as follows: “Statistical analyses will be performed based on the intention-to-treat principle. The independent variables of the clinical trial will be both groups (two levels) and the time, counted in weeks (five levels; T1 to T5). The pattern of missing data will be previously analyzed [55]. A full description of the reasons for possible sample losses will be presented after the end of the study. Exploratory analyses will be performed to verify the distribution of variables, identification of outliers, missing data, and asymmetries. Generalized Estimation Equations (EEG) will be used for univariate analyses, considering the factors group (EG and CG) and time (T1, T2, T3, T4 and T5), as well as the interaction effect (time vs. group). The most appropriated GEE model for each variable will be confirmed by considering the measurement scale, the Quasi-likelihood Information Criterion (QIC) values, the working correlation matrix, the data distribution, and the respective log link. Adjustments for univariate (main effects) and multivariate (interaction effect) comparisons of estimated marginal means (EMM) will be made by the Sidak test.”

6. We note that in the trial record on ClinicalTrials.gov, there are exclusion criteria listed as inclusion criteria. You may want to correct this. Authors’ answer: Thank you for alerting us about this error. The “exclusion criteria” subheading was
added in the trial record on ClinicalTrials.gov. Some exclusion criteria was also corrected in the trial record and in the manuscript.

7. It appears that the ethics approval and financial award documents you sent is not specific to the protocol described in this manuscript. Please clarify the relationship of this protocol to that described in the ethics approval. Was this specific protocol reviewed by the ethics committee and by CNPq? Please provide more detail of the funding review process.

Authors’ answer: The initial version of this study that has been submitted and approved by CNPq and the Research Ethics Committee of the University of Pernambuco (UPE) had a slightly different title than the current version of this manuscript sent to BMC Geriatrics. However, in general, the content of both the initial project and this manuscript is essentially the same. After several re-readings of the initial project, we decided to better detail some aspects throughout the manuscript in relation to the initial project to better understand the potential readers of this protocol. One of the changes (only in the form of the writing) was the title. But the new title represents exactly the same methodological content in terms of the dual-task and study design of the project initially approved by these two institutions. The initial title was: "Effect of simple and task-related functional training programs, cognitive account on functional balance, number of falls, biomechanics and functional activities of older adults: a randomized controlled trial." This title was rewritten as follows: “Dual-task training with progression from variable-to-fixed instructions versus dual-task training with variable-priority on gait speed in community-dwelling older adults: A protocol for a randomized controlled trial Variable - and fixed-priority dual-task for older adults ”. However, the methodological conceptualization of dual-task execution and study design remained the same. Also, we further detail the protocols of both groups to facilitate readers' understanding. In the initial version, the content had to be more succinct because of the reduced amount of characters required by the abovementioned institutions. These modifications made in relation to the initially approved project in no way compromise the quality of the study and what was approved by both the CNPq and the Research Ethics Committee of the University of Pernambuco; on the contrary, these modifications were made in order to improve readers' understanding. It is also noteworthy that the final reports that will be submitted, both to the CNPq and to the UPE Ethics Committee, will be sent according to the current version of this protocol with better protocol detailing and title adjustment.

8. We recommend including a SPIRIT timeline table (see item 13 in the SPIRIT checklist) with summarized secondary outcomes.

Authors’ answer: A SPIRIT timeline table with summarized secondary outcomes was included in the text.

9. Please remove the funding information from the Acknowledgements.

Authors’ answer: Funding information was removed, as suggested.

10. In the Ethics approval and consent to participate statement in the Declarations, please remove all information other than the ethics approval and informed consent process.

Authors’ answer: The required information was removed, as suggested.
11. In the Availability of data and materials statement in the Declarations, please either list how the data will be made available after the conclusion of the study (e.g. "on reasonable request to the first author") or put "not applicable as no data has been generated to write this manuscript."
Authors’ answer: Replaced by “Not applicable as no data has been generated to write this manuscript”.

12. In the Authors' contributions statement in the Declarations, please remove all references to carrying out the study and confirm that all authors have contributed to the design of the study and/or the writing of this manuscript.
Authors’ answer: Information adjusted according to the contribution provided by each author.