Author’s response to reviews

Title: A multimodal and multidisciplinary program to prevent loss of mobility in patients aged over 70 years: study protocol of a multicenter cluster randomized study in primary care (the PRISME-3P study)

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Author’s response to reviews:

Dear Editors,

Thanks for your feedback for the protocol : “A multimodal and multidisciplinary program to prevent loss of mobility in patients aged over 70 years : study protocol of a multicenter cluster randomized study in primary care (the prisme 3-P study). (BMC number: BGTC-D-18-00364).

To answer to the different comments :

1) Thank you for submitting ethics proofs from Committee of Protection of Persons. However, as your documents are not in English, please could you provide translated versions of the relevant parts. These should be endorsed and signed by a contactable person at the institution. Please also
include the original documents. Can you please confirm in your cover letter that you have forwarded the requested documentation to BMCseriesEditorial@biomedcentral.com.

In addition, please clarify whether this ethical approval covers all sites involved in this study.

We had requested an ethical approval and we had a favorable opinion from the Committee for the protection of persons (“Comité de protection des personnes (CPP)” in french) on the 3th November 2016. I had forwarded in this e-mail the requested documentation.

In the method (p12), at the part of “ethics approval and consent to participate”, we have added

“The study protocol was approved by the Sud Est 4 Ethics Committee on October 18, 2016 and cover all sites involved in this study.”

2) Can you please confirm whether this study protocol was peer-reviewed by the funding body.

3) In the Funding statement in the Declarations, please describe the role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript should be declared. In addition, please change the name of the funding body to French Ministry of Social Affairs and Health.

To answer to comments 2 and 3 :

We confirm this study protocol was peer-reviewed by the funding body, which has non influence in the design of the study and collection, analysis, and interpretation of data. It’s a national call for project and about one in five projects is selected. We have added in the declarations, part Funding :

“Study protocol was peer-reviewed as part of the PREPS “Programme de recherche sur la performance du système de soins”. A panel of national experts review and select projects to be funded by the French Ministry of Social Affairs and Health. The PRISME-3P study is supported by a grant from the French ministry of Social Affairs and Health (PREPS-15-0099). The funding body has no influence on the study design, collection, analysis, and interpretation of data and in writing the future manuscript.”

4) In accordance with our Submission Guidelines (https://bmcgeriatr.biomedcentral.com/submission-guidelines/preparing-your-manuscript#preparing+figures), please submit each Figure as a single file. Please remove the figure titles embedded within the figures and re-upload the corrected versions. All figure titles/legends should be placed at the end of the main manuscript, after the References, and not within any of the figure files.
5) Figures 2 and Figures 4 should be changed to Tables.

We have done comments 4 and 5.

6) In the Declarations, please change the heading “Ethical approval” to “Ethics approval and consent to participate” and include a statement on consent to participate and whether it was written or verbal. Also, remove the information about registration on clinicaltrial.gov. Please also included a detailed description of the informed consent procedure, or waiver thereof, in the Methods.

We have modified p 12 (Method) and in the declaration (p 15): “Ethics approval and consent to participate”, remove the information about registration on clinicaltrial.gov, and added that the description of the written consent to participate.

“The study protocol was approved by the Sud Est 4 Ethics Committee on October 18, 2016 and cover all sites involved in this study. The research carried out will be on accordance with the Helsinki Declaration and ICH GCP Guidelines. The study complies with the principles of the data protection act in France. Each GP had to collect a writer consent at the beginning of the procedure. This consent is retained in the CRF. The patient can stop the study at any time with an oral information at his GP.”

We inform you that all authors meet the requirements for authorship, read the manuscript and have no financial or other relationships that might lead to a conflict of interest.

We hope that you will find our paper relevant for publication in your journal.

We remain available for any additional information you may require.

Best Regards,

Perrotin Sofia