Author’s response to reviews

Title: FRAILTOOLS STUDY PROTOCOL: A COMPREHENSIVE VALIDATION OF FRAILTY ASSESSMENT TOOLS TO SCREEN AND DIAGNOSE FRAILTY IN DIFFERENT CLINICAL AND SOCIAL SETTINGS AND TO PROVIDE INSTRUMENTS FOR INTEGRATED CARE IN OLDER ADULTS

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Answer to the Editor:

1) Please confirm in your response whether independent peer review was done as part of the funding application and award process. If so, please send a copy of the peer review comment document to Eloisa.HadeNolasco@springernature.com
Yes, independent peer review was done as part of the funding application and award process. Please, find attached to the e-mail the proposal evaluation form from the European Commission.

2) In the Methods section of the Abstract, please include more detail of the study activities.

We have added (line 5-7, page 2) the sentence “FRAILTOOLS’ main objective is to evaluate the usefulness of frailty scales in the detection of frailty in different clinical and social settings” in substitution to the sentence explaining the aim of the study in the previous version.

In the Methods section we have made several changes, giving a more accurate description of

“A personal interview with each participant will take place to register data on comorbidity (Charlson Index), functional status (SPPB, Barthel and Lawton indexes), cognitive status (MMSE) and frailty status (Fried Frailty Phenotype Criteria, o Frailty Trait Scale – short version, SHARE-FI scale, 35-Items Rockwood Frailty Index, Clinical Frailty Scale, FRAIL scale and Gérontopôle Frailty Screening Tool) in the baseline visit, month 12 and month 18 visit of follow up. At 6 month a phone call will be made to assess whether there has been a fall and to check the vital status”. (line 15-21, page 2)

The first paragraph of the Discussion section has been also changed and now is written as follows: “Many studies have demonstrated the utility of certain assessment tools to evaluate frailty in populations in epidemiological studies. However, their usefulness in social and clinical, mainly geriatric, settings have not been properly assessed, including their ability to predict the individual risk for different adverse outcomes, which is the main interest in daily practice.” (line 22-26, page 2)

3) There is a referencing error at the bottom of page 9.

Done. Eliminated “see”. (line 13, page 10)

4) Please remove all color and shading from your tables. Full guidelines for tables are available here: https://bmcgeriatr.biomedcentral.com/submission-guidelines/preparing-your-manuscript#preparing+tables

Done.

5) In the Ethics approval and consent to participate statement, please include all of and only the following: name, country, and reference number for each ethics committee that approved the
study; one sentence describing the informed consent procedure. All other information currently in this section can be moved to the Methods.

Done.

In the reviewed version of the manuscript, the Ethics approval and consent to participate statement looks as follows:

“The following Ethics Review Boards approved the protocol: Ethics Committee of Getafe University Hospital (Spain) with reference number A17/15; Ethics Committee of Fondazione Policlinico Gemelli Protocollo Unico, Università Cattolica del Sacro Cuore, Italy, with reference number 0027036/16 - 04/07/2016; Committee for the Defence of Individuals (C.P.P.P.) Sud-Ouest et Outre-Mer II (Gérontopôle de Toulouse, France) with reference number 2016-A00819-42; Health Research Authority (HRA, United Kingdom) with reference number IRAS Project ID 213693; Bioethics Committee of the Jagiellonian University (Poland) with reference number 122.6120.227.2016.”. (line 16-23, page 18)

Other information has been moved to the Methods. (line 5-13 page 10, line 1-10 page 11).

6) The Availability of data and materials statement refers to the availability of the data supporting the results to readers. As this is a study protocol, please choose one of the following statements:

"Not applicable as no results are reported."

"When the trial is complete, data will be available [name method - by contacting the corresponding author, or attached to publications reporting the results, or on a public website, for example]."

7) In the Funding statement, please include the role of the funder in the study design, execution, and analysis.

Done.

We have added the following sentence: “The funder did not have any role in the study design, and will not have any role in the execution or analysis”. (line 24-25, page 19)

8) Please move the statement of the trial status to the Methods.

Done.
We have added the following sentence: “The study is ongoing. Follow-up visits finished on November 30th. Statistical analysis will be run until April 1st, 2019. The publication of the full results will take place on the second half of 2019.” (line 8-10 page 14).

9) Please remove the consent form from the manuscript.
Done. In the last version of the manuscript the consent form has been removed.

10) If you would like to publish the file that contains all of the tools, please confirm that this does not violate any copyright. Please include a List of additional files according to the guidelines here: https://bmcgeriatr.biomedcentral.com/submission-guidelines/preparing-your-manuscript#preparing+additional+files

All additional files must be mentioned in the manuscript to be published.

All the scales/tools are properly cited. In addition, all of them but MMSE-Folstein and EuroQl 5D-5L (that are the only ones copyrighted in our knowledge) are provided showing the version used in FRAILTOOLS”. Anyway, they are removed from the manuscript and the documents to be published. The additional file with the tools will be included in attached mail.

11) Please submit a clean, final version of your manuscript without any colored text or highlighting and with track changes turned off.

Done