Author's response to reviews

Title: Prevention of diabetes in overweight/obese children through a family-based intervention program including supervised exercise (PREDIKID project): study protocol for a randomized controlled trial

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Answer to the Reviewer’s Comments
Dear Editor,

Thank you for your comments and the possibility to resubmit the article. Please, find a revision of our manuscript “Prevention of diabetes in overweight/obese children through a family-based intervention program including supervised exercise: rationale, design, and methodology of the PREDIKID randomized controlled trial study”. We would like to thank the Reviewers for their thoughtful and constructive comments. We have considered all of the suggestions, and have incorporated them into the revised manuscript. Changes to the original manuscript are highlighted (in yellow background), and we believe our manuscript is stronger as a result of these modifications. An itemized point-by-point response to the Reviewers’ comments is presented below.

Reviewer 1

Arenaza and co-workers aimed to evaluate the effect of a 22 weeks family-based multidisciplinary intervention program on insulin resistance syndrome in children with high risk to develop type 2 diabetes and to identify the profile of microRNA in circulating exosomes and in peripheral blood mononuclear cells in children with high risk to develop type 2 diabetes and its response to a family-based multidisciplinary intervention program including exercise.

The manuscript is written well and the content is quite interesting. The aims of the manuscript are precisely defined. The article is easy to read and logically structured, with the exception of the methods part.

Answer

Comments appreciated.

Comment

Maybe it’s possible to transfer the rationales (1.4.1 and 1.5.1) to the introduction section.

Answer

Thank you for your comment. We have replaced these paragraphs into the introduction section and some sentences have been shortened (see lines 111-146).
Please reconsider and replace the heading ‘design’ (1.4.2 and 1.5.2) since there is already a headline ‘design’ at the beginning of the methods section (Line 144).

Answer

Thank you for your comment. The headings “design” have been deleted.

Comment

Line 186: please precise the information about randomization. What kind of tool is there used for randomization? Is web-based randomization tool?

Answer

We have completed the information about the randomization method as follows: Randomization of the participants into control or exercise group will be done using Statistical Package for Social Sciences (IBM SPSS Statistics for Windows, version 21, Armonk, New York, USA) (lines 222-224). Thanks

Comment

Line 401: I think there is something missing.

Answer

Thank you for catching this. It was a mistake. It has been deleted

Comment

Line 153: Ethics Committee.

Answer

It has been corrected. Thanks

Comment

Please add information about data management, monitoring and eCRF in the methods section.

Answer

Thank you for your suggestion. We have added into the manuscript the new section “Data management and monitoring” with the following information (see lines 422-436):

Participants’ data will be identified only by a study number (starting with 001) and only the principal investigator and study coordinator will have access to identifiers that can link the data
to the individual participant. Participants who drop out will be noted and their reasons documented. Data will be entered and stored on a standalone computer into excel and SPSS data files, and the information will be password protected. We will assure the quality of data entry by random checking of the data entered. Study data is only accessible by the researchers involved in the trial, and only the principal investigator and investigators in the project will have access to the data for analysis. The investigators will monitor that the informed consent process is conducted appropriately and that informed consent was obtained prior to proceeding with any study procedures. Only participants who meet study eligibility criteria will be enrolled. Data will be kept for ten years after the research is completed and all data (electronic and hard copy) will be destroyed after the storage period. There is no data monitoring committee due to the characteristics of the current study.

Comment

Table 1: Please correct ´mm Hg´ to ´mmHg´

Answer

Done. Thanks.

Comment

Table 2: Typing error ´tryglicerides´- please correct

Answer

Thanks for catching this. It has been corrected.