Author's response to reviews

Title: Effects of a six-month intradialytic physical ACTIvity program and adequate NUTritional support on protein-energy wasting, physical functioning and quality of life in chronic hemodialysis patients: ACTINUT study protocol for a randomised controlled trial

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Author's response to reviews: see over
Dear Pr Hans-Joachim Anders,

Please find enclosed the revised version of our original study protocol titled “Effects of a six-month intradialytic physical ACTIvity program and adequate NUTritional support on protein-energy wasting, physical functioning and quality of life in chronic hemodialysis patients: ACTINUT study protocol for a randomised controlled trial”.

We hope that this article is of enough quality to be published in BMC Nephrology and we are ready to make changes that would be deemed necessary.

Best regards,
On behalf the authors,

Dan HRISTEA
Point-by-point response to the concerns

As requested, we have made a point by point response to all the concerns. Some comments are only presented in the present document; others have been also reported in the manuscript.

Editorial Request:

1. Proofs for study protocol (ethics and funding)-

Thank you for considering BMC XXXX for your manuscript. As you may be aware, it is the policy of the journal not to peer review study protocols where ethical and external funding approval have been obtained, as these processes usually involve peer review and as there is little possibility to change a protocol after enrolment begins.

Therefore, could you please clarify whether you have ethical approval and external funding for your study, and if so, could you send evidence of your approvals to the address below?

A study is considered to be externally funded if the authors have been awarded a grant for the study by a major funding body (e.g. governmental funding/ award from a charitable foundation).

? If a study has not received external funding, then the study protocol will be sent for peer-review with a member of our Editorial Board.

? If a study has received funding/assistance from a commercial organization, this should be clearly stated in the ‘competing interests’ section of your manuscript, and the study protocol will be sent for peer-review by a member of our Editorial Board.

? If 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.

? N.B. Proof of external funding should include details of the amount of funding that was awarded for your study.

The study was financially supported by the Nantes University Hospital (and approved by the Ethical Committee of Nantes Ouest IV – ref: ID RCB n°2012-A01662-41) and by the ACTICLAN association. The sponsor had no role in the design and conduct of the study, in the collection, management, analysis, and interpretation of the data, or in the preparation, review, or approval of the manuscript.

We added this information (section “Sponsor’s role”) in the revised version of the manuscript.

Could you also provide a list of any manuscripts that are under submission with other journals based on this study protocol?

To date, no manuscript is under submission with other journals.

BioMed Central requires all controlled clinical trials to be registered in a suitable publicly accessible registry prior to consideration for publication. The trial registers that currently meet all of the ICMJE guidelines can be found at http://www.icmje.org/faq.html.

The current clinical trial has been registered with www.clinicaltrials.gov (ref: NCT01813851)
Once this information has been received, the editor handling your manuscript will proceed with further consideration of your manuscript.

2. Power Calculation
Please can you include a power calculation in the Methods section.
We added this information in the revised version of the manuscript.

3. Flow Diagram
In accordance with CONSORT guidelines (www.consort-statement.org/index.aspx?o=2965), can you please upload a flow diagram (www.consort-statement.org/consort-statement/flow-diagram0/).

We deliberately chose not to include a study flow diagram of the randomized controlled trial, because the inclusion and the intervention periods are not completed yet. Let us know if we must include this diagram.

4. Table 1
Please can you remove Table 1 from the additional files and include this in the manuscript document. This should appear after the Reference section.
Done.