Author's response to reviews

Title: Effectiveness of oral nutritional supplementation for older women after a fracture: a randomized controlled pilot study

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Version: 4 Date: 1 June 2011

Author's response to reviews: see over
Dear Natasha Mellins-Cohen,

Thank you for in principle accepting our manuscript for publication. We are sorry for the delay in our reply. We have now addressed the comments of both reviewers, and adjusted the text where necessary in the manuscript.

We hope that with these last modifications the paper will be ready for publication.

Kind regards,

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**Reviewer 1 Angela Vivanti**

The reviewer explains her concerns about the definition of malnutrition used in this study.

She reports that in 50% of the cases this was done by reduced albumin alone.

*We thank the reviewer for her comment, and agree that the use of albumin alone was used in 22 (50%) of participants as a means of identifying malnutrition.*

*We think that the definition as described in our method section: “PEM was defined as moderate if the MUAC was less than 10th percentile for age and gender, or if the pre-surgery serum albumin concentration was lower than or equal to 35 g/L” is correct, based on relevant literature (Constans et al. 1992). However we have added a comment of caution about this the Discussion section. We agree there are various ways to define and to assess malnutrition as described by Milne et al. 2009 in their Cochrane Review.*

*We changed the text in the results section as follows to clarify for the readers that a large proportion was included based on their reduced Albumin alone:*

> “Thirty nine percent of participants (7 in control group, and 10 in intervention group) were severely undernourished with both serum albumin < 35 g/l and MUAC less than the 10th percentile for women over 70 years. Fifty percent of participants (10 in control group, and 12 in intervention group) were undernourished with serum albumin <35 g/l, and 11 % of participants (4 in control group, and 1 in intervention group) were considered undernourished with MUAC less than the 10th percentile for women over 70 years”.

**Reviewer 2 Maria Teresa Vidán**

Minor essential revisions:

- Remove “rigorously designed” from the first paragraph in the abstract.

  *This is done.*

- The reviewer suggests to show in Table 2 the average change with respect to baseline in all variables and the results of paired test, instead of the mean of the results at different moments of follow-up, and to discuss the results accordingly.
We thank the reviewer for her suggestion but this was already done in the text of the paper on page 9. We believe that we provided the reader with the best information available by using both the results of the paired tests in the text of the paper and providing tables with the mean of the results at different moments of follow-up.

- The reviewer suggests that it would also be interesting to show the number of patients that do not lose weight (if any) in both groups and the number that increase albumin levels and show improvement in the Barthel score.

We thank the reviewer for her suggestion and have now added the following text in the result section:

“We found 2 participants in the control group and 1 in the intervention group with increased weight after 4 months”.

“We found 3 participants in the control group with increased Barthel Index (mean= 6.7 points), and 7 participants in the intervention group (mean 12.3 points)”.

We decided not to add any text for the serum Albumin as on average the majority increased in both groups.

- In the fourth paragraph of the results section an incorrect referral to Table 3 needs to be changed.

We thank the reviewer for noticing, and this is now done.

- In the fifth paragraph of the results, it is mentioned that the n after 4 months is 33. This figure seems to be wrong as the initial n included in the intervention was 27.

Weight at baseline could only be measured for 23 participants at baseline for both groups, for 38 participants after 40 days, and for 34 participants after 4 months. However, when comparing baseline with the two time-points we could only assess difference in weight for those who were available at two time-points at the same time. Therefore, comparing baseline with forty days could only be assessed for 22 participants, and comparing forty days with four months could only be assessed for 33 participants. These numbers are for both groups together, and not for the intervention group only.

- The reviewer suggests removing the multiple regression analysis because it does not add relevant information and it is not correct to include so many independent variables in the regression model with such small sample of events.

We agree with this comment of the reviewer however don’t think that we need to remove the whole paragraph. We used 5 variables and we included 40 participants. This means that we should have
used a maximum of 4 variables instead. We would prefer to change the regression analysis with deleting one of the variables: group. We already know there was no significant difference between the two groups at the different follow up measurements. We believe that providing the reader with this information is informative.

We adjusted the text as follows:

“We performed a backward stepwise multiple linear regression with change in serum albumin, measured from baseline to 40 days, as dependent variable and age, hip fracture, baseline MUAC and total length of hospital stay (within study period) as independent variables”.

- The reviewer would like clarification or removal of the last sentence in the Discussion section: “it is likely that …. due”.

We adjusted the text as follows: “Consistent with these results, in this small pilot study no difference in number of complications could be measured between the two groups”.

- The reviewer states that in the Discussion the sentence: “we found that total length of hospital stay also had a positive effect on serum albumin after four months” is not based on data about albumin results after 4 months available for the reader in the text or in Table 2. Please add this information or remove the sentence.

We believe that this information is available on page 10 in the Results section. With the regression analysis we found that longer stay in the hospital the change in serum albumin was significantly higher.

- The reviewer suggests to add in the last sentence of the conclusions: Further randomized studies appropriately sized and with rigorous controls of the intervention are needed.

We thank the reviewer for this suggestion and have added the sentence to the final part of the conclusion.