Author's response to reviews

Title: Combined effects of functionally-oriented exercise regimens and nutritional supplementation on both the institutionalised and free-living frail elderly (double-blind, randomised clinical trial)

Authors:

Marek M Zak (mzak1@onet.eu)
Christian Ch Swine (christian.swine@uclouvain.be)
Tomasz T Grodzicki (tomekg@su.krakow.pl)

Version: 3 Date: 28 June 2008

Author's response to reviews: see over
RE: Peer review of the MS: 8923208701823219

Combined effects of functionally-oriented exercise regimens and nutritional supplementation on both the institutionalised and free-living frail elderly (double-blind, randomised clinical trial)

Marek M Zak, Christian Ch Swine and Tomasz T Grodzicki

Dear Professor Stanhope,

To begin with, we are very much indebted to you for all your perceptive comments, as we feel that your critical appraisal has tangibly helped us revise the MS in the way that successfully purged it of all its obvious deficiencies, whilst at the same time highlighting its true merits.

Please kindly note that in structuring our response we took the liberty of quoting verbatim your remarks (converted into MS WORD from the original PDF files) and then had them juxtaposed with our own comments (set in blue font for contrast and greater clarity), so that the discourse is easier to follow.

It is our sincere hope you will find all the revisions in the amended MS to your satisfaction. We are also hopeful that in some instances where our respective views still seem to remain at odds, we have nevertheless managed to make our arguments persuasive enough to alleviate your concerns.

With the very best regards,

Marek Zak, PhD

___________________________________________________________________

MINOR ESSENTIAL REVISIONS

1) Change the number of study participants to the number that completed the study. Eliminate statements that the four groups were of equal size.

Response:
Both Figure 1 and the MS have been amended accordingly to accommodate this requirement.

2) The conclusion that only multi-factorial interventions have clear potential for appreciably improving overall functional status of elderly is not supported by the reported effort. Develop a conclusion that relates to the findings of the reported study such as task specificity (strength training increased strength but not function, Functionally-oriented exercises increased functional scores and not strength.

Response:
The authors concede the point and so the MS has been amended accordingly to accommodate this requirement.
3) The description of the effort to double-blind the study should be restated. While there was an adequate attempt to blind staff to the interventions, it is certainly feasible that staff within any facility or region may communicate and share the nature of the intervention being delivered. Thus, inferences could have been made.

Response:
The authors concede the point and so the MS has been amended accordingly, i.e.
Section: METHODS
Sub-section: Study design
Page: 6
Paragraph: 2

4) Clarify the list of subject inclusion (numbers 2 and 6) and exclusion criteria (numbers 1 and 6).

Response:
The authors concede the point and so the MS has been amended accordingly, i.e.
Section: METHODS
Sub-section: Study population
Page: 7 - 8

5) Eliminate the redundant information (inclusion criteria) under overall assessment of physical function.

Response:
Please kindly note that Table 1 (Baseline characteristics of the study population) merely provides the median values of the respective groups with regard to age, body weight, BMI and BBS, whereas the authors insisted on having the population precisely defined in terms of individual eligibility, hence the deliberate use of the first 4 items in the inclusion criteria as clear cut-off points during the preliminary screening procedure to facilitate precise determination.

It is perhaps also worth noting that through providing median values of the above the authors effectively demonstrated homogeneity of the respective groups, which - as the authors felt - was a fairly important methodological consideration, since upon the commencement of the study regimen there were no statistically significant differences between the groups, so an “even platform”, so to speak, was ensured for all participants at the very start.

6) Describe how the dynamometer (a force measuring instrument) was used to measure joint moments in (N.m). Correct any discrepancies that may exist in the force units.

Response:
In order to measure the torque value, maximal isometric strength was multiplied by the length of the arm of force, i.e. the distance from the axis of the dynamometer to the axis of the joint, whose flexion/extension was tested. The yielded torque value was then expressed in N/m.
Here, for example, is how the testing procedure with the aid of a hand-held HOGGAN dynamometer was applied to the knee extensors:

**E.g. Measurement of the isometric strength - knee extension**

**Start position**
The subjects were seated upright in a rigid chair with the knee flexed to an angle of 90° with the hand-held HOGGAN dynamometer placed by the physiotherapist on the lower leg proximally to the ankle joint just above the ankle.

**Testing**
The subject was then asked to lift the lower leg, i.e. push against the dynamometer held in place by the physiotherapist. The subjects were strongly encouraged to gradually increase the force to the greatest possible level, while the tester was opposing, until the maximal isometric strength was achieved.

To begin with, the subject was allowed two or three practice trials, so as to familiarize himself with the actual procedure. Three formal measurements were then performed and recorded with 1-minute rest periods between the respective trials, whereas the best trial was ultimately accepted as the final result.

All measurements with the aid of a hand-held HOGGAN dynamometer were carried out by the same physiotherapist, so as to ensure that there were no idiosyncratic differences in the actual application of the procedure.

The authors strongly believe that in view of the already substantial size of the MS, the inclusion of the detailed descriptions of the isometric strength measurements with regard to all 4 muscle groups would make its size non-manageable, whilst not really adding to the overall clarity of the discourse.

7) Describe the selection criteria and characteristics of the four exercise bands.

**Response:**
In view of the above query it would appear that this particular passage manifestly lacked in clarity and so the authors decided to have it revised to demonstrate that it all actually adds up.

The following breakdown should illustrate clearly enough how the PRE regimen was pursued by the study subjects.

**RE: PRE**

Four series of resistance exercises (stretches of Thera-Band®) broken down into the following sequential components:

3 x 10 stretches of a band per each discrete muscle group (Cf. Tables 1, 3 and 3A) performed within 1.5 min., followed by 1 min. rest period (used by the therapist to move the band to the other leg). Then the same set of exercises was repeated for the same muscle group on the other leg.
In terms of the time scale, it works out as follows:

\[ 4 \times 1.5 \text{ min. (left leg)} + 4 \times 1.5 \text{ min. (right leg)} = 12 \text{ min (exercises)} \]
\[ + 4 \times 1 \text{ min. x 2 legs - rest interval per leg} \]
\[ \text{(inclusive of repositioning of the band)} = 8 \text{ min.} \]
\[ = 20 \text{ min. - sequence completion} \]

Please kindly refer to the following amended sections of the MS, i.e.
Section: METHODS
Sub-sections: Progressive resistance exercises
Individual allocation of the Thera-Band®
Page: 14

8) Describe the resistance exercises and lower limb positions. Consider providing a figure depicting the exercise elements.

Response:
In view of the fact that the MS is already 30 pages long and the presently recommended revisions might still contribute to having it extend further, the authors feel that incorporation of the detailed descriptions of all exercise regimens followed by the subjects throughout the study would make the overall length of the MS simply non-manageable, not least for the Editors. Therefore the only amendment presently contemplated for the MS is the specific reference that the actual scope of the PRE regimen was closely based on the recommendations put forward by Thera-Band® Academy (Cf. weblink: http://www.thera-bandacademy.com).

The MS has been supplemented with two new references, i.e.
Section: METHODS
Sub-sections: Progressive resistance exercises
Page: 14
and so the REFERENCES section has also been amended accordingly.

9) Eliminate the excessive justification material under the structured exercise regimens and replace the material with a detailed description or table containing information on the actual exercises.

Response:
The MS have been amended accordingly to accommodate this requirement, i.e. i.e.
Section: METHODS
Sub-sections: Exercise regimens
Progressive resistance exercises
Individual allocation of the Thera-Band®
Pages: 11, 14

10) Repeat the request under number 9 above for the methods section related to Functionally-oriented exercise and standard exercises.

Response:
This particular suggestion has been addressed in some detail in the DISCUSSION section of the MS, i.e.

**Section:** DISCUSSION  
**Page:** 23  

11) Eliminate the excessive justification related to the use of NUTRICIA. State a brief summary of this delimitation in the discussion section.

**Response:**
In view of the fact that the trial was actually funded by NUTRICIA RESEARCH FOUNDATION (Grant Ref. No CEBK180/2000) the authors are simply not at liberty to accommodate the Reviewer’s suggestion for contractual reasons.

12) Eliminate the first paragraph in the results section.

**Response:**
The entire paragraph has obviously been misplaced in the MS, as given its clearly interpretative nature it most certainly belongs in the DISCUSSION section, where it has been moved since, following necessary modification.

13) Eliminate Figure 1. It provides redundant summary information.

**Response:**
The authors sought specific guidance on the subject from the editors and were told that the MS must be CONSORT-compliant.

Please kindly look up the following weblinks:

http://www.consort-statement.org/?o=1011;  
http://www.biomedcentral.com/1471-2288/1/2

14) On page 20, the reference to gait speed studied by others is in fact relevant to the focus of the manuscript since the 6MW test is a measure of average velocity (distance/time=average rate) and may be compared.

**Response:**
The authors concede the point and so the MS have been amended accordingly to accommodate this requirement, i.e. this paragraph has been deleted.

15) The last paragraph on page 20 provides little insight into the results of the study and should be eliminated.

**Response:**
In view of the fact that core data presentation with regard to the respective muscle groups at issue has been substantially reshuffled in the revised version of the MS (Cf. Table 3 and 3A), the authors are unable to accommodate the Reviewer’s suggestion, as otherwise the discourse would lack in consistency.

16) References to “flawed” methodology must be eliminated. Certainly, methodologies of other studies (much like the one being reported) may be limited
in their scope.

Response: The authors concede the point and the DISCUSSION section in the MS has been amended accordingly, i.e. the incriminated sentence has been deleted.