Author's response to reviews

Title: Effects of resistance and all-round, functional training on quality of life, vitality and depression of older adults living in long-term care facilities: a 'randomized' controlled trial

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Version: 3 Date: 3 Mar 2004

PDF covering letter
Concerns or recommendations of reviewer 1 followed by our reply

Mandatory revisions: Do not use the term Well-being as it cannot be adequately defined. **Revised as suggested:** we replaced the term well-being and used the actual names of the psychological outcomes.

Major Comments

1. The reviewer is not convinced that psychological well-being is a valid construct, besides it is not well defined. **Revised as suggested.**

2. The reviewer wants us to explain why we chose for functional training and a combined functional resistance training. **Our reply:** The main objective of the functional training program was maintenance or improvement of mobility and performance of daily activities essential for independent functioning. The rationale of this training program is described in detail elsewhere (1). Since the performance of daily activities demand a certain degree of strength, speed, endurance, flexibility, and coordination, we chose for an all-round or multi-component program. We chose for functional exercises i.e. exercises that relate closely to functional activities, because of the specificity of training: strength training is expected to improve mainly muscle strength, while an all-round functional program is necessary for an improvement of functional tasks. Functional training has been shown to improve functional ability (2;3). To clarify the type of training we changed the name of the training program into ‘all-round, functional training’.

3. The reviewer states we broke the randomization by randomizing some individuals as couples. **Our reply:** We randomized couples together because we wanted to prevent contamination, and because we expected the compliance to be higher when husband and wife could go to the programs together. Among the 224 randomized subjects there were only 9 couples. Among the 173 analyzed even less. However, we performed an additional analysis in which we excluded one member of the couples and we found no difference in the results.

4. Unfortunately the authors do not document the efficacy of the exercise programs on parameters of physical functioning. The reviewer states that if the programs are not effective in improving strength/function we cannot say that they do not improve well-being. **Our reply:** A detailed description of the effects on fitness and functional performance is described in another manuscript (submitted for publication). In the discussion we included an extra paragraph (page 13) summarizing the changes in fitness and functional status. We do not agree with the statement that a program which is not effective in changing strength or function cannot improve well-being. There are different explanations why subjects may experience psychological benefit from participating in an exercise program, for instance hormonal or metabolic adaptations, alterations in brain monoamines or opioid peptides, the opportunity of socializing, enhanced feelings of competency, or distraction of day-to-day stressors. King et al. (4) compared higher intensity group, higher intensity home and lower intensity home endurance exercise. Their results suggest that change in physical fitness was not necessary to achieve psychological change.

5. The authors need to justify the use of a two days per week training program. **Our reply:** We chose for an exercise frequency of twice a week for several reasons:
   - A twice a week training program has been shown effective in improving strength and function in earlier studies (2;5);
   - We were interested in the effects of different training programs under real-life circumstances. A long-term training frequency of more than twice a week seems not
realistic for this age group since their capacities are limited. Our results show that participating in exercise training twice weekly is already difficult for most older people.

6. Is the warm-up for the strength training thorough enough? Why not use the same warm-up for the functional training and the strength training? How did the combined training group warm up. **Our reply:** We cannot say whether the warm-up of the strength training was thorough enough or not. We did not use the same warm-up for both programs for practical reasons: for the warm-up of the functional training a larger space is needed than available in the rooms where the strength training was performed. The combined group performed once a week the complete strength training session (including warm-up), and once a week the complete functional training session (including warm-up). We clarified the description of the combined training program on page 6.

7. A justification for inclusion and exclusion of muscle groups for the strength training program needs to be given. **Our reply:** The strength training program was designed to improve muscle strength of major muscle groups of both upper and lower body, most important for functional performance on common daily activities. We chose for functional exercises including multiple muscle groups rather than isolated exercises for a single muscle group. The shoulder muscles were trained during the reverse pull-down and the hamstrings during the leg-press exercises. We did not include a specific exercise for the chest, since according to our knowledge an increase in muscle strength in the chest muscles does not significantly contribute to performing daily activities in older people.

8. There was no instructional video for the strength training. The assistants may not have been properly prepared to instruct participants of the strength training. **Our reply:** There was no instructional video for the strength training program, since this program comprises standard exercises performed in the same way every week. The assistants received a clear explanation of the exercises, and the instruction they were expected to give. The primary researcher frequently visited the exercise sessions to check proper instruction and execution of the exercises.

9. According to the reviewer the control program was a relaxation training that may have lead to improvement in the psychological outcome measures. **Our reply:** The control program was not a relaxation training but an educational program with discussions on different topics. In only one of the 24 weeks the topic was relaxation, however, no specific relaxation exercises were taught.

10. Which of the primary outcomes were used in the calculations to power the study? The reviewer would like to see power values and Eta squared. **Our reply:** The power calculations were primarily based on the fitness and functional outcome measures presented in a different manuscript. With these numbers (40 to 45 subjects per group) we are able to detect differences between groups of 0.6 SD in the used outcome variables. It is indeed possible that we were not able to find a significant difference between groups because we ended up with fewer subjects than needed in two of the four groups. However, most differences between groups were small and in favour of the control group. We can therefore say with confidence that the exercise programs were not effective in improving the aspects of well-being examined in this trial. We added a paragraph in the text and in the discussion to clarify this point. We did not calculate eta squared since we are mainly interested in the differences between the groups and not in the explained variance. Besides this, eta squared can not be calculated with multilevel analysis.
11. The reviewer questions whether appropriate statistical procedures have been applied. 

**Our reply:** We have used appropriate statistical procedures: multi-level analysis is the state-of-the art for analyzing these types of trials. However, the reviewer is right in saying that the scales of the outcome measures were ordinal. We decided to analyze the variables as if they were discrete because we are mainly interested in the differences between groups (with the 95% confidence intervals). Non-parametric tests would only provide p-values. And as far as we know multilevel analysis for ordinal outcome measures is not yet available. We added a paragraph in the discussion (page 13) on this point.

12. In the results section provide the mean and range of the participants attendance for each group. In participation rates there is some inconsistency in the text and the tables. **Our reply:** In the text we now give the median class attendance of the 173 subjects who were included in the analysis. Because the distribution of class attendance is not normal we chose to present the median. As the reviewer suggested we added the range (page 9).

13. In the discussion a section should be added listing the limitations of the study. **Revised as suggested (page 13).**

14. Adjust the title to accurately reflect the paper, e.g. randomization is not fully a complete randomization, well-being is a nebulous term. **Revised as suggested:** we changed the term well-being. If the reviewer has still doubts about our randomization procedure after reading our reply to point 3 we are willing to put randomization between quotes.

15. Given the lack of power to show changes the authors may want to combine their exercise groups and analyze the effect on the psychological outcomes. **Our reply:** The differences between groups were small and in favour of the control group. We can therefore say with confidence that the exercise programs were not effective in improving the aspects of well-being used in this trial.

**Concerns or recommendations of reviewer 2 followed by our reply**

1. The authors should describe physical and cognitive functioning of the study participants e.g. % disabled in ADLs, % able to walk independently, % dementia etc. If demented cases were included the reviewer is uncertain of the accuracy of the GDS and VPS. If demented cases were not included the reviewer wants to know the reason why the DQOL was used rather than the widely accepted SF36. **Our reply:** We added the % and number of subjects disabled in ADLs, the average number of ADL disabilities and the % and number of subjects who need a walking aid indoors in table 1. Demented subjects were excluded based on two inclusion criteria, i.e. being able to comprehend the study procedures, and no medical contraindication for study participation. Both criteria were judged by the general practitioner of the subject. We chose to use the DQoL because this questionnaire was especially developed for older people. We, therefore, expected it to be more sensitive in picking up changes.

2. Did exercise training improve physical function? If the training had no effect on physical function, why would we expect an effect on well-being? **Our reply:** see point 4 of reviewer 1.

3. How were the dropout rates calculated? **Our reply:** Drop-out was defined as not attending the post-intervention measurement. The reviewer is right that we made a mistake in calculating the drop-out rates. We changed the numbers in the text (Page 9).
References


