Author’s response to reviews

Title: Exercise therapy for Stress-related Mental Disorder, a randomised controlled trial in primary care.

Authors:

A. Otto Quartero (a.o.quartero@umcutrecht.nl)
Huib Burger (h.burger@epi.umcg.nl)
Marieke Donker (mariekedonker@zonnet.nl)
Niek J de Wit (n.j.dewit@umcutrecht.nl)

Version: 2 Date: 26 April 2011

Author's response to reviews: see over
Dear professor Fahey,

Please receive our response to the comments of the referees as received by email on March 24th. On top of the corrections we made on request of the referees and marked in yellow highlights, we used a professional copyediting service to make textual improvements (not marked in the text).

Reviewer 1.
1. Abstract.
We would not like to create confusion about the contents of the study, but the exercise program was definitely monitored, though not by us. Monitoring was part of the instructions to the physical therapists, which was done in person and by written instructions. We therefore believe that “monitoring” is the proper way to describe the intervention. However, the reviewer rightfully suggests that insufficient patient compliance may have limited the study and that the physical therapists did not report back to our research team on the performance of participants. We reformulated as follows: “Intervention: patients were referred to a physical therapist for instruction and monitoring of physical exercise with intermediate intensity.” We also reformulated our conclusion in line with the reviewers’ suggestion: “Notwithstanding the relatively high drop-out rate, our results suggest that referral to a physical therapist for structured physical exercise is not likely to be very effective in improving recovery from SMD.”

2. Methods
Regarding the intensity of exercise, the physical therapist designed a personal program with the patient based on 5 metabolic equivalents for patients below 55 years of age, and 3–4 metabolic equivalents for those over 55. This level of exercise correlates to the stated level of 50–85% of maximum individual exercise. The type of exercise was chosen based on the patients’ preferences, whereas the therapists took

To the Editor of BioMed Central
Professor Tom Fahey
Attention Jenney Leigh

Date: April 26th, 2011

Re: Exercise therapy for Stress–related Mental Disorder, a randomised controlled trial in primary care. ISRCTN15609105

Manuscript nr: 3365886934860431
particular time to instruct the level of perceived exertion. We included the following text in the paper: “The therapist instructed the patient about the level of perceived exertion”.

3. Conclusions
In line with reviewer’s suggestion of defining the intervention more as a concept, we rewrote the conclusions paragraph as follows: “… we conclude that based on our findings the effectiveness of referral to a physical therapist for structured physical exercise may be seriously questioned.”

Reviewer 2.
Minor revisions
1. We thank the reviewer for the suggestions for improvement of the language in the abstract and adapted it accordingly: “No significant effects of the intervention were detected for any secondary outcome parameter either.”
3. With respect to the issue of initiating physical exercise, the reviewer is completely right to emphasize the difficulties of this task. We do not wish to imply that the GP has an easy job in this. The key is in the word “relatively”, indicating that in our view it will be less difficult for the GP than for anybody else. We reformulated the sentence: “...Probably less difficult than for other caregivers..”
4. We addressed this issue extensively under the heading “procedure” in the Methods section. Apart from the agreeable sensitivity (85%) and specificity (96%), we believe that bias is not likely to have occurred.

Reviewer 3.
Major revisions
1. Hypothesis.
We concur with the reviewer that this is a pragmatic trial in that the results regard the comparative effectiveness of two clinical strategies rather than two circumscripitive interventions. Therefore, we reformulated the intervention and the
conclusion as follows: “Intervention: patients were referred to a physical therapist for instruction and monitoring of physical exercise with intermediate intensity.” “Conclusion: Notwithstanding the relatively high drop-out rate, our results suggest that referral to a physical therapist for structured physical exercise is not likely to be very effective in improving recovery from SMD.”

2. Intervention and conclusion.
The reviewer comments on the fact that we have no data on patient compliance, which is indeed regretful but within the financial limits of the study we had to rely on the professionalism of the physical therapists. However, given the pragmatic nature of the study and the suggested revision we are still able to provide a clinically relevant answer to our hypothesis. On top of that, the collaborating physical therapists received proper oral and written instructions from us; this almost guarantees at least moderate compliance to the intervention strategy.

3. Methods
The essentials of the intervention are the frequency, duration and intensity of the exercise, which was instructed to the physical therapists very clearly. The individual preferences of the participants as to the nature of the exercise were important to support the patient compliance. We sent a questionnaire because this questionnaire was developed and validated just for this purpose. The logistics of the study were managed by the research team in order to minimise the workload for the GP.

4. Discussion
We acknowledge the comments made by the reviewer; we made textual adaptations at several points in the Discussion section.

Minor revisions
1. A first-line psychologist in the Netherlands is a psychologist providing therapy for mild, day-to-day psychological derangements. Their position is comparable to that of a physical therapist i.e. generally self-employed, often working in a health centre close to GP practices. In this study, they have no particular function. Active patients were included because, although they were active, they need not comply to the Guidelines for Healthy Physical Exercise (e.g. at least 5 times per week).

2. Results
We thank the reviewer for her observations; we corrected the percentages in the text.

3. discussion
Textual adaptations were made in line with the suggestions from the reviewer.

4. Conclusion
The conclusion was reformulated.

5. References
We repeated a Pubmed search and added two more recent citations.
6. Consort diagram
We corrected the consort diagram.

We ask you to consider the paper for publication.

On behalf of all authors,

Dr A. Otto Quartero MD PhD.