Author's response to reviews

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

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Re: resubmission of manuscript 3365886934860431 Exercise therapy for Stress-related Mental Disorder, a randomised controlled trial in primary care to BioMed Central Family Practice

Dear Sir

Please find herewith the most recent revision of our paper Exercise therapy for Stress-related Mental Disorder. We addressed the comments of the associate editor concerning the dropouts. In fact, most dropouts happened immediately after randomisation and baseline data were not received from those patients. We explained this more clearly in the paper, and extended the Consort flowchart.

Extensive copyediting took place before our previous submission. We marked our changes in the paper in yellow.

On page 12 we added the following sentence: “The remaining 50 patients (33%) immediately dropped out after randomisation, did not return baseline data and abstained from participation.”

On page 14 we added the following text at the end of the section: “This regarded the control group (28.8 vs. 11.11) more than the intervention group (22.0 vs. 20.6). However, none of the baseline differences were statistically significant. Unfortunately, we were unable to compare baseline data between participants and those 50 patients who immediately dropped out after randomisation because they failed to return the pertaining questionnaires. In addition, they did not provide reasons for drop-out.”

On page 16 we added 2 sentences: “Out of these patients, 30 had been randomized to the intervention and 20 to the care as usual group.” and “The extent and impact of this potential selection bias is unknown and we were unable to compare the baseline characteristics of these early drop-outs with participants because they did not return the questionnaires. Neither did they provide reasons for dropping out. The substantial losses to follow-up represent a major limitation of our study.”

In the consort flowchart we made the following changes

Allocated to Control condition (n = 76)
- Received physical exercise programme (n=56)
- Immediately lost to follow-up without returning baseline data, reasons unknown (n=20)

Allocated to Intervention (n = 76)
- Received physical exercise programme (n=46)
- Immediately lost to follow-up without returning baseline data, reasons unknown (n=30)
I trust we answered your questions satisfactorily,

On behalf of all authors,

Yours sincerely

A.Otto Quartero MD PhD.