Author's response to reviews

Title: Effects of a one week multidisciplinary inpatient self-management programme for patients with fibromyalgia: a randomised controlled trial

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Author's response to reviews: see over
Timothy Shipley
Editor BMC Musculoskeletal Disorders

Dear editor,

Thank you for your positive reply regarding our manuscript. We are very grateful for the reviewers’ valuable comments, which have contributed to an improved manuscript. Our responses to the reviewer’s comments are presented below:

Reviewer 1
The study is oriented to gain insight into the use of self-management programs for patients with fibromyalgia. The methodologies seem to be properly utilized. However, I have concerns about the experimental design utilized. Unless the authors further explain this in the manuscript, I do not know how the current design can tell the difference between their object of study and SMP after effects.

The design has now been clarified in more detail (page 4, lines 14-16).

For me, it is not clear how the changes found after one week of SMP can lead to long-term effects.

We agree, and have changed the text accordingly.

Abstract
1. With only these results, how can you make such strong conclusions? You stating that one week SMP can result in enhanced skills and behaviors that lasts a long-term?

We agree, and have changed the text accordingly (page 2, lines 15-18).

Introduction
1. The rationale does not seem strong enough for the utilization of self-management programs in this patient group.

In the Norwegian Specialized Health Services Act patient education is one of four core tasks. Since FM is a chronic rheumatic disease the hospital offers SMP for FM and eight other diagnostic groups. SMP is also recommended by EULAR.
2. Why authors decided to evaluate one week intervention?

This is now explained in more detail in the text (page 4, lines 7-9).

3. If non-pharmacological recommendations include short-term self-management programmes. What’s the interest of this manuscript?

EULAR recommendations do not say anything about the length of the interventions, only that they must be tailored to patient needs. In our group programme the individual needs are addressed by individual consultations, various exercises and activities. Our SMP is short term and complex and therefore different from most other SMPs. The interest is to see if this SMP has effects.

4. Include a reference supporting “In a study among Norwegian physicians and medical students FM scored lowest on disease prestige”

The reference has been included.

Methods and results

5. “...Of these, 58 participants in the treatment group and 60 in the control group completed the study”. Authors should include the specific reasons for not completing the intervention.

Those who started the intervention completed, but some participants withdrew from the study or were lost to follow-up. This is showed in the flow diagram.

6. Please include reasons for participants’ exclusion in results section (page 9). Exclusion criteria does not exclude other non-pharmacological treatments which are common in this population. May this be the case of your patients?

The reasons for exclusions have been included in the text (page 10, lines 7-9).

Of the 153 patients who agreed to participate three were excluded because they had attended another SMP at the hospital. Of the 150 participants who were included in the study one withdrew and two were lost to follow-up.

7. Why both groups were not equally distributed? (75 in the intervention group and 72 in the waiting list group).

This is now explained in more detail in the text (page 9, lines 1-4).

8. Control group did not receive any treatment at the hospital in the period from inclusion to participating in the SMP. But have they received any treatment out of the hospital?

Unfortunately we have not collected data about what treatment the control group may have received outside the hospital in the control period.

9. Please rewrite the sentence “In order to balance the groups, the baseline 2 variables of the dependent variable were included as a covariate.”
The sentence has been rewritten (page 9, lines 15-16).

10. Please include an ICC analysis between baseline 1 and 2.

The ICC analysis between baseline 1 and 2 is included in Methods (page 9, lines 16-17) and in the Results (page 10, lines 20-21).

11. All questionnaires were sent out by mail and these patients have problems in understanding the items, mainly in the FIQ questionnaire. How did you manage this?

Although there were few missing values, one cannot ignore the fact that there could have been problems or misunderstandings. If participants had difficulty in completing the questionnaire, they could call the project manager. This is now explained in the text (page 8, lines 11-12).

12. Fibromyalgia patients are characterized for a great variability in their symptoms severity and inter-subject variability? In just one week this situation is even more sensitive. Have all patients responded to the intervention? In addition, patients are aged between 20 and 70 years. Are there differences between them?

By choosing the RCT design, we assume that the distribution is similar in both groups. The design takes into account fluctuations and the wide age range. We agree that it would be interesting to explore possible differences between age groups, but have not accounted for such sub-group analyses in the power calculation.

13. Please be caution with the use of textual information “The SMP also makes use of an empowering approach to help patients who, by developing knowledge, attitudes, skills and behaviours, are able to take responsibility for their own health management and daily life…” used in Hamnes et al. (2011)

We agree and have changed the text accordingly (page 6, lines 1-3).

14. In the results section the authors are perhaps over emphasising the effects of a one week multidisciplinary inpatient self-management programme.

We agree and the text has been changed (page 11, line 2).

Discussion

15. Be consistent with the use of FM throughout the manuscript but also with the use of abbreviations (EC-17; GHQ-20,...).

The text has been reviewed and corrected.

16. The discussion should be focused towards your true findings rather than what others have found previously. While that is important to give context to the findings, the reviewer wasn’t sure of what your findings mean and in which context. The discussion needs an entire revision.

The discussion has been revised and focuses more on our findings.

17. In the discussion, the authors should mention the implications for managing fibromyalgia patients if any. But authors state that “there is a possibility that
processes initiated during the current SMP may result in measurable changes after a longer period of time.” If they have not measure these results.

We agree with the comments and the text has been changed.

Lillehammer August 19th, 2012

Yours sincerely

Bente Hamnes