Author's response to reviews

Title: Low back pain education and short term quality of life: a randomized trial [ISRCTN48558333]

Authors:

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Author's response to reviews: see over
Dear Dr. Mau:

1. The major flaw of the study is the inadequate control group. The study cannot answer the question whether the specific content of the back school programme is effective, concerning the chosen outcome of quality of life as measured by the SF-36. Regarding the high proportion of housewives (88% in the intervention group, 75% in the control group), the effect of nonspecific attention particularly in persons with perhaps limited social contacts should have been controlled for. It may well be, that nonspecific attention or the company or others in the patient group with low level physical activity is sufficient to reach same results. For example, participation in a walking group or, if this is not practicable in Iran, another group activity of the same duration as in the intervention group could have answered the question of the specific effect of the programme.
   a. This was a randomized trial. Thus, we randomly allocated each study participants either to back school group (intervention group) or clinic group (control group). As one might see in Table 1 both group are quite similar in most characteristics reported.
   b. The issue of the high proportion of housewives in the study was discussed at the end of discussion section and indicated that in Iran being a housewife involves a considerable amount of physical and social activities.

2. It is necessary to provide more details on the medication in both groups during the study period. In the second paragraph on page 11 ….
   More details on the medication were provided in the method section. The medication for both groups was the same.

3. The information that most of the patients were suffering from discopathies is given rather late on the final page of the article. This important characteristics, and……
   a. The statement that most patients were suffering from discopathies ……. was omitted and instead we added some clinical information in Table 1.
   b. The method of ascertainment already exists in the method section whether we stated that each patient went under careful clinical examination.

4. The discussion lacks focus. For example with the exception of the two sentences at the beginning the second paragraph on page 10 contains a lengthy discussion of trivial aspects of a controlled study design. The following paragraph of the discussion on page 10 and 11 is rather speculative.
   Discussion was tidy-up. The second paragraph in page 10 and the paragraph in page 10-11 were shortened.

5. In table 1 some categories are ill defined e.g., income (household income?, cut offs categories?), definition of the exercise categories always and occasionally, definitions of proper chair, proper shoes and proper bed.
a. Income was clarified in Table 1 that is household income.
b. Exercise categories were clarified in Table 1.
c. Proper chair proper shoes and proper bed were defined in Table 1 as footnotes.

6. The Tables 2 and 5 repeat data. They should be integrated in one table.
Table 2 and Table 5 are presenting different data sets. We think it is impossible to integrate these two tables.

Dr. Hurri

1. One might consider the title once again. The study deals with the short-term outcomes and perhaps that message could by conveyed to the tile as well. The title was revised as recommended: Low back education and short term quality of life: a randomized trial.

2. I would like to see the patient description more precisely:
2.1. What was the length of the low back pain? We only know it was more than 90 days.
2.2. What was the percentage of patients with sciatica?
2.3. The expression ‘All patients had some kind of chronic low back pain….. At least the points 2.1 and 2.2 should be looked more carefully.
2.4. The ability to work remains obscure and it has not been used as an outcome measure. Why? The number of employed was quite low in the beginning of the study and most probably their perceived ability to work as well. Do we know anything more exactly about that and if we do did the perceived to work change?
   a. The exact pain duration was added to Table 1.
   b. The sciatica status for both groups was added to Table 1.
   c. The ability to work as missing outcome measure was acknowledged in the discussion section. Unfortunately, we did not measure this important outcome and addressed as one of the study limitations.

3. Methodological considerations
3.1 There is no description of randomization procedure. That is usually provided and required in RCTs.
3.2. Was the treatment allocation concealed or not?
3.3. Were co-interventions avoided? Were they comparable between the intervention and control group?
3.4. Was the patient blinded to intervention?
3.5. The analysis does not include an intention-to-treat analysis, which is usually required.
   a. The randomization process was added in the method section at the beginning paragraph on page 5.
   b. It was indicated that the treatment allocation was not concealed (page 5).
   c. Co-interventions were avoided and this was indicated in the method section (page 5).
   d. The patients were not blinded to the intervention (page 5).
   e. The intention-to treat analysis was acknowledged.

General changes:
a. E-mails were added in the title page.
b. References were reformatted.
c. Competing interests statement was added.
d. Authors’ contribution was added.

Hope you find the corrections satisfactory.
Wish you all the best.
Yours sincerely
Ali Montazeri