Author's response to reviews

**Title:** Subacute and chronic, non-specific back and neck pain: cognitive-behavioural rehabilitation versus primary care. A randomized controlled trial.

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**Author's response to reviews:** see over
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The Editor
BMC Musculoskeletal disorders

Dear Editor,

We are very grateful for the valuable reviews for our article (MS: 1353493846202608). We enclose a point-by-point response to the concerns of the referees 1, 2 and 3:

Referee 1, J. Bart Staal (10 July 2008), page 2.

Referee 2, Ivan Steenstra (7 July 2008), pages 3-5.


The revised manuscript and the figures are attached in separate files. To facilitate comprehension of our changes, we have added line numbers. We specify within parenthesis where in the revised manuscript the changes are to be found. The numbers in brackets refer to the reference list in the revised manuscript. “Old version” refers to the version of the article of 22 May 2008.

As a consequence of meeting the views of the referees, the length of the manuscript has been increased by 500 words (to 5,250 words) and the number of references from 44 to 49.

Yours sincerely

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Comments on the report by referee 1, J. Bart Staal, 10 July 2008

The paragraph figures refer to the report by J. Bart Staal.

Major compulsory revisions:

1). A discussion is added to try to answer the question why the *Return-to-work share* was substantially higher than expected for the primary-care group (page 17, lines 391-403). The change from the term “health-centre group” to “primary-care group” is described below.

2). The discrepancies from graded activity by the book are described more in detail as a basis for possibly explaining why the positive effect on the subacute rehabilitation-group patients was not seen until the third six-month period (pages 19-20, lines 448-464).

Minor essential revisions:

3). The patients were given verbal and written information about the project by their family doctor (page 11, lines 254-255).

4). The sentence “…which also operates in the subtotal observation periods” has been removed (old version: page 10, line 213).

5). The description of the power calculation has been shortened by removing the sentence “There were positive correlations \( p < 0.05 \) between *Return-to-work share* and (1) low age (\( \leq 44 \) years) and (2) subacute BNP.” (old version: page 11, lines 246-247).

6). To be more consistent, the “health-centre group” has been renamed “primary-care group” (for example, page 2, line 28, and page 7, line 138-139). It is made clearer that participation in the rehabilitation group did not exclude the patient from seeking other care, including primary care (page 7, lines 154-155). The low frequency of primary-care consultations in the rehabilitation group is clarified (page 16, lines 358-359).

7). In addition to BNP, one rehabilitation-group patient suffered from whiplash-associated disorders. Those disorders appeared to be a primary obstacle of working. Thus he was shown to be incorrectly included. However, this was only detected during the initial mapping-out at the rehabilitation centre. The point is clarified by information added beneath Figure 2 (footnote b) and a reference to that footnote in the text (page 16, line 374).

Discretionary revisions:

8). To increase readability, the paragraph Premature cessation has been moved to precede Follow-up (page 12) and the results of the outcome measures are collected under a common caption (page 13, line 308).
Comments on the report by referee 2, Ivan Steenstra, 7 July 2008

The paragraph figures refer to the report by Ivan Steenstra.

Behaviourist: As that term could be misunderstood, we have removed it. It has been replaced by “psychologist or social worker” (for example, page 7, line 145).

Outcome measures

Return-to-work share expresses the percentage of patients who over 18 months regained any degree of work ability for at least 30 days in succession. Return-to-work chance expresses the chance, as expressed in hazard ratios, of achieving any degree of work ability over 18 months irrespective of the duration of that work ability. As the two measures differ in respect of duration, we consider them to be two separate outcome measures. We have added a clarification of that difference (page 8, line 182). Unlike previous research on graded activity, we also included patients with chronic BNP. Only 30% of our patients had subacute BNP, 70% had a sick-listing period exceeding 12 weeks at baseline. For these comparatively more disabled patients, we found it more realistic to apply the possibility of part-time return-to-work. We have added a clarification of this (page 19, lines 454-455). To facilitate comparisons with other studies, we have added information about the degree of work ability at return-to-work (page 14, lines 311-315).

Reference 30 (old version): Net days as a sick-listing measure was described on page 394, but not in the Abstract, in reference 30 of the old version (Arrelöv B, Borgquist L, Ljungberg D, Svärdsudd K: Do GPs sick-list patients to a lesser extent than other physician categories? A population-based study. Fam Pract 2001, 18:393-398). We have replaced this reference with another article by the same authors, where this measure is also described in the Abstract [29].

Analyses and statistics

One of the authors, SEJ, is a professor of statistics. In the mixed linear models we had three explanatory variables: time (0–6, 7–12 or 13–18 months after inclusion, coded as 1, 2 and 3 respectively in the calculations); intervention (rehabilitation group or primary-care group, coded as 1 or 2); subacute or chronic (coded as 1 or 2). We wanted to investigate possible differences (a) over time between (b) the entire rehabilitation group and primary-care group and (c) the subacute and chronic patients in the respective intervention group. We therefore constructed interaction terms that combined a, b and c. The results of those multivariate analyses are shown in the fourth and the fifth lines of the bottom lines of Figures 4 and 5: a x b is a comparison over time of the entire rehabilitation group vs. the entire primary-care group, and a x b x c is a comparison over time of the subacute and chronic patients in the respective groups. Such interaction terms combine the main effects of two or more explanatory variables, none of which is a modifier.

Per-protocol analysis: This analysis was done to investigate the results (1) from the intervention the patients really received and (2) with the exclusion of incorrectly included patients. Sometimes a per-protocol analysis mirrors important differences from the intention-to-treat analysis [19]. Sometimes, as in our study, the differences were marginal.

Blinding: “Analyser” has been replaced by “analyst” (page 10, row 226).
Inclusion procedure: Information about informed consent has been added (page 11, line 258). The paragraph of Ethical approval is moved closer to this and now follows directly after the paragraph Inclusion procedure.

The sentences “Patients who were allocated to the rehabilitation group started the programme within one week. Patients who were allocated to the health-centre group continued care at their health-centres.” have now been moved to Results (page 13, lines 301-303).

The paragraph Premature cessation has been moved to precede Follow-up (page 12).

The sentence “The 95% confidence intervals are shown within brackets.” has been moved to the heading of Table 2.

Concerning the explanation on (old version) page 18, lines 412-414, we have replaced the reference from Anema et al. [8] by Steenstra et al. [18] and have added some more words of the possible explanation (page 18, lines 421-424).

It is true that Heymans et al. collected data for at least 12 months (Heymans MW, de Vet HC, Knol DL, Bongers PM, Koes BW, van Mechelen W: Workers’ beliefs and expectations affect return to work over 12 months. J Occup Rehabil 2006, 16:685-695). However, we have found no study in which those data are used to describe the results of the three interventions [47] for a period longer than six months. Anyhow, we have changed the sentence “However, the follow-up periods in their studies were short (12 and six months respectively)...” (old version: page 18, lines 416-417) to “The follow-up period of those later studies did not exceed 12 months.” (page 18, lines 427-428).

“Extent” is used as a combination of intensity (= treatment measures/time unit) and total sum of measures. Thus it is the quantitative correlate of the qualitative term “content”. To elucidate the comparison with other more extensive programs, we have added “comparatively limited” as a prefix to “extent” (page 19, lines 436-437).

In the description of possible methodological defects, we have clarified the point that graded activity by the book includes full-time return-to work (page 19, line 449). Concerning our modifications of graded activity, we have added explanations of, among other items, why we included part-time return-to-work as a possible rehabilitation goal (pages 19-20, lines 451-458).

No: no limits were set beyond six months. Maybe that indicated irrational recovery expectations for some patients. On the other hand, we saw no difference in favour of the subacute rehabilitation-group patients until after 12 months.

Yes: manual therapy and cortisone injections were delivered within the experimental intervention at the rehabilitation centre. From Table 2 and the Appendix it is seen that those measures were given to a minority of the patients, exclusively during the treatment and investigation phase. To clarify this, we have removed the sentence “Though a hands-off approach was applied to the majority, some of the patients received manual therapy and cortisone injections” (old version: page 19, lines 438-440) and integrated information about
this in the new sentence on pages 19-20, lines 451-458). After a hopefully positive effect of these measures we could also reassure these patients that “nothing is wrong”.

The headings of Tables 2–5 have been completed with information about the method of analysis used.

The sentence in the headings of Table 5, “Hazard ratios for the rehabilitation group…” has been completed with “…as compared with the primary-care group”, and “Reference is the health-centre group” has been deleted.

Figure 1: To clarify the flow diagram, the text in the first box has been changed to “Eligible patients as proposed by the family doctors (n = 147)”.

To avoid misunderstandings, the “health-centre group” has been renamed “primary-care group” (for example, page 2, line 28, and page 7, lines 138-139). It is made clear that participation in the rehabilitation group did not exclude the patient from seeking other care, including primary care (page 7, lines 154-155). The low frequency of primary-care consultations for the rehabilitation group has been clarified (page 16, lines 358-359).

The references to and the listing of legends concerning Figures 4 a and 4 b have been replaced by references and legends for Figures 4 and 5 respectively. Figures 4 a and 4 b existed only in a former version of the article. We are sorry for that omission.

A health-economic evaluation is planned. A discussion of this has been added (page 21, lines 498-501).
Comments on the report by referee 3, Eva Schonstein, 10 August 2008

The paragraph figures refer to the report by Eva Schonstein.

At present, we do not have calculations of the time (days) to return-to-work. However, if the findings of our study are pooled with other studies, it should be possible for us to make such calculations from the raw data we have already collected.