**Author's response to reviews**

**Title:** Evaluation of a structured goal planning and tailored follow-up programme in rehabilitation for patients with rheumatic diseases: Protocol for a pragmatic, stepped-wedge cluster randomized trial

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Reviewer 1:  
1. The statistical analysis is not described in sufficient detail. A stepped-wedge design requires careful analysis, as comparability of the patient groups is not guaranteed. For example, as the control patients are on average included earlier than the experimental patients, the design is vulnerable to time trends unless this is corrected for in the analysis. Also, cluster effects need to be taken into account, as the known treatment may result in a difference in patient mix. (See, for example, Brown and Lilford. BMC Med Res Methodol. 2006; 6:54).  
   Answer: The statistical analysis is now described in more detail.

2. The cost analysis includes subsequent care, but seems to forget the costs of the intervention itself. How will the costs be assessed of the elements that are added to the rehabilitation programme? For example, no explicit time measurements for different types of involved personnel are described.
Answer: Information concerning this is added in the first paragraph at page 10.

Discretionary Revisions

3. The paper does not describe when randomization took place and when the switching date was made known to the participating centres. Also, which patient date determines their randomisation group: admission date or study inclusion date?

Answer: This information is now included in the manuscript in the section describing randomisation and blinding (page 6).

4. In the discussion, it is described how the PGI may be more responsive than standardized measures. It could be added that the PGI may also be more prone to regression to the mean (in both randomisation groups), as the selected areas of life are those that are problematic at baseline. It is not described whether the same areas are scored at 6 and 12 months (in which case regression to the mean is likely), or that new areas can be selected (in which case the improved sensitivity is unlikely).

Answer: The likelihood of regression to the mean is now addressed in the discussion (page 13, second paragraph). A sentence describing that the areas selected at baseline will be scored at 6 and 12 months is added in the description of PGI at page 9.

Reviewer 2:

Page 4, second paragraph (lines 1-4): The first two sentences of the paragraph must be accompanied by references supporting the text.
Answer: References supporting the text are now added.

Page 4, third paragraph (lines 4-10): The last sentences of the paragraph must be accompanied by references supporting the text.
Answer: References supporting the text are now added.

Methods

I am not sure if the verb tenses are sufficiently homogenous throughout the text. This is a study protocol without results. So, the study WILL BE developed, instead of the study WAS developed. The dates when the centres were included (2011 and 2012) do not help to understand the time/sequence of the study (the status of the trial in www.controlled-trials.com is COMPLETE -8/12/2013-). The authors must take care with this.

Answer: The tenses have been corrected throughout the text.

We would also like to thank the reviewer for making us aware of an error in the
registration of the trial in the controlled-trials register. As illustrated in figure 1, the inclusion of participants started August 23rd in 2011 and ended June 30th in 2012. However, as all participants were followed for 12 months, the anticipated end date (of the data collection) should be June 30th in 2013. We have e-mailed the data base editor, who has corrected this in the trial register.

Page 5, second paragraph: The homogeneity of the participating centres (clusters) must be assessed and/or ensured.
Answer: We agree. This issue is also addressed by the first reviewer in his/her first question. Any differences between clusters/centres will be controlled for in the main effect-analysis (see description of statistical analysis at page11).

Page 6, first paragraph (line 1): Was previous multidisciplinary treatment not an exclusion criterion? This should be stated.
Answer: Previous multidisciplinary treatment was not an exclusion criterion. As this is a randomised controlled trial, we expect that the proportion of participants who have had previous multidisciplinary treatment will be equally distributed in the two groups. We prefer not to state inclusion criteria that are not applied in the trial.

Page 6, last paragraph, and page 7, first paragraph: Did the identified opinions and experiences of the providers change the intervention protocols? If so, how were those changes applied?
Answer: As this meeting was held after all telephone follow-up calls (and thereby the intervention period) were completed, the experiences and opinions of the providers did not change the intervention protocol. It will, however, be used in the implementation phase, and also in the development of new models and trials.

Page 7, second paragraph: The usual treatments received by the subjects should be described briefly.
Answer: The usual treatment at each centre is outlined in a new table (table 1).

Page 7, fifth paragraph: The objectives of the new program are interesting but somewhat excessive. The objectives should be tempered.
Answer: We agree that the objectives of the new program are ambitious. The objectives were developed by the project group, they guided the development of the programme, and the trial was designed to evaluate to which degree the objectives are met. We therefore find it difficult to change the objectives at this point in the process.

Page 8, third paragraph: As one of the innovations of this study, the content of the telephone calls should be detailed.
Answer: The content of the goal setting conversations at admission and discharge and in the telephone calls are now outlined in a new table (table 2).
Page 8, fourth paragraph: check references.
Answer: The duplicate reference is now removed.

Page 9 and 10: please, afford reliability data of the assessment tools for this population.
Answer: References to studies providing reliability data is now inserted.

Page 9, third paragraph: why did the authors use two HRQL questionnaires? It is important to explain the relevance of the second assessment (SF-36).
Answer: This is now addressed in the discussion, (second paragraph at page 13).

Page 10, second and third paragraphs: similarly, the authors should explain why two different scales for assessing exercising/physical activity were applied.
Answer: Exercising is one important aspect of physical activity. However (according to the Worlds Health Organisation), physical activity also includes leisure time physical activity (for example: play, games, walking, dancing, gardening, hiking, swimming), transportation (e.g. walking or cycling) and occupational activity (i.e. paid work, house work). In addition to the International Physical Activity Questionnaire-Short Form, (IPAQ-SF), we therefore also include one question that specifically address level of exercising.

Page 12, second paragraph: What are the authors’ reasons for believing that the stepped-wedge design could reduce the drop-out rate?
Answer: Thank you for making us aware of this misunderstanding. We have now changed the text as follows: Furthermore, all participants in the trial will receive rehabilitation, regardless of group allocation. This may reduce the chance that participants refuse participation for fear of ending up in a control group with an inferior treatment. The design may therefore increase the inclusion rate, and also to a large degree keep participants blinded for group allocation.

Page 12, fourth and fifth paragraphs: The order of these two paragraphs could be changed in order to follow a more logical sequence.
Answer: We are not quite sure which paragraphs the reviewer refers to and have therefore kept the original order.

Finally, although the results are not presented, the limitations of the study protocol could add further interesting information (CONSORT 2010 Declaration, item 20).
Answer: We agree that it is important to discuss trial limitations and address sources of potential bias. A paragraph discussing possible limitations in the primary outcome PGI is now added (page 13, second last paragraph in Discussion).