Reviewer's report

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

Version: 2 Date: 11 December 2013

Reviewer: Wilbert van den Hout

Reviewer's report:

The paper describes the design of a pragmatic, stepped-wedge cluster randomized trial. No results are presented. The design is mostly appropriate for the research questions and is consistent with the design as it was described in the ISRCTN trial register in 2011.

Major Compulsory Revisions

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)

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.

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?

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).

Level of interest: An article of limited interest

Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests