Reviewer's report

Title: Cost effectiveness of a multi-stage return to work program for workers on sick leave due to low back pain, design of a trial.

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Reviewer: Niklas Krause

Level of interest: A paper of considerable general medical or scientific interest

Advice on publication: Accept after discretionary revisions

RE: Cost effectiveness of a multi-stage RTW program ....

General Comment
The authors address an important public health problem in their design of this RCT, and the results of their study will be of great significance for the management of subacute and chronic work-related low back pain. It is laudable that the Journal is willing to consider this methodological paper. In addition to all the reasons the authors put forth in their background section for publishing their design and rational for this RCT, the detailed description of the intervention and evaluation approaches is a helpful document for both researchers contemplating intervention or evaluation studies of LBP themselves as well as for research-users who try to make an informed choice between different RTW strategies. One weakness of the current paper is that the rationale for the choice of outcome measurements has not received the same attention than the justification of measurement instruments for independent variables.

Specific Comments (Discretionary Revisions)
1) (Page 3) The section on “Sick Leave in the Netherlands” is very helpful for the readers in the Americas and will facilitate the cross-cultural interpretation of results.

2) (Page 4) The investigators excluded patients with herniated lumbar discs if pareses were found but did not justify this choice. Similarly, patients with “juridical” (spelling) conflict at work were excluded but neither a rational e or definition was provided. An alternative approach may be considered which includes these cases and to adjust for pareses and/or other measures of severity or prognosis in the analyses.

3) (Page 4) Defining the episode of sick-leave or disability leaves many choices to the researchers. It would be good to provide the reader with the rationale for excluding workers who have been sick-listed due to LBP less than one month prior to the current episode of sick leave and to provide a critique of alternative approaches used in the literature.

4) (page 5, first paragraph after the heading treatment allocation) Insert "First" before
"randomization"

5) (Page 5) Why were OP's stratified by economic sectors?

6) (Page 6) Co-interventions: It is not clear how the effect of co-interventions can be measured objectively if one relies on the judgement of the OPs. Alternatively, one could register co-interventions and adjust for them in the final multivariate analyses.

7) (page 14) "Cost effectiveness will be evaluated from both the societal perspective and the employer's perspective." The authors may want to address the possibility of an analysis from the perspective of the injured worker who (together with family) shoulders most of the total burden of disability, especially in the case of chronic disability.

8) (Figure 1) Text in right-hand lower boxes: suggestion to make consistent with upper right-hand boxes: "Usual Care and Graded Activity", "Usual Care Only"

Specific Comments (Compulsory Revisions)

1) (Page 5) The statistical power refers to the ability to detect a difference in "recovery rate (return to work)", however, it is not clear which of the six definitions of RTW listed on page 11/12 were used for the respective sample size calculation. Please clarify.

2) (page 5) A minimum detectable effect of 21% difference in recovery rate was described as "clinically relevant" according to the belief of the researchers. Clinical relevance should be defined and discussed here, because this is a crucial consideration for any (expensive) intervention trial or future intervention. Since part of this RCT is to determine the cost-effectiveness of these interventions from a societal and employer perspective, "clinical" relevance may not be the best criterion (or label) to determine minimum sample sizes. Moreover, if a 21% difference is deemed as relevant for workers with up to eight weeks of sick-leave duration, then a smaller rather than a larger (30%) difference should be relevant for workers with more than 8 weeks of sick-leave. Numerous studies have shown that the probability of RTW decreases with the duration of sick-leave. Studies have also shown that the approximate 7% of cases with duration of sick-leave of more than 12 months are responsible for 84% of all work days lost and 75% of all casts (Hashemi et al., 1997). Given this uneven distribution of costs per case the effectiveness of RTW programs needs to be evaluated using a disability-phase specific approach (Krause et al., 2001). It may be advisable for future studies to oversample workers with longer duration of sick-leave to address the costly problem of chronic work disability and to detect smaller differences in the small high risk groups.

3) (page 6 last to paragraphs) typos: insert "and" before Achilles, insert "of " before obstacles.

4) (page 11) Primary outcome measures. The choice of RTW outcome measures is described as "pragmatic." The authors should provide a rationale and place their choice in the context of the extant literature on measuring RTW outcomes (e.g. Baldwin et al., 1996; Butler et al., 1995; Krause et al., 1999; Krause et al., 2001, among others). Although it may be less of a problem in the Netherlands, the huge discrepancy between RTW outcomes determined by administrative databases and by self-report should be mentioned for the international readership. (see e.g. Dasinger et al., 1999)

5) page 12: "Outcome measure #6: Total number of days of sick-leave: due to any condition or only due to LBP? Please clarify."
Cited Literature


Competing interests:

None declared.