Author's response to reviews

Title: Solution-focused intervention for sick listed employees with psychological problems or muscle skeletal pain: a randomised controlled trial

Authors:

Pal Nystuen (pny@shdir.no)
Kare B Hagen (kare.hagen@diakonsyk.no)

Version: 3 Date: 3 February 2005

Author's response to reviews: see over
### REVIEWER 1; Willy Eriksen

<table>
<thead>
<tr>
<th>REVIEWERS COMMENTS</th>
<th>OUR RESPONSE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General</strong> 1. This paper describes a randomised controlled trial of a solution focused intervention in sick listed employees with psychological problems or muscle skeletal pain. The aim of the intervention was to improve the health and functional ability of the employees and reduce the length of the sick leave. Long-term sick leave causes individual suffering as well as public expense, and there is a lack of effective measures designed to reduce this major public health problem. Hence, the study is of great importance. The study was well conducted. Unfortunately, the number of employees included in the trial, and consequently the statistical power of the trial, turned out lower than the authors had hoped and expected. Still, the results may be of interest to researchers as well as policy makers.</td>
<td></td>
</tr>
</tbody>
</table>

| **Major Compulsory Revisions** 2. The indices of the SF-36 may not be normally distributed. Did the authors investigate this, and which statistical test was used to compare the groups regarding these indices? I cannot see that these issues are addressed? 3. Quite a few statistical comparisons are made in this study. In the primary analyses alone, as many as 10 comparisons are made. One should also take into account the secondary analyses. When many comparisons are conducted, the nominal p-values for each variable may be misleading, because the risk of type I error cumulates with each statistical test performed. However, I cannot see that the authors mention this problem either under Methods or in the Discussion. It is important to acknowledge that implementation of multiple comparison procedures has a philosophical component, involving a researcher’s position on the balance between statistical power and control over Type I error. Hence, the use of a traditional level of statistical significance (0.05) is not necessarily wrong. Still, the issue should be addressed, and the authors should explain how they think about this matter (either in Methods or Discussion). 4. The authors mention that 15-20 responders returned the questionnaire between 7-10 months after the intervention, while they should have returned it at 6-month follow-up. Do the authors know whether these late responders were evenly distributed between the groups? If there are data on this, they should be reported. As there may be a decline |

| 2. Added section on page 10, second par: “The distribution of SF-36 scores was normally distributed in most of the subscales in our sample (except Physical functioning and Role Physical). Since the non-parametrical test (Mann-Whitney U) showed no statistical differences in PF- and RP scores, only the parametric test results are shown in Table 5.” 3. Added section on page 11, second par: “Due to multiple comparisons in the statistical analysis, we considered using the Bonferroni correction to reduce the risk of type I error. However, since the primary analyses showed no effect and this method is highly conservative (in fact some p-values would have exceeded 1), we chose not to use this correction.” 4. As suggested we looked in to this in more detail and have corrected and rephrased the sentence at page 10, first par: “There were twenty-five late responders returning the questionnaire between 7-10 months after the intervention started. Since they were equally distributed between the two groups; eleven in the control group and fourteen were in the intervention group (Odds Ratio 1.03 95CI 0.40-2.66, p=0.94), it is unlikely that this may have affected the results.” |
in health complaints over time after a “crisis”, an uneven distribution of late responders may have influenced the results. This problem may be mentioned in the Discussion.

5. The Discussion is interesting and well written. My concern is the conclusion. The authors state that “The observed differences in the SF-36 subscale of mental health and return to work rate at six months follow-up……indicate that the intervention is effective”. In my view, this conclusion is hardly supported by the data, especially when taking into account the multiple comparison problem. The authors may want to reconsider this statement and perhaps make the conclusion more cautious.

Discretionary Revisions

6. The authors have published an article earlier in BMC Public Health that describes the results of a solution focused intervention, but I cannot find any reference to this article. Would it not be appropriate to mention this trial/article?

7. The authors find that some of the secondary analyses reveal significant or borderline significant associations. It would be of interest to see more figures (in parantheses), supporting these statements: e.g. mean vs. mean. So far, the authors have only given p-values and ES.

5. Conclusion is changed as suggested: “The main conclusions from this study indicate that the intervention is no more effective than standard follow-up in either improving return to work or increasing perceived health. The observed differences in secondary analyses are clinically interesting and might indicate that the intervention is effective for those on sick leave due to mental health problems. Large pragmatic trials are difficult to perform within this field, but are highly needed to establish better evidence for current policy and practice.”

6. We have added a line and a reference to the previous article on page 5, second par: “In a previous study we measured the feasibility of offering this intervention to sick listed employees with mental health problems or muscle skeletal disease [8]. Only 31% were reached by telephone and 15% attended the information meetings, while 11% participated in the project.”

7. Figures on mean differences are added as suggested on page 13, second par; Interesting differences were found when comparing participants with mental health problems (n=25) with control (n=15) on the SF-36 subscales of social functioning (mean diff 15.5, p=0.067, ES=0.62) and mental health (mean diff 15.5, p=0.041, ES=0.71).
REVIEWER 2; Jos H Verbeek

REVIEWERS COMMENTS  OUR RESPONSE

General
Summary:
The authors revised an earlier manuscript in which they reported a feasibility study on the effectiveness of a solution-focused intervention in workers on long term sick leave. Apparently it was not published and now it is submitted again with a larger number of participants (N=103). Workers were randomised to either a solution-focused course (N=53) or to regular care (N=50). There was no significant difference in return to work or the SF-36.

Comments in general:
Same comments as in my previous review. I am happy that a study like this is performed and adequately reported. There are too few of them in the literature.

The study is adequately designed and reported. The major problem seems to be that the potential participants are not interested to take the course. Like I said in my previous review, the feasibility of the intervention seems to be very low. I do understand that the authors are enthusiastic about the solution-focussed method, but it simply does not seem to be attractive to the participants if only 1 in 7 are willing to participate. I still wonder why the authors do not consider other models of intervention for long-term sick leave. There is considerable evidence that self-perceived disability is an important factor and that it is amenable to change. I feel that their enthusiasm for their intervention is not warranted by the results of their study. For example, concluding that the intervention is effective in the last paragraph is not justified by the data.

I do not agree with their opinion about the difficulty of offering a RCT to workers on sick leave. Offering randomisation to patients with cancer is much more difficult and encounters the same kind of problems.

The results on feasibility was reported in our previous study, while the current study is a study of the effectiveness of this intervention on work related outcomes as well as health related issues measured by SF-36. Every year there are least 50000 long term sick listed employees with mental health problems, 1/7 of this number is 7142 individuals which still is a substantial number of people. We have added the reference to the published study as well as a line commenting it on page 5, second par; "In a previous study we measured the feasibility of offering this intervention to sick listed employees with mental health problems or muscle skeletal disease [8]. Only 31% were reached by telephone and 15% attended the information meetings, while 11% participated in the project."

The conclusions in abstract and article are changed to according to suggestions

In our experience, in health care there is a better understanding of the necessity to perform randomised controlled trials, while in areas of social work the resistance among case workers is a factor to take in to account.

Detailed comments:
- Question is new and well designed
- Methods are appropriate
- Data seem sound, however I miss data on working conditions and occupation of the participants.
These are important predictors of return to work and potential sources of bias.
- Discussion is not balanced in my view. Since the uptake is so low, the intervention is not feasible in the current form. I would like to see a comparison with different types of person-directed interventions in different settings such as hospital based or rehabilitation based. Now, the discussion focuses almost exclusively on inherent weaknesses of the study. However, I feel that there should

See our previous comment

We believe this is a very important issue, but beyond the scope of this article. This is more appropriate to consider in a review of different interventions for sick listed employees.
be more room for the conclusion that the intervention simply does not work.  
- Title would improve from replacing follow-up by intervention.  
- Abstract: The one but last sentence should read. “A voluntary solution-focused intervention offered by social-security offices is not effective. However, it might have an effect in the subgroup of participants with psychological problems only.”
- Writing: still some spelling mistakes left: page 4 para 2 heath>health, page 12 Treated on > treat of.

<table>
<thead>
<tr>
<th>Major Compulsory Revisions</th>
<th>Conclusion changed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change conclusion in abstract</td>
<td>Title changed as suggested</td>
</tr>
<tr>
<td>Minor Essential Revisions</td>
<td>Abstract changed to: “A voluntary solution-focused intervention offered by social-security offices is no more effective than regular follow up. However, it might have an effect in the subgroup of participants with psychological problems only.”</td>
</tr>
<tr>
<td>Add data on working conditions and occupation of participants</td>
<td>Spelling corrected as suggested</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Discretionary Revisions</th>
<th>Title changed as suggested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change title</td>
<td></td>
</tr>
</tbody>
</table>