Author's response to reviews

Title: Effect of simulated dawn on quality of sleep - a community-based trial

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PDF covering letter
To the Editorial Board of *BMC Psychiatry*,

Please find revised version of our article (ms: 1675607093126410), now titled “Effect of simulated dawn on quality of sleep – a community-based trial”.

We have re-analyzed the data and extensively revised the manuscript. The details of the changes are in our response to reviewers’ comments. We hope that the manuscript, in its revised form, is found suitable for publication in the *BMC Psychiatry*.

Yours truly,

Sami Leppämäki, M.D.
Response to the reviewers’ most helpful comments

Reviewer: Dr Lam

Compulsory revisions

1. The raw data are now presented in Table 1, which gives the GSQS after the first and the last night and the average score for the period. However, the statistical analyses are based on all observations, of which there were 54 (8 weeks, two nights for adjustment of the dawn simulator) for each subject, and presenting this data as whole does not seem to be worthwhile.

2. The Groningen Sleep Quality Scale has been validated on depressed inpatients, but not on the general population. This is admittedly a weakness, which has now been addressed in the discussion. Two new references to clinical trials have been added (Meesters et al., Meijman et al.). In addition, some unpublished data are presented. The GSQS items are now presented in Appendix 1. In the original paper, we used an inverse scoring system on the GSQS (higher score denoting better quality of sleep). This has now been changed, so the scores are comparable to other trials.

3. The study population was a sample of one thousand adult Finns, drawn randomly from the National Population Register. The subjects were sent a letter describing the experimental procedure and inviting them to contact the study nurse if they were able and willing to participate in the study. No reference to sleeping problems and/or seasonal changes in mood was made in the recruitment letter. The methods section now more clearly describes the recruitment procedure.

4. A more detailed description of dawn simulation studies is now provided in the introduction.

5. Relevant information of the dropouts is now presented in the results.

6. We have re-run the statistical analyses, and included seasonality, morningness-eveningness and pre-intervention expectations as new variables in the model. None of the new variables were significant, but they did effect the model as a whole: the improvement in sleep is now visible after six days use of dawn simulator. The results are presented in table 2. The interpretation is as follows: in the treatment groups, the quality of sleep was 0.94 point worse at the beginning and, using a linear scale, the quality of sleep improved (the GSQS score decreased) –0.19 points per day. No post-hoc or sub-group testing has been done.
Discretionary revisions

1. We agree. This sentence has been removed from the discussion. Pre-intervention expectations have been added as a variable in the model. Expectations were not significant, but this does not rule out the possibility of a placebo effect.

2. This is an extremely interesting question. Actually, we did get the SPAQ score, which is now included in the statistical analysis. Surprisingly, however, this had no effect on the trial result.

3. We agree!
Compulsory revisions

1.-3. The raw data are now presented in Table 1, which gives the GSQS after the first and the last night and the average score for the period. However, the statistical analyses are based on all observations, of which there were 54 (8 weeks, two nights for adjustment of the dawn simulator) for each subject, and presenting this data as whole does not seem to be worthwhile. The Groningen Sleep Quality Scale has been validated on depressed inpatients, but not on the general population. This is admittedly a weakness, which has now been addressed in the discussion. Two new references to clinical trials have been added (Meesters et al., Meijman et al.). In addition, some unpublished data are presented. The GSQS items are now presented in Appendix 1. In the original paper, we used an inverse scoring system on the GSQS (higher score denoting better quality of sleep). This has now been changed, so the scores are comparable to other trials.

4. 6 of the enrolled subjects withdrew before the study started, this is now addressed to in the Results.

5. Mean light intensity chosen by the participants was 214 lux. This important fact is now presented in the Results.

6. The participants were asked to stay on their normal, regular sleep-wake cycle.

7. Only one subject reported side effects attributed to the light ('light made nervous'), this is now reported in the Results. 9.2% of those who completed the study reported some side effects, which did not interfere with the study.
Reviewer: Dr Terman

Dr Terman notes that BMC Psychiatry does not impose a word limit on manuscripts. In our opinion, brevity can often be considered a virtue in scientific writing. However, we agree with dr Terman on this paper being too short in its original form and thus many important and necessary facts are not presented.

Title
The title has been changed from 'controlled trial' to 'community-based trial'. The study design (ABAB, 'a double cross-over') is explained in the introduction.

Background
a-i This section has been re-written to make it more clear and concise.

Methods
a We agree. Changed.
b We agree. Changed.
c This paper presents the results from the Finnish sample of the bi-national study, so the population is more homogeneous. In this paper we concentrate on the quality of sleep as measured on the Groningen Sleep Quality Scale, and have analyzed it with a sophisticated statistical model. It must be noted that for each participant who completed the study, we have 54 observations. Simply using the first and last night of each study period to draw conclusions would miss a considerable amount of the data. We report now important variables (seasonality, morningness-eveningness, pre-intervention expectations) not presented in the original abstract. Raw data are now presented in Table 1. We feel that the paper at least now, in its revised form, is worth a full publication.
d Methods section has been re-written to include the relevant information about the study design questioned by dr Terman.
e We agree. Deleted.
f In the final analysis were included only those subjects who provided fullld data.
g We agree. These data are now presented.
h The Groningen Sleep Quality Scale has been validated on depressed inpatients, but not on the general population. This is admittedly a weakness, which has now been addressed in the discussion. Two new references to clinical trials have been added (Meesters et al., Meijman et al.). In addition, some unpublished data are presented. The GSQS items are now presented in Appendix 1. In the original paper, we used an inverse scoring system on the GSQS (higher score denoting better quality of sleep). This has now been changed, so the scores are comparable to other trials.
Results

a  A more detailed description of the drop-outs is now presented.
b  The raw data are now presented in Table 1, which gives the GSQS after the first and the last night and the average score for the period. However, the statistical analyses are based on all observations, of which there were 54 (8 weeks, two nights for adjustment of the dawn simulator) for each subject, and presenting this data as whole does not seem to be worthwhile.

Discussion

a  We agree. We now draw our conclusions more carefully. 35% of the subjects who completed the study felt they had benefited from the intervention. From the statistical analysis we see on average a mean improvement of 1.7 points during the two week period. We did not do any post-hoc analyses, and did not split the subjects into subgroups.
b  We agree. This does not explain our results.
c  Expectations were measured, and are now included in the model.
d  See also a. We have re-run the statistical analyses, and included seasonality, morningness-eveningness and pre-intervention expectations as new variables in the model. None of the new variables were significant, but they did effect the model as a whole: the improvement in sleep is now visible after six days use of dawn simulator. The results are presented in table 2. The interpretation is as follows: in the treatment groups, the quality of sleep was 0.94 point worse at the beginning and, using a linear scale, the quality of sleep improved (the GSQS score decreased) –0.19 points per day. No post-hoc or sub-group testing has been done.
e  We agree. This sub-group testing has been deleted.

Conclusion

a  We agree.
b  Study was carried out on a ‘normal’ population, not suffering from any major sleep disorders, so post-hoc analyses on specific items would result in very small subgroups, from which eliciting meaningful changes would be difficult.
c  We agree. Changed.

d  See Methods; answer to question h, on the GSQS.
We used the ‘specific’ GSQS scale, recorded after each night. Considering the study design, we have a ‘baseline’ value to which to compare the change on only half of the subjects (those who started without light). These data are presented by group in Table 1. See also Methods;h on GSQS, and the lack of validation data of which score constitutes a sleep disturbance or disorder.