Author’s response to reviews

Title: Sleep disturbances in an arctic population: The Tromso study

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Author’s response to reviews:

Dear Editor!

We are pleased to resubmit the following manuscript for possible publication in BMC Health Services Research: Sleep disturbances in an arctic population: The Tromso study.

We are grateful for the valuable reports of the referees and the opportunity we get to improve this manuscript. We have now made a revision of our paper in the light of the referees' comments. Below, please find a summary of the changes made.

Referee 1:

1. While the authors mention the economic effects of insomnia in the last part of the protocol, for stylistic purposes it may merit mention in the introduction given the importance of the factor.

Response: We agree! The economic aspects of insomnia are now mentioned both in the Abstract and in the Background-section.

2. Page 5: Interestingly sleep deprivation may not only be associated with depression but also treatment for treatment-resistant depression despite not being used that much anymore for such purposes.

Response: Yes, although sleep problems are especially prevalent in depression, it is of great interest that depression can be "turned off" by “therapeutic” sleep deprivation. Research designed to enhance the neurobiological understanding of the mechanism is needed, but is not within the scope of the present study.

3. Page 6: how is BMI associated with sleep duration i.e. high or low?

Response: Elevated BMI is associated with short sleep duration. This is now clarified in the text (page 6).

4. Page 8, first paragraph: it would be good for the authors to mention some
theory behind the pathophysiology of sleep insomnia along with some pertinent references.

Response: We have now included some aspects of the pathophysiology of insomnia, with references (page 8).

5. Page 8, paragraph 2, line 4: is it the intention of the study to arrive at some consensus as to what study scales should be used to evaluate insomnia? If so, this should be mentioned.

Response: It is not our intention to reach consensus as to what sleep assessment tools should be used to evaluate insomnia, but we would like to inform the reader of the variety of tools that exists. In the present research we will use some of the most validated tools available, like PSQI and EES.

6. Can the authors generalize from this study to other populations given the distinctive aspects of the Arctic population and its unique weather/seasonal changes?

Response: This is an interesting question that we will be able to answer when the future data are analysed. At this point we do not know whether the seasonality affects sleep at all in this study population. Few studies have addressed relationships between seasonality and sleep duration, but at resent report reports relatively small effects of season on sleep, with an uncertain clinical significance (Oyane, N., 2008. J Sleep Res 17(1): 63-72).

7. Scales used are good.

8. Sample population is ambitious but a wonderful number to achieve if feasible.

Response: Thank you! We agree!

9. Why did the authors decide on only 10% of the various age groups they did and all inhabitants in other age groups? Was this arbitrary based on practicalities?

Response: The Tromso Sleep Study is a part of the much larger Tromso VI Study, with its own central scientific committee. We did not have any influence on the selection of participants.

10. Is any follow-up planned of the population over time?

Response: We do consider a follow-up of the sleep complaint group and its control group.

11. Requires CONSORT diagram flow chart of the study.

Response: CONSORT guidelines are for randomized controlled trials, and should not be needed the present study.
Referee 2:

Controls are matched to the cases (how?)

Response: The control group will be age- and gender-matched.

Issues that emerge are representativeness: presumably the study collects enough data to allow you to say if participants are reasonably representative of the general population.

Response: We believe the Tromsø Study will provide a reasonably representative picture of the general population, as the participants are randomly selected within this geographical area and a large sample size.

It's obviously a sensible strategy to get a subset of the study group at higher risk of sleep disorder: but is it known how reliable this question and this cut-off are?

Response: The validity of the initial selection criterion (sleep disturbances more than once a week) is not known. This criterion represents the most conservative response to the question: "During the last 12 months, how often have you experienced sleep disturbances?", which is a part of the main Tromso study. We have little influence on the way this question is phrased, as it is repeatedly used in several previous Tromso-studies and is decided to remain unchanged. We believe this criterion will be sensitive for the inclusion of insomniacs, but its cut-off is not really unknown.

…a formal sample size calculation would reassure. There must be one for the main study.

Response: We have now included sample size calculations in the paper (page 16).

…what happens if a 'control' reaches the 'case' levels on the sleepiness questionnaire - this should allow you to measure the reliability of the screening questionnaire?

Response: We have discussed this question, and one possibility is to exclude pairs where one or both subjects have changed their "status of sleep", i.e. gone from healthy control to insomniac or vise versa. This is now clarified in the text (page 16).

What response rate do you expect to Q2?

Response: The Tromso studies are known for their high response-rates, and based on previous surveys, we expect a response rate around 80-90%.

The piece about using the questionnaire at different times of the year is quite
confusing: when will the study be done? Do you expect a difference between answers to the screening questionnaire (Q1) at different times of the year?

Response: We will present (a random) half of the study population with Q2 in May-June and the rest in November-December. Statistically, the matched pairs will be analysed according to whether they were a "summer-pair" or a "winter-pair". This is now clarified in the text (page 12). Few studies have addressed relationships between seasonality and sleep duration, but at resent report reports relatively small effects of season on sleep, with an uncertain clinical significance (Oyane, N., 2008. J Sleep Res 17(1): 63-72).

Q2 could be further described: could you attach it to this paper?

Response: The Q2 is made up by sleep assessment tools like PSQI, EES and Bergen insomnia scale. Questions regarding sleep time, sleep need, nightmares, sleep medications and restless legs are also included. As a whole, Q2 exists in Norwegian only, and we are not currently planning to translate the questionnaire. However, PSQI and EES are available in English versions.

Your terminology for variables is a little confusing. I suggest you distinguish between outcome variables … ; explanatory variables…

Response: We agree and are grateful for the remark! The terminology is now revised.

It would be useful to provide a set of pre-specified associations to study, with a justification for each from the literature. This would be an expanded Table 2.

Response: We agree! Table 2 is now expanded with these pre-specified associations.

…you need to explain why you elect to analyse what are basically continuous variables, for example the ESS goes from '0' to '24', as categorical variables, for example, excessive sleepiness 'yes' or 'no'.

Response: Sleep assessment tools, such as ESS and PSQI, are (although continuous variables) usually treated as binary in large population-based studies, based on their cut-off values for "normal" vs. "insomnia". For clinicians, however, a more accurate grading of insomnia is usually needed and the whole scale is used to grade insomnia into e.g. "mild", "moderate" or "severe". In this study we will firstly treat the insomnia scales as binary, but it may be of interest to subdivide the scores into degrees of insomnia.

I suggest you review your strategy like this: "First we will carry out a series of tabular analyses..."

Response: We agree, and the statistical strategy is now revised according to the suggestion by the referee.
Missing values: the usual approach to deal with missing values is some form of multiple imputation. SPSS has some facilities for this

Response: We agree, and have changed the text accordingly (page 15).

Variable selection - it is not appropriate to use p-values below 0.05 for variable selection for multi-variate models. The relevant criterion is does the additional variable make a difference to the model or to any of the other variables?

Response: We agree, and have altered the strategy for selections for variables. This is clarified in the text (page 16).

Sincerely yours

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