Author’s response to reviews

Title: Development and evaluation of an intervention aiming to reduce fatigue in airline pilots. Design of a randomised controlled trial.

Authors:

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Author’s response to reviews: see over
Dear Mr. Shipley,

Please find enclosed the revised manuscript “Development and evaluation of an intervention aiming to reduce fatigue in airline pilots. Design of a randomised controlled trial.” by Alwin van Drongelen, Allard J. van der Beek, Hynek Hlobil, Tjabe Smid, and Cécile R.L. Boot.

We would like to thank the editor and the reviewers for their constructive comments. After receiving your request for revision of the manuscript at the 16th of August, we made the following adjustments:

REVIEWER1:
Minor Essential Revisions
1. Page 4 Para 2 I believe "dosed" should be "dozed"
Response: "Dosed" was changed into "dozed"

2. Page 4 Para 3 I believe "restrain" should be "avoidance"
Response: "Restrain" was changed into "avoidance"

3. Page 4 Para 4 I believe "advices" should be "advice" (also repeated on page 6, 9, 10 and 16) and accordingly "differ" should become "differs".
Response: “Advices” was changed into "advice" on page 4, 6, 9, 10, 16, and the abstract. Accordingly, verbs were adjusted.

4. Some mention of caffeine and medication should be made.
Response: On page 4, paragraph 3, we adjusted a sentence as follows: “Moreover, the intake or avoidance of food may diminish jet lag symptoms during certain phases of the sleep/wake cycle, and caffeine can temporarily alleviate fatigue [3].” We chose not to mention medication as this was not part of our intervention, although it was part of the standard information of the airline company on the project website, available for all pilots.

Discretionary revisions:
1. Page 8 if there were ten focus groups and 30 people, then doesn’t this mean that rather than "a minimum of 3" in each group, there must have been exactly 3 in each group?
Response: We agree this is somewhat confusing. We tried to have at least 3 people in each group. However, sometimes more pilots attended, and sometimes someone did not show up. In the end, 30 pilots in total did attend the focus groups. Therefore we adjusted the sentence into: “For each aircraft type, two focus groups were organised. Considering five different types of aircrafts, ten focus groups were held. A total of 30 pilots attended the focus groups, heterogeneous regarding age, gender and job title.”
2. The website link in the text clearly displays the name of the airline involved; whilst this is reasonably obvious, it may not be desired to make it this explicit.
Response: Thank you very much for this comment, we removed the link to the website.

3. Page 17 the discussion might also refer explicitly to the potential for greater Hawthorne Effect amongst the intervention group as a result of being intensively studied.
Response: We have added the following to the discussion section:
“Although we chose to offer the control group a minimal intervention rather than no intervention, more attention was given to the intervention group. Because of this, the Hawthorne effect cannot be fully excluded.”

REVIEWER2:
1. The intervention is evidence based on a limited set of references. There is for example no reference to any Cochrane reviews on the intervention for work related fatigue and the evidence about the mode of implementation.
Response: We have now added the following references to the background section:

In recent years, more knowledge has become available about the influencing factors on disturbance of the circadian rhythm, and possible countermeasures of fatigue [12-14]. It has been shown that by correct timing of exposure to and avoidance of daylight, the most important biorhythm synchronizer (or zeitgeber) [2,12,13], jet lag symptoms can be reduced. Additionally, an optimal timing and duration of sleep can reduce the disturbance of the biological clock and thereby, reduce fatigue [2,13,14]. Further, correct timing of certain types of physical activity can enhance sleep duration and quality [3]. Moreover, the intake or avoidance of food may diminish jet lag symptoms during certain phases of the sleep/wake cycle, and caffeine can temporarily alleviate fatigue [3,12-14]. Additionally, the specific macronutrient composition of meals has shown to be able to stimulate either alertness or relaxation [15,16]. Based on these findings, several measures have been proposed to counter the negative effects of the aforementioned working conditions of flight crew.
Further, to improve adherence, these interventions should be designed to allow individuals to tailor it to their own specific needs. This so called tailoring can significantly affect behaviour regarding safety, smoking, physical activity and dietary intake [24,27,28].

2. One wonders why for example and incentive program was not considered as part of this intervention? There are good examples if such successful intervention in improving the overall health of participants. Such improvement also has a cost benefit the company on many terrains?
Response: During the focus groups, we asked the pilots what would make them use the advices as much as possible. Their response was that the advice should be specific, up to date and with them all the time. Incentives were not mentioned by our target population at any time.

3. Dilution of the intervention is discussed with pilots from the intervention arm sharing information with pilots from the control arm. By tracking the extent of joint flights and time by pilots from the two arms this could be a secondary analysis to see if dilution happened. Crossed mixed effects regression models could be considered.
Response: Thank you for this suggestion. Unfortunately, we do not have access to the specific flight schedules of the individual participants.

4. The sample size is a robust estimation and is based on a comparison between the arms at the end of the study (six months?). The sample size calculation is therefor not directly linked the analysis of the primary outcome which will be a mixed effect linear regression model of the repeated measures of each participant. including the baseline value into this repeated measures modelling will enhance the power of detecting an time by arm interaction and also improve precision of the estimation of intervention effect at the two time points post randomisation.
Response: Thank you for this suggestion.

5. A dropout rate of 25% is high. Reminders are being send out but the study team should consider approaching the pilots who did not comply to complete the endpoint questionnaires irrespective of there compliance status.
Response: We apologise as this was not entirely clear. We used two different reminders: 1. to enhance compliance with the intervention and 2. to enhance response to the questionnaires. Therefore, we added a sentence on page 10 to make this more clear: “Reminders will be sent to increase the response rate.”

6. The sample size requirement for the study is substantial but one assumed that this airline has enough Dutch speaking pilots with smartphones to me this study requirement?
Response: As mentioned in the discussion, more than 65% of the Dutch population owned a smartphone or tablet in 2012. Since the pilots of the present airline company use a smartphone or tablet to consult work and flight related information, this percentage is expected to be higher in our target population.
7. It would be advisable for the study team to state that an analysis plan will be developed prior to the finalisation of the dataset.
Response: A sentence was added to page 14, second paragraph: “A detailed analysis plan will be developed prior to finalisation of the dataset.”

8. P10. Line 3 from the bottom. It is stated that results will be shared with participants through a newsletter during the intervention period. Results should not be shared by participants or by investigators during this period.
Response: We fully agree and we do not intend to share results before the end of the study. The information we shared with the participants will not be outcome-related (e.g. how many pilots participated or how many pilots filled in the questionnaires). Therefore, we changed the sentence into: “During the intervention period, all participants will be kept involved by sending a regular newsletter with information about the study in general, and upcoming questionnaires.”

9. There is no information relating to the funding of this research and whether it is completely independent of the industry in which it is being implemented or conducted.
Response: This study is funded through internal funds of the VU University Medical Center only. Therefore, the study is independent of the industry or the airline company involved. If requested, we will add this information to the manuscript.

10. Safety. Does the research team have legal requirements to report events where pilots report extreme fatigue or complete imbalance in work-private life?
Response: Participants will only fill in the questionnaires and are not explicitly asked to report any adverse events to the researchers. If they do however, we will report these events to the Medical Ethical Committee (according to the Dutch law on research involving human subjects). We are not allowed to search for, and report participants who indicate high levels of fatigue or work-private life imbalance in the questionnaires. If requested, we will add this information to the manuscript.

Yours sincerely,

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