**Reviewer's report**

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

**Version:** 2  **Date:** 29 July 2013

**Reviewer:** Carl J Lombard

**Reviewer's report:**

The authors present a well design protocol for the evaluation of an intervention to reduce fatigue in airline pilots of a commercial company. Although the detail of the intervention is sparse (one broad outlines are given) the design of the tailoring at the individual level and implementation is well described. 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.

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?

The primary outcome seem relevant and is measured using a reliable instrument. 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.

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.

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.

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?
It would be advisable for the study team to state that an analysis plan will be developed prior the finalisation of the dataset.

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.

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.

Safety
Does the research team have an legal requirements to report events where pilots report extreme fatigue or complete imbalance in work-private life?

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
'I declare that I have no competing interests'