Author's response to reviews

Title: Association between difficulty initiating sleep in older adults and the combination of leisure-time physical activity and consumption of milk and milk products: a cross-sectional study

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Author's response to reviews: see over
Responses to the reviewers

The authors wish to thank you for your thorough consideration of our manuscript and for providing such constructive feedback. The quality of our manuscript has certainly improved as a result of your comments. This manuscript has been reviewed and edited by a professional English editing service.

We highlighted all of our changes in blue in the revised manuscript.

Reviewer #1 Jae-Young Lim

General comment:
This is a meaningful trial to investigate independent associations between DIS (difficulty initiating sleep) and engaging in LTPA (leisure time physical activity) or consuming milk and milk products, and to examine whether combining these two habits is more strongly associated with a lower prevalence of DIS.

Our response:
Thank you for interest and constructive comments. We tried to be as thorough as possible in our responses.

Major Compulsory Revisions
Comment 1:
However, this manuscript doesn’t seem to have appropriate sample size and well-control baseline characteristics of old people to support whether the author's conclusions are valid. I wonder whether one subgroup (Not engaging LTPA and Not consuming milk) had enough sample size (n=19, 4.8%) for statistical power to find out the association between DIS and LTPA along with milk consumption (Table 4). Sample size for analysis of odds ratio was relatively small compared to other subgroups (n=38, 86, 254). Therefore, the procedure to determine proper sample size of subgroups needs to be included.

Our response:
To determine proper sample sizes, we first looked for studies with a design and purpose similar to our own. However, we could not find a study that fit our criteria and it was difficult to estimate proper sample size. Additionally, although we expected that more
participants with poor health habits would take part in our investigation, there were actually very few people who did not engage in LTPA or consume dairy. To verify this investigation’s results, there needs to be future work with a large sample size of older adults with poor health habits. In the discussion, we state that our research may include the selection/sampling biases you mention (P14, L15 to P15, L1) and that further studies with larger sample sizes are need (P15, L1–3).

Although this study has some limitations, our research of the current literature indicates that this is the first study to show that practicing LTPA along with consuming dairy is related to decreased prevalence of DIS. We believe our findings are thought-provoking and contribute to the development of an effective non-invasive prescription for facilitating sleep in older adults.

Comment 2:
Second, I’m concerned about the accuracy of milk, yogurt, or cheese consumption amount measured by self-reported questionnaire.

Our response:
Unfortunately, validity and reliability of the questionnaire that we used for assessing milk and milk product consumption in the present study have not been confirmed. However, numerous studies have used self-reported questionnaires to evaluate the frequency and portion size of dairy consumption (Willett et al., American Journal of Epidemiology, 1985; Huybrechts et al., British Journal of Nutrition, 2007; Michaëlsson et al., Bone, 2003; Hallström et al., Osteoporosis International, 2006; Ozawa et al., Journal of the American Geriatrics Society, 2014). They have confirmed a moderate correlation (r = 0.4–0.6) with weighed dietary recording, which is considered the gold standard of dietary assessment methods (Michaëlsson et al., Bone, 2003; Ozawa et al., Journal of the American Geriatrics Society, 2014). Additionally, we supplied examples of portion sizes (e.g. a glass of milk = 200 ml) with the questions to help participants answer the questions as accurately as possible. Therefore, it is fair to say that there is some validity in the scale used in the present study. We added an explanation of accuracy with dietary assessment in the methods paragraph (P7, L7–8, L12–15). In addition, we have included the possibility of under/overestimation by subjective measurement as a possible limitation of this study (P15, L6–9).
Comment 3:
Third, DIS (difficulty initiating sleep) is one of the insomnia, and may be related to other neuropsychiatric disorders (eg. depression, anxiety disorder, cognitive impairment, etc.). Therefore, these conditions which may have a potential influence on DIS need to be considered in the baseline characteristics of older people. If necessary, they could be included in multiple logistic analysis as a confounding factor.

Our response:
As the reviewer indicated, depressive symptoms and cognitive function/dementia are potential confounders for DIS (Ancoli-Israel and Cooke, Journal of the American Geriatrics Society, 2005). Unfortunately, we did not evaluate these factors, but we added this limitation to our revised manuscript (P15, L4–6).
Reviewer #2 Maarit Katariina Valtonen

General comment:
This is an interesting manuscript on the cross-sectional association between difficulty initiating sleep in older adults and the combination of leisure-time physical activity and consumption of milk and milk products. The manuscript is well-written and reports an interesting relationship between physical activity, milk consumption and sleep. I have, however, some concerns about the bias in the study. I would like the interpretation of the findings to be more cautious. Here are my suggestions for revision:

Our response:
Thank you for interest and constructive comments. We tried to be as thorough as possible in our responses

Major Compulsory Revisions
Comment 1:
Introduction: I would like the authors to be clearer what the gaps in the literature are on this topic. Is there any RCTs published on milk consumption, physical activity and sleep?

Our response:
We modified our introduction to incorporate the reviewer’s comment. (P4, L15; P5, L5–6, L9–10)

Comment 2:
Methods: The authors should report the period of recruitment and the data collection.

Our response:
We added explanations on data collection to the revised manuscript (P6, L4, L6).

Comment 3:
Methods: Please describe how the potential confounders were measured and why were those variables chosen as confounders.

Our response:
We added a new paragraph about the potential confounders (P8, L5–10). In addition,
since we did not include depression and cognitive function status as confounders in our analysis, we added an explanation about this in the paragraph on limitations (P15, L4–6).

Comment 4:
Methods: A reader needs to know if the subjective measures, such as the physical activity and milk consumption questionnaires, are valid and reliable.

Our response:
In this study, we evaluated LTPA using the Physical Activity Scale for the Elderly whose validity and reliability have been confirmed (Hagiwara et al., Geriatrics & Gerontology International, 2008). Concerning to accuracy of assessing dairy consumption, we mentioned in the response to “comment 2 of reviewer #1”.

Comment 5:
Results: How many people were eligible to the study? Is the sample representative of the population? What were the possible reasons for non-participation?

Our response:
As mentioned in the data collection paragraph, 421 older adults were eligible for the analysis (P6, L7–8). Because almost all participants joined the study after responding to an invitation letter or local advertisement, the proportion of older adults with poor living habits (e.g. inactive, low consumption of dairy products or insomnia) or those in poor health might be underestimated. Hence, we may not be able to generalize our results to other populations. We included these observations on our study population in the paragraph on limitations (P14, L15 to P15, L1).

Comment 6:
Results: In table 4 the authors report non-significant associations between LTPA or milk, and DIS. Is it possible that these groups were under-powered and therefore didn’t reach statistical significance?

Our response:
As the reviewer has pointed out, some of the groups may have been underpowered, especially regarding those participants who did not engage in LTPA or consume dairy
products. Therefore, participating in LTPA with no dairy consumption or dairy consumption with no LTPA habits (Table 4) may have been significantly associated with lower prevalence of DIS if we had been able to obtain a larger sample size. We added this observation in our discussion on the limitations of this study (P15, L1–3).

Comment 7:
Discussion: I would like the authors to discuss the results in both directions. Is it possible the people who sleep better are more likely to have a healthier lifestyle?

**Our response:**
Yes, there is a bidirectional relationship between physical activity and sleep (Holfeld and Ruthig, Sleep, Journal of Applied Gerontology, 2014; Dzierzewski et al., Journal of Sleep Research, 2014), thus, we need future studies on causality surrounding this subject. For the potential inversion of causality, we added an explanation in the paragraph on limitations (P15, L10–13).

Comment 8:
Discussion: I would like the authors to discuss the potential bias in this study. How did the use of sleeping medication effect the results? I wonder if the participants had any chronic illnesses or used other medications, and how that biased the results. Is there a possibility of selection bias?

**Our response:**
Although we included the use of sleeping pills as a covariate (Glass et al., BMJ, 2005) to adjust for possible decreased sleep onset latency with its use, we did not evaluate chronic illnesses (e.g. heart disease, lung disease, depression and dementia) (Foley et al., Journal of Psychosomatic Research, 2004) or number of medications used (Ancoli-Israel and Cook, Journal of the American Geriatrics Society, 2005), which are regarded as potential confounders for insomnia. We also discussed this limitation in the revised manuscript (P15, L4–6). A major limitation of this study is the possibility of sampling bias, and our results may include more data from healthier individuals. Thus, the possibility that our participants may suffer from the effects of chronic illness or medication use is decreased.
Comment 9:
Discussion: Are the findings generalizable to other populations?

**Our response:**
As we mentioned in the response to “comment 5,” our results may not be generalized to other populations because of the possibility of selection/sampling bias.

Comment 10:
Discussion: Is there any evidence that populations, who consume more milk such as in Scandinavian, people have less insomnia?

**Our response:**
To our knowledge, there is no cross-national research pertaining to the association between dairy consumption and insomnia, and it might be difficult to predict poor sleep only through dairy intake. However, a meta-analysis has shown that the prevalence of insomnia in Scandinavian countries is equal or slightly higher than in other countries, including Japan (Ohayon, Sleep Medicine Review, 2002; Zhang et al., Sleep, 2006).

*Discretionary Revisions*

Comment 11:
Results: Please report the covariates in the result section as well.

**Our response:**
We added the information about covariates to the results section (P10, L4–5, L11–12, L17–18, P11, L2).