

Decision for round #2

We would like to thank the authors for their tremendous work in responding to the reviewers' comments. This has improved the article, which already had several strengths.

However, one reviewer highlighted some remaining issues, and I agree with him. The reviewer also indicated ways to respond to his comments. If the authors decide to respond to the latter, I will be pleased to review the article again.

Review by Silvio Maltagliati, 14 Jan 2025 11:32

I have carefully reviewed the authors' point-by-point responses to my comments and appreciate the effort they have put into addressing them. However, I still have major concerns that remain to be addressed.

- Absence of evidence is not evidence of absence (e.g., Alderson, 2004). On several occasions in the manuscript, the authors confuse the absence of statistical evidence ($p > .05$) with the absence of an effect (which would require an equivalence test or a Bayesian approach to be demonstrated). For example: 'Interestingly, active smoking was not associated with sleep difficulties.' should read 'Results showed no evidence of an association between active smoking and sleep difficulties.' Please adjust the manuscript throughout.

Thank you very much for this meaningful observation. We have adjusted the entire manuscript following the reviewer's comments.

- The abstract states that passive smoking affects sleep. But in fact, this effect is only observed in one sleep variable out of three. Please be more specific in the abstract. "The incidence of sleep problems in pregnant women was shown to be associated with exposure to cigarette smoke (passive smoking), while controlling for a range of individual variables (age, education, place of residence, satisfaction with the woman's life, and economic situation, pregnancy complications, levels of state anxiety and depressive symptoms, trimester of pregnancy, nausea or vomiting during pregnancy, and COVID-19 infections)" could read 'Passive smoking was associated with one of the three variables used to assess sleep problems (i.e., waking up early).'

We have rewritten the abstract, adding a passage according to the reviewer's suggestion:

„Passive smoking was associated with one of the three variables used to assess sleep problems (waking up too early) while controlling for a range of individual variables (age, education, place of residence, satisfaction with the woman's life, and economic situation, pregnancy complications, levels of state anxiety and depressive symptoms, trimester of pregnancy, nausea or vomiting during pregnancy, and COVID-19 infections).

- The term 'stimulant' is often used to define the smoking variable, but the actual measure is smoking. There is not measure of the concentration of stimulant in the study. For example: 'Each aspect of sleep difficulties and stimulant use', 'Sleep problems and stimulants use assessment'. Please reword throughout the manuscript.

Thank you for your valuable suggestion. We have rewritten the entire manuscript removing the term "stimulant", and using the term "smoking" to define the variable under study.

- The term 'incidence' does not seem appropriate as there seem to be a single measurement period. Therefore, it would be difficult to assert whether these are new or pre-existing cases. The term prevalence may be more appropriate. That being said, using 'sleep problems' may work as well (no mention of incidence or prevalence).

Thank you and we agree with the comment. The word "incidence" has been replaced by "prevalence" or has been removed from the manuscript, depending on the context of the text.

- I agree with the Recommender's suggestion to add a Figure and recommend adding at least one figure or a panel of several figures as figures are always useful for the readers to clarify the results. For example, a figure including the 6 ORs of passive and active smoking the 3 sleep variables, with a note to say that these results come from different models and are aggregated in a single figure for clearer illustration purposes.

Thank you very much for your comment. A figure has been added to the text as suggested by the reviewer:

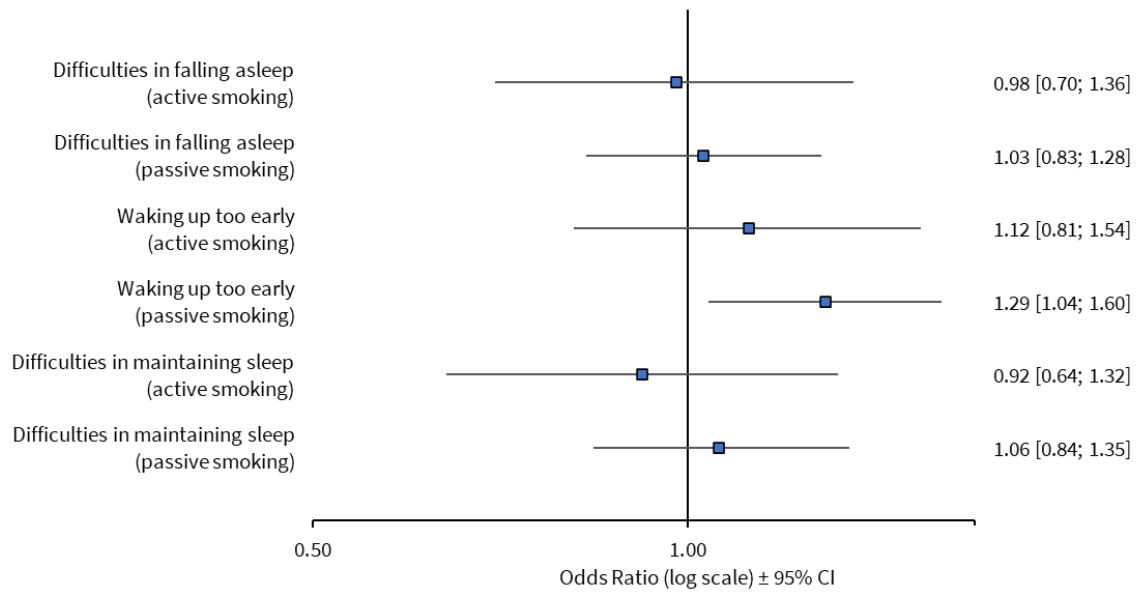


Figure 1: Forest plot showing results of multivariate logistic regression of sleep problems. The plot shows the probability of sleep problems in pregnant women concerning active or passive smoking. Odds ratios and 95% confidence intervals (CI) from various models are shown (Table 2-4). Significant correlations are when CIs do not overlap with 1.

- In Table 1, the asterisks are not needed. The footnote is sufficient.

Thank you for your suggestion. The asterisks in Table 1 have been removed.

- I am still a bit hesitant regarding the interpretation of the findings and their links with previous literature. Indeed, authors state that "their results are consistent with those obtained by other researchers". However, if I am correct, previous research focused on active smoking, not passive smoking. As such, I wonder whether we can say that these results are actually consistent. Could authors please check that the Discussion section closely follow their findings?

We do agree with the reviewer that previous literature on the maternal passive smoking and sleeping problems is highly limited. In the articles published so far, their authors have largely focused on presenting the relationship between active smoking and various health parameters, omitting passive smoking or treating smoking as a general phenomenon, without distinguishing its type. Particularly relevant to the interpretation of the results and their connections with previous literature in the context of passive smoking was the article by Ohida et al. in 2007, which presented a significant association between passive smoking and shortened sleep duration in pregnant women, which is consistent with our results (waking up too early is associated with shortened sleep duration). Unfortunately, we were unable to find other similar work, that we added in the manuscript (lines: 347,365,366 in the corrected manuscript).

- I suggest adding a 'Limitations' section. Among other points, I suggest adding two limitations: The sleep variables are open to interpretation (e.g., too early; 'maintain sleep') and could therefore be more accurate. Since 3 variables were used to test for sleep problems and address the same research question, a conservative statistical approach to reduce the risk of type 1 errors would be to correct for the number of partial tests ($n = 3$) (Bonferroni correction), reducing the significance threshold to $.05/3 = .016$. Such correction would make the association between passive smoking and weaking up early non-significant).

The "Limitations" section has been added. We have rewritten the limitation sections adding two additional limitations, as suggested by the reviewer (lines: 433-469 in the corrected manuscript). However, we are not convinced we need to apply the Bonferroni correction in our analysis. While it is true that the Bonferroni correction will reduce the risk of Type I errors, it may overestimate the probability of Type II (false negative) errors due to the correction's excessive conservativeness and the small number of outcome variables (3 in our case) (Perneger et al., 1998; Schulz et al., 2005; Streiner et al., 2011). In addition, our article is mainly an exploration of the issue, due to, among other things, the minimal number of previous projects in this area, to encourage further research focusing on testing more specific hypotheses (Althouse, 2016).

Althouse, A. D. (2016). Adjust for multiple comparisons? It's not that simple. *The Annals of thoracic surgery*, 101(5), 1644-1645.

Perneger T. V. (1998). What's wrong with Bonferroni adjustments. *BMJ (Clinical research ed.)*, 316(7139), 1236–1238. <https://doi.org/10.1136/bmj.316.7139.1236>

Schulz, K. F., & Grimes, D. A. (2005). Multiplicity in randomised trials I: endpoints and treatments. *Lancet (London, England)*, 365(9470), 1591–1595. [https://doi.org/10.1016/S0140-6736\(05\)66461-6](https://doi.org/10.1016/S0140-6736(05)66461-6)

Streiner, D. L., & Norman, G. R. (2011). Correction for multiple testing: is there a resolution?. *Chest*, 140(1), 16–18. <https://doi.org/10.1378/chest.11-0523>

Reference:

Alderson P. Absence of evidence is not evidence of absence. *BMJ*. 2004;328(7438):476–477. <https://doi.org/10.1136/bmj.328.7438.476>

Thank you very much for this useful reference.

Review by Florian Chouchou, 19 Nov 2024 07:07

Most of my comments have been addressed, particularly in the discussion.

Review by Jean-Philippe Chaput , 13 Nov 2024 20:29

Thank you for revising the manuscript based on the feedback received. I think the authors adequately addressed the comments raised in their revised paper and I have nothing further to suggest. I feel the paper can be accepted.