Reviewer’s report

Title: Sample Size Determination for Mediation Analysis of Longitudinal Data

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Reviewer: Xiaonan Xue

Reviewer's report:

This paper presented a method to estimate sample size for mediation analysis in longitudinal studies. However, it is a bit of misleading to refer the data considered in the paper as longitudinal data because no change over time in the response variable was considered, while typically in longitudinal data we try to model the change in the response variable measured over time. Therefore, it is more suitable to call the presented method as "mediation analysis for correlated data", such as family data or other types of clustered data. Besides, the very same topic for longitudinal data has already been studied, please see (1), where the outcome Yij depends on the risk factor Xi and the mediator Mi and time tij and the interaction between risk factor/mediator with time. The difference in the presented model, in addition to no time element, is that both the mediator M and the risk factor X can vary within person. The potential application of this model will benefit greatly from a motivating example that is clearly described. I find the following sentences very confusing (page 5 lines 4-16):"In the model, an initial variable X is mediated in the lower level, but the mediator M and outcome Y are affected by upper-level variations. A simple scenario for this model is a longitudinal experimental study in which subjects are randomly assigned to a treatment, and mediating variable M, such as a psychosocial measure, is believed to change individual behavior". What is the response variable? What does it mean for "mediated in the lower (upper) level"? It is quite cumbersome to have to keep searching the sample size needed for a mediation analysis to achieve 80% power. Readers will find it difficult to adopt a method like this. In Wang and Xue (2016), methods were presented to calculate the sample size for mediation analysis directly using either the joint significance test or the Sobel method. The authors should also examine the possibility of calculating the sample size analytically instead of empirically via iterations. What software the authors used for implementing the methods? How long does it take to run for one single scenario? Is the program available for the readers to use?1.Wang C, Xue X. Power and sample size calculations for evaluating mediation effects in longitudinal studies. Statistical methods in medical research. 2016;25(2):686-705. Epub 2012/12/12. doi: 10.1177/0962280212465163. PubMed PMID: 23221975; PMCID: PMC3883797.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess
Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

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Quality of written English
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