Author’s response to reviews

Title: Inter-rater reliability and concurrent validity of ROBINS-I: Protocol for a cross-sectional study

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Reviewer’s comments
Reviewer #1: The manuscript entitled "Inter-rater reliability and concurrent validity of ROBINS-I: Protocol for a cross-sectional study" reported a detailed research plan. The most highlights are that the results of the study will provide knowledge on: 1) the effect of additional guidance in the use of ROBINS-I, 2) concurrent validity of ROBINS-I by comparing NOS and ROBINS-I. The research plan is critical important to reduce potential bias of research results. Generally, the manuscript with a good writing and reporting quality, but there are some concerns in the present version.

Author reply: Thank you.

1. The authors need to provide detailed information on Microsoft Excel, such as, version number.
Author reply: Thank you. As suggested, we have provided a detailed information on Microsoft Excel in the revised protocol manuscript (with tracked changes and highlights).

2. The authors should report how to prepare the guidance document, who to write it, and what the content is, etc.

Author reply: Thank you. As suggested, we have provided details in the revised protocol manuscript (with tracked changes and highlights) on how we will prepare the guidance document, who will write it and what will be the content.

3. The authors should report how to provide the training courses, who is trainer, and his/her background knowledge on ROBINS-I, etc.

Author reply: Thank you. As suggested, we have provided details in the revised protocol manuscript (with tracked changes and highlights) on how we will provide the training session, who is the trainer and the qualifications of the trainer.

4. For the clarity, "Nonrandomized" ("Keywords" section) and "Non-randomized" should report identically in the whole paper, for example, only use "Non-randomized" in the full paper.

Author reply: Thank you. As suggested, we have made sure to keep it as “Non-randomized” throughout the revised manuscript and in the list of key words.

5. The authors reported that reviewers with varied academic background and experience on the use of ROBINS-I will participate in assessment, if conclude a better outcome (higher consistency between different academic background), and this result may illustrate ROBINS-I with good reliability and availability. However, if conclude a worse outcome (lower consistency between different academic background), how to balance the influence of other factors, whether the potential influential factors should be reported in this protocol?

Author reply: Thank you for the great question. As ROBINS-I tool was designed to be used by anyone irrespective of their academic background or experience, lower consistency between reviewers in real world reflects on the ROBINS-I tool itself. The goal of our study is to assess the reliability of the tool in the real world setting, so we did not propose to adjust for potential confounding factors in our study. To provide clarity on this, we have added a sentence in the discussion section of our revised protocol manuscript (with tracked changes and highlights). We sincerely hope this answers your question.

6. In "Sample selection", authors reported "cardiology clinical trials" that is confused for me. Besides, the knowledge of clinical specialty may influence the assessment process and results.

Author reply: Thank you. We chose this field as we have conducted previous systematic reviews on cardiology topics and we were aware that there are non-randomized studies that we could use for evaluation. Most systematic reviewers are not clinicians, so we rely on content experts when needed, for guidance on clinical matters. This mimics real life practice in which this tool is intended to be used. We sincerely hope this answers your question.
7. According to your manuscript, the assessment process major includes two stages. First stage, without guidance, paired-reviewers will assess the selected sample. Second, with guidance, same paired-reviewers will assess the same sample. This will overstate the effect of guidance. Although authors stated this limitation, I thought this question need to be solve cautiously.

Author reply: We agree with the concerns raised by the reviewer. Ideally, we would have proposed a randomization of the reviewers to two groups (with guidance, and without guidance). Since we do not have enough reviewers, for feasibility, we decided to use the same reviewers for both stages. We acknowledge that this may potentially bias the effect of guidance. We will address this by assessing the correlation between adjudications made during the two stages, for each of the reviewers. We have added a sentence to the data analysis section of our revised protocol manuscript (with tracked changes and highlights). A poor correlation between adjudications made during the two stages, for each of the reviewers in our study would indicate that the training and guidance have been useful. We have also added a sentence to the discussion section of our revised protocol manuscript (with tracked changes and highlights) to further highlight this potential bias. Thank you.