

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Reporting of methodological studies in health research: a protocol for the development of the Methodological Study reporting Checklist (MISTIC)
AUTHORS	Lawson, Daeria; Puljak, Livia; Pieper, Dawid; Schandelmaier, Stefan; Collins, Gary; Brignardello-Petersen, Romina; Moher, David; Tugwell, Peter; Welch, Vivian A.; Samaan, Zainab; Thombs, Brett; Nørskov, Anders; Jakobsen, Janus; Allison, David; Mayo-Wilson, Evan; Young, Taryn; Chan, An-Wen; Briel, Matthias; Guyatt, Gordon; Thabane, Lehana; Mbuagbaw, Lawrence

VERSION 1 – REVIEW

REVIEWER	Mi Du The University of Adelaide
REVIEW RETURNED	05-Sep-2020

GENERAL COMMENTS	<p>In the protocol article entitled ‘Reporting of methodological studies in health research: a protocol for the development of the METhodological study Reporting Checklist (METRIC)’ by Lawson et al, the authors have clearly defined ‘methodological studies’, and proposed a design of a tool to promote consistent and transparent reporting of ‘methodological studies’, which will be very useful to improve the quality of ‘methodological studies’. I look forward to seeing the final results from their research. The article is well-written, clear and scientifically rigorous. However, I have some concerns for authors to think about:</p> <p>Comments:</p> <ul style="list-style-type: none"> • Does ‘methodological studies’ is an appropriate terminology? Though the authors have stated that this definition does not include statistical methodological studies, to me, ‘methodological studies’ not only include the conduct of the whole study, but more importantly include the statistical methods. The authors need to think more about this. • The authors plan to limit their search to the last ten years. Is that because in these years there is an increasing number of ‘methodological studies’ as shown in Figure 1 (Page 9 line 42)? However, on Page 9 line 47, the authors have stated the importance of ‘methodological studies’ in the past 20 years. As I know, the reporting guidelines for systematic reviews have existed for over 20 years, which means there should be a number of ‘methodological studies’ existing prior 2009, why not including them? Therefore, I suggest including at least 20 years of search. • Page 10 line 54. It would be better if the authors list one or two examples of the questions that the ‘methodological studies’ try to answer. Because it is easier for readers to see the differences
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	<p>between traditional systematic reviews and 'methodological studies'.</p> <ul style="list-style-type: none"> • Page 15 line 18. During the data extraction, do the authors want to extract the findings of risk of bias assessment in the included study? E.g. did the authors conduct risk of bias assessment? what was the distribution of studies with low, unclear and high risk-of-bias? I feel that this is also important to report. • Page 21 line 36. Do the authors want to create reporting checklist for the section 'Title', 'Abstract', and 'Supplementary information and others' as well? For example, we usually expect the researchers to indicate the type of their study in the title. • It would be better if the authors could share the intended timeline for developing this tool.
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REVIEWER	Edward Duncan University of Stirling, Scotland, UK
REVIEW RETURNED	07-Oct-2020

GENERAL COMMENTS	This is a very clearly written and well described methodological protocol. The authors convincingly argue for why their study is required and clearly set out how they will conduct their study. If the authors have not yet started, then they may wish to consider adding PsychInfo to their listed health-related databases.
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REVIEWER	Abimbola Ayorinde University of Warwick, UK
REVIEW RETURNED	08-Oct-2020

GENERAL COMMENTS	<p>The proposed research is interesting and addresses an important gap in the literature.</p> <p>I would suggest that the authors consider using another terminology to replace "methodological studies". There are different categories of methodological studies. For example, there are methodological studies with existing studies as the unit of analysis (may be referred to as 'methodological secondary studies'/research-on-research/meta-epidemiology/ meta-research) and there are methodological primary studies (for example, methodological studies of survey techniques, studies on how to improve participation rates). I think the term "methodological studies" is broad and it made the protocol a little difficult to follow initially. It later became clear that the authors may be more interested in "research reporting standards for studies that investigate the design, conduct, analysis, or reporting of other health studies". The name METHodological study ReportIng Checklist (METRIC) for the proposed tool may be confusing. It may be better to use a name that reflects the specific type of methodological studies the authors will focus on.</p> <p>I would also suggest that the authors expand on the eligibility criteria, particularly to highlight more examples of methodological studies that will be excluded.</p>
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VERSION 1 – AUTHOR RESPONSE

REVIEWER 1

Comment:

In the protocol article entitled 'Reporting of methodological studies in health research: a protocol for the development of the METHodological study ReportIng Checklist (METRIC)' by Lawson et al, the authors have clearly defined 'methodological studies', and proposed a design of a tool to promote consistent and transparent reporting of 'methodological studies', which will be very useful to improve the quality of 'methodological studies'. I look forward to seeing the final results from their research. The article is well-written, clear and scientifically rigorous. However, I have some concerns for authors to think about:

Response:

We thank the reviewer for their thorough review and helpful suggestions to improve this manuscript.

Comment:

Does 'methodological studies' is an appropriate terminology? Though the authors have stated that this definition does not include statistical methodological studies, to me, 'methodological studies' not only include the conduct of the whole study, but more importantly include the statistical methods. The authors need to think more about this.

Response:

We agree with the reviewer that when reviewing study methods this should also include an evaluation of the statistical methods, and that many methodological studies evaluate this important component. In excluding "statistical methodological studies", we did not intend to confuse readers or suggest that we are not including methodological studies that evaluate statistical methods/plans in other studies. The kinds of statistical studies we are excluding are studies testing new algorithms or analytical methods, simulation studies¹, which are distinctly different and already have their own reporting guidelines or can be reported in a commentary-style format. We have elaborated on Page 6, Lines 93-94 and Page 11, Lines 196-201 to clarify that these studies are eligible.

1. Rahmandad H and Sterman JD: Reporting guidelines for simulation-based research in social sciences. *Syst Dyn Rev* 2012, 28: 396-411.

Comment:

The authors plan to limit their search to the last ten years. Is that because in these years there is an increasing number of 'methodological studies' as shown in Figure 1 (Page 9 line 42)? However, on Page 9 line 47, the authors have stated the importance of 'methodological studies' in the past 20 years. As I know, the reporting guidelines for systematic reviews have existed for over 20 years, which means there should be a number of 'methodological studies' existing prior 2009, why not including them? Therefore, I suggest including at least 20 years of search.

Response:

Initially, we planned to limit the search to the past 10 years as a result of our discussions that older studies may be less relevant in contributing novel reporting items for the reporting checklist. However, we have revisited this discussion and agree with the reviewer regarding the importance of evaluating literature over a longer timeframe. We have revised this in the manuscript (Page 10, Lines 176-177) to highlight that we did not limit our search by any timeframe.

Comment:

Page 10 line 54. It would be better if the authors list one or two examples of the questions that the 'methodological studies' try to answer. Because it is easier for readers to see the differences between traditional systematic reviews and 'methodological studies'.

Response:

We thank the reviewer for raising this point. For example, if researchers are interested in investigating changes in reporting quality overtime, they may adopt a before-after or interrupted time series design. We have added further clarification with an example on Page 8, Lines 130-135.

Comment:

Page 15 line 18. During the data extraction, do the authors want to extract the findings of risk of bias assessment in the included study? E.g. did the authors conduct risk of bias assessment? what was the distribution of studies with low, unclear and high risk-of-bias? I feel that this is also important to report.

Response:

If referring to when the authors of methodological studies conduct a risk of bias assessment on a sample of studies – we have no plans to extract these individual findings for each included record in the methodological study, nor analyze these results further (e.g. such as evaluating or commenting on the distributions found by the methodological study authors). In this study, we would only summarize the general findings of the methodological study. For example, if the risk of bias assessment was a key objective, we would report this and note the findings. Although we agree that this information is important, we do not believe that this data would be useful or relevant to the ultimate goal of this project which is: to summarize methodological studies in order to categorize them and identify candidate reporting items for the reporting checklist.

Comment:

Page 21 line 36. Do the authors want to create reporting checklist for the section 'Title', 'Abstract', and 'Supplementary information and others' as well? For example, we usually expect the researchers to indicate the type of their study in the title.

Response:

We intend to discuss the appropriate formats for the reporting checklist which includes how the guidance should be laid out (e.g. by article section, including the title and abstract). We have provided additional clarification in Table 2 under the first bullet point in the "second video conference" section. We agree with the reviewer that reporting the "type of study" in the title is a good idea and facilitates improvements in indexing, searching and retrieval.

Comment:

It would be better if the authors could share the intended timeline for developing this tool.

Response:

We have added a new figure/Gantt chart to the supplementary file outlining the timeline for this research.

REVIEWER 2

Comment:

This is a very clearly written and well described methodological protocol. The authors convincingly argue for why their study is required and clearly set out how they will conduct their study. If the authors have not yet started, then they may wish to consider adding PsychInfo to their listed health-related databases.

Response:

We thank the reviewer for their time and positive comments to improve this manuscript. At this stage, we have performed our search in June 2020 and have completed screening articles. However, we agree with the reviewer and we plan to include PsychInfo in future search updates.

REVIEWER 3

Comment:

The proposed research is interesting and addresses an important gap in the literature. I would suggest that the authors consider using another terminology to replace “methodological studies”. There are different categories of methodological studies. For example, there are methodological studies with existing studies as the unit of analysis (may be referred to as ‘methodological secondary studies’/research-on-research/meta-epidemiology/ meta-research) and there are methodological primary studies (for example, methodological studies of survey techniques, studies on how to improve participation rates). I think the term “methodological studies” is broad and it made the protocol a little difficult to follow initially. It later became clear that the authors may be more interested in “research reporting standards for studies that investigate the design, conduct, analysis, or reporting of other health studies”. The name METHodological study ReportIng Checklist (METRIC) for the proposed tool may be confusing. It may be better to use a name that reflects the specific type of methodological studies the authors will focus on.

Response:

We are grateful to the reviewer for their feedback on this manuscript. We agree with the reviewer regarding the difficulties in coming to an agreement on appropriate nomenclature. The topic of what to call these studies is increasingly debated in the research community, and a constant point of discussion during our team meetings¹. This conversation forms one of the key objectives of our research – that is, to come to a consensus on the most appropriate terminology for methodological studies. At this stage, after extended preliminary discussions, our team has agreed that the terminology “methodological study” is the most objective and encompassing term for the types of studies that we are interested in. It is also intentionally broad, and this will form one of the key points of discussion during the planned consensus exercises and meetings. We have highlighted in the text (Page 8, Lines 142-147) that the wide variety of names is part of the problem, and consensus-based discussions will shed light on the appropriate name(s).

For example, the studies that the reviewer mentions (e.g. studies on how to improve participation rates, such as those tracked in the SWAT/SWAR registries) will be included in our review as part of our assessment and efforts to categorize and classify these studies. We opted to first identify, and then subsequently to classify and name these studies based on their various characteristics. However, any further refinement regarding the name(s) and categories will only possible after we complete the review of the literature.

We noted one major exclusion (Page 11, Lines 196-199) wherein statistical methods studies where the research report is not the unit of analysis are outside the scope of the current project (e.g. studies that are more analytical in nature such as simulation studies, etc.).

1. Puljak L: Methodological studies evaluating evidence are not systematic reviews. J Clin Epidemiol 2019, 110:98-99.

Comment:

I would also suggest that the authors expand on the eligibility criteria, particularly to highlight more examples of methodological studies that will be excluded.

Response:

We will exclude simulation studies, studies testing new statistical methods (i.e. there is no specific unit of analysis) and experimental studies of methods (i.e. the unit of analysis is not a research report). We have clarified this on Page 11, Lines 196-199.

VERSION 2 – REVIEW

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	The University of Adelaide, Australia
REVIEW RETURNED	09-Nov-2020

GENERAL COMMENTS	Thanks for revising the manuscript. I do not have any further comments.
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REVIEWER	Abimbola Ayorinde University of Warwick, United Kingdom
REVIEW RETURNED	10-Nov-2020

GENERAL COMMENTS	<p>I appreciate the authors for the detailed response and the revisions made to the manuscript.</p> <p>I understand the challenges with coming up with an appropriate name. With the term 'methodological studies', it is not immediately clear that only methodological studies that have 'other studies' as the unit of analysis will be included. The fact that another reviewer also highlighted potential issues with using 'methodological studies' shows the importance of developing a consensus-based nomenclature. I look forward to the results of this work.</p>
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