

August 10th, 2020

Pre-analysis plan

This is a previous plan for extracting and analyzing complementary data for a SEES-initiative study. The SEES-initiative full protocol is available at <https://osf.io/2cu8g/>.

Purpose

In this study, our overall aim will be to explore prevalence of systematic reviews with meta-analysis (SRMAs) with registration record and methodological protocols, as well as the integrity of prespecified and published outcomes from the total of SRMAs assessed by the SEES initiative in 2019. Our specific aims are as follows: 1) to assess the matching between descriptions of study outcomes documented in registration records and in final publications, determining the frequency of outcome discrepancies whenever identifiable (i.e. either omitted or added outcomes); 2) to assess the consistency between primary and secondary outcomes pre-specified in registration records and those defined in the final publication; 3) to describe if there is a non-planned outcomes modification statement.

Data extraction

To explore our purpose, data already extracted using the SEES form will be used, such as author names, year and journal of publication, previous registration record or methodological protocol and statement about non-planned modification.

In addition, the following complementary data will be extracted:

- 1) Description of each outcome assessed in the registration record/methodological protocol and in the final publication. Herein, an outcome is defined as a variable that was intended for comparison between groups to assess the efficacy or harm of a given intervention.[1]
- 2) Which outcomes were designated as primary and secondary in the registration record/methodological protocol and in the final publication. Primary and secondary outcomes were those that were explicitly reported as such in the registry and in the final publication.
- 3) If outcomes were presented in the methods and/or results in the final publication.
- 5) Date of registration and number of versions.
- 6) Date of publication acceptance.

Only previously registered SRMAs will be considered. Data extraction will be performed via a spreadsheet by two reviewers independently and checked by two others. The spreadsheet is available at <https://osf.io/ntw7d/>.

Analysis plan

The data will be described in counts and relative frequencies, through tables and figures.

According to our overall aim, from the total of SRMAs assessed by the SEES initiative in 2019, the quantity of studies with previous registration and methodological protocols will be explored regarding prevalences of registered SRMAs and existing methodological protocols, as well as integrity of prespecified and published outcomes.

To achieve our specific aims, we will quantify the number of studies that omitted or added outcomes from registration to final publication, as well as identify the number of outcomes that were omitted or added, if any. If outcomes were different because the one reported in the registration record was more imprecise than that reported in the article, we will classify the study as having “imprecise outcome registration.”[2] In addition, we will quantify whether studies were consistent in the designation of primary and secondary outcomes from the registration to publication. Finally, we will describe if there was a statement when these inconsistencies in outcomes occurred.

The descriptive analysis will be guided by some central questions, comparing registration record with final publication:

- 1) Are the outcomes the same?
- 2) If outcomes are the same, were there any changes in outcomes?
- 3) If changes occurred, was there any statement in the final publication?
- 4) Was there a change in the designation of which outcomes were primary and secondary?
- 5) Are the outcomes described in the SRMA methods?
- 6) Are the outcomes described in the SRMA results?

Based on these central questions, we will carry out a critical discussion about the importance of registration and available methodological protocols to increase transparency and reproducibility of SRMAs in the field of exercise sciences.

References

1. Chan A-W, Hróbjartsson A, Haahr MT, Gøtzsche PC, Altman DG. Empirical evidence for selective reporting of outcomes in randomized trials: comparison of protocols to published articles. *JAMA*. 2004;291: 2457–2465.
2. Mathieu S, Boutron I, Moher D, Altman DG, Ravaud P. Comparison of registered and published primary outcomes in randomized controlled trials. *JAMA*. 2009;302: 977–984.