

Risk of Bias

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Introduction

The extent to which a systematic review/meta-analysis (SR/MA) can draw conclusions about the effects of an intervention depends on whether the data and results from the included studies are valid. In particular, an SR/MA of invalid studies may produce a misleading result, yielding a narrow confidence interval around the wrong intervention effect estimate. The evaluation of the validity of the included studies is therefore an essential component of SR/MAs, and should influence the analysis, interpretation, and conclusions of the SR/MA. Standardized “risk of bias” (RoB) tools are used to measure the extent of various types of biases from individual studies.

The validity of a study may be considered to have two dimensions. The first dimension is whether the study is asking an appropriate research question. This is often described as ‘external validity’, and its assessment depends on the purpose for which the study is to be used. External validity is closely connected with the generalizability or applicability of a study’s findings. The second dimension of a study’s validity relates to whether it answers its research question ‘correctly’, that is, in a manner free from bias. This is often described as ‘internal validity’. A good meta-analysis should assess both external validity and internal validity and should incorporate measures to minimize the risk of such biases.

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