

Item 25: Risk of bias in studies

Present assessments of risk of bias for each included study.

Title	1	Title
Abstract	2	See tip sheets for Abstracts
Summary	3	Plain language summary
Open Science	4	Registration and protocol <i>a. Registration information</i> <i>b. Accession of protocol</i> <i>c. Protocol amendments</i>
	5	Support
	6	Competing interests
	7	Availability of data and other materials
Introduction	8	Rationale
	9	Objectives
Methods	10	Followed guidelines
	11	Eligibility criteria
	12	Information sources
	13	Search strategy
	14	Selection process
	15	Data collection process
	16	Data items
	17	Study risk of bias assessment
	18	Measurement properties
	19	Synthesis methods <i>a. Eligibility processes</i> <i>b. Methods for synthesis</i> <i>c. Causes of inconsistency</i> <i>d. Sensitivity analyses</i>
	20	Certainty assessment
Results	21	Formulating recommendations
	22	Study selection <i>a. Results of search and selection</i> <i>b. Excluded reports with reasons</i>
	23	OMI characteristics <i>a. Characteristics of OMIs</i> <i>b. Interpretability aspects of OMIs</i> <i>c. Feasibility aspects of OMIs</i>
	24	Study characteristics
	25	Risk of bias in studies
	26	Results of individual studies
	27	Results of syntheses <i>a. Results of syntheses conducted</i> <i>b. Results of causes of inconsistency</i> <i>c. Results of sensitivity analyses</i>
	28	Certainty of evidence
29	Recommendations	
Discussion	30	Discussion <i>a. Interpretation of results</i> <i>b. Limitations of evidence</i> <i>c. Limitations of review processes</i> <i>d. Implications</i>

Tips for reporting this item:

- Present tables or figures indicating the risk of bias of each study on a measurement property (considering a format that will facilitate understanding of risk of bias in studies in relation to the results).

Examples:

In a review examining the measurement properties of diabetes-specific PROMs measuring physical functioning, the authors presented a table combining the risk of bias ratings with the ratings of the measurement property (item #26). In the appendix, they provided a more extensive table, combining the risk of bias ratings with the results and ratings of measurement properties (item #26). The appendix also shows the synthesized results, consisting of the summarized or pooled result with the overall rating (item #27a), and the certainty of the evidence (item #28). The authors also provide an explanation for common suboptimal risk of bias ratings in the main text, when discussing each measurement property.

“For the other PROMs [patient-reported outcome measures], the development was rated as inadequate, because the construct of the included physical functioning subscale was not clearly described or the PROM was not pilot tested. [...] If studies had inadequate quality for structural validity or cross-cultural validity/measurement invariance, this was often due to small sample sizes. [...] Reliability was evaluated for six PROMs or subscales. All studies with inadequate quality had a time interval that was considered to be too long (i.e., more than 4 weeks). [...] Three studies were of inadequate quality, because they did not apply an appropriate statistical method to compare subgroups.”

The [E&E](#) contains an abridged version of this table and appendix.

Elsman EBM et al. Systematic review on the measurement properties of diabetes-specific patient-reported outcome measures (PROMs) for measuring physical functioning in people with type 2 diabetes. *BMJ Open Diabetes Res. Care*, 2022;10(3):e002729. <https://doi.org/10.1136/bmjdr-2021-002729>.

See the [E&E](#) for more examples.

From: Elsman EBM, Mokkink LB, Terwee CB, Beaton D, Gagnier JJ, Tricco AC, et al. Guideline for reporting systematic reviews of outcome measurement instruments (OMIs): PRISMA-COSMIN for OMIs 2024. *J Clin Epidemiol*, 2024. <https://doi.org/10.1016/j.jclinepi.2024.111422>.

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