PRISMA - COSMIN OUTCOME Measurement Instruments

Full report

Item 17: Study risk of bias assessment

Specify the methods used to assess risk of bias in the included studies, e.g., including details of the tool(s) used, how many reviewers assessed each study and each measurement property and whether they worked independently, and if applicable, details of automation tools/AI used in the process.

Title	1	Title
Abstract	2	See tip sheets for Abstracts
Summary	3	Plain language summary
Open Science	4	Registration and protocol *a. Registration information* *b. Accession of protocol* *c. Protocol amendments*
	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 *a. Eligibility processes* *b. Methods for synthesis* *c. Causes of inconsistency* *d. Sensitivity analyses*
	20	Certainty assessment
	21	Formulating recommendations
Results	22	Study selection *a. Results of search and selection* *b. Excluded reports with reasons*
	23	OMI characteristics *a. Characteristics of OMIs* *b. Interpretability aspects of OMIs* *c. Feasibility aspects of OMIs*
	24	Study characteristics
	25	Risk of bias in studies
	26	Results of individual studies
	27	Results of syntheses *a. Results of syntheses conducted* *b. Results of causes of inconsistency* *c. Results of sensitivity analyses*
	28	Certainty of evidence
	29	Recommendations
Discussion	30	Discussion *a. Interpretation of results* *b. Limitations of evidence* *c. Limitations of review processes* *d. Implications*

Tips for reporting this item:

- Specify the tool(s) (and version) used to assess risk of bias in the included studies.
- Report how many reviewers assessed risk of bias in each study, whether multiple reviewers worked independently (such as assessments performed by one reviewer and checked by another), and any processes used to resolve disagreements between assessors.
- See the E&E for specifics on what other details should be reported for study risk of bias assessment.

Examples:

"Two authors […] independently evaluated the measurement properties in each article against the COSMIN Risk of Bias checklist. […] Study quality was assessed separately for each measurement property using a four-point rating system (very good, adequate, doubtful or inadequate). The 'worst score counts' principle was used, where the overall rating for each measurement property is given by the lowest rating of any standard in the box [citation provided]."

Sabah SA et al. Patient-reported outcome measures following revision knee replacement: a review of PROM instrument utilisation and measurement properties using the COSMIN checklist. *BMJ Open,* 2021;11(10):e046169. https://doi.org/10.1136/bmjopen-2020-046169.

"Methodological quality assessment: The methodological quality of the included studies was assessed by two independent reviewers, using the COSMIN Risk of Bias (RoB) checklist [citation provided]. The studies' methodological quality was assessed per measurement property separately. That is, per measurement property, only the boxes pertaining to that measurement property were used. Each box consists of four or more items, all of which were rated on a 4-point rating scale (i.e., "very good", "adequate", "doubtful", or "inadequate"). The studies' overall score per measurement property was equal to the lowest rated item of the respective box (i.e., "the worst score counts" principle). Discrepancies between reviewers were discussed and solved by consensus."

Ratter J et al. Content validity and measurement properties of the Lower Extremity Functional Scale in patients with fractures of the lower extremities: a systematic review. *Journal of Patient-Reported Outcomes,* 2022;6(1):1-14. https://doi.org/10.1186/s41687-022-00417-2.

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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