

Item 4c: Registration and protocol – Protocol amendments

Describe and explain any amendments to information provided at registration or in the protocol.

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> 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 <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
21	Formulating recommendations	
Results	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	29	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:

- Report details of any amendments to information provided at registration or in the protocol, noting: a) the amendment itself, b) the reason for the amendment, and c) the stage of the review process at which the amendment was implemented.

Examples:

“The protocol is available through ResearchGate [citation to protocol provided]. There were no deviations from the protocol [...].”

Brekke M et al. Quality of Life instruments and their psychometric properties for use in parents during pregnancy and the postpartum period: a systematic scoping review. *Health Qual. Life Outcomes*, 2022;20(1):1-19. <https://doi.org/10.1186/s12955-022-02011-y>.

“The objectives section has been revised, compared to the a priori protocol, to provide more clarity without changing the overall objectives of the review. [...] Further inclusion criteria were added while identifying and screening the literature to complement those of the a priori protocol: Instruments needed to be multidimensional (e.g. include more dimensions than only information needs). [...] In contrast to the a priori protocol, Embase was searched as recommended by COSMIN, and CINAHL was searched instead of OVID Nursing.”

Kipfer S & Pihet S. Reliability, validity and relevance of needs assessment instruments for informal dementia caregivers: a psychometric systematic review. *JBI evid. synth.*, 2020;18(4):704. <https://doi.org/10.11124/JBISRIIR-2017-003976>.

From: Elsmann 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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