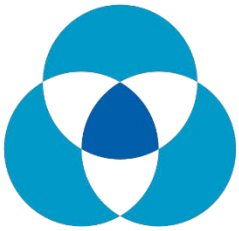
PRISMA - COSMIN
OUTCOME
Measurement Instruments



Guideline for Reporting Systematic Reviews of Outcome Measurement Instruments

Explanation & Elaboration - Abstracts

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June 2024

Content

PRISMA-COSMIN for OMIs 2024

PRISMA: **P**referred **R**eporting **I**tems for **S**ystematic reviews and **M**eta-**A**nalyses
COSMIN: **CO**nsensus-based **S**tandards for the selection of health **M**easurement **IN**struments
OMI: **O**utcome **M**easurement **I**nstrument

Background

OMIs are used by healthcare professionals or researchers to measure outcomes and refer to how an outcome is measured (e.g., with a questionnaire, performance-based test, lab test, or single rating scale). Systematic reviews evaluating the quality of OMIs are important in the evidence-based selection of the most appropriate OMI. COSMIN has developed a comprehensive and widespread guideline to conduct these systematic reviews; however, key information is often missing in published reports. This hinders the appraisal of the quality of OMIs, and impacts the decisions of users (e.g., researchers, healthcare providers, patients and policymakers) regarding the appropriateness of an OMI. Until now, authors of OMI systematic reviews have been encouraged to complete and adhere to the widely used PRISMA 2020 guideline.[1] This guideline does not include all essential information for systematic reviews of OMIs, limiting the reproducibility (ability to replicate the results using the same data) and interpretability (the ability to understand and interpret the findings) of such reviews. PRISMA-COSMIN for OMIs 2024 aims to harmonize reporting of systematic reviews of OMIs.

This guideline

PRISMA-COSMIN for OMIs 2024 is a stand-alone extension of PRISMA 2020, specifically intended for reporting systematic reviews of OMIs where *at least one measurement property of at least one OMI is evaluated*. PRISMA-COSMIN for OMIs 2024 is not intended for reviews that only provide an overview (i.e., characteristics) of the OMIs used, as these review types are more scoping in nature. Moreover, PRISMA-COSMIN for OMIs 2024 is **not a quality assessment instrument or risk of bias tool to gauge the quality of a systematic review** and should not be confused with tools that have specifically been developed for that purpose.

PRISMA-COSMIN for OMIs 2024 is intended for all systematic reviews of OMIs, conducted with any methodology or tools; it does not specifically apply to systematic reviews conducted with the methodology or tools from the COSMIN initiative.

PRISMA-COSMIN for OMIs 2024 might also be used to report systematic reviews of instruments other than *outcome* measurement instruments, for example systematic reviews in which experience measures or process measures are being evaluated. It depends however on the methodology that is used to conduct those systematic reviews if PRISMA-COSMIN for OMIs 2024 is applicable to these systematic reviews.

PRISMA-COSMIN for OMIs 2024 consists of:

- A checklist for **full reports** containing 54 (sub)items, including the abstract items
- A checklist for **abstracts** (journal or conference abstracts) containing 13 items
- An Explanation & Elaboration (E&E) document for **full reports** and abstracts
- An Explanation & Elaboration (E&E) document for **abstracts** (this document)
- A flow diagram (available for download and included in the E&E for full reports)

Explanation & Elaboration

In this document, for each abstract item, we explain why reporting of each item is recommended in the abstract, with evidence supporting the inclusion of the item whenever possible. We present bullet points that detail the reporting recommendations and include exemplars of good reporting from published systematic reviews of OMIs abstracts. This structure is similar to the structure of the Explanation & Elaboration (E&E) document of PRISMA 2020.[2] Where possible, we used the exact same wording and phrasing as the PRISMA 2020 E&E, published open access and distributed under the terms of the Creative Commons CC BY 4.0 license, to facilitate implementation of the guidance.

We encourage authors to use this document in conjunction with the abstract checklist. Box 1 includes a glossary of terms used throughout PRISMA-COSMIN for OMIs 2024.

Box 1. Glossary of terms used in PRISMA-COSMIN for OMIs 2024

Systematic review

A study design that uses explicit, systematic methods to collect data from primary studies, critically appraises the data, and synthesizes the findings descriptively or quantitatively in order to address a clearly formulated research question.[2-4] Typically, a systematic review includes a clearly stated objective, pre-defined eligibility criteria for primary studies, a systematic search that attempts to identify all studies that meet the eligibility criteria, risk of bias assessments of the included primary studies, and a systematic presentation and synthesis of findings of the included studies.[4] Systematic reviews can provide high quality evidence to guide decision making in healthcare, owing to the trustworthiness of the findings derived through systematic approaches that minimize bias.[5]

Outcome domain

Refers to *what* is being measured (e.g., fatigue, physical function, blood glucose, pain).[6,7] Other terms include construct, concept, latent trait, factor, attribute.

Outcome measurement instrument (OMI)

Refers to *how* the outcome is being measured, i.e., the OMI used to measure the outcome domain. Different types of OMIs exist such as questionnaires or patient-reported outcome measures (PROMs) and their variations, clinical rating scales, performance-based tests, laboratory tests, scores obtained through a physical examination or observations of an image, or responses to single questions.[6,7] An OMI consists of a set of components and phases, i.e., 'equipment', 'preparatory actions', 'collection of raw data', 'data processing and storage', and 'assignment of the score'.[8] A specific type of OMIs is clinical outcome assessments (COAs),[9] which specifically focus on outcomes related to clinical conditions, often emphasizing the patient's experience and perspective.

Report

A document with information about a particular study or a particular OMI. It could be a journal article, preprint, conference abstract, study register entry, clinical study report, dissertation, unpublished manuscript, government report, or any other document providing relevant information such as a manual for an OMI or the PROM itself.[2] A **study report** is a document with information about a particular study like a journal article or a preprint.

Record
The title and/or abstract of a report indexed in a database or website. Records that refer to the same report (such as the same journal article) are "duplicates".[2]

Study
The empirical investigation of a measurement property in a specific population, with a specific aim, design and analysis.

Quality
The technical concept 'quality' is used to address three different aspects defined by COSMIN, OMERACT, and GRADE: 1) quality of the OMI refers to the measurement properties; 2) quality of the study refers to the risk of bias; and 3) quality of the evidence refers to the certainty assessment.[7,10,11]

Measurement properties
The quality aspects of an OMI, referring to the validity, reliability, and responsiveness of the instrument's score.[12] Each measurement property requires its own study design and statistical methods for evaluation. Different definitions for measurement properties are being used. COSMIN has a taxonomy with consensus-based definitions for measurement properties.[12] Another term for measurement properties is psychometric properties.

Feasibility
The ease of application and the availability of an OMI, e.g., completion time, costs, licensing, length of an OMI, ease of administration, etc.[10,13] Feasibility is not a measurement property, but is important when selecting an OMI.[7]

Interpretability
The degree to which one can assign meaning to scores or change in scores of an OMI in particular contexts (e.g., if a patient has a score of 80, what does this mean?).[12] Norm scores, minimal important change and minimal important difference are also relevant concepts related to interpretability. Like feasibility, interpretability is not a measurement property, but is important to interpret the scores of an OMI and when selecting an OMI.[7]

Measurement properties' results
The findings of a study on a measurement property. Measurement properties' results have different formats, depending on the measurement property. For example, reliability results might be the estimate of the intraclass correlation coefficient (ICC), or structural validity results might be the factor loadings of items to their respective scales and the percentage of variance explained.

Measurement properties' ratings
The comparison of measurement properties' results against quality criteria, to give a judgement (i.e., rating) about the results. For example, the ICC of an OMI might be 0.75; this is the result. A quality criterion might prescribe that the ICC should be >0.7. In this case the result (0.75) is thus rated to be sufficient.

Risk of bias
Risk of bias refers to the potential that measurement properties' results in primary studies systematically deviate from the truth due to methodological flaws in the design, conduct or

analysis.[2,14] Many tools have been developed to assess the risk of bias in primary studies. The COSMIN Risk of Bias checklist for PROMs was specifically developed to evaluate the risk of bias of primary studies on measurement properties.[15] It contains standards referring to design requirements and preferred statistical methods of primary studies on measurement properties, and is specifically intended for PROMs. The COSMIN Risk of Bias tool to assess the quality of studies on reliability or measurement error of OMIs can be used for any type of OMI.[8]

Synthesis
Combining quantitative or qualitative results of two or more studies on the same measurement property and the same OMI. Results can be synthesized quantitatively or qualitatively. Meta-analysis is a statistical method to synthesize results. Although this can be done for some measurement properties (i.e., internal consistency, reliability, measurement error, construct validity, criterion validity, responsiveness), it is not very common in systematic reviews of OMIs because the point estimates of the results are not used. Instead, the score obtained with an OMI is used. End-users therefore only need to know whether the result of a measurement property is sufficient or not. For some measurement properties (i.e., content validity, structural validity, cross-cultural validity/measurement invariance) it is not even possible to statistically synthesize the results by meta-analysis or pooling. In general, most often the robustness of the results is described (e.g., the found factor structure, the number of confirmed and unconfirmed hypotheses), or a range of the results is provided (e.g., the range of Cronbach's alphas or ICCs).

Certainty (or confidence) assessment
Together with the **synthesis**, often an assessment of the certainty (or confidence) in the body of evidence is provided. Authors conduct such an assessment to reflect how certain (or confident) they are that the synthesized result is trustworthy. These assessments are often based on established criteria, which include the risk of bias, consistency of findings across studies, sample size, and directness of the result to the research question.[7] A common framework for the assessment of certainty (or confidence) is GRADE (Grading of Recommendations Assessment, Development, and Evaluation).[11] A modified GRADE approach has been developed for communicating the certainty (or confidence) in systematic reviews of OMIs.[7]

OMI recommendations
Systematic reviews of OMIs provide a comprehensive overview of the measurement properties of OMIs and support evidence-based recommendations for the selection of suitable OMIs for a particular use. Unlike systematic reviews of interventions, systematic reviews of OMIs often make recommendations about the suitability of OMIs for a particular use, although in some cases this might not be appropriate (e.g., if restricted by the funder). Making recommendations also facilitates much needed standardization in use of OMIs, although their quality and score interpretation might be context dependent. Making recommendations essentially involves conducting a synthesis at the level of the OMI, across different measurement properties, taking feasibility and interpretability into account as well. Various methods and tools for OMI recommendation exist (e.g., from COSMIN, OMERACT and others).[7,16,17]

Most of the following information has been reused from Page et al., 2021.[2] We used standardized language in the E&E to indicate whether reporting recommendations for each item (referred to as "elements" throughout) are essential or additional. *Essential elements* should be reported in the

abstract for all systematic reviews of OMIs (except for those preceded by "If…," which should only be reported where applicable). These have been selected as essential because transparent and complete reporting of these elements is important for users to assess the trustworthiness and applicability of a review's findings, or their reporting would aid in reproducing the findings. *Additional elements* are those which are not essential but provide supplementary information that may enhance the completeness and usability of systematic review abstracts.

We found reporting exemplars for each checklist item from published systematic reviews of OMIs abstracts. We have edited the examples by removing names and/or initials of authors. We have spelled out abbreviations to aid comprehension, except when this concerned names of OMIs, which we printed in *italic*. On page 21-22 of this document, we also provide two fictional examples of 350-word abstracts in which all Abstract reporting items are included.

Citing PRISMA-COSMIN for OMIs 2024

In order to encourage its wide dissemination, the guideline is published open access in several journals. Please use one of the following when referring to PRISMA-COSMIN for OMIs 2024:

- 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. *Quality of Life Research* (2024), doi: https://doi.org/10.1007/s11136-024-03634-y.
- 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. *Journal of Clinical Epidemiology* (2024), doi: https://doi.org/10.1016/j.jclinepi.2024.111422.
- 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. *Health and Quality of Life Outcomes* (2024), doi: https://doi.org/10.1186/s12955-024-02256-9.
- 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. *Journal of Patient-Reported Outcomes* (2024), doi: https://doi.org/10.1186/s41687-024-00727-7.

Abstract – Title

Title

Item #2.1: Identify the report as a systematic review and include as applicable the following (in any order): outcome domain of interest, population of interest, name/type of OMIs of interest, and measurement properties of interest.

Explanation: Inclusion of "systematic review" in the title facilitates identification by potential users (patients, healthcare providers, policy makers, researchers, etc.) and appropriate indexing in databases.[2] Terms such as "review", "literature review", "evidence synthesis", or "knowledge synthesis" are not recommended because they do not distinguish systematic and non-systematic approaches.[2] The objective or question that the systematic review addresses often includes four key elements: the outcome domain, population, name or type of OMI and the measurement properties.[7] It is therefore recommended to include these four key elements in the title of the review, if word count permits, unless certain key elements are clearly irrelevant or redundant. For example, if the objective of the review is to evaluate the measurement properties of a certain OMI in a specific population, it might be irrelevant to include the outcome if that is clear from the name of the OMI. If multiple measurement properties are evaluated in the review, authors can state "measurement properties" or "quality" instead of listing each of the measurement properties. If multiple OMIs are evaluated in the review, authors can state the type of OMI (for example patient-reported outcome measures (PROMs) or performance-based tests). If different types of OMIs are evaluated in the review, authors can state "outcome measurement instruments".

Essential elements

- Identify the report as a systematic review in the title.[2]
- Report an informative title that provides key information about the main objective or question that the review addresses, for example with respect to the outcome domain of interest, population of interest, name/type of OMI of interest, and/or measurement properties of interest (which can also be referred to as the quality of the OMIs).[7]

Example of item #1

Example 1: "Systematic review on the measurement properties of diabetes-specific patient-reported outcome measures (PROMs) for measuring physical functioning in people with type 2 diabetes"[18]

Example 2: "Content Validity of Patient-Reported Outcome Measures Developed for Assessing Health-Related Quality of Life in People with Type 2 Diabetes Mellitus: a Systematic Review"[19]

Example 3: "A systematic review of the measurement properties of the Body Image Scale (BIS) in cancer patients"[20]

Abstract – Open Science

Funding

Item #2.2: Specify the primary source of funding for the review.

Explanation: As with any research report, authors should be transparent about the sources of funding received to conduct the systematic review.[2] The abstract should include the main source of funding for the systematic review, whether from host institutions or from external funders,[21] unless the journal has a designated section to report this information. For conference abstracts, this information should always be reported.

Essential elements

- Specify the main funding source for the systematic review.

Example of item #2.2

*"*Funding: The source of funding: Frans Huygen Stichting."[22]

Registration

Item #2.3: Provide the register name and registration number.

Explanation: Registration of systematic reviews provides a record of reviews that have been initiated, even if they have not been published.[21] It is therefore a means of alerting researchers to systematic reviews that are in progress, and serves as a public record of the proposed systematic review.[21] Registration also helps to detect reporting bias (i.e., publication bias) by enabling better identification of unpublished systematic reviews.[21,23] The abstract should record the name of the database with which the review is registered, and the registration number,[21] unless the journal has a designated section to report this information. For conference abstracts, this information should always be reported.

Essential elements

- Provide registration information for the review, including register name and registration number, or state that the review was not registered.[2]

Example of item #2.3

*Example 1: "*This systematic review was registered in the PROSPERO international prospective register of systematic reviews, with registration number CRD42019130936."[24]

Example 2: "PROSPERO registration CRD42021282032"[25]

Abstract – Background

Objectives

Item #2.4: Provide an explicit statement of the main objective(s) or question(s) the review addresses.

Explanation: The objectives in an abstract should convey succinctly the aim or research question the systematic review addresses.[21] An explicit and concise statement of the main review objective(s) or question(s) will help readers understand the scope of the review.[2] Such statements may be written in the form of aims or objectives ("… to examine the measurement properties of…") or as questions ("what are the measurement properties of….?", "what is the quality of…").[2,26] The objective or question that the systematic review addresses often includes four key elements: the outcome domain, population, name or type of OMI, and the measurement properties.[7] It is therefore recommended to include these four key elements in the objective(s) or question(s) the review addresses, unless certain key elements are clearly irrelevant or redundant. For example, if the objective of the review is to evaluate the measurement properties of a certain OMI in a specific population, it might be irrelevant to include the outcome if that is clear from the name of the OMI. If multiple measurement properties are evaluated in the review, authors can state "measurement properties" or "quality" instead of listing each of the measurement properties. If multiple OMIs are evaluated in the review, authors can state the type of OMI (for example patient-reported outcome measures (PROMs) or performance-based tests). If different types of OMIs are evaluated in the review, authors can state "outcome measurement instruments".

The objective or question could also be linked to the rationale for the systematic review, for example, to provide an overview of the quality of available OMIs or to select the best OMI for a particular use (e.g., in a core outcome set or a clinical trial).

Essential elements

- Provide an explicit statement of the main objective(s) or question(s) the review addresses.[2]
- Use the four key elements (outcome domain, population, name or type of OMI and the measurement properties of interest) as applicable to formulate the objective(s) or question(s).[7]

Additional elements

- Consider linking the main objective(s) or question(s) to the rationale for the review (for example, to provide an overview of the quality of available OMIs or to select the best OMI for a particular use).

Example of item #2.4

*Example 1: "*We aimed to systematically assess the measurement properties of diabetes-specific patient-reported outcome measures (PROMs) for measuring physical functioning, one of the core outcomes, in adults with type 2 diabetes."[18]

Example 2: "We aimed to systematically evaluate the content validity of patient-reported outcome measures (PROMs) specifically developed to measure (aspects of) health-related quality of life (HRQOL) in people with type 2 diabetes."[19]

Example 3: "The aim of this study was to systematically review measurement properties of the *BIS* among cancer patients."[20]

Abstract – Methods

Eligibility criteria

Item #2.5: Specify the inclusion and exclusion criteria for the review.

Explanation: Specifying the main criteria used to decide what evidence was eligible should enable readers to understand the scope of the review and verify the inclusion decisions.[2] The inclusion and exclusion criteria often relate to the four key elements: the outcome domain, population, name or type of OMI, and the measurement properties.[7] For a study to be included, often the aim should be to evaluate one or more of the measurement properties of interest, report on the development of an OMI, or report on its interpretability and feasibility aspects.[7]

Essential elements

- Briefly specify the main study characteristics used to decide whether a study was eligible for inclusion in the review, which can include the outcome domain, population, name/type of OMI, and/or measurement properties of interest,[7] and other characteristics, such as eligible study design(s) and setting(s).

Additional elements

- Consider specifying eligibility criteria with regard to report characteristics, such as year of dissemination, language, and report status (for example, whether reports such as unpublished manuscripts and conference abstracts were eligible for inclusion).[2]

Example of item #2.5

Example 1: "Eligible studies were peer-reviewed English language publications that sampled a population of children with mean age between 5 and 12 years and focused on developing and evaluating at least one psychometric property of a teacher proxy-report instrument for assessing one or more of the 30 APLF [Australian Physical Literacy Framework] elements."[24]

Example 2: "Studies reporting on the development and/or validation of any PROMs [patient-reported outcome measures] for uncomplicated UTIs [urinary tract infections] in women were considered eligible."[27]

Example 3: "Studies on development of the *LEFS* and/or the evaluation of one or more measurement properties of the *LEFS* in patients with lower extremity fractures were included […]."[28]

Information sources

Item #2.6: Specify the information sources (e.g., databases, registers) used to identify studies and the date when each was last searched.

Explanation: Authors should provide a brief description of the information sources searched or consulted, including the dates when each source was last searched, to allow readers to assess the completeness and currency of the systematic review.[2] If multiple information sources were used, the total number of databases could be specified instead. In the abstract, it is sufficient to state the month and year information sources were searched.

Essential elements

- Specify the date (month and year) when each source (such as database, register, website, organization) was last searched or consulted.[2]
- If bibliographic databases were searched, specify for each database its name (such as MEDLINE, CINAHL) or state the number of databases searched if multiple databases were searched.

Additional elements

- If study registers (such as PROSPERO), and other online repositories (such as the COSMIN database) were searched, consider specifying the name of each source and any restrictions that were applied.[2]

Example of item #2.6

*Example 1: "*MEDLINE, Embase, AMED and PsycINFO were searched from inception to 1 July 2020 […] unlimited by publication date or language."[29]

Example 2: "[…] we reviewed empirical research published from 1980 through February 2020 with an updated search in March 2021 in Medline, Embase, PsycINFO, Health and Psychological Instruments, CINAHL, ERIC, and Web of Science databases."[30]

Example 3: "Nine databases were searched from January 1996 to October 2020."[31]

Risk of bias

Item #2.7: Specify the methods used to assess risk of bias in the included studies.

Explanation: Limitations in the design and conduct of individual studies can raise questions about the internal validity of their findings.[14] An important aspect of a systematic review is therefore to assess the validity of individual studies by means of a risk of bias assessment.[21] Risk of bias refers to the potential for study findings to systematically deviate from the truth due to methodological flaws in the design, conduct or analysis.[14] Authors should describe the methods used to assess risk of bias in the included studies.[21] If the review was conducted following established guidance (e.g., the COSMIN guideline for systematic reviews or the OMERACT filter), items #2.7, #2.8 and #2.9 can be summarized into one general statement, as it can be inferred that the tools and methods within the guidance were used (see examples 4 and 5).

Essential elements

- Specify the method(s) used to assess risk of bias in the included studies.
- If the review was conducted following established guidance, methods used to assess risk of bias (item #2.7), rate the results of a measurement property (item #2.8), and synthesize the results (item #2.9) can be summarized into a general statement referring to that guidance.

Example of item #2.7

Example 1: "Methodological quality of the included studies was evaluated using the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) risk of bias checklist."[32]

Example 2: "For critical appraisal, the COSMIN Risk of Bias tool for reliability and measurement of error was used."[33]

Example 3: "The Agency for Healthcare Research and Quality (AHRQ) checklists was used to assess the risk of bias for each included study."[34]

Example 4: "Following the OMERACT Filter 2.1 instrument selection process, [...]."[35]

Example 5: "Data extraction and quality assessment (including a risk of bias evaluation) of the included studies was undertaken [...] in accordance with COSMIN guidelines."[36]

Measurement properties

Item #2.8: Specify the methods used to rate the results of a measurement property.

Explanation: To interpret the results, readers need to know how the results of a measurement property were rated. Authors should describe the methods used to rate the results of a measurement property, both for each individual study and for the summarized or pooled results (if different). If the review was conducted following established guidance (e.g., the COSMIN guideline for systematic reviews or the OMERACT filter), items #2.7, #2.8, and #2.9 can be summarized into one general statement, as it can be inferred that the tools and methods within the guidance were used (see examples 4 and 5).

Essential elements

- Specify the method(s) used to rate the results of a measurement property.
- If the review was conducted following established guidance, methods used to assess risk of bias (item #2.7), rate the results of a measurement property (item #2.8), and synthesize the results (item #2.9) can be summarized into a general statement referring to that guidance.

Example of item #2.8

Example 1: "The COSMIN criteria for good measurement properties were used to judge the results of the studies [...]."[37]

Example 2: "The measurement properties were then scored using quality criteria (positive/negative/indeterminate)."[38]

Example 3: "Furthermore, available evidence of the reliability, validity, responsiveness, and interpretability of the included scales was rated according to published quality criteria."[39]

Example 4: "Following the OMERACT Filter 2.1 instrument selection process, [...]."[35]

Example 5: "Data extraction and quality assessment (including a risk of bias evaluation) of the included studies was undertaken [...] in accordance with COSMIN guidelines."[36]

Synthesis methods

Item #2.9: Specify the methods used to present and synthesize results.

Explanation: Results of multiple studies on a measurement property are mostly synthesized by summarizing them qualitatively. For some measurement properties (i.e., internal consistency, reliability, measurement error, construct validity, responsiveness), results can be pooled or meta-analyzed, although this is not commonly done in systematic reviews of OMIs, because the point estimates of these results are generally not used. The methods used to synthesize the results should be specified in the abstract. If word count permits, details on the assessment of certainty (or confidence) can also be provided. If the review was conducted following established guidance (e.g., according to the COSMIN guideline for systematic reviews or the OMERACT filter), items #2.7, #2.8, and #2.9 can be summarized into a general statement, as it can be inferred that the tools and methods within the guidance were used (see examples 4 and 5).

Essential elements

- Report the methods used to synthesize the results.
- If meta-analysis was done, specify the meta-analysis model.
- If the review was conducted following established guidance, methods used to assess risk of bias (item #2.7), rate the results of a measurement property (item #2.8), and synthesize the results (item #2.9) can be summarized into a general statement referring to that guidance.

Additional elements

- Consider providing details about the certainty (or confidence) assessment.

Example of item #2.9

Example 1: "Data analysis and synthesis followed COSMIN methodology for reviews of outcome measurement instruments."[40]

Example 2: "Extracted evidence was qualitatively synthesized and evaluated […]."[41]

Example 3: "We used the COSMIN criteria to summarize and rate the psychometric properties of each PROM [patient-reported outcome measure]. A modified Grading, Recommendations, Assessment, Development, and Evaluation (GRADE) system was used to assess the certainty of evidence."[31]

Example 4: "Following the OMERACT Filter 2.1 instrument selection process, [...]."[35]

Example 5: "Data extraction and quality assessment (including a risk of bias evaluation) of the included studies was undertaken [...] in accordance with COSMIN guidelines."[36]

Abstract – Results

Included studies

Item #2.10: Give the total number of included OMIs and study reports.

Explanation: Providing the number of included OMIs and reports enables readers to understand the extent of the evidence included in the systematic review. If different versions of the same OMI are found, this should also be reported because each version of an OMI is considered a separate OMI (except for language versions).[7]

Essential elements

- Report the total number of OMIs included in the review.
- Report the total number of study reports included in the review.

Additional elements

- Consider reporting the number of separate versions of OMIs included in the review.

Example of item #2.10

Example 1: "Out of 6423 screened publications, 32 original articles were eligible for inclusion in this review, reporting evidence on the measurement properties of 22 self- and/or proxy-reported questionnaires (including seven cultural adaptations) for various pediatric orthopedic conditions, including cerebral palsy (CP) and obstetric brachial plexus palsy (OBPP)."[36]

Example 2: "In total 21 articles were included, describing 12 versions of 7 unique diabetes-specific PROMs or subscales measuring physical functioning."[18]

Example 3: "We included 24 articles describing the development and/or evaluation of 21 instruments."[22]

Synthesis of results

Item #2.11: Present the syntheses of results of OMIs, indicating the certainty of the evidence.

Explanation: The main syntheses of results (i.e., those most relevant to the aim of the review) should be given in the abstract.[21] For example, if a study evaluates all measurement properties but pre-specified that content validity and structural validity were imperative for the conclusions, then syntheses of at least those measurement properties should be provided for the most relevant OMIs. Along with the syntheses of results, the certainty of the evidence for each of these syntheses could be provided, if word count permits, as this shows the confidence in the trustworthiness of the synthesized results.[7,42]

Essential elements

- Report the results of the main syntheses conducted.

Additional elements

- Consider reporting the overall level of certainty in the body of evidence (such as high, moderate, low, or very low) for each main synthesis.

Example of item #2.11

Example 1: In a review examining the measurement properties of diabetes-specific PROMs measuring physical functioning,[18] the authors pre-specified that at least sufficient content validity, structural validity, and internal consistency was needed for an OMI to be recommended. In the abstract, the authors report the results of these syntheses for the PROMs that were found to have sufficient ratings for these measurement properties, along with the certainty of the evidence for content validity.

"Both had sufficient ratings for aspects of content validity, although with mostly very low-quality evidence. Sufficient ratings for structural validity, internal consistency, and reliability were also found for both instruments, but responsiveness was rated inconsistent for both instruments. The other PROMs or subscales often had insufficient aspects of content validity, or their unidimensionality could not be confirmed."[18]

Example 2: In a review examining the validity and reliability of quality of life questionnaires in patients with ankylosing spondylitis and non-radiographic axial spondylarthritis,[34] the authors opted to present the syntheses of the instruments with the most favorable measurement properties.

"Cronbach's alpha (α) Coefficients were generally high (0.79–0.97) for overall scales. The ankylosing spondylitis quality of life (ASQOL) and evaluation of ankylosing spondylitis quality of life (EASi-QoL) questionnaires showed the strongest measurement properties in high-quality studies. The correlation coefficient for test–retest reliability of the ASQOL questionnaire was 0.85 (95% CI 0.80 to 0.89). The pooled Cronbach's α coefficients of the ASQOL questionnaire and the EASi-QoL questionnaire were high."[34]

Abstract – Discussion

Limitations of evidence

Item #2.12: Provide a brief summary of the limitations of the evidence included in the review (e.g., study risk of bias, inconsistency, and imprecision).

Explanation: The abstract should briefly describe the limitations of the evidence across studies.[21] Briefly summarizing the completeness, applicability, and uncertainties in the evidence included in the review should help readers interpret the findings appropriately.[2] For example, authors might acknowledge that they identified few eligible studies or studies with a small number of participants, leading to imprecision; have concerns about risk of bias in studies or missing results; found studies with conflicting results, leading to inconsistency; or identified studies that only partially or indirectly address the population of interest, leading to concerns about their relevance and applicability to particular patients, settings, or other target audiences.[2]

Essential elements

- Provide a brief summary of the limitations of the evidence included in the review (e.g., study risk of bias, inconsistency, and imprecision).

Example of item #2.12

Example 1: "However, due to the high heterogeneity of the studies available, these results should not be considered conclusive."[43]

Example 2: "In interpreting the outcomes, one should therefore be aware that not all relevant aspects of physical functioning may be accounted for in the *LEFS*."[28]

Example 3: "The *HAQ*, however, was frequently associated with considerable ceiling effects while the *SF-36* has limited content coverage."[39]

Example 4: "The quantity and quality of the evidence on the other measurement properties of the included questionnaires varied substantially with insufficient sample sizes and/or poor methodological quality resulting in significant downgrading of evidence quality."[36]

Interpretation

Item #2.13: Provide a general interpretation of the results and important implications.

Explanation: To help readers interpret the results, an overall summary of the main findings should be given.[21] This could include an indication of what is clear, what important uncertainties remain, and whether further research is needed to address these.[21] If there is not enough evidence from well-conducted studies to answer the review's question, this should be made clear to the reader.[21] If the conclusions of the review differ substantially from previous systematic reviews, then some explanation might also be provided.[21] Possible implications for policy and practice should be stated.[21] The general interpretation and implications could be linked to the rationale of the review (for example, to provide an overview of the quality of available OMIs or to select the best OMI for a particular use (e.g., in a core outcome set or a clinical trial)).

Essential elements

- Provide a general interpretation of the results and important implications.

Additional elements

- Consider linking the general interpretation and important implications to the rationale for the review (for example to provide an overview of the quality of available OMIs or to select the best OMI for a particular use).

Example of item #2.13

Example 1: "We suggest considering the KDQOL-36 for use in pre-dialysis patients; the KDQOL-SF or KDQOL-36 for dialysis patients and the ESRD-SCLTM for use in transplant recipients. However, further research is required to evaluate the measurement error, structural validity, responsiveness and patient acceptability of PROMs [patient-reported outcome measures] used in CKD [chronic kidney disease]."[44]

Example 2: "The first studies into the Dutch–Flemish PROMIS-PF item bank and the UE [upper extremity] subdomain show promising results, with especially high quality evidence for sufficient structural validity and measurement precision. However, more studies, and with higher methodological quality, are needed to study the instruments derived from these item banks. These studies should also evaluate content validity, reliability and responsiveness."[37]

Example 3: "Our review shows there is extensive evidence on the internal consistency and structural validity of QoL [quality of life] instruments used on parents during pregnancy and the postpartum period, but that the evidence on other psychometric properties is sparse. Validation studies and primary studies are needed to provide evidence on the reliability, validity, responsiveness, and interpretability of QoL instruments for this target group, in particular for fathers and partners."[45]

Example 4: "Smartphone applications showed sufficient intra-rater reliability, inter-rater reliability, and validity to measure neck ROM [range of motion] in people with and without neck pain. However, the quality of evidence and the confidence in the findings are low. High-quality research with large sample sizes is needed to further provide evidence to support the measurement properties of smartphone applications for the assessment of neck ROM."[46]

Abstract – Examples containing all Abstract reporting items

Here, we provide two fictional examples that contain all Abstract reporting items within 350 words. These examples can be used by authors who are drafting their abstract, either for conferences or for journals. Example 1 is based on a conference abstract submitted to the 9th Annual PROMIS® International Conference by Stallwood et al.,[47] whereas example 2 is based on a journal abstract as published by Elsman et al., 2022.[18]

Example 1: **Measurement properties of pediatric PROMIS questionnaires for overall pediatric health: a systematic review**

Background: The International Consortium for Health Outcomes Measurement (ICHOM) recently developed a standard set for overall pediatric health outcomes in routine care, which recommends Patient-Reported Outcomes Measurement Information System (PROMIS) measures to measure global health and cognitive functioning.

Objective: To systematically evaluate whether the PROMIS Pediatric Scale v1.0- Global Health 7+2, PROMIS Parent Proxy Scale v1.0- Global Health 7+2, and the PROMIS Parent Proxy Short Form v1.0 - Cognitive Function 7a have sufficient measurement properties to be recommended for their target age groups in pediatric healthcare, according to the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines.

Methods: Embase, PsycINFO, and Web of Science were searched from year of inception of the Outcome Measurement Instruments measures to May 25, 2020; MEDLINE was searched up to October 24, 2022. Studies were included if they reported on the development or aimed to evaluate at least one measurement property of the aforementioned PROMIS measures. We used the COSMIN guideline for systematic reviews to appraise eligible studies (e.g., risk of bias of studies and measurement properties' results), synthesize, and descriptively summarize the overall evidence to determine whether these measures can be recommended for use.

Results: Screening of over 4000 titles and abstracts yielded 4 to 6 eligible study reports for each measure. While all measures met the minimum COSMIN criteria for recommending its use (i.e., sufficient evidence for content validity, and at least low-quality evidence for sufficient structural validity and internal consistency), the quality of the evidence for content validity was low due to poor reporting.

Conclusion: The PROMIS measures evaluated in this review measure their intended construct for their targeted age group and are fit-for-purpose for child health outcome measurement. Implementation of standard outcome sets with measures that are valid, reliable, and responsive to change will lay the foundation for value-based child and adolescent healthcare. As most studies included in this review were conducted in English speaking populations, future research is needed to confirm if these measures are valid and reliable in other languages.

Funding: No funding was received for this study.

Registration: OSF: https://osf.io/vx92r/

Example 2: **Systematic review on the measurement properties of diabetes-specific patient-reported outcome measures (PROMs) for measuring physical functioning in people with type 2 diabetes**

Objective: To systematically assess the measurement properties of diabetes-specific patient-reported outcome measures (PROMs) for measuring physical functioning, one of the core outcomes, in adults with type 2 diabetes.

Methods: Studies reported in English were included if they reported on the development or validation of a diabetes-specific PROM or subscale measuring physical functioning. Embase and MEDLINE were searched from year of inception to January 1, 2022. Risk of bias was evaluated with the COSMIN Risk of Bias checklist. Measurement properties of PROMs or subscales were rated using Terwee's criteria. If multiple studies on the same measurement property for the same PROM were found, results were synthesized descriptively.

Results: In total 21 study reports were included, describing 12 versions of 7 unique diabetes-specific PROMs or subscales measuring physical functioning. In general, there were few high-quality studies on measurement properties of PROMs measuring physical functioning in adults with type 2 diabetes. The Dependence/Daily Life subscale of the Diabetic Foot Ulcer Scale—Short Form (DFS-SF) and the Impact of Weight on Activities of Daily Living Questionnaire (IWADL) were most extensively evaluated. Both had sufficient ratings for aspects of content validity, although mostly with very low-quality evidence. Sufficient ratings for structural validity, internal consistency, and reliability were also found for both instruments, but responsiveness was rated inconsistent for both instruments. The other PROMs or subscales often had insufficient aspects of content validity, or their unidimensionality could not be confirmed.

Discussion: This systematic review showed that the Dependence/Daily Life subscale of the DFS-SF and the IWADL could be used to measure physical functioning in people with type 2 diabetes in research or clinical practice, while keeping the limitations of these instruments in mind. The measurement properties that have not been evaluated extensively for these PROMs should be evaluated in future studies. High risk of bias was found for many of the included studies, especially for the measurement properties content validity, structural validity, and reliability, leading to more uncertainty in the body of evidence.

Registration: The study protocol was registered in the PROSPERO database, number CRD42021234890.

Funding: No specific funding was received for this research.

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