COSMIN
www.cosmin.nl

COMET INITIATIVE

Selecting outcome measurement instruments for COS

C.A.C. (Sanna) Prinsen, PhD
Caroline B. Terwee, PhD

VU University Medical Center
Amsterdam Public Health research institute
Department of Epidemiology and Biostatistics

VU university medical center

mim KNOWLEDGECENTER MEASUREMENTINSTRUMENTS

EMGO+ Institute for Health and Care Research

COSMIN
www.cosmin.nl

‘What to measure’

‘How to measure’

The Author(s) *Trials* 2017, **18**(Suppl 3):280
DOI 10.1186/s13063-017-1978-4

Trials

REVIEW Open Access

The COMET Handbook: version 1.0

Paula R. Williamson[1*], Douglas G. Altman[2], Heather Bagley[1], Karen L. Barnes[1], Jane M. Blazeby[3], Sara T. Brookes[3], Mike Clarke[4,5], Elizabeth Gargon[1], Sarah
Cecilia A. C. Prinsen[6], Jochen Schmitt[7], C

Prinsen *et al. Trials* (2016) 17:449
DOI 10.1186/s13063-016-1555-2

Trials

RESEARCH Open Access

How to select outcome measurement instruments for outcomes included in a “Core Outcome Set” – a practical guideline

Cecilia A. C. Prinsen[1*], Sunita Vohra[2,3,4], Michael R. Rose[5], Maarten Boers[1,6], Peter Tugwell[7], Mike Clarke[8], Paula R. Williamson[9] and Caroline B. Terwee[1]

COSMIN
www.cosmin.nl

COSMIN-COMET collaboration

COSMIN: COnsensus-based **S**tandards for the selection of health **M**easurement **IN**struments initiative

COSMIN aims to improve the selection of outcome measurement instruments in research and clinical practice

COSMIN tools:

- Taxonomy of measurement properties
- Methodology for systematic reviews of outcome measurement instruments
- Database of systematic reviews of outcome measurement instruments

COSMIN
www.cosmin.nl

Content

Four steps in the selection of OMIs for COS

1. Conceptual considerations
2. Finding all available OMIs
3. Quality assessment of the OMIs
    a) Measurement properties
    b) Feasibility
4. Selection of OMIs for COS

COSMIN
www.cosmin.nl

1. Conceptual considerations

Aspects to consider **before** starting to search for outcome measurement instruments:

a) Construct of interest

b) Target population

Aspects to consider:

Are the **constructs to be measured** (i.e. core outcomes) and the **population of interest** clearly (enough) described in the scope of the COS or is more detail required for the selection of instruments?

COSMIN
www.cosmin.nl

1. Conceptual considerations

a) Construct of interest

COS developers should agree in detail upon the construct to be measured before starting to search for outcome measurement instruments

For example:

Construct: pain → What exactly do you want to measure?

Pain intensity, pain interference, pain behaviour?
Average pain last week, current pain, achievement of an acceptable pain state, area under the curve of pain scores during a given period of time, … ?

COSMIN
www.cosmin.nl

1. Conceptual considerations

b) Target population

Explore relevant subgroups and determine if there will be separate recommendations needed for outcome measurement instruments most applicable to each of the potential subgroups

For example: age, gender, disease characteristics, etc

Also consider the context of use

For example: inpatient or outpatient setting, administration mode, country/language version, etc

COSMIN
www.cosmin.nl

2. Finding all existing instruments

It is recommended that COS developers aim for finding **all** existing instruments

Three sources of information:

a. Use existing, good quality and up-to-date **systematic reviews** of outcome measurement instruments

b. Perform a comprehensive **literature search or systematic review** if a good systematic review is not available (MEDLINE, EMBASE)

c. Use other sources (optional)

COSMIN
www.cosmin.nl

COSMIN database

www.cosmin.nl or http://database.cosmin.nl/

Search !

Keywords

Author

Drop down menu

COSMIN methodology for systematic reviews

COSMIN

www.cosmin.nl

Publications

Prinsen CAC, Mokkink LB, Bouter LM, Alonso J, Patrick DL, de Vet HCW, Terwee CB. COSMIN guideline for systematic reviews of Patient-Reported Outcome Measures. Qual Life Res in press.

Terwee CB, Prinsen CAC, Chiarotto A, Westerman MJ, Patrick DL, Alonso J, Bouter LM, de Vet HCW, Mokkink LB. COSMIN standards and criteria for evaluating the content validity of Patient-Reported Outcome Measures: a Delphi study. Qual Life Res in press.

Mokkink LB, de Vet HCW, Prinsen CAC, Patrick DL, Alonso J, Bouter LM, Terwee CB. COSMIN Risk of Bias checklist for systematic reviews of Patient-Reported Outcome Measures. Qual Life Res 2017, Dec 19 [Epub].

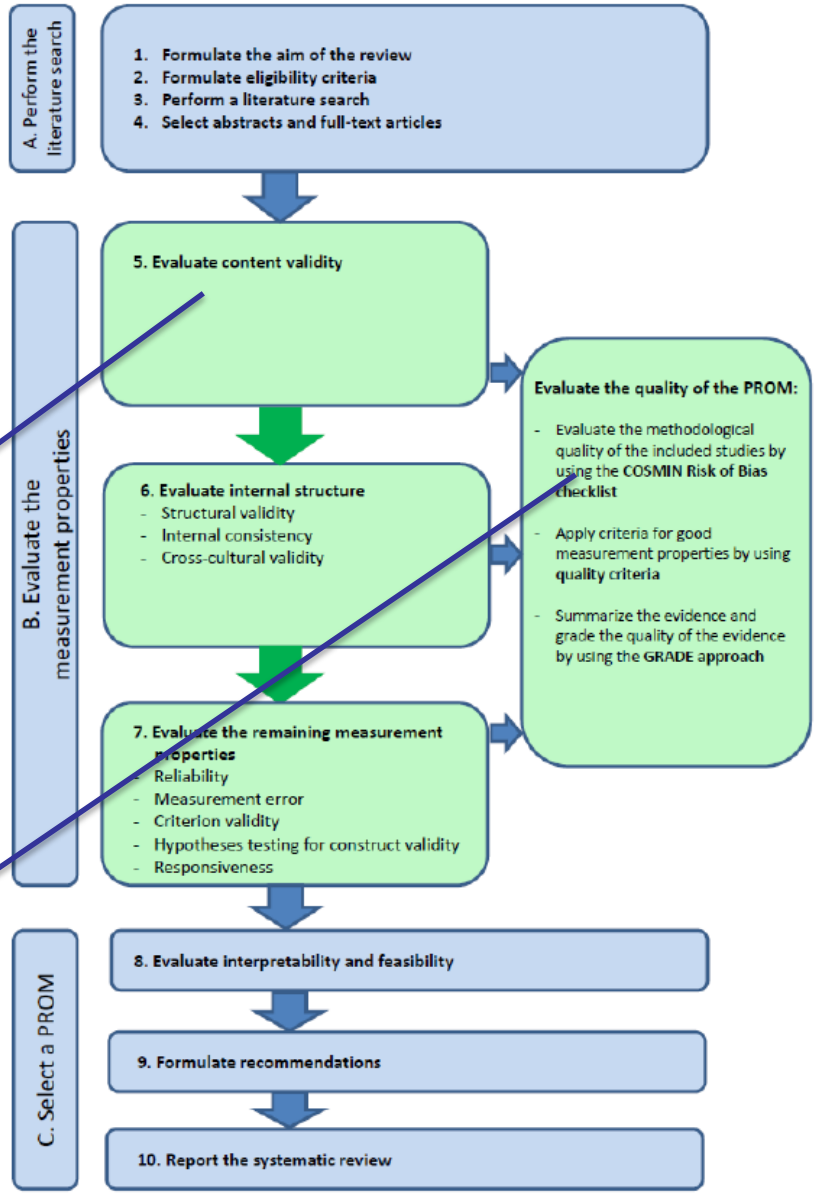


Figure 2. Ten steps for conducting a systematic review of PROMs [4]

COSMIN methodology for systematic reviews

COSMIN
www.cosmin.nl

Four steps in the selection of OMIs for COS

1. Conceptual considerations
2. Finding all available OMIs
3. Quality assessment of the OMIs
   a) Measurement properties
   b) Feasibility
4. Selection of OMIs for COS

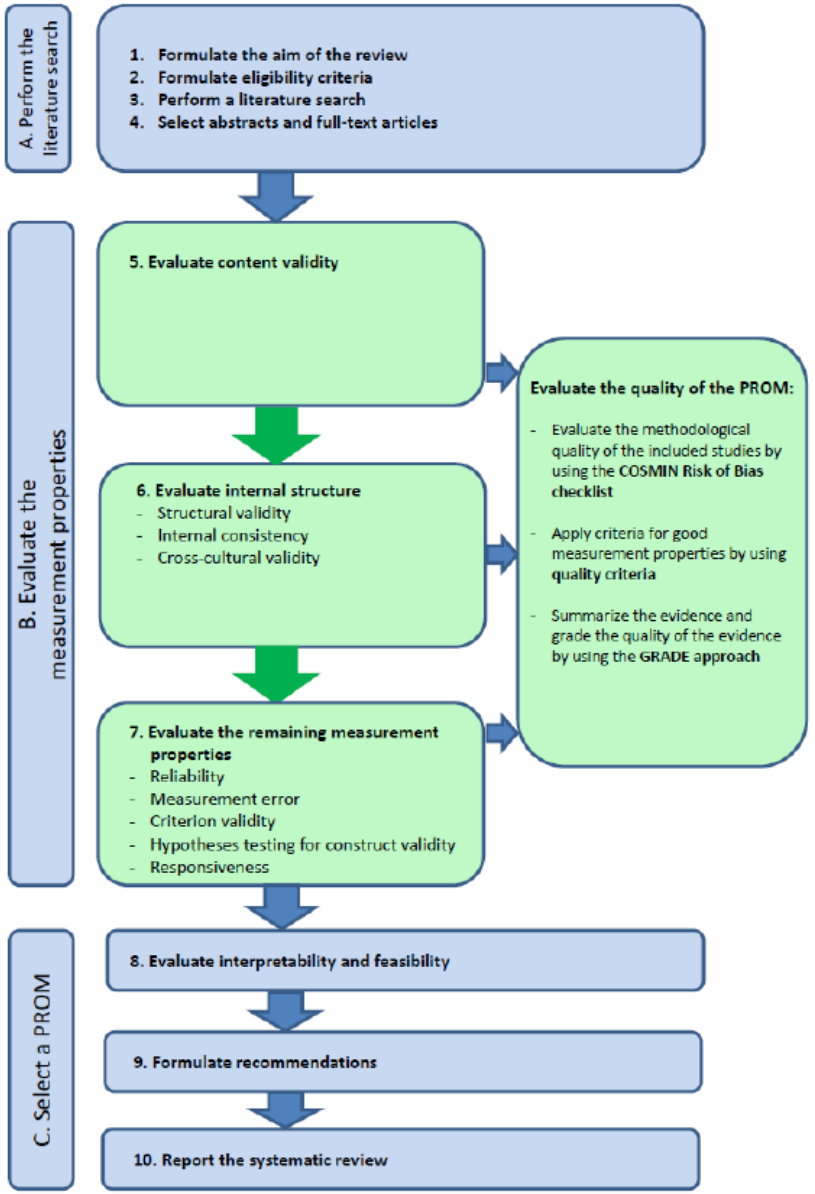


Figure 2. Ten steps for conducting a systematic review of PROMs [4]

COSMIN
www.cosmin.nl

4. Selection of OMIs for COS

"We recommend that an outcome measurement instrument can be provisionally included in a COS if there is ***at least strong evidence for good content validity and for good internal consistency*** *(if applicable), and if the instrument seems feasible."*

"Conversely there should be an absence of strong evidence that one or more other measurement properties are poor."

"When no instrument with good content validity is available, we recommend developing a new instrument, followed by a quality assessment of the instrument."

COSMIN
www.cosmin.nl

COSMIN criteria for determing the evidence for measurement properties

The total body of evidence for a measurement property is rated as sufficient (good) or insufficient based on criteria for good measurement properties

example

Reliability	+	ICC or weighted Kappa ≥ 0.70
	?	ICC or weighted Kappa not reported
	–	ICC or weighted Kappa < 0.70

COSMIN
www.cosmin.nl

COSMIN (GRADE) grading of the quality of the evidence

Each rating is accompanied by a grading for the quality of the evidence (based on GRADE)

Table 5. Definitions of quality levels

Quality level	Definition
High	We are very confident that the true measurement property lies close to that of the estimate* of the measurement property
Moderate	We are moderately confident in the measurement property estimate: the true measurement property is likely to be close to the estimate of the measurement property, but there is a possibility that it is substantially different
Low	Our confidence in the measurement property estimate is limited: the true measurement property may be substantially different from the estimate of the measurement property
Very low	We have very little confidence in the measurement property estimate: the true measurement property is likely to be substantially different from the estimate of the measurement property

COSMIN
www.cosmin.nl

COSMIN (GRADE) grading of the quality of the evidence

The quality of the evidence is high unless there is risk of bias, inconsistency, imprecision, or indirectness of results.

Quality of evidence	Lower if
High	Risk of bias -1 Serious -2 Very serious -3 Extremely serious Inconsistency -1 Serious -2 Very serious Imprecision -1 total n=50-100 -2 total n<50 Indirectness -1 Serious -2 Very serious
Moderate	
Low	
Very low	

Risk of bias	Downgrading for Risk of Bias
No	There are multiple studies of at least adequate quality, or there is one study of very good quality available
Serious	There are multiple studies of doubtful quality available, or there is only one study of adequate quality
Very serious	There are multiple studies of inadequate quality, or there is only one study of doubtful quality available
Extremely serious	There is only one study of inadequate quality available

COSMIN
www.cosmin.nl

Example conclusions

"There is low quality evidence for insufficient internal consistency of instrument X"

"There is moderate quality evidence for sufficient test-retest reliability of instrument X"

"There is no evidence on the responsiveness of instrument X"

COSMIN
www.cosmin.nl

COSMIN recommendations for selecting instruments

PROMs are categorized into three categories

(A) PROMs with evidence for sufficient content validity (any level) AND at least low quality evidence for internal consistency;

(B) PROMs categorized not in A or C.

(C) PROMs with high quality evidence for an insufficient measurement property

"We recommend that an outcome measurement instrument can be provisionally included in a COS if there is ***at least strong evidence for good content validity and for good internal consistency*** *(if applicable), and if the instrument seems feasible."*

COSMIN
www.cosmin.nl

Consider new outcome measurement instruments

Newly developed instruments are often based on more patient input → Better content validity

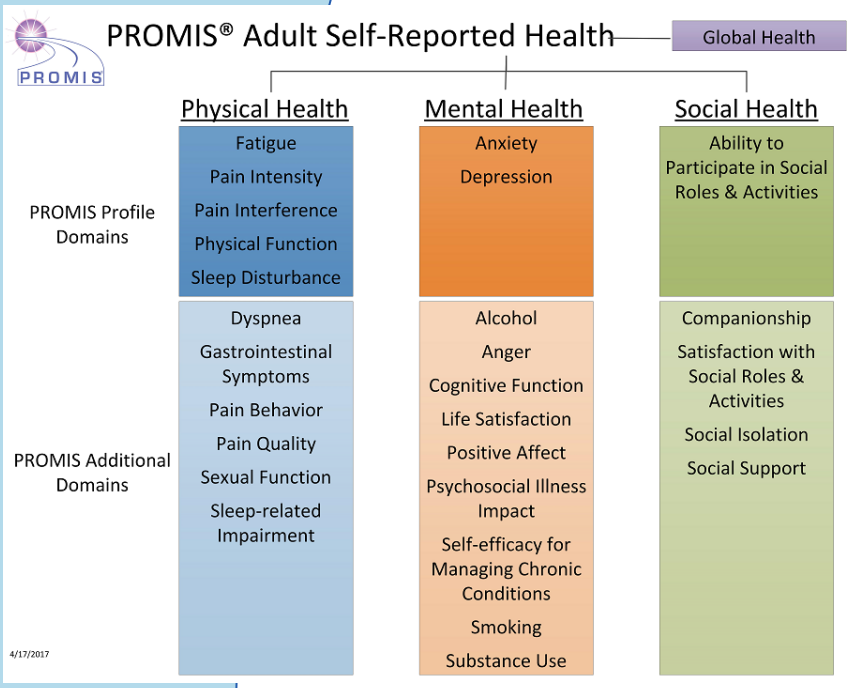
Newly developed instruments are increasingly based on Item Response Theory (IRT) → better internal structure, better reliability, better interpretability

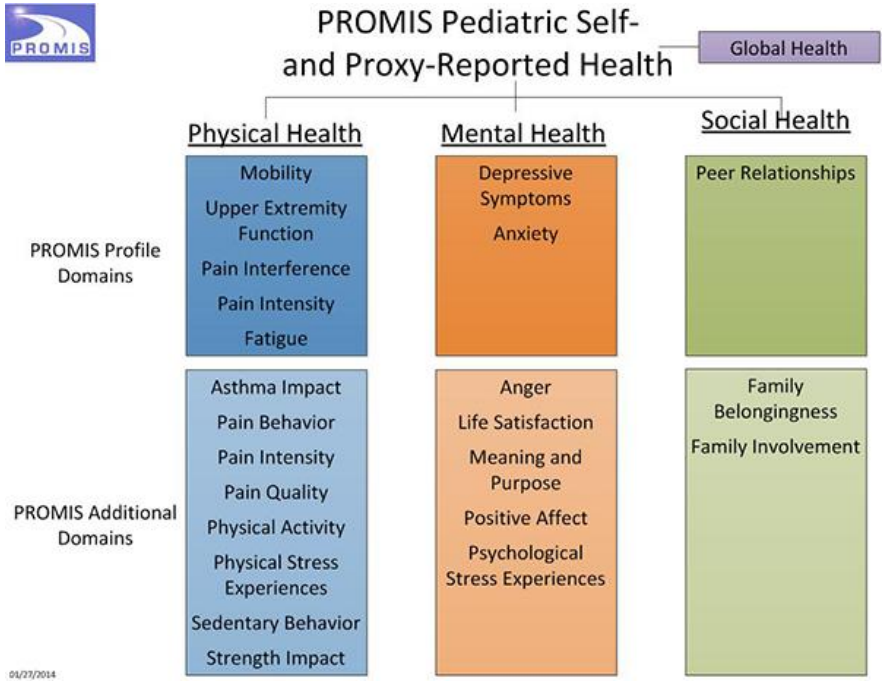
COSMIN
www.cosmin.nl

Patient-Reported Outcomes Measurement Information System (PROMIS)

PROMIS contains generic IRT-based instruments than can be used across patient populations

(www.healthmeasures.net/promis)

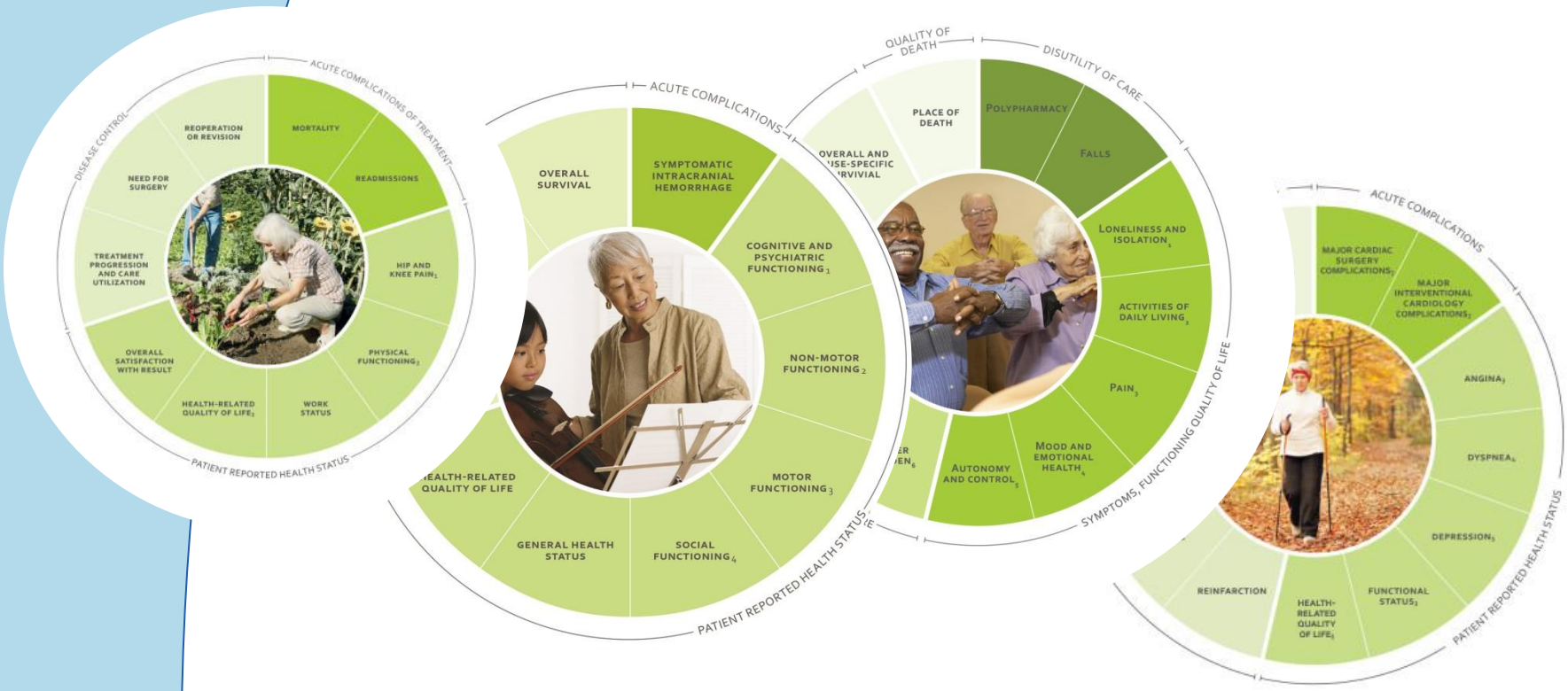




COSMIN
www.cosmin.nl

Consider ICHOM sets

The International Consortium for Health Outcomes Measurement (ICHOM) develops Standard Sets for clinical practice → content overlaps with COS



COSMIN
www.cosmin.nl

4. Selection of OMIs for COS

*"We recommend, in principle, to **select only one outcome measurement instrument** for each outcome in a COS. This will enhance the comparability of future clinical trials."*

*"If the outcome of interest is a **complex outcome** (e.g., pain) that consists of multiple aspects that are being measured by different outcome measurement instruments (e.g., pain intensity, pain interference), we recommend that these different aspects be considered as different outcomes."*

COSMIN
www.cosmin.nl

Summary

Four steps in the selection of OMIs for COS

1. Conceptual considerations
2. Finding all available OMIs
3. Quality assessment of the OMIs
    a) Measurement properties
    b) Feasibility
4. Selection of OMIs for COS

Consider new, preferably IRT-based instruments

COSMIN
www.cosmin.nl

Questions?

c.prinsen@vumc.nl