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Measurement properties of patient-reported outcome measures (PROMs) used in adult patients with chronic kidney disease: a systematic review protocol

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Keywords: measurement properties, psychometric, chronic kidney disease, chronic renal failure, quality of life, QoL.

Word count: 2,051

ABSTRACT

Introduction: Chronic kidney disease (CKD) is associated with symptoms that can significantly reduce the quality of life (QoL) of patients. Patient-reported outcome measures (PROMs) may facilitate the assessment of the impact of disease and treatment on the quality of life, from a patient perspective. PROMs can be used in research and routine clinical practice.

Methods and analysis: A systematic review of studies evaluating the measurement properties of PROMs in adults with CKD will be conducted. MEDLINE, EMBASE, PsycINFO and CINAHL Plus will be systematically searched from inception. Hand searching of reference lists and citations of included studies will be carried out. At least two reviewers will independently screen the titles and abstracts of all the studies retrieved during the systematic search to determine their eligibility. The COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist will be used to appraise the methodological quality of the selected studies following the full text review. Data on the study population, questionnaire characteristics and measurement properties will be extracted from the selected papers. Finally, a narrative synthesis of extracted data will be undertaken.

Ethics and dissemination: Ethical permissions are not required for this study as data from published research articles will be used. Findings will be disseminated through publication in a peer-reviewed journal and presented at conferences.

This systematic review will provide a comprehensive assessment of the measurement properties of PROMs currently available for use in adult patients with CKD and present evidence which may inform the selection of measures for use in research and clinical practice.

PROSPERO registration number: CRD42016035554

Strengths and limitations of this study

- A key strength of this systematic review is that multiple databases will be searched by multiple independent reviewers, with no language or publication date restrictions, thus minimising the risk of selection bias.
- A further strength is that the methodological quality of selected studies will be evaluated using the validated COSMIN checklist.
- This review will include studies relating to chronic kidney disease in adults and exclude studies of all other kidney conditions and children, this decision has been taken to ensure the results are focused on the study research question.

Keywords: measurement properties, psychometric, chronic kidney disease, chronic renal failure, quality of life, QoL, symptoms, patient-reported outcome measures, PROM.

INTRODUCTION

Chronic Kidney Disease (CKD) is defined as the existence of kidney damage (i.e. pathological abnormalities or markers of damage) for 3 months or more; and/or an estimated Glomerular Filtration Rate (eGFR) less than 60ml/min/1.73m^2 for three months or longer, with or without kidney damage.[1]

CKD affects up to 16% of adults in the UK [2] and is associated with poor outcomes, with a high proportion of patients dying before reaching end stage renal disease.[3, 4] According to the UK Department of Health, the total cost of providing renal care by the National Health Service (NHS) was £1.64 billion in 2009-2010.[5] Aside from these overt costs, the NHS bears other costs accrued from treating associated conditions while patients and caregivers have to contend with possible loss of income.[5]

Patients with CKD often suffer simultaneously from multiple symptoms related to the condition or side effects of their medical treatment.[6] These clusters of symptoms may exert an adverse effect not only on their physical health but also on their psychological and emotional well-being; giving rise to what is described as a 'symptom burden'.[7] A review by Almutary et al.[8] identified 30 symptoms associated with CKD, with five symptoms (fatigue, drowsiness, pain, pruritus and dry skin) particularly common in all stages.[8] They concluded that the overall symptom burden was high regardless of disease stage.[8] This symptom burden is now acknowledged as the most important predictor of diminished health-related quality of life (HRQoL) in patients with CKD.[9]

In a clinical context, HRQoL refers to the manner in which the physical, emotional and social well-being of an individual is affected by a disease and/or its

treatment.[10] HRQoL can be measured using self-administered, validated questionnaires also known as patient-reported outcomes measures (PROMs).[11, 12]

PROMs have numerous applications in clinical trials and routine clinical settings. They are employed in clinical trials as measures of effectiveness and pharmaceutical companies may use PROM data to support product approvals and labelling claims.[13] PROMs can aid the reporting of serious adverse events due to drug toxicities [14] and trial data can also influence clinical care and health policy.[15, 16]

In routine clinical practice, PROMs are mainly used as tools for benchmarking and hospital performance assessment.[17] However, PROMs also have the potential to assist in the delivery of personalised care.[11, 17-21]

Currently, primary and secondary care records in the UK are being linked together such that patient information is more readily available to clinicians when required.[22] The integration of patient-reported outcome (PRO) data with other routinely collected clinical data could provide an opportunity for revolutionising the UK healthcare system by facilitating the delivery of stratified medicine, enhancing clinical audits, and assisting with the designing of pragmatic trials.[12, 21]

Given the vast array of PROMs in existence, [23] the selection of an appropriate measure for any purpose requires the careful consideration of their measurement properties in order to derive any meaningful benefit from their application. It is crucial that such decisions are backed by the best evidence available, preferably from a recent systematic review.[12]

A scoping search identified two relevant systematic reviews namely: a 2010 review by Gibbons and Fitzpatrick and a 2012 review by Wyld et al.[24, 25] Although both reviews presented evidence of the measurement properties of PROMs in CKD, there is a realistic possibility that more relevant research work has been done since their publication.[26] In addition, the Wyld et al. study focused entirely on utility measures, and both studies had eligibility criteria which might have excluded potentially relevant studies.[24, 25]

Therefore, after considering the issues above, we concluded that a full systematic review is required. The aim of this systematic review will be to evaluate the measurement properties of PROMs currently available for use in adults with CKD. This study will draw from the methods used by the earlier reviews, with appropriate modifications to ensure that the most up-to-date and robust evidence is obtained.

METHODS AND ANALYSIS

Design

The protocol has been registered with PROSPERO (registration number CRD42016035554). It was developed using the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) checklist.[27]

The review will be conducted and reported in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.[28]

Search strategy

The following electronic databases will be systematically searched from inception: MEDLINE (Ovid), EMBASE (Ovid), PsycINFO (Ovid) and CINAHL Plus (EBSCO). Literature search results will be uploaded to Endnote X7 (©Thomson Reuters). There will be no publication period or language restrictions.[29] The UK Renal Registry will be searched and expert recommendations from members of the review team will be followed up to help identify any additional measures currently under development.

The search strategy for MEDLINE was developed in consultation with an information specialist at the Institute of Applied Health Research, University of Birmingham. Two existing search filters, the sensitivity search filter developed by Terwee et al. and the Oxford PROM filter,[30, 31] were combined with key terms for renal disease generated by the review team. The MEDLINE search strategy was adapted for use and piloted on all the databases. (See Appendixfor the full search strategy).

Selection of studies

To be considered for selection, an article must focus on PROMs used specifically for measuring QoL and/or CKD symptoms (the constructs of interest). In addition, the following inclusion and exclusion criteria will be applied.

Inclusion criteria:

1. Articles reporting PROM development in CKD populations.
2. Articles explicitly reporting the assessment of one or more psychometric properties for PROM(s) in CKD populations.
3. Articles reporting cross-cultural validation of PROMs in CKD populations.

Exclusion criteria:

1. Clinician-assessed instruments.
2. Instrument development studies solely in patients with acute kidney injury (AKI).
3. Instruments developed solely for use in patients below 18 years of age.
4. Trials or studies evaluating the effectiveness of interventions where a PROM questionnaire is used as an endpoint.
5. Editorials, reviews and conference abstracts.

One reviewer (OLA) will independently screen the titles and abstracts of all the studies retrieved during the systematic search to determine their eligibility. Two further reviewers (TK and AG) will each independently screen 50% of titles and abstracts. Full-text articles will be obtained for studies that potentially meet the eligibility criteria and will again be independently reviewed by the investigators (OLA, TK and AG). Reasons for exclusion at the full text stage of screening will be

recorded. At any stage, if the reviewers are unable to reach a consensus, a third reviewer will be consulted (MC/DK). Hand searching of reference lists and citations of selected papers will be conducted.

The process of selection will be summarised using a PRISMA flow diagram.

Appraisal of the methodological quality of selected studies

All eligible papers will be independently appraised by the reviewers using the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist.[32, 33] The COSMIN checklist is a validated critical appraisal tool designed for the systematic evaluation of the methodological quality of studies of the measurement properties of health measurement instruments.[33]

The COSMIN 4-point rating scale will be used to score each item in the relevant boxes of the checklist as 'excellent', 'good', 'fair' or 'poor'.[33] The 'worst score counts' method will be used to determine the overall rating for each selected paper.[33]

The following measurement properties as defined by Mokkink et al. will be evaluated [34]:

1. Reliability -"The proportion of the total variance in the measurements which is because of 'true' differences among patients" [34]

2. Internal consistency - "The degree of the interrelatedness among the items" [34]

3. Measurement error - "The systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured" [34]

4. Content validity - "The degree to which the content of an HR-PRO instrument is an adequate reflection of the construct to be measured" [34]

5. Construct validity - "The degree to which the scores of an HR-PRO instrument are consistent with hypotheses (for instance with regard to internal relationships, relationships to scores of other instruments, or differences between relevant groups) based on the assumption that the HR-PRO instrument validly measures the construct to be measured" [34]

6. Cross-cultural validity - "The degree to which the performance of the items on a translated or culturally adapted HR-PRO instrument are an adequate reflection of the performance of the items of the original version of the HR-PRO instrument" [34]

7. Criterion validity - "The degree to which the scores of an HR-PRO instrument are an adequate reflection of a 'gold standard'" [34]

8. Responsiveness -"The ability of an HR-PRO instrument to detect change over time in the construct to be measured" [34]

Data extraction

Data from selected studies will be extracted independently by the reviewers, using a piloted data collection form, with disagreements resolved through discussion and, if necessary, consultation with a third reviewer. Extracted data will be presented in tables.

Data on the following will be extracted:

(1) Characteristics of the study population (including age, gender, ethnicity and stage of CKD)

(2) Questionnaire Characteristics (including name/version, language, scoring method, domains, number of items)

(3) Evidence regarding the measurement properties of the questionnaire

(4) Setting and purpose for which questionnaire is administered, interpretability and operational characteristics such as patient acceptability, and feasibility of administration for staff will also be reported.

Data synthesis

The quality criteria developed by Terwee et al. will be used for the overall rating of the evidence supporting measurement properties as 'positive', 'indeterminate' or 'negative'.[35]

The findings on the measurement property of each PROM will be synthesised across studies in order to ascertain the level of evidence for each instrument while taking into consideration the methodological quality of the selected studies.[36]

This overall level of evidence will be rated as ‘strong’, ‘moderate’, ‘limited’ or ‘conflicting’ following the Cochrane Back Review Group guideline.[37]

ETHICS AND DISSEMINATION

Ethical permissions are not required for this study as data from published research articles will be used. Findings will be disseminated through publication in a peer-reviewed journal and presented at conferences.

DISCUSSION

We acknowledge that studies will evaluate differing measurement properties; therefore evidence might be limited or unavailable for some measurement properties.

This systematic review will present a comprehensive assessment of the measurement properties of PROMS currently available for use in adult patients with CKD and provide vital evidence which may inform the selection of measures for use in research and clinical practice.

Abbreviations

PROSPERO: International Prospective Register of Systematic Reviews; MEDLINE: The Medical Literature Analysis and Retrieval System Online; EMBASE: Excerpta Medica dataBASE; PsycINFO: Psychological Information Database; CINAHL Plus: Cumulative Index to Nursing and Allied Health Literature; COSMIN: COnsensus-based Standards for the selection of health Measurement Instruments.

Acknowledgement

We thank Susan Bayliss who assisted with the development of the search strategy as detailed in the methods section of the protocol.

Authors' Contributions

MC is the guarantor. The study was conceived and designed by MC, DK, PC and TM. OLA drafted the protocol manuscript. OLA, MC, DK, PC and TM contributed to the development of the search strategy. The selection criteria were developed by OLA, MC, DK, PC,TM, TK and AG. OLA piloted the search strategy on the databases. The manuscript was reviewed and the final draft approved by all authors.

Competing interests

The authors declare that there are no competing interests.

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The Health Foundation is not involved in any other aspect of the project, such as the design of the project's protocol, data collection, analysis and interpretation of results.

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MEDLINE (R) (Ovid) 1946 to 21/12/15

Note: Sets 1 to 6 are based on the Oxford PROM Filter.[1] Set 13 is the sensitive search filter for measurement properties developed by Terwee et al. [2]

1. (HR-PRO or HRPRO or HRQL or HRQoL or QL or QoL).ti,ab.

2. quality of life.mp.

3. (health index* or health indices or health profile*).ti,ab.

4. health status.mp.

5. ((patient or self or child or parent or carer or proxy) adj (appraisal* or appraised or report or reported or reporting or rated or rating or based or assessed or assessment*)).ti,ab.

6. ((disability or function or functional or functions or subjective or utility or utilities or wellbeing or well being) adj2 (index or indices or instrument or instruments or measure or measures or questionnaire* or profile or profiles or scale or scales or score or scores or status or survey or surveys)).ti,ab.

7. ((((patient adj reported adj outcome adj measure*) or patient) adj reported adj outcome*) or capability or capabilities).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

8. 1 or 2 or 3 or 4 or 5 or 6 or 7

9. (Renal replacement therapy or APD or Automated Peritoneal Dialysis or CAPD, Continuous Ambulatory Peritoneal Dialysis or CCPD or Continuous cyclic peritoneal dialysis or dialysis or h*emofiltration or h*emodiafiltration or h*emodialysis or kidney transplant* or predialysis or renal replacement or renal transplant*).mp.

10. (CRF or chronic renal failure or CKF or chronic kidney failure or kidney disease* or renal disease or kidney failure or renal failure or CKD or chronic kidney disease or ESKD or end stage kidney disease or ESKF or end stage kidney failure or ESRF or end stage renal failure or ESRD or end stage renal disease or kidney insufficiency).mp.

11. Renal Insufficiency, Chronic/

12. 9 or 10 or 11

13. ((((((((((((((((((((((((((Instrumentation or method* or Validation Studies or Comparative Study).mp. or psychometrics/ or psychometr*.mp. or clinimetr*.mp. or clinometr*.mp. or outcome assessment health care/ or outcome assessment*.ti,ab. or outcome measure*.mp. or observer variation/ or observer variation*.ti,ab. or Health Status Indicators/ or reproducibility of results/ or reproducib*.ti,ab. or discriminant analysis/ or reliab*.ti,ab. or unreliab*.ti,ab. or valid*.ti,ab. or coefficient of variation.ti,ab. or coefficient*.ti,ab. or homogeneity.ti,ab. or homogeneous.ti,ab. or internal consistency.ti,ab. or cronbach*.ti,ab.) and alpha*.ti,ab.) or item*.ti,ab.) and correlation*.ti,ab.) or selection*.ti,ab. or reduction*.ti,ab. or agreement.mp. or precision.mp. or imprecision.mp. or precise value*.mp. or test-retest.ti,ab. or test.ti,ab.) and retest.ti,ab.) or reliab*.ti,ab.) and test.ti,ab.) or retest.ti,ab. or stability.ti,ab. or interrater.ti,ab. or inter-rater.ti,ab. or intrarater.ti,ab. or intra-rater.ti,ab. or intertester.ti,ab. or inter-tester.ti,ab. or intratester.ti,ab. or intra-tester.ti,ab. or interobserver.ti,ab. or inter-observer.ti,ab. or intraobserver.ti,ab. or intra-observer.ti,ab. or intertechnician.ti,ab. or inter-technician.ti,ab. or intratechnician.ti,ab. or intra-technician.ti,ab. or interexaminer.ti,ab. or inter-examiner.ti,ab. or intraexaminer.ti,ab. or intra-examiner.ti,ab. or interassay.ti,ab. or inter-assay.ti,ab. or intraassay.ti,ab. or intra-assay.ti,ab. or interindividual.ti,ab. or inter-individual.ti,ab. or intraindividual.ti,ab. or intra-individual.ti,ab. or interparticipant.ti,ab. or inter-participant.ti,ab. or intraparticipant.ti,ab. or intra-participant.ti,ab. or kappa*.ti,ab. or kappa's.ti,ab. or repeatab*.mp. or replicab*.mp. or repeated.mp.) and measure*.mp.) or finding*.mp. or result*.mp. or test*.mp. or generaliza*.ti,ab. or generalisa*.ti,ab. or concordance.ti,ab. or intraclass.ti,ab.) and correlation*.ti,ab.) or discriminative.ti,ab. or known group.ti,ab. or factor analysis.ti,ab. or factor analyses.ti,ab. or factor structure.ti,ab. or factor structure.ti,ab. or dimension*.ti,ab. or subscale*.ti,ab. or multitrait.ti,ab.) and scaling.ti,ab. and analysis.ti,ab.) or analyses.ti,ab. or item discriminant.ti,ab. or interscale correlation*.ti,ab. or error.ti,ab. or errors.ti,ab. or individual variability.ti,ab. or interval variability.ti,ab. or rate variability.ti,ab. or variability.ti,ab.) and analysis.ti,ab.) or value*.ti,ab. or uncertainty.ti,ab.) and measurement.ti,ab.) or measuring.ti,ab. or standard error of measurement.ti,ab. or sensitiv*.ti,ab. or responsive*.ti,ab. or limit*.ti,ab.) and detection.ti,ab.) or minimal detectable concentration.ti,ab. or interpretab*.ti,ab. or minimal.ti,ab. or minimally.ti,ab. or clinical.ti,ab. or clinically.ti,ab.) and important.ti,ab.) or significant.ti,ab. or detectable.ti,ab.) and change.ti,ab.) or difference.ti,ab. or small*.ti,ab.) and real.ti,ab.) or detectable.ti,ab.) and change.ti,ab.) or difference.ti,ab. or meaningful change.ti,ab. or ceiling effect.ti,ab. or floor effect.ti,ab. or Item response model.ti,ab. or IRT.ti,ab. or Rasch.ti,ab. or Differential item functioning.ti,ab. or DIF.ti,ab. or computer adaptive testing.ti,ab. or item bank.ti,ab. or cross-cultural equivalence.ti,ab.

14. (PRO integration or Clinical PRO application* or telePRO or automated PRO algorithm* or screening purpose* or PRO questionnaire* or Patient-reported outcome questionnaire* or Patient-reported symptom* or Patient-centred care or Patient self-report* or Self-report health or Self-rated health or Self-reported measure* of health or Health outcome* or Health communication* or Hospital performance evaluation* or Automated telephone survey system* or paper-based survey* or web-based survey* or web-based PRO platform* or web-based system* or PRO collection* or PRO measure* or PRO intervention* or PRO assessment intervention* or PRO data or PRO assessment* or Routine PRO assessment* or Routine PRO collection or Symptom assessment* or Symptom monitoring or Symptom data or Functional status or Electronic PRO assessment* or Electronic PRO system* or ePRO or

ePRO* or ePRO system* or PRO system* or Generic PRO system* or PRO-based clinical alert system*).mp.

15. 13 or 14

16. 8 and 12 and 15

EMBASE (Ovid) 1974 to 21/12/15

Note: Set 4 is the sensitive search filter for measurement properties developed by Terwee et al. and adapted for EMBASE.[2]

1. (Renal replacement therapy or APD or Automated Peritoneal Dialysis or CAPD, Continuous Ambulatory Peritoneal Dialysis or CCPD or Continuous cyclic peritoneal dialysis or dialysis or h*emofiltration or h*emodiafiltration or h*emodialysis or kidney transplant* or predialysis or renal replacement or renal transplant*).mp.

2. (CRF or chronic renal failure or CKF or chronic kidney failure or kidney disease* or renal disease or kidney failure or renal failure or CKD or chronic kidney disease or ESKD or end stage kidney disease or ESKF or end stage kidney failure or ESRF or end stage renal failure or ESRD or end stage renal disease or kidney insufficiency).mp.

3. (PRO integration or Clinical PRO application* or telePRO or automated PRO algorithm* or screening purpose* or PRO questionnaire* or Patient-reported outcome questionnaire* or Patient-reported symptom* or Patient-centred care or Patient self-report* or Self-report health or Self-rated health or Self-reported measure* of health or Health outcome* or Health communication* or Hospital performance evaluation* or Automated telephone survey system* or paper-based survey* or web-based survey* or web-based PRO platform* or web-based system* or PRO collection* or PRO measure* or PRO intervention* or PRO assessment intervention* or PRO data or PRO assessment* or Routine PRO assessment* or Routine PRO collection or Symptom assessment* or Symptom monitoring or Symptom data or Functional status or Electronic PRO assessment* or Electronic PRO system* or ePRO or ePRO* or ePRO system* or PRO system* or Generic PRO system* or PRO-based clinical alert system*).mp.

4. ((exp questionnaire/ or exp named inventories/ or questionnaires/) and rating scales/) or exp psychometry/ or exp outcome assessment/ or exp pain assessment/ or exp disability/ or exp validity/ or exp reliability/

5. *patient/ or *outcome assessment/ or *questionnaire/ or *"quality of life"/ or *self report/

6. 3 or 4

7. 1 or 2

8. 5 and 6 and 7

PsycINFO (Ovid) 1967 to 21/12/15

Note: Sets 1 to 6 are based on the Oxford PROM Filter.[1] Set 11 is the sensitive search filter for measurement properties developed by Terwee et al.[2]

1. (HR-PRO or HRPRO or HRQL or HRQoL or QL or QoL).ti,ab.

2. quality of life.mp.

3. (health index* or health indices or health profile*).ti,ab.

4. health status.mp.

5. ((patient or self or child or parent or carer or proxy) adj (appraisal* or appraised or report or reported or reporting or rated or rating or based or assessed or assessment*)).ti,ab.

6. ((disability or function or functional or functions or subjective or utility or utilities or wellbeing or well being) adj2 (index or indices or instrument or instruments or measure or measures or questionnaire* or profile or profiles or scale or scales or score or scores or status or survey or surveys)).ti,ab.

7. ((((patient adj reported adj outcome adj measure*) or patient) adj reported adj outcome*) or capability or capabilities).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]

8. 1 or 2 or 3 or 4 or 5 or 6 or 7

9. (Renal replacement therapy or APD or Automated Peritoneal Dialysis or CAPD, Continuous Ambulatory Peritoneal Dialysis or CCPD or Continuous cyclic peritoneal dialysis or dialysis or h*emofiltration or h*emodiafiltration or h*emodialysis or kidney transplant* or predialysis or renal replacement or renal transplant*).mp.

10. (CRF or chronic renal failure or CKF or chronic kidney failure or kidney disease* or renal disease or kidney failure or renal failure or CKD or chronic kidney disease or ESKD or end stage kidney disease or ESKF or end stage kidney failure or ESRF or end stage renal failure or ESRD or end stage renal disease or kidney insufficiency).mp.

11. ((((((((((((((((((((((((((Instrumentation or method* or Validation Studies or Comparative Study).mp. or psychometrics/ or psychometr*.mp. or clinimetr*.mp. or clinometr*.mp. or outcome assessment health care/ or outcome assessment*.ti,ab. or outcome measure*.mp. or observer variation/ or observer variation*.ti,ab. or Health Status Indicators/ or reproducibility of results/ or reproducib*.ti,ab. or

discriminant analysis/ or reliab*.ti,ab. or unreliab*.ti,ab. or valid*.ti,ab. or coefficient of variation.ti,ab. or coefficient*.ti,ab. or homogeneity.ti,ab. or homogeneous.ti,ab. or internal consistency.ti,ab. or cronbach*.ti,ab.) and alpha*.ti,ab.) or item*.ti,ab.) and correlation*.ti,ab.) or selection*.ti,ab. or reduction*.ti,ab. or agreement.mp. or precision.mp. or imprecision.mp. or precise value*.mp. or test-retest.ti,ab. or test.ti,ab.) and retest.ti,ab.) or reliab*.ti,ab.) and test.ti,ab.) or retest.ti,ab. or stability.ti,ab. or interrater.ti,ab. or inter-rater.ti,ab. or intrarater.ti,ab. or intra-rater.ti,ab. or intertester.ti,ab. or inter-tester.ti,ab. or intratester.ti,ab. or intra-tester.ti,ab. or interobserver.ti,ab. or inter-observer.ti,ab. or intraobserver.ti,ab. or intra-observer.ti,ab. or intertechnician.ti,ab. or inter-technician.ti,ab. or intratechnician.ti,ab. or intra-technician.ti,ab. or interexaminer.ti,ab. or inter-examiner.ti,ab. or intraexaminer.ti,ab. or intra-examiner.ti,ab. or interassay.ti,ab. or inter-assay.ti,ab. or intraassay.ti,ab. or intra-assay.ti,ab. or interindividual.ti,ab. or inter-individual.ti,ab. or intraindividual.ti,ab. or intra-individual.ti,ab. or interparticipant.ti,ab. or inter-participant.ti,ab. or intraparticipant.ti,ab. or intra-participant.ti,ab. or kappa*.ti,ab. or kappa's.ti,ab. or repeatab*.mp. or replicab*.mp. or repeated.mp.) and measure*.mp.) or finding*.mp. or result*.mp. or test*.mp. or generaliza*.ti,ab. or generalisa*.ti,ab. or concordance.ti,ab. or intraclass.ti,ab.) and correlation*.ti,ab.) or discriminative.ti,ab. or known group.ti,ab. or factor analysis.ti,ab. or factor analyses.ti,ab. or factor structure.ti,ab. or factor structure.ti,ab. or dimension*.ti,ab. or subscale*.ti,ab. or multitrait.ti,ab.) and scaling.ti,ab. and analysis.ti,ab.) or analyses.ti,ab. or item discriminant.ti,ab. or interscale correlation*.ti,ab. or error.ti,ab. or errors.ti,ab. or individual variability.ti,ab. or interval variability.ti,ab. or rate variability.ti,ab. or variability.ti,ab.) and analysis.ti,ab.) or value*.ti,ab. or uncertainty.ti,ab.) and measurement.ti,ab.) or measuring.ti,ab. or standard error of measurement.ti,ab. or sensitiv*.ti,ab. or responsive*.ti,ab. or limit*.ti,ab.) and detection.ti,ab.) or minimal detectable concentration.ti,ab. or interpretab*.ti,ab. or minimal.ti,ab. or minimally.ti,ab. or clinical.ti,ab. or clinically.ti,ab.) and important.ti,ab.) or significant.ti,ab. or detectable.ti,ab.) and change.ti,ab.) or difference.ti,ab. or small*.ti,ab.) and real.ti,ab.) or detectable.ti,ab.) and change.ti,ab.) or difference.ti,ab. or meaningful change.ti,ab. or ceiling effect.ti,ab. or floor effect.ti,ab. or Item response model.ti,ab. or IRT.ti,ab. or Rasch.ti,ab. or Differential item functioning.ti,ab. or DIF.ti,ab. or computer adaptive testing.ti,ab. or item bank.ti,ab. or cross-cultural equivalence.ti,ab.

12. (PRO integration or Clinical PRO application* or telePRO or automated PRO algorithm* or screening purpose* or PRO questionnaire* or Patient-reported outcome questionnaire* or Patient-reported symptom* or Patient-centred care or Patient self-report* or Self-report health or Self-rated health or Self-reported measure* of health or Health outcome* or Health communication* or Hospital performance evaluation* or Automated telephone survey system* or paper-based survey* or web-based survey* or web-based PRO platform* or web-based system* or PRO collection* or PRO measure* or PRO intervention* or PRO assessment intervention* or PRO data or PRO assessment* or Routine PRO assessment* or Routine PRO collection or Symptom assessment* or Symptom monitoring or Symptom data or Functional status or Electronic PRO assessment* or Electronic PRO system* or ePRO or ePRO* or ePRO system* or PRO system* or Generic PRO system* or PRO-based clinical alert system*).mp.

13. 11 or 12

14. *Organ Transplantation/ or *Hemodialysis/ or *Kidneys/ or *Kidney Diseases/ or Renal Insufficiency, Chronic.mp.

15. 9 or 10 or 14

16. 8 and 13 and 15

CINAHL (via EBSCO host) inception to 21/12/15

Note: S1 is based on the Oxford PROM Filter.[1] S3 is the sensitive search filter for measurement properties developed by Terwee et al. [2]

S1. ((HR-PRO or HRPRO or HRQL or HRQoL or QL or QoL).ti,ab.) OR quality of life.mp. OR ((health index* or health indices or health profile*).ti,ab.) OR health status.mp. OR (((patient or self or child or parent or carer or proxy) adj (appraisal* or appraised or report or reported or reporting or rated or rating or based or assessed or assessment*)).ti,ab.) OR (((disability or function or functional or functions or subjective or utility or utilities or wellbeing or well being) adj2 (index or indices or instrument or instruments or measure or measures or questionnaire* or profile or profiles or scale or scales or score or scores or status or survey or surveys)).ti,ab.) OR (((((patient adj reported adj outcome adj measure*) or patient) adj reported adj outcome*) or capability or capabilities).mp)

S2. (MH "Kidney Failure, Chronic/TH/TM/TD/SU/SS/RF/RH/PF/PR/PC/PP/PA/NU/MO/ME/ET/EI/EP/ED/EC/DT/DI/CO/CL") OR "((Renal replacement therapy or APD or Automated Peritoneal Dialysis or CAPD, Continuous Ambulatory Peritoneal Dialysis or CCPD or Continuous cyclic peritoneal dialysis or dialysis or h*emofiltration or h*emodiafiltration or h*emodialysis or kidney transplant* or predialysis or renal replacement or renal transplant*).mp.) OR ((CRF or chronic renal failure or CKF or chronic kidney failure or kidney disease* or renal disease or kidney failure or renal failure or CKD or chronic kidney disease or ESKD or end stage kidney disease or ESKF or end stage kidney failure or ESRF or end stage renal failure or ESRD or end stage renal disease or kidney insufficiency).mp.) OR (*Organ Transplantation/ or *Hemodialysis/ or *Kidneys/ or *Kidney Diseases/ or Renal Insufficiency, Chronic.mp.)"

S3. ""(((((((((((((((((((((((((((Instrumentation or method* or Validation Studies or Comparative Study).mp. or psychometrics/ or psychometr*.mp. or clinimetr*.mp. or clinometr*.mp. or outcome assessment health care/ or outcome assessment*.ti,ab. or outcome measure*.mp. or observer variation/ or observer variation*.ti,ab. or Health Status Indicators/ or reproducibility of results/ or reproducib*.ti,ab. or discriminant analysis/ or reliab*.ti,ab. or unreliab*.ti,ab. or valid*.ti,ab. or coefficient of variation.ti,ab. or coefficient*.ti,ab. or homogeneity.ti,ab. or homogeneous.ti,ab. or internal consistency.ti,ab. or cronbach*.ti,ab.) and alpha*.ti,ab.) or item*.ti,ab.) and correlation*.ti,ab.) or selection*.ti,ab. or reduction*.ti,ab. or agreement.mp. or precision.mp. or imprecision.mp. or precise value*.mp. or test-retest.ti,ab. or test.ti,ab.) and retest.ti,ab.) or reliab*.ti,ab.) and test.ti,ab.) or retest.ti,ab. or stability.ti,ab. or interrater.ti,ab. or inter-rater.ti,ab. or intrarater.ti,ab. or intra-rater.ti,ab. or intertester.ti,ab. or inter-tester.ti,ab. or intratester.ti,ab. or intra-tester.ti,ab. or interobserver.ti,ab. or inter-observer.ti,ab. or intraobserver.ti,ab. or intra-

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S4. ((PRO integration or Clinical PRO application* or telePRO or automated PRO algorithm* or screening purpose* or PRO questionnaire* or Patient-reported outcome questionnaire* or Patient-reported symptom* or Patient-centred care or Patient self-report* or Self-report health or Self-rated health or Self-reported measure* of health or Health outcome* or Health communication* or Hospital performance evaluation* or Automated telephone survey system* or paper-based survey* or web-based survey* or web-based PRO platform* or web-based system* or PRO collection* or PRO measure* or PRO intervention* or PRO assessment intervention* or PRO data or PRO assessment* or Routine PRO assessment* or Routine PRO collection or Symptom assessment* or Symptom monitoring or Symptom data or Functional status or Electronic PRO assessment* or Electronic PRO system* or ePRO or ePRO* or ePRO system* or PRO system* or Generic PRO system* or PRO-based clinical alert system*).mp.)""

S5. S3 or S4

S6. S1 and S2 and S5

References

(1) PROM Group, A.M., Carolina Casañas i Comabella, Monica Hadi, Elizabeth Gibbons, Ray Fitzpatrick, Nia Roberts, *PROM GROUP CONSTRUCT & INSTRUMENT TYPE FILTERS.* 2010.

(2) Terwee, C.B., et al., *Development of a methodological PubMed search filter for finding studies on measurement properties of measurement instruments.* Qual Life Res, 2009. **18**(8): p. 1115-23.

PRISMA-P (preferred reporting items for systematic review and meta-analysis protocols) 2015 checklist: recommended items to address in a systematic review protocol

Section and topic	Item No	Checklist item	Page number
Administrative information			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	Not applicable
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	3, 7 CRD42016035554
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	15
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Not applicable
Support:			
Sources	5a	Indicate sources of financial or other support for the review	16
Sponsor	5b	Provide name for the review funder and/or sponsor	16
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	16

Section and topic	Item No	Checklist item	Page number
Introduction			
Rationale	6	Describe the rationale for the review in the context of what is already known	6
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
Methods			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	8
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	7
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	7
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	7 - 9
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	8 & 9
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	12

Section and topic	Item No	Checklist item	Page number
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	12
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	10 & 11
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	10 & 11
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	10 COSMIN
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	Not applicable
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Not applicable
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	13
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Not applicable
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	13

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

BMJ Open

Measurement properties of patient-reported outcome measures (PROMs) used in adult patients with chronic kidney disease: a systematic review protocol

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Keywords:	Chronic renal failure < NEPHROLOGY, chronic kidney disease, measurement properties, psychometric property, quality of life, patient-reported outcome measures

Measurement properties of patient-reported outcome measures (PROMs) used in adult patients with chronic kidney disease: a systematic review protocol

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Keywords: measurement properties, psychometric, chronic kidney disease, chronic renal failure, quality of life, QoL.

Word count: 2,309

ABSTRACT

Introduction: Chronic kidney disease (CKD) is associated with symptoms that can significantly reduce the quality of life (QoL) of patients. Patient-reported outcome measures (PROMs) may facilitate the assessment of the impact of disease and treatment on the quality of life, from a patient perspective. PROMs can be used in research and routine clinical practice.

Methods and analysis: A systematic review of studies evaluating the measurement properties of PROMs in adults with CKD will be conducted. MEDLINE, EMBASE, PsycINFO and CINAHL Plus will be systematically searched from inception. Hand searching of reference lists and citations of included studies will be carried out. Two reviewers will independently screen the titles and abstracts of all the studies retrieved during the systematic search to determine their eligibility. The COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist will be used to appraise the methodological quality of the selected studies following the full text review. Data on the study population, questionnaire characteristics and measurement properties will be extracted from the selected papers. Finally, a narrative synthesis of extracted data will be undertaken.

Ethics and dissemination: Ethical permissions are not required for this study as data from published research articles will be used. Findings will be disseminated through publication in a peer-reviewed journal and presented at conferences.

This systematic review will provide a comprehensive assessment of the measurement properties of PROMs currently available for use in adult patients with CKD and present evidence which may inform the selection of measures for use in research and clinical practice.

PROSPERO registration number: CRD42016035554

Strengths and limitations of this study

- A key strength of this systematic review is that multiple databases will be searched by multiple independent reviewers, with no language or publication date restrictions, thus minimising the risk of selection bias.
- A further strength is that the methodological quality of selected studies will be evaluated using the validated COSMIN checklist.
- This review will include studies relating to chronic kidney disease in adults and exclude studies of all other kidney conditions and children, this decision has been taken to ensure the results are focused on the study research question.

Keywords: measurement properties, psychometric, chronic kidney disease, chronic renal failure, quality of life, QoL, symptoms, patient-reported outcome measures, PROM.

INTRODUCTION

Chronic Kidney Disease (CKD) is defined as the existence of kidney damage (i.e. pathological abnormalities or markers of damage) for 3 months or more; and/or an estimated Glomerular Filtration Rate (eGFR) less than 60ml/min/1.73m^2 for three months or longer, with or without kidney damage.[1]

CKD affects up to 16% of adults in the UK [2] and is associated with poor outcomes, with a high proportion of patients dying before reaching end stage renal disease.[3, 4] According to the UK Department of Health, the total cost of providing renal care by the National Health Service (NHS) was £1.64 billion in 2009-2010.[5] Aside from these overt costs, the NHS bears other costs accrued from treating associated conditions while patients and caregivers have to contend with possible loss of income.[5]

Patients with CKD often suffer simultaneously from multiple symptoms related to the condition or side effects of their medical treatment.[6] These clusters of symptoms may exert an adverse effect not only on their physical health but also on their psychological and emotional well-being; giving rise to what is described as a 'symptom burden'.[7] A review by Almutary et al.,[8] identified 30 symptoms associated with CKD, with five symptoms (fatigue, drowsiness, pain, pruritus and dry skin) particularly common in all stages.[8] They concluded that the overall symptom burden was high regardless of disease stage.[8] This symptom burden is now acknowledged as the most important predictor of diminished health-related quality of life (HRQoL) in patients with CKD.[9]

In a clinical context, HRQoL refers to the manner in which the physical, emotional and social well-being of an individual is affected by a disease and/or its

treatment.[10] HRQoL can be measured using self-administered, validated questionnaires also known as patient-reported outcomes measures (PROMs).[11, 12]

PROMs have numerous applications in clinical trials and routine clinical settings. They are employed in clinical trials as measures of effectiveness and pharmaceutical companies may use PROM data to support product approvals and labelling claims.[13] PROMs can aid the reporting of serious adverse events due to drug toxicities [14] and trial data can also influence clinical care and health policy.[15, 16]

In routine clinical practice, PROMs are mainly used as tools for benchmarking and hospital performance assessment.[17] However, PROMs also have the potential to assist in the delivery of personalised care.[11, 17-21]

Currently, primary and secondary care records in the UK are being linked together such that patient information is more readily available to clinicians when required.[22] The integration of patient-reported outcome (PRO) data with other routinely collected clinical data could provide an opportunity for revolutionising the UK healthcare system by facilitating the delivery of stratified medicine, enhancing clinical audits, and assisting with the designing of pragmatic trials.[12, 21]

Given the vast array of PROMs in existence, [23] the selection of an appropriate measure for any purpose requires the careful consideration of their measurement properties in order to derive any meaningful benefit from their application. It is crucial that such decisions are backed by the best evidence available, preferably from a recent systematic review.[12]

A scoping search identified two relevant systematic reviews namely: a 2010 review by Gibbons and Fitzpatrick and a 2012 review by Wyld et al.[24, 25] Although both reviews presented evidence of the measurement properties of PROMs in CKD, there is a realistic possibility that more relevant research work has been done since their publication.[26] In addition, both studies had eligibility criteria which might have excluded potentially relevant studies.[24, 25] Gibbons et al., restricted their review to studies published in English language and conducted in English speaking populations within the UK, North America, or Australasia. They also excluded studies with sample sizes less than 50.[24] Wyld et al., focused on studies that assessed preference-based (utility) measures excluding studies that evaluated HR-QOL measures that did not have a utility component and only included studies conducted in other languages if they provided an English abstract.[25]

Therefore, after considering the issues above, we concluded that a full systematic review is required. The aim of this systematic review will be to evaluate the measurement properties of PROMs currently available for use in adults with CKD.

This review will include studies that assess the measurement properties of generic, utility as well as disease-specific PROM instruments in patients at any stage of CKD. Recent methodological advances and guidelines [27-29] will be employed to ensure that the most up-to-date and robust evidence is obtained.

METHODS AND ANALYSIS

Design

The protocol has been registered with PROSPERO (registration number CRD42016035554). It was developed using the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) checklist.[29]

The review will be conducted and reported in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.[30]

Search strategy

The following electronic databases will be systematically searched from inception: MEDLINE (Ovid), EMBASE (Ovid), PsycINFO (Ovid) and CINAHL Plus (EBSCO). Literature search results will be uploaded to Endnote X7 (©Thomson Reuters).There will be no publication period or language restrictions.[27] The UK Renal Registry will be searched and expert recommendations from members of the review team will be followed up to help identify any additional measures currently under development.

The search strategy for MEDLINE was developed in consultation with an information specialist at the Institute of Applied Health Research, University of Birmingham. Two existing search filters, the sensitivity search filter developed by Terwee et al., and the Oxford PROM filter,[31, 32] were combined with key terms for renal disease generated by the review team. The MEDLINE search strategy was adapted for use and tested on all the databases. (See Appendix for the full search strategy).

Selection of studies

To be considered for selection, an article must focus on PROMs used specifically for measuring QoL and/or CKD symptoms (the constructs of interest). In addition, the following inclusion and exclusion criteria will be applied.

Inclusion criteria:

1. Articles reporting PROM development in all CKD populations.
2. Articles explicitly reporting the assessment of one or more psychometric properties for PROM(s) in all CKD populations.
3. Articles reporting cross-cultural validation of PROMs in all CKD populations.

Exclusion criteria:

1. Clinician-assessed instruments.
2. Instrument development studies solely in patients with acute kidney injury (AKI).
3. Instruments developed solely for use in patients below 18 years of age.
4. Trials or studies evaluating the effectiveness of interventions where a PROM questionnaire is used as an endpoint.
5. Editorials, reviews and conference abstracts.

All titles and abstracts will be screened by two independent reviewers (OLA and TK/AG).

Full-text articles will be obtained for studies that potentially meet the eligibility criteria and will again be independently reviewed by the investigators (OLA and TK/AG). .

Abstracts that do not provide the reviewers with enough information to make a decision will be taken forward for full text screening thus minimizing the risk of missing potentially eligible articles.

Reasons for exclusion at the full text stage of screening will be recorded. At any stage, if the reviewers are unable to reach a consensus, a third reviewer will be consulted (MC/DK). Hand searching of reference lists and citations of included papers will be conducted.

The process of selection will be summarised using a PRISMA flow diagram.

Appraisal of the methodological quality of selected studies

All eligible papers will be independently appraised by two reviewers using the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist.[28, 33] The COSMIN checklist is a validated critical appraisal tool designed for the systematic evaluation of the methodological quality of studies of the measurement properties of health measurement instruments.[28]

The COSMIN checklist employs a 4-point rating scale which allows the rating of items relating to each measurement property as 'excellent', 'good', 'fair', or 'poor' depending on the methodological quality of each study. If a study meets all the requirements for an item it is rated 'excellent' for that item. Conversely, if a study fails to meet the requirements for an item, it is given a lower rating commensurate to its quality.[28]

The overall quality rating for each measurement property is determined using the 'worst score counts' method.[28] This means that the methodological quality for each measurement property will be determined by taking the lowest rating of its items.

The following measurement properties as defined by Mokkink et al., will be evaluated [34]:

1. Reliability - "The proportion of the total variance in the measurements which is because of 'true' differences among patients" [34]

2. Internal consistency - "The degree of the interrelatedness among the items" [34]

3. Measurement error - "The systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured" [34]

4. Content validity - "The degree to which the content of an HR-PRO instrument is an adequate reflection of the construct to be measured" [34]

5. Construct validity - "The degree to which the scores of an HR-PRO instrument are consistent with hypotheses (for instance with regard to internal relationships, relationships to scores of other instruments, or differences between relevant groups) based on the assumption that the HR-PRO instrument validly measures the construct to be measured" [34]

6. Cross-cultural validity - "The degree to which the performance of the items on a translated or culturally adapted HR-PRO instrument are an adequate reflection of the performance of the items of the original version of the HR-PRO instrument" [34]

7. Criterion validity - "The degree to which the scores of an HR-PRO instrument are an adequate reflection of a 'gold standard'" [34] The consensus by the COSMIN panel was that no gold standard exists for PROMs even though some authors consider widely used instruments as 'gold standards'. An exception made by the panel is the comparison of a shortened measure to the original longer version, in which case, the original version can be regarded as the gold standard.[28, 33]

8. Responsiveness - "The ability of an HR-PRO instrument to detect change over time in the construct to be measured" [34]

Data extraction

Data from selected studies will be extracted independently by two reviewers, using a data collection form, with disagreements resolved through discussion and, if necessary, consultation with a third reviewer. Extracted data will be presented in tables. Where appropriate, the results will be presented in separate sections/tables for instruments assessed in pre-dialysis, dialysis and kidney transplant patients.

Data on the following will be extracted:

(1) Characteristics of the study population (including age, gender, ethnicity and stage of CKD)

(2) Questionnaire Characteristics (including name/version, language, scoring method, domains, number of items)

(3) Evidence regarding the measurement properties of the questionnaire

(4) Setting and purpose for which questionnaire is administered, interpretability and operational characteristics such as patient acceptability, and feasibility of administration for staff will also be reported.

Data synthesis

Two sets of criteria will be used to assess the *quality of the measurement properties [27, 35]:*

- The quality criteria proposed by Terwee et al.,[35] will be used to rate the *results of studies of measurement properties as* 'positive', 'indeterminate' or 'negative'.[35]
- The modified criteria reported in Terwee et al 2011[27] (Originally proposed by the Cochrane Back Review Group) [36] will be used to synthesis findings on the measurement property of each PROM across studies in order to ascertain the level of evidence for each instrument while taking into consideration the methodological quality of the selected studies. This overall level of evidence will be rated as ‘strong’, ‘moderate’, ‘limited’, ‘conflicting’ or 'unknown'. [27]

ETHICS AND DISSEMINATION

Ethical permissions are not required for this study as data from published research articles will be used. Findings will be disseminated through publication in a peer-reviewed journal and presented at conferences.

DISCUSSION

We acknowledge that studies will evaluate differing measurement properties; therefore evidence might be limited or unavailable for some measurement properties.

This systematic review will present a comprehensive assessment of the measurement properties of PROMS currently available for use in adult patients with CKD and provide vital evidence which may inform the selection of measures for use in research and clinical practice.

Abbreviations

PROSPERO: International Prospective Register of Systematic Reviews; MEDLINE: The Medical Literature Analysis and Retrieval System Online; EMBASE: Excerpta Medica dataBASE; PsycINFO: Psychological Information Database; CINAHL Plus: Cumulative Index to Nursing and Allied Health Literature; COSMIN: COnsensus-based Standards for the selection of health Measurement Instruments.

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Authors' Contributions

MC is the guarantor. The study was conceived and designed by MC, DK, PC and TM. OLA drafted the protocol manuscript. OLA, MC, DK, PC and TM contributed to the development of the search strategy. The selection criteria were developed by OLA, MC, DK, PC, TM, TK and AG. OLA piloted the search strategy on the databases. The manuscript was reviewed and the final draft approved by all authors.

Competing interests

The authors declare that there are no competing interests.

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The Health Foundation is not involved in any other aspect of the project, such as the design of the project's protocol, data collection, analysis and interpretation of results.

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MEDLINE (R) (Ovid) 1946 to 21/12/15

Note: Sets 1 to 6 are based on the Oxford PROM Filter.[1] Set 13 is the sensitive search filter for measurement properties developed by Terwee et al. [2]

1. (HR-PRO or HRPRO or HRQL or HRQoL or QL or QoL).ti,ab.

2. quality of life.mp.

3. (health index* or health indices or health profile*).ti,ab.

4. health status.mp.

5. ((patient or self or child or parent or carer or proxy) adj (appraisal* or appraised or report or reported or reporting or rated or rating or based or assessed or assessment*)).ti,ab.

6. ((disability or function or functional or functions or subjective or utility or utilities or wellbeing or well being) adj2 (index or indices or instrument or instruments or measure or measures or questionnaire* or profile or profiles or scale or scales or score or scores or status or survey or surveys)).ti,ab.

7. ((((patient adj reported adj outcome adj measure*) or patient) adj reported adj outcome*) or capability or capabilities).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

8. 1 or 2 or 3 or 4 or 5 or 6 or 7

9. (Renal replacement therapy or APD or Automated Peritoneal Dialysis or CAPD, Continuous Ambulatory Peritoneal Dialysis or CCPD or Continuous cyclic peritoneal dialysis or dialysis or h*emofiltration or h*emodiafiltration or h*emodialysis or kidney transplant* or predialysis or renal replacement or renal transplant*).mp.

10. (CRF or chronic renal failure or CKF or chronic kidney failure or kidney disease* or renal disease or kidney failure or renal failure or CKD or chronic kidney disease or ESKD or end stage kidney disease or ESKF or end stage kidney failure or ESRF or end stage renal failure or ESRD or end stage renal disease or kidney insufficiency).mp.

11. Renal Insufficiency, Chronic/

12. 9 or 10 or 11

13. ((((((((((((((((((((((((((Instrumentation or method* or Validation Studies or Comparative Study).mp. or psychometrics/ or psychometr*.mp. or clinimetr*.mp. or clinometr*.mp. or outcome assessment health care/ or outcome assessment*.ti,ab. or outcome measure*.mp. or observer variation/ or observer variation*.ti,ab. or Health Status Indicators/ or reproducibility of results/ or reproducib*.ti,ab. or discriminant analysis/ or reliab*.ti,ab. or unreliab*.ti,ab. or valid*.ti,ab. or coefficient of variation.ti,ab. or coefficient*.ti,ab. or homogeneity.ti,ab. or homogeneous.ti,ab. or internal consistency.ti,ab. or cronbach*.ti,ab.) and alpha*.ti,ab.) or item*.ti,ab.) and correlation*.ti,ab.) or selection*.ti,ab. or reduction*.ti,ab. or agreement.mp. or precision.mp. or imprecision.mp. or precise value*.mp. or test-retest.ti,ab. or test.ti,ab.) and retest.ti,ab.) or reliab*.ti,ab.) and test.ti,ab.) or retest.ti,ab. or stability.ti,ab. or interrater.ti,ab. or inter-rater.ti,ab. or intrarater.ti,ab. or intra-rater.ti,ab. or intertester.ti,ab. or inter-tester.ti,ab. or intratester.ti,ab. or intra-tester.ti,ab. or interobserver.ti,ab. or inter-observer.ti,ab. or intraobserver.ti,ab. or intra-observer.ti,ab. or intertechnician.ti,ab. or inter-technician.ti,ab. or intratechnician.ti,ab. or intra-technician.ti,ab. or interexaminer.ti,ab. or inter-examiner.ti,ab. or intraexaminer.ti,ab. or intra-examiner.ti,ab. or interassay.ti,ab. or inter-assay.ti,ab. or intraassay.ti,ab. or intra-assay.ti,ab. or interindividual.ti,ab. or inter-individual.ti,ab. or intraindividual.ti,ab. or intra-individual.ti,ab. or interparticipant.ti,ab. or inter-participant.ti,ab. or intraparticipant.ti,ab. or intra-participant.ti,ab. or kappa*.ti,ab. or kappa's.ti,ab. or repeatab*.mp. or replicab*.mp. or repeated.mp.) and measure*.mp.) or finding*.mp. or result*.mp. or test*.mp. or generaliza*.ti,ab. or generalisa*.ti,ab. or concordance.ti,ab. or intraclass.ti,ab.) and correlation*.ti,ab.) or discriminative.ti,ab. or known group.ti,ab. or factor analysis.ti,ab. or factor analyses.ti,ab. or factor structure.ti,ab. or factor structure.ti,ab. or dimension*.ti,ab. or subscale*.ti,ab. or multitrait.ti,ab.) and scaling.ti,ab. and analysis.ti,ab.) or analyses.ti,ab. or item discriminant.ti,ab. or interscale correlation*.ti,ab. or error.ti,ab. or errors.ti,ab. or individual variability.ti,ab. or interval variability.ti,ab. or rate variability.ti,ab. or variability.ti,ab.) and analysis.ti,ab.) or value*.ti,ab. or uncertainty.ti,ab.) and measurement.ti,ab.) or measuring.ti,ab. or standard error of measurement.ti,ab. or sensitiv*.ti,ab. or responsive*.ti,ab. or limit*.ti,ab.) and detection.ti,ab.) or minimal detectable concentration.ti,ab. or interpretab*.ti,ab. or minimal.ti,ab. or minimally.ti,ab. or clinical.ti,ab. or clinically.ti,ab.) and important.ti,ab.) or significant.ti,ab. or detectable.ti,ab.) and change.ti,ab.) or difference.ti,ab. or small*.ti,ab.) and real.ti,ab.) or detectable.ti,ab.) and change.ti,ab.) or difference.ti,ab. or meaningful change.ti,ab. or ceiling effect.ti,ab. or floor effect.ti,ab. or Item response model.ti,ab. or IRT.ti,ab. or Rasch.ti,ab. or Differential item functioning.ti,ab. or DIF.ti,ab. or computer adaptive testing.ti,ab. or item bank.ti,ab. or cross-cultural equivalence.ti,ab.

14. (PRO integration or Clinical PRO application* or telePRO or automated PRO algorithm* or screening purpose* or PRO questionnaire* or Patient-reported outcome questionnaire* or Patient-reported symptom* or Patient-centred care or Patient self-report* or Self-report health or Self-rated health or Self-reported measure* of health or Health outcome* or Health communication* or Hospital performance evaluation* or Automated telephone survey system* or paper-based survey* or web-based survey* or web-based PRO platform* or web-based system* or PRO collection* or PRO measure* or PRO intervention* or PRO assessment intervention* or PRO data or PRO assessment* or Routine PRO assessment* or Routine PRO collection or Symptom assessment* or Symptom monitoring or Symptom data or Functional status or Electronic PRO assessment* or Electronic PRO system* or ePRO or

ePRO* or ePRO system* or PRO system* or Generic PRO system* or PRO-based clinical alert system*).mp.

15. 13 or 14

16. 8 and 12 and 15

EMBASE (Ovid) 1974 to 21/12/15

Note: Set 4 is the sensitive search filter for measurement properties developed by Terwee et al. and adapted for EMBASE.[2]

1. (Renal replacement therapy or APD or Automated Peritoneal Dialysis or CAPD, Continuous Ambulatory Peritoneal Dialysis or CCPD or Continuous cyclic peritoneal dialysis or dialysis or h*emofiltration or h*emodiafiltration or h*emodialysis or kidney transplant* or predialysis or renal replacement or renal transplant*).mp.

2. (CRF or chronic renal failure or CKF or chronic kidney failure or kidney disease* or renal disease or kidney failure or renal failure or CKD or chronic kidney disease or ESKD or end stage kidney disease or ESKF or end stage kidney failure or ESRF or end stage renal failure or ESRD or end stage renal disease or kidney insufficiency).mp.

3. (PRO integration or Clinical PRO application* or telePRO or automated PRO algorithm* or screening purpose* or PRO questionnaire* or Patient-reported outcome questionnaire* or Patient-reported symptom* or Patient-centred care or Patient self-report* or Self-report health or Self-rated health or Self-reported measure* of health or Health outcome* or Health communication* or Hospital performance evaluation* or Automated telephone survey system* or paper-based survey* or web-based survey* or web-based PRO platform* or web-based system* or PRO collection* or PRO measure* or PRO intervention* or PRO assessment intervention* or PRO data or PRO assessment* or Routine PRO assessment* or Routine PRO collection or Symptom assessment* or Symptom monitoring or Symptom data or Functional status or Electronic PRO assessment* or Electronic PRO system* or ePRO or ePRO* or ePRO system* or PRO system* or Generic PRO system* or PRO-based clinical alert system*).mp.

4. ((exp questionnaire/ or exp named inventories/ or questionnaires/) and rating scales/) or exp psychometry/ or exp outcome assessment/ or exp pain assessment/ or exp disability/ or exp validity/ or exp reliability/

5. *patient/ or *outcome assessment/ or *questionnaire/ or *"quality of life"/ or *self report/

6. 3 or 4

7. 1 or 2

8. 5 and 6 and 7

PsycINFO (Ovid) 1967 to 21/12/15

Note: Sets 1 to 6 are based on the Oxford PROM Filter.[1] Set 11 is the sensitive search filter for measurement properties developed by Terwee et al.[2]

1. (HR-PRO or HRPRO or HRQL or HRQoL or QL or QoL).ti,ab.

2. quality of life.mp.

3. (health index* or health indices or health profile*).ti,ab.

4. health status.mp.

5. ((patient or self or child or parent or carer or proxy) adj (appraisal* or appraised or report or reported or reporting or rated or rating or based or assessed or assessment*)).ti,ab.

6. ((disability or function or functional or functions or subjective or utility or utilities or wellbeing or well being) adj2 (index or indices or instrument or instruments or measure or measures or questionnaire* or profile or profiles or scale or scales or score or scores or status or survey or surveys)).ti,ab.

7. ((((patient adj reported adj outcome adj measure*) or patient) adj reported adj outcome*) or capability or capabilities).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]

8. 1 or 2 or 3 or 4 or 5 or 6 or 7

9. (Renal replacement therapy or APD or Automated Peritoneal Dialysis or CAPD, Continuous Ambulatory Peritoneal Dialysis or CCPD or Continuous cyclic peritoneal dialysis or dialysis or h*emofiltration or h*emodiafiltration or h*emodialysis or kidney transplant* or predialysis or renal replacement or renal transplant*).mp.

10. (CRF or chronic renal failure or CKF or chronic kidney failure or kidney disease* or renal disease or kidney failure or renal failure or CKD or chronic kidney disease or ESKD or end stage kidney disease or ESKF or end stage kidney failure or ESRF or end stage renal failure or ESRD or end stage renal disease or kidney insufficiency).mp.

11. ((((((((((((((((((((((((((Instrumentation or method* or Validation Studies or Comparative Study).mp. or psychometrics/ or psychometr*.mp. or clinimetr*.mp. or clinometr*.mp. or outcome assessment health care/ or outcome assessment*.ti,ab. or outcome measure*.mp. or observer variation/ or observer variation*.ti,ab. or Health Status Indicators/ or reproducibility of results/ or reproducib*.ti,ab. or

discriminant analysis/ or reliab*.ti,ab. or unreliab*.ti,ab. or valid*.ti,ab. or coefficient of variation.ti,ab. or coefficient*.ti,ab. or homogeneity.ti,ab. or homogeneous.ti,ab. or internal consistency.ti,ab. or cronbach*.ti,ab.) and alpha*.ti,ab.) or item*.ti,ab.) and correlation*.ti,ab.) or selection*.ti,ab. or reduction*.ti,ab. or agreement.mp. or precision.mp. or imprecision.mp. or precise value*.mp. or test-retest.ti,ab. or test.ti,ab.) and retest.ti,ab.) or reliab*.ti,ab.) and test.ti,ab.) or retest.ti,ab. or stability.ti,ab. or interrater.ti,ab. or inter-rater.ti,ab. or intrarater.ti,ab. or intra-rater.ti,ab. or intertester.ti,ab. or inter-tester.ti,ab. or intratester.ti,ab. or intra-tester.ti,ab. or interobserver.ti,ab. or inter-observer.ti,ab. or intraobserver.ti,ab. or intra-observer.ti,ab. or intertechnician.ti,ab. or inter-technician.ti,ab. or intratechnician.ti,ab. or intra-technician.ti,ab. or interexaminer.ti,ab. or inter-examiner.ti,ab. or intraexaminer.ti,ab. or intra-examiner.ti,ab. or interassay.ti,ab. or inter-assay.ti,ab. or intraassay.ti,ab. or intra-assay.ti,ab. or interindividual.ti,ab. or inter-individual.ti,ab. or intraindividual.ti,ab. or intra-individual.ti,ab. or interparticipant.ti,ab. or inter-participant.ti,ab. or intraparticipant.ti,ab. or intra-participant.ti,ab. or kappa*.ti,ab. or kappa's.ti,ab. or repeatab*.mp. or replicab*.mp. or repeated.mp.) and measure*.mp.) or finding*.mp. or result*.mp. or test*.mp. or generaliza*.ti,ab. or generalisa*.ti,ab. or concordance.ti,ab. or intraclass.ti,ab.) and correlation*.ti,ab.) or discriminative.ti,ab. or known group.ti,ab. or factor analysis.ti,ab. or factor analyses.ti,ab. or factor structure.ti,ab. or factor structure.ti,ab. or dimension*.ti,ab. or subscale*.ti,ab. or multitrait.ti,ab.) and scaling.ti,ab. and analysis.ti,ab.) or analyses.ti,ab. or item discriminant.ti,ab. or interscale correlation*.ti,ab. or error.ti,ab. or errors.ti,ab. or individual variability.ti,ab. or interval variability.ti,ab. or rate variability.ti,ab. or variability.ti,ab.) and analysis.ti,ab.) or value*.ti,ab. or uncertainty.ti,ab.) and measurement.ti,ab.) or measuring.ti,ab. or standard error of measurement.ti,ab. or sensitiv*.ti,ab. or responsive*.ti,ab. or limit*.ti,ab.) and detection.ti,ab.) or minimal detectable concentration.ti,ab. or interpretab*.ti,ab. or minimal.ti,ab. or minimally.ti,ab. or clinical.ti,ab. or clinically.ti,ab.) and important.ti,ab.) or significant.ti,ab. or detectable.ti,ab.) and change.ti,ab.) or difference.ti,ab. or small*.ti,ab.) and real.ti,ab.) or detectable.ti,ab.) and change.ti,ab.) or difference.ti,ab. or meaningful change.ti,ab. or ceiling effect.ti,ab. or floor effect.ti,ab. or Item response model.ti,ab. or IRT.ti,ab. or Rasch.ti,ab. or Differential item functioning.ti,ab. or DIF.ti,ab. or computer adaptive testing.ti,ab. or item bank.ti,ab. or cross-cultural equivalence.ti,ab.

12. (PRO integration or Clinical PRO application* or telePRO or automated PRO algorithm* or screening purpose* or PRO questionnaire* or Patient-reported outcome questionnaire* or Patient-reported symptom* or Patient-centred care or Patient self-report* or Self-report health or Self-rated health or Self-reported measure* of health or Health outcome* or Health communication* or Hospital performance evaluation* or Automated telephone survey system* or paper-based survey* or web-based survey* or web-based PRO platform* or web-based system* or PRO collection* or PRO measure* or PRO intervention* or PRO assessment intervention* or PRO data or PRO assessment* or Routine PRO assessment* or Routine PRO collection or Symptom assessment* or Symptom monitoring or Symptom data or Functional status or Electronic PRO assessment* or Electronic PRO system* or ePRO or ePRO* or ePRO system* or PRO system* or Generic PRO system* or PRO-based clinical alert system*).mp.

13. 11 or 12

14. *Organ Transplantation/ or *Hemodialysis/ or *Kidneys/ or *Kidney Diseases/ or Renal Insufficiency, Chronic.mp.

15. 9 or 10 or 14

16. 8 and 13 and 15

CINAHL (via EBSCO host) inception to 21/12/15

Note: S1 is based on the Oxford PROM Filter.[1] S3 is the sensitive search filter for measurement properties developed by Terwee et al. [2]

S1. ((HR-PRO or HRPRO or HRQL or HRQoL or QL or QoL).ti,ab.) OR quality of life.mp. OR ((health index* or health indices or health profile*).ti,ab.) OR health status.mp. OR (((patient or self or child or parent or carer or proxy) adj (appraisal* or appraised or report or reported or reporting or rated or rating or based or assessed or assessment*)).ti,ab.) OR (((disability or function or functional or functions or subjective or utility or utilities or wellbeing or well being) adj2 (index or indices or instrument or instruments or measure or measures or questionnaire* or profile or profiles or scale or scales or score or scores or status or survey or surveys)).ti,ab.) OR (((((patient adj reported adj outcome adj measure*) or patient) adj reported adj outcome*) or capability or capabilities).mp)

S2. (MH "Kidney Failure, Chronic/TH/TM/TD/SU/SS/RF/RH/PF/PR/PC/PP/PA/NU/MO/ME/ET/EI/EP/ED/EC/DT/DI/CO/CL") OR "((Renal replacement therapy or APD or Automated Peritoneal Dialysis or CAPD, Continuous Ambulatory Peritoneal Dialysis or CCPD or Continuous cyclic peritoneal dialysis or dialysis or h*emofiltration or h*emodiafiltration or h*emodialysis or kidney transplant* or predialysis or renal replacement or renal transplant*).mp.) OR ((CRF or chronic renal failure or CKF or chronic kidney failure or kidney disease* or renal disease or kidney failure or renal failure or CKD or chronic kidney disease or ESKD or end stage kidney disease or ESKF or end stage kidney failure or ESRF or end stage renal failure or ESRD or end stage renal disease or kidney insufficiency).mp.) OR (*Organ Transplantation/ or *Hemodialysis/ or *Kidneys/ or *Kidney Diseases/ or Renal Insufficiency, Chronic.mp.)"

S3. ""(((((((((((((((((((((((((((Instrumentation or method* or Validation Studies or Comparative Study).mp. or psychometrics/ or psychometr*.mp. or clinimetr*.mp. or clinometr*.mp. or outcome assessment health care/ or outcome assessment*.ti,ab. or outcome measure*.mp. or observer variation/ or observer variation*.ti,ab. or Health Status Indicators/ or reproducibility of results/ or reproducib*.ti,ab. or discriminant analysis/ or reliab*.ti,ab. or unreliab*.ti,ab. or valid*.ti,ab. or coefficient of variation.ti,ab. or coefficient*.ti,ab. or homogeneity.ti,ab. or homogeneous.ti,ab. or internal consistency.ti,ab. or cronbach*.ti,ab.) and alpha*.ti,ab.) or item*.ti,ab.) and correlation*.ti,ab.) or selection*.ti,ab. or reduction*.ti,ab. or agreement.mp. or precision.mp. or imprecision.mp. or precise value*.mp. or test-retest.ti,ab. or test.ti,ab.) and retest.ti,ab.) or reliab*.ti,ab.) and test.ti,ab.) or retest.ti,ab. or stability.ti,ab. or interrater.ti,ab. or inter-rater.ti,ab. or intrarater.ti,ab. or intra-rater.ti,ab. or intertester.ti,ab. or inter-tester.ti,ab. or intratester.ti,ab. or intra-tester.ti,ab. or interobserver.ti,ab. or inter-observer.ti,ab. or intraobserver.ti,ab. or intra-

observer.ti,ab. or intertechnician.ti,ab. or inter-technician.ti,ab. or intratechnician.ti,ab. or intra-technician.ti,ab. or interexaminer.ti,ab. or inter-examiner.ti,ab. or intraexaminer.ti,ab. or intra-examiner.ti,ab. or interassay.ti,ab. or inter-assay.ti,ab. or intraassay.ti,ab. or intra-assay.ti,ab. or interindividual.ti,ab. or inter-individual.ti,ab. or intraindividual.ti,ab. or intra-individual.ti,ab. or interparticipant.ti,ab. or inter-participant.ti,ab. or intraparticipant.ti,ab. or intra-participant.ti,ab. or kappa*.ti,ab. or kappa's.ti,ab. or repeatab*.mp. or replicab*.mp. or repeated.mp.) and measure*.mp.) or finding*.mp. or result*.mp. or test*.mp. or generaliza*.ti,ab. or generalisa*.ti,ab. or concordance.ti,ab. or intraclass.ti,ab.) and correlation*.ti,ab.) or discriminative.ti,ab. or known group.ti,ab. or factor analysis.ti,ab. or factor analyses.ti,ab. or factor structure.ti,ab. or factor structure.ti,ab. or dimension*.ti,ab. or subscale*.ti,ab. or multitrait.ti,ab.) and scaling.ti,ab. and analysis.ti,ab.) or analyses.ti,ab. or item discriminant.ti,ab. or interscale correlation*.ti,ab. or error.ti,ab. or errors.ti,ab. or individual variability.ti,ab. or interval variability.ti,ab. or rate variability.ti,ab. or variability.ti,ab.) and analysis.ti,ab.) or value*.ti,ab. or uncertainty.ti,ab.) and measurement.ti,ab.) or measuring.ti,ab. or standard error of measurement.ti,ab. or sensitiv*.ti,ab. or responsive*.ti,ab. or limit*.ti,ab.) and detection.ti,ab.) or minimal detectable concentration.ti,ab. or interpretab*.ti,ab. or minimal.ti,ab. or minimally.ti,ab. or clinical.ti,ab. or clinically.ti,ab.) and important.ti,ab.) or significant.ti,ab. or detectable.ti,ab.) and change.ti,ab.) or difference.ti,ab. or small*.ti,ab.) and real.ti,ab.) or detectable.ti,ab.) and change.ti,ab.) or difference.ti,ab. or meaningful change.ti,ab. or ceiling effect.ti,ab. or floor effect.ti,ab. or Item response model.ti,ab. or IRT.ti,ab. or Rasch.ti,ab. or Differential item functioning.ti,ab. or DIF.ti,ab. or computer adaptive testing.ti,ab. or item bank.ti,ab. or cross-cultural equivalence.ti,ab.)

S4. ((PRO integration or Clinical PRO application* or telePRO or automated PRO algorithm* or screening purpose* or PRO questionnaire* or Patient-reported outcome questionnaire* or Patient-reported symptom* or Patient-centred care or Patient self-report* or Self-report health or Self-rated health or Self-reported measure* of health or Health outcome* or Health communication* or Hospital performance evaluation* or Automated telephone survey system* or paper-based survey* or web-based survey* or web-based PRO platform* or web-based system* or PRO collection* or PRO measure* or PRO intervention* or PRO assessment intervention* or PRO data or PRO assessment* or Routine PRO assessment* or Routine PRO collection or Symptom assessment* or Symptom monitoring or Symptom data or Functional status or Electronic PRO assessment* or Electronic PRO system* or ePRO or ePRO* or ePRO system* or PRO system* or Generic PRO system* or PRO-based clinical alert system*).mp.)""

S5. S3 or S4

S6. S1 and S2 and S5

References

(1) PROM Group, A.M., Carolina Casañas i Comabella, Monica Hadi, Elizabeth Gibbons, Ray Fitzpatrick, Nia Roberts, *PROM GROUP CONSTRUCT & INSTRUMENT TYPE FILTERS.* 2010.

(2) Terwee, C.B., et al., *Development of a methodological PubMed search filter for finding studies on measurement properties of measurement instruments.* Qual Life Res, 2009. **18**(8): p. 1115-23.

PRISMA-P (preferred reporting items for systematic review and meta-analysis protocols) 2015 checklist: recommended items to address in a systematic review protocol

Section and topic	Item No	Checklist item	Page number
Administrative information			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	Not applicable
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	3, 7 CRD42016035554
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	16
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Not applicable
Support:			
Sources	5a	Indicate sources of financial or other support for the review	17
Sponsor	5b	Provide name for the review funder and/or sponsor	17
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	17

Section and topic	Item No	Checklist item	Page number
Introduction			
Rationale	6	Describe the rationale for the review in the context of what is already known	6
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
Methods			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	8
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	7
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	7
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	7 - 9
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	8 & 9
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	13

Section and topic	Item No	Checklist item	Page number
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	13
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	11 & 12
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	11 & 12
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	10 COSMIN
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	Not applicable
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Not applicable
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	14
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Not applicable
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	14

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.