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Which patient-reported outcome measures are used following revision knee replacement, and are they validated?

A systematic scoping review of measurement properties and evaluation with the COSMIN checklist

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Which patient-reported outcome measures are used following revision knee replacement, and are they validated?

A systematic review of measurement properties and evaluation with the COSMIN checklist

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Abstract

Objectives
To identify: (i) Patient Reported Outcome Measures (PROMs) used to evaluate symptoms, health status or quality of life following discretionary revision (or re-revision) knee joint replacement, and (ii) validated joint-specific PROMs, their measurement properties and quality of evidence.

Design
(i) Scoping review; (ii) Systematic review following the COnsensus-based Standards for selection of health status Measurement INstruments (COSMIN) checklist.

Data sources
MEDLINE, Embase, AMED and PsycINFO were searched from inception to 1 July 2020 using the Oxford PROM filter unlimited by publication date or language.

Eligibility criteria for selecting studies
Studies reporting on the development, validation or outcome of a joint-specific PROM for revision knee joint replacement were included.

Results
51 studies reported PROM outcomes using 8 joint-specific PROMs. 27 out of 51 studies (52.9%) were published within the last five years. PROM development was inadequate or doubtful for each of the eight PROMs studied. Validation studies were available for only three joint-specific PROMs: Knee Injury and Osteoarthritis Outcome Score (KOOS), Lower Extremity Activity Scale (LEAS), and Western Ontario and McMaster Universities Arthritis Index (WOMAC). 25 out of 27 (92.6%) measurement properties were rated either insufficient, indeterminate, or not assessed. The quality of supporting evidence was mostly low or very low. Each of the validated PROMs was rated ‘B’ (potential for recommendation but require further evaluation).

Conclusion
Joint-specific PROMs are increasingly used to report outcomes following revision knee joint replacement, but these instruments have insufficient evidence for their validity. Future research should be directed toward understanding the measurement properties of these instruments in order to inform clinical trials and observational studies evaluating the outcomes from joint-specific PROMs.
**Article Summary**

**Strengths and limitations of this study**

1. This systematic review was motivated by the James Lind Alliance Priority Setting Partnership question: “How should we measure the outcomes following revision knee surgery in a way that is meaningful to patients?”

2. This is the first study to examine current utilisation of patient-reported outcome measures (PROMs) together with quality of PROM development and validation studies in the setting of revision knee joint replacement.

3. This review used a sensitive search strategy based on the Oxford PROM filter to identify relevant articles.

4. PROM development and validation studies were appraised using a validated tool - CONsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) checklist.
Introduction

Primary knee replacement is a successful procedure that improves quality of life for the majority of patients by reducing pain and improving joint function (1). However, approximately 20% of patients are dissatisfied following surgery (2) and 3.5% of primary knee replacements have undergone revision surgery by 10 years (3). Approximately, 6000 revision knee replacement procedures are performed each year in the United Kingdom (UK) (3). 85% of procedures are for discretionary indications, where the goal of surgery is to improve joint function and quality of life. This contrasts to non-discretionary surgery (such as for infection or fracture), which is necessary to prevent catastrophic joint failure or new comorbidity. For discretionary procedures, it is critical that we understand the patient perspective.

Patient-reported outcome measures (PROMs) are widely used for this purpose in lower limb surgery. Many PROMs aim to report quality of life and functional outcomes, whilst others assess sporting performance, activities of daily living or psychological health. However, not all have optimal measurement properties (4,5). For primary knee replacement, many PROMs have good quality evidence for their validity (6,7). This has facilitated utilisation of PROMs to support patient choice and manage health care providers (8–10), with many schemes also including revision procedures. A prominent example is the NHS PROMs programme (8), which has collected data from more than 10,000 patients who have undergone revision knee replacement. However, interpretation of this data has been critically limited by a lack of PROM validation.

Revision knee replacement is one of the most expensive procedures in modern healthcare (11) and high-quality PROM data is important to evaluate cost-effectiveness (12). Whilst generic PROMs can be used to compare patients, they may miss important items in specific populations (13). The COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) initiative provides tools to aid systematic reviews and selection of measurement instruments (14). The ideal PROM is developed or subsequently validated in the population of interest, has good measurement properties and is supported by high-quality evidence. PROM instruments meeting these criteria can be selected for a core outcome set in order to standardise outcome measurement. If there are no suitable PROMs, then further validation studies may be required or the development of a new PROM. For revision knee replacement, no systematic review has evaluated PROMs in current use, their measurement properties or the quality of this evidence. This limits meta-analysis of previous research and design of future trials.

The aims of this review were: (i) to scope the literature to identify PROMS in current use for evaluation of symptoms, health status or quality of life following discretionary revision (or re-revision) knee replacement, and (ii) to identify validated joint-specific PROMs, their measurement properties and quality of evidence.
Methods
This section is structured to follow the COSMIN Handbook (14). PROSPERO does not accept registration of scoping reviews.

Patient and Public Involvement
Patients and the public were involved in the design, or conduct, or reporting, or dissemination plans of our research. This article was motivated by the James Lind Alliance Priority Setting Partnership for revision knee replacement (15), particularly the question: “How should we measure the outcomes following revision knee surgery in a way that is meaningful to patients?”

Part A: Aim and literature search
Step 1: Aims (described above)

Step 2: Study eligibility criteria
Randomised and non-randomised studies were eligible for inclusion. Revision knee replacement was defined as any procedure where an arthroplasty component was removed, modified or added. This included isolated liner exchange, secondary patellar resurfacing and re-revision procedures. Studies where the majority of procedures were performed for non-discretionary indications (such as infection or malignancy) were excluded, as well as amputations and arthrodesis procedures. Since 85% of revisions are for discretionary indications, studies where the indication was not specified were deemed eligible for inclusion. PROMs were required to address one of the following domains:
- Pain (e.g. Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain subscale (16)),
- Function (e.g. WOMAC functional limitation subscale),
- Combined pain and function (e.g. Oxford Knee Score (17)),
- Joint-related health status (e.g. Knee Injury and Osteoarthritis Outcome Score [KOOS] quality of life [QOL] (18)), or
- Patient activity (e.g. Lower Extremity Activity Scale [LEAS] (19)).

Collectively, we have termed these ‘joint-specific’ PROMs. The focus of this study was not to examine generic health-related quality of life instruments (e.g. EuroQol 5-dimension score (20)). However, we did report the use of these instruments in conjunction with a joint-specific PROM. Outcome scores not considered to be patient-centred were excluded; for example, surgeon-completed scores such as the Bristol Knee Score (BKS), Hospital for Special Surgery Knee Score, and the Knee Society Score (KSS). Studies with less than fifty patients were excluded as their sample size would be considered inadequate when applying COSMIN rules for rating of measurement properties and evidence quality (7).

Step 3: Search strategy
This is provided in Appendix 1. MEDLINE, Embase, AMED and PsycINFO were searched on 1st July 2020 using the Oxford PROM filter (21). Searches were translated for each database. There were no limitations on language or publication date. The citations of included studies were searched to identify additional articles.

Step 4: Study selection
Two authors (SAS and EAH) independently reviewed title and abstract for all records returned by the search against eligibility criteria. Disagreement was resolved through discussion of the full text publication. Data were extracted on name and type of PROM, geography, journal, year of publication and number of patients.

**Part B: Evaluation of measurement properties of the included PROMs**

*Steps 5, 6 and 7: Content validity, Internal structure, Reliability and Responsiveness*

Descriptions of terminology for measurement properties are provided in Appendix 3. Each measurement property was evaluated in three separate sub-steps:

**Sub-step 1: Evaluation of methodological quality**

Two authors (SAS and SGFA) independently evaluated the measurement properties in each article against the COSMIN Risk of Bias checklist. A priori hypotheses for construct validity and responsiveness were set (Appendix 2 - Table 1). Study quality was assessed separately for each measurement property using a four-point rating system (very good, adequate, doubtful or inadequate). The “worst score counts” principle was used, where the overall rating for each measurement property is given by the lowest rating of any standard in the box (22).

**Sub-step 2: Application of criteria for good measurement properties (GMP)**

Two authors (SAS and SGFA) independently extracted data on: PROM characteristics (intended construct for measurement, measurement properties, method of administration), study sample (number of patients, patient demographics, diagnosis) and study details (setting, country, language). Disagreement was resolved through discussion. The results from each study on a measurement property were assigned a quality rating as: sufficient (+), insufficient (-) or indeterminate (?).

**Sub-step 3: Summary and grading of quality of evidence**

This section refers to rating the quality of the PROM as a whole. PROMs were qualitatively summarised and assigned a four-point quality rating. A modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (omitting publication bias) was used to assign evidence quality as high, moderate, low or very low (23).

**Part C: Selecting a PROM**

*Step 8: Description of interpretability and feasibility*

Interpretability and feasibility were analysed descriptively as per COSMIN guidance (14).

*Step 9: Formulation of recommendations*

PROMs were categorised into three categories: (A) Sufficient content validity and at least low-quality evidence for internal consistency; (B) Between ‘A’ and ‘C’; and (C) High-quality evidence for an insufficient measurement property. PROMs rated ‘A’ can be recommended for use. PROMs rated ‘B’ have potential for recommendation but require further evaluation. PROMs rated ‘C’ should not be recommended.

*Step 10: Reporting of the systematic review*

The PRISMA flow diagram is provided in Figure 1.
Results

Part A

Study selection

1205 unique articles were identified for screening. 66 full text articles were assessed for eligibility. 51 studies were included in the scoping review, reporting on 8 joint-specific PROMs. Four studies met inclusion criteria for PROM validation, describing measurement properties for three PROMs (Figure 1).

Characteristics of studies reporting PROM outcomes for revision knee replacement

Fifty-one studies reported on PROM outcomes (Tables 1 & 2) recruiting a median of 104 (range 51 – 1391) patients. Study designs included 1 (2.0%) randomised controlled trial, 14 (27.5%) prospective cohort studies, 29 (56.9%) retrospective cohort studies, 3 (5.9%) reports from national joint registries, 3 (5.9%) cross-sectional surveys and 1 (2.0%) data analysis of routinely-collected secondary care data. Twenty-five studies (49.0%) were from Europe, 19 (37.3%) from North America, 6 (11.8%) from Asia and 1 (2.0%) from Australasia. The joint-specific PROMs reported were the WOMAC Index (25 studies, 49.0%), OKS (19 studies, 37.3%), KOOS (8 studies, 15.7%), Lower Extremity Activity Scale (LEAS, 4 studies, 7.8%), University of California Los Angeles Activity Score (UCLA, 4 studies, 7.8%), Kujala score (2 studies, 3.9%), Lower Extremity Functional Scale (LEFS, 2 studies, 3.9%), and the Lysholm score (1 study, 2.0%). The majority of studies were published within the past five years (27/51 (52.9%) studies) (Appendix 2 Figure 1).

Part B

Quality of PROM development studies

The PROM development studies for the 8 disease-specific PROMS identified above are summarised in Table 3. The overall rating for each of these studies was either ‘doubtful’ (n=1, 12.5%) or ‘inadequate’ (n=7, 87.5%). Six of these studies were rated ‘inadequate’ as they did not recruit a sample representative of revision knee replacement. In particular, the LEAS study used a surgeon panel in lieu of patients for content validity. Five studies (62.5%) were rated ‘doubtful’ due to a lack of specificity in their descriptions of the construct to be measured. For example, whilst it was clear that the Kujala score was developed to evaluate anterior knee pain, the aspect of pain to be measured was not specified. The origin of the construct was not clear for five studies (62.5%). Concept elicitation used inappropriate methodology in five studies (62.5%, ‘inadequate’ rating), and was survey-based in two (25.0%, ‘doubtful’ rating). However, the OKS used experienced interviewers to collect qualitative data (‘very good’).

Characteristics of PROM validation studies

Four studies (19,24–26) from the scoping review validated three joint-specific PROMs (KOOS, LEAS, WOMAC) (Table 4). The mean age of patients in the included studies ranged from 67 to 77 years. Female patients accounted for 50 to 78% of the study populations. The primary objective of the included articles varied from validation of a PROM, validation of another instrument with the PROM as a comparator, development of a new instrument and reporting of clinical outcome after revision knee replacement. The characteristics of the PROMs included in the validation studies are described in Table 5.
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Quality of studies on measurement properties

In total, 20 measurement properties for the KOOS, LEAS and WOMAC were evaluated (Table 6). There were 40 additional opportunities to evaluate measurement properties that were not attempted. 2 (10.0%) measurement properties were rated ‘very good’, 5 (25.0%) ‘adequate’, 3 (15.0%) ‘doubtful’ and 10 (50.0%) ‘inadequate’. For structural validity, de Groot’s evaluation for the KOOS was rated ‘inadequate’ due to an insufficient sample size for factor analysis (less than five times the number of participants). Three out of four (75.0%) studies that reported on responsiveness were rated ‘inadequate’ due to their construct approach. For example, Saleh et al (25) used an ‘inadequate’ comparator instrument for development of the LEAS - the measurement properties of the WOMAC are not well enough known for revision. Ghomrawi et al (19) did not set hypotheses for construct validity, and their statistical methodology did not allow these to be evaluated at review. Two studies reported on reliability. These were rated ‘adequate’ as, whilst they chose an appropriate interval, they did not also ensure patients were stable.

Quality of the evidence for measurement properties of the PROMs

The quality of the evidence for measurement properties of the included PROMs is provided in Table 7. 25 out of 27 (92.6%) measurement properties were rated either insufficient, indeterminate, or not assessed. The only measurement property to receive a ‘sufficient’ rating was reliability for both the KOOS and LEAS, supported by ‘low’ and ‘moderate’ quality evidence respectively.

Part C

Data on the interpretability of the studies is summarised in Table 8. The mode of PROM administration was unclear for all studies except de Groot et al (24). Missing responses ranged from 25-60%. No study reported on missing items within a PROM instrument. Floor and ceiling effects were not reported, except by Saleh et al (25). No PROM met criteria either to be recommended or not recommended for use. Each of the validated PROMs (i.e. KOOS, LEAS and WOMAC) were therefore assigned recommendation ‘B’, indicating that further evidence is needed.
**Discussion**

This review has demonstrated the increasing use of PROMs to evaluate symptoms and functional outcomes following discretionary revision knee replacement. The majority of studies were retrospective and observational, with only one randomised controlled trial.

Eight different joint-specific PROMs were identified, with the WOMAC index (25 studies, 49.0%) and the OKS (19 studies, 37.3%) the most frequent. Only three joint-specific PROMs were supported by a validation study: KOOS, LEAS and WOMAC. Each of these validation studies had ‘low’ or ‘very low’ quality evidence and the majority of measurement properties were either not evaluated or rated ‘inadequate’ or ‘indeterminate’. As such, each of these PROMs requires more evidence in order to be recommended for use.

**Secondary findings and relation to other studies**

Musculoskeletal disorders account for one-third of all reviews on the COSMIN database (27). At least three reviews have evaluated the measurement properties of PROMs following primary knee replacement, with the Oxford Knee Score (OKS) and WOMAC supported by the best evidence (6,7,28). This is the first review to examine measurement properties of PROMs following revision knee replacement. Revision surgery differs importantly from primary surgery, meaning that evidence from one cannot simply be transferred to the other. For example, whilst primary knee replacement treats predominantly osteoarthritis, revision knee replacement treats many varied disease processes (29). The revision patient population is also more comorbid and may have different expectations and goals from surgery (30).

**Strengths and weaknesses**

This study has a number of important strengths, including the use of a broad search strategy based on the Oxford PROM filter (21), and the application of latest COSMIN guidelines. The use of a priori hypotheses by our review team to evaluate construct validity and responsiveness is novel and meant these properties could be considered even when not a focus of the original article. This study was motivated by the James Lind Alliance Priority Setting Partnership for revision knee replacement, which generated the question: “How should we measure the outcomes following revision knee surgery in a way that is meaningful to patients?” (31). As such, outcome scores that were not patient completed were excluded. We acknowledge that this has restricted the number of eligible studies from North America, where use of the Knee Society Score (KSS) is prevalent.

**Implications for practice**

We have not put forward a PROM for recommendation because the quality of the available evidence was low, and data were lacking for many of the measurement properties. However, we can make recommendations to direct future research and to move towards developing a core outcome set for discretionary revision knee replacement. First, we wish to highlight that standards for reporting of psychometric studies have changed considerably over the past twenty years (6). COSMIN tools are not limited to systematic reviews and may be used guide the scope and detail required to develop a new instrument or to evaluate an existing one. Second, this study has highlighted a number of common methodological flaws that result in high risk of bias. For example, when evaluating structural validity, none of the validation studies performed confirmatory factor analysis to understand whether the PROM scores reflected the dimensionality of the construct. For reliability, test conditions were not
recorded with sufficient detail to ensure that not only the repeat interval was appropriate, but also that the patient remained stable. For interpretability, none of the studies calculated a minimal important change (MIC) nor comprehensively assessed floor and ceiling effects. Third, we recommend that future studies planning to use an existing joint-specific PROM to evaluate outcomes after revision surgery do so in conjunction with a validated generic health-related quality of life instrument (such as the Short Form-36 (SF36) (32) or EuroQol 5-dimension score (EQ5D) (20)). Whilst neither the EQ5D or SF36 were developed in patients undergoing revision knee replacement, their measurement properties have been studied extensively and allow generalisability between different conditions. This approach will provide valuable information on construct validity and responsiveness in the future.

Conclusion

In conclusion, joint-specific PROMs are increasingly used to report outcomes following revision knee replacement, but these instruments have insufficient evidence for validity. Future research is needed to target the deficiencies highlighted by this review in order to inform clinical trials and observational studies evaluating these outcomes.
Details of contributors:

SAS: concept, study selection and scoping review, assessment of methodological quality, analysis, writing and editing paper, guarantor.

EAH: study selection and scoping review, critically revising paper

SGFA: assessment of methodological quality, critically revising paper

AA: critically revising paper

AJP: concept, methodology, writing and editing paper

SH: concept, methodology, writing and editing paper

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**Figures and Tables**

**Figure 1.** PRISMA flow diagram. The full search strategy is provided in Appendix 1.

[Flow diagram showing the PRISMA flow process]
| Authors          | Year | Country      | Journal         | Study design       | No. revision knees | PROM used | Study design |
|------------------|------|--------------|-----------------|--------------------|--------------------|-----------|--------------|
| Agarwal (33)     | 2018 | UK           | The Knee        | Prospective cohort | 104                | EQ5D      | Y            |
| Baier (34)       | 2013 | Germany      | J Orth Sci      | Retrospective cohort | 78                | KOOS      | Y            |
| Baker (29)       | 2012 | UK           | CORR            | Joint Registry     | 797                | Kujala    | Y            |
| Bin Abd Razak (35)| 2019 | Singapore   | J Knee Surg     | Retrospective cohort | 163               | LEAS      | Y            |
| Boelch (36)      | 2018 | Germany      | Int Orth        | RCT                | 51                 | LEFS      | Y            |
| Dahm (37)        | 2007 | US           | JOA             | Cross-section Prospective cohort | 335               | Lysholm   | Y            |
| de Groot (24)    | 2008 | Netherlands  | Health Qual Life| Routine data       | 54                | OKS       | Y            |
| Eibich (38)      | 2018 | UK           | BMJ Open        | Routine data       | 1391               | SF12      | Y            |
| Ghanem (39)      | 2007 | US           | CORR            | Prospective cohort | 80                | SF36      | Y            |
| Ghanem (26)      | 2010 | US           | JBJS(Am)        | Retrospective cohort | 152               | UCLA      | Y            |
| Gomez-Vallejo (40)| 2018 | Spain       | J Orth Traum    | Retrospective cohort | 67                | WOMAC     | Y            |
| Grayson (41)     | 2016 | US           | JOA             | Retrospective cohort | 177               |           |              |
| Greidanus (42)   | 2011 | US           | JOA             | Retrospective cohort | 60                |           |              |
| Hamilton (43)    | 2017 | UK           | JOA             | Prospective cohort | 53                |           |              |
| Hanna (44)       | 2011 | UK           | CORR            | Retrospective cohort | 56                |           |              |
| Hartley (45)     | 2002 | UK           | BJJ             | Prospective cohort | 60                |           |              |
| Witt (46)        | 2015 | US           | J Knee Surg     | Prospective cohort | 95                |           |              |
| Huang (47)       | 2014 | US           | Orthopedics     | Prospective cohort | 96                |           |              |
| Kasmire (48)     | 2014 | US           | The Knee        | Prospective cohort | 175               |           |              |
| Kim (49)         | 2009 | South Korea  | JBJS(Am)        | Retrospective cohort | 157               |           |              |
| Kim (50)         | 2015 | South Korea  | JOA             | Retrospective cohort | 228               |           |              |
| Klim (51)        | 2020 | Austria      | KSSTA           | Retrospective cohort | 93                |           |              |
| Konrads (52)     | 2015 | Germany      | Int Orth        | Retrospective cohort | 62                |           |              |
| Konrads (53)     | 2019 | Germany      | J Knee Surg     | Retrospective cohort | 135               |           |              |
|   | Kurmis (54) | 2019 | Australia | JOA | Retrospective cohort | 321 | Y   | Y   |
|---|-------------|------|-----------|-----|----------------------|-----|-----|-----|
| 2 | Larsen (55) | 2020 | Denmark   | BMC Sports Sci | Retrospective cohort | 51  |     | Y   |
| 3 | Lavernia (56) | 2011 | US | CORR | Retrospective cohort | 132 | Y   | Y   |
| 5 | Leta (57) | 2016 | Norway | JBJS(Am) | Joint Registry | 1346 | Y   | Y   |
| 6 | Leta (58) | 2016 | Norway | Int Orth | Joint Registry | 308 | Y   | Y   |
| 7 | Lim (59) | 2017 | Singapore | BJJ | Retrospective cohort | 75  | Y   | Y   |
| 8 | Lim (60) | 2019 | Singapore | The Knee | Retrospective cohort | 70  |     | Y   |
| 9 | Lunebourg (61) | 2015 | France | JOA | Retrospective cohort | 54  |     | Y   |
| 11 | Luque (62) | 2014 | Spain | Int Orth | Retrospective cohort | 125 |     | Y   |
| 14 | M-Hernandez (63) | 2017 | Spain | KSSTTA | Prospective cohort | 134 |     | Y   |
| 15 | Malviya (64) | 2012 | UK | KSSTTA | Prospective cohort | 175 |     | Y   |
| 17 | Masri (65) | 2006 | Canada | JOA | Retrospective cohort | 126 | Y   | Y   |
| 19 | Meek (66) | 2003 | Canada | BJJ | Prospective cohort | 107 |     | Y   |
| 20 | Meek (67) | 2004 | Canada | JOA | Cross-section | 67  | Y   | Y   |
| 21 | Mulholl (68) | 2007 | US | J Knee Surg | Prospective cohort | 291 | Y   | Y   |
| 22 | Oliver (69) | 2020 | Spain | Orth Surg | Retrospective cohort | 89  | Y   | Y   |
| 25 | Rajgopal (70) | 2017 | India | JOA | Retrospective cohort | 98  |     | Y   |
| 26 | Richards (71) | 2011 | Canada | JOA | Cross-section | 72  | Y   | Y   |
| 27 | Saleh (25) | 2005 | US | JBJS(Am) | Prospective cohort | 297 | Yes | Y   |
| 28 | Sandford (72) | 2017 | Canada | CORR | Retrospective cohort | 450 | Y   | Y   |
| 30 | Scior (73) | 2019 | Germany | JOA | Prospective cohort | 482 |     | Y   |
| 32 | Stambough (74) | 2014 | US | BJJ | Retrospective cohort | 81  | Y   | Y   |
| 33 | Stockwell (75) | 2019 | Canada | The Knee | Retrospective cohort | 234 |     | Y   |
| 35 | Weber (76) | 2018 | Germany | BioMed RI | Retrospective cohort | 68  |     | Y   |
| 36 | Weiss (77) | 2014 | Sweden | Acta Orthop | Retrospective cohort | 65  | Y   | Y   |
| 38 | Zhamilov (78) | 2017 | Turkey | JOA | Retrospective cohort | 92  | Y   | Y   |

EQSD = EuroQol 5-dimension score, KOOS = Knee injury and osteoarthritis outcome score; LEAS = Lower extremity activity scale; LEFS = Lower extremity functional scale; OKS = Oxford Knee Score; SF = Short Form; UCLA = University of California Los Angeles Activity Score; WOMAC = Western Ontario and McMaster Universities Arthritis Index.
Table 2. Summary characteristics for studies reporting PROMs following revision knee replacement

| Number of studies (%) |
|-----------------------|
| **No. patients**     | median 104 (range 51 - 1391) |
| **Continent**        |                             |
| Europe               | 25 (49%)                   |
| North America        | 19 (37.3%)                 |
| Asia                 | 6 (11.8%)                  |
| Australasia          | 1 (2%)                     |
| **Type of study**    |                             |
| Randomized controlled trial | 1 (2%)               |
| Prospective cohort   | 14 (27.5%)                 |
| Retrospective cohort | 29 (56.9%)                 |
| Joint Registry       | 3 (5.9%)                   |
| Routine data analysis| 1 (2%)                     |
| Cross-sectional survey| 3 (5.9%)                 |
| **Joint-specific PROMs** |                        |
| KOOS                  | 8 (15.7%)                  |
| Kujala                | 2 (3.9%)                   |
| LEAS                  | 4 (7.8%)                   |
| LEFS                  | 1 (2%)                     |
| Lysholm               | 1 (2%)                     |
| OKS                   | 19 (37.3%)                 |
| UCLA                  | 4 (7.8%)                   |
| WOMAC                 | 25 (49%)                   |
| **Generic PROMs**    |                             |
| EQ5D                  | 7 (13.7%)                  |
| SF12                  | 8 (15.7%)                  |
| SF36                  | 18 (35.3%)                 |

Number of studies reporting each measure (%), EQ5D = EuroQol 5-dimension score, KOOS = Knee injury and osteoarthritis outcome score; LEAS = Lower extremity activity scale; LEFS = Lower extremity functional scale; OKS = Oxford Knee Score; SF = Short Form; UCLA = University of California Los Angeles Activity Score; WOMAC = Western Ontario and McMaster Universities Arthritis Index
### Table 3. Quality of PROM development

| PROM | Clear construct | Clear origin of construct | Clear target population for which the PROM was developed | Clear context of use | Concept elicitation\(^1\) | Total PROM design | General design requirements | Cognitive interview (CI) study\(^a\) | Comprehensibility | Comprehensiveness | Total CI study | TOTAL PROM DEVELOPMENT |
|------|-----------------|---------------------------|-------------------------------------------------------|---------------------|--------------------------|----------------------|---------------------------|-----------------------------|------------------|------------------|-------------------|---------------------|
| Joint-specific | | | | | | | | | | | | |
| KOOS (18) | D | D | VG | D | I | I | I | Yes | | | | |
| Kujala (79) | D | D | VG | VG | I | I | I | No | | | | |
| LEAS (25) | VG | VG | VG | VG | I | I | I | No | | | | |
| LIFS (80) | VG | VG | VG | D | D | D | D | No | | | | |
| Lysholm | D | D | VG | VG | I | VG | I | No | | | | |
| Oxford Knee Score (17) | D | D | VG | VG | I | VG | I | No | | | | |
| WOMAC (16) | VG | VG | VG | VG | I | D | I | Yes | | | | |
| UCLA (81) | D | D | VG | VG | I | I | I | No | | | | |
| Generic | | | | | | | | | | | | |
| EuroQol 5D (20) | I | D | VG | VG | I | I | I | I | | | | |
| SF-36 (32) | VG | VG | VG | VG | I | I | I | I | | | | |
| SF-12 (82) | VG | VG | VG | VG | I | I | I | I | | | | |

KOOS = Knee injury and osteoarthritis outcome score; LEAS = Lower extremity activity scale; SF = Short-Form; UCLA = University of California at Los Angeles; WOMAC = Western Ontario and McMaster Universities Arthritis Index

VG = Very good, A = Adequate, D = Doubtful, I = Inadequate, N = Not assessed

1 Where the PROM was not developed in a sample representing the target population, the concept elicitation was not further rated

2 Empty cells indicate that a CI study (or part of it) was not performed
| Study        | Instrument(s) | Primary objective                                           | Country (Language)       | Population (Inclusion/Exclusion criteria) | Enrolled (n) | LTFU (n) | Final (n) | Age (years) | Female (%) | FU (months) | Indications for revision |
|--------------|---------------|-----------------------------------------------------------|--------------------------|------------------------------------------|--------------|----------|-----------|-------------|------------|-------------|--------------------------|
| de Groot     | KOOS          | To validate the Dutch translation of KOOS                 | Netherlands (Dutch)      | Inc: Revision TKR Exclusion: Unable to understand Dutch written language. | 54           | 7        | 47        | 77          | 78         | NR          | NR                      |
| (2008)       | SF-36         | VAS for pain                                              |                          |                                          |              |          |           |             |            |             |                          |
| Saleh        | LEAS          | To develop and validate the Lower Extremity Activity Scale | United States (English)  | Inc: First revision TKR capable of completing questionnaires in English and >= 18 years Ex: Re-revision, failed UKR, poly. exchange only, bone tumour, reflex sympathetic dystrophy, unfit for revision TKR, neurological deficit of affected limb, referred pain from spine, declined to participate, concern about compliance, inability to consent, progressive muscular condition of quadriceps, infection delay, stiffness not requiring component revision. | 297          | 12       | 285       | 68.6        | 55         | 6           | Instability n=82 (28.8%) |
| (2005)       | WOMAC         |                                                          |                          |                                          |              |          |           |             |            |             | Tibial osteolysis n=78 (27.4%) |
| Ghomrawi     | LEAS          | To characterise patterns of functional improvement after revision total knee arthroplasty over a two-year period using | United States (English)  | As per Saleh et al (2005)                | 308          | 87       | 221       | 68.7        | 55         | 24          | Instability 28.9%*       |
| (2009)       | SF-36         | Lower Extremity Activity Scale                            |                          |                                          |              |          |           |             |            |             | Fem. loosening 14.1%     |
| (19)         | WOMAC         |                                                          |                          |                                          |              |          |           |             |            |             | Infection 10.4%          |
| Ghanem       | WOMAC         | To determine validity and responsiveness of the Knee Society Rating System | United States (English)  | Inc: Revision TKR Ex: Infection (n=85), Patella or poly. exchange only (n=35); Conversion of UKR or internal fixation (n=15), Non-prosthetic failure (n=4) | 165          | 13       | 152       | 67          | NR         | 24          | Mechanical failure:      |
| (2010)       | KSS           |                                                          |                          |                                          |              |          |           |             |            |             | Aseptic loosening 69.7%   |
| (26)         | 4-point Likert|                                                          |                          |                                          |              |          |           |             |            |             | Knee instability 30.3%    |
Table 5. Characteristics of the joint-specific PROMs evaluated in validation studies.

| Instrument | Year developed | Original language | Target population | Intended construct / Domains | No. questions | Best/worst score |
|------------|----------------|--------------------|-------------------|-----------------------------|---------------|-----------------|
| **Symptoms and functional status** | | | | | | |
| KOOS (18)  | 1998           | English & Swedish  | Younger and more active subjects at risk of knee osteoarthritis following knee injury | Pain  
Symptoms  
Activities of daily life function | 42 questions | 100/0 |
| WOMAC (16) | 1982           | English            | Patients with OA of the hip or knee | Pain  
Stiffness  
Knee-related quality of life  
Function and daily activities | 24 questions | 0/96 |
| **Activity-level** | | | | | | |
| LEAS (25)  | 2005           | English            | Patients awaiting or had undergone primary or revision lower limb joint replacement | Physical activity | 1 question | 18/1 |

KOOS = Knee injury and osteoarthritis outcome score; LEAS = Lower extremity activity scale; SF-36 = Short-Form 36; WOMAC = Western Ontario and McMaster Universities Arthritis Index
| PROM  | Study                  | Structural validity | Internal consistency | Cross-cultural validity | Reliability | Measurement error | Criterion validity | Convergent validity | Known groups validity | Comparison with gold standard | Comparison with other instruments | Comparison between subgroups | Comparison before/after intervention |
|-------|------------------------|---------------------|---------------------|-------------------------|--------------|------------------|---------------------|---------------------|----------------------|-------------------------------|-----------------------------|-------------------------------|---------------------------------|
| KOOS  | de Groot (24)          | I                   | VG                  | I                       | A            | A                | N                   | D                   | N                    | N                            | N                           | N                             | N                               |
| LEAS  | Saleh (25)             | N                   | N                   | N                       | A            | A                | N                   | I                   | N                    | N                            | I                           | N                             | A                               |
| LEAS  | Ghomrawi (19)          | N                   | N                   | N                       | N            | N                | N                   | N                   | N                    | N                            | I                           | I                             | I                               |
| WOMAC | Ghanem (26)            | N                   | N                   | N                       | N            | N                | D                   | N                   | N                    | N                            | D                           | N                             | VG                              |
| WOMAC | Ghomrawi (19)          | N                   | N                   | N                       | N            | N                | N                   | N                   | N                    | N                            | I                           | I                             | I                               |

KOOS = Knee injury and osteoarthritis outcome score; LEAS = Lower extremity activity scale, WOMAC = Western Ontario and McMaster Universities Arthritis Index; VG = Very good, A = Adequate, D = Doubtful, I = Inadequate, N = Not assessed
|                        | KOOS | LEAS | WOMAC |
|------------------------|------|------|-------|
| **QUALITY OF EVIDENCE** |      |      |       |
| Overall Rating         | + / - / ? | + / - / ? | + / - / ? |
| Structural validity    | -    | N    | N     |
| Internal consistency   | ?    | N    | N     |
| Cross-cultural validity| ?    | N    | N     |
| Measurement invariance | ?    | N    | N     |
| Reliability            | +    | +    | N     |
| Measurement error      | ?    | ?    | ?     |
| Criterion validity     | N    | N    | N     |
| Construct validity     | -    | -    | N     |
| Responsiveness         | N    | N    | N     |

KOOS = Knee injury and osteoarthritis outcome score; LEAS = Lower extremity activity scale; N = not assessed; WOMAC = Western Ontario and McMaster Universities Arthritis Index, + = sufficient, - = insufficient, ? = indeterminate
Table 8. Interpretability including missing items, response rate and floor/ceiling effects

| Instrument and study | Administration | Missing responses (%) | Missing items (%) | Overall % achieving lowest possible total score (floor) | Overall percentage achieving highest possible score (ceiling) | Items Domains with >15% responses with lowest score (floor) | Items Domains with >15% responses with highest score (ceiling) | MIC |
|---------------------|----------------|-----------------------|-------------------|------------------------------------------------------|---------------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|-----|
| **Symptoms and functional status** | | | | | | | | |
| KOOS | de Groot (2008) (24) | Postal | 25 | NR | NR | NR | Sports/ Recreation | Nil | NR |
| WOMAC | | | | | | | | | |
| Ghomrawi (2009) (19) | Unclear | 30.5 | NR | NR | NR | NR | NR | NR | NR |
| Ghanem (2010) (26) | Unclear | NR | NR | NR | NR | NR | NR | NR | NR |
| Saleh (2005) (25) | Unclear | NR | NR | NR | NR | NR | NR | NR | NR |
| **Health-related quality of life** | | | | | | | | |
| SF-36 | de Groot (2008) (24) | Postal | NR | NR | NR | NR | NR | NR | NR |
| Ghomrawi (2009) (19) | Unclear | 30.5 | NR | NR | NR | NR | NR | NR | NR |
| Ghanem (2010) (26) | Unclear | NR | NR | NR | NR | NR | NR | NR | NR |
| **Activity-level** | | | | | | | | |
| LEAS | Ghomrawi (2009) (19) | Unclear | 30.5 | NR | NR | NR | NR | NR | NR |
| Saleh (2005) (25) | Unclear | 59.6* | NR | 0 | 0 | NR | NR | NR | NR |

KOOS = Knee injury and osteoarthritis outcome score; LEAS = Lower extremity activity scale; SF-36 = Short-Form 36; WOMAC = Western Ontario and McMaster Universities Arthritis Index; *Reported response rate was 96%. However, histograms have 177 or 178 patients out of a possible 297 (59.6%).
Appendix 1: Search Strategy

This search strategy incorporates the PROM filter from the Oxford PROM group (21).

Databases: MEDLINE, Embase, AMED, PsycInfo

Search strategy for Ovid MEDLINE:
Arthroplasty, Replacement, Knee/
((arthroplast* or replacement* or resurface*) adj3 knee*).ti,ab.
Knee Prosthesis/
((prosthes* or implant*) adj3 knee*).ti,ab.
(tka or tkr or ukr or uka).ti,ab.
1 or 2 or 3 or 4 or 5
revision*.ti,ab.
modular exchange*.ti,ab.
Reoperation/
(reoperation or re-operation or "repeat surg*").ti,ab.
7 or 8 or 9 or 10
6 and 11
(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.
12 and 13
### Appendix 2: Tables & Figures

**Appendix 2 Table 1. Generic hypotheses to evaluate construct validity and responsiveness**

| Hypotheses                                                                 |
|----------------------------------------------------------------------------|
| 1   Correlations with (changes in) instruments measuring similar constructs should be ≥0.50 |
| 2   Correlations with (changes in) instruments measuring related, but dissimilar constructs should be lower, i.e. 0.30-0.50. |
| 3   Correlations with (changes in) instruments measuring unrelated constructs should be <0.30. |
| 4   Correlations defined under 1, 2, and 3 should differ by a minimum of 0.10. |
| 5   Meaningful changes between relevant (sub)groups (e.g. patients with expected high vs low levels of the construct of interest) |
| 6   For responsiveness, the area under the curve should be ≥0.70 |

This table is reproduced from de Vet et al (84) and is included in the COSMIN manual for systematic reviews of PROMS (14).
Appendix 2 Figure 1. Histogram demonstrating increasing numbers of studies reporting on PROMS following revision knee replacement over time.
Appendix 3: Definitions of measurement properties

This manuscript uses COSMIN definitions throughout. A more detailed explanation of the COSMIN taxonomy, domains and definitions can be found within the COSMIN manual for systematic reviews of PROMS (14).

Content validity
Validity is “the degree to which a PROM measures the construct” intended (85). Content validity refers to “the degree to which the content of a PROM is an adequate reflection of the construct to be measured” (14). COSMIN provide a bespoke user manual to evaluate content validity (86).

Internal structure
Structural validity is the degree to which the PROM scores reflect the dimensionality of the construct being measured (85). Construct validity is “the degree to which the scores of a PROM are consistent with hypotheses”, assuming that the PROM is a valid instrument to measure the construct (85). Internal consistency is the “interrelatedness among PROM items” (85). Cross-cultural validity evaluates the performance of an adapted PROM compared to the original version (85).

Reliability
Reliability refers to “the degree to which a measurement is free from measurement error” (85).

Responsiveness
Responsiveness is the ability of a PROM to detect change over time (85).

Interpretability
Interpretability is the degree to which qualitative meaning can be assigned to a PROM score.

Feasibility
Feasibility is the ease of application of a PROM for its context of use. The measurement properties were analysed descriptively as per COSMIN guidance.
## PRISMA 2009 Checklist

| Section/topic | # | Checklist item | Reported on page # |
|---------------|---|---------------|--------------------|
| **TITLE**     |   |               |                    |
| Title         | 1 | Identify the report as a systematic review, meta-analysis, or both. | 1                 |
| **ABSTRACT**  |   |               |                    |
| Structured summary | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. | 2                 |
| **INTRODUCTION** | |             |                    |
| Rationale     | 3 | Describe the rationale for the review in the context of what is already known. | 4                 |
| Objectives    | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). | 4                 |
| **METHODS**   |   |               |                    |
| Protocol and registration | 5 | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number. | N/A               |
| Eligibility criteria | 6 | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. | 5                 |
| Information sources | 7 | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched. | 5                 |
| Search        | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. | 5&32              |
| Study selection | 9 | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis). | 5                 |
| Data collection process | 10 | Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators. | 5&6               |
| Data items    | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. | 5&6               |
| Risk of bias in individual studies | 12 | Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis. | 6                 |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means). | 6                 |
| Synthesis of results | 14 | Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I²) for each meta-analysis. | 6                 |
## PRISMA 2009 Checklist

| Section/topic                      | # | Checklist item                                                                                                                                                                                                 | Reported on page # |
|-----------------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Risk of bias across studies       | 15| Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).                                                                 | 6                 |
| Additional analyses               | 16| Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.                                                                  | N/A               |
| **RESULTS**                       |   |                                                                                                                                                                                                             |                   |
| Study selection                   | 17| Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.                                                                 | 19                |
| Study characteristics             | 18| For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.                                                                                                                                  | 20/21/24          |
| Risk of bias within studies       | 19| Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).                                                                                                                                                      | 26                |
| Results of individual studies     | 20| For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.                                                                 | 26                |
| Synthesis of results              | 21| Present results of each meta-analysis done, including confidence intervals and measures of consistency.                                                                                                                                                    | 27                |
| Risk of bias across studies       | 22| Present results of any assessment of risk of bias across studies (see Item 15).                                                                                                                             | 27                |
| Additional analysis               | 23| Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).                                                                                                                                                  |                   |
| **DISCUSSION**                   |   |                                                                                                                                                                                                             |                   |
| Summary of evidence               | 24| Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).                                                                 | 9                 |
| Limitations                       | 25| Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).                                                                                                                 | 9                 |
| Conclusions                       | 26| Provide a general interpretation of the results in the context of other evidence, and implications for future research.                                                                                                                                       | 10                |
| **FUNDING**                       |   |                                                                                                                                                                                                             |                   |
| Funding                           | 27| Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.                                                                                                                          | 11                |

*From:* Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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Patient-reported outcome measures following revision knee replacement: A review of PROM instrument utilisation and measurement properties using the COSMIN checklist

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| Secondary Subject Heading | Surgery                                       |
| Keywords         | Knee < ORTHOPAEDIC & TRAUMA SURGERY, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, Adult orthopaedics < ORTHOPAEDIC & TRAUMA SURGERY |
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Patient-reported outcome measures following revision knee replacement: A review of PROM instrument utilisation and measurement properties using the COSMIN checklist

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Abstract

Objectives
To identify: (i) Patient Reported Outcome Measures (PROMs) used to evaluate symptoms, health status or quality of life following discretionary revision (or re-revision) knee joint replacement, and (ii) validated joint-specific PROMs, their measurement properties and quality of evidence.

Design
(i) Scoping review; (ii) Systematic review following the COnsensus-based Standards for selection of health status Measurement INstruments (COSMIN) checklist.

Data sources
MEDLINE, Embase, AMED and PsycINFO were searched from inception to 1 July 2020 using the Oxford PROM filter unlimited by publication date or language.

Eligibility criteria for selecting studies
Studies reporting on the development, validation or outcome of a joint-specific PROM for revision knee joint replacement were included.

Results
51 studies reported PROM outcomes using 8 joint-specific PROMs. 27 out of 51 studies (52.9%) were published within the last five years. PROM development was rated 'inadequate' for each of the eight PROMs studied. Validation studies were available for only three joint-specific PROMs: Knee Injury and Osteoarthritis Outcome Score (KOOS), Lower Extremity Activity Scale (LEAS), and Western Ontario and McMaster Universities Arthritis Index (WOMAC). 25 out of 27 (92.6%) measurement properties were rated either insufficient, indeterminate, or not assessed. The quality of supporting evidence was mostly low or very low. Each of the validated PROMs was rated ‘B’ (potential for recommendation but require further evaluation).

Conclusion
Joint-specific PROMs are increasingly used to report outcomes following revision knee joint replacement, but these instruments have insufficient evidence for their validity. Future research should be directed toward understanding the measurement properties of these instruments in order to inform clinical trials and observational studies evaluating the outcomes from joint-specific PROMs.
Article Summary

Strengths and limitations of this study

1. This is the first study to apply the Consensus-based Standards for the selection of health Measurement INstruments (COSMIN) checklist to report the quality of PROM development and validation studies for revision knee joint replacement.
2. Our search strategy was based on the Oxford PROM filter, which has been shown to be a sensitive tool for identifying relevant studies.
3. PROM instruments that were not patient completed were excluded, which maintained a patient-focus, but limited the number of eligible instruments for evaluation.
4. Whilst our study has critically summarised PROM measurement properties, qualitative studies may be needed in the future to provide deeper insights into the outcomes from revision knee replacement that are most important to patients.
Introduction

Primary knee replacement is a successful procedure that improves quality of life for the majority of patients by reducing pain and improving joint function (1). However, approximately 13% of patients are dissatisfied with the outcome from knee replacement (2), with higher rates in younger patients (3) and those with partial thickness cartilage loss (4). Many of these patients are managed with supportive treatment (5). However, at ten years following primary knee replacement, 3.5% of patients will have undergone revision surgery. In total, 6500 revision knee replacement procedures are performed each year in the United Kingdom (UK) (6). The majority of these procedures (~85%) are for discretionary indications, where the goal of surgery is to improve joint function and quality of life (6). These contrast to non-discretionary procedures (such as for infection or fracture), which are necessary to prevent catastrophic joint failure or new comorbidity. To measure the success or otherwise of the outcome from discretionary revision knee replacement, it is important that we understand the patient perspective.

Patient-reported outcome measures (PROMs) are widely used for this purpose in lower limb surgery. Many PROMs aim to report quality of life and functional outcomes, whilst others assess sporting performance, activities of daily living or psychological health. However, not all have optimal measurement properties (7,8). For primary knee replacement, many PROMs have good quality evidence for their validity (9,10). This has facilitated utilisation of PROMs to support patient choice and manage health care providers (2,11,12), with many schemes also including revision procedures. A prominent example is the NHS PROMs programme (2), which has collected data from more than 10,000 patients who have undergone revision knee replacement (13). However, interpretation of this data has been critically limited by a lack of PROM validation.

Revision knee replacement is one of the most expensive procedures in modern healthcare (14) and high-quality PROM data is important to evaluate cost-effectiveness (15). Whilst generic PROMs can be used to compare patients, they may miss important items in specific populations (16). The COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) initiative provides tools to aid systematic reviews and selection of measurement instruments (17). The ideal PROM is developed or subsequently validated in the population of interest, has good measurement properties and is supported by high-quality evidence. PROM instruments meeting these criteria can be selected for a core outcome set in order to standardise outcome measurement. If there are no suitable PROMs, then further validation studies may be required or the development of a new PROM. For revision knee replacement, no systematic review has evaluated PROMs in current use, their measurement properties or the quality of this evidence. This limits meta-analysis of previous research and design of future trials.

The aims of this review were: (i) to scope the literature to identify PROMS in current use for evaluation of symptoms, health status or quality of life following discretionary revision (or re-revision) knee replacement, and (ii) to identify validated joint-specific PROMs, their measurement properties and quality of evidence.
**Methods**

This section is structured to follow the COSMIN Handbook and a figure to illustrate our methods is provided in a Supplementary file, Appendix 1 (17).

**Patient and Public Involvement**

Patients and the public were involved in the design, or conduct, or reporting, or dissemination plans of our research. This article was motivated by the James Lind Alliance Priority Setting Partnership for revision knee replacement (18), particularly the question: “How should we measure the outcomes following revision knee surgery in a way that is meaningful to patients?”

**Part A: Aim and literature search**

**Step 1: Aims (described above)**

**Step 2: Study eligibility criteria**

Randomised and non-randomised studies were eligible for inclusion. Revision knee replacement was defined as any procedure where an arthroplasty component was removed, modified or added. This included isolated liner exchange, secondary patellar resurfacing and re-revision procedures. Studies where the majority of procedures were performed for non-discretionary indications (such as infection or malignancy) were excluded, as well as amputations and arthrodesis procedures. Since 85% of revisions are for discretionary indications, studies where the indication was not specified were deemed eligible for inclusion. PROMs were required to address one of the following domains:

- Pain (e.g. Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain subscale (19)),
- Function (e.g. WOMAC functional limitation subscale),
- Combined pain and function (e.g. Oxford Knee Score (20)),
- Joint-related health status (e.g. Knee Injury and Osteoarthritis Outcome Score (KOOS) quality of life (QOL) (21)), or
- Patient activity (e.g. Lower Extremity Activity Scale (LEAS (22)).

Collectively, we have termed these ‘joint-specific’ PROMs. The focus of this study was not to examine generic health-related quality of life instruments (e.g. EQ-5D (23)). However, we did report the use of these instruments in conjunction with a joint-specific PROM. Outcome scores not considered to be patient-centred were excluded; for example, surgeon-completed scores such as the Bristol Knee Score (BKS), Hospital for Special Surgery Knee Score, and the Knee Society Score (KSS). Studies with less than fifty patients were excluded as their sample size would be considered inadequate when applying COSMIN rules for rating of measurement properties and evidence quality (10).

**Step 3: Search strategy**

This is provided in Appendix 2. MEDLINE, Embase, AMED and PsycINFO were searched on 1st July 2020 using the Oxford PROM filter (24). Searches were translated for each database. There were no limitations on language or publication date. The citations of included studies were searched to identify additional articles.

**Step 4: Study selection**
Two authors (SAS and EAH) independently reviewed title and abstract for all records returned by the search against eligibility criteria. Disagreement was resolved through discussion of the full text publication. Data were extracted using a calibrated form on name and type of PROM, geography, journal, year of publication and number of patients. Data were summarised using counts with percentage frequency for each of the data items collected.

Part B: Evaluation of measurement properties of the included PROMs

Steps 5, 6 and 7: Content validity, Internal structure, Reliability and Responsiveness

Descriptions of terminology for measurement properties are provided in Appendix 3. Each measurement property was evaluated in three separate sub-steps:

Sub-step 1: Evaluation of methodological quality

Two authors (SAS and SGFA) independently evaluated the measurement properties in each article against the COSMIN Risk of Bias checklist. A priori hypotheses for construct validity and responsiveness were set (Appendix 4 - Table 1). Study quality was assessed separately for each measurement property using a four-point rating system (very good, adequate, doubtful or inadequate). The “worst score counts” principle was used, where the overall rating for each measurement property is given by the lowest rating of any standard in the box (25).

Sub-step 2: Application of criteria for good measurement properties (GMP)

Two authors (SAS and SGFA) independently extracted data on: PROM characteristics (intended construct for measurement, measurement properties, method of administration), study sample (number of patients, patient demographics, diagnosis) and study details (setting, country, language). The few disagreements were resolved through discussion. The results from each study on a measurement property were assigned a quality rating as: sufficient (+), insufficient (-) or indeterminate (?).

Sub-step 3: Summary and grading of quality of evidence

This section refers to rating the quality of the PROM as a whole. PROMs were qualitatively summarised and assigned a four-point quality rating. A modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (omitting publication bias) was used to assign evidence quality as high, moderate, low or very low (26).

Part C: Selecting a PROM

Step 8: Description of interpretability and feasibility

Interpretability and feasibility were analysed descriptively as per COSMIN guidance (17).

Step 9: Formulation of recommendations

PROMs were categorised into three categories: (A) Sufficient content validity and at least low-quality evidence for internal consistency; (B) Between ‘A’ and ‘C’; and (C) High-quality evidence for an insufficient measurement property. PROMs rated ‘A’ can be recommended for use. PROMs rated ‘B’ have potential for recommendation but require further evaluation. PROMs rated ‘C’ should not be recommended.
Step 10: Reporting of the systematic review

The PRISMA flow diagram is provided in Figure 1.

Results

Part A

Study selection

1205 unique articles were identified for screening. 66 full text articles were assessed for eligibility. 51 studies were included in the scoping review, reporting on 8 joint-specific PROMs. Four studies met inclusion criteria for PROM validation, describing measurement properties for three PROMs (Figure 1).

Characteristics of studies reporting PROM outcomes for revision knee replacement

Fifty-one studies reported on PROM outcomes (Tables 1 & 2) recruiting a median of 104 (range 51 – 1391) patients. Study designs included 1 (2.0%) randomised controlled trial, 14 (27.5%) prospective cohort studies, 29 (56.9%) retrospective cohort studies, 3 (5.9%) reports from national joint registries, 3 (5.9%) cross-sectional surveys and 1 (2.0%) data analysis of routinely-collected secondary care data. Twenty-five studies (49.0%) were from Europe, 19 (37.3%) from North America, 6 (11.8%) from Asia and 1 (2.0%) from Australasia. The joint-specific PROMs reported were the WOMAC Index (25 studies, 49.0%), OKS (19 studies, 37.3%), KOOS (8 studies, 15.7%), Lower Extremity Activity Scale (LEAS, 4 studies, 7.8%), University of California Los Angeles Activity Score (UCLA, 4 studies, 7.8%), Kujala score (2 studies, 3.9%), Lower Extremity Functional Scale (LEFS, 2 studies, 3.9%), and the Lysholm score (1 study, 2.0%). The majority of studies were published within the past five years (27/51 (52.9%) studies) (Appendix 4 Figure 1).

Part B

Quality of PROM development studies

The quality of PROM development for the 8 disease-specific PROMS identified in Part A is summarised in Table 3. The construct to be measured was clear in two studies (25%), with the remainder rated ‘inadequate’. One example of a study rated ‘inadequate’ was the Kujala study (27). This rating was made because, whilst the score was designed to measure anterior knee symptoms, the specific aspects of these symptoms to be measured were not described (such as pain intensity or pain interference). The Lysholm score (28) was rated ‘very good’ due to a specific description (defining “the lowest activity level needed during walking, running, or jumping to produce giving way or pain and swelling”). The origin of the construct to be measured was clear in only two studies (25.0%). One example of a study rated ‘very good’ for this property was the LEFS study (29), which referenced the World Health Organization’s International Classification of Functioning, Disability and Health (ICF) conceptual framework (30). The context of use was rated ‘very good’ for three studies (37.5%). These studies provided at least one clear description of the intended application of the instrument. For example, the OKS was designed to evaluate patients before and after knee replacement surgery (20). All studies were rated as ‘very good’ for their description of a clear target population. Whilst many studies provided a very broad description (for example, the LEFS described patients “with lower-extremity orthopaedic conditions” (31)), the COSMIN guidance is permissive for rating this property. However, the PROM
development sample was rated ‘inadequate’ for all studies either because the patient sample was not correspondingly broad or, taking a view on the patient sample of interest in this review, did not recruit a sample representative of discretionary revision knee replacement. Whilst the LEAS study did recruit patients with revision knee replacements for some aspects of PROM development, a surgeon panel was used in lieu of patients for content validity, justifying an ‘inadequate’ rating (29). In summary, the total PROM development was rated ‘inadequate’ for all studies based on the “worst score counts” principle recommended by COSMIN. However, this does not reflect positive ratings for some aspects of PROM development as described above.

Characteristics of PROM validation studies

Four studies (22,29,32,33) from the scoping review validated three joint-specific PROMs (KOOS, LEAS, WOMAC) (Table 4). The mean age of patients in the included studies ranged from 67 to 77 years. Female patients accounted for 50 to 78% of the study populations. The primary objective of the included articles varied from validation of a PROM, validation of another instrument with the PROM as a comparator, development of a new instrument and reporting of clinical outcome after revision knee replacement. The characteristics of the PROMs included in the validation studies are described in Table 5.

Quality of studies on measurement properties

In total, 20 measurement properties for the KOOS, LEAS and WOMAC were evaluated (Table 6). There were 40 additional opportunities to evaluate measurement properties that were not attempted. 2 (10.0%) measurement properties were rated ‘very good’, 5 (25.0%) ‘adequate’, 3 (15.0%) ‘doubtful’ and 10 (50.0%) ‘inadequate’. For structural validity, de Groot’s evaluation for the KOOS was rated ‘inadequate’ due to an insufficient sample size for factor analysis (less than five times the number of participants). Three out of four (75.0%) studies that reported on responsiveness were rated ‘inadequate’ due to their construct approach. For example, Saleh et al (29) used an ‘inadequate’ comparator instrument for development of the LEAS - the measurement properties of the WOMAC are not well enough known for revision. Ghomrawi et al (22) did not set hypotheses for construct validity, and their statistical methodology did not allow these to be evaluated at review. Two studies reported on reliability. These were rated ‘adequate’ as, whilst they chose an appropriate interval, they did not also ensure patients were stable.

Quality of the evidence for measurement properties of the PROMs

The quality of the evidence for measurement properties of the included PROMs is provided in Table 7. 25 out of 27 (92.6%) measurement properties were rated either insufficient, indeterminate, or not assessed. The only measurement property to receive a ‘sufficient’ rating was reliability for both the KOOS and LEAS, supported by ‘low’ and ‘moderate’ quality evidence respectively.

Part C

Data on the interpretability of the studies is summarised in Table 8. The mode of PROM administration was unclear for all studies except de Groot et al (32). Missing responses ranged from 25-60%. No study reported on missing items within a PROM instrument. Floor and ceiling effects were not reported, except by Saleh et al (29). No PROM met criteria either to be recommended or not recommended for use. Each of the validated PROMs (i.e.
KOOS, LEAS and WOMAC) were therefore assigned recommendation ‘B’, indicating that further evidence is needed.
**Discussion**

This review has demonstrated the increasing use of PROMs to evaluate symptoms and functional outcomes following discretionary revision knee replacement. The majority of studies were retrospective and observational, with only one randomised controlled trial.

Eight different joint-specific PROMs were identified, with the WOMAC index (25 studies, 49.0%) and the OKS (19 studies, 37.3%) the most frequent. Only three joint-specific PROMs were supported by a validation study: KOOS, LEAS and WOMAC. Each of these validation studies had ‘low’ or ‘very low’ quality evidence and the majority of measurement properties were either not evaluated or rated ‘inadequate’ or ‘indeterminate’. As such, each of these PROMs requires more evidence in order to be recommended for use.

**Secondary findings and relation to other studies**

Musculoskeletal disorders account for one-third of all reviews on the COSMIN database (34). At least three reviews have evaluated the measurement properties of PROMs following primary knee replacement (9,10,35). These studies found that many PROM instruments had limited evidence to support their measurement properties, justifying the need for further research. We are not aware of previous reviews that have examined the measurement properties of PROMs following revision knee replacement. Whilst many of the goals from discretionary revision knee replacement are shared with primary knee replacement, there are important differences in the patient populations and disease processes being treated and the surgical interventions themselves. For example, whilst primary knee replacement treats predominantly osteoarthritis, revision knee replacement treats many varied disease processes (36). The revision patient population is also more comorbid and may have different expectations from surgery (37). As such, the evidence for PROMs developed in primary knee replacement cannot necessarily be assumed to be transferrable across.

**Strengths and weaknesses**

This study has a number of important strengths, including the use of a broad search strategy based on the Oxford PROM filter (24), and the application of latest COSMIN guidelines. The use of a priori hypotheses by our review team to evaluate construct validity and responsiveness is novel and meant these properties could be considered even when not a focus of the original article. This study was motivated by the James Lind Alliance Priority Setting Partnership for revision knee replacement, which generated the question: “How should we measure the outcomes following revision knee surgery in a way that is meaningful to patients?” (38). As such, outcome scores that were not patient completed were excluded. We acknowledge that this has restricted the number of eligible studies from North America, where use of the Knee Society Score (KSS) is prevalent. In the future, qualitative studies to explore patients’ reasons for choosing surgery and to identify the outcomes that are most important to patients may be needed.

**Implications for practice**

We have not put forward a PROM for recommendation because the quality of the available evidence was low, and data were lacking for many of the measurement properties. However, we can make recommendations to direct future research and to move towards developing a core outcome set for discretionary revision knee replacement. First, we wish to highlight that standards for reporting of psychometric studies have changed considerably over the past twenty years (9). COSMIN tools are not limited to systematic reviews and may
be used guide the scope and detail required to develop a new instrument or to evaluate an existing one. Second, this study has highlighted a number of common methodological flaws that result in high risk of bias. For example, when evaluating structural validity, none of the validation studies performed confirmatory factor analysis to understand whether the PROM scores reflected the dimensionality of the construct. For reliability, test conditions were not recorded with sufficient detail to ensure that not only the repeat interval was appropriate, but also that the patient remained stable. For interpretability, none of the studies calculated a minimal important change (MIC) nor comprehensively assessed floor and ceiling effects.

Third, we recommend that future studies planning to use an existing joint-specific PROM to evaluate outcomes after revision surgery do so in conjunction with a validated generic health-related quality of life instrument (such as the Short Form-36 (SF36) (39) or EQ-5D (23)). Whilst neither the EQ-5D or SF36 were developed in patients undergoing revision knee replacement, their measurement properties have been studied extensively and allow generalisability between different conditions. This approach will provide valuable information on construct validity and responsiveness in the future.

Conclusion

In conclusion, joint-specific PROMs are increasingly used to report outcomes following revision knee replacement, but these instruments have insufficient evidence for validity. Future research is needed to target the deficiencies highlighted by this review in order to inform clinical trials and observational studies evaluating these outcomes.
Details of contributors:
SAS: concept, study selection and scoping review, assessment of methodological quality, analysis, writing and editing paper, guarantor.

EAH: study selection and scoping review, critically revising paper

SGFA: assessment of methodological quality, critically revising paper

AA: critically revising paper

AJP: concept, methodology, writing and editing paper

SH: concept, methodology, writing and editing paper

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Data sharing statement: All available data is provided in the manuscript and supplementary tables.
**Figure legends**

Figure 1. PRISMA flow diagram. The full search strategy is provided in Appendix 2 within the Supplementary file.
| Authors | Year | Country | Journal | Study design | No. revision knees | Validation Study? | PROM(s) used |
|---------|------|---------|---------|--------------|-------------------|------------------|--------------|
| Hartley (40) | 2002 | UK | BJJ | Prospective cohort | 60 | | SF36, WOMAC |
| Meek (41) | 2003 | Canada | BJJ | Prospective cohort | 107 | | SF36, WOMAC |
| Meek (42) | 2004 | Canada | JOA | Cross-section | 67 | | OKS, SF36, WOMAC |
| Saleh (29) | 2005 | US | JBS(Am) | Prospective cohort | 297 | Yes | LEAS, WOMAC |
| Masri (43) | 2006 | Canada | JOA | Retrospective cohort | 126 | | OKS, SF36, WOMAC |
| Dahm (44) | 2007 | US | JOA | Cross-section | 335 | | UCLA |
| Ghanem (45) | 2007 | US | CORR | Prospective cohort | 80 | | SF36, WOMAC |
| Mulhalli (46) | 2008 | Netherlands | Health Qual Life | Prospective cohort | 54 | Yes | KOOS, SF36 |
| Brem (35) | 2009 | US | JBS(Am) | Prospective cohort | 308 | Yes | LEAS, SF36, WOMAC |
| Kim (47) | 2009 | South Korea | JBS(Am) | Retrospective cohort | 157 | | WOMAC |
| Ghanem (43) | 2010 | US | JBS(Am) | Retrospective cohort | 152 | Yes | SF36, WOMAC |
| Greidanus (48) | 2011 | US | JOA | Retrospective cohort | 60 | | OKS, SF12, WOMAC |
| Hanna (49) | 2011 | UK | CORR | Retrospective cohort | 56 | | OKS |
| Lavermia (50) | 2011 | US | CORR | Retrospective cohort | 132 | | SF36, WOMAC |
| Richards (51) | 2011 | Canada | JOA | Cross-section | 72 | | SF36, UCLA, WOMAC |
| Baker (36) | 2012 | UK | CORR | Joint Registry | 797 | | EQ-5D, OKS |
| Malviya (52) | 2012 | UK | KSSTA | Prospective cohort | 175 | | SF36, WOMAC |
| Baier (53) | 2012 | Germany | J Orth Sci | Retrospective cohort | 78 | | WOMAC |
| Huang (54) | 2014 | US | Orthopedics | Prospective cohort | 96 | | SF36, WOMAC |
| Kasmi (55) | 2014 | US | The Knee | Retrospective cohort | 175 | | SF36, WOMAC |
| Luque (56) | 2014 | Spain | Int Orth | Retrospective cohort | 125 | | OKS |
| Stambough (57) | 2014 | US | BJ | Retrospective cohort | 81 | | UCLA |
| Weiss (58) | 2014 | Sweden | Acta Orthop | Retrospective cohort | 65 | | EQ-5D, KOOS |
| Hilt (59) | 2015 | US | J Knee Surg | Prospective cohort | 95 | | KOOS, LEAS, SF36 |
| Kim (60) | 2015 | South Korea | JOA | Retrospective cohort | 228 | | WOMAC |
| Konrads (61) | 2015 | Germany | Int Orth | Retrospective cohort | 62 | | Kujala, OKS, SF36 |
| Luneburg (62) | 2015 | France | JOA | Retrospective cohort | 54 | | KOOS |
| Grayson (63) | 2016 | UK | JOA | Retrospective cohort | 177 | | UCLA |
| Leta (64) | 2016 | Norway | JBS(Am) | Joint Registry | 1346 | | EQ-5D, KOOS |
| Leta (65) | 2016 | Norway | Int Orth | Joint Registry | 308 | | EQ-5D, KOOS |
| Hamilton (66) | 2017 | UK | JOA | Prospective cohort | 53 | | OKS |
| Lim (67) | 2017 | Singapore | BJ | Retrospective cohort | 75 | | OKS, SF36 |
| M-Hernandez (68) | 2017 | Spain | KSSTA | Prospective cohort | 134 | | SF12, WOMAC |
| Rajgopal (69) | 2017 | India | JOA | Retrospective cohort | 98 | | WOMAC |
| Sandiford (70) | 2017 | Canada | CORR | Retrospective cohort | 450 | | OKS, SF36, WOMAC |
| Zhamilov (71) | 2017 | Turkey | JOA | Retrospective cohort | 92 | | LEFS |
| Agarwal (72) | 2018 | UK | The Knee | Prospective cohort | 104 | | EQ-5D, OKS |
| Boelch (73) | 2018 | Germany | Int Orth | RCT | 51 | | OKS, SF36 |
| Eibich (74) | 2018 | UK | BMJ Open | Routine data | 1391 | | EQ-5D, OKS |
| Gomez Vallejo (75) | 2018 | Spain | J Orth Traum | Retrospective cohort | 67 | | SF36, WOMAC |
| Weber (76) | 2018 | Germany | BioMed RI | Retrospective cohort | 68 | | EQ-5D, WOMAC |
| Bin Abd Razak (77) | 2019 | Singapore | J Knee Surg | Retrospective cohort | 163 | | OKS, SF36 |
| Konrads (78) | 2019 | Germany | J Knee Surg | Retrospective cohort | 135 | | Kujala, OKS, SF36 |
| Kurmis (79) | 2019 | Australia | JOA | Retrospective cohort | 321 | | OKS, WOMAC |
| Lim (80) | 2019 | Singapore | The Knee | Retrospective cohort | 70 | | OKS, SF36 |
| Scior (81) | 2019 | Germany | JOA | Prospective cohort | 482 | | OKS |
| Stockwell (82) | 2019 | Canada | The Knee | Retrospective cohort | 234 | | OKS |
| Klim (83) | 2020 | Austria | KSSTA | Retrospective cohort | 93 | | SF36, WOMAC |
| Larsen (84) | 2020 | Denmark | BMC Sports Sci | Retrospective cohort | 51 | | KOOS |
| Oliver (85) | 2020 | Spain | Orth Surg | Retrospective cohort | 89 | | KOOS, Lysholm |

KOOS = Knee injury and osteoarthritis outcome score; LEAS = Lower extremity activity scale; LEFS = Lower extremity functional scale; OKS = Oxford Knee Score; SF = Short Form; UCLA = University of California Los Angeles Activity Score; WOMAC = Western Ontario and McMaster Universities Arthritis Index
Table 1. Summary characteristics for studies reporting PROMs following revision knee replacement

| Number of studies (%) |                   |
|-----------------------|-------------------|
| **No. patients**      | median 104 (range 51 - 1391) |
| Continent             |                   |
| Europe                | 25 (49%)          |
| North America         | 19 (37.3%)        |
| Asia                  | 6 (11.8%)         |
| Australasia           | 1 (2%)            |
| Type of study         |                   |
| Randomized controlled trial | 1 (2%)   |
| Prospective cohort    | 14 (27.5%)        |
| Retrospective cohort  | 29 (56.9%)        |
| Joint Registry        | 3 (5.9%)          |
| Routine data analysis | 1 (2%)            |
| Cross-sectional survey| 3 (5.9%)          |
| Joint-specific PROMs  |                   |
| KOOS                  | 8 (15.7%)         |
| Kujala                | 2 (3.9%)          |
| LEAS                  | 4 (7.8%)          |
| LEFS                  | 1 (2%)            |
| Lysholm               | 1 (2%)            |
| OKS                   | 19 (37.3%)        |
| UCLA                  | 4 (7.8%)          |
| WOMAC                 | 25 (49%)          |
| Generic PROMs         |                   |
| EQ-5D                 | 7 (13.7%)         |
| SF12                  | 8 (15.7%)         |
| SF36                  | 18 (35.3%)        |

Number of studies reporting each measure (%), KOOS = Knee injury and osteoarthritis outcome score; LEAS = Lower extremity activity scale; LEFS = Lower extremity functional scale; OKS = Oxford Knee Score; SF = Short Form; UCLA = University of California Los Angeles Activity Score; WOMAC = Western Ontario and McMaster Universities Arthritis Index
Table 3. Quality of PROM development

| PROM                    | Clear construct | Clear origin of construct | Clear target population for which the PROM was developed | Clear context of use | PROM developed in sample representing the target population | Concept elicitation | Total PROM design | CI study performed in sample representing the target population | Comprehensiability | Comprehensiveness | Total CI study | TOTAL PROM DEVELOPMENT |
|-------------------------|-----------------|---------------------------|--------------------------------------------------------|---------------------|-----------------------------------------------------------|---------------------|------------------|---------------------------------------------------------------|------------------|---------------------|---------------------|------------------------|
| joint-specific          |                 |                           |                                                        |                     |                                                           |                     |                  |                                                               |                  |                     |                     |                        |
| KOOS (21)               | I               | D                         | VG                                                     | D                   | I                                                          | I                   | Yes              |                                                               |                  |                     |                     | 1                      |
| Kujala (27)             | I               | D                         | VG                                                     | D                   | I                                                          | I                   | No               |                                                               |                  |                     |                     | 1                      |
| LEAS (29)               | I               | D                         | VG                                                     | VG                  | I                                                          | I                   | No               |                                                               |                  |                     |                     | 1                      |
| LEFS (31)               | I               | VG                        | VG                                                     | VG                  | I                                                          | I                   | No               |                                                               |                  |                     |                     | 1                      |
| Lysholm (28)            | VG              | D                         | VG                                                     | VG                  | I                                                          | I                   | No               |                                                               |                  |                     |                     | 1                      |
| Oxford Knee Score (20)  | I               | D                         | VG                                                     | VG                  | I                                                          | I                   | No               |                                                               |                  |                     |                     | 1                      |
| WOMAC (19)              | VG              | VG                        | VG                                                     | VG                  | I                                                          | I                   | Yes              |                                                               |                  |                     |                     | 1                      |
| UCLA (86)               | I               | D                         | VG                                                     | D                   | I                                                          | I                   | No               |                                                               |                  |                     |                     | 1                      |
| generic                 |                 |                           |                                                        |                     |                                                           |                     |                  |                                                               |                  |                     |                     |                        |
| EQ-5D (23)              | I               | D                         | VG                                                     | VG                  | I                                                          | I                   |                  |                                                               |                  |                     |                     | 1                      |
| SF-36 (39)              | VG              | VG                        | VG                                                     | VG                  | I                                                          | I                   |                  |                                                               |                  |                     |                     | 1                      |
| SF-12 (87)              | VG              | VG                        | VG                                                     | VG                  | I                                                          | I                   |                  |                                                               |                  |                     |                     | 1                      |

KOOS = Knee injury and osteoarthritis outcome score; LEAS = Lower extremity activity scale; SF = Short-Form; UCLA = University of California at Los Angeles; WOMAC = Western Ontario and McMaster Universities Arthritis Index

VG = Very good, A = Adequate, D = Doubtful, I = Inadequate, N = Not assessed

1 Where the PROM was not developed in a sample representing the target population, the concept elicitation was not further rated

2 Empty cells indicate that a CI study (or part of it) was not performed
| Study        | Instrument(s) | Primary objective                                      | Country (Language) | Population (Inclusion/Exclusion criteria) | Enrolled (n) | LTFU (n) | Final (n) | Age (years) | Female (%) | FU (months) | Indications for revision |
|--------------|---------------|--------------------------------------------------------|--------------------|-------------------------------------------|--------------|-----------|-----------|-------------|-------------|--------------|------------------------|
| de Groot (2008) | KOOS, SF-36 | To validate the Dutch translation of KOOS               | Netherlands (Dutch) | Inc: Revision TKR Exclusion: Unable to understand Dutch written language. | 54           | 7         | 47        | 77 (36-89) | 78          | NR           | NR                     |
| Saleh (2005) | LEAS, WOMAC  | To develop and validate the Lower-Extremity Activity Scale | United States (English) | Inc: First revision TKR capable of completing questionnaires in English and >= 18 years Ex: Re-revision, failed UKR, poly. exchange only, bone tumour, reflex sympathetic dystrophy, unfit for revision TKR, neurological deficit of affected limb, referred pain from spine, declined to participate, concern about compliance, inability to consent, progressive muscular condition of quadriceps, infection delay, stiffness not requiring component revision. | 297          | 12        | 285       | 68.6 (r 34 - 85) | 55          | 6           | Instability 28.9%*, Poly. wear 24.5%, Failed poly. insert 18.1%, Malalignment 9.4%, Fem. loosening 14.1%, Fem. lysis 22.5%, Tibial loosening 22.2%, Patella lysis 9.4% |
| Ghomrawi (2009) | LEAS, SF-36 | To characterise patterns of functional improvement after revision total knee arthroplasty over a two-year period using Lower-Extremity Activity Scale | United States (English) | As per Saleh et al (2005) | 308          | 87        | 221       | 68.7 (r 34 - 85) | 55          | 24          | Instability 28.9%*, Poly. wear 24.5%, Failed poly. insert 18.1%, Malalignment 9.4%, Fem. loosening 14.1%, Fem. lysis 22.5%, Tibial loosening 22.2%, Patella lysis 9.4% |
| Ghanem (2010) | WOMAC | To determine validity and responsiveness of the Knee Society Rating System | United States (English) | Inc: Revision TKR Ex: Infection (n=85), Patella or poly. exchange only (n=35); Conversion of UCR or internal fixation (n=15), Non-prosthetic failure (n=4) | 165          | 13        | 152       | 67 (r 36 - 89) | NR          | 24          | Mechanical failure: Aseptic loosening 69.7%, Knee instability 30.3% |

Age = mean (sd) or (r = indicating range); KOOS = Knee injury and osteoarthritis outcome score; KSS = Knee Society Rating system; LEAS = Lower extremity activity scale; Lig. = Ligamentous; LTFU – Lost to follow-up; NR = Not reported; Poly. = polyethylene; SF-36 = Short-Form 36; WOMAC = Western Ontario and McMaster Universities Arthritis Index, * Data for this population are provided in a separate paper by Mulhall et al (88), number of patients not provided only percentages.
Table 5. Characteristics of the joint-specific PROMs evaluated in validation studies.

| Instrument | Year developed | Original language | Target population | Intended construct / Domains | No. questions | Best/worst score |
|------------|----------------|-------------------|-------------------|-------------------------------|---------------|-----------------|
| **Symptoms and functional status** | | | | | | |
| KOOS (21)  | 1998           | English & Swedish | Younger and more active subjects at risk of knee osteoarthritis following knee injury | Pain, Symptoms, Activities of daily life function | 42 questions | 100/0           |
| WOMAC (19) | 1982           | English           | Patients with OA of the hip or knee | Pain, Stiffness, Knee-related quality of life, Function and daily activities | 24 questions | 0/96            |
| **Activity-level** | | | | | | |
| LEAS (29)  | 2005           | English           | Patients awaiting or had undergone primary or revision lower limb joint replacement | Physical activity | 1 question | 18/1            |

KOOS = Knee injury and osteoarthritis outcome score; LEAS = Lower extremity activity scale; SF-36 = Short-Form 36; WOMAC = Western Ontario and McMaster Universities Arthritis Index.
Table 6. Quality of studies on measurement properties

| PROM | Study          | Structural validity | Internal consistency | Cross-cultural validity | Reliability | Measurement error | Criterion validity | Construct validity | Responsiveness   |
|------|----------------|---------------------|----------------------|-------------------------|-------------|-------------------|--------------------|-------------------|------------------|
|      |                |                     |                      |                          |             |                   |                    |                   | KOOS  | de Groot (32) | I     | VG   | I   | A  | A  | N  | D  | N  | N  | N  | N  | N  |
|      |                |                     |                      |                          |             |                   |                    |                   | LEAS  | Saleh (29)   | N    | N    | N   | A  | A  | N  | I  | N  | N  | I  | N  | A  |
|      |                |                     |                      |                          |             |                   |                    |                   | LEAS  | Ghomrawi (22) | N    | N    | N   | N  | N  | N  | N  | N  | N  | I  | N  | I  | I  |
| WOMAC| Ghanem (33)    | N                    | N                    | N                        | N           | N                 | D                  | N                 | WOMAC | Ghomrawi (22) | N    | N    | N   | N  | N  | N  | N  | N  | N  | I  | I  | I  |

KOOS = Knee injury and osteoarthritis outcome score; LEAS = Lower extremity activity scale, WOMAC = Western Ontario and McMaster Universities Arthritis Index; VG = Very good, A = Adequate, D = Doubtful, I = Inadequate, N= Not assessed
Table 7. Quality of the evidence for measurement properties of the PROMs

| KOOS          | OVERALL RATING | QUALITY OF EVIDENCE | LEAS          | OVERALL RATING | QUALITY OF EVIDENCE | WOMAC         | OVERALL RATING | QUALITY OF EVIDENCE |
|---------------|----------------|---------------------|---------------|----------------|---------------------|---------------|----------------|---------------------|
| Structural validity | -              | Very low            | N             | N              | N                   | N             | N              | N                   |
| Internal consistency | ?              | Moderate           | N             | N              | N                   | N             | N              | N                   |
| Cross-cultural validity | ?              | Very low           | N             | N              | N                   | N             | N              | N                   |
| Measurement invariance | ?              | Very low           | N             | N              | N                   | N             | N              | N                   |
| Reliability     | +              | Low                | +             | Moderate       |         | N             | N              | N                   |
| Measurement error | ?              | Low                | ?             | Very low       |         | N             | N              | N                   |
| Criterion validity | N              | N                  | N             | N              | N                   | N             | N              | N                   |
| Construct validity | -              | Low                | -             | Very low       |         | ?             | Very low       |                      |
| Responsiveness  | N              | N                  | ?             | Very low       |         | ?             | Very low       |                      |

KOOS = Knee injury and osteoarthritis outcome score; LEAS = Lower extremity activity scale; N = not assessed; WOMAC = Western Ontario and McMaster Universities Arthritis Index, + = sufficient, - = insufficient, ? = indeterminate
Table 8. Interpretability including missing items, response rate and floor/ceiling effects

| Instrument and study | Administration | Missing responses (%) | Missing items (%) | Overall % achieving lowest possible total score (floor) | Overall percentage achieving highest possible score (ceiling) | Items/Domains with >15% responses with lowest score (floor) | Items/Domains with >15% responses with highest score (ceiling) | MIC |
|----------------------|----------------|----------------------|------------------|-------------------------------------------------------|----------------------------------------------------------|-----------------------------------------------------------|----------------------------------------------------------|-----|
| **Symptoms and functional status** | | | | | | | | |
| KOOS de Groot (2008) (32) | Postal | 25 | NR | NR | NR | Sports/Recreation | Nil | NR |
| WOMAC | | | | | | | | |
| Ghomrawi (2009) (22) | Unclear | 30.5 | NR | NR | NR | NR | NR | NR |
| Ghanem (2010) (33) | Unclear | NR | NR | NR | NR | NR | NR | NR |
| Saleh (2005) (29) | Unclear | NR | NR | NR | NR | NR | NR | NR |
| **Health-related quality of life** | | | | | | | | |
| SF-36 de Groot (2008) (32) | Postal | NR | NR | NR | NR | NR | NR | NR |
| Ghomrawi (2009) (22) | Unclear | 30.5 | NR | NR | NR | NR | NR | NR |
| Ghanem (2010) (33) | Unclear | NR | NR | NR | NR | NR | NR | NR |
| **Activity-level** | | | | | | | | |
| LEAS | | | | | | | | |
| Ghomrawi (2009) (22) | Unclear | 30.5 | NR | NR | NR | NR | NR | NR |
| Saleh (2005) (29) | Unclear | 59.6* | NR | 0 | 0 | NR | NR | NR |

KOOS = Knee injury and osteoarthritis outcome score; LEAS = Lower extremity activity scale; SF-36 = Short-Form 36; WOMAC = Western Ontario and McMaster Universities Arthritis Index; *Reported response rate was 96%. However, histograms have 177 or 178 patients out of a possible 297 (59.6%).
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Figure 1. PRISMA flow diagram. The full search strategy is provided in Appendix 1 within the Supplementary file.

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Appendix 1: Search Strategy

This search strategy incorporates the PROM filter from the Oxford PROM group (24).

Databases: MEDLINE, Embase, AMED, PsycInfo

Search strategy for Ovid MEDLINE:

Arthroplasty, Replacement, Knee/
((arthroplast* or replacement* or resurface*) adj3 knee*).ti,ab.
Knee Prosthesis/
((prosthes* or implant*) adj3 knee*).ti,ab.
(tka or tkr or ukr or uka).ti,ab.
1 or 2 or 3 or 4 or 5
revision*.ti,ab.
modular exchange*.ti,ab.
Reoperation/
(reoperation or re-operation or "repeat surg*").ti,ab.
7 or 8 or 9 or 10
6 and 11
(HR-PRO or HRPRO or HRQoL 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.
12 and 13
Appendix 2: Tables & Figures

Appendix 2 Table 1. Generic hypotheses to evaluate construct validity and responsiveness

| Hypotheses                                                                                      |
|-----------------------------------------------------------------------------------------------|
| 1  Correlations with (changes in) instruments measuring similar constructs should be ≥ 0.50    |
| 2  Correlations with (changes in) instruments measuring related, but dissimilar constructs should be lower, i.e. 0.30-0.50. |
| 3  Correlations with (changes in) instruments measuring unrelated constructs should be < 0.30. |
| 4  Correlations defined under 1, 2, and 3 should differ by a minimum of 0.10.                   |
| 5  Meaningful changes between relevant (sub)groups (e.g. patients with expected high vs low levels of the construct of interest) |
| 6  For responsiveness, the area under the curve should be ≥ 0.70.                               |

This table is reproduced from de Vet et al (89) and is included in the COSMIN manual for systematic reviews of PROMS (17).

Appendix 2 Figure 1. Histogram demonstrating increasing numbers of studies reporting on PROMS following revision knee replacement over time.

![Histogram demonstrating increasing numbers of studies reporting on PROMS following revision knee replacement over time.](image)
Appendix 3: Definitions of measurement properties

This manuscript uses COSMIN definitions throughout. A more detailed explanation of the COSMIN taxonomy, domains and definitions can be found within the COSMIN manual for systematic reviews of PROMS (17).

Content validity
Validity is “the degree to which a PROM measures the construct” intended (90). Content validity refers to “the degree to which the content of a PROM is an adequate reflection of the construct to be measured” (17). COSMIN provide a bespoke user manual to evaluate content validity (91).

Internal structure
Structural validity is the degree to which the PROM scores reflect the dimensionality of the construct being measured (90). Construct validity is “the degree to which the scores of a PROM are consistent with hypotheses”, assuming that the PROM is a valid instrument to measure the construct (90). Internal consistency is the “interrelatedness among PROM items” (90). Cross-cultural validity evaluates the performance of an adapted PROM compared to the original version (90).

Reliability
Reliability refers to “the degree to which a measurement is free from measurement error” (90).

Responsiveness
Responsiveness is the ability of a PROM to detect change over time (90).

Interpretability
Interpretability is the degree to which qualitative meaning can be assigned to a PROM score.

Feasibility
Feasibility is the ease of application of a PROM for its context of use. The measurement properties were analysed descriptively as per COSMIN guidance.
Appendix 4: COSMIN methodology for conducting a systematic review of PROM instruments

This diagram is reproduced from the COSMIN manual for systematic reviews of PROMs (17).
| Section/topic | # | Checklist item                                                                                                                                                                                                 | Reported on page # |
|---------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| TITLE         |   |                                                                                                                                                                                                               |                   |
| Title         | 1 | Identify the report as a systematic review, meta-analysis, or both.                                                                                                                                              | 1                 |
| ABSTRACT      |   |                                                                                                                                                                                                               |                   |
| Structured summary | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. | 2                 |
| INTRODUCTION  |   |                                                                                                                                                                                                               |                   |
| Rationale     | 3 | Describe the rationale for the review in the context of what is already known.                                                                                                                                     | 4                 |
| Objectives    | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).                                                                 | 4                 |
| METHODS       |   |                                                                                                                                                                                                               |                   |
| Protocol and registration | 5 | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.                                               | N/A               |
| Eligibility criteria | 6 | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.                                                   | 5                 |
| Information sources | 7 | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.                                             | 5                 |
| Search        | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.                                                                                  | 5&32              |
| Study selection | 9 | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).                                                        | 5                 |
| Data collection process | 10 | Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.                                                  | 5&6               |
| Data items    | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.                                                                              | 5&6               |
| Risk of bias in individual studies | 12 | Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis. | 6                 |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means).                                                                                                                                     | 6                 |
| Synthesis of results | 14 | Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I² for each meta-analysis).                                                             | 6                 |
# PRISMA 2009 Checklist

### RESULTS

| Section/topic                      | #  | Checklist item                                                                                                                                                                                                 | Reported on page # |
|-----------------------------------|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Risk of bias across studies       | 15 | Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).                                                                     | 6                 |
| Additional analyses               | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.                                                                   | N/A               |
| Study selection                   | 17 | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.                                                       | 19                |
| Study characteristics             | 18 | For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.                                                                  | 20/21/24          |
| Risk of bias within studies       | 19 | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).                                                                                                      | 26                |
| Results of individual studies     | 20 | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. | 26                |
| Synthesis of results              | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency.                                                                                                       | 27                |
| Risk of bias across studies       | 22 | Present results of any assessment of risk of bias across studies (see Item 15).                                                                                                                               | 27                |
| Additional analysis               | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).                                                                                           |                   |

### DISCUSSION

| Section/topic                      | #  | Checklist item                                                                                                                                                                                                 |                      |
|-----------------------------------|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Summary of evidence               | 24 | Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).                       | 9                   |
| Limitations                       | 25 | Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).                                                     | 9                   |
| Conclusions                       | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research.                                                                                          | 10                  |

### FUNDING

| Section/topic                      | #  | Checklist item                                                                                                                                                                                                 |                      |
|-----------------------------------|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Funding                           | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.                                                                 | 11                  |

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: [www.prisma-statement.org](http://www.prisma-statement.org)
| SECTION               | ITEM | PRISMA-ScR CHECKLIST ITEM                                                                                                                                                                                                 | REPORTED ON PAGE # |
|-----------------------|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| TITLE                 | 1    | Identify the report as a scoping review.                                                                                                                                                                                      | 1                 |
| ABSTRACT              | 2    | Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.          | 2                 |
| INTRODUCTION          | 3    | Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.                                                      | 4                 |
| Objectives            | 4    | Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives. | 4                 |
| METHODS               | 5    | Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number. | N/A               |
| Protocol and          | 6    | Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.                                                                 | 5                 |
| Eligibility criteria  | 7    | Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed. | 5                 |
| Information sources*  | 8    | Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.                                                                                               | Appendix 1        |
| Search                | 9    | State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.                                                                                                        | 5/6               |
| Selection of          | 10   | Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators. | 6                 |
| sources of evidence†  |      |                                                                                                                                                                                                                            |                   |
| Data charting         | 11   | List and define all variables for which data were sought and any assumptions and simplifications made.                                                                                                                     | 6                 |
| process‡              |      |                                                                                                                                                                                                                            |                   |
| Critical appraisal of | 12   | If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).                                      | N/A               |
| individual sources of |      |                                                                                                                                                                                                                            |                   |
| evidence§             |      |                                                                                                                                                                                                                            |                   |
| SECTION | ITEM | PRISMA-ScR CHECKLIST ITEM | REPORTED ON PAGE # |
|---------|------|--------------------------|-------------------|
| Synthesis of results | 13 | Describe the methods of handling and summarizing the data that were charted. | 6 |
| RESULTS | | | |
| Selection of sources of evidence | 14 | Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram. | Fig 1 |
| Characteristics of sources of evidence | 15 | For each source of evidence, present characteristics for which data were charted and provide the citations. | Tables 1 & 2 |
| Critical appraisal within sources of evidence | 16 | If done, present data on critical appraisal of included sources of evidence (see item 12). | N/A |
| Results of individual sources of evidence | 17 | For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives. | Tables 1 & 2 |
| Synthesis of results | 18 | Summarize and/or present the charting results as they relate to the review questions and objectives. | Tables 1 & 2 |
| DISCUSSION | | | |
| Summary of evidence | 19 | Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups. | 10 |
| Limitations | 20 | Discuss the limitations of the scoping review process. | 10 |
| Conclusions | 21 | Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps. | 11 |
| FUNDING | | | |
| Funding | 22 | Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review. | 12 |

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where sources of evidence (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.
† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with information sources (see first footnote).
‡ The frameworks by Arksey and O’Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.
§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.