BMJ Open

Patient-reported outcomes in studies evaluating shared decision-making interventions: protocol for a systematic review and meta-analysis

Sang Ho Yoo [1], Myonghwa Park [2], Min Ji Kim [1,3]

To cite: Yoo SH, Park M, Kim MJ. Patient-reported outcomes in studies evaluating shared decision-making interventions: protocol for a systematic review and meta-analysis. *BMJ Open* 2026;**16**:e124305. doi:10.1136/bmjopen-2026-124305

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2026-124305).

Received 16 June 2026
Accepted 01 September 2026

Check for updates

© Author(s) (or their employer(s)) 2026. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ Group.

[1]Department of Medical Humanities and Ethics, Hanyang University College of Medicine, Seoul, Korea (the Republic of)
[2]College of Nursing, Chungnam National University, Daejeon, Korea (the Republic of)
[3]Department of Health Policy and Management, College of Health Science, Korea University, Seoul, Korea (the Republic of)

Correspondence to
Dr Min Ji Kim;
drphkim@gmail.com

ABSTRACT

Introduction Shared decision-making (SDM) aims to align health decisions with evidence and patients' values, preferences and circumstances. Patient-reported outcomes (PROs) are central to evaluating SDM because many relevant outcomes, including feeling informed, understanding risks, decisional conflict, decisional regret and treatment burden, can be assessed only from the patient's perspective. However, which PROs are used in SDM intervention studies and whether intervention effects vary across PRO constructs remain unclear. This protocol describes a systematic review that will map PROs and synthesise effects by PRO construct, where data permit.

Methods and analysis This systematic review protocol is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols guidelines. We will search seven databases—PubMed, Embase, CINAHL, Web of Science Core Collection, Scopus, CENTRAL and PsycINFO—from inception to the date of the final search, supplemented by ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform, reference-list screening and forward citation tracking. Randomised and non-randomised comparative studies will be synthesised separately, while single-arm studies will contribute to outcome mapping only. PROs will be defined as outcomes reported or completed directly by patients, while patient-reported SDM process measures will be classified separately. Two reviewers will independently screen titles/abstracts and full texts and extract data. Risk of bias will be assessed independently, using appropriate design-specific tools, for all comparative studies eligible to contribute to effect synthesis. Outcomes will be mapped to prespecified domains. Meta-analysis will be performed where studies are sufficiently comparable; otherwise, narrative synthesis will follow Synthesis Without Meta-analysis guidance. The certainty of evidence will be assessed using the Grading of Recommendations Assessment, Development and Evaluation.

Ethics and dissemination Ethical approval is not required because this review will use non-identifiable aggregate information from existing study reports and trial registries and will not involve primary data collection from human participants or identifiable personal data. Findings will be disseminated through peer-reviewed publications and academic conferences.

PROSPERO registration number CRD420261413222.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This protocol uses a population, intervention, comparator, outcome and study design-based eligibility framework to distinguish outcome mapping from comparative effect synthesis of shared decision-making (SDM) interventions.
⇒ Patient-reported outcomes (PROs) will be classified into prespecified outcome constructs, allowing decision-related, health-related and patient-reported behavioural outcomes to be synthesised separately, while patient-reported SDM process measures are mapped separately.
⇒ Searches will cover seven major bibliographic databases without date or language restrictions and will be supplemented by ClinicalTrials.gov, WHO International Clinical Trials Registry Platform, reference-list screening and forward citation tracking.
⇒ Substantial clinical, methodological and measurement heterogeneity may limit quantitative synthesis for some PRO domains.
⇒ Single-arm intervention studies, if included, will contribute only to outcome mapping and not to comparative effect estimates.

INTRODUCTION

Healthcare systems have shifted from volume-based models, which emphasise the quantity of services delivered, to value-based care, which prioritises outcomes that matter to patients, quality, equity and efficient resource use.[1 2] This shift has been reinforced by the emergence of patient-centred care, identified by the Institute of Medicine as one of the core aims of improving healthcare systems in the 21st century.[3] Patient-centred care requires clinicians to consider not only medical evidence but also patient values, preferences and circumstances when making clinical decisions.[3]

Shared decision-making (SDM) is widely regarded as the principal and ethical approach to patient-centred care.[4 5] It can be understood as a collaborative communication

BMJ Open: first published as 10.1136/bmjopen-2026-124305 on 15 September 2026. Downloaded from http://bmjopen.bmj.com/ on October 12, 2026 at Hanyang University Medical Library . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

process through which patients, clinicians, family members or primary caregivers make clinical decisions informed by the available evidence and what matters to patients.[4] SDM is particularly important in preference-sensitive situations in which more than one clinically reasonable option exists and the balance of benefits, harms and burdens depends on individual values, preferences and contexts.[6] In empirical research, SDM interventions may include patient-facing, clinician-facing or multicomponent strategies,[7] such as patient decision aids, decision coaching, clinician communication training and consultation tools, provided that they are designed to make decisions explicit, present options, communicate benefits and harms, elicit patient values and support deliberation.[5 8]

As interest in SDM has grown, empirical studies have examined SDM across diverse diseases and clinical settings, including emergency medicine,[9] palliative care[10] and other contexts.[11] Many outcomes relevant to SDM are subjective. Clinicians may observe treatment uptake or clinical response, but they cannot directly determine whether patients feel informed, understand risk information, experience decisional conflict or regret or find treatment burden acceptable after a decision has been made.[12 13] Patient-reported outcomes (PROs), defined as reports that come directly from patients without interpretation by clinicians or others, are therefore particularly relevant for evaluating SDM interventions.[14] These outcomes capture the dimensions of decision-making and care that are meaningful from the patient's perspective.[15]

In SDM intervention studies, PROs may include decision-related outcomes,[16] such as knowledge, risk perception, decisional conflict,[12] decision quality, decision regret[13] and satisfaction[17]; health-related outcomes, such as health-related quality of life, symptoms, functioning, psychological well-being and treatment burden; and patient-reported behavioural outcomes, such as self-reported adherence or treatment uptake.[14] Heterogeneity in outcome selection and measurement may limit comparability across studies, obscure the patient-reported benefits that are most responsive to SDM and hinder the development of consistent outcome frameworks for future SDM trials and implementation studies.[18 19]

This review addresses this gap by mapping the PROs used to evaluate SDM interventions and synthesising evidence regarding their effects across PRO constructs. By clarifying what has been measured and whether SDM interventions have improved these outcomes, this review will inform outcome selection, intervention evaluation and future study design in SDM research.[18 19]

Objective

The primary aim of this systematic review is to identify all patient-reported or patient-completed outcome constructs in studies evaluating SDM interventions. These constructs will be classified according to a prespecified, review-specific operational taxonomy: decision-related PROs, health-related PROs, patient-reported behavioural outcomes, patient-reported SDM process or perceived involvement measures and other PROs. The secondary aim is to synthesise intervention effects for specific, conceptually coherent outcome constructs nested within the first three PRO domains and, separately for patient-reported SDM or perceived involvement measures and other PROs, provided that sufficiently comparable data are available. Different outcome constructs within the same broad domains will not be statistically pooled. Patient-reported measures of the SDM process will be mapped and synthesised separately, while other PROs will first be classified inductively. Observer-rated or clinician-rated SDM measures will not be included in the PRO synthesis. Non-patient-reported clinical or healthcare utilisation outcomes will be extracted only as contextual secondary outcomes where relevant.

Review question

The review questions are structured according to the population, intervention, comparator, outcome and study design (PICOS) framework for intervention reviews, as illustrated in table 1.[20 21] The review will address the following questions:

- What PROs have been used as outcomes in studies evaluating SDM interventions?
- What are the effects of SDM interventions on these PROs compared with relevant comparators?

METHODS AND ANALYSIS

Study design

This systematic review protocol was developed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) guidelines (online supplemental file 1).[22] It was prospectively registered in the International Prospective Register of Systematic Reviews database on 2 June 2026 (register no. CRD420261413222).[23] The completed review will be reported in accordance with the PRISMA 2020 statement.[24] Any important protocol amendments will be dated, described with reasons and updated in PROSPERO; deviations will be reported in the completed review.

Eligibility criteria

The eligibility criteria were established in accordance with the PICOS framework, which was consistent with the review questions. The eligible population will include patients involved in health-related decision-making in clinical settings. Eligible interventions will include those explicitly designed to promote or support SDM, such as patient decision aids, decision coaching, clinician communication training, consultation tools and multicomponent SDM implementation strategies. Interventions will be considered eligible if they aim to facilitate at least one core element of SDM, such as making the decision explicit, presenting available options, communicating benefits and harms, eliciting patients' values or preferences, supporting deliberation or integrating

BMJ Open: first published as 10.1136/bmjopen-2026-124305 on 15 September 2026. Downloaded from http://bmjopen.bmj.com/ on October 12, 2026 at Hanyang University Medical Library . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Table 1 PICOS framework

No.	PICOS component	Definition for this review
1	Population	Patients involved in health-related decision-making across clinical settings.
2	Intervention	Interventions explicitly designed to promote or support SDM, such as patient decision aids, decision coaching, clinician communication training, consultation tools and multicomponent SDM implementation strategies.
3	Comparator	Usual care, no intervention, minimal intervention, attention control or alternative decision-support/SDM intervention.
4	Outcome	Patient-reported or patient-completed outcomes used to evaluate SDM interventions, including decision-related PROs, health-related PROs and patient-reported behavioural outcomes. Patient-reported SDM process or perceived involvement outcomes will be mapped separately. Observer-rated, clinician-rated, registry-based and administrative outcomes will not be included in the primary PRO synthesis unless directly reported by patients.
5	Study design	Randomised and non-randomised intervention studies, including individually randomised trials, cluster randomised trials, quasi-experimental studies, controlled before-and-after studies, interrupted time-series studies and non-randomised comparative intervention studies. Single-arm intervention studies may be included for outcome mapping only.

PICOS, population-intervention-comparator-outcome-study design; PRO, patient-reported outcome; SDM, shared decision-making.

patient preferences.[8] Interventions will be excluded if they provide general health education only; do not address a specific health-related decision or preference-sensitive situation; do not include components intended to support patient involvement, value clarification, deliberation or patient–clinician decision-making; or evaluate patient-centred care broadly without a discernible SDM component.[25]

Eligible comparators will include usual care, no intervention, minimal intervention, attention control or alternative SDM interventions. Studies without a comparator will contribute to outcome mapping only, and thus will not contribute to comparative effect synthesis.[21] For this review, PRO will be operationalised broadly as patient-reported or patient-completed outcomes collected directly from patients without clinician, observer or proxy interpretation.[14] Eligible PROs will include decision-related patient-completed outcomes, such as knowledge, risk perception, decisional conflict, decision quality, decision regret and decision satisfaction; health-related PROs, such as health-related quality of life, symptoms, functioning, psychological well-being and treatment burden; and patient-reported behavioural outcomes, such as self-reported adherence or treatment uptake or intention to act. Patient-reported SDM process or perceived involvement measures will be mapped separately because they assess the process or experience of SDM rather than downstream patient outcomes. Observer-rated or clinician-rated SDM measures, registry-based uptake, claims-based healthcare utilisation and clinical outcomes will be extracted descriptively as contextual secondary outcomes where relevant, but will not be included in the primary PRO synthesis unless they are directly reported by patients (table 2).[26]

Eligible study designs will include randomised and non-randomised intervention studies evaluating SDM interventions. These will include individually randomised trials, cluster randomised trials, quasi-experimental studies, controlled before-and-after studies, interrupted time-series studies and non-randomised comparative intervention studies. Single-arm intervention studies may be included for outcome mapping; however, studies without a comparator or sufficient design features to estimate the intervention effect will not contribute to the comparative effect synthesis.[21 27 28] There will be no restrictions on publication year or language. Reports published in languages other than English or Korean will be translated as needed for eligibility assessment and data extraction.[29] If generative artificial intelligence translation is used, it will be limited to the initial draft translation of titles, abstracts or relevant full text. When necessary, translated material used for final review decisions will be verified against the original text by professional translators. The review will report the use of generative artificial intelligence or machine-translation tools, along with their versions, source languages and verification process.

Information sources

The following databases will be searched from their inception to the final search date: PubMed, Excerpta Medica Database (Embase) via Elsevier, Cumulative Index to Nursing and Allied Health Literature (CINAHL) via EBSCOhost, Web of Science Core Collection via Clarivate, Scopus via Elsevier, Cochrane Central Register of Controlled Trials (CENTRAL) via the Cochrane Library and Psychological Information (PsycINFO) via EBSCOhost. In addition, ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (WHO ICTRP) will be searched to identify ongoing, completed but unpublished or otherwise unreported eligible studies and to inform the assessment of missing results. We will also review the reference lists of the included studies and

BMJ Open: first published as 10.1136/bmjopen-2026-124305 on 15 September 2026. Downloaded from http://bmjopen.bmj.com/ on October 12, 2026 at Hanyang University Medical Library . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Table 2 Review-specific operational taxonomy for classifying PROs

Domain	Included outcomes	Separate/exclude/decision rule
Decision-related patient-reported or patient-completed outcomes	Knowledge, risk perception, decisional conflict, decision quality, decision regret and decision satisfaction when completed or reported directly by patients.	Classified as downstream decision-related outcomes. Patient-reported SDM process measures are mapped separately.
Health-related PROs	Health-related quality of life, symptoms, functioning, psychological well-being and treatment burden.	Clinician-rated clinical response, laboratory outcomes and mortality are contextual outcomes, not PROs.
Patient-reported behavioural outcomes	Self-reported adherence, treatment uptake, intention to act or patient-reported implementation of the chosen option.	Registry-recorded, claims-recorded or clinician-recorded uptake/adherence will be extracted only as contextual secondary outcomes.
Patient-reported SDM process/perceived involvement outcomes	Perceived involvement, participation in decision-making, SDM-Q-9, CollaboRATE and similar patient-reported SDM process or experience measures.	Mapped and, where appropriate, summarised separately; not pooled with downstream PRO domains. Observer-rated or clinician-rated SDM measures will not be included in the PRO synthesis.
Other PROs	PROs that do not fit the prespecified domains but are reported directly by patients.	Classified inductively and reported transparently; pooled only if conceptually and methodologically coherent.

PRO, patient-reported outcome; SDM, shared decision-making; SDM-Q-9, The 9-item Shared Decision Making Questionnaire.

relevant reviews and conduct forward citation tracking to identify additional SDM intervention studies.

Search strategy

The search strategy will combine controlled vocabulary and free-text terms for SDM and evaluation. In PubMed, the search strategy will include Medical Subject Headings and title/abstract terms. Outcome terms will be included where appropriate, but will not be used as mandatory search concepts to avoid restricting the retrieval of eligible SDM intervention studies. The draft PubMed search strategy will be developed with an experienced medical or health sciences librarian and reviewed using the Peer Review of Electronic Search Strategies checklist before being adapted to other databases,[30] including Embase, CINAHL, Web of Science Core Collection, Scopus, CENTRAL and PsycINFO. The literature search will be reported in accordance with the PRISMA extension for reporting literature searches in systematic reviews (PRISMA-S),[31] while the review as a whole will be reported in accordance with the PRISMA 2020 statement.[24] Draft search strategies for PubMed, ClinicalTrials.gov and WHO ICTRP are provided in online supplemental file 2. Trial registries will be searched using simplified terms related to SDM, decision support and decision aids. Registry records will be used to identify ongoing or completed but unpublished studies and, where linked to published reports, to check prespecified outcomes against reported outcomes.

Data management

All identified records will be imported into EndNote V.2025.3.1 (Clarivate Analytics, Pennsylvania, USA) for deduplication using automated and manual procedures. Deduplicated records will then be uploaded to Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia) for screening and study selection.

Study selection

The reviewers will independently screen article titles and abstracts against the eligibility criteria after pilot calibration on a sample of records to ensure consistent interpretation of the criteria. The same two researchers will independently assess the full texts of potentially eligible studies. Disagreements at either stage will be resolved through discussion or, if necessary, adjudication by a third reviewer.[21] The number of studies and reasons for exclusion at every stage will be recorded.[24]

During full-text screening, researchers will determine whether each study meets all applicable eligibility criteria: (1) evaluates an eligible SDM intervention, (2) includes an eligible comparator where required, (3) involves patients in making health-related decisions or (4) assesses at least one eligible PRO. Outcome measures will be classified during data extraction rather than being used as the primary basis for study eligibility.[21] Trial registry records will be screened using the same eligibility criteria, where applicable. Ongoing studies and completed studies without available results will be recorded separately and will not contribute to effect synthesis unless sufficient outcome data are available. When a registry record is linked to a published report, the records will be collated and treated as a single study.

Data extraction

A standardised extraction form will be developed and piloted. Two reviewers will independently extract data using the piloted form, and discrepancies will be resolved by consensus or adjudication by a third reviewer. If additional clarification or missing numerical data are

BMJ Open: first published as 10.1136/bmjopen-2026-124305 on 15 September 2026. Downloaded from http://bmjopen.bmj.com/ on October 12, 2026 at Hanyang University Medical Library . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Table 3 Draft data extraction form

Categories	Subcategories
Study	Author(s); year of publication; country of origin; journal; study design; funding source; conflicts of interest; trial registration number and registry source; publication type; publication status.
Population	Sample size; sex; age; disease/condition; disease stage/duration; timing of decision; inclusion/exclusion criteria; relevant socio-demographic factors; family or primary caregiver characteristics.
Clinical context	Setting; medical specialty; acute/chronic/palliative/screening context.
Decision context	Decision type; preference-sensitive situation; timing of decision; involved decision-makers.
Intervention	Intervention type; components; theoretical basis; target recipient; provider; delivery mode; materials; duration; fidelity; intensity/frequency; family or primary caregiver involvement; implementation setting; comparator.
Outcome	Domain according to the operational taxonomy in table 2 (decision-related PROs; health-related PROs; patient-reported behavioural outcomes; patient-reported SDM process/perceived involvement outcomes; other PROs); outcome domain; name; instrument/scale; primary/secondary outcome; registry-prespecified or protocol-prespecified outcome status where available; assessment timing; time point category (immediate, short-term, medium-term or long-term); baseline and follow-up schedule; respondent/source; validity/reliability; sensitivity-analysis category; whether the outcome is directly patient-reported/patient-completed or contextual only.
Effect data	Group sample sizes; baseline and follow-up values; change scores; means; SDs; SEs; medians and IQRs where applicable; event counts and denominators; adjusted and unadjusted effect estimates; CIs; p values; intracluster correlation coefficients where applicable; covariates used in adjusted models
Risk of bias information	Information required for RoB 2 and ROBINS-I assessments, including randomisation and allocation procedures where applicable; baseline comparability; confounding; cointerventions; participant selection; intervention classification; deviations from intended interventions; missing outcome data; outcome measurement and selective reporting.
Synthesis variables	Comparison group; effect metric; subgroup category; data included in meta-analysis or narrative synthesis.
Certainty of evidence	GRADE domain judgements; overall certainty; reasons for downgrading.

GRADE, Grading of Recommendations Assessment, Development and Evaluation; PRO, patient-reported outcome; RoB, Risk of Bias; ROBINS-I, Risk Of Bias In Non-randomised Studies of Interventions; SDM, shared decision-making.

required, the study authors will be contacted where feasible. Table 3 provides an overview of the extraction form, which includes study characteristics, population, clinical context, decision context, intervention components, outcome components, effect data, information required for risk-of-bias assessment, variables for synthesis and components related to the certainty of evidence. Intervention characteristics will be extracted using the Template for Intervention Description and Replication-informed categories where possible.[25] Patient-reported SDM process measures and perceived involvement outcomes will be extracted and classified separately because they assess the process or experience of SDM rather than downstream patient outcomes. For studies with available trial registration records, we will extract registry source, registration number, recruitment status, study completion status, prespecified outcomes and availability of results, where reported.

Two reviewers will independently classify each outcome according to the primary construct defined by the instrument development paper, manual or supporting validation literature. Disagreements will be resolved through discussion, or if necessary, adjudication by a third reviewer. Subscales measuring distinct constructs will be classified separately, while composite measures will be assigned to their primary construct. Outcomes that cannot be mapped to prespecified domains will be classified as other PROs.

Risk of bias assessment

The risk-of-bias assessment will be constrained to randomised and non-randomised comparative studies eligible to contribute to the intervention effect synthesis. Two researchers will independently assess the risk of bias for each relevant outcome result from these studies. Single-arm studies, which will contribute only to outcome mapping, will not undergo a formal risk-of-bias assessment. Individually randomised trials will be assessed using the Cochrane Risk of Bias (RoB) 2, and cluster randomised trials will be assessed using the cluster-randomised version of RoB 2.[27] Non-randomised comparative intervention studies will be assessed using the Risk Of Bias In Non-randomised Studies of Interventions (ROBINS-I).[28] Disagreements will be resolved through discussion or adjudication by a third researcher. Risk-of-bias judgements will be incorporated into sensitivity analyses and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) assessments.[32]

BMJ Open: first published as 10.1136/bmjopen-2026-124305 on 15 September 2026. Downloaded from http://bmjopen.bmj.com/ on October 12, 2026 at Hanyang University Medical Library . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Where trial registration records or protocols are available, prespecified outcomes and analyses will be compared with published reports to inform risk-of-bias judgements related to selection of the reported result and selective outcome reporting.

Data synthesis and reporting

The PRISMA flow diagram will show the number of records identified and screened, reports assessed for eligibility and excluded with reasons and studies included.[24] The data synthesis will proceed in two stages. First, all eligible patient-reported or patient-completed outcome measures will be mapped and classified into the prespecified operational taxonomy outlined in table 2. Second, intervention effects will be synthesised for specific outcome constructs nested within the first three PRO domains; different constructs within the same broad domain (such as knowledge, decisional conflict and decision regret) will not be statistically pooled. Patient-reported SDM processes or perceived involvement measures will be mapped and synthesised separately from downstream PROs, whereas other PROs will first be classified inductively, and subsequently synthesised only if they form a conceptually coherent construct. Non-patient-reported clinical or healthcare utilisation outcomes will not enter the PRO effect synthesis and will be reported only as contextual secondary outcomes. Therefore, the candidate unit for quantitative synthesis will be a specific outcome construct within a clinically and methodologically coherent population, intervention, comparator and follow-up period.[21]

Before statistical pooling, clinical and methodological heterogeneity will be assessed through structured tabulation and comparison of prespecified study characteristics. Clinical heterogeneity will be assessed in relation to patient population, clinical context, decision type, intervention components, delivery mode, intensity, comparator content, outcome construct and assessment timing. Methodological heterogeneity will be assessed regarding study design, unit of allocation and analysis, effect estimand, adjustment for confounding or clustering, missing-data handling and risk of bias. These assessments will be used to determine whether studies address a sufficiently similar synthesis question to be pooled, to define clinically and methodologically coherent synthesis groups and to interpret or explore statistical heterogeneity. Where studies are judged too clinically or methodologically dissimilar for statistical pooling, results will be synthesised narratively. Pooling decisions will not be based on statistical heterogeneity metrics alone.[21]

Randomised and non-randomised intervention studies will not be combined in the same meta-analysis. Individually randomised and cluster-randomised trials may be combined when they address the same synthesis question and the effect estimates appropriately account for clustering. Non-randomised comparative studies will be synthesised separately. Where necessary, studies with materially different design features or effect estimands (such as controlled before-and-after and interrupted time-series studies) will also be analysed separately. Adjusted effect estimates will be preferred for non-randomised studies, and unadjusted estimates will not be pooled with the adjusted estimates. Studies judged to be at critical risk of bias using ROBINS-I will not contribute to the quantitative effect synthesis. Single-arm studies will only contribute to outcome mapping.[21 28]

Within each design-specific synthesis group, a meta-analysis will be conducted when the studies are sufficiently comparable regarding population, intervention, comparator, outcome construct and assessment timing. Mean differences will be calculated for continuous outcomes measured using the same scale. When different instruments assess the same construct, standardised mean differences will be used. Risk ratios will be used for dichotomous outcomes where event-count data permit. Adjusted ORs or other ratio measures reported by non-randomised studies will be synthesised using generic inverse-variance methods where appropriate, and only with studies reporting comparable estimands. Where pooling is judged as meaningful and residual between-study heterogeneity is anticipated, random-effects models will be used; model choice will not be a substitute for evaluating clinical and methodological comparability.[21]

Statistical heterogeneity will be assessed by visual inspection of forest plots and using the I^2 statistic, between-study variance estimate and Cochran's Q test. It will be interpreted in conjunction with the magnitude and direction of effects and the number of contributing studies. Where sufficient studies are available, prespecified subgroup analyses will be considered according to intervention type, clinical context, decision type, comparator type, follow-up period and risk of bias. Where subgroup effects are compared, formal tests for subgroup differences will be used, rather than comparisons of statistical significance within individual subgroups.[21]

Missing or unclear numerical data will be requested from the study authors where feasible. If necessary, effect estimates will be derived or imputed using the methods recommended in the Cochrane Handbook, and assumptions will be reported transparently.[21] Sensitivity analyses will be conducted within each design-specific synthesis, and will exclude studies at a high risk of bias according to RoB 2, studies at a serious risk of bias according to ROBINS-I and studies requiring substantial imputation of effect estimates. Because randomised and non-randomised studies will be synthesised separately, the exclusion of non-randomised studies will not be treated as a sensitivity analysis of a combined estimate. For cluster-randomised trials, effect estimates adjusted for clustering will be used where available. If clustering has not been accounted for, where sufficient information is available, the effective sample size will be adjusted using an intracluster correlation coefficient. For multiarm studies, intervention groups will be combined or comparator groups will be split as appropriate, to avoid double-counting. If at least 10 unique studies contribute to a design-specific meta-analysis for a specific outcome construct, small-study

BMJ Open: first published as 10.1136/bmjopen-2026-124305 on 15 September 2026. Downloaded from http://bmjopen.bmj.com/ on October 12, 2026 at Hanyang University Medical Library . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

effects and potential publication bias will be explored using funnel plots and formal statistical tests, whenever relevant. Evidence from ClinicalTrials.gov and the WHO ICTRP, including ongoing and completed studies without available results, will be considered when assessing the potential impact of missing results and publication bias.[21]

Where a meta-analysis is not appropriate, findings will be synthesised without a meta-analysis in accordance with the Synthesis Without Meta-analysis guideline.[26] Comparative studies will be grouped first by study design and then by specific outcome construct within the domains outlined in table 2. Where relevant, studies will be further grouped by population or clinical context, intervention, comparator and follow-up period. The direction, magnitude and certainty of the effects will be reported transparently for each outcome construct; conclusions will not be based solely on the number of statistically significant findings. For the synthesis, the direction of the effects will be harmonised so that positive effect estimates indicate a beneficial effect of the SDM intervention, whenever feasible. For outcomes where lower scores indicate better outcomes (such as decisional conflict or decision regret) effect directions will be reversed or clearly labelled.

All eligible measures will be retained for outcome mapping. If a study reports multiple instruments measuring the same outcome construct, one estimate will be selected for a given synthesis, prioritising the instrument designated by the study authors as the primary measure of that construct. If no primary measure is specified, the instrument most directly aligned with the review's construct definition (based on the instrument development paper, manual or supporting validation literature) will be selected. This selection will be made without reference to effect magnitude or statistical significance.[21]

Follow-up period has been prespecified to reduce selective time point selection and address the statistical dependence arising from repeated measurements of the same participants.[21] Immediate outcomes will be defined as those assessed during or at completion of the intervention or index consultation, and before a subsequent follow-up assessment. Short-term outcomes will comprise subsequent assessments up to and including 3 months, medium-term outcomes as those assessed >3 and ≤6 months and long-term outcomes as those assessed >6 months after the intervention. Similar post-intervention categories (1–3 months, 4–6 months and >6 months) have been used in a past systematic review and meta-analysis of decision aids.[33] These are pragmatic analytical windows intended to distinguish proximal effects on decision-making from early implementation or adjustment and more sustained downstream outcomes; thus, they are not presented as universally validated clinical thresholds. The exact assessment times will also be reported and considered when determining comparability. If multiple assessments are reported within a period, the assessment closest to intervention completion will be selected for the immediate category, whereas the longest follow-up assessment within each subsequent category will be selected to represent the most sustained effect within that window. Each study will contribute no more than one effect estimate per outcome construct and period category to a given meta-analysis.[21]

The certainty of evidence will be assessed separately for the randomised and non-randomised bodies of evidence for each main outcome construct using the GRADE approach. Certainty will be rated as high, moderate, low or very low, while considering risk of bias, inconsistency, indirectness, imprecision and publication bias.[32] Information from trial registries, including completed studies without available results and discrepancies between registered and reported outcomes, will inform judgements about publication bias and missing results, where relevant. A summary of the findings, tables or figures will be presented for key outcome constructs where sufficient data are available.

Patient and public involvement

None.

ETHICS AND DISSEMINATION

Ethical approval is not required because this review will use non-identifiable aggregate information from existing study reports and trial registries and will not involve primary data collection from human participants. The results will be disseminated through publication in a peer-reviewed journal and presentations at national and international academic conferences. The findings may also provide guidance for selecting PRO domains and outcome measures for evaluating SDM interventions in research and clinical practice.

DISCUSSION

This systematic review will provide a structured overview of PROs assessed in studies evaluating SDM interventions and will synthesise the effects of SDM interventions on these PROs compared with relevant comparators.[22] By combining PRO mapping with effect synthesis, this review will clarify which patient-reported benefits have been prioritised in SDM intervention research and what effects are observed across decision-related, health-related and patient-reported behavioural PRO constructs.[24]

Focusing on PROs is particularly relevant because the intended effects of SDM interventions are closely linked to patients' understanding, preferences, values, deliberation and experiences of living with healthcare decisions. Outcomes such as knowledge, risk perception,[16] decisional conflict,[12] decision regret,[13] satisfaction,[17] adherence and health-related quality of life are either directly reported by patients or strongly dependent on patients' subjective appraisals.[14]

Previous reviews have examined interventions to increase the use of SDM[7] and effects of decision aids,[16] and recent syntheses have described SDM intervention effects and the broader SDM research landscape in

BMJ Open: first published as 10.1136/bmjopen-2026-124305 on 15 September 2026. Downloaded from http://bmjopen.bmj.com/ on October 12, 2026 at Hanyang University Medical Library . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

specific healthcare systems.[34 35] However, less attention has been paid to which PROs have been measured in SDM intervention studies globally and whether intervention effects differ across prespecified PRO constructs.[17] This review will complement existing evidence by linking outcome mapping with effect synthesis, thereby clarifying both what has been measured and whether SDM interventions appear to affect these outcomes.

Several methodological challenges are anticipated. First, SDM interventions vary in content, intensity, delivery mode, target recipient, provider and implementation context.[26] Second, PROs may be measured using different instruments, scales and time points, which may limit comparability across studies and reduce the feasibility of meta-analyses in some domains.[18 19] Third, studies may assess both proximal PROs, such as knowledge, risk perception and decisional conflict and downstream PROs, such as decision regret, satisfaction, treatment burden, adherence and health-related quality of life. Contextual secondary outcomes, such as clinical outcomes or healthcare utilisation outcomes, may also be reported but will not be included in the primary PRO synthesis unless they are directly reported by patients.[21]

To address these issues, outcomes will be classified into prespecified PRO domains and patient-reported SDM process measures or perceived involvement outcomes will be distinguished from downstream decision-related, health-related and behavioural PROs. When studies are sufficiently comparable in terms of population, intervention, comparator, outcome construct and assessment timing, a meta-analysis will be conducted.[21] Where statistical pooling is inappropriate, findings will be synthesised narratively in accordance with Synthesis Without Meta-analysis guidance,[26] and the certainty of evidence for key outcome constructs will be assessed using GRADE.[32]

This review may have some limitations. First, the broad definition of SDM interventions, encompassing patient-facing, clinician-facing and multicomponent strategies, may introduce clinical and methodological heterogeneity and require careful application of the eligibility criteria. Second, the inclusion of non-randomised intervention studies may increase susceptibility to confounding and other biases,[28] although risk of bias will be assessed using established tools[27] and incorporated into sensitivity analyses and GRADE judgements.[32] Third, incomplete reporting of PROs, variations in outcome instruments and differences in follow-up duration may limit comparability across studies. Searching ClinicalTrials.gov and WHO ICTRP may help identify ongoing or completed but unpublished studies and support assessment of missing results, although registry records may themselves be incomplete or inconsistently updated. Finally, single-arm intervention studies, if included, will contribute only to outcome mapping and will not be used to estimate comparative intervention effects.

Despite these limitations, the findings of this review may have meaningful implications for future SDM trials and implementation studies. By identifying which PROs have been used, how they have been measured and which domains appear to show SDM intervention effects, this review may support more consistent outcome selection and contribute to the development of outcome frameworks for both SDM research and practice.[19] Greater consistency in outcome selection may improve comparability across studies and strengthen the interpretability of evidence syntheses.[18]

In conclusion, this protocol describes a systematic approach to identifying how PROs are assessed in studies evaluating SDM interventions and to synthesising the effects of these interventions across PRO constructs.[22 24] The review will inform outcome selection, intervention evaluation and future research design in SDM.

Contributors S-HY contributed to conceptualisation, funding acquisition, project administration, supervision and writing—review and editing. MP contributed to methodology and writing—review and editing. MJK contributed to conceptualisation, methodology, project administration, visualisation, writing—original draft and writing—review and editing. All authors have reviewed and approved the final manuscript for submission. MJK is the guarantor and corresponding author and accepts full responsibility for the overall content, integrity of the protocol and conduct of the planned review.

Funding This research was supported by a grant from the Korea Health Technology R&D Project through the Patient-Doctor Shared Decision Making Research Center (PDSDM), funded by the Ministry of Health and Welfare, Republic of Korea (grant number: RS-2023-KH142275). The funder has no role in the development of this protocol and will have no role in the conduct, analysis or interpretation of the review, preparation of the report or decision to submit the complete review for publication.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: https://creativecommons.org/licenses/by-nc/4.0/.

ORCID iDs
Sang Ho Yoo https://orcid.org/0000-0001-9030-1365
Myonghwa Park https://orcid.org/0000-0002-0329-0010
Min Ji Kim https://orcid.org/0000-0002-8444-4025

REFERENCES

1 Berwick DM, Nolan TW, Whittington J. The triple aim: care, health, and cost. *Health Aff (Millwood)* 2008;27:759–69.
2 Lewis C, Horstman C, Blumenthal D, *et al*. Value-based care: what it is, and why it's needed (explainer). *Commonwealth Fund* 2023.
3 Institute of Medicine Committee on Quality of Health Care in America. *Crossing the quality chasm: A new health system for the 21st century*. Washington (DC): National Academies Press, 2001.

BMJ Open: first published as 10.1136/bmjopen-2026-124305 on 15 September 2026. Downloaded from http://bmjopen.bmj.com/ on October 12, 2026 at Hanyang University Medical Library . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

4 Kim MJ, Yoo S-H. Patient-centered care and shared decision-making: core concepts and implementation strategies: a narrative review. *J Korean Med Assoc* 2025;68:559–72.
5 Elwyn G, Frosch D, Thomson R, *et al*. Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27:1361–7.
6 van der Horst DEM, Garvelink MM, Bos WJW, *et al*. For which decisions is Shared Decision Making considered appropriate? - A systematic review. *Patient Educ Couns* 2023;106:3–16.
7 Légaré F, Adekpedjou R, Stacey D, *et al*. Interventions for increasing the use of shared decision making by healthcare professionals. *Cochrane Database Syst Rev* 2018;7:CD006732.
8 Bomhof-Roordink H, Gärtner FR, Stiggelbout AM, *et al*. Key components of shared decision making models: a systematic review. *BMJ Open* 2019;9:e031763.
9 Flynn D, Knoedler MA, Hess EP, *et al*. Engaging patients in health care decisions in the emergency department through shared decision-making: a systematic review. *Acad Emerg Med* 2012;19:959–67.
10 Bélanger E, Rodríguez C, Groleau D. Shared decision-making in palliative care: a systematic mixed studies review using narrative synthesis. *Palliat Med* 2011;25:242–61.
11 Lu C, Li X, Yang K. Trends in Shared Decision-Making Studies From 2009 to 2018: A Bibliometric Analysis. *Front Public Health* 2019;7:384.
12 O'Connor AM. Validation of a Decisional Conflict Scale. *Med Decis Making* 1995;15:25–30.
13 Brehaut JC, O'Connor AM, Wood TJ, *et al*. Validation of a Decision Regret Scale. *Med Decis Making* 2003;23:281–92.
14 Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health. Patient-reported outcome measures: use in medical product development to support labeling claims. Rockville, MD U.S. Department of Health and Human Services Food and Drug Administration; 2009.
15 Kingsley C, Patel S. Patient-reported outcome measures and patient-reported experience measures. *BJA Education* 2017;17:137–44.
16 Stacey D, Lewis KB, Smith M, *et al*. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2024;1:CD001431.
17 Joosten EAG, DeFuentes-Merillas L, de Weert GH, *et al*. Systematic review of the effects of shared decision-making on patient satisfaction, treatment adherence and health status. *Psychother Psychosom* 2008;77:219–26.
18 Young AE, Brookes ST, Avery KNL, *et al*. A systematic review of core outcome set development studies demonstrates difficulties in defining unique outcomes. *J Clin Epidemiol* 2019;115:14–24.
19 Clarke M, Williamson PR. Core outcome sets and systematic reviews. *Syst Rev* 2016;5:11.
20 Schardt C, Adams MB, Owens T, *et al*. Utilization of the PICO framework to improve searching PubMed for clinical questions. *BMC Med Inform Decis Mak* 2007;7:16.
21 Higgins J, Thomas J, Chandler J, *et al*. *Cochrane handbook for systematic reviews of interventions version 6.5*. Cochrane, 2024.
22 Shamseer L, Moher D, Clarke M, *et al*. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *BMJ* 2015;350:g7647.
23 Kim MJ, Yoo S-H. Patient-reported outcomes (PROs) in studies evaluating shared decision-making interventions: a systematic review and meta-analysis. PROSPERO; 2026. Available: https://www.crd.york.ac.uk/PROSPERO/view/CRD420261413222 [Accessed 3 Jun 2026].
24 Page MJ, McKenzie JE, Bossuyt PM, *et al*. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71.
25 Hoffmann TC, Glasziou PP, Boutron I, *et al*. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:g1687.
26 Campbell M, McKenzie JE, Sowden A, *et al*. Synthesis without meta-analysis (SWiM) in systematic reviews: reporting guideline. *BMJ* 2020;368:l6890.
27 Sterne JAC, Savović J, Page MJ, *et al*. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ* 2019;366:l4898.
28 Sterne JA, Hernán MA, Reeves BC, *et al*. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ* 2016;355:i4919.
29 Walpole SC. Including papers in languages other than English in systematic reviews: important, feasible, yet often omitted. *J Clin Epidemiol* 2019;111:127–34.
30 McGowan J, Sampson M, Salzwedel DM, *et al*. PRESS Peer Review of Electronic Search Strategies: 2015 Guideline Statement. *J Clin Epidemiol* 2016;75:40–6.
31 Rethlefsen ML, Kirtley S, Waffenschmidt S, *et al*. PRISMA-S: an extension to the PRISMA Statement for Reporting Literature Searches in Systematic Reviews. *Syst Rev* 2021;10:39.
32 Guyatt GH, Oxman AD, Vist GE, *et al*. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ* 2008;336:924–6.
33 Vasan Thakumar A, Chua ES, Chern CWJ, *et al*. Effectiveness of decision aids on decisional conflict and treatment or disease knowledge among women diagnosed with breast cancer: a systematic review and meta-analysis. *J Cancer Surviv* 2026.
34 Kwon Y, Nam S, Shin S, *et al*. Shared Decision-Making in Korean Healthcare: A Scoping Review. *J Korean Med Sci* 2025;40:e273.
35 Yun H, Woo K-S, Lee D-Y, *et al*. A systematic review of the effects of shared decision-making in the South Korean healthcare system. *Front Public Health* 2025;13:1667803.

BMJ Open: first published as 10.1136/bmjopen-2026-124305 on 15 September 2026. Downloaded from http://bmjopen.bmj.com/ on October 12, 2026 at Hanyang University Medical Library . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.