Journal of Pain Research

Dovepress
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REVIEW

Core Outcome Sets for Pain Disorders: A Systematic Review of Research and Reporting Quality

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Purpose: To systematically review the current research status of Core Outcome Sets (COS) for pain-related diseases and to evaluate the methodological quality of existing COS.

Methods: Two researchers independently conducted a comprehensive search of both English and Chinese databases. Studies were screened and data were extracted based on predefined inclusion criteria. The methodological quality of the identified COS was assessed using the Core Outcome Set-STAndards for Development (COS-STAD), which includes 11 criteria covering the scope, stakeholder involvement, and the consensus process.

Results: 24 COS were included in the final analysis out of 2150 records initially identified. These COS were primarily developed by organizations or research teams in Europe, Asia, and North America. The included COS covered 22 pain-related disorders, most of which (8 [33%]) were classified as symptoms, signs, or clinical findings according to the ICD-11 classification. One or more of the eight recognized methodologies were used in developing each COS. The most common combination included systematic reviews, Delphi surveys, qualitative interviews, and consensus meetings (6 [25%]). Among key stakeholder groups, clinical experts were most frequently involved (22 [92%]), whereas industry representatives were less engaged (5 [21%]). Only 5 COS (20%) fully met the 11 COS-STAD criteria, indicating room for methodological improvement. The highest scores were for health issue coverage (24/24 points), followed by the involvement of healthcare professionals in reflecting disease experiences (23/24 points). In contrast, the average score for intervention coverage was lowest (15/24), followed by constructing the initial outcome list (18/24). These findings suggest that greater emphasis should be placed on incorporating the perspectives of both professionals and patients during the initial outcome selection process.

Conclusion: The development of Core Outcome Sets should adhere closely to guidelines established by the Core Outcome Measures in Effectiveness Trials (COMET) Initiative. Greater emphasis should be placed on the inclusion and evaluation of interventions. In addition, the perspectives of healthcare professionals and patients should be more thoroughly integrated during the design of the initial outcome list to enhance the relevance and applicability of COS in clinical practice.

Keywords: pain, core outcome set, methodological quality assessment, systematic review

Introduction

Pain is an aversive sensory and emotional experience associated with, or resembling,[1] actual or potential tissue damage. It functions both as a symptom and as an independent pathological condition.[2]

Pain-related disorders are pervasive, including acute traumatic pain, chronic pain, and cancer-related pain.[3] Epidemiological data show that chronic pain affects 20% to 30% of the global population and continues to increase

Received: 14 May 2025
Accepted: 8 July 2025
Published: 28 July 2025

annually.[4] In China, over 300 million people suffer from chronic pain, with about 20 million new cases each year. These disorders cause significant physical distress and severely reduce quality of life, often leading to psychological issues such as anxiety and depression.[5] However, clinical research on pain-related conditions faces many challenges. The subjective nature of pain complicates its assessment and reduces the comparability and reliability of study results. In addition, the multidimensional nature of pain-including intensity, duration, functional impact, and quality of life-has not yet been incorporated into a unified evaluation framework.[6] Current assessment methods remain fragmented and inconsistent, hindering the comprehensive evaluation of patient status and treatment efficacy.

In clinical research, outcome measures are essential for evaluating intervention efficacy. Their scientific validity and methodological rigor directly influence study findings' reliability and clinical relevance.[7] However, challenges remain in outcome selection and reporting, including inconsistent definitions, inappropriate choices, measurement variability, and selection bias.[8] Studies on the same disease often use different outcome measures,[9] and the lack of standardization further limits comparability. To address these issues, the Core Outcome Measures in Effectiveness Trials (COMET) initiative promotes the development of Core Outcome Sets (COS)-standardized outcome sets established through expert consensus and patient input, serving as benchmarks for clinical trials in specific fields.[9,10] COS development has become more systematic with the introduction of the Core Outcome Set-Standards for Development (COS-STAD).[11] COS-STAD outlines 11 minimum standards across three domains: scope, stakeholder involvement, and consensus process. It provides structured guidance and enhances both the scientific rigor and practical relevance of COS.

In recent years, international research on COS for pain-related disorders has advanced rapidly. For instance, the development of COS for postoperative pain and chronic low back pain has reached a relatively mature stage, with construction methods incorporating the Delphi technique, systematic reviews, and consensus meetings, thereby gradually establishing a standardized development process.[12,13] However, for other pain types, such as neuropathic pain and cancer-related pain, research remains in its early stages, and the content and scope of the COS have yet to be fully established. In China, research on pain-related COS began relatively late and is currently focused primarily on developing core outcome systems for chronic pain,[14] though the overall number of such studies remains limited.

Although notable progress has been made in the development of COS for pain-related disorders, significant challenges and limitations persist. On one hand, substantial variability exists among research teams regarding COS construction methods, outcome selection, and the application of measurement tools, which undermines the consistency and reliability of research findings.[15] On the other hand, the quality of existing COS reports remains inconsistent, with notable deficiencies in the description of scope, methodological detail, consensus-building processes, and result presentation. These shortcomings hinder the broader adoption and clinical application of COS.

Furthermore, cultural and geographical factors also play a critical role in shaping COS development and applicability. Pain perception and reporting are influenced by cultural norms, beliefs, and language, which vary considerably across populations. For example, Sharma et al[16] highlighted significant differences in pain-related beliefs and coping strategies among countries, affecting how outcomes are valued and prioritized. In addition, variations in healthcare delivery systems and stakeholder expectations across regions-such as the emphasis on patient autonomy in Western countries versus professional authority in East Asia-can further influence COS content and methodology.[17,18]

In light of these issues, this study addressed the following research question: What is the current status of COS development for pain-related disorders, and how well do existing COS adhere to recognized methodological standards, such as the COS-STAD? To answer this, we systematically reviewed the literature and evaluated methodological quality using COS-STAD. The findings aim to inform researchers and promote the standardized development and use of COS in pain research and clinical practice.

Methods

Literature Search

PubMed, Medline Ovid, Cochrane, Web of Science, Embase, COMET, CNKI, Wanfang, VIP, and SinoMed were searched by computer, and the core index sets of pain disorders were retrieved. The English search terms are pain, analgesia, ache, core outcome set, COS, outcome measure, and outcome assessment. The Chinese search terms were

pain, ache, analgesia, core outcomes, outcome indicators, and Core Outcome Set. The search time limit was until 31 July 2024. The search strategy is available in Appendix 1.

Inclusion Criteria

Focusing on COS for painful diseases, including the COS research process and outcome report.

Exclusion Criteria

(1) literature review and conference abstracts; (2) COS methodology; (3) COS research protocol; (4) repetitively published studies; (5) Unfinished COS.

Literature Screening

The literature was imported into EndNote X9 for plagiarism screening. Two investigators independently screened the title and abstract, and then the full text was screened according to the inclusion and exclusion criteria. If there were disagreements, they were resolved through discussion, or the third investigator was consulted.

Data Extraction

An information extraction table was created using Excel 2019, which included the development organization, first author, year, country, disease, registry, protocol, interventions, methods for selecting outcome measures, stakeholders, core outcome measures, and measurement tools.

Quality Assessment

Two review authors independently assessed the methodological quality of the included studies using COS-STAD. Disagreements were resolved by discussion with a third investigator to reach consensus. The evaluation criteria of COS-STAD include a. Scope specification: including health status, target population, and intervention. b. Stakeholders: including patients with or their representatives of relevant diseases, and health care professionals with experience with relevant diseases. c. Consensus process: The initial list of outcomes considers the views of health care professionals and patients, the scoring process is predefined, the consensus process is predefined, the outcome criteria for inclusion/exclusion/addition are pre-defined, and care is taken to avoid ambiguous language. We assessed COS against all items of the COS-STAD and calculated a score of 1 for reporting (Y) and 0 for unreported (N).

Statistical Analysis

To assess the impact of the COS-STAD guideline introduced in 2017, COS were grouped by publication date (pre-2017 vs post-2017). Total COS-STAD scores were calculated for each study. Data distribution was tested for normality. Normally distributed variables were presented as mean±standard deviation (SD) and compared using an independent samples *t*-test. Non-normally distributed variables were expressed as median (interquartile range, IQR) and analyzed with the Mann–Whitney *U*-test. A p-value < 0.05 was considered statistically significant. All analyses were performed using SPSS version 23.0.

Results

According to the search strategy, a total of 2150 documents were retrieved. 755 duplicate documents were eliminated by EndNote X9. 1203 articles were eliminated by reading abstracts, and 165 articles were eliminated by reading the full text, and finally 27 articles were included, of which 24 were Core Outcome Sets and 3 were core outcome measurement tools. Figure 1 shows the details of flow chart.

Basic Characteristics of the Included Studies

The study found that the COS of pain disorders was mainly developed by organizations in Europe, Asia, and North America, 5 by the United Kingdom, 4 by China, and 4 by the United States. A total of 22 diseases were involved and classified according to ICD-11, including symptoms, signs, or clinical findings (8 items), musculoskeletal system or connective tissue disorders (3

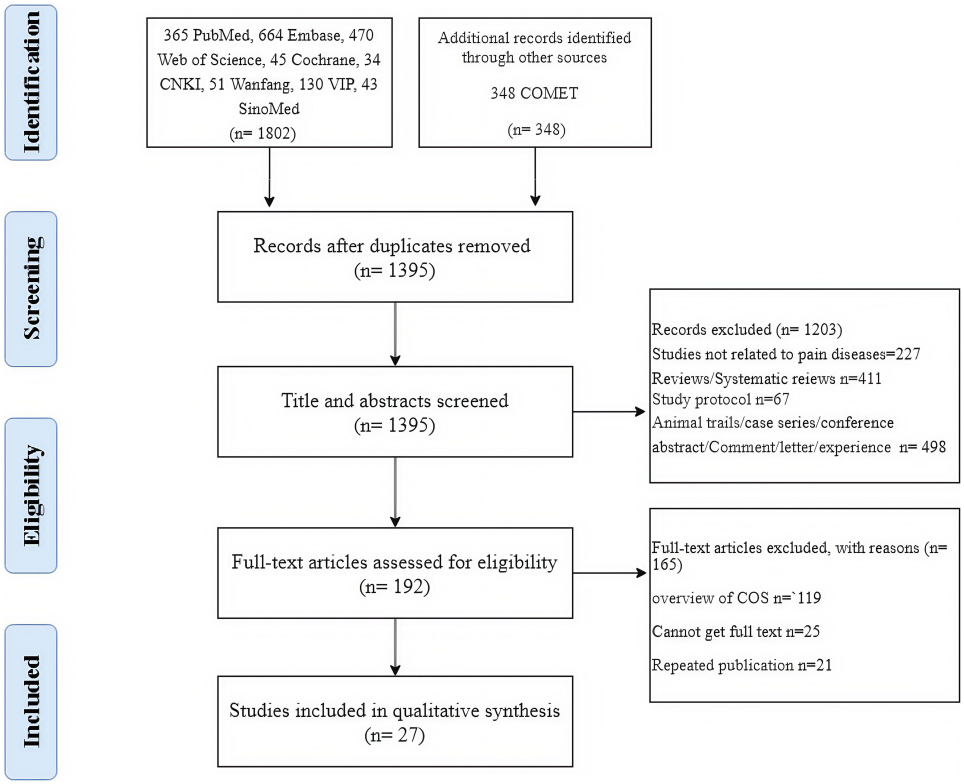

Figure 1 Flow chart of literature screening.

items), nervous system (3 items), genitourinary system (1 item), circulatory system (1 item), digestive system (1 item), and 7 studies were not classified. Eight studies were registered on the COMET website, one study was registered on both the UKCRN and COMET websites, and only two studies published study protocols. Of the included studies, nine studies reported all/any of the interventions covered by COS, and seven did not report on the interventions covered by COS. Nineteen studies used a combination of methods to form a core set of Outcomes, including systematic reviews (15), Delphi surveys (21), qualitative interviews (10), and consensus meetings (14). In 24 studies, clinicians (22) were the most common participants, followed by patients/carers (20) and researchers (14). The basic characteristics of the included studies are shown in Table 1.

Table 1 Basic Characteristics of the Included Studies

Research	Country	Registration/ Protocol	Disease	Intervention	Methods for Forming COS	Stakeholders
Bohm-Starke, N 2024[19]	Sweden	COMET Protocol	Induces vestibular pain	All interventions	①②③	abc
Venda Nova, C 2023[20]	UK	COMET	Trigeminal neuralgia	Not mentioned	①②③④	abc
Ye 2023[21]	China	Not mentioned	Clinical pain in critically ill patients	Not mentioned	①②③④⑤	abc
Arimitsu, T2023[22]	Japan	Not mentioned	Japanese newborn pain	Not mentioned	②	acd
Kim, P. W2022[23]	Korea	Not mentioned	Primary dysmenorrhea	Herbs	①②	a
Zhang 2021[24]	China	COMET	Stable angina	Chinese medicine	①②③④	abcefg
Wan 2021[14]	China	COMET	Chronic low back pain	Chinese medicine	①②③④	abcefh
Haywood, K2021[25]	UK	COMET	Chronic episodic migraine	Preventive interventions	①②③④	abc

(*Continued*)

Table 1 (Continued).

Research	Country	Registration/ Protocol	Disease	Intervention	Methods for Forming COS	Stakeholders
Palermo, T. M 2021[26]	USA	Not mentioned	Chronic pain in children	Any intervention	②③	ac
Pogatzki-Zahn, E. M 2021[12]	USA	Protocol	Perioperative pain	Any intervention	①④	abcef
Remus, A 2021[27]	Ireland	COMET	Pelvic girdle pain	Any intervention	①②③④	abce
Li 2020[28]	China	COMET	Migraine	Acupuncture intervention	①②③④	abcd
Michalk, Katrin2020[29]	Germany	Not mentioned	Neck pain	Physiotherapy	①②	ac
Zeevenhooven, J 2020[30]	Netherlands	Not mentioned	Functional abdominal pain in children	Pharmacological and non-pharmacological interventions	①②③	ac
Chiarotto, A2018[13]	Netherlands	Not mentioned	Nonspecific low back pain	All interventions	②	abc
Kaiser, U 2018[31]	Germany	COMET	Chronic pain	Interdisciplinary multimodal pain	①②③	abc
Steutel, N. F2017[32]	Netherlands	Not registered	Infantile colic	Any intervention	②	ac
Mackie, S. L2017[33]	UK	Not mentioned	Polymyalgia rheumatica	Any intervention	①②④	ac
Grieve, S 2017[34]	UK	Not mentioned	Complex regional pain syndrome	Not mentioned	⑥	abc
Wylde, V2015[35]	UK	UKCRNCOMET	Chronic pain after knee replacement	Not mentioned	①②④⑦	ac
Mease, P 2009[36]	USA	Not mentioned	Fibromyalgia syndrome	Not mentioned	②⑦	abc
Schumacher, H. R 2009[37]	New Zealand	Not mentioned	Acute and chronic gout	Not mentioned	②③⑥	ai
McGrath, P. J 2008[38]	Canada	Not mentioned	Chronic recurrent pain in children	All interventions	②③	bef
Turk, D. C2024*[39]	USA	Not mentioned	Chronic pain	All interventions	③	bef

Notes: ① Systematic review; ② Delphi Survey; ③ Consensus meetings; ④ Qualitative interviews; ⑤ Theoretical Methods of Operations Research; ⑥ Seminar; ⑦ Focus groups; a. Clinician; b. Researchers; c. Patients and caregivers; d. Nurse; e. Policy makers; f. Representatives of pharmaceutical companies; g. Clinical Pharmacologist; h. Editor of Medical Journal; i. OMERACT 9. participants. *Includes core indicator evaluation tools.

Results of COS Methodological Assessment

Five COS met all 11 criteria, with the highest score of 24/24 for health issues covered by COS, followed by healthcare professionals with patient disease experience (23/24 points); The interventions covered by the COS had the lowest mean score (15/24 points), followed by an initial list of outcomes that considered the views of health care providers and patients (18/24 points). The results of the methodological quality assessment of the COS are shown in Table 2. A heatmap of COS-STAD item reporting is shown in Figure 2.

Table 2 Results of Methodological Quality Assessment of COS

Research	Range				Stakeholders			Consensus Process					Score
	1a	1b	1c	1d	2a	2b	2c	3a	3b	3c	3d	3e	
Nina Bohm-Starke2024[19]	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	N	Y	10
Carolina Venda Nova2023[20]	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	11
Ye 2023[21]	Y	Y	N	N	Y	Y	Y	Y	Y	Y	N	N	8
Takeshi Arimitsu2023[22]	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	11
Pyung-Wha Kim2022[23]	Y	Y	Y	Y	Y	Y	N	N	Y	Y	Y	N	9
Zhang 2021[24]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12
Wan 2021[14]	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	10
Kirstie Haywood2021[25]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12
Tonya M. Palermo2021*[26]	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	11
Esther M. Pogatzki-Zahn2021[12]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12

(*Continued*)

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Table 2 (Continued).

Research	Range				Stakeholders			Consensus Process					Score
	1a	1b	1c	1d	2a	2b	2c	3a	3b	3c	3d	3e	
Alexandria Remus2021*[27]	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	11
Li 2020[28]	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11
Katrin Michalk2020[29]	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	11
Judith Zeevenhooven2020[30]	N	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Y	9
Alessandro Chiarotto2018[13]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12
Kaiser Ulrike2018[31]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	12
Nina F Steutel2017[32]	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Y	10
Sarah L. Mackie2017[33]	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	11
Grieve, Sharon2017[34]	Y	Y	Y	N	Y	Y	Y	N	N	Y	Y	Y	9
V. Wylde2015[35]	N	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	10
PHILIP MEASE2009[36]	Y	Y	N	N	Y	Y	Y	Y	Y	N	N	Y	8
H.RALPH SCHUMACHER2009[37]	Y	Y	N	Y	Y	N	N	Y	Y	Y	Y	Y	9
Patrick J. McGrath2008[38]	Y	Y	Y	Y	Y	Y	N	N	N	N	N	Y	7
Dennis C Turk2004*[39]	Y	Y	N	N	Y	Y	N	N	N	Y	N	Y	6
Score	21	24	19	15	19	23	20	18	21	22	19	21	-

Notes: 1a COS research or practice scenario of application; 1b Health issues covered by COS; 1c Populations covered by COS; 1d Interventions covered by COS; 2a Investigators using COS; 2b Health care professionals with experience with patients' diseases; 2c Patients with related diseases or their representatives; 3a Initial list of Outcomes that takes into account the views of medical staff and patients; 3b Pre-defined scoring process; 3c pre-describe the consensus definition; 3d pre-defined criteria for inclusion/exclusion/addition of Outcomes; 3e focus on the linguistic description of the list of outcome Outcomes to avoid ambiguity. Y, item was reported and scored 1; N, item was not reported and scored 0.

Results of Statistical Analysis

Of the 24 COS included in the review, 5 were published before 2017 and 19 after. Before the release of COS-STAD in 2017, the average score of COS-STAD was 8.0, while the average score after 2017 was 10.6. The median total COS-STAD score was significantly higher in the post-2017 group compared to the pre-2017 group (11 [IQR 10–12] vs 8 [IQR 6.75–9.25], $p = 0.001$, Mann–Whitney *U*-test), indicating a notable improvement in methodological quality following the release of the COS-STAD recommendations. Results are shown in Figure 3.

Overview of COS in Included Studies

The core outcome measures of the included studies covered 11 domains, including pain (intensity, frequency, duration), quality of life, physical functioning, emotional and psychological functioning, social functioning, safety indicators, endpoints, laboratory indicators, medication use, disease-specific measures, and treatment satisfaction. The five domains with the highest frequency were pain (22 [92%]), quality of life (14 [58%]), physical function (13 [54%]), safety indicators (8 [33%]), emotional and psychological functioning (7 [29%]). The five COSs in the included studies that met all the criteria for quality evaluation are shown in Table 3.

Discussion

Research Status of COS

In recent years, both the volume and methodological rigor of COS have markedly increased, reflecting growing recognition of the importance of standardized outcome measures in clinical trials.[40] This study included 24 COS covering 22 pain-related conditions, mainly developed by teams across Europe, Asia, and North America using methods such as systematic reviews, Delphi surveys, qualitative interviews, and consensus meetings. These approaches have enhanced methodological quality. However, only 20% fully adhered to COS-STAD standards, indicating room for improvement. The highest compliance was observed for the coverage of health conditions (24/24 points), whereas lower scores were noted for the inclusion of interventions (15/24 points) and the initial outcome list (18/24 points), suggesting that COS

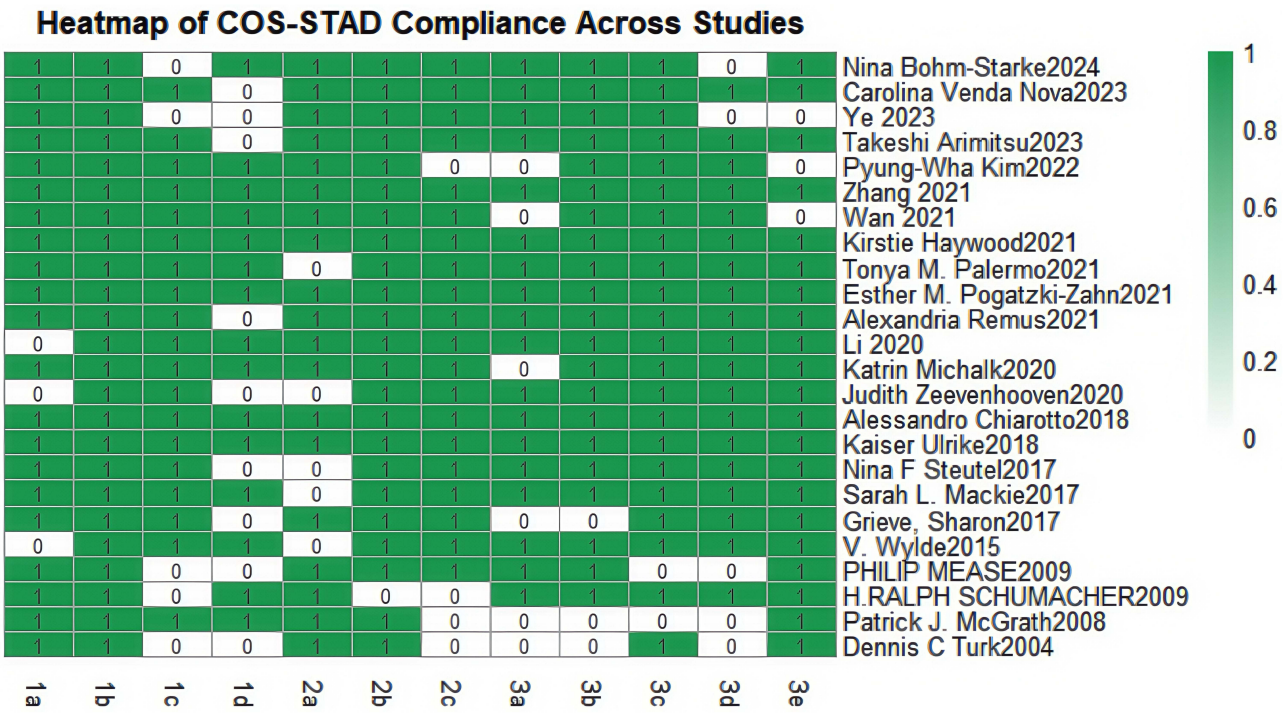

Figure 2 Heatmap of COS-STAD Criteria Reporting.

Notes: 1a COS research or practice scenario of application; 1b Health issues covered by COS; 1c Populations covered by COS; 1d Interventions covered by COS; 2a Investigators using COS; 2b Health care professionals with experience with patients' diseases; 2c Patients with related diseases or their representatives; 3a Initial list of Outcomes that takes into account the views of medical staff and patients; 3b Pre-defined scoring process; 3c pre-describe the consensus definition; 3d pre-defined criteria for inclusion/exclusion/addition of Outcomes; 3e focus on the linguistic description of the list of outcome Outcomes to avoid ambiguity. Green indicates reported (1) and white indicates not reported (0).

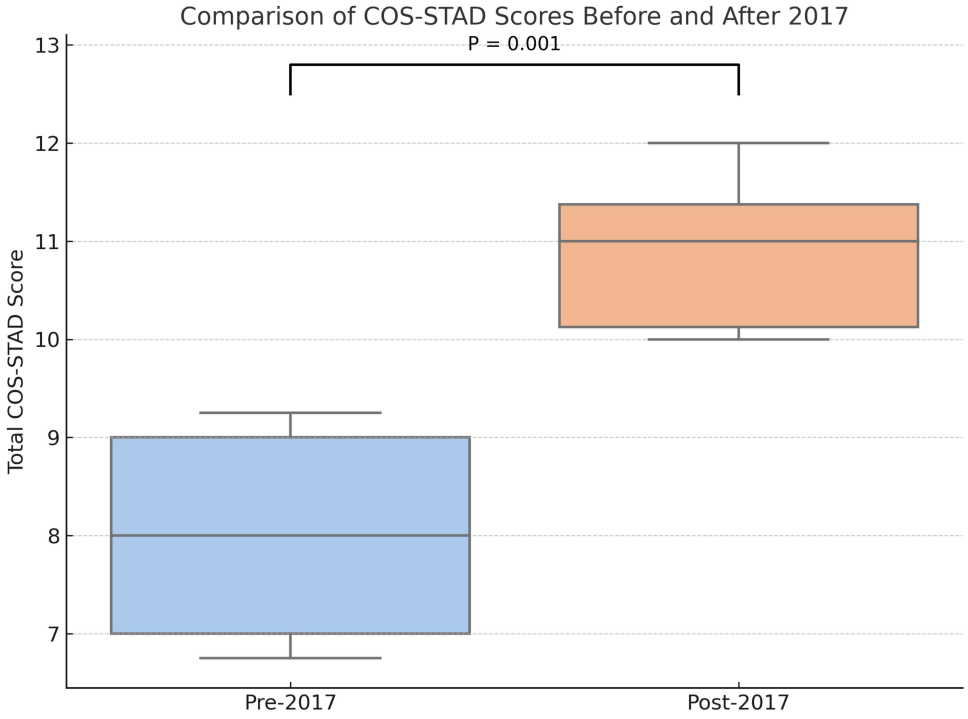

Figure 3 Comparison of COS-STAD Scores Before and After 2017.

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Table 3 Core Outcome Sets Meeting All Criteria

Study	Disease	Core Outcome Measure Set
Mingyan Zhang2021[24]	Stable angina	Angina attacks (frequency, duration of attacks, Seattle Angina Scale), exercise treadmill test, cardiovascular events, ECG QT interval
Kirstie Haywood2021[25]	Chronic episodic migraine	Migraine-specific pain (11-point numerical rating scale) Migraine-specific quality of life (Migraine Functional Impact Questionnaire)
Esther M. Pogatzki-Zahn202[12]	Perioperative pain	Physical function, pain intensity at rest, pain intensity at activity, adverse events, and self-healing efficacy
Alessandro Chiarotto2018[13]	Nonspecific low back pain	Physical function (Oswestry Disability Index version 2.1a or 24-item Roland Morris Disability Questionnaire), pain intensity (NRS), health-related quality of life (SF12 or 10-item PROMIS Global Health Scale)
Kaiser Ulrike2018[31]	Chronic pain	Pain intensity, pain frequency, physical activity, emotional well-being, social roles and activity satisfaction, work capacity, health-related quality of life, and patient fulfillment of treatment expectations

Notes: NRS Numeric Rating Scale; SF12 Short Form 12.

design has focused more on disease characteristics while overlooking the practicality of interventions and clinical implementation. Furthermore, the participation rate of industry representatives was only 21%, underscoring the need to strengthen the diversity of stakeholder involvement.

Recent studies have also highlighted methodological challenges. Systematic reviews indicate that Delphi studies often suffer from high attrition and inconsistent patient engagement, influenced by survey design, feedback mechanisms, and recruitment methods.[41] To address this, some COS developers use mixed-method approaches and structured feedback loops. Rating scale differences (eg, 5-point vs 9-point) also affect outcome prioritization, emphasizing the need for piloting and methodological transparency.[42] Although PROs are often included, many COS lack guidance on instrument selection. Guidelines such as COSMIN–COMET and PROMIS are increasingly recommended to ensure validity and comparability.[8]

Study registration and protocol pre-publication are key to enhancing COS transparency and reproducibility.[43] Yet only 2 COS (8%) were pre-published and 9 (37%) registered in the COMET database, revealing significant gaps.[44] Registration can improve design robustness, reduce bias, and prevent duplication.[9] Moreover, the open dissemination of research plans promotes greater stakeholder engagement,9 thereby increasing the overall impact and practical applicability of COS development and implementation.

Since the release of COS-STAD in 2017, COS quality has improved significantly. Clear standards offer strong methodological guidance, supporting consistency and transparency. Moreover, our findings further indicate that improved adherence to COS-STAD-particularly in stakeholder involvement, transparent reporting, and protocol registration-may contribute to future guideline development and clinical trial design in pain medicine. Enhancing the methodological quality and consistency of outcome reporting can support evidence synthesis, improve trial comparability, and promote more patient-centered research. Therefore, efforts to strengthen COS-STAD compliance should be viewed not only as a methodological refinement but also as a foundation for advancing clinical relevance and practical application. Alongside COS-STAD, the COMET Initiative introduced tools such as COS-STAR[45] and COS-STAP[46] to support reporting and protocol development. COS-STAR promotes transparent outcome selection and stakeholder reporting, while COS-STAP ensures consistent methodology from design to implementation. Together, these tools have advanced the quality, comparability, and integration of COS across studies.

International teams have played a major role in advancing COS for pain-related conditions. For example, OMERACT–OARSI updated the core outcome set for hip and knee osteoarthritis using a three-round Delphi, establishing a benchmark for musculoskeletal trials.[47] The IMI PainCare PROMPT project similarly used a rigorous Delphi process with multi-stakeholder input to develop a perioperative pain COS, consistent with COS-STAD.[48] In addition to

content standardization, many European research groups have focused on implementation feasibility. A Dutch-led Delphi study established a COS for acute postoperative lumbar spine pain, prioritizing practical domains such as pain intensity, analgesic use, mobilization, length of hospital stay, and safety outcomes.[49] Furthermore, a meta-epidemiological review highlighted the low uptake of core domains in back pain trials, calling for COS that are not only methodologically sound but also feasible in practice.[50]

In contrast, COS development in China began later but has made clear progress. Beyond pain intensity, recent COS increasingly include functional and psychosocial domains, such as anxiety and depression. Traditional therapies, including Chinese medicine, are also being incorporated to better reflect treatment practices.[51,52] However, challenges remain, including selecting appropriate instruments for diverse diseases and addressing healthcare disparities across regions.[53] With globalization, domestic research increasingly integrates international experience, aligning with global standards while adapting to local contexts, thus strengthening the foundation for scientific evaluation and management of pain-related diseases.[54]

Recommendations for Future Core Set Creation

In the future, the development of COS should prioritize both methodological rigor and practical utility. This will help improve their scientific validity, scope, and feasibility in clinical settings. First, COS trial registration and protocol publication must be further promoted to enhance transparency and support collaboration. These practices help reduce redundancy,[55] ensure efficient resource use, and strengthen the credibility and reproducibility of COS studies. Early disclosure of study protocols also facilitates peer review and stakeholder input, contributing to a more cohesive research environment.[56] Second, the development of COS should place greater emphasis on geographic, ethnic, and cultural diversity.[53] COS should be tailored to reflect population-specific needs to enhance global relevance and acceptance. International collaboration among researchers, clinicians, and patient groups will be essential to ensure COS are adaptable across healthcare systems and sociocultural contexts. Involving a wide range of stakeholders will improve the relevance, inclusiveness, and real-world uptake of COS.[8] With these improvements, future COS initiatives can promote standardization, transparency, and global alignment in outcome evaluation.[43] This will ultimately support more effective and patient-centered care.

To improve COS relevance and usability, stakeholders from diverse fields should be actively involved. This includes healthcare professionals, researchers, policymakers, industry representatives, social workers, patients, and caregivers.[11] Broad participation ensures that COS reflects varied needs and priorities across healthcare environments. It also helps identify gaps and reduce bias in outcome selection.[53] After defining a COS, developers must choose appropriate measurement tools to ensure consistent and accurate outcome assessment. Tools should be selected based on the COMET Health Measurement Tool Selection Criteria and COSMIN standards[57] Applying these criteria ensures that the selected measurement tools are valid, reliable, and responsive, thereby improving the usability and scalability of COS in both research and clinical practice. Adaptable instruments enhance consistency and comparability across healthcare settings and populations, supporting more effective evidence-based decision-making. By promoting stakeholder engagement and applying robust measurement standards, future COS development can achieve greater scientific rigor, clinical relevance, and global applicability, ultimately improving the quality and consistency of outcome assessment.[58]

Furthermore, the implementation of existing COS should be evaluated across healthcare systems and cultural settings. Differences in infrastructure, clinical practice, regulations, and populations may affect how COS are adopted. Systematic evaluations in diverse settings are needed to identify barriers and enablers. Tailored implementation strategies should reflect local healthcare delivery models,[45] resource availability, and patient needs. This includes assessing the alignment of COS with national guidelines and clinical protocols. Collaboration with providers, policymakers, and patients is critical to ensure COS are both practical and sustainable in daily practice.

Monitoring and feedback mechanisms are also needed to improve COS use.[59] Real-world data can reveal performance gaps,[60] inform methodology refinement and improve COS usability. Cross-border and interdisciplinary collaboration will enhance generalizability and adaptability. Addressing these challenges will build a stronger foundation for high-quality and consistent clinical research. In turn, this will advance more standardized, patient-centered, and globally applicable healthcare practices.

Conclusion

The development of COS must follow the COMET Initiative guidelines to ensure methodological rigor. Beyond academic quality, high-quality COS enhances comparability across trials, supports evidence synthesis, informs clinical guidelines, and prioritizes patient-centered outcomes. Future efforts should emphasize early protocol registration, validated measurement tools, and inclusive stakeholder engagement, particularly patients and clinicians. By promoting transparency and standardization, COS can strengthen the global utility of outcome reporting and support more reliable, patient-focused decision-making in both research and healthcare policy.

Data Sharing Statement

All data generated or analyzed during this study are included in this published article and its supplementary information files.

Funding

This work was supported by the project from the Open Project of National Clinical Research Center for Chinese Medicine Acupuncture and Moxibustion (Grant No. NCRCOP2023009) and the Innovation team for Research on Dominant Diseases of Acupuncture and Moxibustion (Grant No. 4042502034).

Disclosure

All authors declare that they have no conflict of interest.

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