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Using patient-reported outcomes in clinical studies for cardiovascular diseases of Traditional Chinese medicine worldwide: a cross-sectional study

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Abstract

Background and purpose Cardiovascular diseases (CVD) represent a major global health challenge. Clinical research is increasingly leveraging patient perspectives to evaluate the efficacy of Traditional Chinese Medicine (TCM) in treating these conditions. This study reviews and summarizes the application and characteristics of Patient-reported outcomes (PROs) in TCM for CVD, the overarching goal is to provide a resource that can guide potential research directions for PROs endpoints in future TCM CVD clinical research.

Methods We searched clinical studies of TCM for CVD from the World Health Organization International Clinical Trials Registry Platform registered between January 1, 2010, and February 22, 2025. The outcome types, whether PRO measures (PROMs) explicitly mentioned, study design, clinical study phases,age, gender, and geographic region were analyzed. We classified the studies that explicitly specified PROs into 15 categories based on the International Classification of Diseases-11 (ICD-11),and compared their PROMs with the Core Outcome Measures in Effectiveness Trials (COMET).

Results A total of 636 TCM CVD studies were included, of which 394 employed PROs. However, 103 studies did not specify the PROMs utilized, including 33 that involved TCM syndrome scores. None of the most frequently used PROMs were TCM-specific. The most frequently studied disease categories — chronic coronary heart diseases and heart failure — employed PROMs that were basically aligned with COMET recommendations. In contrast, other disease categories were not aligned with COMET.

Conclusion In TCM clinical research on CVD, PROs have been commonly adopted as outcome measures, with usage steadily increasing. However, the application of TCM-specific PROMs remains limited, revealing a significant gap. PROMs recommended by COMET should be further investigated across a broader range of CVD categories. Furthermore, there is an urgent need for patient-centered research on TCM syndrome scores, highlighting the importance of developing robust, standardized TCM-specific PROMs tailored to this field.

Keywords Traditional Chinese medicine, Patient-reported outcomes, Cardiovascular diseases, Clinical trial registry

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Introduction

In 2021, an estimated 19.91 million deaths globally were attributed to cardiovascular diseases (CVD), representing a 21.56% increase (95% UI, 16.41%–27.49%) from 2010 [1]. CVD remains the leading cause of global mortality [2], and its high symptomology burden significantly impacts health-related quality of life (HRQoL) [3, 4]. Therefore, The perspective of patients is particularly important in CVD [5]. HRQoL is generally assessed by patient-reported outcomes (PROs) [6]. The United States Food and Drug Administration (FDA) define PRO as follows: "A PRO is any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" [7]. The instruments used to measure PROs are commonly referred to as patient-reported outcome measures (PROMs).

In recent years, Traditional Chinese medicine (TCM) has demonstrated significant potential in the field of CVD [8, 9]. The number of clinical studies on PROs in TCM has consistently increased over the past few decade [10]. More importantly, PROs align closely with TCM's traditional emphasis on subjective patient reporting [11]. Since ancient times, Chinese medicine practitioners have relied on patients' chief complaints as primary indicators of treatment outcomes.

This study reviews the applications of PROs in TCM for CVD, summarise the specific PROMs used, and compares them with Core Outcome Measures in Effectiveness Trials(COMET) framework. The overarching goal is to provide a resource that can guide potential research directions for PROs endpoints in future TCM CVD clinical research.

Materials and methods

Data sources and searches

Data were collected from the World Health Organization International Clinical Trials Registry Platform (ICTRP) between January 1, 2010, and February 22, 2025. The search terms included "traditional Chinese medicine", "decoction", "Chinese herbs", "acupuncture", among others (the complete search strategy is provided in Supplementary Method S1). This study adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.

Study selection and data collection

We included TCM clinical studies for CVD worldwide and examined the PROMs most frequently employed in studies targeting specific diseases. CVD refers to diseases of the circulatory system listed in Chapter 11 of ICD-11 (International Classification of Diseases-11). Similar disorders were grouped into the same categories due to the significant heterogeneity of target diseases, as outlined in Supplementary Method S2. Repeated studies were included only once.

The information gathered to review and summarize the application and characteristics of PROs encompassed two categories: (1) fundamental information (e.g., registration number, date of registration, scientific title, region/country, participant age and gender, clinical study phase) and (2) crucial information (e.g., outcomes (including PROMs), Chinese medicine interventions, target diseases). We also searched the COMET database (https://www.comet-initiative.org/) for recommended PROMs applicable to these diseases.

The eligible studies were categorized into four groups based on the reported outcomes: (1) studies that registered PROs as primary endpoints; (2) studies that registered PROs as secondary outcomes; (3) studies that registered PROs as both primary and secondary endpoints; (4) studies that did not mention the use of PROs in their registration.

Statistical analysis

Data on the features of the included studies were extracted independently by two reviewers (Hao Liu and Yuanyuan Lin) using predesigned data extraction forms. The PROMs utilized in each study were summarized according to a predefined classification system to identify the most and least commonly employed instruments. For quantitative analysis, only entries that specified the names of the PROMs were considered. Descriptive statistics were conducted to characterize the clinical trial phases, study types, participants' ages and genders, TCM interventions, geographical regions and countries, diseases, and PROMs of the included studies using IBM SPSS Statistics, Version 22.0 (IBM Corp.).

Results

Search results

As shown in Fig. 1, a total of 694 studies were initially retrieved. After removing 44 duplicates and 14 studies unrelated to cardiovascular research, 636 studies remained for analysis, of which 394 employed PROs. However, 103 studies did not specify the PROMs utilized, including 33 that involved TCM syndrome scores.

Studies characteristics

As shown in Fig. 2, the number of TCM clinical registration studies utilized PROs continued increased between 2010 and 2025 (Fig. 2).

Table 1 summarizes the characteristics of the included studies, icluding the outcome types, explicitly mentioned PROMs, study design, clinical study phases, age, gender, and geographic regions. Among the 394

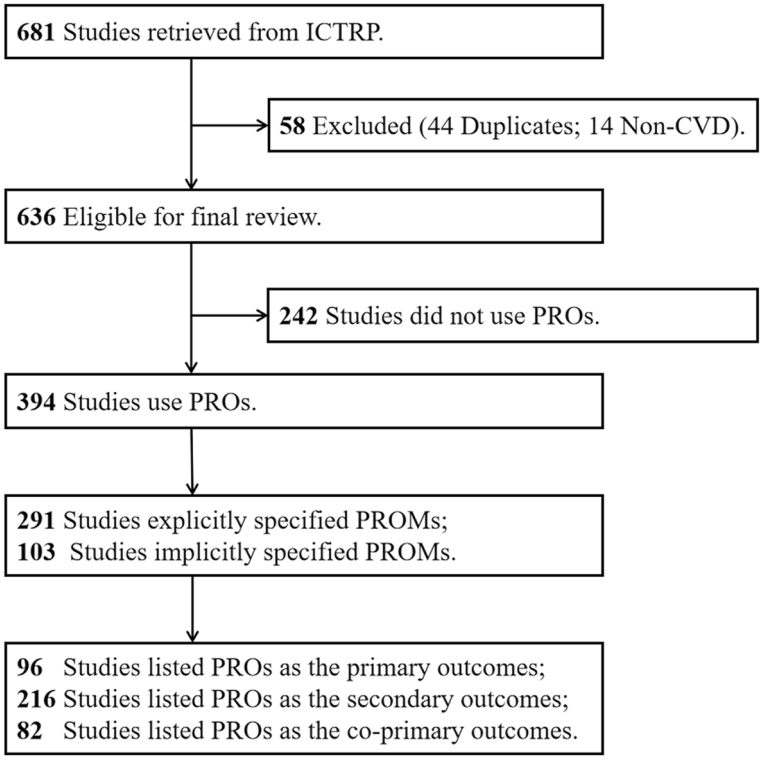

Fig. 1 Flowchart of study identification. ICTRP: International Clinical Trials Registry Platform; CVD: cardiovascular diseases; PROs: patient-reported outcomes; PROMs: patient-reported outcomes measures

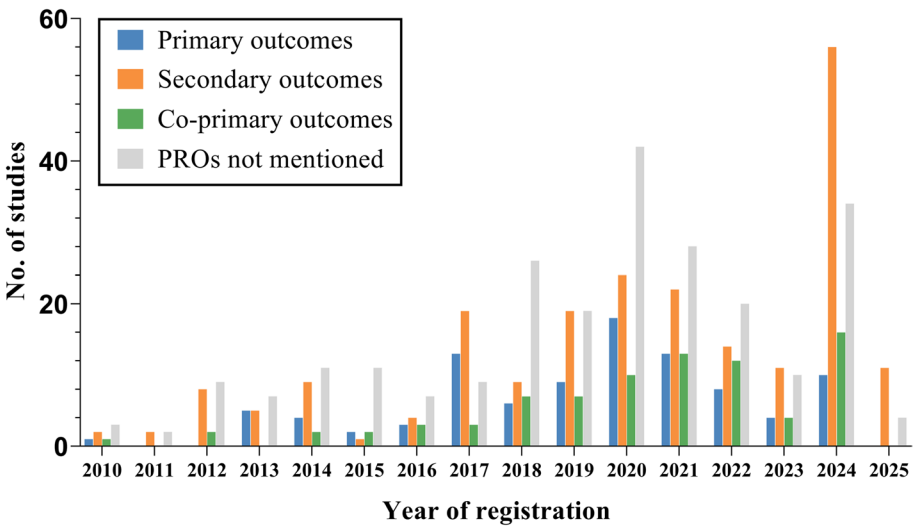

Fig. 2 Number of clinical studies analyzed

studies that employed PROs, secondary outcomes were the most frequent, followed by primary outcomes. The majority of studies were interventional, whereas only a small number were observational. Chinese herbal medicine was the most commonly used intervention, followed by acupuncture and TCM exercises. Most of these studies were conducted in China.

Table 1 Characteristics of all studies and PRO studies

	Total, No. (%)	
Characteristics	All studies	PRO studies
No	636	394
Outcomes Type		
Primary outcomes	96 (15.1)	96 (24.4)
Secondary outcomes	216 (34.0)	216 (54.8)
Co-primary outcomes	82 (12.9)	82 (20.8)
PROs not mentioned	242 (38.1)	0 (0)
Whether the PROMs are explicitly mentioned		
PROMs explicitly specified	291 (45.8)	290 (73.6)
PROMs implicitly specified	103 (16.2)	104 (26.4)
PROMs not mentioned	242 (38.1)	0 (0)
Study design		
Interventional study	602 (94.7)	379 (96.2)
Observational study	30 (4.7)	14 (3.6)
Cause/Relative factors study	4 (0.6)	1 (0.3)
Clinical study phases		
Early stage	167 (26.3)	112 (28.4)
1	28 (4.4)	19 (4.8)
2	36 (5.7)	22 (5.6)
3	19 (3.0)	9 (2.3)
4	129 (20.3)	87 (22.1)
Other clinical study phases*[1]	39 (6.1)	20 (5.1)
Unclear	218 (34.3)	125 (31.7)
Minimum age		
Under 17	5 (0.8)	5 (1.3)
18—60	563 (88.5)	352 (89.3)
Over 61	10 (1.6)	6 (1.5)
Unclear	58 (9.1)	31 (7.9)
Gender		
Male	9 (1.4)	4 (1.0)
Female	12 (1.9)	8 (2.0)
Both	610 (95.9)	380 (96.4)
Unclear	5 (0.8)	2 (0.5)
Chinese medicine interventions		
Chinese herbal medicines	358 (56.3)	231 (58.6)
Acupuncture	199 (31.3)	104 (26.4)
Traditional Chinese Medicine Exercise Therapy	31 (4.9)	27 (6.9)
Massage	17 (2.7)	10 (2.5)
Copping	2 (0.3)	1 (0.3)
Other interventions*[2]	29 (4.6)	21 (5.3)
Regions		
WHO Western Pacific Region		
China	528 (83.0)	336 (85.0)
South Korea	13 (2.0)	7 (1.8)
Australia	6 (0.9)	5 (1.3)
Japan	2 (0.3)	1 (0.3)
Singapore	1 (0.2)	1 (0.3)
WHO Eastern Mediterranean Region		
Iran	40 (6.3)	20 (5.1)
Pakistan	1 (0.2)	1 (0.3)
WHO Region of the Americas		
United States	10 (1.6)	6 (1.5)
Brazi1	8 (1.3)	2 (0.5)
Canada	1 (0.2)	1 (0.3)
WHO European Region		
Spain	3 (0.5)	2 (0.5)
Turkey	3 (0.5)	1 (0.5)
Germany	2 (0.3)	2 (0.5)
United Kingdom	2 (0.3)	2 (0.5)
Denmark	1 (0.2)	1 (0.3)
France	1 (0.2)	0
Nederland	1 (0.2)	0
Sweden	1 (0.2)	0
Switzerland	1 (0.2)	0
Russian Federation	1 (0.2)	0
WHO South-East Asia Region		
India	6 (0.9)	4 (1.0)
Thailand	3 (0.5)	1 (0.3)
Nepal	1 (0.2)	0

① Other clinical study phases*[1]: Including combined phases 1–2 or 2–3 or 3–4, and including observational studies

② Other interventions*[2]: Including merged utilizing a variety of TCM therapies or no interventions

Health conditions and PROs

To assess the disease distribution of the 394 PRO studies and the application of PROMs, we categorized similar target diseases into 15 conditions according to ICD-11. The distribution of conditions and participants is illustrated in Fig. 3a and b. Among the 394 studies, chronic coronary heart diseases, hypertension, and heart failure were the top three conditions for which PROs were used as outcomes, and they also involved the largest number of participants.

PROMs used in clinical studies

Table 2 provides an overview of the PROMs utilized five or more times, with the SAQ being the most frequently employed, followed by the SF-8/12/36 and MLHFQ. Notably, no TCM-specific PROMs were among those.

Table 3 summarizes the PROMs utilized across various categories of CVD and their alignment with COMET recommendations. The SAQ was the most commonly employed PROM for both chronic and acute coronary heart diseases, while the MLHFQ was predominantly used for heart failure. The SF-8/12/36 was the most frequently applied PROM for arrhythmias, diseases of the lymphatic vessels or lymph nodes and

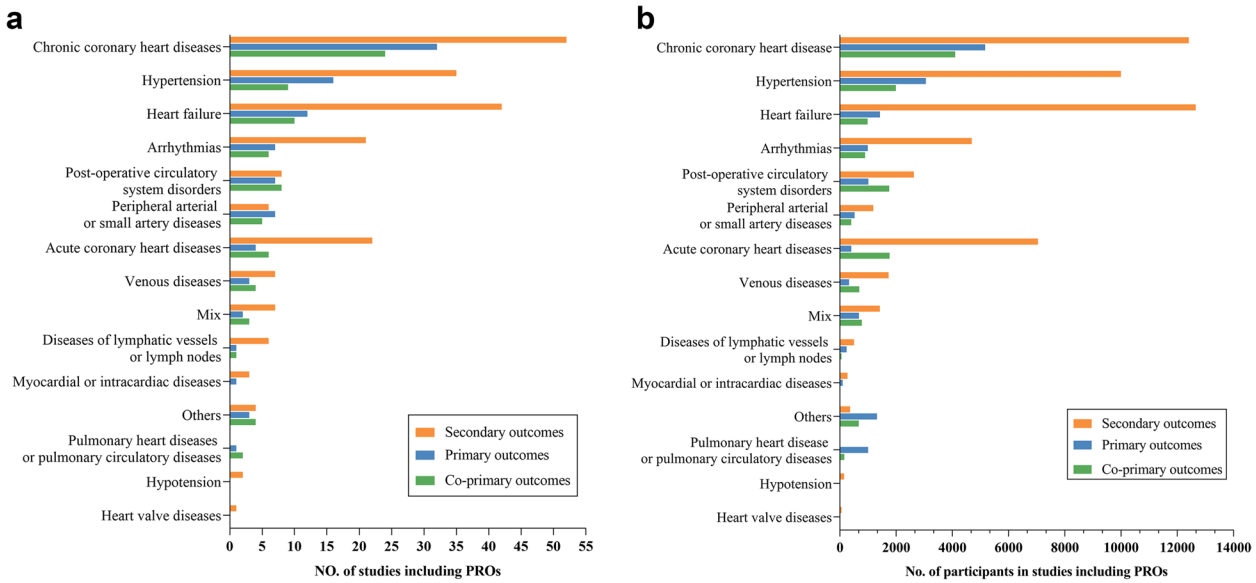

Fig. 3 **a** Number of studies including PROs. **b** Number of participants in studies including PROs. Mix: means the study's target disorders included the combination of two or more cardiovascular conditions, such as hypertension and coronary heart disease complicated with heart failure, coronary heart disease with slow arrhythmias, atrial fibrillation with chronic heart failure. Others: means that the included studies were recruiting patients with cardiovascular disease combined with other systemic conditions, such as coronary artery disease combined with diabetes

Table 2 Number of PROMs applied

PROM	No	PROM	No	PROM	No
SAQ	99	EQ-5D	16	PHQ-2/9	8
SF-8/12/36	51	KCCQ	16	HADS	8
MLHFQ	47	SAS	13	WHOQOL	6
VAS	39	SDS	12	STAI	6
PSQI	27	GAD-7	9	NRS	6

Abbreviations: *EQ-5D* European Quality of Life Five Dimension Five Level Scale Questionnaire, *GAD-7* Generalized Anxiety Disorder-7, *HADS* Hospital Anxiety and Depression Scale, *KCCQ* Kansas City Cardiomyopathy Questionnaire, *NRS* Numeric Rating Sale, *MLHFQ* Minnesota Living with Heart Failure Questionnaire, *PHQ-2/9* Patient Health Questionnaire-2/9, *PSQI* Pittsburgh Sleep Quality Index, *SAQ* Seattle Angina Questionnaire, *SAS* Self-Rating Anxiety Scale, *SDS* Self-rating Depression Scale, *SF-8/12/36* Short-Form 8/12/36-item Health Survey, *STAI* State-Trait Anxiety Inventory, *WHOQOL* World Health Organization Quality of Life Scale, *VAS* Vsual Analog Scale

hypotension. Notably, the two most frequently studied disease categories—chronic coronary heart diseases and heart failure—the PROMs employed were basically aligned with COMET recommendations. In contrast, other categories did not.

Discussion

Summary of findings

This cross-sectional study analyzed the application and characteristics of PROs in clinical studies of TCM for CVD conducted worldwide from 2010 to 2025. Our findings indicate that PROs are commonly used in this field, with over half of the studies incorporating PROs, and their usage has shown a continued increase. However, TCM-specific PROMs remain inadequately utilized. Additionally, a subset of these studies (103/394) did not adequately report the specific PROMs employed. PROMs that align with COMET recommendations are only applied in studies of the two most common CVD categories.

Strengths and limitations

First, we conducted a search of clinical study registration data, which provides a more comprehensive overview than is typically obtained from published articles. This registration information includes nearly all clinical studies, regardless of their completion status or publication. Second, we utilized the WHO-ICTRP, which is highly comprehensive, incorporating registration data from multiple national and institutional clinical trial registries, including ClinicalTrials.gov, the International Traditional Medicine Clinical Trial Registry, the Chinese Clinical Trial Registry, and the EU Clinical Trials Register, among other. This extensive coverage facilitates a thorough examination of PROs in global TCM clinical studies. Third, by cross-referencing the PROMs employed in these studies with those recommended by the COMET initiative, we gain clearer insight into how well real-world practices align with theoretically recommended measures.

Table 3 Frequency of the use of PROMs by conditions

Conditions												
	No.(%) S/L*	**PRO Ms Name**	**No. (S/L)**	**PRO Ms Name**	**No. (S/L)**	**PRO Ms Name**	**No. (S/L)**	**PRO Ms Name**	**No. (S/L)**	**PRO Ms Name**	**No. (S/L)**	**Core outcome set of PROs in the COMET[#1]**
Total No	291 (100)											
Chronic coronary heart diseases	91 (31.3) 39/52	SAQ	68 (27/41)	SF-8/12/36	17 (6/11)	VAS	15 (9/6)	SAS	8 (4/4)	SDS	8 (3/5)	SAQ-7/SF-8/36/RDS/ PHQ-2/QLI-Cardiac IV/ QLMI-2/MacNew Heart Disease HRQoL Questionnaire [12, 13],
Heart failure	56 (19.2) 30/26	MLHFQ	33 (16/17)	KCCQ	14 (9/5)	SF-8/12/36	5 (2/3)	EQ-5D	4 (4/0)	PSQI	3 (2/1)	MLHFQ/KCCQ/CHFQ/ EQ-5D/ SF-36 [14]
Hypertension	34 (11.7) 19/15	PSQI	12(6/6)	SF-8/12/36	10 (6/4)	VAS	3(3/0)	MLHFQ	2(0/2)	SAS	2(1/1)	EQ-5D/VR-12/ PROMIS-10/SF-12 [15]
Acute coronary heart diseases	25 (8.6) 12/13	SAQ	16 (6/10)	VAS	3 (2/1)	PSQI	3 (1/2)	NRS	2 (1/1)	EQ-5D	1 (0/1)	No core outcome set studies
Post operative circulatory system disorders	18 (6.2) 10/8	VAS	6 (5/1)	SAQ	3 (0/3)	SF-8/12/36	3 (0/3)	PHQ-9	2 (0/2)	GAD-7	2 (0/2)	No core outcome set studies
Arrhythmias	18 (6.2) 10/8	SF-8/12/36	8 (4/4)	EQ-5D	5 (5/0)	AFEQT	4 (4/0)	SAQ	3 (1/2)	VAS	2 (1/1)	No core outcome set studies
Peripheral arterial or small artery diseases	15 (5.2) 12/3	VAS	6 (6/0)	STAI	2 (2/0)	MPQ	2 (1/1)	SF-8/12/36	1 (1/0)	EQ-5D	1 (1/0)	Ongoing in core outcome set studies
Mix[#1]	10 (3.4) 3/7	SAQ	5 (3/2)	MLHFQ	5 (0/5)	SF-8/12/36	1 (0/1)	KCCQ	1 (0/1)	MPQ	1 (1/0)	Not applicable
Other[#3]	9(3.1) 4/5	SAQ	4 (1/3)	PSQI	2 (1/1)	SAS	2 (2/0)	SF-8/12/36	1 (0/1)	MLHFQ	1 (1/0)	Not applicable
Venous diseases	5 (1.7) 2/3	VAS	2 (1/1)	NRS	2 (1/1)	SF-8/12/36	1 (0/1)					CIVIQ/CCVUQ/EQ-5D/ RAND-36/AVVQ [16]
Diseases of lymphatic vessels or lymph nodes	4 (1.4) 4/0	SF-8/12/36	2 (2/0)	VAS	1 (1/0)	FACT-B	1 (1/0)	MYMOP	1 (1/0)			No core outcome set studies
Pulmonary heart diseases or pulmonary circulatory diseases	2(0.7) 2/0	CAT	2 (2/0)	HADS	1 (1/0)	STAI	1 (1/0)					Ongoing in core outcome set studies

Table 3 (continued)

Conditions												
	No.(%) S/L*	**PRO Ms Name**	**No. (S/L)**	**PRO Ms Name**	**No. (S/L)**	**PRO Ms Name**	**No. (S/L)**	**PRO Ms Name**	**No. (S/L)**	**PRO Ms Name**	**No. (S/L)**	**Core outcome set of PROs in the COMET[#1]**
Myocardial or intracardiac diseases	2(0.7) 2/0	MLHFQ	2 (2/0)	WHOQOL	1 (1/0)							No core outcome set studies
Hypotension	2(0.7) 1/1	SF-8/12/36	2 (1/1)									Ongoing in core outcome set studies
Heart valve disases	0											EQ-5D/ IDCV [17]

Only the precise number of PROMs is reported, not the proportion of conditions, because a study may use many PROMs

* S: Small sample size (N < median); L: Large sample size (N ≥ median)

1 The COMET: The COMET Initiative brings together people interested in the development and application of agreed standardised sets of outcomes, known as "core outcome sets" (COS). These sets represent the minimum that should be measured and reported in all clinical trials of a specific condition, but COS are also suitable for use in routine care, clinical audit and research other than randomised trials. The existence or use of a core outcome set does not imply that outcomes in a particular study should be restricted to those in the relevant core outcome set. Rather, there is an expectation that the core outcomes will be collected and reported, making it easier for the results of studies to be compared, contrasted and combined as appropriate; while researchers continue to explore other outcomes as well. COMET aims to collate and stimulate relevant resources, both applied and methodological, to facilitate exchange of ideas and information, and to foster methodological research in this area. (https://www.comet-initiative.org/)

2 Mix means the study's target disorders included the combination of two or more cardiovascular conditions, such as hypertension and coronary heart disease complicated with heart failure、coronary heart disease with slow arrhythmias、atrial fibrillation with chronic heart failure

3 Other indicates that the included studies were recruiting patients with cardiovascular disease combined with other systemic conditions, such as coronary artery diseases combined with diabetes

Abbreviations: *AFEQT* Atrial Fibrillation Effect on Quality of Life, *AVVQ* Aberdeen Varicose Vein Questionnaire, *BES* The Basic Empathy Scale, *CAT* COPD Assessment Test, *CCVUQ* Charing Cross Venous Ulcer Questionnaire, *CHFQ* The Chronic Heart Failure Questionnaire, *CIVIQ* Chronic Venous Insufficiency Quality of Life Questionnaire, *EQ-5D* European Quality of Life Five Dimension Five Level Scale Questionnaire, *FACT-B* Functional Assessment of Cancer Therapy—Breast Cancer, *GAD-7* Generalized Anxiety Disorder-7, *HADS* Hospital Anxiety and Depression Scale, *IDCV* Heart Valve Disease Impact on Daily Life Questionnaire, *KCCQ* Kansas City Cardiomyopathy Questionnaire, *MacNew Heart Disease HRQoL Questionnaire* MacNew Heart Disease health-related quality of life questionnaire, *MPQ* McGill Pain Questionnaire, *NRS* Numeric Rating Sale, *MLHFQ* Minnesota Living with Heart Failure Questionnaire, *MYMOP* Measure Your Medical Outcome Profile, *PHQ-2/9* Patient Health Questionnaire-2/9, *PROMIS-10* PROs Measurement Information System-10, *PSQI* Pittsburgh Sleep Quality Index, *QLI-Cardiac IV* Quality of Life Index-Cardiac Version IV, *QLMI-2* Quality of Life after Myocardial Infarction Questionnaire Version 2, *RAND 36* R AND 36-Item Health Survey, *RDS* Rose Dyspnea Score, *SAQ* Seattle Angina Questionnaire, *SAS* Self-Rating Anxiety Scale, *SDS* Self-rating Depression Scale, *SF-8/12/36* Short-Form 8/12/36-item Health Survey, *STAI* State-Trait Anxiety Inventory, *WHOQOL* World Health Organization Quality of Life Scale, *VAS* Vsual Analog Scale, *VR-12* Veterans RAND 12-Item Health Survey

Despite these strengths, our study has several limitations. First, because clinical study registration data are not subject to the same rigorous peer review process as published articles, some records may include incomplete or inaccurate information, which could limit the reliability of our findings. Second, while our study presents the frequency of different PROMs used for CVD and assesses their alignment with COMET guidelines, it does not offer specific recommendations on which PROMS might be optimal for clinical or research settings.

Comparison with previous research

We found no studies that review and summarize the application and characteristics of PROs in the context of TCM for CVD. Recent systematic reviews have focused on broad categories of CVD [18], as well as specific conditions such as heart failure [19], atrial fibrillation [20], large-vessel vasculitis [21], and aortic dissection [22]. In contrast to these reviews, which primarily emphasize the use of the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) tool for assessing PROMs quality, our study specifically examines how PROMs are applied in TCM for CVD. These prior reviews provide valuable direction for our future work, as discussed in Sect. *4.4, 'Implications for Future Research'*.

Implication of future research

The application of TCM-specific PROMs in the context of CVD remains extremely limited. The reasons for this are unclear, whether due to a lack of TCM-specific PROMs, concerns regarding the quality of existing tools, or insufficient awareness of these instruments. To address this gap, the next step should involve conducting a systematic review of TCM-specific PROMs in CVD. This review should include studies that have developed and/or validated health status PROMs in cardiovascular populations. The evaluation process should adhere to FDA recommendations and COSMIN criteria to assess the quality of TCM-specific PROMs. The goal is to provide a resource to guide the selection of appropriate PROMs for various CVD in both clinical research and practice settings. In doing so, this will help identify high-quality TCM-specific PROMs and promote their integration into clinical studies of TCM. Additionally, these TCM-specific PROMs should be actively included in databases such as PROQOLID (https://eprovide.mapi-trust.org/about/about-proqolid) and the National Institutes of Health (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS) to facilitate the wider dissemination of these tools.

Our study also reveals that most clinical studies of CVD employ PROMs that are inconsistent with the COMET recommendations, except for those focusing on the three most common CVDs. Therefore, it is essential to strengthen the COMET recommendations for PROMs in other less common CVD categories in future research to more effectively capture patient-reported health status in these conditions. Furthermore, many studies aim to measure TCM syndrome scores but fail to specify the PROMs used. To address this, future research should follow FDA recommendations and COSMIN criteria when developing PROMs for TCM syndrome scores.

Finally, when registering clinical trials, it is imperative to explicitly report the specific PROMs utilized. This underscores the importance of clearly disclosing the particular PROMs employed in clinical trial registration when PROs are being considered as an outcome measure.

Conclusion

In the clinical research on CVD within TCM, PROs have been commonly adopted as outcome measures, with their use steadily increasing. However, the application of TCM-specific PROMs remains limited, revealing a significant gap in this area. PROMs recommended by COMET require further investigation in a broader range of CVD categories. Furthermore, there is an urgent need for patient-reported research on TCM syndrome scores, highlighting the importance of developing robust, standardized PROMs tailored to this field.

Abbreviations

CVD	Cardiovascular disease
TCM	Traditional Chinese Medicine
PROs	Patient-reported outcomes
PROMs	Patient-reported outcome measures
ICD-11	International Classification of Diseases-11
COMET	Core Outcome Measures in Effectiveness Trials
HRQoL	Health-related quality of life
FDA	Food and Drug Administration
ICTRP	World Health Organization International Clinical Trials Registry Platform
WHO	World Health Organization
COSMIN	Consensus-based Standards for the selection of health Measurement Instruments
NIH	National Institutes of Health
PROMIS	Patient-Reported Outcomes Measurement Information System

Supplementary Information

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Additional file 1.

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Not applicable.

Authors' contributions

Yutong Fei, and Hongguo Rong conceived the protocol; Hao Liu wrote the article; Hongguo Rong, and Yuanyuan Lin,and Xinyue Zhang contributed to analysis and interpretation of data; Xingmiao Guan , Minjing Luo , Changhao Liang and Yutong Fei, critically revised the manuscript. Every author unanimously accepts complete responsibility for guaranteeing the honesty and precision of the content and has thoroughly reviewed and endorsed the final draft. The author in

charge had complete access to all the data in the research and took the ultimate responsibility for deciding to submit the manuscript for publication.

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Data availability
The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Ethics approval and consent to participate
This study used publicly available data and did not require ethical approval.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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