SYSTEMATIC REVIEW

Measurement Properties of Patient-Reported Outcome Measures for Medication Adherence in Cardiovascular Disease: A COSMIN Systematic Review

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Abstract

Background and Objective Several medication adherence patient-reported outcome measures (MA-PROMs) are available for use in patients with cardiovascular disease (CVD); however, little evidence is available on the most suitable MA-PROM to measure medication adherence in patients with CVD. The aim of this systematic review is to synthesise the measurement properties of MA-PROMs for patients with CVD and identify the most suitable MA-PROM for use in clinical practice or future research in patients with CVD.

Methods An electronic search of nine databases (PubMed, MEDLINE, CINAHL, ProQuest Health and Medicine, Cochrane Library, PsychInfo, Scopus, Embase, and Web of Science) was conducted to identify studies that have reported on at least one of the measurement properties of MA-PROMs in patients with CVD. The methodological quality of the studies included in the systematic review was evaluated using the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) checklist.

Results A total of 40 MA-PROMs were identified in the 84 included studies. This review found there is a lack of moderate-to-high quality evidence of sufficient content validity for all MA-PROMs for patients with CVDs. Only eight MA-PROMs were classified in COSMIN recommendation category A. They exhibited sufficient content validity with very low-quality evidence, and moderate-to-high quality evidence for sufficient internal consistency. The 28 MA-PROMs that meet the requirements for COSMIN recommendation category 'B' require further validation studies. Four MA-PROMs including Hill–Bone Compliance Medication Scale (HBMS), the five-item Medication Adherence Report Scale (MARS-5), Maastricht Utrecht Adherence in Hypertension (MUAH), and MUAH-16 have insufficient results with high quality evidence for at least one measurement property and consequently are not recommended for use in patients with CVD. Two MA-PROMs (Adherence to Refills and Medications Scale [ARMS] and ARMS-7) are comprehensive and have moderate to high quality evidence for four sufficient measurement properties.

Conclusion From the eight MA-PROMs in COSMIN recommendation category A, ARMS and ARMS-7 were selected as the most suitable MA-PROMs for use in patients with CVD. They are the most comprehensive with be best quality evidence to support their use in clinical practice and research.

1 Introduction

Cardiovascular diseases (CVDs) are a major public health burden that is impacting on sustainable human development [1]. Worldwide, it is estimated that CVDs affect 422 million people, making them the leading cause of death globally, with an estimated one-third of all death attributed to CVDs [2]. Of these global deaths, in excess of 75% occur in low- and middle-income countries (LMIC) [3]. To reduce the risk of developing CVDs, behavioural changes, such as cessation of cigarette smoking, reducing harmful use of alcohol, increased physical activity and a healthy diet, are

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Key Points

This systematic review used COSMIN guidelines to provide synthesised evidence on the measurement properties of MA-PROMs for patients with CVD.

ARMS and ARMS-7 were selected as the most suitable PROMs from the eight identified MA-PROMs (ABQ, ARMS, ARMS-7, MAS, MASES-R, MEDS, MTQ-Purposeful action, and SEAMS) for patients with CVD.

The findings of this review could assist healthcare providers and researchers to select the most suitable PROM to evaluate adherence to medication for CVD in their context.

recommended [4]. In patients with either established CVD or those who are at higher risk for future CVDs, long-term medication usage is required [5], and it is reported that more than half the patients with chronic diseases do not take their medications as prescribed (low medication adherence) [6].

Medication adherence is a complex phenomenon affected by multiple factors. The World Health Organization (WHO) defined adherence as "*the extent to which a person's behaviour—taking medication, following a diet or executing lifestyle changes, corresponds with agreed recommendations from a healthcare provider*" [6, p.3]. There is growing evidence that taking medications as prescribed is linked with better clinical, humanistic and economical outcomes [7]. In patients with CVD, non-adherence could lead to a failure to control disease symptoms, higher risk of future cardiovascular complications, preventable hospital readmissions or early death [8, 9].

Under-utilisation of medications has an economic impact as significant resources are wasted due to healthcare-related costs associated with hospital admissions, readmissions and/or complications occurring when medication is under-utilised [7]. It has been estimated that sub-optimal use of medications resulted in unnecessary costs of US$475B per annum worldwide and non-adherence is considered to contribute 57% (US$269B) of these unnecessary costs [10]. It has been found that medication adherence in patients with congestive heart failure and hypertension reduced average annual total health care spending per individual by US$7823 and US$3908, respectively [11]. Appropriate interventions should be designed to improve medication adherence, thereby promoting better health and reducing wastage of health-care resources [12].

Interventions to improve medication adherence have only demonstrated limited effectiveness in previous research [7, 13]. This could be because the interventions did not

necessarily consider multiple facets of non-adherence and were not individualised at the patient level to consider specific reasons for non-adherence, such as intentional or non-intentional non-adherence [14]. Improving medication adherence begins with a valid and reliable assessment of medication adherence through appropriate consideration of the reasons for, and the level of, any non-adherence prior to choosing an appropriate intervention [15].

Currently, there is no consensus on a universal method of adherence measurement and there has been debate over a 'gold standard' for measuring adherence [16]. According to the WHO, medication adherence measures are classified into two categories: objective measures and subjective measures [6]. Objective measures of medication adherence are considered to be more reliable and accurate than subjective methods [6, 17], and may include approaches such as electronic monitoring, pharmacy and/or other health-care provider records, pill counts, or biochemical measures. However, objective measures may involve additional costs and the procedures require more time than routine clinical practice allows [17]. Subjective measures involve approaches such as self-report and healthcare provider assessment [6].

Patient-reported outcome measures (PROMs) are self-report instruments designed to capture information on patients-reported outcomes (PROs) [18–20]. Patient-reported outcomes are defined as "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" [21], and PROMs are used to collect these data for healthcare decision making [22]. Patient-reported outcomes provide patients' perspectives on their health condition or health behaviour. Medication-taking behaviour is one of the PROs that could be evaluated in clinical practice and research to inform medication adherence support, treatment benefits or harms, and be used as a proxy indicator of clinical progress, disease complications, hospital admissions, healthcare costs and death [6, 20, 23]. Patient-reported outcome measures are the most extensively used measure of medication adherence, primarily because they are relatively inexpensive, easy to undertake, take a short amount of time, and are less invasive than objective measures. Medication adherence PROMs (MA-PROMs) may use questions about the extent of non-adherence or reasons for non-adherence [15], and can be used in large population samples. Patient-reported outcome measures have two main weaknesses, recall and social desirability bias, which may result in overestimation of adherence [15–17]. Medication adherence patient-reported outcome measures should be of sufficient quality to ensure that the results are representative; therefore, the most suitable PROM with evidence of reliability, validity, and comprehensiveness should be selected [15].

A number of different MA-PROMs are available for public use to assess medication adherence for patients with CVDs, and each of these cover a range of methods, domains and measurement properties [24–26]. Owing to the vulnerability of PROMs to overestimation, identifying the most suitable PROM requires a rigorous assessment with standardised guidelines. The COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) group established an international consensus-based taxonomy terminology, and definitions of measurement properties for PROMs [27]. With the clinical utility becoming one of the critical features of PROMs integrated into clinical practice and research [28], clinical utility should be taken into account during selection of suitable PROMs [29]. The term "feasibility" is used in the COSMIN guidelines to refer to clinical utility suggesting that feasibility applies to PROMs, whereas clinical utility is more related to an intervention [29–31]. In this review, feasibility (clinical utility) is used to evaluate whether a MA-PROM can be applied easily for the intended context of use (i.e., for evaluation of initiation, implementation or discontinuation phases of medication adherence in people with CVD) considering the constraints of time or cost [29, 32]. Completion time, copyright issue, length of PROM, type and method of administration were included as elements of feasibility in the selection of the MA-PROMs [29, 31].

The purpose of this project was to undertake a systematic review of the available MA-PROMs for people with CVD, evaluate their quality and feasibility, and to decide if they are adequate for purpose; could be improved; or if an entirely new MA-PROM is required. A preliminary search was conducted in the Cochrane Database of Systematic Reviews, PROSPERO and the Joanna Briggs Institute (JBI) Database of Systematic Reviews and Implementation Reports, and no systematic reviews were found on the quality of MA-PROMs in CVD.

2 Methods

This systematic review used the COSMIN guidelines to evaluate the measurement properties of MA-PROMs [29, 31, 33, 34] and followed the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines [35]. The protocol was registered with PROSPERO (registration number CRD42019124291) and published in JBI Evidence Synthesis [36].

The search strategy for this systematic review followed a priori published protocol [36], the three-step method was used [37] and COSMIN guided the choice of major concepts [29]. The main concepts were generated based on Population (patients aged ≥ 18 years with CVD, i.e., hypertension, dyslipidaemia, congestive heart failure, coronary heart disease or stroke either alone or with other diseases). Instrument (any PROM), Construct (at least one of the three phases of medication adherence (initiation, implementation or discontinuation) and Outcome (at least one of the following measurement properties: content validity, structural validity, internal consistency, cross-cultural validity/measurement invariance, reliability, measurement error, criterion validity, hypothesis testing for construct validity or responsiveness). The authors used the sensitive search filter for measurement properties developed by Terwee et al. [38].

Nine databases including PubMed, ProQuest Health and Medicine, MEDLINE, Cochrane Library, CINAHL, PsychInfo, Web of Science, Embase, and Scopus were searched from inception to Dec 31, 2021. Forward citation tracking was conducted from databases to include additional articles. All articles published in any language were included with no date limit. Non-English studies were included until data extraction to acknowledge their existence and a possible language bias [29].

The authors included studies of any study design that reported on the measurement properties of MA-PROMs among adults with CVD. Based on the COSMIN guidelines [29] studies that used a PROM only to measure outcomes or to validate other PROMs as a comparator, were excluded. Three levels of screening were performed, namely title screening, abstract screening and full-text screening using EndNote X9 (Clarivate Analytics, PA, USA). Two reviewers (HGT and JS, SW or ETE) independently screened the titles then abstracts of articles for eligibility for further evaluation. Full-text articles were obtained and independently reviewed by two authors (HGT and JS, SW or ETE) to confirm if the article met the eligibility criteria. Disagreements were resolved through discussion. The process of identifying relevant articles was reported in a PRISMA flow chart [39]. The inclusion criteria and operational definitions based on COSMIN guidelines on measurement properties [27] were described in detail in a priori published protocol [36].

Data were extracted from articles included in the review using data-extraction tools guided by the COSMIN checklist [31]. The data-extraction tools were pilot tested on five randomly selected studies. The pilot study was conducted by two authors until both authors (HGT and JS) were able to record all identified relevant information and were both in agreement. Data extraction was conducted by one reviewer (HGT) and cross-checked by a second reviewer (JS, SW or ETE). Disagreements were resolved through discussion between the authors.

The nominated corresponding author of an article was contacted to request missing information when necessary. If authors did not respond, the requested information was reported as "unknown".

Descriptive statistics were used for the general characteristics of the studies and MA-PROMs. The data from the

included studies were synthesised using tables for the risk of bias, and results of measurement properties. The adherence domain(s) that each MA-PROM measured were described using Medication Adherence Model (MAM), which depicts both intentional and unintentional reasons for non-adherence [40]. Medication Adherence Model has nine domains for non-adherence, three related to each of unintentional reasons (Pattern Behaviour), intentional reasons (Purposeful Action) and Feedback [40]. In this review, a MA-PROM is said to be comprehensive if the items of the PROM capture information on the extent of both medication-taking and prescription filling and at least two domains each from intentional reasons (Pattern Behaviour) and unintentional reasons for non-adherence (Purposeful Action and Feedback) in the MAM framework (Table 2).

Ten COSMIN boxes containing standards were used to evaluate risk of bias/methodological quality of studies on PROM development (COSMIN box 1), content validity (COSMIN box 2) and eight other measurement properties (COSMIN boxes 3 to 10) [29, 31, 34]. The methodological quality for each measurement property and study, including PROM development studies, was evaluated and an overall rating score given for each PROM using COSMIN scoring [34, 41]. The quality of evidence was graded as high; moderate; low; or very low for the overall ratings using a modified GRADE approach for content validity [29, 34]. For PROMs with inadequate quality of development study, and inadequate quality or no content validity studies, the quality of evidence for content validity was obtained from reviewer's ratings and graded as "very low" [34]. The risk of bias, imprecision, inconsistency, and indirectness were considered to downgrade quality of evidence [29].

2.1 Formulating Recommendations for the Use of MA-PROMs in Patients with CVD

To select the most suitable MA-PROM for evaluation of medication adherence for people with CVD, recommendations were generated in relation to both the construct (medication adherence) and target population (patients with CVD) based on the methodological quality and sufficiency of results. Three categories of recommendations based on COSMIN guideline were used for this review [29].

A. Patient-reported outcome measures with any level of evidence for sufficient content validity AND at least low-quality evidence for sufficient internal consistency.
B. Patient-reported outcome measures categorised not in A or C.
C. Patient-reported outcome measures with high-quality evidence for an insufficient measurement property

We can recommend MA-PROMs in category 'A' for use in the evaluation of medication adherence in patients with CVD, as these MA-PROMs can be seen trusted. There is a potential to use MA-PROMs in category 'B', but further validation study is required to evaluate the quality of these MA-PROMs. Medication adherence PROMs of category C should not be recommended for use. COSMIN guidelines suggest that if no PROMs from category 'A' are identified and only PROMs from category 'B' are available, the PROM with best evidence on sufficient content validity can be recommended on a preliminary basis, until further evidence is obtained [31].

The COSMIN guideline recommends selecting the most suitable PROM from category "A" [29]. Further comparison of these PROMs was performed based on additional measurement properties, other than content validity and internal consistency, with the best evidence. Finally, contexts and feasibility aspects were considered to select the most suitable MA-PROM for people with CVD.

3 Results

The search strategy identified 8691 records. After removal of duplicates, title/abstract and full test screening processes, 69 records met the inclusion criteria (Fig. 1). Five articles using backward citation tracking from the reference list, and 10 articles with forward citation tracking were included, resulting in a final sample of 84 articles. A PRISMA flow-diagram of the search procedures and results is provided in Fig. 1.

The study characteristics of the 84 included articles [42–125], each reporting a unique study, are presented in Supplementary data, Table S1. Of these, nine studies [47, 51, 65, 66, 78, 80, 118, 119, 125] evaluated two MA-PROMs simultaneously, whereas one study [85] included three MA-PROMs. The largest number of studies were conducted in the USA (26/84). Only two studies were undertaken in Africa [85, 99]. English was the most common target language for MA-PROMs within the studies (n = 31, 37%), while there were seven studies in Chinese, six studies in Persian, five each in Brazilian Portuguese, German, and Turkish, four studies in Arabic, three each in Korean, Polish and Spanish, and two in European Portuguese. The MA-PROM language was not described in five studies conducted in Brazil (3), Denmark (1), and India (1). Other eight MA-PROM languages were used once as a target language for the MA-PROM, including Czech, French, Kannada, Malay, Runyankore/Rukiga, Thai language and Xhosa. The most common study setting was hospital-outpatient services (n = 39, 46%). Patients with a single specific disease were recruited in 76% of the studies (n = 64), of which 48 studies (75%) included patients with hypertension. Nearly 95% (n = 80)
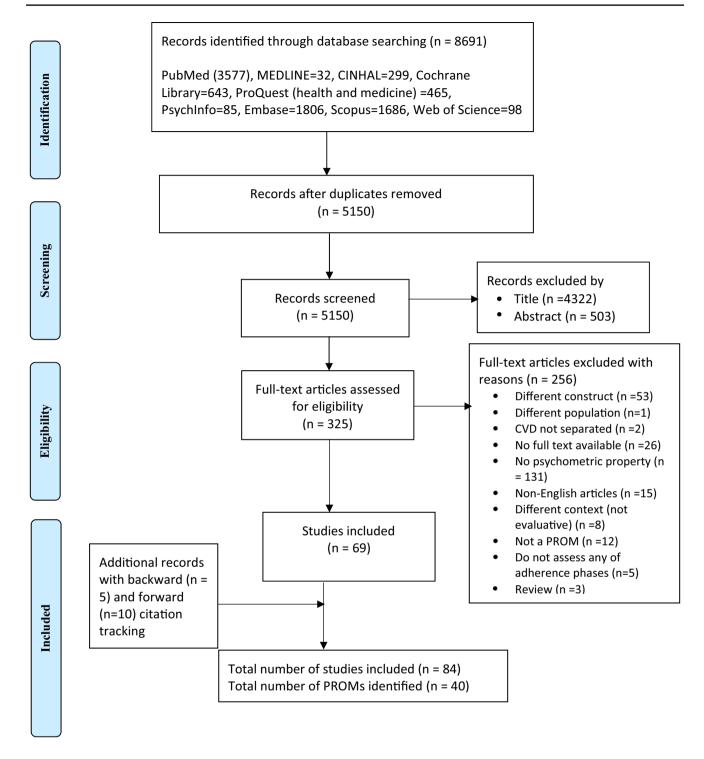
Fig. 1 PRISMA flow diagram for search results. *CVD* cardiovascular disease, *PROM* patient-reported outcome measure

of the included studies employed a cross-sectional design to evaluate MA-PROMs for their measurement properties.

Forty separate MA-PROMs were evaluated by the 84 studies included in this review. Of the 40 MA-PROMs, the eight-item Morisky Medication Adherence Scale (MMAS-8) (*n* = 18) was the most frequently evaluated MA-PROM, followed by Morisky Green Levine Scale (MGLS) (*n* = 8). Characteristics for all included MA-PROMs are provided in Table 1. Most MA-PROMs (*n* = 32, 78%) were generic measures of medication adherence, and 8 were specific to hypertension [51, 71, 77, 85, 89, 103, 110, 121]. None of the included MA-PROMs evaluated all three phases of

medication adherence. Almost all MA-PROMs had items that evaluated the implementation phase (39/40), while 20 MA-PROMs had items dealing with the discontinuation phase. No MA-PROMs had items related to the initiation phase of medication adherence.

The MA-PROMs included between 1 and 28 items [66, 89, 105, 125] and most (35/40) used a Likert scale, with between 3 and 10 points, as a response format for their items. A recall period, from 1 day [50, 95, 103] to 1 year, [103] was specified in 14 of the included MA-PROMs. A combination of different recall periods was used within six MA-PROMs [47, 50, 56, 92, 93, 103] . The recall period for VAS varied across studies [66, 125].

Medication adherence patient-reported outcome measures may have licensing information and cost to use. Two MA-PROMs are licensed and subject to charge [95, 97]. Six MA-PROMs are in the public domain [65, 66, 96, 98, 102, 105, 125] while 12 MA-PROMs are free of charge provided that the specific conditions are met [45, 81, 92, 93, 103, 114, 119, 121].

The included MA-PROMs were classified into three groups based on the information that items asked about. Group-1: items about the extent of non-adherence only [60, 66, 105, 119, 125]. Group-2: items about reasons for non-adherence (intentional, unintentional reasons or both). Ten asked about both intentional and unintentional reasons for non-adherence [51, 71, 86, 96, 97, 102, 116, 119, 121, 122]. Two asked about intentional reasons only [74, 120] and one [73] asked about unintentional reasons only. Group-3: items asks about both the extent of, and reasons for, non-adherence [45, 50, 54–56, 65, 67, 77, 78, 81, 85, 89, 91–93, 95, 98, 103, 110, 113, 114, 117, 126]. Six MA-PROMs [50, 54, 81, 92, 93, 98] in Group-3 were comprehensive enough to capture information on the extent of both medication-taking and prescription-filling and at least two additional domains from both intentional and unintentional reasons for non-adherence from the MAM framework [40] (Table 2).

3.1 Evaluating the Measurement Properties of MA-PROMs in CVD

3.1.1 Overall Content Validity

Patient-reported outcome measures development was rated for the 24 original MA-PROMs [45, 60, 77, 78, 81, 86, 89, 96, 97, 102, 103, 105, 113, 114, 116, 119–122, 127–130] and 13 MA-PROMs [46, 50, 51, 53–56, 65, 67, 70, 80, 85, 92, 95, 110, 117] were modified versions of the original MA-PROMs. Patient-reported outcome measures development was not rated for 3 MA-PROMs [66, 71, 91, 125], the development studies for two were published in a language other than English [71, 91], and a development study could not be found for one [66]. However, all three of these

original MA-PROMs were included in this review because their measurement properties had been evaluated among people with CVD.

The quality PROM development was obtained from PROM design (concept elicitation) and cognitive interview studies (Table 3). The concept elicitation for 21 MA-PROMs did not involve patients in their development and was therefore deemed inadequate [45, 50, 56, 60, 77, 78, 81, 97, 102, 103, 105, 113, 114, 119, 120, 122, 126]. The concept elicitation for one study [98] was rated very good as patients representative of the target population were involved in a qualitative study [130] of very good quality. The concept elicitation was of adequate quality for four MA-PROMs because items were generated from a sample representing the target population using a qualitative study of adequate quality [86, 119, 128, 129].

Cognitive interviews with patients were reported for the development of ten original MA-PROMs [45, 60, 77, 81, 102, 113, 116, 119, 121, 122]. Cognitive interviews were rated doubtful for all of these MA-PROMs because at least one of the standards for cognitive interviews was rated doubtful. The overall quality of PROM development was rated inadequate for most of the MA-PROMs (32/40). Only two had doubtful quality on the overall PROM development, both having doubtful quality for both concept elicitation and cognitive interview parts [116, 121].

Of the 35 studies that evaluated the content validity of an existing MA-PROM, 21 involved only patients [42, 44, 47, 52, 55, 59, 61, 62, 68, 70, 72, 75, 76, 79, 84, 88, 90, 99, 109, 115, 131], 4 involved only experts [67, 89, 103, 124], and 10 involved both patients and experts [46, 54, 63, 64, 73, 74, 86, 108, 117, 123] (Table 4). No studies that were not development studies were found on content validity for 21 of the identified MA-PROMs [45, 50, 51, 56, 60, 66, 71, 78, 80, 85, 91–93, 96, 97, 105, 110, 113, 119–121, 125]. All 31 content validity studies involving patients were of doubtful quality for relevance and comprehensibility, and none evaluated the comprehensiveness aspect of the content validity. Of the 14 content validity studies involving experts, three studies [54, 103, 117] evaluated comprehensiveness with doubtful quality for two MA-PROMs [54, 117] and inadequate quality for one [103]. Of all studies involving experts, evaluated relevance, only two had adequate quality [89, 123].

3.1.2 Measurement Properties Other Than Content Validity

All 84 included studies evaluated at least one measurement property. The methodological quality ratings for each study of measurement properties for a MA-PROM and the rating for the overall result per MA-PROM are available in Supplementary Data – Table S2. Internal consistency (78 studies) was the most frequently evaluated measurement property. A total of 75 studies were found on construct validity (54

Table 1 Characteristics of PROMs for medication adherence

PROM (reference)	Developed based on	Subscale, item no.	Response format	Recall period	Data collection method	Administration method	Completion time	Licensing information; cost	Adherence Phases based on Vrijens et al. study [139]	Generic or Specific
ABM [78]	MMAS-8, MARS and self-constructed questions	4, 12	5-point LS	General	By mail	Self-administered	NR	Unknown	Implementation Discontinuation	Generic
ABQ [97]	Literature review	3, 14	4-point LS	General	Paper-based	self-administered	NR	Licensed, subject to charge	Implementation Discontinuation	Generic
ARMS [81]	Literature review, MGLS and Hill-Bone Compliance Scale	2, 12	4-point LS	General	Paper-based	Interviewer-administered	NR	Copyright © with Emory University; Free to use for non-profit or student	Implementation Discontinuation	Generic
ARMS-7 [67]	ARMS [81]	2, 7	4-point LS	General	Paper-based	Both interviewer and self-administered	NR		Implementation Discontinuation	Generic
ARMS-10 [55]	ARMS [81]	2, 10	4-point LS	General	Paper-based	Self-administered	NR		Implementation Discontinuation	Generic
ASK-12 [92]	ASK-20	3, 12	5-point LS	1 week, 1 month, 3 months	Paper-based	Self-administered	NR	Require a free registration on Mappi	Implementation Discontinuation	Generic
ASK-20 [93]	Lit review, patient focus groups and expert review	1, 20	5-point LS	1week, 1 month, 3 months	Paper-based	Self-administered	NR	research trust; free of charge to use	Implementation Discontinuation	Generic
ASRQ [105]	Compliance Questionnaire Rheumatology [146]	1, 1	6-point LS	General	Paper-based	Interviewer-administered	NR	Public domain	Implementation	Generic
Brief Medication Questionnaire [114]	Literature review	3, 9	Y/N	7 days and 6 months	paper based	Interviewer-administered	NR	Free to use with written permission required	Implementation	Generic
PRAT [56]	3-item Brief Medication Questionnaire and 2 self-constructed items	1, 5	3-point LS; Y/N; Choice	7 days and general	Telephone	Interviewer-administered	NR	Unknown	Implementation	Generic

Table 1 (continued)

PROM (reference)	Developed based on	Subscale, item no.	Response format	Recall period	Data collection method	Administration method	Completion time	Licensing information; cost	Adherence Phases based on Vrijens et al. study [139]	Generic or Specific
HBMS [110]	Hill–Bone compliance scale [77]	1, 8	4-point LS	General	Paper-based	self-administered		Unknown	Implementation	HTN specific
Hill–Bone Compliance Scale [77]	Literature review Experts clinical experience	3, 14	4-point LS	General	Paper-based	Both interviewer and self-administered	5 mins		Implementation	HTN specific
HBCS-SF [85]	Hill–Bone compliance scale	3, 10	4-point LS	General	Paper-based	Interviewer administered	NR		Implementation	HTN specific
INAS [120]	Qualitative study and self-constructed questions	2, 13	5-point LS	6 months	Paper-based	Self-administered	NR	Unknown	Discontinuation	Generic
LMAS-14 [50]	MMAS-8 and experts focus group discussion	4, 14	4-point LS	1 day, 2 weeks, General	Paper-based	NR	NR	Unknown	Implementation Discontinuation	Generic
MARS-5 [126]	MARS-10 [126]	1, 5	5-point LS	General	Paper-based and by mail	Interviewer administered	10–15 mins	Unknown	Implementation Discontinuation	Generic
MAS [122]	Literature review, research experience, TPB, and HBM	3, 17	10-point LS	General	Paper-based	NR	10–15 min	Unknown	Implementation	Generic
MAS-CAD [113]	Literature review and consensus of experts	4, 25	5-point LS	General	Paper-based	Interviewer administered	15–20 min	Unknown	Implementation	Generic
MASES [98]	Patient interviews [130]	1, 26	3-point LS	General	Paper-based	Self-administered	5 min	Public domain	Implementation	Generic
MASES-R [65]	MASES [98]	1,13	4-point LS	General	Paper-based	Self-administered	NR	Public domain	Implementation	Generic
MBG [91]	MBG (Alfonso, 2008) [147]	3,12	5-point LS	General	Paper-based	Interviewer administered	NR	Unknown	Implementation	Generic
MGLS [96]	Literature review, and (Green et al., 1975) [148]	1,4	Yes or no	General	Paper-based	interviewer administered	NR	Public domain	Implementation Discontinuation	Generic

Table 1 (continued)

PROM (reference)	Developed based on	Subscale, item no.	Response format	Recall period	Data collection method	Administration method	Completion time	Licensing information; cost	Adherence Phases based on Vrijens et al. study [139]	Generic or Specific
MMAS-8 [95]	MGLS [96] and experience of researchers	1, 8	Y/N and 5-point LS	General	Paper-based	Interviewer-administered	NR	Copyrighted, subject to charge	Implementation Discontinuation	Generic
MAR-Scale [116]	Literature review and qualitative study	5, 15	5-point LS	General	Online survey	Self-administered	NR	Unknown	Implementation Discontinuation	Generic
MAR-Scale (Revised) [117]	MAR-Scale [116] and qualitative study	4, 19	8-point anchor	7 days	Online survey	Self-administered	NR	Unknown	Implementation Discontinuation	Generic
ChMAR-Scale [54]	MAR-Scale (Revised) [117]	6, 24	5-point anchor	1 month	Paper-based	Self-administered	NR		Implementation Discontinuation	Generic
MEDS [45]	Literature review and qualitative study	5, 16	5-point LS	6 months	Online survey	Self-administered	NR	Requires written agreement to use	Implementation	Generic
MTQ-Patterned Behaviour [73]	A qualitative study [128, 129]	3, 16	7-point LS	General	Paper-based	NR	NR	Unknown	Implementation	Generic
MTQ-Purposeful action [74]	A qualitative study [128, 129]	2, 12	7-point, LS	General	paper based	NR	NR	Unknown	Implementation	Generic
MUAH [121]	Patient interviews	4, 25	7-point LS	General	paper based	Interviewer-administered	25 mins	Free to use with permission	Implementation	HTN specific
MUAH-16 [51]	MUAH [121]	4, 16	7-point LS	General	NR	NR	NR	Free to use with permission	Implementation	HTN specific
QAM-Q [60]	Self-constructed	4, 4	Open ended, Dichotomous	7 days	Paper-based	Interviewer administered	NR	Unknown	Implementation Discontinuation	Generic
QATSH [103]	Literature review and expert panel review	3, 12	choices and Y/L	1 day, 1 week, 1 month and 1 year	NR	NR	NR	Free to use with permission	Implementation	HTN specific
RRMAI [86]	Literature review and Patient interviews	3, 15	5-point LS	General	paper based	NR	NR	Unknown	Implementation	Generic
SEAMS [102]	Literature, expertise and patient-interview	1, 13	3-point LS	General	paper based	Self-administered	NR	Public domain	Implementation	Generic

Table 1 (continued)

PROM (reference)	Developed based on	Subscale, item no.	Response format	Recall period	Data collection method	Administration method	Completion time	Licensing information; cost	Adherence Phases based on Vrijens et al. study [139]	Generic or Specific
TAQPH [89]	Literature review and focus group	6,28	4-point LS	General	paper based	Both self and Interviewer administered	NR	Unknown	Implementation Discontinuation	HTN specific
TASHP [71]	TASHP (Chinese) [149]	4, 25	5-point LS	1 month	paper based	Self-administered	NR	Unknown	Implementation Discontinuation	HTN specific
VAS [66]	Unknown	1, 1	0 -100 scale	Between appointments, [66] General [125]	paper based	Self-administered	NR	Public domain	Implementation	Generic
Voils Extent [119]	Patient interview	1, 3	5-point LS	7 days	paper based	Interviewer administered	NR	Free to use with written agreement	Implementation Discontinuation	Generic
Voils Reasons [119]	MASES [48], Literature review, Patient focus group[150]	1, 21	5-point LS	7 days	paper based	Interviewer administered	NR	Free with written agreement	Implementation Discontinuation	Generic

HBM Health Belief Model, *HTN* hypertension, *LS* Liker Scale, *NR* not reported, *PROM* patient-reported outcome measure, *TPB* theory of planned behaviour *Y/N* Yes or No, *ABM* Adherence Behaviour Measure, *ABQ* Adherence Barriers Questionnaire, *ARMS* Adherence to Refills and Medications Scale, *ASK* Adherence Starts with Knowledge, *ASRQ* Adherence Self-Report Questionnaire, *ChMAR-Scale* the Chinese Medication Adherence Reasons Scale, *HBCS-SF* Short Form Hill–Bone Compliance Scale, *HBMS* Hill-Bone Compliance Medication Scale, *INAS* Intentional Non-Adherence Scale, *LMAS-14* the 14-item Lebanese Medication Adherence Scale, *QATSH* Questionnaire on Adherence to Treatment for Systemic arterial HTN, *MAR-Scale* Medication Adherence Reasons Scale, *MARS-5* the 5-item Medication Adherence Report Scale, *MAS* Medication Adherence Scale, *MAS-CAD* Medication Adherence Scale for Coronary Artery Disease, *MASES* Medication Adherence Self-Efficacy Scale, *MASES-R* the Revised Medication Adherence Self-Efficacy Scale, *MBG* Martín-Bayarre-Grau, *MEDS* Medication Adherence Estimation and Differentiation Scale, *MGLS* Morisky Green Levine Scale, *MMAS-8* the 8-item Morisky Medication Adherence Scale, *MTQ* Medication Taking Behaviour, *MUAH* Maastricht Utrecht Adherence in HTN, *PRAT* Patient-Reported Adherence Tool, *QAM-Q* Questionário de Adesão a Medicamentos – Qualiaids, *QATSH* Questionnaire on Adherence to Treatment for Systemic arterial HTN, *RRMAI* the Reasoning and Regulating Medication Adherence Instrument, *SEAMS* Self-Efficacy for Appropriate Medication Use Scale, *TAQPH* Treatment Adherence Questionnaire for Patients with HTN, *TASHP* Therapeutic Adherence Scale for Hypertensive Patients, *VAS* visual analogue scale

Table 2 Domains/Content of PROMs for medication adherence included in this review

PROMs	Extent of non-adherence		Reasons for non-adherence using the Medication Adherence Model (MAM)						Feedback		
			Unintentional non-adherence			Intentional non-adherence					
	Medication taking	Prescription filling	Remembering	Access	Routines	Perceived need	Perceived safety	Perceived effectiveness	Facts	Prompts	Events
ABM [78]	✓		✓		✓	✓	✓	✓			
ABQ [97]	✓		✓	✓		✓	✓		✓	✓	
ARMS [81]	✓	✓	✓	✓	✓	✓		✓			
ARMS-7 [67]	✓	✓	✓	✓		✓		✓			
ARMS-10 [55]	✓	✓	✓			✓		✓			
ASK-12 [92]	✓	✓	✓	✓	✓	✓	✓	✓			
ASK-20 [93]	✓	✓	✓	✓	✓	✓	✓	✓			
ASRQ [105]	✓		✓			✓					
Brief Medication Questionnaire [114]	✓		✓			✓	✓	✓			
PRAT [56]	✓		✓			✓					
Hill–Bone Compliance Scale [77]	✓	✓	✓			✓		✓			
HBCS-SF [85]	✓	✓	✓			✓		✓			
HBMS [110]	✓	✓	✓			✓		✓			
INAS [120]	✓			✓		✓	✓	✓			
LMAS-14 [50]	✓		✓	✓	✓	✓	✓	✓		✓	✓
MARS-5 [126]	✓		✓		✓	✓	✓				
MAS [122]	✓		✓	✓	✓	✓	✓	✓	✓		
MAS-CAD [113]	✓		✓	✓	✓	✓	✓	✓		✓	
MASES [98]	✓	✓	✓	✓	✓	✓	✓	✓	✓		
MASES-R [65]	✓		✓	✓	✓	✓	✓		✓		
MBG [91]	✓		✓			✓	✓				
MAR-Scale [116]	✓	✓	✓	✓	✓	✓		✓		✓	
MAR-Scale (Revised) [117]	✓	✓	✓	✓	✓	✓		✓			
ChMAR-Scale [54]	✓		✓	✓	✓	✓	✓	✓	✓	✓	
MEDS [45]	✓		✓			✓			✓		
MGLS [96]	✓		✓		✓	✓	✓	✓	✓		
MMAS-8 [95]	✓		✓	✓	✓	✓	✓	✓			
MTQ-Patterned Behaviour [73]				✓							
MTQ-Purposeful action [74]					✓						
MUAH [121]			✓		✓	✓	✓	✓	✓	✓	
MUAH-16 [51]			✓		✓	✓	✓	✓	✓		
QAM-Q [60]	✓					✓					
QATSH [103]	✓				✓	✓			✓		
RRMAI [86]			✓		✓	✓					
SEAMS [102]			✓	✓	✓	✓	✓				✓

Table 2 (continued)

PROMs	Extent of non-adherence		Reasons for non-adherence using the Medication Adherence Model (MAM)								
			Unintentional non-adherence			Intentional non-adherence			Feedback		
	Medication taking	Prescription filling	Remembering	Access	Routines	Perceived need	Perceived safety	Perceived effectiveness	Facts	Prompts	Events
TAQPH [89]	✓		✓			✓		✓	✓		
TASHP [71]		✓	✓		✓	✓	✓	✓		✓	
VAS [66]	✓										
Voils Extent [119]	✓		✓	✓	✓	✓					
Voils Reasons [119]							✓				✓

PROM patient-reported outcome measure, *ABM* Adherence Behaviour Measure, *ABQ* Adherence Barriers Questionnaire, *ARMS* Adherence to Refills and Medications Scale, *ASK* Adherence Starts with Knowledge, *ASRQ* Adherence Self-Report Questionnaire, *ChMAR-Scale* the Chinese Medication Adherence Reasons Scale, *HBCS-SF* Short Form Hill–Bone Compliance Scale, *HBMS* Hill-Bone Compliance Medication Scale, *INAS* Intentional Non-Adherence Scale, *LMAS-14* the 14-item Lebanese Medication Adherence Scale, *QATSH* Questionnaire on Adherence to Treatment for Systemic arterial HTN, *MAR-Scale* Medication Adherence Reasons Scale, *MARS-5* the 5-item Medication Adherence Report Scale, *MAS-CAD* Medication Adherence Scale for Coronary Artery Disease, *MASES* Medication Adherence Self-Efficacy Scale, *MASES-R* the Revised Medication Adherence Self-Efficacy Scale, *MBG* Martín-Bayarre-Grau, *MEDS* Medication Adherence Estimation and Differentiation Scale, *MGLS* Morisky Green Levine Scale, *MMAS-8* the 8-item Morisky Medication Adherence Scale, *MTQ* Medication Taking Behaviour, *MUAH* Maastricht Utrecht Adherence in HTN, *PRAT* Patient-Reported Adherence Tool, *QAM-Q* Questionário de Adesão a Medicamentos – Qualiaids, *QATSH* Questionnaire on Adherence to Treatment for Systemic arterial HTN, *RRMAI* the Reasoning and Regulating Medication Adherence Instrument, *SEAMS* Self-Efficacy for Appropriate Medication Use Scale, *TAQPH* Treatment Adherence Questionnaire for Patients with HTN, *TASHP* Therapeutic Adherence Scale for Hypertensive Patients, *VAS* visual analogue scale

studies on convergent validity and 38 studies on known-group validity [KGV]). Structural validity and reliability were evaluated in 64 and 37 studies, respectively. Only three studies [65, 87, 103] evaluated the structural validity based on item response theory (IRT); two studies [65, 103] using a 2-parameter logistic model, and one study[87] using Rasch model. The remaining studies employed classical test theory (CTT). Five studies [81, 87, 88, 102, 108] on cross-cultural validity, and three studies [49, 77, 96] on responsiveness were found. No included studies evaluated measurement error or criterion validity. The methodological quality was evaluated for each measurement property across studies (Table 4). The quality of structural validity was rated as 'very good' in only 35% of studies (23/64). Nearly half of studies (52%, 41/78) on internal consistency had a 'very good' quality rating. About 62% of the studies (23/37) on reliability scored either a 'doubtful' or 'inadequate' quality rating. All but one study scored 'doubtful' for cross-cultural validity (5/5). One study reporting on the evaluation of construct validity using KGV had a very good rating [76], the quality of all other studies evaluating KGV was doubtful. All studies reporting on responsiveness (3/3) were rated 'doubtful'. The highest number of measurement properties, other than content validity, evaluated in a single study was five out eight (Table 4) [81, 102].

3.2 Evidence Synthesis per PROM

Medication adherence patient-reported outcome measures were classified into three groups based on whether the items gathered information on the extent of and/or the reasons for medication non-adherence (Table 5). They were also grouped with regard to the quality of the overall evidence for each measurement property [29, 31].

Eight MA-PROMs were classified in COSMIN recommendation category 'A'; four in each of Group-2 [74, 97, 102, 122] and Group-3 [45, 65, 67, 81]. These MA-PROMs had sufficient results for both content validity (with very low quality of evidence) and internal consistency (with moderate-to-high-quality evidence). The four MA-PROMs in Group-3 with category 'A' were prioritised for MA-PROM selection as they are more comprehensive. Of these MA-PROMs, Adherence to Refills and Medications Scale (ARMS) [81] or ARMS-7 [67] have high-quality evidence for sufficient results on a higher number of measurement properties, including structural validity, internal consistency, reliability (moderate-quality for ARMS), and construct validity. In addition, the original ARMS had sufficient result on measurement invariance with low-quality evidence. Consequently, the most suitable MA-PROMs for people with CVD are ARMS or ARMS-7.

Four MA-PROMs had high quality evidence of insufficient results for at least one measurement property and were

Table 3 Quality of the PROM development ("V": Very good; "A": Adequate; "D": Doubtful; "I": Inadequate [33])

PROM (Reference)	PROM design							Cognitive interview (CI) study[a]				Total PROM development
	General design requirements					Concept elicitation[b]	Total PROM design	General design requirements	Comprehensibility	Comprehensiveness	Total CI study	
	Clear construct	Clear origin of construct	Clear target population for which the PROM was developed	Clear context of use	PROM developed in the target population			CI study performed in sample representing the target population				
ABM [78]	V	V	V	V	I		I				I	I
ABQ [97]	V	V	V	V	I		I				I	I
ARMS [81]	V	V	V	V	I		I	A	D	D	D	I
ARMS-7 [81][c]	V	V	V	V	I		I	A	D	D	D	I
ARMS-10 [81][c]	V	V	V	V	I		I	A	D	D	D	I
ASK-20 [127]	V	V	V	V	V	D	D				I	I
ASK-12 [127][c]	V	V	V	V	V	D	D				I	I
ASRQ [105]	V	D	V	V	I		I				I	I
Brief Medication Questionnaire [114]	V	D	V	V	I		I				I	I
PRAT [56, 114][c]	V	D	V	V	I		I				I	I
Hill-Bone compliance scale [77]	V	V	V	V	I		I	V	A	D	D	I
HBCS-SF [77][c]	V	V	V	V	I		I	V	A	D	D	I
HBMS [77][c]	V	V	V	V	I		I	V	A	D	D	I
INAS [120]	V	V	V	V	I		I				I	I
LMAS-14 [50][c]	V	D	V	V	I		I				I	I
MARS-5 [126][d]	V	V	V	V	I		I				I	I
MAS [122]	V	D	V	V	I		I	V	D	D	D	I
MAS-CAD [113]	V	V	V	V	I		I	V	D	D	D	I
MASES [98, 130]	V	V	V	V	V	V	V				I	I
MASES-R [98, 130][c]	V	V	V	V	V	V	V				I	I
MBG [91]												I

The development study is non-English and unrated

Table 3 (continued)

PROM (Reference)	PROM design							Cognitive interview (CI) study[a]				Total PROM development
	General design requirements					Concept elicitation[b]	Total PROM design	General design requirements	Comprehensibility	Comprehensiveness	Total CI study	
	Clear construct	Clear origin of construct	Clear target population for which the PROM was developed	Clear context of use	PROM developed in the target population			CI study performed in sample representing the target population				
MAR-Scale [116]	V	V	V	V	V	D	D	V	D	D	D	D
MAR-Scale (Revised) [116][c]	V	V	V	V	V	D	D	V	D	D	D	D
ChMAR-Scale [116][c]	V	V	V	V	V	D	D	V	D	D	D	D
MEDS [45]	V	V	V	V	I	I	I	V	D	D	D	I
MGLS [96, 148]	V	V	V	V	V	D	D				I	I
MMAS-8 [96, 148][c]	V	V	V	V	V	D	D				I	I
MTQ-Patterned behaviour [128, 129]	V	V	V	V	V	A	A				I	I
MTQ Purposeful [128, 129]	V	V	V	V	V	A	A				I	I
MUAH [121]	V	D	V	V	V	A	D	V	D	D	D	D
MUAH-16 [121][c]	V	D	V	V	V	A	D	V	D	D	D	D
QAM-Q [60]	V	D	V	V	I		I	D	D	D	D	I
QATSH [103]	V	V	V	V	I		I	V	I	D	I	I
RRMAI [86]	V	V	V	V	V	A	A				I	I
SEAMS [102]	V	V	V	V	I		I	A	D	D	D	I
TAQPH [89]	V	V	V	V	V	D	D				I	I
TASHP [71]	Unknown	The development study is non-English and unrated										
VAS [66]												
Voils Extent [119]	V	D	V	V	I	I	I	V	D	D	D	I

Table 3 (continued)

PROM (Reference)	PROM design							Cognitive interview (CI) study[a]				Total PROM development
	General design requirements					Concept elicitation[b]	Total PROM design	General design requirements	Comprehensibility	Comprehensiveness	Total CI study	
	Clear construct	Clear origin of construct	Clear target population for which the PROM was developed	Clear context of use	PROM developed in the target population			CI study performed in sample representing the target population				
Voils Reasons [119]	V	V	V	V	V	A	A		I		I	I

CVD cardiovascular disease, *PROM* patient-reported outcome measure, *ABM* Adherence Behaviour Measure, *ABQ* Adherence Barriers Questionnaire, *ARMS* Adherence to Refills and Medications Scale, *ASK* Adherence Starts with Knowledge, *ASRQ* Adherence Self-Report Questionnaire, *ChMAR-Scale* the Chinese Medication Adherence Reasons Scale, *HBCS-SF* Short Form Hill–Bone Compliance Scale, *HBMS* Hill-Bone Compliance Medication Scale, *INAS* Intentional Non-Adherence Scale, *LMAS-14* the 14-item Lebanese Medication Adherence Scale, *QATSH* Questionnaire on Adherence to Treatment for Systemic arterial HTN, *MAR-Scale* Medication Adherence Reasons Scale, *MARS-5* the 5-item Medication Adherence Report Scale, *MAS* Medication Adherence Scale, *MAS-CAD* Medication Adherence Scale for Coronary Artery Disease, *MASES* Medication Adherence Self-Efficacy Scale, *MASES-R* the Revised Medication Adherence Self-Efficacy Scale, *MBG* Martín-Bayarre-Grau, *MEDS* Medication Adherence Estimation and Differentiation Scale, *MGLS* Morisky Green Levine Scale, *MMAS-8* the 8-item Morisky Medication Adherence Scale, *MTQ* Medication Taking Behaviour, *MUAH* Maastricht Utrecht Adherence in HTN, *PRAT* Patient-Reported Adherence Tool, *QAM-Q* Questionário de Adesão a Medicamentos – Qualiaids, *QATSH* Questionnaire on Adherence to Treatment for Systemic arterial HTN, *RRMAI* the Reasoning and Regulating Medication Adherence Instrument, *SEAMS* Self-Efficacy for Appropriate Medication Use Scale, *TAQPH* Treatment Adherence Questionnaire for Patients with HTN, *TASHP* Therapeutic Adherence Scale for Hypertensive Patients, *VAS* visual analogue scale

[a]Empty cells indicate that a CI study (or part of it) was not performed

[b]When the PROM was not developed in a sample representing the target population, the concept elicitation was not further rated;

[c]Modified version of the original PROM

[d]Modified version of the original PROM developed in population other than CVD

Table 4 Quality of studies on measurement properties for MA-PROM ("V": Very good; "A": Adequate; "D": Doubtful; "I": Inadequate [33])

MA-PROM (Reference)	Content validity					Structural validity	Internal consistency	Cross-cultural validity	Reliability	Measurement error	Criterion validity	Construct validity		Responsiveness			
	Asking patients		Comprehensibility	Asking experts								Convergent validity	Known groups validity	Comparison with gold standard	Comparison with other instruments	Comparison between subgroups	Comparison before and after intervention
	Relevance	Comprehensiveness		Relevance	Comprehensiveness												
ABM [78]						D	V										
ABQ [97]						A	V					V	D				
ARMS [81]						A	V	D	D			V	D				
ARMS [88]			D			A	V	D					D				
ARMS [131]			D			V	V										
ARMS-7 [67]				D		V	V		A								
ARMS-7 [46]			D	D		A	V		A			V					
ARMS-10 [55]			D			A	I		A				D				
ASK-20 [93]							D		A			A;I					
ASK-12 [92]						D	D		A			A;I					
ASRQ [105]												D					
ASRQ [125]												A					
Brief Medication Questionnaire [114]												D					
Brief Medication Questionnaire [47]			D				D		D			A	D				
PRAT [56]												A					
Hill-Bone compliance scale [77]						A	V						D			D	
Hill-Bone compliance scale [75]			D			A	V										
Hill-Bone compliance scale [115]			D			D	D		D				D				
Hill-Bone compliance scale [85]							D						D				
Hill-Bone compliance scale [83]						A	V										
HBCS-SF [85]							D						D				
HBMS [85]							D						D				
HBMS [80]						A	I					A	D				
HBMS [110]						D	V					A	D				
INAS [120]						A	V					A;D					
LMAS-14 [50]						A	V					A	D				
MARS-5 [84]			D				D		I			A	D				
MARS-5 [90]			D				D		D			D					

Table 4 (continued)

MA-PROM (Reference)	Content validity					Structural validity	Internal consistency	Cross-cultural validity	Reliability	Measurement error	Criterion validity	Construct validity		Responsiveness			
	Asking patients		Comprehensibility	Asking experts								Convergent validity	Known groups validity	Comparison with gold standard	Comparison with other instruments	Comparison between subgroups	Comparison before and after intervention
	Relevance	Comprehensiveness		Relevance	Comprehensiveness												
MARS-5 [87]						[a]V	V	D				A					
MARS-5 [118]												A					
MARS-5 [53]						D	V		D				D				
MAS [122]						D	V					A; D					
MAS-C [124]				D		A	V					A					
MAS-CAD [113]						V	I		D								
MASES [98]						D	V		D				D				
MASES [68]			D			A	D		D				D				
MASES [78]						D	V										
MASES [104]						A	I						D				
MASES [65]						[a]V	D		D								
MASES-R [65]						D	V					A					
MASES-R [70]			D			V	V						D				
MBG [91]						D	D		D								
MAR-Scale [116]			D			A	V					A; D					
MAR-Scale [108]			D	D	D	[b]V, [c]A	V	D	D							D	
MAR-Scale (Revised) [117]			D	D	D	A	D					A; D					
ChMAR Scale [54]			D	D	D	A	D					A, D	D				
MEDS [45]						V	V					D					
MGLS [96]						D	V					D	D				
MGLS [47]							D		I			A	D				
MGLS [48]						A	V					D	D				
MGLS [80]							D										
MGLS [118]												A					
MGLS [101]												A					
MGLS [106]							D					V					
MGLS [111]													D				
MMAS-8 [95]						V	V					A	D				
MMAS-8D [43]						A	I					A	D				
MMAS-U [99]			D			A	V		A								
MMAS-8 [44]			D			D	V										
MMAS-8 [52]			D			V	V					A					

Table 4 (continued)

MA-PROM (Reference)	Content validity — Asking patients Relevance	Content validity — Asking patients Comprehensiveness	Comprehensibility	Asking experts Relevance	Asking experts Comprehensiveness	Structural validity	Internal consistency	Cross-cultural validity	Reliability	Measurement error	Criterion validity	Construct validity Convergent validity	Construct validity Known groups validity	Responsiveness Comparison with gold standard	Comparison with other instruments	Comparison between subgroups	Comparison before and after intervention
MMAS-8 [59]			D				D		D				D				
MMAS-8 [66]												A					
MMAS-8 [72]			D			D	I		D				D				
MMAS-8 [76]			D			V	I		A			V	V				
MMAS-8 [79]			D			V	V		D								
MMAS-8 [94]						A	I		D				D				
MMAS-8 [82]												A					
MMAS-8 [107]							D					A	D				
MMAS-K [109]			D			D	I					A	D				
C-MMAS-8 [123]			D	A			D		D			D	D				
MMAS-8 [112]							D						D				
P-MMAS-8 [62]			D			V	D		D				D				
MMAS-8 [69]												D	D				
MTQ Patterned behaviour [73]			D	D		D	V		A			A; D					
MTQ Purposeful action [74]			D	D		V	V		A			A; D					
MUAH [121]						A	V		D			D					
MUAH [51]						V											
MUAH-16 [51]						V	V					A;D					
QAM-Q [60]							D					A;D					
QATSH [103]				I	I	aA	D										
RRMAI [86]	D		D	D		A	D		A			A					
SEAMS [63]			D	D		V	V		D			A					
SEAMS [102]						A	V	D	D			V	D				
SEAMS [100]						V	I										
SEAMS [42]			D			D	I		D								
TAQPH [89]				A		V	V		A			V					
P-TAQPH [61]			D			V	I		A			A	D				
S-TAQPH [64]			D	D		A	I										
TASHP [71]						V	V						D				
VAS [125]												A					
VAS [66]												D					
Voils Extent [119]						V	V		A			A; D	D				

Table 4 (continued)

MA-PROM (Reference)	Content validity					Structural validity	Internal consistency	Cross-cultural validity	Reliability	Measurement error	Criterion validity	Construct validity		Responsiveness			
	Asking patients			Asking experts								Convergent validity	Known groups validity	Comparison with gold standard	Comparison with other instruments	Comparison between subgroups	Comparison before and after intervention
	Relevance	Comprehensiveness	Comprehensibility	Relevance	Comprehensiveness												
Voils Extent [49]						V	V						D			D	
Voils Extent [58]						V						A					
Voils Reasons [119]									A								

PROM patient-reported outcome measure, *ABM* Adherence Behaviour Measure, *ABQ* Adherence Barriers Questionnaire, *ARMS* Adherence to Refills and Medications Scale, *ASK* Adherence Starts with Knowledge, *ASRQ* Adherence Self-Report Questionnaire, *ChMAR-Scale* the Chinese Medication Adherence Reasons Scale, *HBCS-SF* Short Form Hill–Bone Compliance Scale, *HBMS* Hill-Bone Compliance Medication Scale, *INAS* Intentional Non-Adherence Scale, *LMAS-14* the 14-item Lebanese Medication Adherence Scale, *QATSH* Questionnaire on Adherence to Treatment for Systemic arterial HTN, *MAR-Scale* Medication Adherence Reasons Scale, *MARS-5* the 5-item Medication Adherence Report Scale, *MAS* Medication Adherence Scale, *MAS-CAD* Medication Adherence Scale for Coronary Artery Disease, *MASES* Medication Adherence Self-Efficacy Scale, *MASES-R* the Revised Medication Adherence Self-Efficacy Scale, *MBG* Martín-Bayarre-Grau, *MEDS* Medication Adherence Estimation and Differentiation Scale, *MGLS* Morisky Green Levine Scale, *MMAS-8* the 8-item Morisky Medication Adherence Scale, *MTQ* Medication Taking Behaviour, *MUAH* Maastricht Utrecht Adherence in HTN, *PRAT* Patient-Reported Adherence Tool, *QAM-Q* Questionário de Adesão a Medicamentos – Qualiaids, *QATSH* Questionnaire on Adherence to Treatment for Systemic arterial HTN, *RRMAI* the Reasoning and Regulating Medication Adherence Instrument, *SEAMS* Self-Efficacy for Appropriate Medication Use Scale, *TAQPH* Treatment Adherence Questionnaire for Patients with HTN, *TASHP* Therapeutic Adherence Scale for Hypertensive Patients, *VAS* visual analogue scale

a Stands for analysis based on the item response theory (IRT) or RASCH

b Structural validity assessed by confirmatory factor analysis (CFA) (The criteria to rate CFA is available in the 2018 criteria for good measurement properties[29, 31]

c Structural validity assessed by exploratory factor analysis (EFA) (Additional criteria used for EFA: First factor accounts for at least 20% of the variability AND ratio of the variance explained by the first to the second factor greater than 4[132]

classified in COSMIN recommendation category 'C'. Two MA-PROMs in Group-2 (Maastricht Utrecht Adherence in Hypertension [MUAH], and MUAH-16) and two in Group-3 (Hill–Bone Compliance Medication Scale [HBMS] and the five-item Medication Adherence Report Scale [MARS-5]). There was high-quality evidence on insufficient structural validity for MUAH, insufficient internal consistency for MAUH-16 and MARS-5, and insufficient construct validity for HBMS.

Most of the MA-PROMs had very low-quality evidence for content validity. Only two MA-PROMs [54, 117] had moderate-quality evidence for sufficient results on overall content validity based on the evidence from more than one content validity study with doubtful methodological quality. There was no high-quality evidence on insufficient content validity for any of the MA-PROMs; consequently, the other measurement properties for each MA-PROM were further evaluated.

The most commonly used MA-PROM, the eight-item Morisky Medication Adherence Scale (MMAS-8), exhibited high-quality evidence for sufficient construct validity, and low-quality evidence for sufficient reliability (downgraded due to risk of bias and inconsistent results). However, the overall rating of MMAS-8 on internal consistency cannot be determined because the results per study on structural validity of MMAS-8 were inconsistent (only 57% of studies had the same factor structure with inconsistent results (should be 75% or greater).

The 4-item Morisky Green Levine Scale (MGLS) from Group-2 was the second most frequently evaluated MA-PROM, and there was low-quality evidence for sufficient structure validity and responsiveness, and very low-quality evidence for sufficient reliability, but it exhibited insufficient internal consistency with low-quality evidence, and insufficient construct validity with moderate-quality evidence (downgraded due to inconsistent results).

4 Discussion

This systematic review used the COSMIN guidelines to evaluate measurement properties [29, 33, 34] and feasibility [29, 132] to select the most suitable MA-PROM for people with CVD. Results on the evaluation of medication adherence using the selected PROM(s) should be trustworthy for use in patients with CVDs. A suitable PROM requires at least both sufficient content validity with any level of evidence and sufficient internal consistency with at least low-quality evidence [132] according to COSMIN guidelines [29, 31]. Eight of the 40 identified MA-PROMs were found to have sufficient content validity (all with very low quality evidence), and sufficient internal consistency with moderate to high quality evidence based [29, 31, 45, 46, 65, 74, 81, 97, 102, 122].

Of these eight MA-PROMs, only ARMS and ARMS-7 are comprehensive and have moderate to high quality evidence for three other measurement properties, including structural validity, reliability, and construct validity.

Despite favourable findings on the quality of measurement properties, previous systematic reviews [133, 134] did not recommend ARMS and ARMS-7 as suitable MA-PROMs. The primary reason for this difference is that both reviews [133, 134] did not follow the COSMIN category of recommendations, which requires sufficient content validity with any level of evidence, and sufficient internal consistency with at least low-quality evidence as a prerequisite for category "A". Instead, the previous reviews [133, 134] recommended PROMs with a higher number of measurement properties with at least moderate-quality evidence for sufficient results. One review [133] found that the ARMS exhibited strong evidence of sufficient content validity and internal consistency which, according to the COSMIN guideline, should have been classified as recommendation category "A". On the other hand in the review [133], MMAS-8 showed insufficient internal consistency with strong evidence and no content validity rating (COSMIN recommendation category "C") and was recommended as a suitable MA-PROM for people at risk of metabolic disorders [133]. The other review [134] reported that both ARMS and ARMS-7 have high-quality evidence for sufficient internal consistency and low-quality evidence for sufficient content validity (ARMS) and indeterminate content validity (ARMS-7) [134]. Consequently, according to the COSMIN category of recommendations [29, 31] the ARMS should have been recommended at least as a suitable MA-PROM by the authors [134]. Another issue in the previous reviews [29, 31, 133, 134] is that the summarised result with a level of evidence for content validity was not rated for some MA-PROMs. According to COSMIN criteria, content validity should be rated as either sufficient, insufficient, or inconsistent, but not indeterminate. The result of content validity should be rated at least with the reviewers' rating of the PROM itself and grading the evidence with very-low quality when the development study is inadequate and there is no or inadequate content validity studies [34].

Content validity is the first and most important measurement property to be considered for the selection of a PROM because there should be evidence to confirm that the items of a PROM are relevant, comprehensive, and comprehensible in relation to the construct (e.g., medication adherence) and target population (e.g., people with CVD) [34, 132]. The lack of high-quality evidence on content validity of PROMs to measure medication adherence for people with CVD is highlighted by this review. Most of the MA-PROMs had very low-quality evidence for content validity. For MA-PROMs that were developed without patient involvement, in both concept elicitation and cognitive interview, content

Table 5 Quality of evidence for measurement properties of the PROMs

PROM	Quality of evidence for the overall result of measurement properties[a]													COSMIN recommendation categories[b]
	Content validity				Internal structure				Remaining measurement properties					
	Content validity	Relevance	Comprehensiveness	Comprehensibility	Structural validity	Internal consistency	Cross-cultural validity	Measurement invariance	Reliability	Measurement error	Criterion validity	Construct validity	Responsiveness	
GROUP-1 (PROMs that seek to obtain information on the extent of non-adherence only)														
ASRQ [105]	±VL	+VL	−VL	+VL								−M		B
QAM-Q [60]	±VL	+VL	−VL	+VL								±		B
VAS [66, 125]												−M		B
Voils Extent [119]	±VL	+VL	−VL	+L	+H	+H			−M			+H	+L	B
GROUP-2 (PROMs that seek to obtain information on reasons for non-adherence only														
ABQ [97]	+VL	+VL	+VL	+VL	+M	+M						−M		A
INAS [120]	±VL	±VL	−VL	+VL	+L	+L						±		B
MAS [122]	+VL	+VL	+VL	+L	+M	+M						±		A
MAR-Scale [116]	+VL	+L	+L	+M	+H	±		+M	+M			−M		B
MGLS [96]	±VL	+L	−VL	+VL	+L	−L			+VL			c−M		B
MTQ-Patterned behaviour [73]	+VL	+VL	+VL	+L	−L	?						−M		B
MTQ-Purposeful action [74]	+VL	+M	+M	+M	+H	+H			+M			−M		A
MUAH [121]	+L	+M	+M	+L	−H	?			+L			−M		C
MUAH-16 [51]	+VL	+M	+VL	+L	+H	−H						−M		C
RRMAI [86]	+VL	+M	+M	+VL	−M	?			?			−M		B
SEAMS [102]	+VL	+VL	+L	+M	+H	+H	+L		cL			d+M		A
TASHP [71]					+H	+H						+L		B
Voils Reason [119]	+VL	+M	+M	+VL					−M					B
GROUP-3 (PROMs that seek to obtain information on extent of adherence and reasons for non-adherence)														
ABM [78]	+VL	+VL	+VL	+VL	?	?								B
ARMS [81]	+VL	+VL	+L	+M	+H	+H		+L	+M			+H		A
ARMS-7 [67]	+VL	+M	+VL	+M	+H	+H			+H			+H		A
ARMS-10 [55]	+VL	+VL	+VL	+M	+M	?			+L			+L		B
ASK-20 [93]	+VL	+L	+L	+VL		?			+L			+L		B
ASK-12 [92]	+VL	+L	+L	+VL	?	?			+L			+L		B
Brief Medication Questionnaire [114]	+VL	+VL	+VL	+M		?			+VL			±		B
PRAT [56]	+VL	+VL	+VL	+VL								±		B

Table 5 (continued)

PROM	Quality of evidence for the overall result of measurement properties[a]													COSMIN recommendation categories[b]
	Content validity				Internal structure				Remaining measurement properties					
	Content validity	Relevance	Comprehensiveness	Comprehensibility	Structural validity	Internal consistency	Cross-cultural validity	Measurement invariance	Reliability	Measurement error	Criterion validity	Construct validity	Responsiveness	
Hill–Bone compliance scale [77]	+VL	+VL	+VL	+M	?	?			+L			[c]+L	+L	B
HBCS-SF [85]	+VL	+VL	+VL	+VL	±	?						–VL		B
HBMS [110]	+VL	+VL	+VL	+VL	?	?						–H		C
LMAS-14 [50]	+VL	+VL	+VL	+VL	?	?						+M		B
MARS-5 [126]	+VL	+VL	+VL	+M	+H	–H		+L	–VL			+M		C
MAS-CAD [113]	+VL	+VL	+VL	+L	+H	?			–L					B
MASES [98]	+VL	+M	+M	+M	±	?			–L			+M		B
MASES-R [65]	+VL	+M	+M	+M	+H	+H			–L			–M		A
MBG [91]	+M	+M	+M	+M	?	?			+L					B
MAR-Scale (Revised) [117]	+M	+M	+M	+M	?	?						–M		B
ChMAR Scale [54]	+M	+M	+M	+M	?	?						+M		B
MEDS [45]	+VL	+VL	+VL	+L	+H	+H						+L		A
MMAS-8 [95]	+VL	+L	+VL	+M	±	?			[c]+L			+H		B
QATSH [103]	±VL	±VL	–VL	+VL	?	?								B
TAQPH [89]	+VL	+L	+L	+M	[c]–M				+L			[d]+H		B

The evidence for inconsistent results of content validity is graded to indicate whether the evidence is from available studies (development or content validity studies), or the PROM itself (reviewers' rating)

COSMIN COnsensus-based Standards for the selection of health Measurement Instruments, *PROM* patient-reported outcome measure, *ABM* Adherence Behaviour Measure, *ABQ* Adherence Barriers Questionnaire, *ARMS* Adherence to Refills and Medications Scale, *ASK* Adherence Starts with Knowledge, *ASRQ* Adherence Self-Report Questionnaire, *ChMAR-Scale* the Chinese Medication Adherence Reasons Scale, *HBCS-SF* Short Form Hill–Bone Compliance Scale, *HBMS* Hill–Bone Compliance Medication Scale, *INAS* Intentional Non-Adherence Scale, *LMAS-14* the 14-item Lebanese Medication Adherence Scale, *QATSH* Questionnaire on Adherence to Treatment for Systemic arterial HTN, *MAR-Scale* Medication Adherence Reasons Scale, *MARS-5* the 5-item Medication Adherence Report Scale, *MAS* Medication Adherence Scale, *MAS-CAD* Medication Adherence Scale for Coronary Artery Disease, *MASES* Medication Adherence Self-Efficacy Scale, *MASES-R* the Revised Medication Adherence Self-Efficacy Scale, *MBG* Martín-Bayarre-Grau, *MEDS* Medication Adherence Estimation and Differentiation Scale, *MGLS* Morisky Green Levine Scale, *MMAS-8* the 8-item Morisky Medication Adherence Scale, *MTQ* Medication Taking Behaviour, *MUAH* Maastricht Utrecht Adherence in HTN, *PRAT* Patient-Reported Adherence Tool, *QAM-Q* Questionário de Adesão a Medicamentos – Qualiaids, *QATSH* Questionnaire on Adherence to Treatment for Systemic arterial HTN, *RRMAI* the Reasoning and Regulating Medication Adherence Instrument, *SEAMS* Self-Efficacy for Appropriate Medication Use Scale, *TAQPH* Treatment Adherence Questionnaire for Patients with HTN, *TASHP* Therapeutic Adherence Scale for Hypertensive Patients, *VAS* visual analogue scale

[a] "+": Sufficient; "–": Insufficient; "±": Inconsistent; "?": Indeterminate; "H": High; "M": Moderate; "L": Low VL: Very Low [29, 31, 34].

[b] COSMIN recommendations category "A" (most suitable for evaluating medication adherence in people with CVD), "B" (may have the potential to be recommended, but further validation studies are needed) and "C" (not recommended)[29]

[c] Overall rating has been determined by the majority of the results for inconsistent results and the quality of evidence is downgraded for inconsistency

[d] Overall rating has been determined by the higher-quality studies for inconsistent results.

validity should be evaluated for a use in patients with CVD. This is because content validity studies can provide stronger evidence than the PROM development study. Poorly developed PROM (inadequate quality) can have high quality evidence on content validity provided that there is at least one content validity study with very good or adequate quality [34]. Additional content validity studies are also required for all MA-PROMs included in this review to provide high quality evidence for sufficient relevance, comprehensiveness and comprehensibility. The content validity studies should include both patients and experts in the field [34].

Apart from content validity, the most frequently evaluated measurement properties were construct validity, internal consistency and structural validity. Consistent findings of internal consistency, construct validity, and structural validity in a previous systematic review of MA-PROMs for patients at risk of metabolic syndrome were found [133], while construct validity and internal consistency in another review of MA-PROMs for all chronic diseases [134] were found as the most frequently evaluated measurement properties.

No studies in the current review evaluated criterion validity, which is consistent with a previous review [134]. Criterion validity was reported in the other review for studies that reported correlations, area under the curve, sensitivity, or specificity regardless of the type of outcome comparator used [133]. However, the COSMIN guidelines [31, 33] suggested that there is no gold standard measure for PROMs, unless the original PROM is used as a comparator for the validation of the modified version PROM. In such a case, the original PROM becomes the default gold standard measure [31]. None of the studies evaluating a modified version of a MA-PROM used original PROM as a comparator for validation purposes in the current review.

Structural validity is the second measurement property to be considered for the selection of PROM and it is also a prerequisite for internal consistency [132]. Few studies had very good quality on structural validity using CFA or IRT/Rasch model. According to COSMIN guidelines, the use of Cronbach's alpha for the total score of multidimensional scale cannot be interpreted unless there is evidence for unidimensionality from a high-order or bi-factor CFA [29].

Most reliability studies had doubtful or inadequate methodological quality. As a result of an inappropriate time interval for test-retest, different test conditions, or choice of statistical methods. A 2-week time interval is often deemed appropriate for the evaluation test-retest reliability [135]. The test and the retest conditions, such as mode of administration, and settings, should be similar. For PROMs with continuous scores, the intraclass correlation coefficient (ICC) should be calculated [135] using a two-way random effects model [136]. The methodological quality for all studies on KGV (except for one study) was doubtful, mainly

because the important characteristics, such as age, gender, etc., were not reported for the two groups (e.g., between groups with controlled and uncontrolled blood pressure) when comparing the score of a PROM [31]. Responsiveness can only be evaluated in studies that use a longitudinal study design to measure changes over time in medication adherence. Consequently, only three studies [49, 77, 96] evaluated responsiveness.

Four of the identified MA-PROMS (MUAH, MUAH-16, HBMS and MARS-5) cannot be recommended for use in patients with CVD as they were classified in COSMIN recommendation category 'C'. Most of the identified MA-PROMs, including MMAS-8, were classified in the COSMIN recommendation category of 'B'. These MA-PROMs could still potentially be recommended; however, further validation studies are required.

The MMAS-8 was the most frequently evaluated MA-PROM for patients with CVD. It has inconsistent structural validity and indeterminate internal consistency and was classified in the COSMIN recommendation category of 'B'. Consequently, it requires further validation studies to provide evidence for sufficient structural validity and to obtain interpretable and sufficient internal consistency with at least low-quality evidence. Morisky Medication Adherence Scale-8 exhibited sufficient construct validity with high-quality evidence, and sufficient reliability with low-quality evidence. Using the 2010 COSMIN guidelines [137] and different target populations, a previous review-1 by Kim et al reported that MMAS-8 had strong evidence for sufficient structural validity, and insufficient internal consistency for people at risk for metabolic syndrome [133]. In the Kwan et al review-2 [134], MMAS-8 exhibited inconsistent structural validity, internal consistency and construct validity with high quality evidence for people with any medical condition. Another review-3 of reliability and validity of MMAS-8 in chronic diseases found that MMAS-8 had sufficient pooled results of internal consistency but the reliability (test-retest) and criterion validity were not sufficient in hypertensive patients [138]. A difference between the current review and the review-3 [138] may be attributable to the use of different guidelines for methodological quality assessment (COSMIN vs QUADAS-2).

The eight MA-PROMs in COSMIN category "A" should be used with caution considering different contexts such as the domains, phases of medication adherence to be measured or target language, and feasibility, including cost and time to complete the PROM. In terms of context, MA-PROMs that have items about extent of non-adherence, intentional and unintentional reasons for non-adherence, and measure both implementation and discontinuation phases are more comprehensive and can be prioritised to select the most suitable MA-PROM. Defined by Vrijens et al [139], that adherence to medication is the process by which patients

take their medication as prescribed, further divided into three quantifiable phases: 'Initiation', 'Implementation' and 'Discontinuation', is reported in the current review. Most MA-PROMs had items that could evaluate the implementation of prescribed medications. Of the eight MA-PROMs in COSMIN recommendation category "A", only Adherence Barriers Questionnaire (ABQ), ARMS and ARMS-7 measure both the implementation and discontinuation phases of medication adherence. Considering domains of medication adherence, ABQ has items that ask about reasons for non-adherence (intentional and unintentional), whereas ARMS and ARMS-7 are more comprehensive having items that capture information about the extent of (medication taking, and refills), unintentional and intentional non-adherence. Unlike ARMS, ARMS-7 does not seek information on the routine subdomain of unintentional non-adherence, and is missing some important items including skipping doses (extent of non-adherence), and being careless (remembering), changing dosing to suit needs (routine), forgetting to take medication due to frequent dosing (remembering), and not refilling medication due to high cost (access).

Feasibility aspects (clinical utility) should also be taken into consideration when selecting a PROM and may include any costs for using the PROM (i.e., copyright), time required to complete the PROM, length of the PROM, mode of administration, and response format [132]. Of the MA-PROMs categorised in COSMIN recommendation category 'A', only ABQ is licensed and subject to charge [95, 97]. Response format of the PROM should consider different factors including the intended target population; for example, the visual analogue scale (VAS) response format is not appropriate for patients with visual impairment [140]. Ceiling or floor effects could be avoided by using PROMs with a polytomous response format, such as a ≥4-item Likert scale [21]. The ARMS and ARMS-7 have a frequency response format with 4-point Likert scale, and free of charge for students and not-for-profit organisations.

4.1 Implications for Clinical Practice and Research

The current study has gone some way towards enhancing understanding of the quality and clinical usability of the available MA-PROMs for people with CVD. Cardiovascular medications are an important intervention for the prevention of CVD, control of symptoms, and reduction of complications and their associated hospital admission. Non-adherence could mask the benefits of treatment leading to misinformed decisions in clinical practice and research, necessitating the need to monitor medication adherence. Clinicians or researchers can use MA-PROMs to monitor medication adherence and assist in the identification of whether treatment failure is due to non-adherence or ineffective treatment and therefore facilitate informed treatment decisions

[15]. Another use of MA-PROMs is to identify patients at risk for non-adherence, along with possible reasons for non-adherence, assisting patient-clinician interaction and shared decision making, to facilitate tailored care and ultimately improve CVD treatment outcomes [141, 142].

Before the integration of MA-PROMs into clinical practice and research, a number of factors need to be considered. MA-PROMs should be chosen on the basis of demonstrated feasibility, reliability and measurement accuracy rather than popularity. Clinicians and researchers should ensure items of the selected MA-PROM capture the important information relevant to the targeted CVD and medication adherence. Before using a PROM in clinical practice there should be evidence that a change in the PROM score is due to a 'true' change in the construct of interest rather than by chance. A measurement obtained using selected MA-PROM (adherent or non-adherent) should be meaningfully linked to one of the targeted clinical endpoints of CVD, such as blood pressure, cholesterol level, or symptom control. This information could be obtained using a known-group validity or discriminative validity [29, 31].

COSMIN guidelines are currently being used to evaluate the clinimetric properties of PROMs [143–145] and a recent review by Carrozzino et al has advocated the use of a clinimetric methodological approach to evaluate PROMs for clinical use [28]. Authors of future systematic reviews of PROMS for clinical use should consider whether to use COSMIN guidelines, clinimetric methodological approach or a combination of the two.

4.2 Strengths and Limitations

The strengths of this review lie in the methods including the use of the latest 2018 COSMIN guidelines [29, 33, 34], following a prior published protocol [36], and using a published sensitive search terms for measurement properties [38]. Another strength of this review is that PROM development and content validity studies were evaluated because content validity is the first and most important measurement property for decision in the selection of suitable PROMs. In addition to measurement properties, the context and feasibility aspects of the MA-PROMs were evaluated to guide the selection of the most suitable MA-PROM for people with CVD.

The review has some potential limitations. The study findings should be interpreted with a degree of caution in terms of clinimetric properties. The measurement properties of MA-PROMs were evaluated based on COSMIN guidelines that are more focused on classical psychometric criteria than clinical criteria and may miss some clinimetric issues. Another limitation is that the review focuses on all types of CVD with more evidence being obtained for HTN than other CVD. Therefore, careful consideration should be taken

when a MA-PROM suitable for all CVD is preferred and we recommend selecting a generic PROM with COSMIN recommendation category 'A'. Non-English articles were not included which may be a source of language bias and results of this review are not generalisable to medical conditions other than CVD.

5 Conclusion

Forty MA-PROMs were identified in this systematic review. Of these, eight were classified using the COSMIN criteria as the most suitable for evaluating medication adherence in people with CVD and four as not recommended. Adherence to Refills and Medications Scale and ARMS-7 were identified as the most suitable MA-PROMs as they had the highest quality evidence for good measurement properties and were the most comprehensive. They measure both implementation and discontinuation phases of medication adherence, have a 4-point Likert scale frequency response format, and are free of charge for use by students and non-profit organisations. Most MA-PROMs require further studies for people with CVD to obtain higher quality evidence, particularly for content validity.

Declarations

Conflicts of interests The authors have no relevant financial or non-financial interests to disclose.

Ethics approval All procedures in this study were in accordance with the 1964 Helsinki declaration (and its amendments).Ethics approval was not required for this systematic review as it did not involve human participants or animals.

Consent to participate Not applicable.

Consent for publication Not applicable.

Availability of data and material All data supporting the reported findings has been included in this tables and supplementary data.

Code availability Not applicable.

Author contributions HGT: Conceptualisation, Literature searches, Article screening, Data extraction, Rating quality of studies, Writing—original draft. SW: Article screening, Cross check data extraction, Rating quality of studies, Writing—review & editing. ETd: Article screening, Cross check data extraction, Rating quality of studies, Writing—review & editing. MJS: Conceptualisation, Article screening, Cross check data extraction, rating quality of studies and results, Writing—review & editing. All authors read and approved the final manuscript.

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