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Psychometric properties of self-report instruments for assessing self-care in patients with oncological diseases: a systematic review based on COSMIN guidelines

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ABSTRACT

Objective To identify self-report self-care scales for patients with cancer and critically evaluate their measurement properties.

Design Systematic literature review based on COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) methodology.

Data sources A comprehensive search was conducted from database inception to March 2025 through PubMed, CINAHL, Embase, Scopus, Web of Science and APA PsycINFO. Potentially eligible articles were also identified by consulting the reference lists of the included studies.

Eligibility criteria Studies were eligible if they reported on the development or validation of self-report instruments measuring self-care in adult patients with cancer and provided data on at least one measurement property as defined by the COSMIN framework.

Data extraction and synthesis This review adhered to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement. Risk of bias and methodological quality were assessed according to COSMIN criteria. A modified Grading of Recommendations Assessment, Development and Evaluation approach was applied to determine the level of evidence for each psychometric property and to formulate recommendations for instrument use.

Results 30 studies involving 26 instruments were included. Three instruments, the self-management instrument for patients with breast cancer undergoing adjuvant therapy, the Self-Care of Oral Anticancer Agents Index and the Leuven questionnaire for Patient Self-care during Chemotherapy, were strongly recommended (Grade A) based on adequate content validity and internal consistency. In contrast, the Self-Care Agency Scale and the Breast Cancer-Related Lymphoedema Self-Care Scale were not recommended (Grade C) due to high-quality evidence for insufficient structural validity and internal consistency, respectively. Most instruments received a Grade B, indicating potential for use but requiring further validation.

Conclusions This review highlights several gaps in psychometric evaluations, emphasising the need for future research to conduct more rigorous assessments of the measurement properties of current instruments and to develop tools that measure self-care in a broader population of oncology patients.

Registration number PROSPERO (CRD42024519219; 16 March 2024).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This review followed the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) methodology to systematically assess risk of bias and measurement properties of self-report self-care instruments developed for patients diagnosed with cancer.
⇒ A comprehensive search strategy was applied across multiple databases and supplemented by reference list screening.
⇒ Methodological quality and certainty of evidence were evaluated using COSMIN criteria and a modified Grading of Recommendations Assessment, Development and Evaluation approach.
⇒ Quantitative synthesis was not feasible because most instruments were evaluated in a single study.
⇒ The availability of psychometric evidence was limited for several measurement properties across the included instruments.

INTRODUCTION

Cancer represents a major public health, social and economic issue of the 21st century and is the third leading cause of death worldwide.[1] According to demographic-based projections, the number of new cancer diagnoses will reach 35 million by 2050.[2]

Breakthroughs in oncology treatments are gradually transforming advanced cancer from a fatal and incurable disease into a chronic condition.[3 4] Nonetheless, many patients continue to experience persistent,

treatment-related symptoms that impair adherence, functional status and quality of life, leading to increased hospitalisations and postacute care use[5–9]

Moreover, oncology care is predominantly delivered in outpatient settings, and symptoms occurring in the days following treatment require patients to manage their condition at home.[10] Therefore, in synergy with medical therapy, self-care plays a crucial role in the success of cancer treatment.[11] Given the chronicisation of advanced cancer, it has become progressively more important for patients to take an active role in their own care; accordingly, the body of knowledge on cancer self-care has expanded substantially in recent years. Self-care is defined as a process through which individuals maintain health and well-being through health-promoting practices (self-care maintenance), monitor symptoms and changes in health status (self-care monitoring) and respond to symptoms when they occur (self-care management).[12 13] In patients with cancer, better self-care behaviours, such as maintaining a balanced diet, engaging in regular exercise, ensuring adequate sleep and effectively managing symptoms, are associated with increased quality of life and survival rates, as well as lower healthcare utilisation.[14 15]

In recent years, the topic of self-care in cancer has increasingly gained the interest of researchers and clinicians. A growing body of research underscores the complexity of cancer-related self-care, which involves managing symptoms that vary in intensity, timing and distress, significantly impacting overall well-being. Effective self-care requires a comprehensive approach that integrates preventive strategies to mitigate complications alongside targeted interventions to address existing symptoms in order to promote better outcomes during and after treatments.[16–18] Consequently, researchers have developed and validated various instruments to capture the multifaceted nature of the self-care construct. These tools are typically self-reported, as the perception of one's own ability to engage in self-care activities is subjective, and these activities are usually performed at home (eg, adherence to healthy lifestyle and therapeutic regimes and self-monitoring of side effects),[12] making direct observation unfeasible.

Before being used in clinical practice and research, self-care instruments should be developed through a series of methodological steps, including item generation and face and content validity. Moreover, to ensure further adequate validity and reliability, the tools should be tested for other psychometric properties, such as different types of construct validity and internal consistency.[19 20] The selection of a high-quality self-report tool should imply a valid and reliable measure of the self-care construct in patients with cancer, given the significant health outcomes associated with it. According to the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN), the use of low-quality or unspecific instruments can be detrimental to clinical practice and research due to the risk of invalid conclusions as well as a waste of resources and time.[21]

Systematic reviews of self-care patient-reported outcome measures are available mainly outside the oncology field. These reviews suggest that, despite the proliferation of instruments, the evidence supporting several measurement properties is often incomplete or of variable quality. Systematic reviews in chronic conditions (eg, diabetes and chronic heart failure) identified multiple instruments but frequently reported gaps in content validity and underassessment of cross-cultural validity/measurement invariance, measurement error and responsiveness.[22–24] To date, no published systematic reviews have comprehensively evaluated the psychometric properties of self-report instruments measuring self-care in adult patients with cancer. A COSMIN-based systematic review protocol has been published focusing on patient-reported outcome measures of self-management in cancer survivors[25]; however, this work has not yet resulted in a completed review and addresses a related but conceptually distinct construct. Therefore, a comprehensive synthesis of the psychometric properties of self-care instruments in oncology is still lacking, which provides the rationale for the present study.

Aim

This systematic review aimed to critically evaluate the psychometric properties of the existing instruments measuring self-care behaviours in adult patients with cancer.

METHODS

This systematic review adheres to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) protocols guidelines,[26 27] whose protocol has been registered in PROSPERO (ID: CRD42024519219) and previously published.[28] The quality assessment of the psychometric properties of included instruments, data extraction and synthesis were performed according to COSMIN guidelines.[29]

Eligibility criteria

Articles were considered eligible for review if the corresponding full text was available and (1) reported one or more generic or disease-specific self-care self-report instruments developed for adult patients diagnosed with cancer, (2) assessed at least one measurement property of the instrument, either as an explicit aim of the study or, when instrument validation was not the primary objective, by nonetheless reporting the development and/or validation process and the corresponding psychometric properties.

Self-care behaviours were operationalised according to principles postulated in the middle-range theory of self-care of chronic illness,[13] where they are categorised into the dimensions of self-care maintenance, self-care monitoring and self-care management. 'Maintenance' refers to the activities performed to maintain a stable condition, including physical and emotional well-being

(eg, medication adherence, physical activity and healthy diet). Self-care monitoring concerns those practices to keep signs and symptoms of the disease under control (eg, monitoring blood pressure or body temperature and the side effects of the prescribed medications). Self-care management involves the response to such signs and symptoms (eg, contacting healthcare providers or taking medications to relieve symptoms).

Articles were excluded if (1) studies explored self-care as an outcome measure (eg, observational studies), (2) instruments were not self-report but completed by caregivers or healthcare professionals, (3) published in languages different from English, Spanish or Italian and (4) studies reported psychometric properties of proxy measures of self-care (eg, motivation and self-efficacy). No time limits were given for this review since the earliest self-care theorisation occurred in the 1950s.[30]

Search strategy

The research question was formulated using the Population, Exposure, Outcome framework,[31] where P=adult patients diagnosed with cancer, E=instruments developed for assessing self-care and O=psychometric properties of the instruments. PubMed (via Medline), CINAHL (via EBSCOhost), Embase (via Ovid), Scopus (via Elsevier), Web of Science (via Clarivate Analytics) and APA PsycINFO (via EBSCOhost) were systematically searched from database inception to March 2025, with no publication date restrictions applied. A search strategy for each database is reported in online supplemental table S1. Potential eligible articles were also searched via reference lists of the included studies in order to ensure a more comprehensive retrieval of the existing literature.

Study selection process

All records obtained through the search string were imported into EndNote V.X9.1 where duplicates were removed.[32] Next, abstract and full-text screening was performed independently by two authors with the support of Rayyan.[33] Disagreements were resolved by consulting a third evaluator. To assess inter-rater agreement between the two evaluators, Cohen's kappa coefficient was computed. This coefficient ranges from −1 to 1, with values of at least 0.61 indicating satisfactory agreement.[34]

Data extraction

For each included article, the following information was extracted: target population (demographic and clinical characteristics), sample size, original language, instrument (number of items, range of scores, dimensionality and component of self-care covered). The psychometric properties extracted were those identified by the COSMIN guidelines.[29]

Data synthesis and quality appraisal

The COSMIN Risk of Bias Checklist[35] was used to assess the methodological quality of the studies. This instrument consists of 116 items grouped into 10 boxes evaluating: (1) instrument development, (2) content validity (ie, the extent to which the content of an instrument is an adequate reflection of the measured construct,[29] (3) structural validity (ie, the degree to which the scores of an instrument properly reflect the dimensional structure of the measured construct,[29] (4) internal consistency (ie, the coherence or redundancy among the components of a scale,[36] (5) cross-cultural validity/measurement invariance (ie, the psychometric equivalence of a construct across groups or across time,[37] (6) reliability (ie, whether an assessment tool consistently produces the same result when applied in similar patients and conditions,[38] (7) measurement error (ie, the discrepancies in a score that are not due to actual changes in the construct being measured,[39] (8) criterion validity (ie, the degree to which the scores of an instrument reflect a 'gold standard',[29] (9) hypotheses testing for construct validity (ie, the degree to which the scores of an instrument are consistent with hypotheses[29] and (10) responsiveness (ie, ability of a tool to detect change over time in the construct to be measured.[29] Items included in each domain of the checklist can be rated as 'very good', 'adequate', 'doubtful', 'inadequate' and 'not applicable'. According to 'the worst score counts' principle, the lowest rating of any item in the box was considered to determine the overall quality of a study. Any discrepancy of opinion was resolved by consensus between the two reviewers, and if no consensus was reached, the consultation of a third reviewer was requested.

Once the measurement properties of the instruments were extracted, their quality was rated according to the three criteria proposed by Mokkink and colleagues,[35] namely sufficient (+), insufficient (–) or indeterminate (?). Criteria for good measurement properties according to COSMIN guidelines are summarised in online supplemental table S2.

Quality of evidence assessment and recommendations

A modified GRADE[40] was used in this step to grade the quality of evidence of the instruments. According to this approach, the evidence is rated as 'high', 'moderate', 'low' or 'very low' on the basis of four factors: (1) risk of bias (ie, the methodological quality of the studies), (2) inconsistency (ie, unexplained inconsistency of the results across studies), (3) imprecision (ie, the total sample size of the available studies) and (4) indirectness (ie, evidence originating from populations, interventions or outcomes that differ from those of interest in the review). For each instrument and each measurement property, we first summarised the available results and then downgraded the quality of evidence when there were serious concerns regarding one or more of these factors. Risk of bias was judged using the COSMIN Risk of Bias checklist, with one-, two- or three-level downgrades applied in the presence of serious, very serious or extremely serious risk of bias, respectively. Imprecision was evaluated based on the total sample size across all studies contributing to a given measurement property (no downgrade for total n>100; one-level downgrade for total n between 50 and 100; two-level downgrade for total n<50). For instruments and measurement properties for which only one study was available, this total sample size therefore corresponded to the

sample size of that single study. In line with COSMIN guidance, no additional downgrading was applied solely on the basis of sample size for measurement properties for which specific sample-size requirements are already incorporated in the COSMIN Risk of Bias checklist (ie, content validity, structural validity and cross-cultural validity).[29] Finally, recommendations were summarised into three categories as follows: (1) instruments with evidence for sufficient content validity (any level) and at least low-quality evidence for sufficient internal consistency (category A), (2) instruments categorised not in category A or C (category B) and (3) instruments with high-quality evidence for an insufficient measurement property (category C).[29]

Patient and public involvement

Patients and the public were not involved in the design or planning of this systematic review, nor in the dissemination of its results.

RESULTS

A total of 11 525 records were retrieved from the six databases. Once the duplicates were removed, 6750 articles were uploaded to Rayyan and subsequently screened. The level of agreement between the evaluators was satisfactory (Cohen's kappa=0.72). The article selection process led to the inclusion of 30 studies, involving a total of 26 instruments measuring self-care behaviours in patients with cancer. The different selection stages and reasons for exclusion are summarised in the PRISMA flowchart (figure 1)

Study characteristics

The included articles described eight validation studies, one development study and 19 mixed studies (both development and validation processes were described). Additionally, two qualitative studies were included, which were conducted to guide the item generation phase, and their methodological quality was assessed to evaluate the risk of bias.[41 42] Online supplemental table S3 offers an overview of the instruments discussed in this review. In summary, these self-care instruments are validated for a wide variety of oncological diseases, reflecting different behaviours across different stages and treatment modalities. Some tools are tailored to a specific condition, including breast cancer,[43–47] prostate cancer,[48 49] head and neck cancer[50] and cervical cancer.[51] Others are for a general population of oncological patients.[52 53] Some tools capture behaviours related to the management of

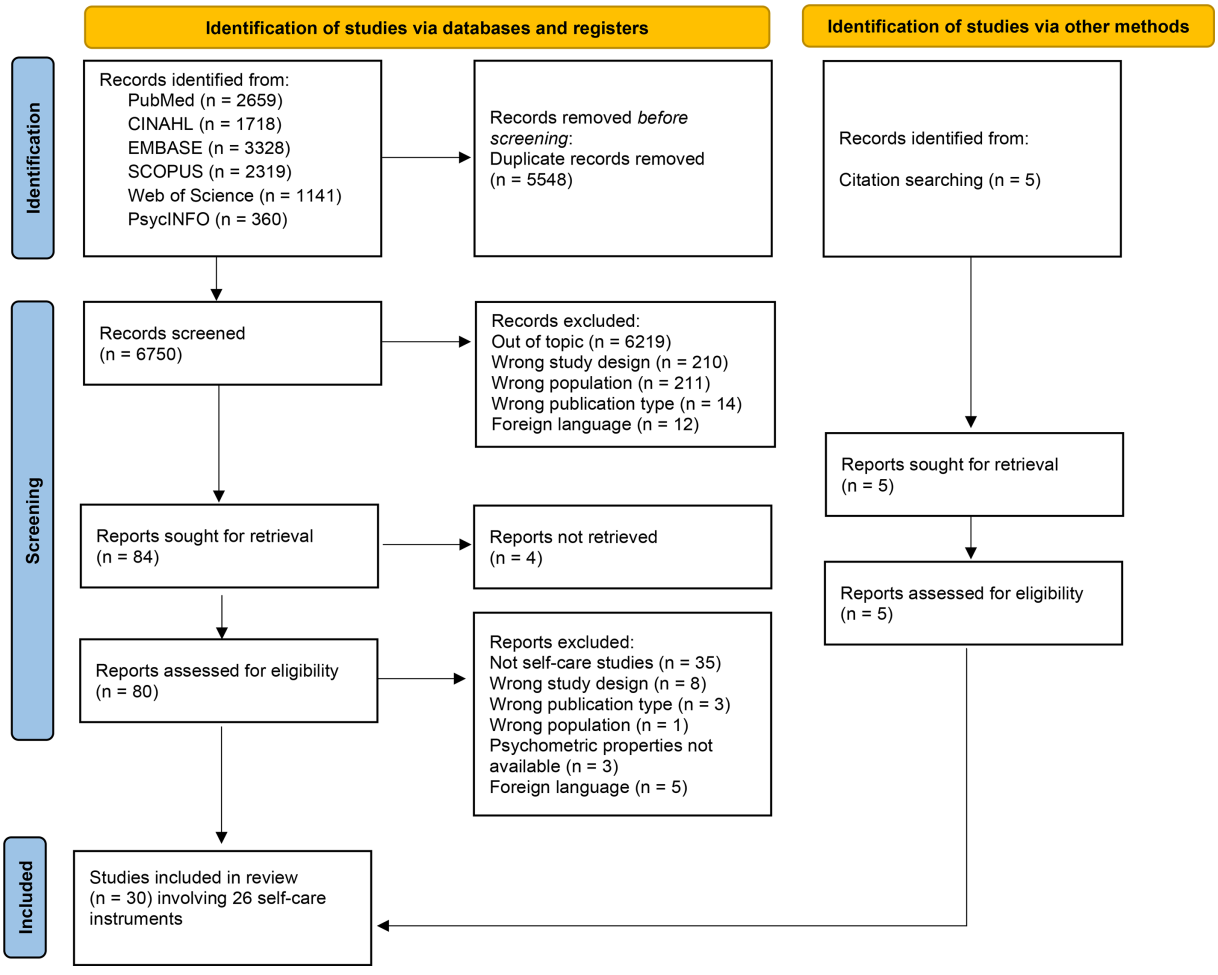

Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart

specific conditions, such as ostomies[54] or related to the management of complications, such as lymphoedema,[55 56] fatigue[57] or analgesic therapy.[58–60] Some instruments are designed for a broader cancer population with specific treatment regimens (ie, chemotherapy, oral antineoplastic agents and immunomodulators).[61–68] Most instruments target individuals with solid cancers, while only three of them measure behaviours performed by patients with haematologic cancers.[67 69 70] Regarding the original validation language, the most represented ones are English (eight instruments), Chinese (five instruments), Italian (four instruments) and Japanese (three instruments). Questionnaires are mostly multidimensional, reflecting the inherent nature of the self-care construct. In unidimensional instruments (10 studies), the most measured behaviour is medication adherence (online supplemental table S3).

Risk of bias evaluation

The results from the risk of bias assessment are summarised in table 1. The properties evaluated were instrument development (20 studies), content validity (20 studies), structural validity (18 studies), internal consistency (26 studies), reliability (11 studies), measurement error (two studies) and hypothesis testing for construct validity (14 studies). Only one study assessed cross-cultural validity/measurement invariance, while no one described criterion validity and responsiveness. Most studies show deficiencies in the development phase; 10 of them were rated 'Inadequate',[44 51 53–55 60–62 69 70] and five 'Doubtful'.[45 49 50 66 68] In detail, only four studies adopted an appropriate qualitative data collection for the process of item pool generation.[42 48 57 64] Regarding the content validity phase, few studies adopted an approach that involves both patients and professionals, in order to improve relevance, comprehensibility and comprehensiveness of the instrument,[46 60 64] and many of them only relied on expert consensus to measure content validity. Several studies have been rated as 'Doubtful', due to the limited number of professionals involved.[44 48 51 53 55–57 61 62 65 66 68 69] Structural validity was rated 'Very good' in 7 out of 18 studies,[44 46 47 53 63 66 69] while 10 were evaluated as 'Adequate'.[48 52 54–56 58 59 61 62 68] Only one study was rated 'Inadequate'.[60] In articles with higher methodological quality, confirmatory factor analysis was performed. Those reporting only the results of exploratory factor analysis[52 56 58 59 61 62 68] or with a sample size that was not seven times the number of items and greater than or equal to 100[48 54 55 60] were instead considered 'Adequate' or 'Inadequate' as recommended. The fourth box of the checklist concerns internal consistency and is often measured using Cronbach's alpha. Almost all the studies included in the review measured this property, and the methodological quality was rated as 'Very good' in 19 articles. According to COSMIN guidelines, in the absence of structural validity evaluation, internal consistency should be downgraded.[29] As a result, the methodological quality of seven studies was rated as 'Doubtful'.[43 45 49 50 65 67 70] Measurement invariance was evaluated in one study, and the methodological quality was good.[47] Only 10 studies evaluated test-retest reliability, and most of the included articles only measured internal consistency as a reliability index. The methodological quality of reliability assessment was evaluated as 'Very good'[45 46 49 54 56 60 65] and 'Adequate'[59 61 66 69] in seven and four studies, respectively. Measurement error was evaluated in two studies, and in both of them, the methodological quality was rated as 'Very good', since SE measurement[46] and limits of agreement[57] were properly performed. Construct validity was reported in 14 studies with 'Very good'[48 50 54 56 58–61 63 67 68] to 'Adequate' methodological quality. Downgrading occurred in this domain since there was uncertainty that the measurement properties of the comparator were applicable to the population of interest.[44 46 53]

Psychometric properties results

The psychometric properties of the included instruments are detailed in online supplemental table 4, with a synthesis of their overall quality presented in table 2. According to COSMIN guidelines, content validity rating involves three key elements: relevance of the items for the construct of interest, comprehensibility and comprehensiveness. The scoring for each dimension followed the 10 criteria for good content validity suggested by COSMIN.[71] A sufficient rating (+) was given when the three aspects of relevance, comprehensibility and comprehensiveness were fully met, as determined by the quality of instruments' development and content validity studies and the reviewer's judgement.[46 51 55 57 60 62 64] Studies were rated as insufficient (−) when relevance, comprehensibility and comprehensiveness were all inadequate.[50 51 70] Several studies received an indeterminate rating (?) since not enough information on relevance, comprehensibility and comprehensiveness was reported. 18 studies reported results for structural validity. 11 articles used confirmatory factor analysis to estimate the model fit, and many of them were deemed sufficient.[44 46 47 55 63 68 69] Self-care Agency Scale (SAC),[53] self-management scale for lower urinary tract symptoms in patients with cancer after radical prostatectomy[48] and Opioid Self-management Scale for patients with advanced cancer (OSSA)[60] scales were rated as insufficient, since Comparative Fit Index (CFI) and Mean Squared Error of Approximation (RMSEA) values did not adhere to COSMIN guidelines (ie, CFI >0.95 or RMSEA <0.06).[71] The remaining instruments in which structural validity was measured were scored as indeterminate[52 54 56 58–62 66]; in fact, only exploratory factor analysis was performed, and it was not possible to draw conclusions in accordance with the COSMIN guidelines, which require more robust psychometric testing methods. 26 studies assessed internal consistency, and most of them received a sufficient rating,[43 44 46–48 51–56 58 59 61–63 66] as Cronbach's alpha value was ≥0.70 for each unidimensional scale or subscale.[29] The experience with and adherence to oral antineoplastic agents scale developed by Talens[68]

Table 1 Methodological quality of the studies

Instrument	Instrument development	Content Validity	Structural validity	Internal consistency	Cross-cultural validity/ measurement invariance	Reliability	Measurement error	Construct validity
A-BET	Doubtful	Adequate	NE	Doubtful	NE	Very good	NE	NE
A-HT	Doubtful	Adequate	NE	Doubtful	NE	Very good	NE	NE
BCRL self-care	Inadequate	Doubtful	Adequate	Very good	NE	NE	NE	NE
BQSSM	Inadequate	Inadequate	Adequate	Very good	NE	Very good	NE	Very good
Cervical cancer patients' knowledge and practice of self-care management of treatment-related adverse events questionnaire	Inadequate	Doubtful	NE	Very good	NE	NE	NE	NE
DMARS-4	NE	NE	Adequate	Very good	NE	NE	NE	Very good
EXPAD-ANEO	Doubtful	Doubtful	Adequate	Very good	NE	NE	NE	Very good
HBSCP	Inadequate	Doubtful	Very good	Very good	NE	NE	NE	Adequate
HNC-PSMI	Doubtful	Adequate	NE	Doubtful	NE	NE	NE	Very good
IM-SMS	Inadequate	Doubtful	Very good	Very good	NE	Adequate	NE	NE
L-PaSC	Inadequate	Doubtful	Adequate	Very good	NE	NE	NE	NE
L-PaSC-P	NE	Doubtful	NE	Doubtful	NE	Very good	NE	NE
LSMBQ	Inadequate	Doubtful	Adequate	Very good	NE	Very good	NE	Very good
MMAM	NE	NE	Adequate	Very good	NE	Adequate	NE	Very good
OCAS	Inadequate	Doubtful	Adequate	Very good	NE	Adequate	NE	Very good
OCSMS	Doubtful	Doubtful	Very good	Very good	NE	Adequate	NE	NE
OSSA	Inadequate	Doubtful	Inadequate	Very good	NE	Very good	NE	Very good
PIH	NE	NE	Adequate	Very good	NE	NE	NE	NE
SAC	Inadequate	Doubtful	Very good	Very good	NE	NE	NE	Adequate
SBSMS	NE	NE	Very good	Very good	Very good	NE	NE	NE
SCOAAI	Adequate	Very good	Very good	Very good	NE	NE	NE	Very good
SCUQ	NE	NE	NE	Doubtful	NE	NE	NE	NE
Self-assessment adherence questionnaire	Inadequate	NE	NE	Doubtful	NE	NE	NE	NE
SMAT-B	Very good	Very good	Very good	Very good	NE	Very good	Very good	Adequate
SMSFS-A	Adequate	Doubtful	NE	NE	NE	NE	Very good	NE

Continued

Table 1 Continued

Instrument	Instrument development	Content Validity	Structural validity	Internal consistency	Cross-cultural validity/ measurement invariance	Reliability	Measurement error	Construct validity
SMS-LUTS-RP	Adequate	Doubtful	Adequate	Very good	NE	NE	NE	Very good
TAM	NE	NE	NE	Doubtful	NE	NE	NE	Adequate

A-BET, adherence-breast endocrine therapy; A-HT, adherence-hormone therapy; BCRL-self care, Breast Cancer-Related Lymphoedema Self-Care Scale; BQSSM, Behaviour Questionnaire for Stoma Self-Management; DMARS-4, Danish version of the Medication Adherence Report Scale; EXPAD-ANEO, experience with and adherence to oral antineoplastic agents; HBSCP, Health Behaviour Scale for patients with cancer; HNC-PSMI, Head and Neck Cancer Patient Self-management Inventory; IM-SMS, Immunosuppressive Medication Self-Management Scale ; L-PaSC, Leuven Questionnaire for patient self-care during chemotherapy; L-PaSC-P, Persian Version of the L-PaSC; LSMBQ, Lymphoedema Self-Management Behaviour Questionnaire; MMAM, Morisky medication adherence measure; NE, not evaluated; OCAS, Oral Chemotherapy Adherence Scale; OCSMS, Oral Chemotherapy Self-management Scale; OSSA, Opioid Self-management Scale for patients with advanced cancer; PIH, partners in health; SAC, Self-Care Agency Scale; SBSMS, sedentary behaviour strategy self-management; SCOAAI, Self-Care of Oral Anticancer Agents Index; SCUQ, Self-Care Utilisation Questionnaire; SMAT-B, self-management instrument for patients with breast cancer undergoing adjuvant therapy; SMS-LUTS-RP, Self-management Scale for lower urinary tract symptoms in patients with cancer after radical prostatectomy; TAM, treatment adherence measure.

used McDonald's omega coefficient to evaluate internal consistency, and the quality of this property was sufficient since the coefficient value was 0.07. Instruments with a Cronbach's alpha ≤0.70 were rated as insufficient,[55 67 69 70] while the internal consistency of the remaining studies was rated as 'indeterminate', even though all Cronbach's alpha values were ≥0.70,[45 49 50 65] since the 'at least low evidence of sufficient structural validity' criteria were not met.[71] Test-retest reliability was assessed in 10 articles. The Intraclass Correlation Coefficient (ICC) was calculated in six studies, and the quality of this psychometric property was rated as sufficient for SMAT-B,[46] Persian Version of the Leuven Questionnaire for patient self-care during chemotherapy (L-PaSC-P),[65] Behaviour Questionnaire for Stoma Self-Management,[54] Lymphoedema Self-Management Behaviour Questionnaire[56] and OSSA[60] instruments. The adherence-breast endocrine therapy[45] and adherence-hormone therapy[49] questionnaires were found to be insufficient, indeed, although the individual items demonstrated excellent ICC (ranging from 0.84 to 1), the instrument as a whole showed inadequate test-retest reliability (values not shown in the papers). The quality of reliability for the remaining instruments was considered indeterminate because test-retest reliability was estimated with Pearson's/Spearman's correlation coefficient.[59 61 66 69] Measurement error was evaluated in self-management instrument for patients with breast cancer undergoing adjuvant therapy (SMAT-B)[46] and Managing Symptoms Scale-Fatigue Subscale for patients with advanced cancer (SMSFS-A)[57] and deemed sufficient and indeterminate, respectively. Only the study on the sedentary behaviour strategy self-management scale[47] reported measurement invariance testing, demonstrating invariance of the tool across educational level, body status, and years since diagnosis, thus meeting the COSMIN criteria for a sufficient score.[71] Construct validity was assessed in 14 articles; specifically, hypotheses for convergent validity were tested. Included self-care instruments were compared with different measures assessing variables such as self-efficacy,[46 54 56 61 63] quality of life,[46 53 54 67] symptom burden,[48 50 58 59] physical functioning,[44] behaviour patterns,[44 58] emotional distress[50] and other self-care measures.[53 60 68] For this domain, results were rated as sufficient for most studies, since the obtained results were in accordance with the original hypothesis.[44 46 48 50 53 56 59–61 67 68] In contrast, only one instrument did not reach a sufficient rating, since the obtained results did not align with the initial assumption and the quality of convergent validity was deemed inadequate.[58]

Quality of evidence and formulation of recommendations

Table 2 also provides the quality of evidence assigned to each psychometric property of the included instruments and the formulation of the degree of recommendation. As suggested by the COSMIN group, a modified GRADE approach was adopted to assess the quality of the evidence.[40] The rating ranged to 'high', 'moderate', 'low'

Table 2 Evaluation of the psychometric properties of the instruments and formulation of recommendations

Instrument	Content validity	Structural validity	Internal consistency	Reliability	Measurement error	Hypotheses testing for construct validity	Cross-cultural validity/ measurement invariance	Recommendation
A-BET	+/Moderate	N/A	?/Moderate	–/Moderate	N/A	N/A	N/A	**B**
A-HT	+/Moderate	N/A	?/Moderate	–/Moderate	N/A	N/A	N/A	**B**
BCRL self-care	+/Low	+/Moderate	–/High	N/A	N/A	N/A	N/A	**C**
BQSSM	?/Very low	?/Moderate	+/High	+/High	N/A	+/High	N/A	**B**
Cancer patients' knowledge and practice of self-care management of treatment-related adverse events questionnaire	–/Low	N/A	+/Low	N/A	N/A	N/A	N/A	**B**
DMARS-4	N/A	?/Moderate	+/Low	N/A	N/A	–Low	N/A	**B**
EXPAD-ANEO	±/Low	+/Moderate	+/High	N/A	N/A	+/High	N/A	**B**
HBSCP	±/Low	+/High	+/High	N/A	N/A	+/Moderate	N/A	**B**
HNC-PSMI	–/Moderate	N/A	?/High	N/A	N/A	+/High	N/A	**B**
IM-SMS	?/Low	+/High	–/Moderate	?/Low	N/A	N/A	N/A	**B**
L-PaSC	+/Low	?/Moderate	+/High	N/A	N/A	N/A	N/A	**A**
L-PaSC-P	?/Low	N/A	?/Moderate	+/High	N/A	N/A	N/A	**B**
LSMBQ	?/Low	?/Moderate	+/High	+/High	N/A	+/High	N/A	**B**
MMAM	N/A	?/Moderate	+/High	?/Moderate	N/A	+/High	N/A	**B**
OCAS	?/Low	?/Moderate	+/High	?/Moderate	N/A	+/High	N/A	**B**
OCSMS	?/Low	?/High	+/High	?/Moderate	N/A	N/A	N/A	**B**
OSSA	+/Moderate	–/Low	+/High	+/High	N/A	+/High	N/A	**B**
PIH	N/A	?/Moderate	+/High	N/A	N/A	N/A	N/A	**B**
SAC	?/Low	–/High	+/High	N/A	N/A	+/Moderate	N/A	**C**
SBSMS	N/A	+/High	+/High	N/A	N/A	N/A	+/High	**B**
SCOAAI	+/High	+/High	+/High	N/A	N/A	+/High	N/A	**A**
SCUQ	N/A	N/A	+/High	N/A	N/A	N/A	N/A	**B**
Self-assessment adherence questionnaire	–/Very low	N/A	–/Low	N/A	N/A	N/A	N/A	**B**
SMAT-B	+/High	**+/**High	+/High	+/High	+/High	+/Moderate	N/A	**A**

Continued

Table 2 Continued

Instrument	Content validity	Structural validity	Internal consistency	Reliability	Measurement error	Hypotheses testing for construct validity	Cross-cultural validity/ measurement invariance	Recommendation
SMSFS-A	+/Low	N/A	N/A	N/A	+/Low	N/A	N/A	B
SMS-LUTS-RP	?/Low	–/Moderate	+/High	N/A	N/A	+/High	N/A	B
TAM	N/A	N/A	–/Very low	N/A	N/A	+/Very low	N/A	B

A-BET, adherence-breast endocrine therapy; A-HT, adherence-hormone therapy; BCRL-self care, Breast Cancer-Related Lymphoedema Self-Care Scale; BQSSM, Behaviour Questionnaire for Stoma Self-Management; DMARS-4, Danish version of the Medication Adherence Report Scale; EXPAD-ANEO, experience with and adherence to oral antineoplastic agents; HBSCP, Health Behaviour Scale for Cancer Patients; HNC-PSMI, Head and Neck Cancer Patient Self-management Inventory; IM-SMS, Immunosuppressive Medication Self-Management Scale ; L-PaSC, Leuven Questionnaire for Patient Self-care during Chemotherapy; L-PaSC-P, Persian version of the L-PaSC; LSMBQ, Lymphoedema Self-Management Behaviour Questionnaire; MMAM, Morisky medication adherence measure; N/A, not applicable; OCAS, Oral Chemotherapy Adherence Scale; OCSMS, Oral Chemotherapy Self-management Scale; OSSA, Opioid Self-management Scale for patients with advanced cancer; PIH, partners in health; SAC, Self-Care Agency Scale; SBSMS, sedentary behaviour strategy self-management; SCOAAI, Self-Care of Oral Anticancer Agents Index; SMAT-B, self-management instrument for patients with breast cancer undergoing adjuvant therapy; SMSFS-A, Managing Symptoms Scale-Fatigue Subscale for patients with advanced cancer; SMS-LUTS-RP, Self-management Scale for lower urinary tract symptoms in patients with cancer after radical prostatectomy; TAM, treatment adherence measure.

or 'very low' on the basis of risk of bias, inconsistency, imprecision and indirectness. Since in this review most instruments were supported by a single study, with some exceptions such as Self-Care of Oral Anticancer Agents Index (SCOAAI) and SMAT-B, for which evidence from multiple studies was considered across different phases of development and validation, inconsistency and imprecision did not contribute to determining the evidence quality rating. Once the quality of the evidence was assessed according to these parameters, recommendations were formulated by assigning a rating from A to C. The grade rating 'A', indicating recommendation for use, was reached SMAT-B,[46] SCOAAI[63] and L-PaSC,[62] due to sufficient content validity and high evidence of sufficient internal consistency. Two instruments were rated as 'C', and therefore not recommended for use, because high-quality evidence was found for an insufficient psychometric property. Specifically, SAC obtained high evidence for insufficient structural validity[60] and Breast Cancer-Related Lymphoedema Self-Care Scale achieved high evidence for insufficient internal consistency.[55] Most of the instruments were rated 'B', since they had the potential to be recommended for use but further research is required. For example, some questionnaires belong to this grey area because internal consistency[57 64] or content validity[43 47 52 58 59 67] were not assessed or reported; however, for most of them, studies with sufficiently robust methodology to provide a synthesis judgement on their use are not available.[44 45 48–51 54–56 60 61 66 68 69]

DISCUSSION

This systematic review aimed to summarise and critically appraise the psychometric properties of existing instruments measuring self-care behaviours in adult patients with cancer. The COSMIN taxonomy[29] constituted the framework for extracting data, evaluating the methodological quality and performing analysis and synthesis of the included articles. A proper assessment of self-care behaviours is essential during the cancer care pathway, as it improves health outcomes such as quality of life, reduced complications and hospitalisation and allows the enhancement of patients' autonomy and the delivery of personalised, high-quality health interventions.[11 16 72]

Our findings suggest that most instruments do not have sufficient evidence to confirm their adequacy for this study population since only a few of them underwent a comprehensive validation process. While most studies reported psychometric properties such as content validity, internal consistency and structural validity, other aspects like test-retest reliability, measurement error, cross-cultural validity, criterion validity and responsiveness have been minimally or not explored at all. Instead, regarding criterion validity, since no gold standard is available for measuring self-care behaviours in patients with cancer, in papers that nonetheless mention this property through correlation with other constructs (eg, self-efficacy), it has been considered as convergent

validity. Although one study presented the results of the cross-cultural adaptation and psychometric evaluation of the L-PasC-P scale, cross-cultural validity was not formally assessed, and only pilot testing of the translated version was performed.[65] According to COSMIN guidelines, evaluating this measurement property requires data from at least two culturally distinct groups.[29] Cross-cultural validity is particularly significant in the context of self-care, as culture can shape self-care behaviours and the factors influencing them, such as confidence, habits, motivation and social support.[13] Furthermore, culture can impact how individuals monitor, interpret, label and explain their symptoms.[73]

Overall, the included instruments showed several recurring shortcomings in terms of methodological quality and completeness of psychometric evaluation. Most of the validation studies analysed were assigned to category B and were therefore weakly recommended. One possible explanation might be that most instruments were supported by a single study, although for some instruments (eg, SCOAAI), evidence was available from more than one study addressing different phases of development and validation. Major deficiencies were identified during the item development and content validity phases, considered to be crucial by COSMIN guidelines, as they represent a precondition for other psychometric properties and allow the construct of interest to be captured in its totality through active involvement of patients and professionals.[20] Several studies have exclusively focused on exploring the self-care construct in oncology patients and generating items through an extensive literature review. Even if time-consuming, best practice suggests a combination of quantitative and qualitative methods to support item generation and content validity evaluation.[74] However, some studies adopted a partial methodology, often including only consensus surveys with experts, with a number of participants that was frequently insufficient to ensure robust findings. Indeed, in a quantitative approach (eg, surveys), it is recommended to engage a minimum of 30 experts to ensure adequate methodological quality.[75] The calculation of the content validity index[76] alone is not considered a sufficient parameter for measuring the quality of this psychometric property, since it assesses the agreement between experts regarding the relevance of the instrument's items and does not include the perspective of the target population. These findings are consistent with those obtained in recent systematic reviews that assessed the psychometric properties of self-report tools developed for oncological patients or subjects with other types of chronic diseases.[77 78] These reviews suggest that increasing the involvement of the population of interest is a key requirement in the development of future instruments.

Despite shortcomings in several instruments being identified, some tools performed better than others. For example, the SMAT-B, a 31-item questionnaire[46] and SCOAAI, a 32-item questionnaire,[63] received a Grade A of recommendation as they met the COSMIN criteria from both a methodological and quality of its psychometric properties perspective. The underlying reason for such rigour may lie in the fact that the entire validation process was COSMIN-driven and, therefore, no important issues were identified during the critical appraisal phase. It is important to notice that COSMIN guidelines have existed for more than 15 years[79 80]; despite that, only a few of the included articles appeared to adhere to them, even the most recent ones. Therefore, the use of different benchmarks to verify the instruments' properties than those suggested by the COSMIN group could be an additional reason for the reduced psychometric quality of the revised tools. According to our findings, SMAT-B,[46] SCOAAI[63] and L-PaSC[62] questionnaires appear to be the most feasible and recommended tools. Unfortunately, these instruments are limited to measuring self-care behaviours in highly specific cancer populations (ie, breast cancer) or in individuals undergoing specific therapies to treat the disease or manage related symptoms (such as chemotherapy or oral anticancer agents). A more generic instrument could enable assessment of self-care levels in a broader segment of patients with cancer, regardless of the diagnosis or treatment received. This could facilitate the generalisability of the results and the implementation of more comprehensive and inclusive self-care support interventions. Last but not least, in multidisciplinary clinical settings managing various oncology conditions, a more generic instrument could alleviate the burden on healthcare providers by reducing the need to use multiple tools for assessing self-care in specific contexts, thereby enhancing the feasibility of these instruments in daily clinical practice.

Limitations and strengths

Some limitations should be taken into consideration in this systematic review. First, a quantitative pooled summary of the results was not feasible due to the presence of only one study for almost all the instruments. A possible explanation could be that our search strategy was not sensitive enough in capturing all relevant studies, or also that the researchers do not appear to validate further the instruments in other contexts or populations of other cultures. Second, there is a potential selection bias due to the language that may have led to the exclusion of relevant studies. Although several articles were excluded due to language, we aimed to expand inclusion criteria beyond studies written exclusively in English, also considering those in Spanish and Italian, given the research team's proficiency in these languages. Furthermore, we considered the possibility that multiple language versions of the same instrument had been validated; however, among the articles included in this review, only one questionnaire was formally evaluated in more than one language. As a result, our synthesis and recommendations primarily apply to the language versions assessed in the included studies, given that the psychometric properties of an instrument may vary across languages.[75] Lastly, despite the rigorous methodological approach we ensured, the evaluation of

the instrument's psychometric properties and level of recommendation might differ when performed by other researchers. The main strength is certainly the provision of an initial mapping of existing instruments to measure self-care in the cancer population, which can be a useful guide for health professionals and researchers.

Recommendations for practice and research

Based on the COSMIN grading of the quality of evidence, three instruments can currently be strongly recommended (Grade A) for assessing self-care in adult patients diagnosed with cancer: the SMAT-B, the SCOAAI and the L-PaSC. These instruments demonstrated at least adequate content validity and internal consistency, supported by studies of acceptable methodological quality. In clinical practice, their use should be guided by the target population and treatment context: the SMAT-B for women with breast cancer receiving adjuvant therapy, the SCOAAI for patients treated with oral anticancer agents, and the L-PaSC for patients undergoing chemotherapy.

Several other instruments identified in this review demonstrated promising measurement properties but cannot yet be strongly recommended because of limitations in the quality of the validation studies and/or the completeness of the available evidence. Future research should therefore prioritise high-quality validation studies of these existing instruments, with particular attention to rigorous assessments of content validity involving both patients and clinicians, longitudinal designs to evaluate responsiveness and stability over time and adequate sample sizes. Cross-cultural adaptation and validation in additional languages and cultural settings are also needed, as the psychometric properties of self-care instruments may vary across different linguistic and cultural contexts. Meaningful patient involvement is essential to ensure that questionnaire items reflect patients' experiences, priorities and language. In line with COSMIN guidelines, content validity is the most important measurement property and requires direct input from the target population.

Furthermore, most of the instruments identified in this review are limited to measuring self-care behaviours in highly specific cancer populations or in patients receiving particular treatments to manage the disease or its related symptoms. The development and validation of a more generic self-care instrument, suitable for use across different cancer diagnoses and treatment pathways, could facilitate the assessment of self-care levels in a broader segment of the oncology population. This, in turn, may enhance the generalisability of research findings and support the implementation of more comprehensive and scalable self-care support interventions.

CONCLUSIONS

This systematic review aimed to examine the psychometric characteristics of self-report instruments designed to measure self-care behaviours in cancer populations, underlining the need to improve the validation process of existing and future instruments, according to the principles established by COSMIN guidelines. These findings may have important clinical and research implications. From a clinical perspective, results from this review may guide healthcare professionals in choosing the most suitable tool for assessing and monitoring self-care levels in this population. Future research should focus on a more thorough and rigorous evaluation of the psychometric properties of currently existing instruments and on the development of tools that measure self-care in a generalist population of oncological patients. The validation process of new instruments should take more emphasis on involving patients during the item generation and content validity phases. This approach would allow for a more comprehensive exploration of the wide range of self-care behaviours and perspectives of this vulnerable population. Finally, the identification and validation of high-quality instruments may also have implications for designing future studies investigating interventions to improve self-care in the oncology field.

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