

Postprint: A Systematic Review of Fatigue Assessment Tools in Cancer Patients Based on COSMIN Guidelines

Authors: Zhou Hongmei, He Lin, Xu Hui, Wang Ning, Xu Hui

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Abstract

Background Accurate assessment of fatigue in cancer patients facilitates precise identification of fatigue severity and the development of targeted interventions. Currently, a wide variety of fatigue assessment tools for cancer patients exist both domestically and internationally; however, there is a lack of systematic integration of the psychometric properties of these scales, which creates difficulties in the rational and standardized selection of assessment instruments.

Objective To evaluate the methodological and measurement properties of fatigue measurement tools for cancer patients.

Methods A search was conducted in CNKI, Wanfang Data, VIP, SinoMed, PubMed, Embase, Cochrane Library, and Web of Science for studies on fatigue assessment tools for cancer patients, with the search period spanning from database inception to May 31, 2024. After independent screening and cross-checking by two researchers, the included studies were evaluated according to the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN), and recommendations were generated.

Results A total of 22 studies were included, encompassing 22 fatigue assessment tools for cancer patients: Pediatric Quality of Life Inventory™ Multidimensional Fatigue Scale (PedsQLTMMFS), Chinese version of PedsQLTMMFS, Functional Assessment of Cancer Therapy-Fatigue (FACT), Chinese version of FACT (FACT-F), Multidimensional Fatigue Inventory-20 (MFI-20), Chinese version of MFI-20, Cancer-Related Fatigue Scale, Cancer-Related Fatigue Comprehensive Screening Scale, Cancer-Related Fatigue Self-Assessment Scale, Multidimensional Fatigue Symptom Inventory (MFSI), Chinese version of MFSI-Short Form (MFSI-SF), Fatigue Symptom Inventory (FSI), Daily Fatigue Cancer Scale (DFCS), Child Fatigue Scale, Chinese version of Child Fatigue Scale

(CF-C), Cancer Fatigue Scale (CFS), Chinese version of CFS (CFS-C), Cancer Fatigue Scale (CF), Brief Fatigue Inventory (BFI), Cancer-Related Fatigue Questionnaire, Piper Fatigue Scale-Revised (PFS-R), and Schwartz Cancer Fatigue Scale (SCFS). The content validity of all assessment tools was rated as “indeterminate,” with evidence quality being moderate or lower; among them, 19 scales received a B-level recommendation, and 3 scales received a C-level recommendation.

Conclusion Currently, the MFSI is recommended for assessing fatigue in cancer patients (recommendation level B); however, its methodological quality and measurement properties remain to be improved.

Full Text

Preamble

A Systematic Review of Fatigue Assessment Tools for Cancer Patients Based on the COSMIN Guidelines

ZHOU Hongmei¹, HE Lin², XU Hui^{3*}, WANG Ning^{2,3}

¹Liaoning University of Chinese Medicine, Shenyang 110085, China

²China Medical University Cancer Hospital, Shenyang 110085, China

³Department of Nursing, Liaoning Provincial Cancer Hospital, Shenyang 110085, China

*Corresponding author: XU Hui, Chief nurse; E-mail: cmuxuhui@16.com

Abstract

Background

Accurate assessment of fatigue in cancer patients is essential for identifying severity levels and developing targeted interventions. Although numerous fatigue assessment tools exist for cancer patients both domestically and internationally, systematic integration of their measurement properties is lacking, creating difficulties in selecting appropriate instruments for standardized evaluation.

Objective

To evaluate the methodological quality and measurement properties of fatigue measurement tools for cancer patients.

Methods

Studies on fatigue assessment tools for cancer patients were searched in CNKI, Wanfang Data, VIP, SinoMed, PubMed, Embase, Cochrane Library, and Web of Science from database inception to May 31, 2024. Two researchers independently screened studies and cross-checked results. Included studies were evaluated according to the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) to generate recommendations.

Results

Twenty-two articles were included, encompassing 22 cancer patient-related fatigue assessment tools: PedsQL™ Multidimensional Fatigue Scale (PedsQL™MFS), Chinese version of PedsQL™MFS, Functional Assessment of Cancer Therapy-Fatigue Scale (FACT-F), Chinese version of FACT-F, Multidimensional Fatigue Inventory (MFI-20), Chinese version of MFI-20, Cancer-Related Fatigue Scale, Cancer-Related Fatigue Comprehensive Screening Scale, Self-rating Scale for Cancer-Related Fatigue, Multidimensional Fatigue Symptom Inventory (MFSI), Chinese version of MFSI-Short Form (MFSI-SF), Fatigue Symptom Inventory (FSI), Daily Fatigue Cancer Scale (DFCS), Childhood Fatigue Scale, Chinese version of Childhood Fatigue Scale (CF-C), Cancer Fatigue Scale (CFS), Chinese version of CFS (CFS-C), Cancer Fatigue Scale (CF), Brief Fatigue Inventory (BFI), Cancer-Related Fatigue Questionnaire, Piper Fatigue Scale-Revised (PFS-R), and Schwartz Cancer Fatigue Scale (SCFS). Content validity was uncertain for all assessment tools, with evidence quality rated as moderate or below. Nineteen scales received a Grade B recommendation, and three scales received a Grade C recommendation.

Conclusion

The MFSI is currently recommended for assessing fatigue in cancer patients (Grade B recommendation), though its methodological quality and measurement properties require further improvement.

Keywords

Carcinoma; Fatigue; Assessment tools; Measurement properties; COSMIN; Quality evaluation

Introduction

Research from the National Cancer Center in 2024 shows that cancer patient survival rates continue to improve [1]. Cancer-related fatigue (CRF) represents one of the most prevalent and distressing symptoms among cancer patients [2], affecting not only work, social interactions, emotional stability, daily activities, and overall quality of life, but also leading some patients to discontinue treatment and impacting long-term survival quality [3]. Studies indicate that approximately 52.07% of cancer patients experience severe fatigue [4]. The National Comprehensive Cancer Network (NCCN) CRF guidelines (2023 edition) [5] define CRF as “a distressing, persistent, subjective sense of physical, emotional, and/or cognitive tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning.” Accurate assessment of patient fatigue symptoms is crucial for developing effective interventions. Currently, numerous assessment tools exist for cancer patient fatigue, varying considerably in measurement content and scoring methods, yet systematic evaluation of their psychometric properties is lacking,

leaving clinicians without adequate guidance for tool selection.

This study follows the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) [6] to evaluate the methodological quality and measurement properties of cancer patient fatigue assessment tools, aiming to identify high-quality instruments and provide clinical evidence for future fatigue assessment and empirical research in cancer patients.

Methods

1.1 Inclusion and Exclusion Criteria

Inclusion criteria:

(1) Study subjects were cancer patients; (2) Studies evaluated measurement properties of cancer patient fatigue assessment tools; (3) At least one measurement property was evaluated; (4) Full-text articles available in Chinese or English.

Exclusion criteria:

(1) Scales used solely as outcome measures (e.g., in intervention studies); (2) Secondary studies (reviews, systematic reviews); (3) Duplicate publications.

1.2 Search Strategy

Eight databases were searched from inception to May 31, 2024: CNKI, Wanfang Data, VIP, SinoMed, PubMed, Embase, Cochrane Library, and Web of Science. The search strategy developed by Terwee et al. [7] was adapted using a combination of subject headings and free-text terms. Chinese search terms included: “癌” (cancer), “癌症” (cancer), “肿瘤” (tumor), “疲劳” (fatigue), “疲惫” (exhaustion), “倦怠” (lassitude), “量表” (scale), “问卷” (questionnaire), “工具” (tool), “信度” (reliability), and “效度” (validity). English search terms included: “neoplasms,” “cancer,” “tumor,” “carcinoma,” “oncology,” “fatigue,” “exhaustion,” “lassitude,” “tiredness,” “burnout,” “assessment,” “evaluation,” “instrument,” “questionnaire,” “measurement,” “tool,” “scale,” “reliab,” “valid,” and “psychometr.” *The PubMed search strategy was: (“neoplasms” [MeSH Terms] OR “cancer” [Title/Abstract] OR “tumor” [Title/Abstract] OR “oncology” [Title/Abstract]) AND (“fatigue” [MeSH Terms] OR “exhaustion” [Title/Abstract] OR “lassitude” [Title/Abstract] OR “tiredness” [Title/Abstract] OR “burnout” [Title/Abstract] OR “tired” [Title/Abstract] OR “weariness” [Title/Abstract] OR “low energy” [Title/Abstract]) AND (“tool” [Title/Abstract] OR “instrument” [Title/Abstract] OR “questionnaire” [Title/Abstract]) AND (“reliab” [Title/Abstract] OR “valid” [Title/Abstract] OR “psychometr” [Title/Abstract]).*

1.3 Literature Screening and Data Extraction

Two researchers independently screened literature and extracted data according to the inclusion and exclusion criteria. Extracted data included: author, publication year, scale name, country, sample size, study subjects and sources, scale

dimensions, number of dimensions and items, scoring method, completion time, and retest interval.

1.4 Evaluation Steps

Two researchers trained in evidence-based methodology independently evaluated the methodological quality, measurement properties, and evidence levels of included studies according to the COSMIN guidelines (2018 edition) [6]. Disagreements were resolved by a third reviewer to form final recommendations.

1.5.1 COSMIN Risk of Bias Checklist

The COSMIN Risk of Bias Checklist [7] was used to evaluate methodological quality across 10 domains: scale development, content validity, structural validity, internal consistency, stability, measurement error, hypothesis testing, cross-cultural validity, criterion validity, and responsiveness. A 4-point rating system was applied: very good (V), adequate (A), doubtful (D), and inadequate (I). The lowest item score determined the overall domain rating following the “worst score counts” principle.

1.5.2 COSMIN Quality Criteria

The COSMIN quality criteria [8] were used to evaluate nine measurement properties: content validity, structural validity, internal consistency, stability, measurement error, hypothesis testing, cross-cultural validity, criterion validity, and responsiveness. Each property was rated as sufficient (+), insufficient (-), or uncertain (?).

1.5.3 COSMIN Modified GRADE

The COSMIN modified GRADE approach [9] was used to grade evidence quality. Each measurement property started as “high quality” and was downgraded based on four factors: risk of bias, inconsistency, indirectness, and imprecision, resulting in four final grades: high, moderate, low, or very low. Recommendations were formulated based on measurement properties and evidence grades [10]: Grade A (recommended) required sufficient content validity (+) and sufficient internal consistency (+); Grade B (not Grade A or C, shows potential but requires further research); Grade C (high-quality evidence shows any measurement property is insufficient (-)).

Results

2.1 Literature Screening

The search yielded 6,564 articles, with 10 additional articles identified through reference tracking. After removing duplicates, 4,896 articles remained. Following title/abstract screening and full-text review according to inclusion and

exclusion criteria, 22 articles [11-32] were finally included. The literature screening process is shown in Figure 1 [Figure 1: see original paper].

2.2 Basic Characteristics of Included Studies

The 22 included studies involved 22 assessment tools: PedsQL™MFS, Chinese version of PedsQL™MFS, FACT-F, Chinese version of FACT-F, MFI-20, Chinese version of MFI-20, Cancer-Related Fatigue Scale, Cancer-Related Fatigue Comprehensive Screening Scale, Self-rating Scale for Cancer-Related Fatigue, MFSI, Chinese version of MFSI-SF, FSI, DFCS, Childhood Fatigue Scale, Chinese version of Childhood Fatigue Scale (CF-C), Cancer Fatigue Scale (CFS), Chinese version of CFS (CFS-C), Cancer Fatigue Scale (CF), BFI, Cancer-Related Fatigue Questionnaire, PFS-R, and SCFS. Six studies [11,21,25,30-31] focused on specific cancer types. One scale [29] was unidimensional, while the rest were multidimensional. Two studies [18,28] used numeric rating scales, one [22] used a visual analog scale, and the remainder used Likert scales. Basic characteristics are presented in Table 1 .

2.3 Evaluation of Methodological Quality and Measurement Properties

None of the 22 included studies evaluated measurement error, cross-cultural validity, or responsiveness. Other methodological quality and measurement property evaluations are shown in Table 2 .

2.3.1 Content Validity Except for three studies [12,15,29], all others evaluated content validity through expert consultation. Two studies [18-19] consulted both experts and patients, employing quantitative surveys and qualitative interviews with detailed descriptions and analyses, resulting in “sufficient” measurement properties. However, none of the 22 studies clearly described whether experienced interviewers were employed, whether interviews were transcribed verbatim, or whether at least two researchers participated in analysis, leading to “doubtful” methodological quality ratings.

2.3.2 Structural Validity Except for three studies [11-12,23], the remaining 19 conducted exploratory factor analysis (EFA) and/or confirmatory factor analysis (CFA). Nine studies [14,15,17-20,25-26,28] performed CFA, with two [17,25] achieving comparative fit index (CFI) >0.95 and adequate sample size, resulting in “very good” methodological quality and “sufficient” measurement properties. Six studies [13,16,24,27,29,32] showed that at least 50% of variance was explained or Pearson correlation coefficients ≥ 0.80 [33], yielding “sufficient” measurement properties. Three studies [12,23,30] had “inadequate” methodological quality due to lack of CFA/EFA reporting [12,23] or insufficient sample size [30]. All studies used classical test theory (CTT).

2.3.3 Criterion Validity Currently, no gold standard exists for cancer-related fatigue. COSMIN recommends using the original scale as the gold standard for newly developed brief scales [6]. LEE et al. [34] suggest that in the absence of an original scale, tools with similar measurement scope or more comprehensive multidimensional instruments may serve as gold standards. Eight studies [16-22,29] reported criterion validity. Two studies [17,22] demonstrated “very good” methodological quality and “sufficient” measurement properties (correlation with BFI = 0.7 [17]; AUC = 0.86 using MFI as gold standard [22]). Three studies [16,18-19,20] had “inadequate” methodological quality due to using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire as reference [16], lacking original scale reference [20], or showing correlations <0.70 with validated fatigue scales [18-19]. Two studies [21,29] used POMS-F, SF-36, or FACT-F as references but did not report correlations, resulting in “uncertain” measurement properties.

2.3.4 Internal Consistency All included studies reported internal consistency. Thirteen studies [13-15,17,21-23,26,28-32] reported internal consistency for each dimension with Cronbach’s α coefficients >0.7, yielding “very good” methodological quality and “sufficient” measurement properties. Four studies [12,16,20,27] had “insufficient” measurement properties due to dimension-specific Cronbach’s α coefficients <0.7 and “inadequate” methodological quality. The remaining three studies [11,18-19] had “uncertain” measurement properties.

2.3.5 Stability Ten studies [13-14,21,23-28,30] reported stability. Seven studies [14,21,23-24,26-27,30] had “inadequate” methodological quality due to inappropriate time intervals that did not meet COSMIN’s recommended 2-week interval [35]. Two studies [25,30] reported intraclass correlation coefficients (ICC) >0.7, showing “sufficient” measurement properties. Two studies [13,28] did not report ICC but calculated Pearson or Spearman correlation coefficients with appropriate time intervals, resulting in “doubtful” methodological quality and “uncertain” measurement properties.

2.4 Evidence Level Evaluation and Recommendations

Based on COSMIN modified GRADE, the 22 assessment tools were evaluated for risk of bias, inconsistency, imprecision, and indirectness, with corresponding evidence quality downgrades and recommendations shown in Table 3 .

2.4.1 Risk of Bias All scales had “doubtful” methodological quality for content validity (downgraded by 1 level). One study [11] did not report structural validity, and three studies [12,23,30] had “inadequate” structural validity (downgraded by 2 levels); the remaining 18 studies had “very good/adequate” structural quality (no downgrade). Two studies [24-25] had “inadequate” internal consistency (downgraded by 2 levels), while 20 studies were “very good” (no downgrade). Six studies [14,21,23-24,26,29] had “inadequate” stability (downgraded by 2 levels), three studies [13,25,28] had “doubtful” stability (downgraded

by 1 level). Three studies [17,19,22] had “very good” criterion validity (no downgrade), three [18,21,29] had “doubtful” criterion validity (downgraded by 1 level), and two [16,20] had “inadequate” criterion validity (downgraded by 2 levels).

2.4.2 Imprecision One study [14] was downgraded one additional level due to a validation sample size of 50 (<100 participants).

2.4.4 Indirectness Six studies [11-12,15,21,23-24] included populations other than cancer patients, resulting in an additional one-level downgrade.

Based on these factors, all scales lacked sufficient evidence for content validity and internal consistency, receiving Grade B recommendations. Two scales [16,25] had “inadequate” internal consistency (high-quality evidence), and one scale [31] had “inadequate” structural validity (high-quality evidence), resulting in Grade C recommendations.

Discussion

3.1 Methodological Quality of Cancer Patient-Related Fatigue Scales Needs Improvement

Content validity refers to the degree of correspondence between the content of patient-reported outcome measures (PROMs) and the construct being measured [36]. The most important measurement properties are evaluated from both expert and patient perspectives regarding item relevance, comprehensiveness, and comprehensibility. Relevance is typically measured through questionnaires and qualitative interviews, yet most qualitative studies had methodological issues: failure to report interviewer training, interview guide development, or specific content; unclear whether interviews were recorded and transcribed verbatim; and lack of information on data analysis methods or involvement of two researchers in analysis. Comprehensiveness was primarily assessed through expert consultation using 5-point rating scales, with limited patient involvement. Comprehensibility was evaluated through pilot testing. We recommend conducting cognitive interviews with patients to understand their perspectives on scale items, and providing more detailed descriptions of content validity research methods, procedures, and results while strictly adhering to COSMIN guideline (2018 edition) [6] reporting standards.

Structural validity refers to the correspondence between PROMs dimensions and the construct dimensions [37], primarily assessed through EFA or CFA. When construct dimensions are established, CFA is used; when uncertain, EFA is applied, with CFA being superior [38]. Among 19 studies, six [13,16,24,27,29,32] conducted only EFA without CFA, representing a significant limitation. One study [30] had “inadequate” methodological quality due to sample size being less than five times the number of items. Future scale development or validation should first use EFA to identify factors and their relationships with observed

variables to establish construct dimensions, then apply CFA to verify factor-item relationships, while strictly following COSMIN guideline (2018 edition) [6] sample size requirements.

Internal consistency refers to the interrelatedness among PROMs items [37], typically assessed using Cronbach' s α coefficient, with unidimensionality being a prerequisite. Two studies [24-25] reported only total Cronbach' s α coefficients without dimension-specific values, resulting in “inadequate” methodological quality. We recommend calculating internal consistency for each dimension first, then examining correlations between dimension-specific and total α coefficients.

Stability refers to consistency of results across multiple measurements under identical conditions, encompassing test-retest reliability, intra-rater reliability, and inter-rater reliability [6,36]. Ten studies [13-14,21,23-28,30] reported stability, but all evaluated only test-retest reliability. Seven studies [14,21,23-24,26-27,30] had retest intervals that did not meet COSMIN' s recommended 2-week standard. Two studies [13,28] calculated only Pearson or Spearman correlations without ICC. MOMAYYEZI et al. [30] used a 4-week retest interval without justification or explanation of similar measurement conditions, deviating from COSMIN guidelines. Future studies should provide rigorous design with clear justification for retest intervals, explanation of construct stability and similar measurement conditions, and report ICC and weighted kappa values to improve stability evidence.

Criterion validity reflects how well PROMs results correspond to a “gold standard” [39]. No gold standard currently exists for cancer-related fatigue scales. COSMIN guidelines propose using the original scale as the gold standard for newly developed brief scales [40]. JI Yanbo et al. [17] and BAUSSARD et al. [22] used tools with similar measurement scope as gold standards with correlations >0.70 , showing “sufficient” measurement properties. HAN Qiufeng et al. [16] used a widely used scale as reference, and XUE Xiujuan et al. [20] did not use the original scale as gold standard, both deviating from guidelines. Future scale development should follow COSMIN guidelines by using the original scale as gold standard; when unavailable, select the most comprehensive conceptually-matched tool or consider developing new tools or using multiple tool combinations for more comprehensive criterion validity assessment.

3.2 Measurement Properties of Cancer Patient-Related Fatigue Scales Need Improvement

None of the 22 included studies evaluated cross-cultural validity, measurement error, or responsiveness. Cross-cultural validity refers to the consistency of item scores across different cultural groups, assessed through measurement invariance or differential item functioning (DIF) [39], which validates consistency and accuracy across cultures and enhances overall research reliability. Measurement error includes systematic and random errors [35]; evaluating measurement error helps identify tool problems for targeted improvement and promotes tool

development. Responsiveness indicates longitudinal validity [37], reflecting sensitivity to changes in individual health status. Highly responsive tools can more accurately evaluate treatment effects in clinical practice. Assessing these three properties is essential, and future development/validation should strictly follow guideline requirements to improve tool quality.

3.3 MFSI Scale Can Be Temporarily Recommended but Measurement Properties Still Need Improvement

This systematic review identified 19 scales with Grade B and 3 scales with Grade C recommendations. The MFSI was the most frequently evaluated scale with relatively comprehensive measurement properties. Compared to other Grade B scales, MFSI had moderate-to-high quality evidence supporting its content and structural validity, plus low-to-moderate quality evidence for criterion validity and hypothesis testing. Other scales lacked comprehensive validation. The MFSI was developed through literature review, expert consultation, qualitative interviews, and reference to existing fatigue scales, comprising five dimensions (general fatigue, emotional fatigue, physical fatigue, mental fatigue, and vigor) with 30 items using a 5-point Likert scale (0-4), where higher scores indicate greater fatigue severity. It provides comprehensive fatigue assessment with good clinical utility. DONOVAN et al. [41] systematically reviewed MFSI studies in 2015, finding Cronbach's α coefficients of 0.83-0.90, indicating good psychometric properties. In 2013, XUE Xiujuan et al. [20] validated the Chinese version, finding a total Cronbach's α of 0.89 and split-half reliability coefficients of 0.89 and 0.74, supporting its use for Chinese cancer patients. Therefore, the MFSI can be temporarily recommended, though some measurement properties remain incompletely reported with vague statistical methods, and its methodological quality and evidence grade require further improvement.

Limitations

This study has several limitations: (1) Some COSMIN criteria involve subjectivity, and inclusion of only Chinese and English literature may introduce bias. (2) Some included studies were published before COSMIN guidelines, making certain property evaluations difficult. (3) No validation studies of the scales were included, potentially affecting reliability. Results should be interpreted cautiously.

Conclusion

Following guideline standards, this study comprehensively evaluated cancer patient fatigue assessment tools, finding that methodological and measurement properties require improvement. After comprehensive consideration, the MFSI is temporarily recommended as it multidimensionally assesses cancer-related fatigue, helping healthcare professionals better understand fatigue severity and impact to develop more effective interventions. Future development and valida-

tion of cancer patient fatigue assessment tools should strictly follow COSMIN guidelines to improve tool quality.

Author Contributions

ZHOU Hongmei: conceptualization, data analysis, manuscript writing and revision; HE Lin and WANG Ning: literature collection, data extraction; XU Hui: quality supervision and review.

Conflict of Interest

The authors declare no conflict of interest.

Registration

ZHOU Hongmei: <https://orcid.org/0009-0002-4025-0875>
PROSPERO Registration: CRD42024519924

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Note: Figure translations are in progress. See original paper for figures.

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