Systematic Review of Fear of Cancer Recurrence Assessment Tools Based on COSMIN Guidelines: Postprint

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Abstract

Background Currently, there are numerous scales available domestically and internationally for assessing fear of cancer recurrence, primarily self-report scales. However, there is a lack of systematic evaluation of the psychometric properties of these scales, which creates difficulties in selecting appropriate assessment tools.

Objective To systematically evaluate the psychometric properties and methodological quality of studies on assessment tools for fear of cancer recurrence in cancer patients, and to provide a reference for healthcare professionals to select more suitable assessment tools.

Methods Searches were conducted in PubMed, Embase, Web of Science, CINAHL, CNKI, VIP, Wanfang, and the Chinese Biomedical Literature Database for studies evaluating the psychometric properties of fear of cancer recurrence scales, with the search period from database inception to September 10, 2022. Two researchers independently extracted data. The Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) systematic review guideline was employed to evaluate the included assessment tools, and final recommendations were formulated.

Results A total of 24 studies were included, involving six fear of cancer recurrence instruments: Fear of Cancer Recurrence Inventory (FCRI), Fear of Progression Questionnaire (FOPQ), 7-item Fear of Cancer Recurrence Scale (FCR-7), Single-item Fear of Cancer Recurrence Scale (FCR-1), Cancer Worry Scale (CWS), and Assessment of Survivor Concerns (ASC). Regarding measurement property quality: except for FCR-1 and FCR-7 having "inadequate" content validity and CWS being "not reported," the remaining scales were "indeterminate" ; except for ASC having "adequate" structural validity and FCR-1

being "not reported," the remaining scales were "indeterminate" ; for internal consistency, except for FCR-1 being "indeterminate" and ASC being "inadequate," the remaining scales were "adequate" ; for stability, except for FCR-1 and CWS being "indeterminate" and ASC being "not reported," the other scales were "adequate" ; for criterion validity, except for ASC being "not reported," the remaining scales were "inadequate" ; for cross-cultural validity, FCRI and ASC were "indeterminate," while the remaining scales were not reported. Ultimately, FCRI, FOPQ, FCR-7, FCR-1, and CWS received a Grade B recommendation, while ASC received a Grade C recommendation.

Conclusion Compared with the other five scales, the psychometric properties of FCRI have been more comprehensively evaluated and demonstrate good reliability and validity, thus it can be tentatively recommended for use, though other psychometric properties still require validation.

Full Text

Preamble

A Systematic Review of Cancer Recurrence Fear Assessment Tools Based on COSMIN Guidelines

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Abstract

Background: Currently, numerous scales are available domestically and internationally for assessing fear of cancer recurrence (FCR), most of which are self-report instruments. However, systematic evaluation of the psychometric properties of these scales is lacking, creating difficulties in tool selection.

Objective: To systematically evaluate the measurement properties and methodological quality of assessment tools for FCR in cancer patients, providing a reference for healthcare professionals to select more appropriate evaluation instruments.

Methods: We searched PubMed, Embase, Web of Science, CINAHL, CNKI, VIP, Wanfang, and China Biomedical Literature Database for studies evaluating the psychometric properties of FCR scales from inception to September

10, 2022. Two researchers independently extracted data. The Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) systematic review guidelines were used to evaluate the included tools and formulate recommendations.

Results: Twenty-four studies were included, involving six FCR assessment instruments: Fear of Cancer Recurrence Inventory (FCRI), Fear of Progression Questionnaire (FOPQ), 7-item Fear of Cancer Recurrence Scale (FCR-7), single-item Fear of Cancer Recurrence Scale (FCR-1), Cancer Worry Scale (CWS), and Assessment of Survivor Concerns (ASC). Regarding measurement property quality: content validity was "inadequate" for FCR-1 and FCR-7, "unreported" for CWS, and "uncertain"for the remaining scales; construct validity was "sufficient" for ASC, "unreported" for FCR-1, and "ambiguous" for other scales; internal consistency was "uncertain" for FCR-1, "inadequate" for ASC, and "adequate" for other scales; stability was "uncertain" for FCR-1 and CWS, "unreported" for ASC, and "adequate" for other scales; criterion validity was "inadequate" for all scales except ASC ("unreported"); cross-cultural validity was "uncertain" for FCRI and ASC, and "unreported" for remaining scales. Ultimately, FCRI, FOPQ, FCR-7, FCR-1, and CWS received Level B recommendations, while ASC received Level C.

Conclusion: Compared with the other five scales, FCRI's measurement properties have been more comprehensively evaluated and demonstrate good reliability and validity, making it provisionally recommendable, though further validation of other psychometric properties is still needed.

Keywords: Cancer; Fear of recurrence; Measurement characteristics; Systematic review; Assessment instruments; COSMIN guideline

Introduction

Recent international cancer research data show a rising global cancer incidence [1], with projections exceeding 28.4 million new cases by 2040 and 43.8 million five-year cancer survivors [2]. Due to cancer' s propensity for recurrence and metastasis, fear of cancer recurrence has become one of the most common psychological responses among cancer patients. Fear of cancer recurrence (FCR) refers to "patients' fear and worry about potential future cancer recurrence or progression." Approximately 39% to 97% of cancer patients worldwide report fearing cancer recurrence or deterioration [3], with 49% experiencing moderate to severe FCR [4,5]. At the individual level, high FCR can lead to social avoidance [6], sleep disorders [7], decreased treatment adherence [8], and negative emotions [9]; at the societal level, it contributes to increased clinical healthcare costs. Therefore, scientifically sound and applicable assessment tools are crucial for measuring FCR levels and improving clinical care and research quality.

Currently, numerous scales are available for evaluating FCR, primarily self-

report instruments, yet no systematic evaluation of their psychometric properties exists. Measurement properties are indicators reflecting scale quality, including reliability, validity, and responsiveness, with good psychometric characteristics being prerequisites for scale application. The Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) is an expert-consensus-based guideline for selecting patient-reported outcome measures (PROMs) [10] that can evaluate both the methodological quality and measurement properties of assessment tools to formulate final recommendations. This study systematically reviews FCR assessment tools according to COSMIN guidelines to screen for high-quality instruments and provide evidence-based support for future FCR assessment and empirical research among Chinese cancer patients.

Methods

1.1 Inclusion and Exclusion Criteria

Inclusion criteria: (1) Cancer patients as study subjects; (2) FCR as the study content; (3) Evaluation of at least one measurement property of the tool; (4) Full-text availability in Chinese or English.

Exclusion criteria: (1) Scales applicable only to specific cancer types; (2) Scales used solely as outcome measures in randomized controlled trials; (3) Non-Chinese/English versions; (4) Review articles, duplicate publications, or studies without statistical analysis.

1.2 Search Strategy

We employed a combination of subject headings and free-text terms, supplemented by manual reference checking of included studies. Databases searched included PubMed, Embase, Web of Science, CINAHL, CNKI, VIP, Wanfang, and China Biomedical Literature Database from inception to September 10, 2022. Chinese search terms included: cancer, fear of cancer recurrence, scale, instrument, reliability. English search terms included: fear of cancer recurrence, instrumentation, psychometr*, assessment, reliab*, valid*, cross-cultural equivalence. The specific PubMed search strategy is shown in Figure 1 [Figure 1: see original paper].

1.3 Literature Screening and Data Extraction

Two researchers (the first and second authors) independently screened literature and extracted data according to the search strategy and inclusion/exclusion criteria, with discrepancies resolved by a third party (the third author). Extracted data included first author, development year, scale name, study region, target population (original and validation populations), dimensions/item numbers, and sample size.

1.4 Evaluation Process and Tools

1.4.1 Evaluation Process Two rigorously trained researchers (the first and fourth authors) independently evaluated the methodological quality, measurement properties, and evidence levels of included tools according to COSMIN guidelines [11], with discrepancies resolved by a third party (the fifth author), ultimately forming recommendations.

1.4.2 Evaluation Tools 1.4.2.1 COSMIN Methodological Quality Assessment

The COSMIN Risk of Bias checklist was used to evaluate methodological quality across modules including: scale development (35 items), content validity (31 items), construct validity (4 items), internal consistency (5 items), hypothesis testing (7 items), criterion validity (3 items), stability (8 items), cross-cultural validity (4 items), measurement error (6 items), and responsiveness (13 items). Each module item was rated as "very good (V)," "adequate (A)," "doubtful (D)," or "inadequate (I)," with the lowest score determining the overall rating.

1.4.2.2 COSMIN Measurement Property Quality Evaluation

The COSMIN criteria for measurement properties [12], developed by Terwee et al., evaluate nine measurement properties (content validity, construct validity, internal consistency, cross-cultural validity, reliability, measurement error, criterion validity, hypothesis testing, and responsiveness), with ratings of "sufficient (+)," "insufficient (-)," or "uncertain (?)."

1.4.2.3 Evidence Synthesis, Grading, and Recommendations

(1) Modified GRADE methodology [12] was used to synthesize evidence for each measurement property. Consistent results across studies were summarized as "sufficient (+)," "insufficient (-)," or "uncertain (?)," while inconsistent results were rated as "inconsistent (±)."

(2) Evidence grading: Using the modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, each measurement property started as "high quality" and was downgraded based on risk of bias, inconsistency, imprecision, and indirectness, resulting in four final grades: "high," "moderate," "low," or "very low."

(3) Recommendations: Based on measurement property and evidence grade evaluations [15]: 1) Level A recommendation: Sufficient content validity (any evidence grade) AND sufficient internal consistency (at least low-quality evidence)—recommended for use; 2) Level B recommendation: Neither Level A nor C—potentially applicable but requires further research; 3) Level C recommendation: High-quality evidence showing any measurement property as "insufficient (-)" —not recommended.

Results

2.1 Literature Screening Results

The initial search yielded 3,239 articles, with 6 additional articles identified through manual reference checking. After removing 1,677 duplicates and applying inclusion/exclusion criteria, 24 studies were ultimately included, involving six FCR scales for cancer patients. The screening flowchart is shown in Figure 2 [Figure 2: see original paper].

2.2 Basic Characteristics of Included Studies

The 24 included studies encompassed six FCR assessment instruments: The Fear of Cancer Recurrence Inventory (FCRI), Fear of Progression Questionnaire (FOPQ), 7-item Fear of Cancer Recurrence Scale (FCR-7), single-item Fear of Cancer Recurrence Scale (FCR-1), Cancer Worry Scale (CWS), and Assessment of Survivor Concerns (ASC). Ten studies evaluated the FCRI scale, providing relatively comprehensive assessment of its psychometric and methodological properties, including Li' s [16] 9-item short version and Chinese versions translated by Xu [17] and Su [18]. Five studies evaluated FOPQ, including Youssef' s [19] FOPQ-RS rapid screening version and Wu' s [30] Chinese translation of the FOPQ-SF short form. Basic characteristics are shown in Table 1 .

2.3 Psychometric Properties and Methodological Quality Evaluation

COSMIN categorizes measurement properties into three domains: validity (content validity, construct validity [structural validity, hypothesis testing, cross-cultural validity], criterion validity), reliability (internal consistency, stability, measurement error), and responsiveness. None of the 24 studies [16-39] evaluated measurement error, responsiveness, or hypothesis testing. Other methodological and measurement property quality evaluations are shown in Table 2 .

All 24 studies clearly described the scale' s construct and theoretical model in PROM design. Sixteen studies [16, 17, 19, 21, 24, 26, 28, 29, 31-39] lacked reporting on the scale development process regarding relevance, comprehensiveness, and comprehensibility, resulting in "uncertain" methodological quality ratings. Three studies [20, 25, 27] conducted detailed qualitative interviews and quantitative surveys on concept relevance and comprehensiveness during PROM development, achieving "adequate" methodological quality.

2.3.2 Validity Indicators 2.3.2.1 Content Validity

Fourteen studies [17-23, 25, 27-29, 34-36] evaluated content validity through expert consultation, with eleven studies [17, 18, 20-23, 25, 27-29, 34-36] consulting both experts and patients. While qualitative research on patient "comprehensibility" and "relevance" was common, research on "comprehensiveness"

was insufficient. Among five Chinese translation studies [18, 28, 30, 31, 34], qualitative content was minimal or used only surveys to evaluate content validity with unclear research processes and statistical methods. Additionally, most studies lacked detailed descriptions of qualitative data analysis procedures. Consequently, these studies received "doubtful" methodological quality ratings and "uncertain" or "inadequate" content validity ratings.

2.3.2.2 Construct Validity

Except for three studies [16, 22, 36], all 21 studies conducted exploratory/confirmatory factor analysis. Fourteen studies [17-19, 21, 23-26, 29, 30, 32, 33, 35, 37] used confirmatory factor analysis (CFA) to evaluate structural validity. Three studies [18, 23, 39] achieved comparative fit index (CFI) >0.95 with adequate sample sizes and no other methodological flaws, receiving "very good" methodological quality ratings and "sufficient" structural validity ratings. One study [22] was rated "inadequate" due to insufficient sample size. Two studies [17, 33] used item response theory (IRT) for structural validity evaluation, while others used classical test theory (CTT).

2.3.2.3 Criterion Validity

Currently, no gold standard exists for FCR measurement. COSMIN guidelines state that the original scale can serve as a gold standard for short-form versions. Eight studies [16, 17, 19, 24, 34, 36-38] reported criterion validity but none used the original scale as their gold standard, failing to meet COSMIN criteria. These studies received "inadequate" methodological quality ratings and "insufficient" criterion validity ratings.

2.3.3 Reliability Indicators 2.3.3.1 Internal Consistency

Eighteen studies [17, 18, 20, 21, 23-26, 28-32, 34, 37-39] calculated internal consistency for each dimension, receiving "very good"methodological quality ratings. Sixteen studies reported Cronbach' s α coefficients >0.7 for all dimensions, resulting in "sufficient" internal consistency ratings. One study [39] received an "insufficient"rating due to a Cronbach's α <0.7 for the "health worry"dimension. Five studies [16, 19, 22, 35, 36] did not report dimension-level Cronbach' s α coefficients, receiving "inadequate" methodological quality ratings.

2.3.3.2 Stability

Twelve studies reported test-retest reliability [17, 18, 20-27, 34, 37]. One study [26] achieved "very good" methodological quality, while the remaining eleven failed to report on patient stability between assessments, similarity of testing conditions, or appropriate time intervals, receiving "doubtful" ratings. Most studies used a one-month retest interval, contradicting COSMIN's recommended two-week interval. Four studies [17, 22, 25, 26] reported intraclass correlation coefficients (ICC) >0.7, achieving "sufficient"stability ratings. Other studies only reported Pearson or Spearman correlations without ICC, resulting in "uncertain" stability ratings.

2.3.3.3 Cross-Cultural Validity/Measurement Invariance

Only three studies [17, 23, 25] evaluated measurement invariance across age or gender groups, but two [23, 25] had sample sizes below COSMIN minimum requirements, receiving "inadequate" methodological quality ratings. All three studies received "uncertain" cross-cultural validity ratings. Notably, five Chinese translation studies failed to conduct cross-cultural validity testing, highlighting the need for future research to examine differential item functioning (DIF) across cultures.

2.4 Evidence Grading and Recommendations

We synthesized measurement property quality for each tool and downgraded evidence quality based on risk of bias, inconsistency, imprecision, and indirectness. Evidence grading and recommendations are detailed in Table 3 .

Risk of bias: Except for CWS content validity being "unreported," the other five scales had "inadequate" or "uncertain" content validity, indicating potential major bias and warranting a one-level downgrade. All six scales had "sufficient" structural validity methodology, indicating "no" risk of bias. For internal consistency, four scales had "very good" methodology while two had "inadequate" or "uncertain" methodology, each receiving a one-level downgrade.

Inconsistency: FOPQ showed inconsistency across studies, and FCR-7 showed inconsistency in structural validity and internal consistency, warranting a one-level downgrade. Other scales were each represented by only one study, showing no inconsistency.

Imprecision: FCRI and FCR-1 received one-level downgrades for stability due to retest samples <100 participants. Other scales met sample size requirements.

Indirectness: FOPQ studies included non-cancer chronic disease patients (e.g., diabetes), creating indirectness and warranting a one-level downgrade for all measurement properties.

Considering all downgrading factors, five scales had only moderate or lower-quality evidence supporting "inadequate/uncertain" content validity, resulting in Level B recommendations. ASC received Level C due to "inadequate" internal consistency with high-quality evidence. Details are shown in Table 3.

Discussion

3.1.1 Incomplete Content Validity Reporting with Lack of Qualitative Methods

COSMIN guidelines require evaluating relevance, comprehensiveness, and comprehensibility of assessment tools, with content validity being the most important measurement property. However, the primary deficiency in included studies

was inadequate consideration of content validity. Among five Chinese studies [18, 28, 30, 31, 34], limitations existed in data analysis processes (transcription, analytical methods, researcher qualifications). While Simard and Peter provided detailed descriptions of content validity research design for FCRI and FOPQ development, both lacked transcription process details. Jakobsen [22] conducted detailed qualitative research during FCRI localization but did not clearly describe the number of transcribers. Su [18] consulted only seven nursing experts during the Delphi process, failing to meet COSMIN' s requirement for "including professionals from all relevant disciplines."Humphris [33], Lee [35], and Lebel [35] did not achieve data saturation during scale development, affecting PROM generalizability and comprehensibility. Furthermore, many studies over-relied on expert consultation without adequately considering or clearly describing patient perspectives. Future research should incorporate cognitive interviewing to understand patients' views and comprehension of scales, improving item-content congruence. Study design and data analysis should strictly follow COSMIN standard procedures with rigorous reporting.

3.1.2 Unclear Test-Retest Methods Requiring Further Stability Validation

Stability refers to consistency of results when measuring the same subjects repeatedly using identical methods [40]. Among 24 included studies, 11 did not report stability, 11 had "doubtful" methodological quality for stability, and only 2 achieved adequate or better ratings. For example, Simard [20] used a one-month retest interval without clear justification, contradicting COSMIN' s recommended two-week interval, resulting in "doubtful" methodological quality ratings. Inappropriate retest intervals can overestimate or underestimate reliability [41]. Some studies met time interval requirements but only calculated Pearson/Spearman correlations without ICC, yielding "doubtful"ratings. Stability of the measured construct and similarity of pre-post measurement contexts are also crucial—changes in measurement context may underestimate stability. Most studies failed to provide clear evidence of construct and situational stability, requiring greater attention in future research design.

3.1.3 Insufficient Cross-Cultural Validity Testing for Translated Scales

Cross-cultural validity refers to consistency of item scores when applying tools across different cultural groups, primarily evaluated through measurement invariance or differential item functioning (DIF). Only three studies evaluated cross-cultural validity, but two had inadequate sample sizes per COSMIN guidelines. All five Chinese translation studies failed to conduct cross-cultural validity testing. Future scale adaptation should examine DIF across cultures and ensure adequate sample sizes (>7 times the number of PROM items), with comparable distribution of characteristic variables across groups to enhance comparability.

3.1.4 Inappropriate "Gold Standard" for Criterion Validity, Confusing with Hypothesis Testing

COSMIN guidelines state that patient-reported outcome measures have no "gold standard" in principle, though original scales can serve as gold standards for short-form versions. However, included studies used widely-used scales as "gold standards" for newly developed scales, conflating this with hypothesis testing. For example, eight studies evaluated criterion validity using "construct validity hypothesis testing," which does not meet COSMIN requirements.

3.2 Incomplete Reporting of FCR Scale Psychometric Properties

None of the 24 studies evaluated measurement error, responsiveness, or hypothesis testing. Measurement error includes systematic and random error beyond true score variation. For quantitative data, standard error of measurement should be calculated through retesting; for categorical/ordinal data, percentage agreement is recommended. Hypothesis testing validates construct validity through convergent/discriminant validity and known-groups validity. Responsiveness reflects scale sensitivity to detect changes over time or between groups. Future research should reference COSMIN guidelines to evaluate these properties.

3.3 FCRI Provisionally Recommended but Requires Further Validation

Based on systematic evaluation of psychometric properties and study quality, five scales received Level B recommendations and one received Level C. Considering that content validity is the most important property and only FCRI had moderate-quality evidence supporting its content validity, along with its comprehensive evaluation across ten studies, FCRI can be provisionally recommended. FCRI, based on cognitive-behavioral theory, multidimensionally assesses FCR across seven dimensions (triggers, severity, coping strategies, psychological distress, functional impairment, insight, reassurance seeking) with 42 items using a 5-point Likert scale (0-4, total range 0-168), where higher scores indicate greater FCR. FCRI is mature and widely used, with adaptations including FCRI-P [42] (child version) and a Chinese version translated by Su in 2018.

FOPQ, FCR-7, FCR-1, and CWS received Level B recommendations. FOPQ measures FCR in chronic disease and cancer patients across five dimensions with 43 items, widely used internationally and translated by Huang (2022) and Wu (FOPQ-SF). FCR-7 and FCR-1 are unidimensional scales convenient for quick scoring. CWS was developed for breast cancer patients and validated in colorectal and prostate cancer patients. These four scales show potential but require further research on methodological and measurement properties, particularly: (1) lack of scientific rigor in PROM development, especially missing cognitive interview documentation; (2) "doubtful"or "inadequate"content validity with unclear processes; (3) insufficient cross-cultural validity testing—all five

Chinese studies failed to evaluate this. Future scale development and adaptation should follow scientific guidelines strictly to create more rigorous, high-quality assessment tools.

Conclusion

This systematic review evaluated FCR assessment tools using COSMIN standards, revealing inconsistent methodological quality and incomplete reporting of measurement properties. Except for ASC (Level C), all scales received Level B recommendations. After comprehensive consideration, FCRI is provisionally recommended as it comprehensively assesses FCR multidimensionally, helping healthcare providers identify causes and implement targeted interventions to improve patients' quality of life and mental health. Future research should rigorously validate existing tools using COSMIN standards or develop new high-quality tools for Chinese cancer patients. This review has limitations: inclusion of only Chinese and English literature and limited measurement property studies for some tools may affect conclusion reliability.

Author Contributions: ZHANG Lu-lu conceptualized and designed the study, organized data, and drafted/revised the manuscript. ZHANG Lu-lu, CHEN Huan, LUO Huan, CHEN Ting-ting, and CHEN Xin-yu collected literature and extracted data. GAO Jing supervised quality control and manuscript revision. ZHANG Lu-lu and GAO Jing are responsible for the overall content. All authors approved the final manuscript.

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