BMJ Open Psychometric properties of self-reported financial toxicity measures in cancer survivors: a systematic review

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ABSTRACT

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Dr Weijie Xing; xingweijie@fudan.edu.cn **Objective** The aim of this systematic review was to summarise the psychometric properties of patient-reported outcome measures (PROMs) measuring financial toxicity (FT) in cancer survivors.

Design This systematic review was conducted according to the guidance of the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) methodology.

Data sources Comprehensive searches were performed in PubMed, MEDLINE, Embase, CINAHL, PsycINFO, Web of Science, ProQuest and Cochrane Library from database inception to February 2022.

Eligibility criteria for selecting studies We included studies that reported any PROMs for measuring FT in cancer survivors who were ≥18 years old. FT was defined as perceived subjective financial distress resulting from objective financial burden. Studies that were not validation studies and that used a PROM only as an outcome measurement were excluded. Data extraction and synthesis Two reviewers independently extracted data from the included papers. We used the COSMIN criteria to summarise and evaluate the psychometric properties of each study regarding structural validity, internal consistency, reliability, measurement error, hypothesis testing for construct validity, cross-cultural validity/measurement invariance, criterion validity and responsiveness.

Results A total of 23 articles (21 PROMs) were eligible for inclusion in this study. The findings highlighted that the Comprehensive Score for Financial Toxicity (COST) had an adequate development process and showed better psychometric properties than other PROMs, especially in internal consistency (Cronbach's α =0.92), reliability (intraclass correlation coefficient=0.80) and hypothesis testing (r=0.42– 0.20).

Conclusions From a psychometric property perspective, the COST could be recommended as the most suitable worldwide available measure for use in research and clinical practice across different contexts. We suggest that PROMs should be selected only after careful consideration of the local socioeconomic context. Future studies are warranted to develop various FT PROMs based on different social and cultural backgrounds and to clarify the theoretical grounds for assessing FT.

INTRODUCTION

The rising cost associated with advancements in cancer treatment and lengthening

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is the first systematic review that comprehensively summarised the psychometric properties of 21 patient-reported outcome measures (PROMs) evaluating financial toxicity in cancer survivors.
- ⇒ The results may provide quantitative evidence for researchers and healthcare professionals to choose PROMs measuring cancer survivors' financial toxicity in future scientific research and clinical practice.
- ⇒ This review only included studies that aimed to evaluate the measurement properties of financial toxicity PROMs.

of cancer survivorship poses a significant challenge to survivors, caregivers and public healthcare systems.^{1 2} Total global spending on cancer medications grows at a compound annual growth rate of 6.5%, growing from US\$96 billion in 2013 to US\$173 billion in 2020, which is nearly twice the rate of global gross domestic product growth.³⁻⁵ The majority of cancer survivors in middle-income and low-income countries/regions depend on out-of-pocket payments, which may lead to global inequalities in healthcare expenditures and financial insecurity for vulnerable groups.⁶⁷

The term 'financial toxicity (FT)' has been described as the economic effect of cancer treatment in the age of precision medicine.289 Witte et al described FT as 'the patient-reported outcome (PRO) of perceived subjective financial distress resulting from objective financial burden'.¹⁰ This concept covers both the objective financial burden and the subjective financial distress that cancer survivors face as a result of high out-of-pocket medical expenses. Regarding the terminology, 'financial toxicity', 'financial burden' and 'financial distress' are often used interchangeably in research and share a similar definition.^{10 11} In this review, the authors agreed to consistently use the term 'financial toxicity'. Financial toxicity is usually measured by PRO measures

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(PROMs); choosing a PROM with high validity and reliability is a prerequisite for robust results.

There are a few cancer-specific and generic FT PROMs that have been reported and used in different contexts. As one of the recent cancer-specific FT PROMs, the Comprehensive Score for Financial Toxicity (COST) is the most commonly used measure for assessing FT.¹² In addition to COST, other cancer-specific measures have been widely used, including the Breast Cancer Finances Survey Inventory,¹³ Socioeconomic Well-being Scale (SWBS)¹⁴ and InCharge Financial Distress/Financial Well-being Scale (InCharge).¹⁵ Additionally, validated subscales, such as the Social Difficulties Inventory Cancer Care Outcomes (SDI), the Cancer Care Outcomes Research and Surveillance Consortium patient survey, and Italian version of the Edmonton Symptom Assessment System-Total Care (TC), were also used to evaluate FT.¹⁶⁻¹⁸ However, existing PROMs vary significantly in their state of development and degree of validation, and many PROMs have not been psychometrically tested.

A preliminary literature search was conducted in PubMed, PsycINFO (EBSCO), Cochrane Library (Wiley) and Joanna Briggs Institute (Ovid), which revealed that there exist some reviews regarding measures of FT. Witte et al summarised the content of 352 items from 34 studies measuring FT in cancer survivors.¹⁰ However, this review did not report the psychometric properties of the included PROMs, and most of the included PROMs were not validated through a scientific process, which made it difficult for readers to choose the best measure from existing PROMs to evaluate the level of FT. Salman et al conducted a systematic review and found eight PROMs and two caregiver-reported measures for assessing financial burden in adolescents and young adults.¹⁹ However, this review focused only on PROMs assessing FT in adolescents and young adults with cancer. The psychological properties of FT measures in adult cancer survivors are still unknown.

The reproducibility, reliability and accuracy of PROMs are the fundamental premise for achieving robust results. Therefore, it is necessary to summarise the psychometric properties of existing PROMs for future research. However, this information is still lacking. The aim of this systematic review was to summarise the psychometric properties of PROMs for measuring FT in cancer survivors. The review was conducted according to the guidance of the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) methodology and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.^{20 21} The protocol of this review was published in *BMJ OPEN* in 2020.²² The registration number of the protocol in PROSPERO was CRD42021254721.

METHODS

Search strategy

First, we conducted a limited search via PubMed to capture keywords from which to develop search strategies

for each database. Subsequently, all identified search strategies across databases were performed in PubMed/ MEDLINE, MEDLINE (Ovid), Embase (Ovid), CINAHL (EBSCO), PsycINFO (EBSCO), Web of Science, ProQuest Dissertations and Theses, and Cochrane Library (Wiley). The search time frame was set from database inception to February 2022. To include more studies published in 2021 and 2022, the end date of the search was updated to February 2022.²² In PubMed/Medline, we searched papers in English using MeSH terms ([cancer OR neoplasms] AND ["cancer survivors" OR patient OR survivors] AND "cost of illness") combined with (cancer OR [patient* OR survivor*] AND [cost OR bill* OR expense OR productivity loss OR "out-of-pocket" OR "economic burden" OR "financial toxicity" OR "financial hardship" OR "financial burden"]). The COSMIN measurement properties filter and exclusion filter were also used in the search box. The search strategies for each database are presented in online supplemental appendix 1. Finally, the references of all included studies were manually reviewed to supplement the database search.

Inclusion and exclusion criteria

The inclusion criteria were as follows: (1) studies that reported any PROMs for measuring FT in cancer survivors who were ≥ 18 years old. If the studies reported results in a population combined with both ≥ 18 and < 18years old cancer survivors and the majority of survivors were not <18 years old, the studies were also considered; (2) studies that evaluated at least one measurement property; and (3) studies published in English. The exclusion criteria were as follows: (1) studies that were not validation studies and used a PROM only as an outcome measurement; (2) studies that used a PROM as a comparator for another instrument; (3) studies that did not provide empirical data and (4) if a measure was a quality of life PROM and had a domain that assessed FT, we included only the original version of the PROM. If the measure/domain included only one item and reported the measurement property as an independent domain, the measure/domain was also considered.

Study screening and selection

We imported all identified citations by search strategies into Endnote V.X8 (Clarivate Analytics, Pennsylvania, USA). After duplicates were removed, two reviewers (ZZ and WX) independently screened all titles, abstracts and full texts (ZZ and WX) based on the established inclusion and exclusion criteria. Any disagreements were resolved by a third reviewer (YH).

Quality appraisal

Two reviewers (HW and YS) assessed the methodological quality of the PROM of the included studies by using the COSMIN Risk of Bias Checklist (online supplemental appendix 2).¹⁹ The checklist consisted of 10 domains (116 items), including PROM development, content validity, structural validity, internal consistency, cross-cultural

validity, reliability, measurement error, criterion validity, hypothesis testing and responsiveness. Each measurement property was rated as 'very good', 'adequate', 'doubtful' or 'inadequate quality'. According to the COSMIN guidelines, the methodological quality of a single study is rated based on the worst score count method. For example, if the lowest rating is 'inadequate' in the PROM development domain, the overall methodological quality of that domain is 'inadequate'. The worst score counts method takes into account that inadequate quality items could affect the overall results of the measurement property of each PROM. Any discrepancies were resolved by a third reviewer (ZZ).

Data extraction

Two reviewers (ZZ and WX) independently extracted data from the included papers, including authors, year of publication, PROM, country/language, study design, target population, sample size, domains, number of items, total score range and main findings. The main findings regarding psychometric properties, including content validity, structural validity, internal consistency, cross-cultural validity, reliability, measurement error, criterion validity, hypothesis testing and responsiveness, were also extracted. Any discrepancies were resolved through discussion between the two reviewers.

Data synthesis

We used the COSMIN criteria to summarise and evaluate the psychometric properties of each study regarding structural validity, internal consistency, reliability, measurement error, hypothesis testing for construct validity, cross-cultural validity/measurement invariance, criterion validity and responsiveness. Each measurement property from each study was rated as sufficient (+), insufficient (-) or indeterminate (?). The criteria for the measurement property rating can be found in online supplemental appendix 2. If the ratings of one psychometric property per study were all sufficient (+) or insufficient (-), the results were pooled, and the overall rating was rated as sufficient (+) or insufficient (-). If the ratings were inconsistent, explanations of inconsistency were explored (eg, different languages). For example, in our review, different language, social, economic and cultural contexts may contribute to inconsistencies in psychometric properties. Our review team (ZZ, WJ, HW and YS) discussed the potential explanations of inconsistency. If the review team regarded the explanation as reasonable, we provided ratings ('+', '-' and '?') in subgroups (eg, language subgroup). If the explanation was not reasonable, the overall rating of this measurement property was rated as inconsistent (\pm) .

Assessing certainty of evidence

We used a modified Grading of Recommendations Assessment, Development and Evaluation system to assess the certainty of evidence.¹⁹ Each piece of evidence was graded for risk of bias, inconsistency, imprecision and indirectness. The instructions for downgrading for risk of bias, inconsistency, imprecision and indirectness are shown in Appendix II. Four reviewers (ZZ, WJ, HW and YS) independently assessed the grade. Any discrepancies were resolved by discussion.

Patient and public involvement

No patients or the public were directly involved in the development of the research question, selection of the outcome measures, design and implementation of the study, or interpretation of the results.

RESULTS

Literature search

Figure 1 shows the process of literature screening and selection. A total of 9399 articles were identified via databases. Six articles were found by additional supplementary searches. After duplications were removed, a total of 11 731 articles were retained, 11 669 articles were deleted after reading the title and abstract, and 39 were deleted after full-text reading. Finally, a total of 23 articles (21 PROMs) were eligible for inclusion in this study.¹²¹⁴¹⁶²³⁻⁴²

Study description

Table 1 shows the characteristics of the included studies. All included studies were published from 2005 to 2022. Eight studies were conducted in the USA, ¹² ¹⁴ ²³ ²⁷ ³⁰ ³⁷ ³⁹ ⁴¹ four in the UK, ¹⁶ ²⁹ ³⁵ ³⁸ two in Canada³¹ ³⁶ and two in China (mainland and Hong Kong), ²⁵ ³⁹ India²⁶ ³⁴ and Italy.³³ ⁴² One study was conducted in 12 countries in Europe and North America.²² ²³ Other studies were conducted in Brazil³² and Iran. ³⁴ A total of 12 362 participants were included, ranging from 7³⁶ to 5901⁴¹ per study. The majority of studies assessed FT in multiple types of cancer. Only two studies focused on a single type of cancer, namely, lung, colorectal, or head and neck cancer.³¹ ³⁷

Among the 21 PROMs, 7 were FT-related domains of quality of life PROMs and 14 were independent PROMs focusing on FT. All PROMs were validated in cancer survivors. Fifteen PROMs were in English, ¹²¹⁴¹⁶²³²⁵⁻³¹³⁵³⁷³⁸⁴⁰⁻⁴² and two were in Chinese.^{24 39} Other languages included French,³⁶ Portuguese,³² Italian,^{33 42} Hindi^{25 26} and Persian.³⁴ The number of items evaluating FT ranged from 3⁴⁰ to 23.³⁶ The French version of the Patient Self-Administered Financial Effects Questionnaire (P-SAFE) did not report the total score range of the whole PROM.³⁶

Quality assessment

Methodological quality assessment

Table 2 shows the methodological quality of the 23 included studies by using the COSMIN checklist. In the PROM development domain, only one study was rated as adequate,⁴² three studies were rated as doubt^{12 24 27 29} and the others were rated as inadequate. Two studies reported adequate information in testing the relevance, comprehensiveness and comprehensibility of PROMs.^{12 27 29} One study reported adequate

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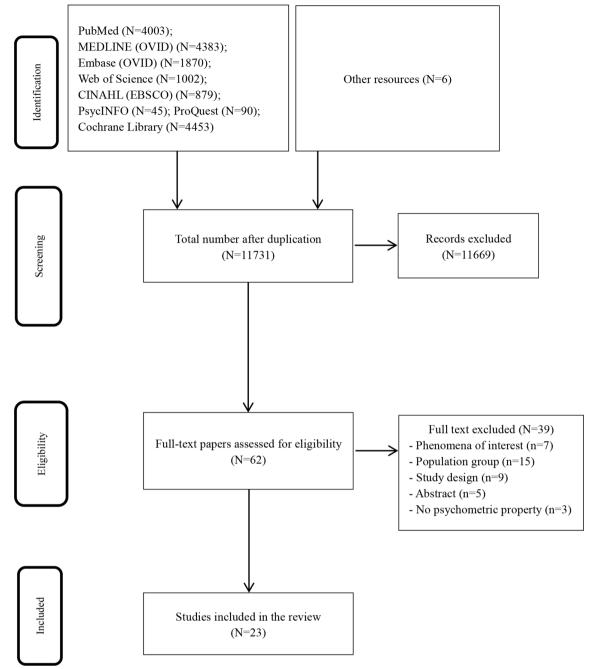


Figure 1 PRISMA flow chat of selection process. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

relevance and comprehensiveness.⁴² Among all studies, the most reported domain was internal consistency, except one study.³⁶ Limited information could be retrieved on cross-cultural validity (3 studies),^{31 32 36} criterion validity (6 studies),^{16 23 33 35 38 40} reliability (10 studies),^{12 16 24 27 28 33 35 38-40 42} and responsiveness (2 studies).^{31 39} No data were identified as measurement error.

Measurement property assessment

Table 3 shows the quality of the psychometric properties retrieved from 21 PROMs. Only the Persian version of the COST-v2 and Subjective Financial Distress Questionnaire (SFDQ) were rated as '+' in structural validity.²⁶³⁴ There were 17 PROMs rated as '+' in internal consistency.^{121416 23 24 26-29 31 32 34 35 37-39 41 42} Eight PROMs were rated as '+'" in reliability.^{12 24 26-29 31 35} Ten PROMs were rated as '+' in hypothesis testing.^{121423 24 27-31 33 35 39} Limited information was retrieved on cross-cultural validity (two PROMs),^{32 36} criterion validity (six PROMs),¹⁶²⁴³³³⁵³⁸⁴⁰ and responsiveness (two PROMs).³¹³⁹ No PROMs reported data on measurement error.

Certainty of evidence

Table 4 shows the certainty of evidence for each measurement property. Among all included PROMs, the COST showed the best psychometric properties compared with other measures. The COST and its

Table 1 Ove	Overview of the included studies	ded studies							
Author (year), country	PROM	Country	Language(s) of PROM	Study design	Target population	Sample size	Measurement domain	No of items	Total score range
Avis ²³ 2005	QLACS financial problems domain	USA	English	Development and validation study	Age: 71.4±11.5 years Male: 42% Cancer type: Breast, bladder, head and neck, gynecologic, prostate, colorectal cancer	242	One domain regarding financial problems	4	4-28
Chan ²⁴ 2021	COST-v2, Traditional Hong Kong Chinese version	Hong Kong	Traditional Chinese	Validation study	Age: 59.9±11.1 years Male: 35.3% Cancer type: Breast, gynaecological, head and neck, gastric and colorectal, genitourinary, lung, naematological, skin, bone and soft tissue, brain and central nervous system cancer and others	640	No subdomain	12	0-44
Dar ²⁵ 2021	COST-v1, India version	India	Hindi or English	Validation study	Age: 49.5±16.8 years Male: 82.8% Cancer type: Tongue, gingival buccal sulcus, buccal mucosa, supraglottic larynx, hypopharynx, parotid and others	29	No subdomain	÷	0-44
Dar ²⁵ 2021	SFDQ	India	Indian or English	Development and validation study	Age: 18%-59 68.3%; ≥60 310.7% Male: 85.9% Cancer type: head and neck cancer	142	Five domains: financial resources; financial spending; psychosocial affect; coping care and coping lifestyles; support seeking	4	0-28
de Alcantara Nogueira ³² 2020	COST-v1, Brazilian version	Brazil	Brazilian Portuguese	Validation study	Mean age: 56 years Male: 40.5% Cancer type: Not specific	126	No subdomain	11	0-44
De Souza ¹² 2014 De Souza ²⁷ 2017	COST-v1	NSA	English	Development study and validation study	Age: 58.4±11.5 years Male: 41.6% Cancer type: Not specified (diagnosis of AJCC stage IV cancer)	233	No subdomain	1	0-44
Durber ²⁸ 2021	COST-v1	Australia	English	Validation study	Age: ≤50 years 23%; 51–64 years 30%; ≥65 years 48% Male: 46% Cancer type: Thoracic, breast, sarcoma, skin, central nervous system, gynaecological, head and neck, colorectal, upper gastrointestinal, urological and miscellaneous cancer	257	No subdomain	£	0-44
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Table 1 Cor	Continued								
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Author (year), country	PROM	Country	Language(s) of PROM	Study design	Target population	Sample size	Measurement domain	No of items	Total score range
Harley ²⁹ 2019	CCEQ financial advice domain	ž	English	Development and validation study	Pilot study: Age: 65 (41-90) yrs Male: 48.5% Cancer type: Breast, colorectal/ gastrointestinal, gynaecological, prostate and renal cancer Final study: Male: 50.0% Cancer type: Breast, colorectal/ gastrointestinal, gynaecological, prostate and renal cancer	103 for pilot study 313 for final study	One domain regarding financial advice	ى	5-25
Head ¹⁴ 2008	SWBS	USA	English	Development and validation study	Age: 59.6±12.7 years Male: 35.7% Cancer type: Breast, melanoma, head and neck, prostate, rectum/ anus, colon, endometrium, lung/ tracheal/bronchus and non-Hodgkin's lymphoma	266	Two domains: material and social capital.	17	0-68
Hueniken ³¹ 2020	НТ	Canada	English	Development and validation study	Age: 61.6 (25.5-88.5) yrs Male: 77.2% Cancer type: Oropharynx, oral cavity, larynx, nasopharynx, hypopharynx cancers and others	430	No subdomain	o	0-100
Ripamonti ³³ 202(Ripamonti ³³ 2020 COST-v2, Italian version	Italy	Italian	Validation study	Age: 61.5±12.7 years Male: 52.5% Cancer type: Breast, Iung, colon, gastric, hepatocellular, endometrial, prostate, sarcoma, bladder, head and neck, Hodgkin lymphoma, non- Hodgkin's lymphoma, leukaemia, myeloma and others	118	No subdomain	÷	0-44
Riva ⁴² 2021	PROFFIT	Italy	Italian or English	Development and validation study	Age: 29–82 years Male: 41.3% Cancer type: breast, lower gastrointestinal tract, genitourinary, thoracic, upper gastrointestinal tract and others	184	No subdomain	Seven outcome items and eight determinant items	0-100
Sharif ³⁴ 2020	COST-v2, Persian version	Iran	Persian	Validation study	Age: 50.0±14.3 years Male: 51.0% Cancer type: Not specific	398	No subdomain	1	0-44
Shilling ³⁵ 2018	PRRS financial well- UK being domain	с Ч	English	Development and validation study	Age: ≤50 years 25%; 51–65 years 41%; ≥66 years 34% Male: 23% Cancer type: breast, gynaecological, lung and melanoma cancers	135	One domain regarding financial well-being	0	0-24
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Author (year), country	PROM	Country	Language(s) of PROM	Study design	Target population	Sample size	Measurement domain	No of items	Total score range
Tremblay ³⁸ 2020	P-SAFE, French Version	Canada	French	Cross-adaption study	Age: 50–59 years 57%; 60–69 years 29%; ≥70 years 34% Male: 14% Cancer type: colorectal, lung, breast and prostate cancer.	2	ЯИ	23	R
Veenstra ³⁷ 2014	PFB	ASU	English	Validation study	Age: <50 years 17%; 50-64 years 37%; 65-74 years 23%; >75 years 24% Male: 53% Cancer type: Stage III colorectal cancer	956	No subdomain	2	2-0
Wright ³⁸ 2005	SDI-21 providing for the family domain	ЧĶ	English	Development and validation study	Age: 53.8±14.1 years Male: Not specific Cancer type: brain, lung cancers and others	271	One domain regarding providing for the family	2J	0-20
Wright ¹⁶ 2011	SDI-16 money matters domain	Х	English	Development and validation study	Age: 56 (18-88) yrs for men; 56 (21- 88) yrs for women Male: 48% Cancer type: breast, gastrointestinal, haematology, gynaecological, germ cell, head and neck, lung, genitourinary and others	652	One domain regarding money matters	ى	0-20
Yu ³⁹ 2021	COST-v1, Simplified Chinese version	Mainland China	Chinese	Validation study	Age: 57.0±9.2 years Male: 45.7% Cancer type: lung, stomach, colorectal and breast cancer	440	No subdomain	£	0-44
Zebrack ⁴⁰ 2010	IOC-CS financial problems domain	USA	English	Validation study	Age: 26.7±5.3 years Male: 48.0% Cancer type: haematological, brain and solid tumours/soft tissue tumours	519	One domain regarding financial problems	ო	1-15
Zhao ⁴¹ 2009	CPILS employment/ financial domain	NSA	English	Validation study	Age: <55 years 48.8%; >55 510.2% Male: 41.6% Cancer type: breast, prostate, colorectal, bladder, uterine, kidney, lung and ovarian cancer; melanoma of skin; non-Hodgkin's lymphoma,	5901	One domain regarding employment/finances	۵	0-12
AJCC, The Americar Cancer-Childhood S SAFE, Patient Self-A Well-being Scale.	n Joint Committee on Car Survivors; NR, not report; F Administered Financial Effe	icer; CCEQ, Chronic >FB, Personal Financ octs questionnaire; C	: Cancer Experiences Question cial Burden; PROFFIT, Patient NLACS, Quality of Life in Adult	nnaire; COST, Comprel -Reported Outcome fo : Cancer Survivors; SDI	AJCC, The American Joint Committee on Cancer; CCEO, Chronic Cancer Experiences Questionnaire; COST, Comprehensive Score for Financial Toxicity; CPILS, Cancer Problems in Living Scale; FIT, Financial Index of Toxicity; IOC-CS, Impact of Cancer-Childhood Survivors; NR, not report; PFB, Personal Financial Burden; PROFFIT, Patient-Reported Outcome for Fighting Financial Toxicity; PROM, Patient-Reported Outcome Measures; PRRS, Patient Roles and Responsibilities Scale; P-SAFE, Patient Self-Administered Financial Effects questionnaire; OLACS, Quality of Life in Adult Cancer Survivors; SDI, Social Difficulties Inventory Cancer Care Outcome; SFDQ, Subjective Financial Distress Questionnaire; SWBS, Socioeconomic Well-being Scale.	Cancer Problems Reported Outcorr utcomes; SFDQ,	in Living Scale; FIT, Financial ne Measures; PRRS, Patient I Subjective Financial Distress	I Index of Toxicity Roles and Respoi Questionnaire; S'	; IOC-CS, Impact of nsibilities Scale; P- WBS, Socioeconomic

	Measurement property: methodological	Measurement p	Measurement property: methodological quality by study	dological quality	/ by study						
Author (year)	PROM	PROM development	Content validity	Structural validity	Internal consistency	Cross-cultural validity	Reliability	Measurement error	Criterion validity	Hypothesis testing	Responsiveness
Avis ²³ 2005	QLACS financial problems domain	Inadequate	R: NR C1: NR C2: NR	Adequate	Very good	R	R	R	Adequate	Doubtful	R
Chan ²⁴ 2021	COST-v2, Traditional Chinese version	Doubtful	R: Doubtful C1: NR C2: Doubtful	Very good	Very good	RN	Doubtful	R	R	Very good	RN
Dar ²⁵ 2021	COST-v1, India version	Inadequate	R: NR C1: NR C2: NR	Inadequate	Very good	R	R	щ	R	R	R
Dar ²⁵ 2021	SFDQ	Inadequate	R: Adequate C1: NR C2: NR	Very good	Very good	RN	RN	К	R	R	R
de Alcantara Nogueira ³² 2020	COST-v1, Brazilian Inadequate version	Inadequate	R: NR C1: NR C2: NR	Very good	Very good	Inadequate	R	щ	R	R	R
De Souza ¹² 2014 De Souza ²⁷ 2017	COST-v1	Doubtful	R: Adequate C1: Adequate C2: Adequate	RN	Very good	NR	Adequate	R	RN	Very good	NR
Durber ²⁸ 2021	COST-v1, Australia Inadequate version	Inadequate	R: NR C1: NR C2: NR	RN	Very good	ĸ	Adequate	К	R	Very good	R
Harley ²⁹ 2019	CCEQ financial advice domain	Doubtful	R: Adequate C1: Adequate C2: Adequate	Adequate	Very good	RN	RN	щ	R	Very good	RN
Head ¹⁴ 2008	SWBS	Inadequate	R: NR C1:Doubt C2: NR	Very good	Very good	NR	RN	R	Very good	Very good	NR
Hueniken ³¹ 2020	FIT	Inadequate	R: NR C1: NR C2: NR	Adequate	Very good	Doubtful	RN	R	R	Very good	Very good
Ripamonti ³³ 2020	COST-v2, Italian version	Inadequate	R: NR C1: NR C2: NR	Inadequate	Very good	NR	Inadequate	R	Very good	Very good	NR
Riva ⁴² 2021	PROFFIT	Adequate	R: Adequate C1: Adequate C2: NR	Adequate	Very good	NR	Adequate	R	NR	NR	NR
Sharif ³⁴ 2020	COST-v2, Persian Inadequate version	Inadequate	R: NR C1: NR C2: NR	Very good	Very good	NR	RN	RN	NR	Inadequate	NR
Shilling ³⁵ 2018	PRRS financial well-being domain	Inadequate	R: NR C1: NR C2: NR	Adequate	Very good	R	Inadequate	R	Inadequate	Inadequate	R

		Measurement	Measurement property: methodological		quality by study						
Author (year)	PROM	PROM development	Content validity	Structural validity	Internal consistency	Cross-cultural validity	Reliability	Measurement error	Criterion validity	Hypothesis testing	Responsiveness
Tremblay ³⁶ 2020	P-SAFE, French Version	Inadequate	R: NR C1: NR C2: NR	NR	NR	Inadequate	NR	R	NR	R	NR
Veenstra ³⁷ 2014	PFB	Inadequate	R: NR C1: NR C2: NR	Very good	Inadequate	NR	RN	К	RN	R	NR
Wright ³⁸ 2005	SDI-21 providing for the family domain	Inadequate	R: Doubt C1: NR C2: NR	Very good	Very good	NR	RN	К	RN	R	NR
Wright ¹⁶ 2011	SDI-16 money matters domain	Inadequate	R: Doubt C1: NR C2: NR	Very good	Very good	NR	Inadequate	К	Inadequate	R	NR
Yu ³⁹ 2021	COST-v1, Simplified Chinese version	Inadequate	R: NR C1: NR C2: NR	Very good	Very good	NR	Very good	R	RN	Doubt	Doubt
Zebrack ⁴⁰ 2010	IOC-CS financial problems domain	Inadequate	R: NR C1: NR C2: Doubt	Adequate	Very good	NR	Adequate	R	Inadequate	Very good	RN
Zhao ⁴¹ 2009	CPILS employment/ financial domain	Inadequate	R: NR C1: NR C2: NR	Very good	Very good	R	RN	NR	ЯN	Very good	NR

PROM	Author (year)	Structural validity	Internal consistency	Reliability	Measurement error	Hypothesis testing	Cross-cultural validity	Criterion validity	Responsiveness
CCEQ financial advice domain	Harley ²⁹ 2019	- (no data)	+ (Cronbach's α=0.71–0.88)	RN	NR	+ (r=0.35–0.39)	NR	RN	NR
COST-v1	De Souza ¹² 2014; De Souza ²⁷ 2017	NR	+ (Cronbach's α=0.92)	+ (ICC=0.80)	RN	+ (r=0.20–0.42)	NR	NR	NR
COST-v1, Australia version	Durber ²⁸ 2021	NR	+ (Cronbach's α=0.89)	+ (ICC=0.80)	NR	+ (r=-0.39–0.52)	NR	NR	NR
COST-v1, Brazilian version	de Alcantara Nogueira ³² 2020	- (RMSEA=1.20)	+ (Cronbach's α=0.83)	NR	NR	R	- (p<0.01)	NR	NR
COST-v1, India version	Dar ²⁵ 2021	- (EFA: χ^2 =60.82)	? (Cronbach's α=0.92)	NR	NR	NR	NR	NR	NR
COST-v1 Simplified Chinese version	Yu ³⁹ 2021	– (CFI=0.86; SRMR=0.08)	+ (Cronbach's α=0.85–0.88)	+ (ICC=0.85)	RN	+ (r=-0.57–0.88)	Я	К	? (no clear hypothesis)
COST-v2, Italian version	Ripamonti ³³ 2020) ? (CFI=1.00; RMSEA=0.04)	? (Cronbach's α=0.83)	+ (ICC=0.79)	NR	+ (r=-0.66–0.15)	R	+ (β=-0.55)	R
COST-v2, Persian version	Sharif ³⁴ 2020	+ (CFI=0.97; RMSEA=0.07)	+ (Cronbach's α=0.89)	RN	NR	? (no clear hypothesis)	R	RN	R
COST-v2, Traditional Chinese version	Chan ²⁴ 2021	– (CFI=0.91; RMSEA=0.15)	+ (Cronbach's α=0.86)	+ (ICC=0.71)	NR	+ (r=-0.46–0.47)	R	RN	R
CPILS employment/ financial domain	Zhao ⁴¹ 2009	_ (EFA: no model data)	+ (Cronbach's α=0.78–0.97)	R	NR	? (no clear hypothesis)	NR	RN	R
EIT	Hueniken ³¹ 2020	– (EFA: no model data)	+ (Cronbach's α=0.77)	+ (ICC=0.70)	RN	+ (r=0.26–0.61)	NR	К	+ (r=-0.25)
IOC-CS financial problems domain	Zebrack ⁴⁰ 2010	– (EFA: no model data)	_ (Cronbach's α=0.70−0.86)	- (ICC ≥0.75)	RN	- (>75% were not significant)	Я	? (no data)	R
PFB	Veenstra ³⁷ 2014	_ (CFA: no model data)	+ (Cronbach's α=0.79)	RN	NR	NR	NR	RN	R
PROFFIT	Riva ⁴² 2021	_ (EFA: no model data)	+ (Cronbach's α=0.87)	+ (ICC=0.80)	N	RN	R	R	R
PRRS financial well-being domain	Shilling ³⁵ 2018	_ (EFA: no model data)	+ (Cronbach's α=0.90)	+ (ICC=0.86)	NR	+ (r=-0.71–0.65)	NR	+ (r=-0.65)	R
P-SAFE, French Version	Tremblay ³⁶ 2020	NR	NR	NR	NR	NR	? (no data)	NR	NR
QLACS financial problems domain	Avis ²³ 2005	– (CFA: no model data)	+ (Cronbach's α=0.72)	R	NR	+ (r=-0.57–0.60)	NR	- (r=-0.72)	NR

PROM	Author (year)	Structural validity	Structural validity Internal consistency	Reliability	Measurement error	Hypothesis testing	Cross-cultural validity	Criterion validity	Responsiveness
SDI-16 money matters domain	Wright ¹⁶ 2011	– (EFA: no model data)	+ (Cronbach's α=0.71–0.82)	R	R	цХ	RN	NR	NR
SDI-21 providing Wright ³⁸ 2005 for the family domain	Wright ³⁸ 2005	– (EFA: no model data)	+ (Cronbach's α=0.50−0.86)	– (Weighted kappa=0.54–0.80)	R	- (33% were not significant)	R	? (r=-0.72)	R
SFDQ	Dar ²⁵ 2021	+ (CFI=0.98, TLI=0.97, RMSEA=0.045, SRMR=0.014)	+ (Cronbach's α=0.85–0.88)	R	Я	RN	NN	R	Ж
SWBS	Head ¹⁴ 2008	– (CFA: no model data)	+ (Cronbach's α=0.92)	К	R	+ (r=-0.57–0.60)	R	+ (r=-0.12-0.03)	R

seven versions were rated as having high evidence of structural validity, internal consistency, hypothesis testing and criterion validity.¹² ²⁴ ²⁵ ²⁷ ²⁸ ³²⁻³⁴ ³⁹ The Financial Index of Toxicity (FIT) and Impact of Cancer-Childhood Survivors (IOC-CS) financial problems domain reported data on five properties and were rated on a scale from 'very low evidence' to 'high evidence'.^{31 40}

DISCUSSION

This systematic review identified 21 PROMs and domains of PROMs evaluating FT in cancer survivors, including the COST (original, Brazilian, India, Italian, Persian, Simplified Chinese, Traditional Chinese version), FIT, Personal Financial Burden, P-SAFE, SWBS, Ouality of Life in Adult Cancer Survivors (QLACS) financial problems domain, Chronic Cancer Experiences Ouestionnaire financial advice domain, Patient-Reported Outcome for Fighting Financial Toxicity (PROFFIT), Patient Roles and Responsibilities Scale financial well-being domain, SDI-21 providing for the family domain, SDI-16 money matters domain, SFDQ, IOC-CS financial problems domain and Cancer Problems in Living Scale (CPILS) employment/ financial domain. Overall, the COST had a complete development process compared with other PROMs and showed the best psychometric properties, especially in terms of internal consistency, reliability and hypothesis testing. To the best of our knowledge, this is the first systematic review that has summarised the psychometric properties of FT PROMs in cancer survivors and reported the certainty of evidence for each property of PROMs. The results may provide quantitative evidence for researchers and healthcare professionals to choose PROMs measuring cancer survivors' FT in future scientific research and clinical practice.

The results highlighted that the COST (of which we studied both version 1 and version 2) had better psychometric properties than other specific and generic PROMs in terms of internal consistency, reliability and hypothesis testing. The COST could be recommended as the most suitable worldwide available measure for use in research and clinical practice across different contexts. Other systematic reviews have also suggested that the COST is a promising measure from a content perspective.^{10 11} From a psychometric standpoint, there are a few issues that one must face when evaluating financial toxicity in cancer survivors using the COST. First, caution should be taken when using the COST in different socioeconomic conditions outside the USA. In some countries in Europe or Asia, the majority of medical expenses are covered by social health insurance, and direct out-of-pocket payments are replaced by prepayment from health insurance contributions.^{43 44} In addition, social security systems can benefit cancer survivors who are not able to work.⁴⁵ These two socioeconomic factors may affect cancer survivors' understanding regarding some items related to medical spending and indirect cost. However, few COST

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validation studies have considered socioeconomic issues, adapted the measure in a local context or provided data on cross-cultural validity. It is recommended that future COST validation studies recruit cancer survivors across multiple social and cultural backgrounds to assess crosscultural measurement invariance.

Second, the original construct and item generation for the COST were based on a literature search; thus, the theoretical grounds for the measure are unclear, and the instrument may not capture detailed information related to the construct. Theoretical frameworks and conceptual models are crucial for self-reported measures to capture subtle changes in constructs.⁴⁶ Although FT is a relatively new concept, certain models can guide item generation in the development of future FT PROMs. Tucker-Seeley and colleagues developed a conceptual model of FT and emphasised three components of financial burden, namely, the material, psychosocial and behavioural domains.⁴⁷ Head developed SWBS based on James Coleman's Theory of Social Class; this scale contains 17 items across 3 domains: human capital, material capital and social capital.^{14 30 48} Witte et al's systematic review analysed 352 different questions regarding financial spending and found six domains (financial spending, financial resources, psychosocial affect, support seeking, coping care and coping lifestyle) that can represent reactions to subjective financial distress.¹⁰ Other theories and models, including the Wreckers theory of financial distress, ecological theory and the functionalist tradition, have also been widely used in cancer survivors.^{49–51} With the increasing number of theoretical studies related to FT, the theoretical grounds for future PROMs need to be clarified.

In addition to the COST, two other PROMs, namely, the FIT and the IOC-CS financial problems domains, also provided adequate data on psychometric properties. The FIT is relatively new and has fewer items than the other included measures. This measure was developed by Hueniken et al and has been validated only in survivors with head and neck cancer.³¹ Head and neck cancer, especially laryngeal and hypopharyngeal cancer, has particularly large impacts on survivors' daily function (eg, speech and eating) after treatment and affects survivors' ability to return to work.^{52 53} Only 32%–59% of head and neck cancer survivors return to work after treatment.⁵⁴ This form of cancer also has short-term and long-term financial consequences for caregivers and their families.⁵⁵ Therefore, future studies should be aware that the FIT may not be directly applicable to other cancer populations.

Regarding PROM development, we found that only two PROMs, PROFFIT and SFDQ, were not developed in the context of English-speaking developed countries such as the USA, the UK and Canada. The socioeconomic contexts and healthcare systems in these countries may be significantly different from those in other parts of the world and ultimately lead to a nuance in the perceived causes and consequences of FT. Previous studies have reported that FT is closely related to broad social determinants of economic circumstances. Factors including healthcare policy, healthcare system, insurance system, specific micro contexts and the level of regional economic development could not only affect the cancer survivors' perceived level of FT but also determine the origins of FT.^{56 57} Additionally, cultural factors (eg, a cultural emphasis on saving and a cultural imperative to have a large family) also affect cancer survivors' perceived financial security and economic burden.⁵⁸

PROFFIT, which was developed in 2021 in the Italian context, also reported higher quality PROM development and content validity than other PROMs. We would consider it to be a good FT PROM against the COSMIN criteria if more validation studies were conducted to report a greater effect size of the measurement properties. Therefore, we recommend that researchers use context-specific measures to assess FT in cancer survivors (eg, using PROFFIT in Italy). Further studies are warranted to develop various FT PROMs based on different social and cultural backgrounds. Worldwide measures, such as COST, should be analysed to determine the differences between social, cultural and economic contexts.

Limitations

We acknowledge that there are some limitations to this study. First, this review included only studies that aimed to evaluate the measurement properties of FT PROMs. Many studies that aimed to explore the level of FT in cancer survivors also reported the reliability and validity of PROMs. Therefore, the PROMs we summarised in this systematic review had higher psychometric quality than other measures that we did not list in this review. Second, we included only studies published in English. Therefore, studies published in other languages were not included, which may affect the conclusion of this review. Third, we included only the original version of the FT domain from PROMs assessing quality of life in cancer survivors, such as the EORTC QLQ-C30 and the QLACS. Over 20 language versions of these PROMs do not provide sufficient details on the FT domain individually.

CONCLUSION

This systematic review summarised the psychometric properties of 20 PROMs evaluating FT in cancer survivors. The findings highlighted that, from a psychometric property perspective, the COST had an adequate PROM development process and showed the best psychometric properties among all examined PROMs, especially in internal consistency, reliability and hypothesis testing; thus, we recommend the COST as the most suitable worldwide available measures for use in research and clinical practice across different contexts. The FIT and the IOC-CS financial problems domain also had adequate psychometric properties. We suggest that PROMs should be selected only after careful consideration of the local socioeconomic context. Future studies are warranted to develop various FT PROMs based on different social and

cultural backgrounds and a clear theoretical basis for assessing FT.

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Contributors WX took full responsibility for the work, had access to the data, and controlled the decision to publish. ZZ and WX designed the systematic review, conducted data searching, extraction and analysis, assessing the certainty of evidence, and wrote the draft of the manuscript. HW and YS conducted quality appraisal and assessing the certainty of evidence. WKWS, LL, JP and YH provided critical comments. All authors approved the final version of the manuscript. WX is the guarantor.

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