Protocol Study

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

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Abstract

Background: The topic of self-care in cancer has garnered increased attention from researchers and clinicians over the years. This has prompted the development and testing of several instruments to capture the multidimensional nature of the self-care construct in cancer patients. Several self-report instruments are available in the literature; however, which instrument exhibits the best reliability and validity remains unclear.

Objective: The aim of this protocol is to identify all available instruments developed for measuring self-care behaviors in adult cancer patients and critically appraise their psychometric properties.

Methods: This systematic review will follow the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines. PubMed, CINAHL, Embase, Scopus, Web of Science, and PsycINFO databases will be searched for relevant articles on the topic. Studies testing the psychometric properties of self-report instruments assessing self-care behaviors in adult cancer patients, published in English, Italian, or Spanish, will be included. Two independent reviewers will assess the eligibility of the studies and extract the data. Risk of bias will be evaluated using the COSMIN Risk of Bias Checklist, and the quality of the results will be assessed based on specific COSMIN criteria.

Discussion: A thorough and critical evaluation of all available evidence for instruments measuring self-care in patients with cancer might have both strong clinical and research implications. The results of this review could drive healthcare

providers in the selection of the most appropriate assessment tool for detecting and monitoring the self-care levels of this population. On the other hand, the results may underline the necessity of validating new instruments.

Keywords: self-care; self-management, neoplasms; self-report; psychometrics, validity, reliability, health behaviour.

Background

Cancer represents a global health issue and the third leading cause of death worldwide, with approximately 10 million deaths estimated[1]. Despite the decline in mortality rates, the prevalence of patients with cancer continues to expand, reflecting both the aging of the population and the new therapies available in oncology, which have led to the transition of cancer to a chronic disease[2].

Despite this significant achievements made in the oncological field, living with cancer remains particularly challenging, with over 90% of patients experiencing one or more burdensome symptoms caused by the disease or its treatment[3]. The persistence of cancer- or treatment-related symptoms can hinder completion of treatment cycles, as well as lead to a decrease in functional status and health-related quality of life[4,5]. This often leads to serious complications such as prolonged hospital length of stay, increased hospital readmissions, greater use of post-acute care facilities, and overall worse survival[6]. Moreover, the symptoms' experience may persist for a long time since treatment onset[7,8], and patients are required to manage their cancer condition at home.

Together with medical and surgical treatments, self-care is key to successful cancer management[9]. Self-care, defined as an ensemble of practices related to health-promoting and disease management behaviors seems to improve cancer patients' quality of life[10,11], and survival, and reduce hospitalization rates[12].

The topic of self-care in cancer has increased the attention of researchers and clinicians over the past decades[13], with studies stressing its complex and multidimensional components[14,15]. This has prompted researchers to develop and test several instruments to capture the different nuances of the self-care construct in patients with cancer. Typically, self-care instruments are self-reported, since the patients' perceived ability to perform self-care activities is a subjective phenomenon and these activities are generally performed at home, making direct observation impractical[16].

Self-reported self-care instruments need to undergo rigorous psychometric testing to ensure they are valid and reliable before their utilization. Hence, the choice of high-quality instruments assessing self-care in this population is important, considering the significant effects of self-care on the health outcomes of cancer patients. Furthermore, using a low-quality instrument can lead to significant consequences in clinical practice and research, including invalid conclusions and a waste of time and resources[17].

A non-comprehensive perusal of the literature suggests that a variety of self-care instruments have been developed during the last decades for patients with cancer such as the Leuven questionnaire for Patient Self-care during Chemotherapy (L-PaSC), the self-management instrument for breast cancer patients undergoing adjuvant therapy (SMAT-B) or the self-care diary (SCD)[18-20]. However, minimal, and inconsistent information can be referred to regarding their methodological quality, making selection of the most suitable instrument for a specific setting complex and time-consuming. Systematic reviews of measurement properties of instruments can help researchers and healthcare professionals select the best measurements for use in research and practice. However, to our knowledge, no reviews of this kind have been conducted so far, which poses the rationale for the objective of this study.

Objective

The aim of this systematic review is to identify the available instruments developed for measuring self-care behaviors in adult patients affected by cancer, and critically appraise their psychometric properties.

Methods

This protocol has been registered on PROSPERO platform (registration code CRD42024519219), and will be developed in accordance with the

Preferred Reporting Items for Systematic reviews and Meta-Analyses Protocols guidelines[21,22]. The quality of the measurement properties of validated instruments will be assessed with the guidelines developed by the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN)[23].

Eligibility criteria

Articles will be considered eligible for inclusion if the full text of the study reports the development and psychometric properties of one or more generic or disease-specific self-care self-report instrument among populations of adults aged ≥ 18 years with cancer. The authors of the articles will be contacted if a full-text version is not available online.

We operationally define any self-care behavior according to the theoretical principles postulated by Riegel et al. in 2012, who describes three dimensions: (i) self-care maintenance, including behaviors performed to keep a condition stable, (ii) self-care monitoring, relating to the practices patients use to monitor signs and symptoms of the disease and (iii) self-care management, or the response to signs and symptoms of the illness[24].

Articles will be excluded if studies use the self-care instruments as outcome measures (e.g., observational studies) without specifying its psychometric properties, if the instruments are completed by caregivers and studies are published in languages different from English, Spanish and Italian. Studies reporting psychometric properties of proxy measures of self-care behaviors (e.g., motivation, self-efficacy) will be excluded. No temporal limits will be set regarding the year of publication, in order to thoroughly explore all pertinent studies on self-care behaviors in cancer patients, encompassing even those predating its formal theorizations[25].

Search strategy

PubMed (via Medline), CINAHL (via EBSCO host), Embase (via Ovid), Scopus, Web of Science (via Clarivate), and PsycINFO (via EBSCO host) databases will be checked for pertinent articles. A search strategy tailored to PubMed database was generated and adapted to the other databases (**Table 1**).

Table 1 Search strategy

Database: PubMed
Search string
((scale*[tiab] OR questionnaire*[tiab] OR tool*[tiab] OR index[tiab]) AND ("Validation Study"[tiab] OR "Validation stud*" OR psychometrics[MeSH] OR psychometr*[tiab] OR reliab*[tiab] OR valid*[tiab] OR "internal consistency"[tiab] OR cronbach*[tiab] OR "cronbach's alpha"[tiab] OR "test-retest"[tiab] OR "test retest" OR reliab*[tiab] OR interrater[tiab] OR "inter-rater"[tiab] OR intrarater[tiab] OR "intra-rater"[tiab] OR "cohen's kappa"[tiab] OR "intra-class correlation"[tiab] OR "factor analys*"[tiab] OR "factor structure*"[tiab] OR "Item response model"[tiab] OR "item response theory"[tiab] OR "Rasch model" OR "Differential item functioning"[tiab]) AND ("Neoplasms"[Mesh] OR Tumor*[tiab] OR Neoplas*[tiab] OR Cancer*[tiab] OR "Malignant Neoplasm*"[tiab] OR Malignan*[tiab] OR tumour*[tiab] OR "Antineoplastic Agents"[Mesh] OR "Antineoplastic Agent*"[tiab] OR "anticancer medicin*"[tiab] OR chemotherap*[tiab] OR"antineoplastic drug*"[tiab] OR "Antineoplastic Agents, Hormonal"[Mesh] OR "hormonal therap*"[tiab] OR "hormonal drug*"[tiab] OR "anticancer immunotherap*"[tiab] OR "antineoplastic immunotherapy"[tiab] OR "targeted drug*"[tiab]) AND ("self-management"[MeSH] OR "self-manag*"[tiab] OR "self care"[Mesh] OR "self-care"[tiab] OR selfcare OR "self care" [tiab] OR "self-monitor*" [tiab] OR "self monitor*"[tiab] OR "self maintenance*"[tiab] OR "self-maintenance*"[tiab] OR "Patient Compliance"[tiab] OR "Patient Compliance"[Mesh] OR compliance [tiab] OR "medication compliance"[tiab] OR "Medication Adherence"[Mesh] OR "medication adherence"[-tiab] OR adhere*[tiab] OR "non adherent"[tiab])) NOT ("Child"[Mesh] OR "Pediatrics"[Mesh] OR "Adolescent"[Mesh] OR child*[tiab] OR pediatric*[tiab] OR paediatric*[tiab] OR adolescen*[tiab] OR teen*[tiab])

Relevant articles will also be sought in the reference lists of all included studies, to ensure a more exhaustive retrieval of the existing literature.

Study selection process

All the references will be imported into EndNote® version X9.1 to remove duplicates[26]. After this initial step, titles, abstracts and full-text screenings will be performed independently by two researchers with the support of Rayyan®[27]. Reasons for exclusion of abstracts or full-text articles will be recorded and presented in the PRISMA flow chart. A third evaluator will resolve potential disagreements. Cohen's

kappa coefficient will be calculated to assess the concordance between the two reviewers. The agreement will be considered almost perfect if equal to or above 0.8, satisfactory if between 0.61 and 0.80, moderate if between 0.41 and 0.60, fair if between 0.21 and 0.40, and poor if below 0.20[28].

Data extraction

For each study included in the review, data regarding study characteristics and measurement properties of any self-care instrument will be extracted. Specifically, we will extract the target population, sample size, administration mode of the instrument, original language of the instrument, subscales, number of items, range of scores, and dimensionality, as well as content validity, structural validity, internal consistency, cross-cultural validity/measurement invariance, reliability, measurement error, criterion validity, and hypothesis testing for the construct validity and responsiveness. Multiple reports of the same study will be considered as a unique source. Data on duplicate samples will be reported if outcomes refer to different psychometric properties.

Quality appraisal and data synthesis

To assess the quality of the psychometric properties of the instruments, COSMIN Risk of Bias Checklist will be adopted[29]. This instrument consists of 116 items organized into ten sections assessing the following aspects: (1) instrument development, (2) Content validity, (3) Structural validity, (4) Internal consistency, (5) Cross-cultural validity/Measurement invariance, (6) Reliability, (7) Measurement error, (8) Criterion validity, (9) Hypotheses testing for construct validity, and (10) Responsiveness. The various items in each domain can be rated as "very good", "adequate", "doubtful", "inadequate", and "not applicable". To determine the overall quality of a study the lowest rating of any item in the box will be considered. For example, if any of the eight items in the reliability box is "inadequate", the overall methodological quality of that specific reliability study will also be rated as "inadequate". The COSMIN evaluation will be performed by two independent reviewers. Any disagreements will be resolved through consensus between the two reviewers, and if no consensus is reached, assistance from a third reviewer will be requested.

The quality of the results will be assessed after extracting the measurement attributes of each included tool using the criteria for good measurement properties suggested by Terwee et al[30]. Each instrument attribute (i.e., structural validity, internal consistency, reliability, measurement error, hypotheses testing for construct validity, cross-cultural validity/ measurement invariance, criterion validity and responsiveness) will be rated as either sufficient (+), insufficient (–), or indeterminate (?).

Once all the evidence regarding each instrument instrument's measurement property has been summarized and evaluated, the subsequent step involves assessing the quality of the evidence. As recommended by COSMIN Group, the grading of the quality will be based on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework[31]. Specifically, a modified GRADE approach is advised, where the quality of the evidence is graded as "high", "moderate", "low", or "very low" on the basis of four factors: (1) risk of bias (i.e., the methodological quality of the studies), (2) inconsistency (i.e., inconsistency of results across studies), (3) imprecision (i.e., total sample size), and (4) indirectness (i.e., evidence from different populations than the population of interest). However, the fourth criterion will not be considered as this review will only include studies with a predefined and fixed patient population.

Discussion

This systematic review aims to explore the development and psychometric properties of all self-report self-care instruments available for the cancer populations. A thorough and critical evaluation of all available evidence for each instrument will be provided, which will have both strong clinical and research implications. From a clinical perspective, the results of this review could drive healthcare providers in the selection of the most appropriate, reliable, and valid assessment tool for detecting and monitoring the self-care levels of this vulnerable population. From the perspective of future research, these findings could promote identification of the most suitable self-care measures in the oncology field, which might have implications for the design of future trials investigating interventions to improve self-care. On the other hand, the findings may suggest the need for validating new instruments, in the case existing ones are incomplete or developed without a robust methodology. Being able to accurately measure self-care levels is critical for

the assessment of the effectiveness of self-care-based interventions in people with cancer. In addition, evidence-based self-care instruments will promote a more thorough exploration of protective and risk factors and outcomes of self-care, thus helping nurses and other healthcare professionals implement tailored patient-centered interventions.

References

1. GBD 2019 Diseases and Injuries Collaborators. Global burden of 369 diseases and injuries in 204 countries and territories, 1990-2019: a systematic analysis for the Global Burden of Disease Study 2019. Lancet. 2020;396(10258):1204-1222.
2. Pituskin E. Cancer as a new chronic disease: Oncology nursing in the 21st Century. Can Oncol Nurs J Rev Can Nurs Oncol. 2022;32(1):87–92.
3. Kang D, Kim S, Kim H, Lee M, Kong SY, Chang YJ, et al. Surveillance of Symptom Burden Using the Patient-Reported Outcome Version of the Common Terminology Criteria for Adverse Events in Patients With Various Types of Cancers During Chemoradiation Therapy: Real-World Study. JMIR Public Health Surveill. 2023;9:e44105.
4. Lewandowska A, Rudzki G, Lewandowski T, et al. Quality of Life of Cancer Patients Treated with Chemotherapy. Int J Environ Res Public Health. 2020;17(19):6938.
5. Röhrl K, Guren MG, Astrup GL, Småstuen MC, Rustøen T. High symptom burden is associated with impaired quality of life in colorectal cancer patients during chemotherapy: A prospective longitudinal study. Eur J Oncol Nurs. 2020;44:101679.
6. Lage DE, El-Jawahri A, Fuh CX, et al. Functional Impairment, Symptom Burden, and Clinical Outcomes Among Hospitalized Patients With Advanced Cancer. J Natl Compr Canc Netw. 2020;18(6):747-754.
7. Deshields TL, Potter P, Olsen S, Liu J. The persistence of symptom burden: symptom experience and quality of life of cancer patients across one year. Support Care Cancer. 2014;22(4):1089-1096.
8. Gegechkori N, Haines L, Lin JJ. Long-Term and Latent Side Effects of Specific Cancer Types. Med Clin North Am. 2017;101(6):1053-1073.
9. Hasanpour-Dehkordi A. Self-care Concept Analysis in Cancer Patients: An Evolutionary Concept Analysis. Indian J Palliat Care. 2016;22(4):388-394..
10. Abdollahi A, Alsaikhan F, Nikolenko DA, et al. Self-care behaviors mediates the relationship between resilience and quality of life in breast cancer patients. BMC Psychiatry. 2022;22(1):825.
11. Hung HY, Wu LM, Chen KP. Determinants of Quality of Life in Lung Cancer Patients. J Nurs Scholarsh. 2018;50(3):257-264.
12. Basch E, Deal AM, Dueck AC, et al. Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment. JAMA. 2017;318(2):197-198.
13. Gao WJ, Yuan CR. Self-management programme for cancer patients: a literature review. Int Nurs Rev. 2011;58(3):288-295.
14. Ahlstedt Karlsson S, Wallengren C, Olofsson Bagge R, Henoch I. "It is not just any pill"-Women's experiences of endocrine therapy after breast cancer surgery. Eur J Cancer Care (Engl). 2019;28(3):e13009.
15. Bryant AL, LeBlanc TW, Albrecht T, et al. Oral adherence in adults with acute myeloid leukemia (AML): results of a mixed methods study. Support Care Cancer. 2020;28(11):5157-5164.
16. Mokkink LB, Prinsen CAC, Bouter LM, de Vet HCW, Terwee CB. The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) and how to select an outcome measurement instrument. Braz J Phys Ther. 2016;20(2):105–13.
17. Jia L, Qiu J, Li P, et al. The self-management instrument for breast cancer patients undergoing adjuvant therapy: Development and psychometric testing using the COSMIN methodology. Asia Pac J Oncol Nurs. 2023;10(9):100268.
18. Coolbrandt A, Van den Heede K, Clemens K, et al. The Leuven questionnaire for Patient Self-care during Chemotherapy (L-PaSC): instrument development and psychometric evaluation. Eur J Oncol Nurs. 2013;17(3):275-283.
19. Nail LM, Jones LS, Greene D, Schipper DL, Jensen R. Use and perceived efficacy of self-care activities in patients receiving chemotherapy. Oncol Nurs Forum. 1991;18(5):883-887.
20. 21. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.
21. Rethlefsen ML, Kirtley S, Waffenschmidt S, et al. PRISMA-S: an extension to the PRISMA Statement for Reporting Literature Searches in Systematic Reviews. Syst Rev. 2021;10(1):39. Published 2021 Jan 26.
22. Prinsen CAC, Mokkink LB, Bouter LM, et al. COSMIN guideline for systematic reviews of patient-reported outcome measures. Qual Life Res. 2018;27(5):1147-1157.
23. Riegel B, Jaarsma T, Strömberg A. A middle-range theory of self-care of chronic illness. ANS Adv Nurs Sci. 2012;35(3):194-204.
24. Denyes MJ, Orem DE, Bekel G, SozWiss. Self-care: a foundational science. Nurs Sci Q. 2001;14(1):48-54.
25. Bramer WM, Giustini D, de Jonge GB, Holland L, Bekhuis T. De-duplication of database search results for systematic reviews in EndNote. J Med Libr Assoc. 2016;104(3):240-243.
26. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan-a web and mobile app for systematic reviews. Syst Rev. 2016;5(1):210.
27. Page MJ, McKenzie JE, Bossuyt PM, et al. Updating guidance for reporting systematic reviews: development

of the PRISMA 2020 statement. J Clin Epidemiol. 2021;134:103-112.
28. Mokkink LB, de Vet HCW, Prinsen CAC, et al. COSMIN Risk of Bias checklist for systematic reviews of Patient-Reported Outcome Measures. Qual Life Res. 2018;27(5):1171-1179.
29. Terwee CB, Bot SD, de Boer MR, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol. 2007;60(1):34-42.
30. Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008;336(7650):924-926.