

Instruments to assess quality of life in ostomized adults: a systematic review protocol

Instrumentos de avaliação sobre qualidade de vida em adultos estomizados: protocolo de revisão sistemática

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ABSTRACT

Objective: To methodologically analyze the results of research studies that investigated psychometric properties (reliability, responsiveness and validity) of quality of life instruments for individuals with elimination ostomies. **Method:** A systematic literature review that will be conducted according to the Consensus-based Standards for selecting health Measurement INstruments (COSMIN) initiative, developed in ten stages. The searches will be conducted in national and international databases, with no language or time restrictions. To assess the methodological quality of the studies, the COSMIN risk of bias checklist will be employed by applying the quality criteria for good measuring properties. Finally, the diverse evidence will be compiled by assessing its quality through the GRADE approach. This study is ongoing and its protocol is registered at the International Prospective Register of Systematic Reviews (PROSPERO) under number CRD42022320642.

Descriptors: Ostomy; Quality of Life; Patient Reported Outcome Measures.

RESUMO

Objetivo: Analisar metodologicamente resultados de pesquisas que investigaram as propriedades psicométricas (confiabilidade, responsividade e validade) de instrumentos de qualidade de vida para pessoas com estomias de eliminação.

Método: Revisão sistemática da literatura que será realizada de acordo com a iniciativa *Consensus-based Standards for the selection of health Measurement Instruments* (COSMIN), desenvolvida em dez etapas. As buscas serão realizadas em bases de dados nacionais e internacionais, sem restrição de idiomas e temporal. Para avaliar a qualidade metodológica dos estudos, empregar-se-á o *checklist* de risco de viés COSMIN, aplicando-se os critérios de qualidade para boas propriedades de medida. Por último, as evidências serão compiladas, avaliando-se sua qualidade através da abordagem GRADE. Este estudo encontra-se em andamento e o protocolo está registrado na *International Prospective Register of Systematic Reviews* (PROSPERO) sob o número CRD42022320642.

Descritores: Estomia; Qualidade de Vida; Medidas de Resultados Relatados pelo Paciente.

INTRODUCTION

Elimination ostomies are surgical interventions for externalizing an intestinal hole through the abdominal wall for the outflow of feces and flatus, called "stoma". According to the segment involved, elimination ostomies can be intestinal (colostomy, ileostomy, jejunostomy) for the elimination of feces and/or gases; or urinary (urostomy), for urine drainage⁽¹⁾. As for the indwelling time, they are classified as provisional/temporary or final/definitive⁽²⁾.

In Brazil, the data about ostomies need to be more accurate, as there is no standardized information registry, making it difficult to determine their epidemiology⁽³⁾. Considering the elimination of ostomies, there is a projection by the International Ostomy Association (IOA) that estimates the proportion of one ostomized person for every one thousand inhabitants in countries with good health care levels. In turn, the rates are higher in less developed countries. From this perspective, a number above 207,000 individuals with

ostomies was projected for Brazil by 2018⁽⁴⁻⁵⁾. The different types of ostomies impact biopsychosocial issues, influencing the drainage characteristics and volume and, thus, the individual's quality of life⁽⁵⁾. Stomas have issues such as waste consistency, specific care, collection material, complications and special conditions of lifestyle adaptation⁽²⁾.

The changes in the health status of ostomized individuals occur mainly at the physical, social, and emotional levels, as they produce loss of a healthy body, triggering vulnerability and lack of self-care⁽⁶⁾. Notably, the marking of a stoma, the diverse information during hospitalization and the inclusion in pre-operative education programs are strongly associated with higher chances of better self-care in ostomized patients⁽⁷⁾.

It is known that self-care in ostomized patients becomes an indicator for promoting assertive interventions, with better maintenance and monitoring in women⁽⁸⁾. A longitudinal and multicenter study conducted with 523 ostomized individuals monitored for six months showed average to high levels of self-care management, with self-efficacy as one of the modifiable variables more associated with self-care, as it promotes changes in behavior⁽⁸⁾.

The Nursing care practice for patients affected by stomas is centered on the biomedical and curative model, in which the body is addressed from a mechanistic perspective and only seen as a place that houses diseases, restricted to technical procedures such as hygiene and collecting bag exchanges. In a higher proportion, patients experience care after discharge with a lack of information regarding the social and emotional spheres, generating fears and misconceptions about care and stoma management⁽⁹⁾.

Faced with any chronic health situation or mutilating surgical need, the circumstance will always be shocking and, specifically dealing with the need to perform a stoma, the possibility of traumatic symptoms arising increases, whether due to the limitations imposed by the condition or by the embarrassment it causes, interfering in the patient's quality of life⁽¹⁰⁾.

For the World Health Organization, "Quality of Life" (QoL) can be defined as the "perception of an individual of their position in life, in the context of the culture and value systems in which they live and concerning their objectives, expectations, standards and concerns", representing a complex and subjective construct that involves people's self-satisfaction in several aspects, such

as health-related, cultural, social and psychological⁽¹¹⁾.

There are more specific aspects within QoL, namely: "Health-Related Quality of life", considered as a construct that encompasses well-being components and physical, emotional, mental, social and behavioral functions as self-perceived and perceived by others⁽¹²⁾. In the health scope, QoL acquires particular importance for Nursing, as it focuses on the person/family and not only the body with a health problem⁽¹³⁾.

The challenges are faced from the moment the diagnosis is made until the adaptation to a new lifestyle that includes changes in the body that influence self-concept, self-care, and social life relations and the mutilation underwent, directly related to the individual's loss of productive capacity; in addition to that, it also means a factor that indicates their lack of control in relation to the body's physiological eliminations, physical beauty and health, being important aspects for people's quality of life⁽¹⁴⁻¹⁵⁾.

Another factor worth highlighting is body image because it is linked to self-esteem, self-image and self-concept and, as well as anxiety, it exerts a strong negative influence on quality of life, especially in patients with colorectal cancer. Therefore, monitoring these individuals after the procedure and the evaluation using validated predictive scales have been effective interventions to investigate the causes and proposals of tools that may improve care. Notably, good body image and emotional self-esteem are substantial factors for the transition inherent to a permanent ostomy⁽¹⁶⁾. Quality of Life validation is one of the most significant outcome measures after major procedures and treatments, and it has been widely used in the health area. It encompasses subjective aspects and quantitative parameters through increasingly essential tools that holistically measure the impact of the disease on the patient's quality of life⁽¹⁷⁻¹⁸⁾.

Considering the outstanding character and importance of this topic, the need for research that presents and analyzes the quality of the evidence of the existing instruments, this survey will provide a broad view of the quality of life assessment instruments in individuals with elimination ostomies and their measuring properties, through a critical evaluation of the methodological quality of the studies, combined with better evidence to help health professionals and researchers choose an adequate predictive tool to be used in care and research.

Thus, the objective is to methodologically analyze research studies that investigated the psychometric properties (reliability, responsiveness, and validity) of quality of life instruments for individuals with elimination ostomies.

METHOD

It is a systematic review protocol that follows the parameters established by the methodology and guidelines outlined in the Consensus-based Standards for selecting health Measurement INstruments (COSMIN)⁽¹⁹⁻²¹⁾. The study protocol was registered at the International Prospective Register of Systematic Reviews (PROSPERO) under number CRD42022320642. The diverse information is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P)⁽²²⁾.

Eligibility

The eligibility criteria for selecting the manuscripts of interest are not restrictive and were formulated according to the COSMIN group criteria and respecting the essential information set forth in PRISMA-P.

The eligibility criteria are in line with the four key elements of the review objective, namely: 1) The Patient-Reported Outcome Measure (PROM) should have as its objective to measure the construct of interest – Quality of Life; 2) The study sample should represent the population of interest – Adults with elimination ostomies; 3) The study should focus on Patient-Reported Outcome Measures (PROMs) – Measuring instruments; and 4) The study objective should be the assessment of one or more measuring properties, the development of a PROM (to assess content validity), or the interpretability assessment of the PROMs of interest.

The following materials will be included: published and non-published full-text papers; any study that has developed an instrument and/or assessed the measuring properties; and any instruments (questionnaires, inventories) and measures (generic, specific). There will be no limitation regarding publication time or language. Studies that only use PROM as the measuring instrument result will be excluded; as well as those in which PROM is employed as validation for another instrument; orally-presented or posted materials, abstracts, editorials or any publication which do not report the assessment of measuring properties (for example, outcome measure or simply a translation).

Search strategy

The searches will be conducted in the following databases: Excerpta Medica Database (Embase); Medical Literature Analysis and Retrieval System Online (MEDLINE via PubMed); Cumulative Index to Nursing & Allied Health Literature (CINAHL complete); Web of Science main collection; PsycINFO (Psychological Information Database); *Centro Latino-Americano e do Caribe de Informação em Ciências da Saúde* (LILACS), *Banco de Dados em Enfermagem* (BDEnf) and *Índice Bibliográfico Español en Ciencias de la Salud* (IBECS) via the Regional Portal of *Biblioteca Virtual em Saúde* (BVS). The additional research methods will include Google Scholar. The search for non-published studies will also consider information sources such as Dissertations and Thesis from ProQuest, DART-Europe and *ResearchGate*. An initial search was performed in Medline via PubMed, followed analyzing titles and abstracts. In addition, a second search, including all keywords and relevant index terms, was conducted in all the databases included. The specific search filters developed by the COSMIN group were considered (Chart 1).

The terms used in this search strategy were selected from the Descriptors in Health Sciences (*Descritores em Ciências da Saúde*, DeCS), the Medical Subject Headings (MeSH), Emtree (Embase subject headings), APA (Thesaurus of Psychological Index Terms) and *Assuntos CINAHL*, as well as using non-controlled descriptors and including the following terms: *Ostomy; Colostomy; Ileostomy; Surgical stomas; Surveys and Questionnaires; Questionnaires; Instrument; Scales; Validation Studies; Psychometric properties and Quality of life*. The sensitive research filter validated for instruments' measuring properties (validity, reliability, and/or responsiveness) was added to the search⁽²³⁾. The articles' lists of references were screened for potentially eligible studies. The complete search strategy in all the databases is available upon request.

Selection of the studies

Selection of the studies will be in charge of two evaluators that will read the titles and abstracts identified in the databases by using the Rayyan software⁽²⁴⁾. Subsequently, the full texts of the studies will be evaluated to confirm their eligibility. Should there be disagreements in any phase, a third reviewer will be called upon to resolve them. After including the eligible full-text studies, a manual search will be carried out in

the lists of references from the articles included in the review. If doubts arise, the corresponding authors will be emailed requesting information about the studies.

Data extraction

Two reviewers from the studies selected for inclusion will extract data independently to avoid the loss of relevant information.

The data to be extracted will include specific details about the studies and the characteristics of the instruments using the COSMIN-specific forms. Disagreements regarding the data will be resolved by consensus, and a third reviewer will be consulted when necessary. The studies' authors may be contacted to provide further information should there be insufficient data or in case of lack of clarity.

Evaluation of the methodological quality

According to the criteria published by the COSMIN group, the quality of the method considered

for developing the different selected manuscripts will be then analyzed by the same independent authors. Should there be no consensus, the same third reader will be consulted again for a final decision.

For each measuring property, the risk of bias will be evaluated using the standardized COSMIN checklists: "Table on characteristics of the included PROMs"; "Table on characteristics of the included study populations"; "Information to extract on the interpretability of PROMs"; "Information to extract on the feasibility of PROMs"; "Table on results of studies on measurement properties"; and "Summary of Findings Tables", and will be classified as "Very good", "Adequate", "Doubtful" or "Inadequate". The overall classification will be based on the "the worst scorings" principle.

Subsequently, the criteria for good measuring properties will be classified (Sufficient [+]/ Insufficient [-]/ Undetermined [?]) with the criteria proposed by the COSMIN group⁽¹⁶⁾. A general

Question	Medline/PubMed search strategy
(1) Construct	"Quality of Life"[Mesh] OR (Life Quality) OR (Health-Related Quality Of Life) OR (Health Related Quality Of Life) OR (HRQL)
(2) Population	"Ostomy"[Mesh] OR (Ostomies) OR (Stoma*) OR "Colostomy"[Mesh] OR (Colostomies) OR "Ileostomy"[Mesh] OR (Ileostomies) OR (Tube Ileostomy) OR (Ileostomies, Tube) OR (Ileostomy, Tube) OR (Tube Ileostomies) OR (Incontinent Ileostomy) OR (Ileostomies, Incontinent) OR (Ileostomy, Incontinent) OR (Incontinent Ileostomies) OR (Loop Ileostomy) OR (Ileostomies, Loop) OR (Ileostomy, Loop) OR (Loop Ileostomies) OR (Continent Ileostomy) OR (Continent Ileostomies) OR (Ileostomies, Continent) OR (Ileostomy, Continent) OR "Surgical Stomas"[Mesh] OR (Stoma, Surgical) OR (Surgical Stoma) OR (Stomata, Surgical) OR (Surgical Stomata) OR (Stomas, Surgical) OR (Intestinal Stoma) OR "Cystostomy"[Mesh] OR (Cystostomies) OR (Vesicostomy) OR (Vesicostomies) OR (Suprapubic Cystostomy) OR (Cystostomies, Suprapubic) OR (Cystostomy, Suprapubic) OR (Suprapubic Cystostomies) OR "Enterostomy"[Mesh] OR (Enterostomies) OR "Cecostomy"[Mesh] OR (Cecostomies) OR (Tube Cecostomy) OR (Cecostomies, Tube) OR (Cecostomy, Tube) OR (Tube Cecostomies) OR "Duodenostomy"[Mesh] OR (Duodenostomies) OR "Jejunostomy"[Mesh] OR (Jejunostomies) OR "Ureterostomy"[Mesh] OR (Ureterostomies)
(3) Type of instruments	"Surveys and Questionnaires"[Mesh] OR (Questionnaires and Surveys) OR (Survey Methods) OR (Methods, Survey) OR (Survey Method) OR (Methodology, Survey) OR (Survey Methodology) OR (Surveys) OR (Survey) OR (Questionnaire Design) OR (Design, Questionnaire) OR (Designs, Questionnaire) OR (Questionnaire Designs) OR (Baseline Survey) OR (Baseline Surveys) OR (Survey, Baseline) OR (Surveys, Baseline) OR (Questionnaire*) OR (Measure*) OR (Scale*) OR (Score*) OR (Assessment) OR (tool*) OR (Instrument*) OR (outcome measurement instruments) OR ("patient-reported outcomes")
(4) Measuring properties of interest	"Validation Studies as Topic"[Mesh] OR (Validation studies) OR (Validation) OR (Validity) OR (Content validity) OR (Criterion validity) OR (concurrent validity) OR (Predictive validity) OR (Structural validity) OR (Construct validity) OR (Cross-cultural validity) OR (Reliability) OR (internal consistency) OR (Measurement error) OR "Psychometrics"[Mesh] OR (Psychometric) OR (Psychometric properties) OR "Reproducibility of Results"[Mesh] OR "Weights and Measures"[Mesh] OR (Measurement property) OR (internal consistency) OR (responsiveness)

<p>(5) Measuring properties of interest (COSMIM filter)16,20</p>	<p>(instrumentation[sh] OR Validation Studies[pt] OR "reproducibility of results"[MeSH Terms] OR reproducib*[tiab] OR "psychometrics"[MeSH] OR psychometr*[tiab] OR clinimetr*[tiab] OR clinometr*[tiab] OR "observer variation"[MeSH] OR observer variation[tiab] OR "discriminant analysis"[MeSH] OR reliab*[tiab] OR valid*[tiab] OR coefficient[tiab] OR "internal consistency"[tiab] OR (cronbach*[tiab] AND (alpha[tiab] OR alphas[tiab])) OR "item correlation"[tiab] OR "item correlations"[tiab] OR "item selection"[tiab] OR "item selections"[tiab] OR "item reduction"[tiab] OR "item reductions"[tiab] OR agreement[tw] OR precision[tw] OR imprecision[tw] OR "precise values"[tw] OR test-retest[tiab] OR (test[tiab] AND retest[tiab]) OR (reliab*[tiab] AND (test[tiab] OR retest[tiab])) OR stability[tiab] OR interrater[tiab] OR inter-rater[tiab] OR intrarater[tiab] OR intra-rater[tiab] OR intertester[tiab] OR inter-tester[tiab] OR intratester[tiab] OR intra-tester[tiab] OR interobserver[tiab] OR inter-observer[tiab] OR intra-observer[tiab] OR intertechnician[tiab] OR inter-technician[tiab] OR intratechnician[tiab] OR intra-technician[tiab] OR interexaminer[tiab] OR inter-examiner[tiab] OR intraexaminer[tiab] OR intra-examiner[tiab] OR interassay[tiab] OR inter-assay[tiab] OR intraassay[tiab] OR intra-assay[tiab] OR interindividual[tiab] OR inter-individual[tiab] OR intraindividual[tiab] OR intra-individual[tiab] OR interparticipant[tiab] OR inter-participant[tiab] OR intraparticipant[tiab] OR intra-participant[tiab] OR kappa[tiab] OR kappa's[tiab] OR kappas[tiab] OR "coefficient of variation"[tiab] OR repeatab*[tw] OR ((replicab*[tw] OR repeated[tw]) AND (measure[tw] OR measures[tw] OR findings[tw] OR result[tw] OR results[tw] OR test[tw] OR tests[tw])) OR generaliza*[tiab] OR generalisa*[tiab] OR concordance[tiab] OR (intraclass[tiab] AND correlation*[tiab]) OR discriminative[tiab] OR "known group"[tiab] OR "factor analysis"[tiab] OR "factor analyses"[tiab] OR "factor structure"[tiab] OR "factor structures"[tiab] OR dimensionality[tiab] OR subscale*[tiab] OR "multitrait scaling analysis"[tiab] OR "multitrait scaling analyses"[tiab] OR "item discriminant"[tiab] OR "interscale correlation"[tiab] OR "interscale correlations"[tiab] OR ((error[tiab] OR errors[tiab]) AND (measure*[tiab] OR correlat*[tiab] OR evaluat*[tiab] OR accuracy[tiab] OR accurate[tiab] OR precision[tiab] OR mean[tiab])) OR "individual variability"[tiab] OR "interval variability"[tiab] OR "rate variability"[tiab] OR "variability analysis"[tiab] OR (uncertainty[tiab] AND (measurement[tiab] OR measuring[tiab])) OR "standard error of measurement"[tiab] OR sensitiv*[tiab] OR responsive*[tiab] OR (limit[tiab] AND detection[tiab]) OR "minimal detectable concentration"[tiab] OR interpretab*[tiab] OR (small*[tiab] AND (real[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR "meaningful change"[tiab] OR "minimal important change"[tiab] OR "minimal important difference"[tiab] OR "minimally important change"[tiab] OR "minimally important difference"[tiab] OR "minimal detectable change"[tiab] OR "minimal detectable difference"[tiab] OR "minimally detectable change"[tiab] OR "minimally detectable difference"[tiab] OR "minimal real change"[tiab] OR "minimal real difference"[tiab] OR "minimally real change"[tiab] OR "minimally real difference"[tiab] OR "ceiling effect"[tiab] OR "floor effect"[tiab] OR "Item response model"[tiab] OR IRT[tiab] OR Rasch[tiab] OR "Differential item functioning"[tiab] OR DIF[tiab] OR "computer adaptive testing"[tiab] OR "item bank"[tiab] OR "cross-cultural equivalence"[tiab])</p> <p>Exclusion filter ("addresses"[Publication Type] OR "biography"[Publication Type] OR "case reports"[Publication Type] OR "comment"[Publication Type] OR "directory"[Publication Type] OR "editorial"[Publication Type] OR "festschrift"[Publication Type] OR "interview"[Publication Type] OR "lectures"[Publication Type] OR "legal cases"[Publication Type] OR "legislation"[Publication Type] OR "letter"[Publication Type] OR "news"[Publication Type] OR "newspaper article"[Publication Type] OR "patient education handout"[Publication Type] OR "popular works"[Publication Type] OR "congresses"[Publication Type] OR "consensus development conference"[Publication Type] OR "consensus development conference, nih"[Publication Type] OR "practice guideline"[Publication Type]) NOT ("animals"[MeSH Terms] NOT "humans"[MeSH Terms])</p>
<p>Final N = 1959 (10/12/22)</p>	<p>#1 AND #2 AND #3 AND (#4 OR #5)</p>

Source: Prepared by the authors, 2022.

Figure 1 - Construction syntax, descriptors/keywords, and Boolean operators used in the MEDLINE/NCBI/PubMed database. Teresina, PI, Brazil, 2022.

conclusion of the quality of an instrument will be then provided. Finally, the quality of the evidence will be classified as "High", "Moderate", "Low" or "Very low" using a modified approach⁽¹⁹⁾ of the Grading of Recommendations Assessment, Development and Evaluation (GRADE).

Data synthesis

Based on the Guideline for systematic reviews of outcome measuring instruments developed by the COSMIN group, the data synthesis will provide recommendations for the instruments that are adequate for use, synthesized into three categories: (i) Most adequate instruments to evaluate the quality of life in adults with elimination ostomies; (ii) Instruments requiring further validation studies; or (iii) Instruments that are not recommended.

The instrument development quality (that is, precise construction, tested in a sample that represents the population) and the findings about the methodological quality of each measuring property per instrument (that is, Very good, Adequate, Doubtful, Inadequate quality) will be detailed in tables generated in Microsoft Excel 2016.

In addition to the methodological quality of the measuring properties, we will report the

instrument's characteristics (name of the instrument, language and study population, use context intended, number of scales and subscales, number of items, answer options) in table format. The characteristics of the study populations, including (that is, geographic location, target population and environment, sample size), as well as the interpretability and feasibility aspects, will be presented in general tables.

A qualitative synthesis will be considered if we can substantially identify more than one published or non-published psychometric study per instrument (for example, mean Cronbach's alpha with a 95% confidence interval). If this is not possible, the results will be summarized qualitatively. A general conclusion of the quality per measuring properties per instrument will be presented in a table format, including a level of evidence (High, Moderate, Low, or Very low).

The validation process will be in charge of two independent reviewers. If necessary, any discrepancies will be resolved with the help of a third reviewer.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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