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# INSTRUMENTS MEASURING QUALITY OF LIFE OF PEOPLE WITH CHRONIC WOUNDS: A SCOPING REVIEW PROTOCOL

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## ABSTRACT

**Objective:** Map the types and details of instruments used in the assessment health-related quality of life (HRQoL) available to people with chronic wounds. **Materials and Methods:** systematic scoping review study will follow the guidelines of the Joanna Briggs Institute and the conformities recommended by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. The databases MEDLINE (PubMed), CINAHL (EBSCO), Web of Science and Scopus will be used for the search. The inclusion criteria considered will be articles that include people with chronic wounds, of any etiology, above 18 years old, and from various health care contexts, that utilize, critique or compare specific measurement instruments of health-related quality of life for this population. Online studies, in any language and without temporal, geographic or cultural limitations will be examined. **Conclusion:** This protocol document describes the process of conducting a systematicscoping review. The review study developed from this protocol contributed to summarize as the best results found in the literature on the instruments currently available to measure HRQoL in people with chronic injuries.

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# INTRODUCTION

People with chronic wounds face restrictions in the following areas: physical, social and psychological. They present limitations for activities of daily life and leisure, and they experience feelings of frustration, anxiety, isolation, depression and negative self-concept, thus compromising their quality of life in all areas. Chronic wounds are considered a public health problem in Brazil and throughout the world, as its occurrence is aggravated by the ageing of the population, owing to the increase in chronic illnesses (Lentsck *et al*, 2018; Gouveia *et al*, 2017; Oliveira *et al*, 2019). On many occasions, disguised as comorbidities, they represent a silent, often undervalued, epidemic for the individual, health care systems, and society (Järbrink *et al*, 2016). It is estimated that between 1% and 4% of the world's population will develop some form of chronic lesion during their lifetime (Cavassan *et al*, 2019).

Around 15% of chronic wounds last for more than a year and have a high potential for relapses (Lindholm e Searle, 2016). They generate high costs for health care services, as they involve home care, prolonged hospitalizations, complex treatments and the use of adjuvant therapies (Kapp e Santamaria, 2017). The European Wound Management Association (EWMA) defined a chronic wound as a lesion in which the physiological process of healing presents a failure in progressing or responding to treatment in a period of four to six weeks and the absence of complete restauration under anatomical and functional aspects after three months (EWMA, 2019). The most common types are venous ulcers, arterial ulcers, diabetic neuropathic ulcers, surgical dehiscence and unusual wounds (IWII, 2016). Complications or deficiencies, like ischemia, and the presence of intrinsic and extrinsic factors, including the use of medication, poor nutrition or comorbidities accentuate its occurrence (Mihai et al, 2018). They can be referred to as wounds that are difficult to heal,

wounds that do not heal, complex wounds or serious injuries (WSE, 2019). Studies (Kapp et al, 2018; Deufert e Graml, 2017; Dias et al, 2014) show that people with chronic wounds face complex challenges, owing to physical and psychosocial factors caused by the lesion. The physical effects include pain, discomfort, mobility impairments, self-care deficits and the incapacity to carry out the activities of daily life. Anxiety, shame, alterations in body image, emotional problems and social isolation are some of the psychosocial factors also caused by the lesion, and that significantly compromise the quality of life of these people (Tavares et al, 2017; Torres et al, 2018). The Health-Related Quality of Life (HRQoL) is a multidimensional construct that covers psychological, physical, social and emotional dimensions, and questions related to wellbeing (Gorecki et al, 2014). Thus, we intend to understand the impact caused by the disease and/or its treatment according to the different dimensions of quality of life. This can be measured through specific and generic questionnaires (Lupepsa e Franco, 2017).Potential negative effects of chronic wounds on physical, psychological, social, spiritual, lifestyle and financial areas of the quality of life are reported in various scientific publications (Gouveia et al, 2017; Kapp et al, 2018; Torres et al, 2018; Frota et al, 2015).

Faced with this problem, attention models focused on considering Patient Reported Outcome Measures (PROMs) have received greater attention in the last few decades, due to their potential to contribute, positively, to the health and wellbeing of patients (Kapp et al, 2018).HRQoL instruments are classified as PROMs and focus on the aspects and impact of health care interventions that are important. The general structure of these tools is composed of a set of questions, divided into categories or dimensions related to a specific area and that have an impact on the quality of life (Wiering et al, 2017). The PROMs stand out as key measures to identify new concepts of care for people with chronic wounds, as they take into consideration the patient's perspective related to his/her health conditions (Wiering et al, 2017; Del Core et al, 2018). Standardized measurement instruments of HRQoL allow for the evaluation of the effectiveness of the therapeutic measures employed, facilitate doctor-patient communication and decision making, prioritize the results and preferences of the patient, and monitor changes in the results during prevention, treatment and rehabilitation, thus turning into a standard to be implemented, as much in clinical care as in research. Thus, setting themselves up as important indicators of results about the performance of the healthcare system (Kapp et al, 2018; Deufert e Graml, 2017). There is a heterogeneity of PROMs instruments to measure HRQoL. The choice will depend on the objective of your proposal, the practicality required and the population to be studied (Blome et al, 2014). Consequently, there is a need to increase the knowledge about the scope and objectives of these instruments, what are the specific dimensions that should be evaluated and in which contexts they were utilized.

In this study, the option was taken to carry out a review of the scope, which will permit a systematic and exploratory mapping of the main HRQoL questionnaires currently used and directed towards people with chronic wounds. The guidelines proposed by the Joanna Briggs Institute (Peters *et al*, 2017) and the conformities recommended by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR):Checklist and Explanation (Tricco *et al*, 2018) will be considered. Before

developing the current protocol review, a preliminary survey was carried out in the JBI Database of Systematic Reviews and Implementation Reports, and in MEDLINE (via PubMed)with the aim b eing to identify the existence of systematic reviews or similar scope reviews that have previously been published or are in progress. In the preliminary search, one study (Augustin et al, 2014) outlined HRQoL concepts and an evaluation methodology for chronic wounds and inflammatory diseases of the skin and even detected 106 validated tools to measure the quality of life of people with such conditions. Another study (Launois, 2015) located 10 quality of life scales utilized for chronic venous disorders, including leg ulcers identifying advantages and deficits of the existing tools. However, until now, no dedicated revisions to the comprehensive investigation of HRQoL evaluation instruments for people with chronic wounds, which consider the frequency of use, fitness of use, quality of life domains, structure and psychometric details of the respective instruments, have been located. Given the knowledge gaps mentioned above, the authors intend, through the scoping review, to explore studies that used HRQoL assessment instruments applied in this specific population, in order to draw from the results, the best available evidence on the main types and details of these instruments, providing information that may contribute to a critical analysis by health professionals to enable appropriate choice of the instrument (s), according to specific indications intended, both in care and in future research in this context, It will also support potential directions for future systematic reviews. Thus, it is opportune to carry out a scope review, due to its methodological adequacy to the studied theme. Based on the foregoing, this protocol has the purpose of establishing guidelines for the production of a scoping review, which has as its objectiveto map the types and details of instruments used in the assessment health-related quality of life (HRQoL)available to people with chronic wounds. The research question is: What is the state of the art about the scientific production on the instruments used to measure the HRQoL of people with chronic wounds?

#### **MATERIALS AND METHODS**

The scoping review will follow the methodological model described by the manual from the Joanna Briggs (Frota *et al*, 2015) Institute and will follow seven main stages:

**Stage** 1: Define and align the objective(s) and question(s)

The objective of this scope review is to map the types and details of instruments used to assessment of health-related quality of life (HRQoL) available to people with chronic wounds. The central question guiding this scoping review were What is the state of the art about the scientific production on the instruments used to measure the HRQoL of people with chronic wounds.

**Stage 2:** Develop and align the inclusion of criteria with the objective(s) and question(s). The inclusion criteria based upon the PCC (Population, Concept and Context):

#### Participants

The current review will consider studies that include people with chronic wounds, adults and/or old people, independent of the wound etiology.

#### Concept

The concept will address the quality of life construct in the face of the questions of the health-illness process related to the existence of chronic wounds. Quality of life has its own specificity when associated with health questions, principally chronic conditions, commonly referred to as HRQoL. This is a subjective measure of the physical, social, psychological and spiritual wellbeing of a person and represents the conception about how a particular disease or intervention affects life. The information about the HRQoL of a patient generally is collected using PROMs' instruments. This implies that the patient responds to a series of questions based on dimensions of physical and social functioning, and mental and spiritual well-being. It can include generic and specific questions about his/her state of health. The answers are analyzed to produce scores from a multidimensional perspective, which establishes quality of life standards or levels. The identified instruments will be summarized by their various components, including tool scope, structure, population, frequency of use and psychometric properties, and will then be grouped into generic and disease-specific questionnaires.

#### Context

The context of this review will consider any health care environment, whether it is outpatient, hospital or home, where people with chronic wounds are attended to and have their quality of life evaluated by way of instruments.

**Stage 3:** Describe the planned approach for evidence seeking, selection, extraction and the creation of charts

Initial research was conducted on MEDLINE (PUBMED) and CINAHL (EBSCO) using a combination of keywords and controlled vocabulary terminology. Second, the results of these searches were analyzed to determine additional additional search terms for title, abstract, author keywords, and database indexing. See Appendix 1 for a complete MEDLINE (PUBMED) search strategy. Lastly, the list of references of the included articles will be consulted to rescue additional studies of potential relevance. The reviewers could then get in contact with the authors of the primary studies to obtain more information if necessary. In the case that there are questions related to translation, advice will be sought from a native speaker. Studies in any language, without temporal, geographic or cultural limitations, will be included.

#### Stage 4: Select evidence

The scope review will consider both experimental and epidemiological studies, including randomized control studies, non-randomized control studies, quasi-experimental studies before and after, prospective and retrospective cohort studies, case-control studies and transversal analytic studies, including case series and reports of individual cases. Quality of life instruments utilized in reviews, adaptation and validation studies, and conference summaries will not be included, with the aim being to avoid the duplication of data. Also, nonoriginal articles, narrative reviews, non-published literature and grey literature will be excluded as this review will focus on instruments, questionnaires or quantitative scales that were submitted to psychometric tests and validated for the target population. Lastly, articles that cover wounds of neoplasia will be omitted, owing to the specificness of their healing physiology.

#### Stage 5: Extract evidence

The databases to be searched include: MEDLINE (PubMed), CINAHL (EBSCO), Web of Science and Scopus. After the search, all the citations identified will be stored in the Mendeley 1.19.4 (Mendeley Ltd., Elsevier, Netherlands) (Elsevier, 2019), management software of references, while the duplicates are removed. Concluding this stage, titles and abstracts will be selected by two independent reviewers for evaluation in relation to the outlined inclusion criteria. The complete text of the studies selected will be recovered and evaluated in detail in relation to the inclusion criteria. The studies that do not attend to the established inclusion criteria will be excluded and the reasons for the exclusion will be registered and reported. An analysis form for the selection of studies was created for better control (Appendix 2). Any divergences that arise between the reviewers in each step of the selection and triage process of the study will be resolved by way of discussion. If a consensus cannot be reached, a third reviewer will be consulted.

#### Stage 6: Map evidence

The results of the selection process will be reported in their entirety in the final report and presented in conformity with the PRISMA-ScR (Tricco et al., 2018) flow diagram. The data will be extracted from the articles included in the scope review by two independent reviewers, using a data extraction tool developed by the reviewers of this research and inspired on the model of Joanna Briggs Institute Reviewer's Manual. The main information to be extracted from the selected articles will include specific details from the studies such as: identifying code (E1, E2, .....), base, periodic, publication year, authors, language, title, objective, study design, target population and sample, HRQoL instrument, main results, most affected dimensions and conclusions (Appendix 3). This is in addition to specific information about the tool, in relation to the structure, type, domains, psychometric properties and author (Appendix 4). The data extraction table will be modified and reviewed as necessary. All modifications will be detailed. Any disagreements between the reviewers will be resolved by way of discussion, in the paradigm of reaching a consensus. However, in the event that disagreements are not sufficiently clarified, they will be resolved by a third reviewer.

**Stage 7**: Sum up the evidence in relation to the objective(s) and question(s)

The characteristics extracted will be presented in table format with aligned information to meet the outlined objective of the scope review and highlight the main results. A narrative and descriptive summary will accompany the tabulated results, in such a way as to respond to the question of the review, and which will supply a detailed summary of the instruments utilized to measure the HRQoL of people with chronic wounds. The findings will provide evidence for the appropriate selection of PROMs, destined to verify the impact caused by the chronic wound on the HRQoL of these people.

#### Conclusion

The scoping review protocol is important as it predefines the objectives and methods of the scope review. It is a systematic approach to conducting and reporting the review and allows process transparency. The protocol provides the plan for the scoping review and is important in limiting the occurrence of

reporting bias. So, this protocol document describes the process of conducting a scoping review on the types and details of instruments used in the health-related quality of life assessment (HRQoL) available to people with chronic wounds. It will contribute to the best evidence found in the literature on the instruments currently available to measure HRQoL in people with chronic wounds. PROMs instruments for assessing HROoL of people with chronic wounds are generally considered sensitive and practicable because they can identify small changes in different dimensions of quality of life using only a few items. The health-related quality of life (HRQoL) of people with chronic wounds measured through standardized PROMs provides an assessment of the impact of chronic wounds on quality of life and makes it possible to understand the potential consequences of the disease, as well as an assessment of therapeutic procedures and medical and nursing interventions. Therefore, a better understanding of the quality of life of people with chronic wounds will help healthcare professionals to optimize care delivery and outcomes for this group of patients.

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# Appendix 1: Initial search

Search strategy for MEDLINE (PubMed)			
Search	Query	Records retrieved	
#1	"quality of life" OR "life quality" OR "health-related quality of life" OR HRQOL OR "quality of life	376935	
	index" OR quality of life assessment		
#2	wound and injuries OR wounds and injury OR wounds OR chronic wounds OR skin ulcer OR leg	1264877	
	ulcer OR foot ulcer OR pressure ulcer OR non-healing wounds		
#3	surveys and questionnaires OR questionnaires OR measures OR scales OR tools OR instruments	5606847	
#4	#1 AND #2 AND # 3	10287	
Not limited to	date, not language limits		

# Appendix 2:

Database and collection date:							
For the articles selected in the search fill in questions 1 through 3							
1- Reference number of t	1- Reference number of the article (order in which the article appears in the search)						
2- DOI or PMIDnumber	2- DOI or PMIDnumber						
3- Inclusioncriteria: PCC	3- Inclusioncriteria: PCC						
() The population of	() The population is composed of people with chronic wounds.	() original study in any language and	() It is not a				
the study is composed	Main types: venous ulcers, arterial ulcers, diabetic neuropathic	from any date that utilizes, critiques or	review study.				
of people older than 18	ulcers, surgical dehiscence and atypical wounds (vasculitis, sickle	compares questionnaires for the					
years old.	cell anemia, pyoderma, Martorell's hypertensive ischemia), in any	measurement of quality of life of people					
	health care environment (outpatient, hospital, community).	with chronic wounds.					

## Appendix 3:

Data extractioninstrument			
IdentifyingCode			
Base			
Periodic			
Publicationyear			
Authors			
Language			
Title			
Objective			
TypesofStudy			
Population (details)			
Concept			
Context			
HRQoLinstrumentused			
Mainresults			
MainConclusions			

# Appendix 4:

Data extractioninstrument		
HRQoLInstrument		
Quality of Life Domains assessed		
Number of items in instrument		
Details of psychometric, validation of tool		
Author		

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