Cultural Adaptation and Validation of the Freiburg Life Quality Assessment-Wound Module to Brazilian Portuguese

Elaine Aparecida Rocha Domingues, José Vitor da Silva, Maiume Roana Ferreira de Carvalho, Uiara Aline de Oliveira Kaizer, Tamy Ananda da Silva, and Thaís Mariane Soares

1 History of the Term Quality of Life

The quality of life began to be studied in the early 1950s, but it was linked to the work dimension, initially recognized as Quality of Work Life (QWL). The studies began in England and were carried out by Eric Trist and his collaborators at the Tavistock Institute, in which they intended to analyze the individual-work-organization relationship. During this research, a socio-technical approach to work organization was developed, based on the work satisfaction and concerning to it [1].

The term quality of life (QOL) was first mentioned in 1920 by Pigou in a book on economics and well-being, in which he linked the quality of life to government support offered to the underclasses and assessed its impact on the people's lives and finances [2].

Germano [3] emphasizes that until the 1970s, the interest in the theme "quality of life" was restricted to the human sciences, and it was studied by philosophers, social scientists, and politicians. From the 1970s, in the context of the epidemiological transition and with the growing interest in giving "voice" to patients, the term "quality of life" is now used in health, usually associated with the absence of disease and physical well-being.

As time goes, quality of life has become the focus of study and reflection increasingly, and since the 1980s, it began to be viewed in a multidimensional perspective, biological, psychological, economic, and cultural, since QOL depends on these factors and it is subjective [3].

The growing concern with issues related to the quality of life comes from the movement within the human and biological sciences, in the sense

E. A. R. Domingues (✉)
Campinas State University, Campinas, SP, Brazil

University of Vale do Rio Verde, Três Corações, MG, Brazil
e-mail: elainerocha.contato@gmail.com

J. V. da Silva
Wenceslau Braz School of Nursing, Itajubá, MG, Brazil

University of Vale do Sapucaí, Pouso Alegre, MG, Brazil
e-mail: enfjvitorsilva@oi.com.br

M. R. F. de Carvalho
University of Vale do Rio Verde, Três Corações, MG, Brazil
e-mail: enf_maiume@yahoo.com.br

U. A. de Oliveira Kaizer
Campinas State University, Campinas, SP, Brazil
e-mail: uiara_oliveira@hotmail.com

T. A. da Silva · T. M. Soares
University of Vale do Sapucaí-UNIVAS, Pouso Alegre, MG, Brazil

Recent Clinical Techniques, Results, and Research in Wounds (2018)
https://doi.org/10.1007/15695_2017_87, © Springer International Publishing AG
Published Online: 14 June 2018

of valuing parameters broader than the control of symptoms, the reduction of mortality, or the increase of the life expectancy. Thus, quality of life is approached by many authors as a synonym of health and, by others, as a more comprehensive concept, in which health conditions would be one of the aspects to be considered [4].

According to the WHOQOL, in 1994, the term quality of life has many definitions because of its subjective nature, and there is no consensus about its meaning. There are several currents of thought that deal with quality of life and additional issues. Due to this wide divergence, most authors adopt the World Health Organization, which states quality of life as "the individual's perception of their position in life, according to the cultural context and value system and about its goals, expectations, standards and concerns" [5].

There is a lack of conceptual consensus on the quality of life among the authors, as they attribute the reason to the extreme complexity of the term and its use in several areas of study [2, 6]. The definition of quality of life in the specialized literature presents itself in different ways. Some define in a global way, emphasizing general satisfaction with life, or divided into sets, generating an approximation to the general concept. The approaches and the use of the indicators are intrinsically linked to the scientific and political interests of each study and research area, as well as the possibilities of operationalization and evaluation [2, 6].

Pereira [7], when conducting a bibliographic review, reaches the consensus that, depending on the area of interest, the concept is often enforced as a synonym for health, happiness, and personal satisfaction, living conditions, and lifestyle, among others. It states that indicators range from income to satisfaction with certain aspects of life. In the face of so many complexities, it becomes difficult to understand the theme quality of life, restricting, then, the operationalization in scientific analysis.

In 1994, the WHOQOL Group developed goals, expectations, standards, and concerns. Semantically, it compares to an ethical matter, from which we must analyze the individual perception of each one.

Etymologically distinguishing the term, quality derives from "qualis" (Latin) whose meaning is the specific manner of something, either considering itself or relating to another group, being able to assume both positive and negative characteristics. However, quality of life, most of the time, is characterized as something positive [8].

The quality of life is related to the subjective well-being, and it includes biological and psychological components, such as emotional well-being, abilities and disabilities awareness, adequate sleep and rest, vitality, and general satisfaction about one's life [9]. It is well known that there are countless definitions of the term quality of life, and there is still no definition that is widely accepted. It is very common to observe that most definitions are associated with several health factors, such as physical and mental well-being, but new literature has shown that quality of life can also be connected to other important elements such as friends, job, family, and everyday situations [9]. It is necessary to emphasize the relevance of some life aspects of people when it comes to an understanding the term quality of life. Kinds of literature emphasize that subjectivities should be considered, such as freedom, love, happiness, and satisfaction [9]. Nowadays, the most accepted concepts of quality of life try to handle with a multiplicity of dimensions discussed in the general or holistic approaches [7].

The main example that can be cited is the concept advocated by the World Health Organization (WHO), in which quality of life reflects the individuals' perception that their needs are being met or that opportunities to achieve happiness and self-fulfillment, regardless of their state of physical health or social and economic conditions, are being denied [10]. Although there is no consensual definition of quality of life, there is considerable agreement among researchers about some characteristics of the construct. According to it, there are three main features of the construct. They are shared by diverse opinion among the most different authors: subjectivity, multidimensionality, and bipolarity [10].

It is increasingly identified that the construct is subjective. It is not a matter of total subjectivity, since there are conditions called external to

the people who are present in the environment and in the working and living conditions that interfere with the analysis they make of their quality of life.

Concerning multidimensionality, it is a consensus among all researchers that quality of life includes at least three dimensions: physical, psychological, and social. When assessing the quality of life, other dimensions can be evidenced, for conceptual, pragmatic, and empirical reasons [11]. It can be deduced about bipolarity that the construct has positive and negative dimensions, which can be applied to several conditions such as the performance of social roles, mobility, autonomy, pain, fatigue, dependence, and others [11]. We can add two other features: complexity and mutability. The concept of quality of life (QOL) becomes complicated and challenging to evaluate because it is multidimensional, bipolar and subjective. On the other hand, the evaluation of this construct changes with time, person, place and cultural and social context. For the same person, changes according to his mood and health. These characteristics also increase the difficulty of evaluation [11].

2 Health-Related Quality of Life (HRQOL)

The interest in the QOL concept in the health area, stems in part, from the new paradigms that have influenced the policies and practices of the sector in the past decades. The determinants of the health-disease process are multifactorial and complex in nature. Thus, health and disease constitute processes understood as a continuum, related to economic, sociocultural aspects, to personal experience and lifestyles. According to this paradigm shift, QOL improvement has become one of the expected results of both healthcare practices and public policies for health promotion and disease prevention [12].

Quality of life in the health area can be identified in two concepts. Quality of life refers to a more generic concept, that is, it has a broader conception and it does not make any reference, different from the HRQOL that makes references to aggravations and dysfunction [2]. The concept of quality of life is very broad because it is linked to several approaches and problems. In the field of technical production, three key areas for analyzing quality of life stood out [2].

The first scope refers to the difference between material and immaterial aspects of quality of life. Material issues are those about basic human needs (housing conditions, water supply, and the health system, that is, the infrastructure aspect). Immaterial issues refer to the environment, cultural heritage, and well-being [2]. The second scope distinguishes individual and common aspects. Individual aspects are related to the economic, personal, and family condition, and the common ones are linked with basic and health services [2]. The third scope brings the difference among real aspects of quality of life that are easily apprehended through the definition of indicators of a quantitative nature and the subjective aspects that refer to subjective perception and the perception individuals have about quality of life [2].

It is possible to observe in the literature that, according to the authors mentioned above, the health approach is quite broad, and it is possible to find unique aspects in this approach that when interrelated gives meaning to the term quality of life in health. We can notice that there is a consensus to having quality of life; it is necessary that some elements be present: physical, emotional aspects, and relationships. All of them must be related to well-being.

To establish a more accurate analysis of these relationships, we used the World Health Organization (WHO) (2006) citation which defines that “Health is a large state of physical, mental and social well-being, not only lack of disease and infirmity.” Based on this definition, it is easy to understand that besides the preservation of physiological capacities, and the organism’s proper functioning, it is necessary that other factors are considered, such as the environment, social life, and relationships [12].

Several factors must be taken into account when relating quality of life and health; subjective and objective spheres need to be met, as well as the culture of the society. The subjective

spheres can be understood as personal actions, whereas the objective spheres can be understood as public programs linked to the population's condition of life improvements [13].

The individual action in their group is intrinsically linked to their state of health because they can define the perception of a positive or negative well-being. Human health state can constantly vary since it is extremely influenced by several factors. We can observe that, when a man is not satisfied with the environment he is in, he starts feeling uncomfortable because of that situation. As a consequence, he gradually feels unwell and even unhappy because he is in a place that takes his well-being out, and thus that position puts him off, jeopardizing one of the first indications defined by the WHO, which is that of mental and social well-being. Then the interference of the environment in the individual's life affects his state of health that, according to several studies, is related to the right quality [13].

Lifestyle can also significantly interfere with a person's state of health because life, when not based on the consciousness of right and wrong, is at risk of compromising and acting unthinkably. It is possible to give an example when we think about a person who abuses alcohol, the lifestyle of alcoholic changes drastically when he loses the notion of his attitudes, and the dependence of alcohol compromises not only health but also relationships with the people who surround him [13].

Human biology and the healthcare system organization are capable of interfering with the individual state of health and quality of life [13]. The relationship between health and quality of life needs to be followed by some elements. They can be divided in the following ways: functional domains, i.e., physical function, cognitive function, involvement in everyday life activities, and subjective health evaluation, and domains of well-being, i.e., body well-being, emotional well-being, self-care, and global perception of well-being [13].

Almeida [13] explains that a person's state of health can suffer changes due to the several characteristics that are part of it, as observed above, and because of these variants, we cannot associate the state of health/illness of a person only to a feature. To understand the health/illness relationship, it is necessary to consider both individual actions and public policies. Studies show that there is a close connection between quality of life and health and socioeconomic aspects. Some authors point that this relationship is focused on the access possibilities that the population has to receive healthcare and that the presence or lack of them directly influences their quality of life. It does not take much to conclude that a reduced healthcare population obviously cannot keep healthy and consequently suffers changes in the capacity to maintain their quality of life [13].

3 Quality of Life in Patients with Wounds

The wound is represented by the interruption of the corporeal tissue continuity, to a bigger or smaller extent, caused by any physical, chemical, and mechanical trauma or caused by a clinical affection, which activates the organic defense [14]. The healing of lesions involves complex anatomical and biological processes that, in a favorable clinical situation, can occur in acceptable time. However, when the lesions become chronic, the treatment can become quite complicated, causing an important impact on these patients' lives [15].

Wounds present classifications based on the characteristics of the lesion, such as etiology, the level of tissue involvement, and the time it lasts. As for the healing period, the wounds can be classified as acute, which are those that heal in less than 6 weeks, and chronic, which heal in a time superior to that mentioned [16–18].

Some types of wounds have significant social and economic impact, due to their enormous potential for chronicity and because they present high global prevalences, such as venous ulcers, pressure injury, injuries caused by diabetic complications, and burns [19–21]. Chronic ulcers are a serious and worldwide problem, responsible for significant morbidity and mortality rates, besides having a considerable economic impact [22].

The high rates of chronic wounds have particular relevance, given the Brazilian sociodemographic characteristics, as a longer life expectancy and less healthy, which contribute to the onset of

chronic diseases [23]. North American statistics indicate a prevalence of 14% of patients with wounds in the world population. Other studies suggest that the indexes may be higher, around 22.8% for the next few years [24].

The wound characteristics, such as the presence of exudate, its odor, pruritus, edema, and the extent of it, and the difficulty in performing basic activities such as bathing and walking are patient complaints that result in changes in lifestyle [25–27]. In the psychological domain, feelings such as fear, anger, depression, anxiety, disturbances, and social isolation are exaggerated in this population, especially in young people [28].

In a study where the authors evaluated the quality of life in 50 patients with venous ulcer who are being treated with compressive therapy by Unna boot, data collection was performed at the time of the study inclusion and was repeated at 4 months, 8 months, and 12 months after the first data collection using the Short Form 36-item (SF-36) questionnaire. During the inclusion of the patient in the study, the average scores of SF-36 were small [28], characterizing a fall in quality of life. After 12 months of Unna boot compressive therapy, the average score was 95.38, characterizing improvement in the quality of life of the analyzed patients ($p = 0.0001$). The authors concluded that patients with a venous ulcer at the beginning of data collection presented low quality of life, and after 8 months of treatment with the Unna boot, an improvement in the quality of life was observed.

The signs and symptoms presented by these individuals should not only be treated in the physical dimension but also emphasize the changes that the wound causes in their life. It is important to point out that tissue repair of a wound does not always mean an improvement in the individual's quality of life. That's possibly due to other comorbidities. That's why it is essential to bring up and care for these impacts caused by the wound, minimizing the biological, psychosocial, and emotional problems that directly affect their quality of life [29].

As soon as these patients demonstrate some dependence on managing activities like domiciliary, leisure, social, and family, they will have their autonomy impaired and automatically become dependent on their relatives and friends, and as a consequence, they have a decline in self-esteem and impairment of self-image and quality of life.

Diseases usually produce changes in the way patients live, especially in those who live with these conditions for a long period. The impact of chronic ulcers on patients' quality of life (QOL) has been the subject of studies since it involves research of many health professionals, known as health-related quality of life studies (HRQOL), and aims to identify critical aspects of the disease process in order to propose interventions that minimize suffering and its negative impact on patients' lives.

In the literature review, the HRQOL concept is dynamic and multidimensional, without consensus among the authors. It is associated with a state of emotional, mental, physical, social, and functional dimensions related to health and presents as synonymous with health perception or state of health. Therefore, there is no accurate measure of QOL; but it is necessary to evaluate the patients' well-being in these dimensions [27, 28]. HRQOL is also defined as the value given to life, weighted by the functional deteriorations, perceptions, and social conditions that are induced by the disease, complications, treatments, and the political and economic organization of the healthcare system. To measure such concepts, questionnaires were designed with the objective of evaluating QOL, which are classified as generic and specific instruments [29, 30].

In relation to the field of application, the measures can be classified as generic, if we use population-based questionnaires without specifying pathologies, being more appropriate to epidemiological studies, planning, and evaluation of the health system, related to the individuals' quality of daily life, subsequent to the experience of diseases, injuries, or medical interventions. Several instruments include indicators for subjective aspects of living with illnesses and injuries, such as feelings of shame and guilt, which have negative consequences on the perception of quality of life on the affected individuals and their families [31, 32].

Therefore, the availability of a particular instrument to evaluate the quality of life in patients with wounds will help with the integral care of the patient, and this instrument can be

used as an indicator of results on the performance of the health system [28].

4 Freiburg Life Quality Assessment-Wound (FLQA-wk)

The FLQA-wk, short version, was developed based on the Freiburg Questionnaire of Quality of Life in venous diseases, specific for venous ulcer and composed of 81 items [33]. For the development of FLQA-wk, 10 of the items were kept unchanged, 10 were modified, 61 questions were extracted, and there were 3 specific items of wounds [40]. The FLQA-wk instrument is composed of 24 questions, divided into 6 domains: physical symptoms (5 questions), daily life (5 questions), social life (3 questions), psychological well-being (4 questions), satisfaction (3 questions), and treatment (4 questions) [34].

The domain "physical symptoms" refers to the physical well-being of the patient, which can be influenced by the condition of the wound. These are specific issues: pain, discharge, pruritus, and bad smell. The "daily life" scale refers to how the wounded individual manages his daily life, while "social life" mentions the patient's relationships with other people. Psychological well-being lists the feelings that the wounded patient can present. The "treatment" domain refers to how the patient feels about the treatment offered by the health team, and the "satisfaction" scale includes how satisfied the individual feels about their health, treatment, and wound conditions.

The answers of the "daily life," "social life," "treatment," and "satisfaction" scales range from never (1 point), few times (2 points), moderately (3 points), quite a few (4 points), and a lot (5 points). For the domains of "psychological well-being" and "physical symptoms," we have the following answers: never (1 point), rarely (2 points), sometimes (3 points), often (4 points), or always (5 points).

The domain "treatment" has a question that evaluates the time spent by the individual to take care of his wound; the answers are no time (1 point), less than 10 min (2 points), 1–30 min (3 points), 30–60 min (4 points), and more than 60 min (5 points).

The FLQA-wk can be filled by the patients themselves, but, if it is necessary, it can be conducted by the researcher through an interview. To calculate the score, it is necessary that 75% of the items are answered and that at least five of the six scales are complete. It evaluates the quality of life of people with chronic wounds in the last week. The scales are calculated by the average of each answer, after recoding the "satisfaction" scale. The total score is computed from the average values of each domain.

The questionnaire also has three visual analog scales, graded from 0 (very bad) to 10 (very good). The individual evaluates his/her quality of life, general health, and wound conditions in the last week. This scale helps in the control of values of the domains, that is, the values are compared with the score of the whole instrument. The higher the value of the score, the bigger the interference with quality of life. The score varies from 1 (better quality of life) to 5 (worse quality of life).

The validation occurred in three distinct studies with individuals with acute and chronic wounds. The first study is a multicenter, uncontrolled research conducted with 175 patients. The research consisted of the evaluation of the quality of life of patients with acute and chronic wounds treated with vacuum therapy. Patients answered the questionnaire, and physicians filled an instrument on wound conditions, both before and after therapy [34]. The tests for validation in this research were the internal consistency, the convergent validity through the correlation of the FLQA-wk items with a generic instrument of quality of life, and the items of the visual analog scale. The ability to detect changes in the quality of life according to the patient's clinical alterations was performed by comparing the FLQA-wk with these variables: wound area and conditions, generic quality-of-life instruments, and global evaluation of quality of life of the visual analog scale.

A cross-sectional observational study of 384 patients with lower limb ulcers undergoing different treatments also evaluated the psychometric properties of FLQA-wk. Patients and physicians completed the questionnaires only in a moment.

The tests performed were internal consistency, convergent validity through the correlation of the FLQA-wk with visual analog scale items, and pain intensity (ranges from 0 to 10) [34].

And finally, a multicenter, randomized research verified the efficiency and safety of keratinocyte transplantation along with compressive therapy in 198 venous ulcer patients. The patients answered the questionnaires on 0 (time 1), on the 28th (time 2), and 56th (time 3) day of therapy. At times 1 and 2, all subjects received the treatment; from time 2 to 3, the patients were randomized. The tests performed were the internal consistency, test-retest, and sensitivity through the correlation of the FLQA-wk items with the success score in the treatment, scored from 1 (very successful) to 5 (no success), and FLQA-wk before and after treatment [34].

The questionnaire presented proper internal consistency in the three studies, with values ≥0.85. The test-retest and the validity were satisfactory [34].

5 Technique

5.1 Cultural Adaptation Procedures

The translation and cultural adaptation process of the FLQA-wk were carried out according to the methodological rules recommended by internationally recognized publications [35–39]. The following steps were carried out: translation, synthesis of translations, back translation, committee of experts, pretest, and focus group. It is pointed out that the author of the questionnaire was previously consulted and the authorization was provided to be adapted and validated for the Portuguese language of Brazil.

5.2 Translation of the Instrument into Portuguese

For the accomplishment of this stage, the first translation of the FLQA-wk instrument for the Portuguese language of Brazil was carried out by two independent, qualified, and bilingual translators, whose native language is Portuguese. Two independent translations were conducted, one of the translators was a nurse with knowledge in the area of wounds, and the other one was a language teacher, who was not from the area and did not know the purpose of the work [35, 37] resulting in two versions: Translation 1 (T1) and Translation 2 (T2).

5.3 Translation Synthesis

Following the translation stage, the two versions (T1 and T2) were synthesized. The analysis of the divergences of both versions was carried out by the two translators, with the researcher who reached a consensus, producing a different translation, synthesis version (SV).

5.4 Back Translation

The synthesis version (SV) of the instrument obtained by consensus was again translated into the original language of the instrument by two other translators who did not participate in the first stage of the process. This procedure checked the validity to ensure that the translated final version is in agreement with the original version of the instrument.

The back translation was carried out by two bilingual translators who had the same mother tongue as the adapted questionnaire and had knowledge of Portuguese language. Both were not from the health area and didn't know about the concepts and objectives of the research, performing the translations independently.

The questionnaire was also sent by e-mail to the authors to verify the adequacy of their original content. It is worth mentioning that the authors requested the instrument in the Portuguese language version so that one of their translators could perform a back translation. At the end of this stage, the versions back translation 1 (BT1) and back translation 2 (BT2) were produced.

Thus, the probability of imperfections decreased, having the quality guarantee of the cultural adaptation of the instrument chosen for this research [35, 39].

5.5 Committee of Experts

The committee of experts components are crucial to achieve transcultural equivalence of the translated instrument and should be made up of bilingual people and specialists from the knowledge area of the instrument, composed of health professionals, language teacher, and methodology specialist [35, 37]. This committee should be multidisciplinary and informed about the objectives and concepts of the study.

At first, the experts received an invitation letter to participate as a member of the committee of experts. After they had accepted, the specialists received all versions of the instrument: translations into Portuguese (T1 and T2), synthesis (SV) and back translations (BT1 and BT2), and a questionnaire for evaluation, which was developed specifically for this stage.

Judges reviewed and compared all translated versions modifying the format of the instrument and changing or deleting the inappropriate items for a final translation. The committee's work aims to determine the semantic, linguistic, cultural, and conceptual equivalence between the original questionnaire and the Portuguese version, to guarantee the understanding and cultural equivalence of the final version [35, 38].

Semantic equivalence is related to the meaning of words, considering the vocabulary and grammar, and the idiomatic equivalence considers the use of idioms and colloquial expressions referring to both languages. In cultural equivalence, the events mentioned in the items of the original questionnaire must be according to the Brazilian cultural experience. Conceptual equivalence is the pertinence appreciation of the concepts and the events experienced by the subjects that are part of Brazilian culture [35].

To facilitate evaluation by the committee, the questionnaire was split into items, that is, each question answered one item. The title was the first item; the general statement was the second item, and so on. The full questionnaire consisted of 42 items.

The committee of experts was formed by:

Judge 1: Nurse, university professor with experience in the care area in wound treatment
Judge 2: Language teacher
Judge 3: Nurse, Ph.D. in nursing, university professor with experience in research methodology
Judge 4: Nurse, Ph.D. in nursing, with experience in studies about quality of life and older adults
Judge 5: Nurse, master in nursing, university professor, with experience in the area of care and studies related to wounds and therapeutic communication
Judge 6: Nurse, enterostomy therapist, university professor, with experience in the care area and studies related to wounds, incontinence, and stoma
Judge 7: Nurse, master of nursing, university professor with experience in studies on quality of life
Judge 8: Nurse, master in nursing, university professor with experience in research methodology

After that, the content of the instrument was validated. The content validity verifies the degree of extension which the subject of interest is contemplated in the dimensions of the instrument [40]. This type of validity refers to a careful analysis of an instrument with the objective of verifying if the items and subitems proposed have a representative within the instrument [41, 42].

Independently, the judges carried out the analysis of the items, verifying their clarity, pertinence, and comprehensiveness, besides evaluating the overall appearance of the instrument. The content validity was assessed by calculating the content validity index (CVI). This test evaluates the level of concordance among judges on certain aspects of the adapted questionnaire and its items [42].

The judges scored the items with values from 1 to 4: 1, not equivalent; 2, it is impossible to evaluate equivalence without reviewing the item;

3, equivalent, but it needs minor changes; and 4, absolutely equivalent.

The score was calculated by summing the items that were highlighted with "3" and "4" dividing the value by the number of judges. The items with grades "1" and "2" were reviewed. For the research, the level of agreement was set equal to or higher than 0.8 [42, 43].

Thus, after the experts' assessment, we had a first translated version (VT1) of the instrument, which was used for the pretest.

5.6 Retest

The final stage of the adaptation process consisted of the pretest when the questionnaire was applied to a sample of subjects with wounds that were not part of the final sample of the study. For this phase, the authors advocated a total of 30–40 people [35, 37].

Patients who agreed to participate in the pretest received guidance on the informed consent form and explanation of the purpose of the research. The purpose of this stage was to evaluate participants' understanding and acceptance of the content of the translated version, verifying in practice how it will be managed. At the end of each completed questionnaire, the participant expressed his/her difficulties in understanding the questions of the questionnaire.

5.7 Focus Group

Due to the difficulties of understanding presented by the interviewees during the pretest related to the items of the questionnaire, it was decided to carry out a focus group with the purpose of adjusting the questionnaire to the highlighted population, for comprehensibility.

The focus group is a qualitative method that aims to obtain data from the discussion focused on specific points. In order to do this, there must be an interaction between the researcher and the research participants. The number of participants may vary from 6 to 10, and the members of the focal group should have similar characteristics and be related to the item to be studied [44]. In this study specifically, the focus group was carried out to assist in the adaptation of a quantitative questionnaire which needed to be improved to facilitate the understanding of the study population. The steps for this group consist of the assembly, conduction of the group, and, finally, the data analysis. Recruitment was carried out by invitation to individuals performing dressing on a skin lesion unit.

5.8 Evaluation of Measurement Properties

The psychometric properties of the FLQA-wk questionnaire were evaluated through reliability and convergent validity.

5.9 Reliability Assessment

The reliability, also called accuracy and reliability of the instrument [40, 45], refers to the "degree of consistency or precision with which the instrument measures the attribute it proposes to measure" [40]. The reliability of the questionnaire was evaluated using two methods: homogeneity (internal consistency) and stability (test-retest).

Internal consistency or homogeneity analyzes whether all items in an instrument measure the same characteristic [46, 47] or the degree of interrelationship between items [45]. It was verified by calculating Cronbach's alpha coefficient for the total score (Cronbach, 1951), and Cronbach's alpha higher than or equal to 0.70 was considered interesting [48, 49].

Stability refers to the consistency of the measurements' repetitions. The use of this method requires that the factor to be measured remains the same as applied to a sample of subjects at two different times, comparing the results obtained [41].

Stability was evaluated through the test-retest, calculating the intraclass correlation coefficient (ICC). The FLQA-wk questionnaire was carried out in 71 subjects under the same conditions, within a 7-day interval.

6 Validity Assessment of FLQA-Wk

Validity is an important measure property to evaluate the quality of an instrument [41], and it refers to the degree to which the data of an instrument actually measures what it is proposed to [39, 40, 46].

The convergence construct validity consists of comparing how one dimension of a new instrument correlates with dimensions of another instrument that measures the same concept, and it is applied concomitantly [39, 41, 50]. The convergent validity was carried out through the correlation of the four domains of Ferrans and Powers Quality of Life Index-Wound Version (health and functioning, psychological and spiritual, family and socioeconomic) with the domains of the FLQA-wk questionnaire. The domains Ferrans and Powers Quality of Life Index-Wound Version (FPQLI-WV) instruments were chosen, taking into account the similarity of the content of these domains with the FLQA-wk questionnaire, as shown in Table 1.

Validity was also evaluated by correlating the total score of the FLQA-wk questionnaire with the patient's score on the visual analog scale (VAS) of quality of life. This scale complements the FLQA-wk instrument and scores the individual's quality of life from 0 (very poor) to 10 (very good) (Table 2).

7 Discussion

The evaluation of the quality of life in health, mainly in the treatment of wounds, has been gaining more space in the clinic, therapeutics, and research services, providing the necessary assistance to the patient by the professionals [51]. Therefore, the application of instruments can be considered an objective measure that assists in the evaluation of the patient's well-being, contributing to quality intervention [52].

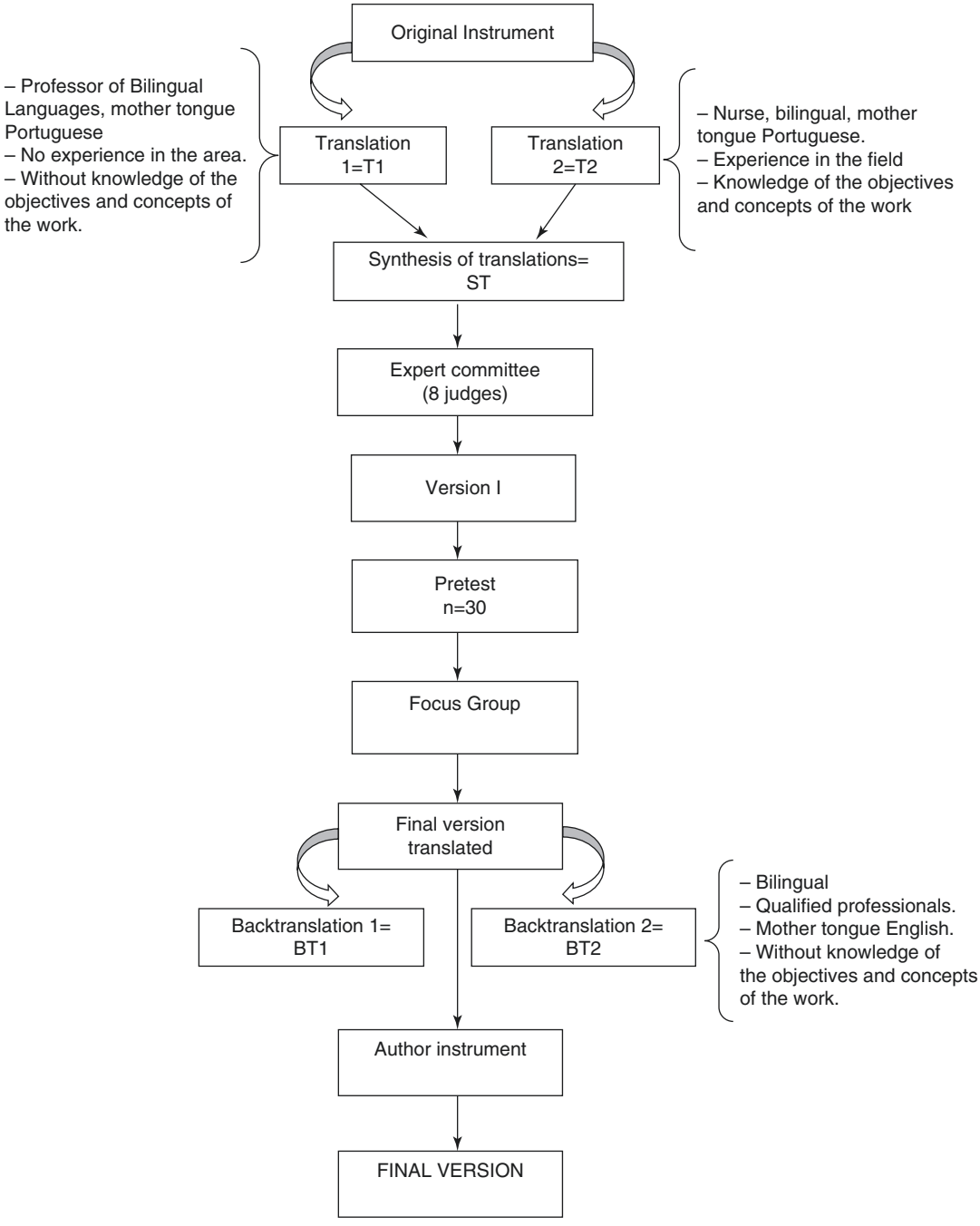
In this context, the cultural adaptation of any instrument is effective but complex and with different recommended methods in the literature [38]. In this research, this process followed the steps of translation, translation synthesis, back translation, committee of experts evaluation, pretest, and focus group [35].

The content validity was carried out with the help of a committee of judges that proved that the questionnaire contains relevant questions, and small changes were made in some items to facilitate the understanding of the highlighted population.

Table 1 Correlations of the FPQLI-WV domains indicated for the achievement of the convergent validity of the Freiburg Life Quality Assessment-Wound questionnaire

Questionnaire	Domains		Freiburg life quality assessment-wound (FLQA-wk)—adapted
Ferrans and powers quality of life index-wound version	Health and functioning	X	Physical symptoms
	Health and functioning	X	Daily life
	Health and functioning	X	Treatment
	Health and functioning	X	Social life
	Psychological/spiritual	X	Psychological well-being
	Psychological/spiritual	X	Satisfaction
	Socioeconomic	X	Satisfaction
	Family	X	Psychological well-being
	Health and functioning	X	Total score
	Total score	X	Total score
	Total score	X	Psychological well-being
	Total score	X	Satisfaction

Table 2 Flowchart of the transcultural translation process



The committee suggested small changes in items, such as synonym substitutions, sentence inversions, and some spelling mistakes following semantic, cultural, conceptual, and idiomatic equivalences. Considering the agreement rate >0.80, the committee of experts suggested small changes in some questions, which were followed. After these changes, Version I was created, which was used in the pretest.

The pretest included 30 subjects with chronic wounds of different etiologies. The individuals' average age was 63.0 years old (standard deviation = 12.8), represented by 79.3% female, 41.4%

married, and 69.0% with incomplete primary education. The venous ulcer presented a higher frequency with 58.6%. The average wound duration was 42 months (standard deviation = 63.7) and with an average number of 1.5 wounds.

Patients with different levels of schooling were selected to allow evaluation of the questionnaire in different degrees of difficulty. Five patients attended the meeting, the average age was 65.4 years, and the educational attainment levels of the participants were two illiterates, two with incomplete elementary education, and one with complete higher education.

The instrument was applied by interview, and 5–10 min was spent for the application. At the end of the interview, participants were asked to express their opinions on the questionnaire verbally. Patients reported that some words made it difficult to understand the questions. Due to these difficulties presented by the participants in the comprehension of some questions, which could produce false results in the analysis of the questionnaire, it was decided to carry out a focus group, to adapt the instrument to the specific population.

The focus group was started explaining the purpose of the meeting and the importance of each participation. The questions of the instrument were read separately and in an easy way to facilitate the follow-up by all, enabling them to understand what was intended with the focus group.

Conducting the focus group were one moderator and two observers. The moderator was responsible for reading the questionnaire and discussion, while the observers analyzed expressions during the discussion. The whole session was recorded with the permission of the attendees. The discussion lasted 1 h and 10 min, and the questionnaire was analyzed and discussed twice. During the reading of the instrument to each question, the participant was asked about the comprehension of the content. According to the reports, associated with the nonverbal expressions that indicated doubt, the item was discussed and they requested to vote for possible changes. After this step, the final translated version (FTV) was elaborated – which was sent to back translation to evaluate the discrepancies between the FTV and the original instrument.

The FVT was sent to one of the authors for consideration. Small changes were requested in the Portuguese questionnaire so that the cultural adaptation of the Freiburg Life Quality Assessment-Wound (FLQA-wk) questionnaire, abbreviated version, reflected the content of the original version. After the changes in the questionnaire, the final version (FV) was created.

Regarding the medical properties, the reliability of the FLQA-wk was evaluated through the internal consistency, represented by Cronbach's alpha, and the stability, through the test-retest, using the intraclass correlation coefficient (ICC).

The adapted instrument (FLQA-wk), containing 24 items, presented an excellent internal consistency since it obtained a total Cronbach's alpha of 0.86. In relation to the domains, the Cronbach's alpha was physical symptoms, 0.63; daily life, 0.83; social life, 0.53; psychological well-being, 0.70; treatment, 0.68; and satisfaction, 0.86.

Concerning stability evaluation, a high value of ICC (0.93) is contacted, which is considered excellent, since the closer to 1, the better the stability of the instrument [46]. The adapted questionnaire showed temporal stability when applied in different moments for the same participants in similar conditions.

The convergent validity was evaluated by carrying out the FLQA-wk correlation with the Ferrans and Powers Quality of Life Index-Wound Version, as well as the quality of life score of the visual analog scale. The analysis was carried out using Spearman's correlation coefficient.

Correlations appear as negative or inverse relationships since the FLQA-wk score indicates that the higher the score, the worse the quality of life, whereas in the FPQLI-WV, the score is the opposite: the higher the score, the better the quality of life.

The correlation of FLQA-wk with the FPQLI-WV domains. The treatment domains (−0.32), daily life (−031), physical symptoms (−0.27), social life (−0.24), and the total score (−0.41) of the FLQA-wk presented satisfactory to moderate correlation and significant with the health and functioning domain of FPQLI-WV.

The psychological well-being domain of FLQA-wk had a moderate and significant correlation with the psychological/spiritual domains (−0.44), family (−0.38), and the total score (−0.40) of FPQLI-WV.

The domain satisfaction showed a moderate and significant correlation with the psychological/

spiritual domains (−0.48), socioeconomic (−0.46), and total score (−0.37) of the IQVFP-VF. The total score (0.36) of the FLQA-wk had a moderate correlation with the total FPQLI-WV score.

Concerning the visual analog scale, the FLQA-wk total score had a moderate and significant correlation with the total quality of life score (−0.38).

Conclusions

The cultural adaptation of the Freiburg Life Quality Assessment-Wound was performed according to the recommended international methodology, resulting in a real version. In the application, the instrument proved to be easy to understand and apply.

The questionnaire was found to be reliable, with a Cronbach's alpha (0.87) and satisfactory temporal stability (0.93). Concerning the validity, the adapted FLQA-wk questionnaire presented a correlation of satisfactory magnitude to moderate magnitude and significant (−0.24 to −0.48; $p < 0.0001$) with the domains of the IQVFP-VF questionnaire.

Therefore, FLQA-wk presented enough healing properties when applied in patients with chronic wounds in the Brazilian population.

References

1. Rodrigues MVC (1991) Qualidade de Vida no Trabalho: evolução e análise no nível gerencial. UNIFOR, Fortaleza
2. Belasco AGS, Sesso RCC (2006) Qualidade de vida: princípios, focos de estudo e intervenções. In: Diniz DP, Schor N (eds) Qualidade de vida. Manole, São Paulo, pp 1–10
3. Germano CM, Bonato D, Maion VH, Avó LR, Melo DG, Fontanella BJ (2016) Possíveis novos determinantes da qualidade de vida de pacientes com câncer de tireóide tratado: um estudo qualitativo. Cien Saude Colet 21(8):2451–2462
4. Fleck MP, Louzada S, Xavier M, Chachamovich E, Vieira G, Santos L, Pinzon V (1999) Aplicação da versão em português do instrumento de avaliação de qualidade de vida da Organização Mundial da Saúde (6WHOQOL-100). Rev Saúde Pública 33(2): 198–205
5. Whoqol Group (1994) The development of the World Health Organization quality of life assessment instrument (the WHOQOL). In: Orley J, Kuyken W (eds) Quality of life assessment: international perspectives. Springer, Heidelberg, pp 41–60
6. Farquhar M (1995) Definitions of quality of life: a taxonomy. J Adv Nurs 22(3):502–508
7. Pereira EF, Teixeira CS, Santos A (2012) Qualidade de vida: abordagens, conceitos e avaliação. Rev Bras Educ Fís Esporte 26(2):241–250
8. Santin S (2002) Cultura corporal e qualidade de vida, vol 27. Kinesis, Santa Maria, pp 116–186
9. Aguglia A, Salvi V, Maina G, Rossetto I, Aguglia E (2011) Fibromyalgia syndrome and depressive symptoms: comorbidity and clinical correlates. J Affect Disord 128(3):262–266
10. Nutbeam D (1998) Promoción de la salud: glossário. World Health Organization, Genebra
11. Paschoal SM (2016) Qualidade de vida na velhice. In: de Freitas EV, Py L (eds) Tratado de Geriatria e Gerontologia, 4th edn. Guanabara Koogan, Rio de Janeiro, pp 79–86
12. Schuttinga JA (1995) Quality of life from a federal regulatory perspective. In: Dimsdale JE, Baum A (eds) Quality of life in behavioral medicine research. Lawrence Erlbaum Associates, Hillsdale, NJ, pp 31–42
13. Almeida MAB, Gutierrez, GL, Marques R (2012) Qualidade de vida: definições e conceitos. In: Almeida MAB, Gutierrez GL, Marques R, organizadores. Qualidade de vida: definição, conceitos e interfaces com outras áreas de pesquisa. Escola de Artes, Ciências e Humanidades, Universidade de São Paulo, São Paulo, pp 13–50
14. Oliveira ACDS, Silva CI, Ramos RS (2016) Úlceras venosas, Arteriais e Mistas. In: Gamba MA, Petri V, MTF C (eds) Feridas: Prevenção, causas e tratamento. Guanabara Koogan, Rio de Janeiro, p 261
15. Yamada BFA, de Gouveia SantosIISantos VLC (2009) Construção e Validação do Índice de Qualidade de Vida de Ferrans & Powers - Versão Feridas. Rev Esc Enferm USP 43:1105–1113
16. Werdin F, Tennenhaus M, Schaller HE, Rennekampff HO (2009) Evidence-based management strategies for treatment of chronic wounds. Eplasty 9:e19
17. Dealey C (2008) Cuidando de feridas. Atheneu, São Paulo
18. de Brito KKG, de Sousa MJ, de Sousa ATO, de Ardújo Menses LB (2013) Dos Santos Oliveira SH, ães Oliveira Soares MJG. Feridas crônicas: abordagem da enfermagem na produção científica da pós-graduação. Rev Enferm 7(2):414–442
19. de Souza Smaniotto PH, Ferreira MC, Isaac C, Galli R (2012) Sistematização de curativos para o tratamento clínico das feridas. Rev Bras Cir Plást 27(4):623–626
20. Hopkins RB, Burke N, Harlock J, Jegathisawaran J, Goeree R (2015) Economic burden of illness associated with diabetic foot ulcers in Canada. BMC Health Serv Res 15(13):1–9
21. Padula WV, Makic MB, Wald HL, Campbell JD, Nair KV, Mishra MK, Valuck RJ (2015) Hospital-acquired pressure ulcers at academic medical centers in the United States, 2008-2012: tracking changes since the

CMS nonpayment policy. Jt Comm J Qual Patient Saf 41(6):257–263
22. Castro SLS, Ferreira NMLA, Roque M, Souza MBB (2012) Vivendo uma situação difícil: a compreensão da experiência da pessoa com úlcera venosa em membro inferior. Rev Estima 10(1):12–19
23. Neves JS, Azevedo RS, Soares SM (2014) Atuação multiprofissional na construção de grupo operativo envolvendo pacientes com lesão de membros inferiores. Rev Norte Mineira Enferm 3(1):86–95
24. Evangelista DG, Magalhães ERM, Moretão DIC, Stival MM, Lima LR (2012) Impacto das feridas crônicas na qualidade de vida de usuários da estratégia de saúde da família. Rev Enferm Centro Oeste Mineiro 2(2):254–263
25. Fagervik-Morton H, Price P (2009) Chronic ulcers and everyday living: Patients' perspective in the United Kingdom. Wounds 21(12):318–323
26. Salomé GM, Pellegrino DMS, Blanes L, Ferreira LM (2011) Self-esteem in patients with diabetes mellitus and foot ulcers. J Tissue Viability 20(3):100–106
27. Salomé GM, Ferreira LM (2012) Quality of life in patients with venous ulcers treated with Unna's boot compressive therapy. Rev Bras Cir Plást 27(3):466–471
28. Dias TYAF, Costa IKF, Salvetti MG, Mendes CKTT, Torres GV (2013) Influência da assistência e características clínica na qualidade de vida de portadores de úlcera venosa. Acta Paul Enferm 26(6):529–534
29. Santo PFE, Almeida SA, Salomé GM (2013) Avaliação do nível de depressão em indivíduos com feridas crônicas. Rev Bras Cir Plást 28(4):665–668
30. Salomé GM, Blanes L, Ferreira LM (2014) The impact of skin grafting on the quality of life and self-esteem of patients with venous leg ulcers. World J Surg 38:233–240
31. Santos LSF, Camacho ACLF, Oliveira BGRB, Nogueira GA, Joaquim FL (2015) Influência da úlcera venosa na qualidade de vida dos pacientes: revisão integrativa. Rev enferm UFPE 9(3):7710–7722
32. Augusto FS (2015) Tradução, adaptação cultural e validação do Cardiff Wound Impact Schedule para a língua portuguesa do Brasil. Dissertação (Mestrado)-Universidade Federal de São Paulo – Programa de Pós-Graduação em Cirurgia Translacional, São Paulo
33. Augustin M, Dieterle W, Zschocke I, Brill C, Trefzer D, Peschen M et al (1997) Development and validation of a disease specific questionnaire on the quality of life of patients with chronic venous insufficiency. Vasa 26(4):291–301
34. Augustin M, Herberger K, Rustenbach SJ, Zschocke I, Blome C (2010) Quality of life evaluation in wounds: validation of the Freiburg life quality assessment-wound module, a disease-specific instrument. Int Wound J 7(6):493–501
35. Beaton D, Bombardier C, Guillemin F, Ferraz MB (2007) Recommendations for the cross-cultural adaptation of the DASH & QuickDASH outcome measure [online]. Institute for Work and Health. http://www.dash.iwh.on.ca/sites/dash/files/downloads/cross_cultural_adaptation_2007.pdf Accessed 8 Apr 2017
36. Guillemin F (1995) Cross-cultural adaptation and validation of health status measures. Scand J Rheumatol 24(2):61–63
37. Beaton DE, Bombardier C, Guillemin F, Ferraz MB (2000) Guidelines for the process of cross-cultural adaptation of self-report measures. Spine 25(24):3186–3191
38. Alexandre NMC, Guirardello EB (2002) Adaptación cultural de instrumentos utilizados en salud ocupacional. Rev Panam Salud Publica 11(2):109–111
39. Mokkink LB, Terwee CB, Patrick DL Alonso J, Stratford PW, Knol DL, Bouter LM, de Vet HCW (2012) COSMIN checklist manual. http://www.cosmin.nl/the-cosmin-checklist_8_5.html. Accessed 8 Apr 2017
40. Mcdowell I, Newell C (1996) Measuring health. A guide to rating scales and questionnaires, 2nd edn. Oxford University Press, New York
41. Polit DF, Beck CT (2011) Fundamentos de Pesquisa em enfermagem: avaliação de evidências para as práticas da enfermagem, 7th edn. Artmed, Porto Alegre
42. Alexandre NMC, Coluci MZO (2011) Validade de conteúdo nos processos de construção e adaptação de instrumentos de medida. Ciênc Saúde Coletiva 16(7):3061–3068
43. Grant JS, Davis LL (1997) Focus on quantitative methods: selection and use of content experts for instrument development. Res Nurs Health 20(3): 269–274
44. Lervolino SA, Pelicioni MCF (2001) A utilização do grupo focal como metodologia qualitativa na promoção da saúde. Rev Esc Enf USP 35(2):115–121
45. Lohr KN, Aaronson NK, Alonso J, Burnam MA, Patrick DL, Perrin EB et al (1996) Evaluating quality-of-life and health status instruments: development of scientific review criteria. Clin Ther 18(5):979–992
46. Lobiondo-Wood EHJP (2001) Avaliação crítica e utilização. Guanabara- Koogan, Rio de Janeiro
47. Terwee CB, Bot SD, de Boer MR, Van Der Windt DA, Knol DL, Dekker J, Bouter LM, de Vet HC (2007) Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol 60(1):34–42
48. DeVon HA, Block ME, Moyle-Wright P, Ernst DM, Hayden SJ, Lazzara DJ, Savoy SM, Kostas-Polston E (2007) A psychometric toolbox for testing validity and reliability. J Nurs Scholarsh 39(2): 155–164
49. Houser J (2008) Precision, reliability, and validity: essential elements of measurement in nursing research. J Spec Pediatr Nurs 13(4):297–299
50. Fayers PM, Machin D (2000) Quality of life: assessment, analysis and interpretation. John Wiley and Sons Ltd, Chichester
51. Jankovic S, Vukicevic J, Djordjevic S, Jankovic J, Marinkovic J, Basra MK (2013) The Cardiff Acne Disability Index (CADI): linguistic and cultural validation in Serbian. Qual Life Res 22(1):161–166
52. Anand SC, Dean C, Nettleton R, Praburaj DV (2003) Health-related quality of life tools for venous-ulcerated patients. Br J Nurs 12(1):48