CONSTRUCTION AND VALIDATION OF A QUESTIONNAIRE ON WOMEN'S QUALITY OF LIFE IN THE MENSTRUAL PERIOD

Patricia Albuquerque Moraes*
Maria Cristina Gabrielloni**
Márcia Barbieri***

ABSTRACT

Objectives: To construct and validate an instrument that evaluates the quality of life of women in the menstrual period. **Method:** Methodological research, which included the following stages: bibliographic research, execution of focus group, preparation of the items of the instrument, content validation through a committee of judges, pretest, data collection and evaluation of the psychometric properties of the instrument to verify its validity and reliability. **Results:** The confirmatory factor analysis did not show a good fit, and exploratory factor analysis was performed, which, after the exclusion of 23 items, resulted in 14 factors that explain 69.6% of the total variance of the data. The correlations between the instrument scores and the WHOQOL-Bref were positive and significant. Cronbach's alpha was adequate for 11 facets, with values ranging from 0.71 to 0.89 and, for the total instrument, was excellent, with alpha of 0.91. The final version of the questionnaire consisted of 42 items, distributed in 11 facets. **Conclusion:** The questionnaire on women's quality of life in the menstrual period (QLMP) presents psychometric properties that translate a valid, reliable and consistent instrument.

Keywords: Quality of Life. Menstruation. Surveys and Questionnaires. Validation Studies.

INTRODUCTION

There is an increasing number of women who care about having a healthy life, free of disabilities, diseases and unpleasant symptoms that harm leisure, interpersonal relationships and work, more than just having a long life. The characteristics of a healthy life are the essence of what health-related quality of life means⁽¹⁾.

Women's health is remembered in the United Nations Agenda for Sustainable Development 2030, where the heads of state and government of the United Nations member countries met, and, on this occasion, signed the terms for the said agenda, as well as approved the Sustainable Development Goals (SDGs) contemplated in 17 Goals and 169 targets. In Objective "Health and Well-being" highlights the goal 3.7, which, by 2030, provides for ensuring universal access to sexual and reproductive health services, including family planning, information and education, as well as the integration of reproductive health in

national strategies and programs^(2,3).

Decades ago, women, for the most part, were housewives, married early, had their first menstruation at 17, had on average five children, breastfed each of them for about two years and, still around 40 years, experienced the menopause. Therefore, they lived with menstruation for much less time than today's women, who in turn end up menstruating earlier, marry later, have one to two children and breastfeed less time as a result of the change in lifestyle⁽⁴⁾.

Contemporary women, like men, have a professional life and need to reconcile professional activities and motherhood as soon as possible. In addition, they experience menopause at an older age, approximately 50 years, thus living with menstruation for much longer⁽⁴⁾.

All these changes in women's lifestyle, in their interests and in the way of conducting their life, as well as the female independence that occurred in the 1960s, with the advent of the contraceptive pill, which contributed to the

*Obstetric Nurse. PhD in Nursing. Invited Professor on the Obstetric and Gynecological Nursing Specialization Course at the Albert Einstein Israelit Institute for Theaching and Research. São Paulo. SP. Brazil. E-mait: oatriciamor4@omail.com: ORCID:0000-0003-3437-9955.

****Obstetric Nurse. PhD in Nursing. Professor of Undergraduate and Postgraduate Nursing at the UNIFESP. São Paulo, SP, Brazil. E-mail: mb.barbi@gmail.com; ORCID: 0000-0002-4662-1983

São Paulo, SP, Brazil. E-mail: patriciamor4@gmail.com; ORCID:0000-0003-3437-9955.

**Obstetric Nurse. PhD in Nursing. Professor of Undergraduate and Postgraduate Nursing at the Federal University of São Paulo (UNIFESP). São Paulo, SP, Brazil. E-mail: crisqabrielloni@gmail.com; ORCID: 0000-0003-2395-9161.

breakup of the sex-pregnancy bond and brought a new awareness about sexuality and pleasure, made women able to decide the best time to have children, as well as allowed to rethink the phenomenon of menstruation⁽⁴⁾.

Menstruation is considered as a physiological phenomenon that is present in women's lives for approximately 40 years, being exempt from it only in the pregnancy-puerperal cycle and when menopause is established. It allows the recognition that a woman is in the reproductive phase⁽⁵⁾.

It is estimated that menstrual abnormalities affect up to one third of women worldwide and can have a debilitating impact on a person's quality of life. Among the most common complaints are headache, dysmenorrhea, irregular cycles, heavy menstrual bleeding, irritability, mood swings, mobility difficulties, among others^(6,7).

Studies that sought to know the quality of life of women in various situations present the psychological domain with the lowest score. Women seek gynecologists more for social and physical factors than for psychological factors. However, 50% of women with heavy menstrual bleeding and mental health problems describe it as the cause of their anxiety and depression^(8,9).

In this context, health problems are directly related to the decrease in the quality of life of an individual, however, it is not possible to say that it is the only factor, because the family, social, financial, spiritual and emotional aspects contribute to this state⁽¹⁰⁾.

Mobility is presented as an important factor in reducing the quality of life of women in several aspects. Transportation and the freedom to come and go are the most cited in quality of life studies. The activity dimension of daily life showed a higher frequency of dissatisfaction regarding the physical domain of the WHOQOL-Bref scale, in a study of quality of life of women with premenstrual syndrome (PMS), activities in women with PMS are affected, with a decrease in their quality of life⁽¹⁵⁾.

However, in the literature, we find divergences in women's opinions about menstruation. There are those who do not care and believe that it is natural, synonymous with fertility and often necessary, while there are

others who do not support it and believe it to be unnecessary and inappropriate bleeding^(12,13).

Thinking about women's health and particularly their menstrual aspect, there is a growing number of women showing interest in spacing or even suspending their menstruation, with the claim that this fact would provide improvement in their health and quality of life^(14,15). However, no instrument was found in the national literature to measure the quality of life of women in this period. Such an instrument would collaborate with treatments and decision-making, providing improved QoL of many women. (Henceforth we will treat quality of life only with the acronym QoL).

Internationally, some instruments have been developed to assess bleeding symptoms and QoL, however, all have a focus on intense or heavy menstrual bleeding and have not yet been adapted to our language and culture⁽¹⁶⁾.

Knowing what the woman feels and thinks about her menstrual period and how these feelings and thoughts can interfere with her quality of life can provide measures that help a healthy life, especially for women who have impairments.

Recognizing the importance of the subject, about the transformation thinking attributions of women in modern society, as well as the change in their standard of living, this study aims to answer the following questions: Why do some women like to and others do not? menstruation interfere with a woman's QoL? How to evaluate a woman's healthy life in the period when she menstruates? To achieve the answers, the objective was to construct and validate an instrument that evaluates the woman's QoL during the menstrual period in order to subsidize nursing and medical interventions that guarantee greater satisfaction of the woman with her life and her physiological aspects.

METHOD

This is a methodological research, referring to the clipping of doctoral thesis of the nursing postgraduate program of the Federal University of São Paulo (2017-2021), held in an outpatient clinic of a public university, focused on

women's health, located in the southern region of the city of São Paulo and which followed the following stages: bibliographic research; focus group; elaboration of the instrument; content validation through a team of judges; pre-test; data collection and evaluation of psychometric properties (reliability and validity).

Bibliographic research was carried out in indexed journals on existing questionnaires in the area of health and quality of life, as well as studies on elaboration and validation of instruments.

Two distinct focus groups were used to construct the instrument. The initial contact to participate in the meetings of these groups was through personal invitation. Women were asked to inform the day of the week and the most appropriate time for the meetings, presenting a proposal for the start date.

The inclusion criteria for participation in the focus group were women in the age group between 20 and 55 years, who were in menacme, who menstruated, exempt from gynecological pathologies and/or others that interfered with the menstrual cycle and who voluntarily agreed to participate in the survey.

The participants in this stage were 19 women, 11 in focus group 1 and eight in focus group 2. The two groups were composed of women of different socioeconomic and cultural levels, heterogeneity of age, styles and living conditions.

Three meetings were held with each group, scheduled days and times, lasting approximately 50 minutes each. The guiding questions of each meeting were based on aspects of the literature on menstrual cycle and experiences of women in the premenstrual and menstrual period. The guiding questions of the first meeting were: 1) What comes to mind when we talk about menstruation? 2) What pleases or dislikes you about your period? And of the second meetingwere: 1) In everyday life, what do you do or stop doing when menstruating? 2) Does the period before menstruation or menstruation interfere with your life? If so, what does it interfere with? In the third and last meeting, the proposal of the content of the previous meetings was presented, with the categories that emerged and that served to compose the instrument for the

evaluation of the QoL of women in the menstrual period.

Based on the results of the focus group stage, the structure of the items that composed the first version of the questionnaire on women's quality of life in the menstrual period was constructed, which presented 77 items distributed six domains: physical, in psychological, level of independence, social relations, environment and personal beliefs/myths. This questionnaire was based on the WHO-World Health Organization QoL assessment instrument, the WHOQOL-100.

Content validity is the determination of the representativeness of items that express a content, based on the judgment of experts in a specific area, with knowledge, skills and practice in relation to the subject, who analyze, through a structured, if the items of the instrument contemplate the universe of content of interest to the researcher, as well as whether the tool is really capable of measuring what is proposed⁽¹⁷⁾.

In line with these criteria, five professionals were invited, three doctors with great experience in the area of gynecology, professors of a public university and two nurses, being an obstetric nurse, PhD, with experience in the construction and validation of questionnaires.

Considered judges, the professionals received the Informed Consent Form (ICF), an invitation letter and an evaluation form that took into account the title and format of the instrument as to clarity, and the assessment of each area of the instrument as to clarity, relevance and scope. After review and adequacy suggested by the judges, a second version of the instrument was obtained containing identification data and questionnaire containing 70 items distributed in six domains that was submitted to the pre-test phase with a portion of the target population.

The participants in the pre-test phase were 34 women, who answered the questionnaire spontaneously and individually, for approximately 15 minutes, while waiting for medical or nursing consultation in the waiting room in the outpatient clinic. No doubts were observed concerning the form of filling or the understanding of the items. Thus, the second

version totaled 70 items, subdivided into six domains.

The convenience sample consisted of women aged between 18 and 55 years, literate, attending a family planning outpatient clinic of a public educational institution, who agreed to and participate voluntarily, menstruating spontaneously and regularly. Women with any comorbidity that interfered with the menstrual cycle, who were in menopause, women who used any hormonal contraceptive method, and women who used the intrauterine device (IUD) were excluded. Importantly, women who participated in the pre-test phase were not included in this population.

Data collection was performed in person from November 2019 to March 2020. The instrument, self-completed, was offered to be answered in the waiting room, while women waited for medical or nursing consultation as well as on educational activities. They received the Informed Consent Form, the Questionnaire on quality of life of the woman in the menstrual period (QLMP) and the questionnaire WHOQOL-Bref.

Due to the emergence of the New Coronavirus Pandemic in March 2020, care and educational attendance in the outpatient clinic were interrupted, impairing the continuity of data collection in a face-to-face manner. The researcher decided to continue collecting in a virtual way through the Google Forms platform, remaining online from June 14 to July 1, 2020. The disclosure was carried out by social media, and by the personal contacts of the researcher, with the population that met the study inclusion criteria.

To evaluate the plausibility of this model to the data, confirmatory factor analysis (CFA) was used. The adequacy of the models were verified through indexes such as root-square error of approximation (RMSEA), comparative fit index (CFI), Tucker-Lewis index (TLI) and normalized chi-square (X2/d.f.). Moreover, exploratory factor analysis (EFA) performed order to in evaluate the dimensionality suggested by the data. The EFA was performed by the main component method and orthogonal rotation VARIMAX. The criterion for selecting the number of factors was eigenvalues above one. The exclusion criteria for the items were those whose commonalities were below 0.5 and factorial loads, below 0.5. The adequacy coefficient of the Kaiser-Meyer-Olkin sample (KMO) and the Barlett sphericity test that evaluates the overall significance of all correlations between the items of the scale considered were considered.

The overall and factor internal consistency were analyzed by Cronbach's alpha coefficient.

The linear associations between women's quality of life scores in the menstrual period and WHOQOL-Bref domains were analyzed using the Sperman correlation. For all statistical tests, a significance level of 5% was adopted.

Analyses were performed using the statistical package Statistical Package for the Social Sciences (SPSS) 20.0 and Stata 12.0.

The study was carried out according to the recommendations of Resolution N. 674, of May 6, 2022, of the National Health Council⁽¹⁸⁾, which regulates research involving human beings, being submitted and approved by the research ethics committee of the institution to which it is linked under the number 2.726.630. For online data collection, there was approval of amendment by the same research ethics committee, under number 4.201.141. All participants signed the Informed Consent Form.

RESULTS

The content validity was performed by the team of judges, who evaluated the clarity of the title and format of the instrument, as well as the clarity, relevance and scope of each domain of the instrument, as shown in chart 1 below.

The scores varied between 0.80 and 1 in the items evaluated in the different domains with an agreement rate of 91%. As for clarity, in the physical domain, which obtained a CVI of 0.60, the suggestions and comments of the committee members were analyzed and the necessary changes were made.

Regarding the characterization of the participants of the research, the information of 469 women was analyzed, whose average age was 31.0 years, with a minimum age of 18 years and maximum of 55 years. Of the total number of women, 70.1% answered the questionnaire online. There was no loss of data due to the lack of completion of the instruments.

Chart 1. Content	Validity	Index	(CVI)	among	members	of t	the tear	n of	judges.	São	Paulo,	SP,
Brazil, 2020.												

Assessed Item	Assessed		J	udg	es		T 3and4	TJ	CVI	Rate %
	aspect	1	2	3	4	5				
Title	Clarity	4	4	4	4	4	5	5	1.00	100%
Format	Clarity	3	3	2	4	4	4	5	0.80	80%
Physical Domain	Clarity	4	4	2	4	2	3	5	0.60	60%
	Relevance	4	4	3	4	4	5	5	1.00	100%
	Scope	4	4	4	4	3	5	5	1.00	100%
Psychological Domain	Clarity	4	4	2	4	3	4	5	0.80	80%
	Relevance	4	4	4	4	3	5	5	1.00	100%
	Scope	4	4	4	4	3	5	5	1.00	100%
Level of Independence Domain	Clarity	4	4	2	4	3	4	5	0.80	80%
	Relevance	4	4	4	4	3	5	5	1.00	100%
	Scope	4	4	3	4	3	4	5	0.80	80%
Social Relations Domain	Clarity	4	4	4	4	2	4	5	0.80	80%
	Relevance	4	4	4	4	3	5	5	1.00	100%
	Scope	4	4	4	4	4	5	5	1.00	100%
Environment Domain	Clarity	4	4	2	4	4	4	5	0.80	80%
	Relevance	4	4	2	4	4	4	5	0.80	80%
	Scope	4	4	4	4	4	5	5	1.00	100%
Myths and Personal Beliefs	Clarity	4	4	4	4	4	5	5	1.00	100%
Domain	Relevance	4	4	4	4	4	5	5	1.00	100%
	Scope	4	4	4	4	3	5	5	1.00	100%

As for schooling, most had completed high school and incomplete higher education (42.2%) and 53.9% were single. Regarding occupation, most were health professionals (30.3%) and professionals in services and commerce (12.8%). Occupations followed the Brazilian Classification of Occupations (BCO) of the Ministry of Labor⁽¹⁹⁾.

There was a distinct distribution of schooling (p<0.001) by group. Women who answered the questionnaire online had higher percentages in schooling, being women with complete postgraduate course (37.4% versus 17.1%). Women who responded in person had higher percentages in incomplete elementary school and complete elementary school/incomplete high school (14.3% versus 1.2%).

Concerning occupation, women responded online presented higher percentages in professionals in Law, Social and Cultural Sciences (8.8% versus 2.9%), teaching professionals (7.6% versus 2.1%) and students (25.8% versus 13.6%) and women who responded in person presented higher percentages without work (19.3% versus 3.6%) and of professionals in services and commerce

(25.7% versus 7.3%).

Regarding the age of menarche, length of menstrual period, time of menstruation (in years) and use of contraceptive methods, no difference was observed in the means among women who responded online of those who responded in person.

The mean age of menarche was 12.1 years and the majority, 66.7%, had a menstrual period lasting up to 5 days, mean 5.4 days. Regarding the use of contraceptive methods, 53.1% of women did not use any method and 40.5% used condoms.

The data presented show homogeneity between the groups, with the exception of education and occupation.

In order to measure the psychometric properties of the QLMP instrument, a confirmatory factor analysis (CFA) was initially performed. The model was adjusted with all 70 items.

In this first model, three items were not significant and, thus, the model was adjusted again with the exclusion of these relationships.

The construct validity through confirmatory factor analysis was verified and, despite the

new adjustment, the data did not confirm the initial theoretical structure because they did not

present acceptable adequacy measures as shown in Table 1.

Table 1. Appropriateness measures of the estimated model. Sao Paulo, SP, Brazil, 2020.

Indicator	Appropriate values	Model 1	Model 2	
c ² /d.f.	< 2	3.297	3.293	
CFI	> 0.90	0.615	0.637	
TLI	> 0.90	0.601	0.623	
RMSEA	< 0.06	0.070	0.070	

Therefore, exploratory factor analysis (EFA) was preformed, which sought to find a way to condense the information contained in several original variables, in a smaller set of new dimensions (factors) with minimal loss of information.

Items whose factorial loads presented values lower than 0.5 or commonalities lower than 0.5 were eliminated. Applying the factor analysis after the exclusion of these factors resulted in 14 factors that explain 69.6% of the total variance of the data. The 14 factors were described in the following facets:

Factor 1 - mobility; factor 2 - mood; factor 3 - menstrual colic; factor 4 - discomfort; factor 5 - body image; factor 6 - safety; factor 7 - pain; factor 8 - beliefs; factor 9 - sexual activity; factor 10 - concentration; factor 11 - financial aspect; factor 12 - habits; factor 13 - comfort

and protection; factor 14 - negative feelings.

Scores were generated for the 14 facets and total of the 47 items through the sum of the scores and subsequent rescheduling in such a way that they ranged from 0 (minimum) to 100 (maximum), meaning that, the closer to 0, the higher the interference of that factor in quality of life and, the closer to 100, the lower the interference.

The convergent validity was also evaluated through the Spearman correlations between the Questionnaire on Women's Quality in the Menstrual Period (QLMP) and the WHOQOL-Bref.

The proposed correlations are highlighted in Table 2. The correlations showed the expected positive direction, showing satisfactory significance level of the instrument.

Table 2. Spearman correlation between QLMP questionnaire scores and WHOQOL-Bref. São Paulo, SP, Brazil, 2020.

	WHOQOL-Bref							
	Physical Aspect		Psych	Psychological			Environment	
	r	p	r	p	r	p	r	p
QLMPTOTAL	0.429	< 0.001	0.437	< 0.001	0.243	< 0.001	0.258	< 0.001
QLMP 1 - Mobility	0.381	< 0.001	0.375	< 0.001	0.224	< 0.001	0.218	< 0.001
QLMP 2 - Mood	0.364	< 0.001	0.420	< 0.001	0.198	< 0.001	0.193	< 0.001
QLMP 3 -Menstrual colic	0.299	< 0.001	0.251	< 0.001	0.097	0.036	0.103	0.025
QLMP 4 - Discomfort	0.169	< 0.001	0.150	< 0.001	0.149	< 0.001	0.182	< 0.001
QLMP 5 -Body image	0.190	< 0.001	0.273	< 0.001	0.120	0.009	0.053	0.248
QLMP 6 - Safety	0.212	< 0.001	0.192	< 0.001	0.171	< 0.001	0.182	< 0.001
QLMP 7 - Pain	0.320	< 0.001	0.294	< 0.001	0.148	0.001	0.159	< 0.001
QLMP 8 - Beliefs	0.055	0.239	0.029	0.527	-0.044	0.343	0.013	0.781
QLMP 9 - Sexualactivity	0.091	0.049	0.126	0.006	0.107	0.020	0.089	0.053
QLMP 10 - Concentration	0.020	0.658	0.054	0.243	-0.037	0.419	-0.044	0.340
QLMP 11 -Financial aspect	0.242	< 0.001	0.175	< 0.001	0.121	0.009	0.271	< 0.001
QLMP 12 - Habits	0.148	< 0.001	0.069	0.136	0.073	0.112	0.168	< 0.001
QLMP 13 - Comfort and protection	0.289	< 0.001	0.252	< 0.001	0.071	0.123	0.119	0.010
QLMP 14 - Negative feelings	0.136	0.003	0.266	< 0.001	0.200	< 0.001	0.071	0.127

Regarding the reliability of the instrument, the first 11 factors showed good or acceptable internal consistencies, where the Cronbach's alpha coefficients ranged from 0.73 to 0.89.

The internal consistency for the 47 items was excellent (0.91).

Table 3. Cronbach's alpha coefficient. São Paulo, SP, Brazil, 2020.

Facets	Cronbach's alpha coefficient
QLMP 1 – Mobility	0.89
QLMP 2 – Mood	0.87
QLMP 3 – Menstrual colic	0.84
QLMP 4 – Discomfort	0.80
QLMP 5 – Body image	0.81
QLMP 6 – Safety	0.77
QLMP 7 – Pain	0.76
QLMP 8 – Beliefs	0.71
QLMP 9 – Sexual activity	0.85
QLMP 10 – Concentration	0.83
QLMP 11 – Financial aspects	0.73
QLMP 12 – Habits	0.56
QLMP 13 – Comfort and protection	0.49
QLMP 14 – Negative feelings	0.25

The last three factors, habits, comfort and protection and negative feelings, which contain seven items in all, have low and unacceptable Cronbach's alpha values. Thus, the researcher decided to exclude 5 items, but keep two due to the relevance with regard to QoL of the woman in the menstrual period.

Thus, after all the analyses performed, the OLMP – Ouestionnaire on women's quality of life in the menstrual period, consisted of 42 items, distributed in 11 facets called mobility, mood, menstrual colic, discomfort, body image, safety, pain, beliefs, sexual activity, concentration and financial aspect. determination of a cutoff point for QoL in the menstrual period is subjective, because the woman can present important complaints in one facet, but not be shaken by the aspects addressed in another.

DISCUSSION

Measuring instruments in the form of questionnaires are important tools and integrate clinical practice in the evaluation of health in a general or specific way.

The bibliographical research, through a broad scientific deepening, unveiled the relevance of building an instrument that evaluated the quality of life of women in such a

delicate period for many.

The activity of the focus group was dynamic, intense and showed spontaneity among participants who experienced those moments naturally, without fatigue or inattention. The participants expressed the meaning of the situations experienced, giving their own interpretation of menstruation. The importance of the heterogeneity of the participants is emphasized, because in socioeconomic and even cultural terms, this fact contributes richly to the discussion and even to the impact of QoL.

Content validity is one of the fundamental methodological steps in instrument validation studies. In the evaluation of the judges who participated in this study, the instrument was considered valid regarding its content and proved to be clear, relevant and comprehensive. Similar results were identified in the validation study of scenarios of clinical simulation in leprosy, and in the adaptation and validation study of the QoL index for Brazilian pregnant women⁽²⁰⁻²¹⁾.

In order to continue the validation of the QLMP questionnaire, the evaluation of the psychometric properties of the instrument was initiated, with the participation of 469 women whose requirements were menstruating and not using any hormonal contraceptive method or

copper IUD at the time. As for the use of contraceptive methods, hormonal methods, in general, as well as copper IUD, are known to have great influence on the menstrual pattern, both in its regularity and in the volume of menstrual flow. Hormonal contraceptives and anti-inflammatories can decrease the volume of menstrual blood by 40 - 50% after a few months of use and the intrauterine system of Levonorgestrel by up to $70\%^{(22)}$.

As the present study deals with the quality of life in the menstrual period, it took care to include a population that did not present any kind of influence in their menstrual characteristics, resulting from the contraceptive methods mentioned.

The QLMP questionnaire had its psychometric properties evaluated through validity and reliability techniques. Construct validity was confirmed by exploratory factor analysis and convergent validity. Internal consistency was verified by Cronbach's alpha coefficient.

Initially, the CFA was performed, however, the theoretical model initially proposed was not confirmed in the values obtained in the adjustment indexes, being performed after the EFA.

Similarly, several studies did not show good adjustments in CFA, but resorted to EFA as a better way to structure their variables. The EFA allows the data structure to suggest the most probable factorial model⁽²³⁾.

During the exploratory process to seek a consistent model that fit adequately to the data of this study, 23 items were excluded because they presented factorial loads and commonalities lower than 0.5.

This elimination of items is present in practically all studies of construction and validation of measurement instruments, because it refines the variables that actually evaluate the construct in question. The WORKER-QOL 76 questionnaire, which evaluates the quality of life of workers, had its initial model composed of 106 items and its final model, 76 items. Similarly, the questionnaire for nursing consultation to patients with type 2 diabetes began with 122 items and obtained a final model with 99 items^(24,25).

The reliability of the QLMP questionnaire

was verified through internal consistency. Cronbach's alpha was adequate for 11 facets, and three facets showed low values. Likewise, some studies also showed low values in Cronbach's alpha and had to review their items⁽²⁶⁾. The internal consistency for the total instrument was 0.91, similar to the validation study of the instrument that evaluates family participation in the care of the hospitalized newborn that presented an alpha for the total instrument of 0.92⁽²⁷⁾.

Thus, all items measure the construct, but, to know if the scale is actually evaluating what is proposed, convergent validation was performed.

Therefore, as the last phase, the convergent validation of the QLMP questionnaire was performed, comparing the results of the responses obtained with the WHOQOL-Bref. The choice to use the WHO instrument to carry out this validation process was made by being one of the most recent instruments; having been idealized by the WHO; having been validated in several cultures; havingits psychometric properties tested in people with pathologies and without health problems, and considering positive and negative aspects in its items.

All facets showed positive correlation with the WHOQOL-Bref domains, and the greatest correlations were with the physical and psychological domains, meeting the validation results of several instruments (28,29). However, the beliefs and concentration facets did not correlate with any WHOQOL-Bref domain.

The particularity of some facets does not necessarily correlate with the domains. As we know, the WHOQOL-Bref does not include beliefs. Similarly, the WHOQOL-Children did not show correlation with the KIDSCREEN-52 in the spiritual/religious aspect and personal beliefs when its psychometric properties were evaluated⁽³⁰⁾.

Therefore, the results of the convergent validity of the QLMP questionnaire showed that the correlations with another measurement instrument containing some related construct were significant.

Thus, the process of construction and validation of the questionnaire of quality of life of women in the menstrual period – QLMP was concluded, presenting results that indicate good

psychometric properties being ready to be used in studies that aim to know the quality of life of women in the menstrual period.

CONCLUSION

All methodological steps for the construction and validation of the measurement instrument were followed as recommended in the literature.

Thus, the questionnaire of quality of life of women in the menstrual period –QLMP - was considered easy to read and interpret, demonstrated satisfactory and reliable psychometric properties, can be used to accurately and individually assess the influence of menstruation on various aspects of quality of life.

CONSTRUÇÃO E VALIDAÇÃO DE UM QUESTIONÁRIO DE QUALIDADE DE VIDA DA MULHER NO PERÍODO MENSTRUAL

RESUMO

Objetivos: Construir e validar um instrumento que avalie a qualidade de vida da mulher no período menstrual. **Método:** Pesquisa metodológica, que contou com as seguintes etapas: pesquisa bibliográfica, realização de grupo focal, elaboração dos itens do instrumento, validação de conteúdo por meio de um comitê de juízes, préteste, coleta de dados e avaliação das propriedades psicométricas do instrumento para se verificar sua validade e confiabilidade. **Resultados:** A análise fatorial confirmatória não mostrou um bom ajuste, sendo realizada a análise fatorial exploratória que, após a exclusão de 23 itens, resultaram 14 fatores que explicam 69,6% da variância total dos dados. As correlações entre os escores do instrumento e o WHOQOL-Bref foram positivas e significativas. O alfa de Cronbach se mostrou adequado para 11 facetas, com valores que variaram de 0,71 a 0,89 e, para o total do instrumento, mostrou-se excelente, com alfa de 0,91. A versão final do questionário ficou constituída por 42 itens, distribuídos em 11 facetas. **Conclusão:** O questionário de qualidade de vida da mulher no período menstrual (QVPM) apresenta propriedades psicométricas que traduzem um instrumento válido, confiável e consistente.

Palavras-chave: Qualidade de Vida. Menstruação. Inquéritos e Questionários. Estudos de Validação.

CONSTRUCCIÓN Y VALIDACIÓN DE UN CUESTIONARIO DE CALIDAD DE VIDA DE LA MUJER EN EL PERÍODO MENSTRUAL

RESUMEN

Objetivos: construir y validar un instrumento que evalúe la calidad de vida de la mujer en el período menstrual. **Método**: investigación metodológica, que contó con las siguientes etapas: investigación bibliográfica, realización de grupo focal, elaboración de los ítems del instrumento, validación de contenido por medio de un comité de jueces, prueba previa, recolección de datos y evaluación de las propiedades psicométricas del instrumento para verificar su validez y fiabilidad. **Resultados**: el análisis factorial confirmatorio no mostró un buen ajuste, siendo realizado el análisis factorial exploratorio que, tras la exclusión de 23 ítems, resultaron 14 factores que explican 69,6% de la varianza total de los datos. Las correlaciones entre las puntuaciones del instrumento y WHOQOL-Bref fueron positivas y significativas. El alfa de Cronbach se mostró adecuado para 11 factores, con valores que variaron de 0,71 a 0,89 y, para el total del instrumento, se mostró excelente, con alfa de 0,91. La versión final del cuestionario quedó constituida por 42 ítems, distribuidos en 11 factores. **Conclusión**: el cuestionario de calidad de vida de la mujer en el período menstrual (CVPM) presenta propiedades psicométricas que traducen un instrumento válido, fiable y consistente.

Palabras clave: Calidad de Vida. Menstruación. Encuestas y Cuestionarios. Estudios de Validación.

REFERENCES

- 1. Silva CM, Cunha CF, Neves KR, Mascarenhas VHA, Caroci-Becker A. Experiências das mulheres quanto às suas trajetórias até o diagnóstico de endometriose. Esc. Anna Nery. 2021;25(4):e20200374. http://dx.doi.org/10.1590/2177-9465-ean-2020-0374
- 2. Organização Pan-Americana de Saúde (OPAS). Objetivos de Desenvolvimento Saudável. 2020. Disponível em: https://www.paho.org/bra/index.php?option=com_content&view =article&id=5849:objetivos- de-desenvolvimento-

sustentavel&Itemid=875

3. Sanhueza A, Carvajal-Vélez L, Mújica OJ, Vidaletti LP, Victora CG, BarrosAJD. Desigualdades relacionadas com o ODS 3 en la salud de las mujeres, los niños y los adolescentes: linha de base para el monitoreo de los ODS en América Latina y el Caribe por medio de encuestas transversais nacionales. Rev Panam Salud Publica. 2022;46:e100.

 $https:/\!/doi.org/10.26633/RPSP.2022.100$

4. Vargens OMC, Marinho DS, Silva ACV, Oliveira ZM. A percepção de mulheres sobre a menstruação: uma questão de solidariedade [Women's perception of menstruation: a question

- of solidarity] [La percepción de mujeres sobre la menstruación: una cuestión de solidaridad]. Rev Enferm UERJ. 2019;27(0):40120. https://doi.org/10.12957/reuerj.2019.40120
- 5. Lima MP, Moreira MA, Maynard DC, Cruz MFA. Alterações fisiológicas e comportamentais da mulher no ciclo menstrual e o impacto da suplementação nutricional. Research, Society and Development. 2021;10(16) e428101623925. http://dx.doi.org/10.33448/rsd-v10i16.23925
- 6. Schoep ME, Nieboer TE, van der Zanden M, Braat DDM, Nap AW. The impact of menstrual symptoms on everyday life: a survey among 42,879 women. Am. J. Obstet. Gynecol. 2019;220:569.e1–
- 569.e7.http://dx.doi.org/10.1016/j.ajog.2019.02.048
- 7. Fernández-Martínez E, Onieva-Zafra MD, Abreu-Sánchez A, Fernández-Muñóz JJ, Parra-Fernández ML. Absenteeism during menstruation among nursing students in Spain. Int J Environ Res Public Health. 2020;17(1):53.http://dx.doi.org/10.3390/ijerph17010053.
- 8. Jain V, Chodankar RR, Maybin JÁ, Critchley HOD. Uterine bleeding: How understanding endometrial physiology underpins menstrual health. Nat Rev Endocrinol. 2022;18(5):290-308. http://dx.doi.org/10.1038/s41574-021-00629-4
- 9. Marcacine PR, Castro SS, Meirelles MCCC, Haas VJ, Walsh IAP. Qualidade de vida, fatores sociodemográficos e ocupacionais de mulheres trabalhadoras. Cienc Saude Colet. 2019;24(3):749–60. https://doi.org/10.1590/1413-81232018243.31972016
- 10. Silva ALN, Carneiro MA, Cabral LMS, Lima LF, Naves ET, Pilger C. (2022). A percepção dos idosos sobre a qualidade de vida e o impacto do grupo de convivência na sua saúde. Cienc Cuid Saude. 2022; 21 e59010.http://dx.doi.org/10.4025/ciencuidsaude.v21i0.59010
- 11. Oliveira BRG, Seabra CAM, Vieira AG, Freires MAL, Macêdo CMT, Feitosa ANA. Síndrome pré-menstrual e suas influências na qualidade de vida. Temas em Saúde. 2020;1(1):204–25. http://dx.doi.org/10.29327/216797.1.1-10
- 12. DeMaria AL, Sundstrom B, Meier S, Wiseley A. The myth of menstruation: how menstrual regulation and suppression impact contraceptive choice. BMC Womens Health. 2019;19(1):125. http://dx.doi.org/10.1186/s12905-019-0827-x
- 13. Bastianelli C, Grandi G, Farris M, Brandolino G, Paoni Saccone G, La Barbiera I, Benagiano G. Attitudes towards menstruation: what women want? An Italian National Survey. Eur J Contracept Reprod Health Care. 2023;8(1):28-35. http://dx.doi.org/10.1080/13625187.2022.2130686
- 14. Nappi RE, Kaunitz AM, Bitzer J. Extended regimen combined oral contraception: A review of evolving concepts and acceptance by women and clinicians. Eur J Contracept Reprod Health Care. 2016 Mar;21(2):106–15. https://doi.org/10.3109%2F13625187.2015.1107894
- 15. Nappi RE, Tiranini L, Bosoni D, Cucinella L, Piccinino M, Cumetti A, et al. Women's attitudes about combined hormonal contraception (CHC) induced menstrual bleeding changes influence of personality traits in an Italian clinical sample. Gynecol Endocrinol. 2023;39(1):2189971.https://doi.org/10.1080/09513590.2023.218
- 16. Lancastle D, Kopp Kallner H, Hale G, Wood B, Ashcroft L, Driscoll H. Development of a brief menstrual quality of life measure for women with heavy menstrual bleeding. BMC Womens Health. 2023;23(1):105. http://dx.doi.org/10.1186/s12905-023-02235-0
 - 17. Polit DF, Beck CT. Métodos mistos e outros tipos especiais

- de pesquisa. In: Polit, DF. Beck, CT, Eds., Fundamentos de pesquisa em enfermagem: Avaliação de evidências para prática de enfermagem, 9. ed. Porto Alegre: Artmed; 2019. 209-222 p.ISBN 9788582714898.
- 18. Brasil. Ministério da Saúde. Conselho Nacional de Saúde. [Internet]. Resolução No 674/2022. Disponível em: https://https://conselho.saude.gov.br/images/Resolucao_674_2022.pdf
- 19. MTE/SPPE. Classificação Brasileira de Ocupações: CBO. Brasília [Internet]. 2002 [citado 14 de outubro de 2020]. Disponível em: http://www.mtecbo.gov.br/cbosite/pages/home.jsf
- 20. Barbosa MS, Morais CGS, Freitas VMS, Alvim LS, Laurindo CR, Souza EOM, Coelho ACO. Elaboração e validação de cenários de simulação clínica em hanseníase: comunicação em saúde. Cienc Cuid Saude.2023;22:e62342.http://dx.doi.org/10.4025/cienccuidsaude.v22i0.62342
- 21. Fernandes RA, Oliveira PM, Freitas NO. Adaptação e validação de Índice de Qualidade de Vida para gestantes brasileiras. Acta Paul Enferm. 2023;36:eAPE013431.
 - http://dx.doi.org/10.37689/acta-ape/2023AO013431.
- 22. Kitawaki J, Akira S, Harada T, Maeda N, Momoeda M, Ota I, et al. Bleeding patterns of women with heavy menstrual bleeding or dysmenorrhoea using the levonorgestrel-releasing intrauterine system: results from a real-world observational study in Japan (J-MIRAI). Eur J Contracep Reprod Health Care. 2022;27(4):300–
- 7.http://dx.doi.org/10.1080/13625187.2022.2067329
- 23. Bravo P, Dois A, Fernámdez-González L, Hernández-Leal MJ, Villarroel L. Validación del instrumento Informed Choice para medir la decisión informada de mamografia em mujeres chilenas usuárias de atención primaria. Aten. Prim. 2021;53(3):101943. https://doi.org/10.1016/j.aprim.2020.08.005
- 24. Martini MR. Construção e validação de um instrumento de pesquisa para avaliar a qualidade de vida de trabalhadores. 2015 [Tese] Porto Alegre (RS). Programa de Pós-graduação em medicina. Universidade Federal do Rio Grande do Sul UFRS. 2015. Disponível em: https://lume.ufrgs.br/handle/10183/129700.
- 25. Pimentel TS. Construção e validação do instrumento para consulta de enfermagem ao indivíduo com Diabetes Mellitus Tipo 2. 2018. [Dissertação] Aracajú (SE). Programa de Pósgraduação em Enfermagem. Universidade Federal de Sergipe UFS. 2018. http://ri.ufs.br/jspui/handle/riufs/8534
- 26. Eleazu FI, Edet BE, Essien EA, Okafor CJ, Okoro AC, Udofia O. Psychometric Properties of the Modified Family Affluence Scale (FAS II) among Adolescents in Nigeria: A Preliminary Report. West Afr J Med. 2023;40(4):397-403. PMID: 37119133.
- 27. Mendes CQS, Boyamian TMDL, Castro NNO, Michelone CSL, Mandetta MA, Balieiro MMFG. Validation of an instrument for family participation in the care of hospitalized newborns. Acta Paul Enferm. 2020;33:1-8. DOI: https://doi.org/10.37689/acta-ape/2020AO022855.
- 28. Sousa AJS, Silva MC, Barreto MCA, Nunes BP, Coutinho BD, Castro SS. Propriedades psicométricas do WHODAS para uso em pessoas com chikungunya no Brasil. Fisioter Pesqui. 2019;26(4):419-426. https://doi.org/10.1590/1809-2950/18036226042019
- 29. Grou TC, Castro SS, Leite CF, Carvalho MT, Patrizzi LJ. Validação da versão brasileira do World Health Organization Disability Assessment Schedule 2.0 em idosos institucionalizados. Fisioter Pesqui. 2021;28(1):77-87.

https://doi.org/10.1590/1809-2950/20024628012021

30. Pinto GMC. Propriedades psicométricas do instrumento WHOQOL-Children para avaliação da qualidade de vida em crianças. 2018. [Dissertação] Ponta Grossa (PR). Programa de

Pós-graduação em Engenharia de Produção. Universidade Tecnológica Federal do Paraná — UTFPR. 2018. Disponível em: http://repositorio.utfpr.edu.br:8080/jspui/handle/1/3073.

Corresponding author: Patricia Albuquerque Moraes. Rua Pitangueiras, 228 ap. 152. Mirandópolis, São Paulo, São Paulo, Brasil. Telefone: 55 1198555-5315, E-mail: patriciamor4@gmail.com

Submitted: 30/11/2022 **Accepted:** 20/08/2023

Attachment 1. QLMP - Women's quality of life questionnaire in the menstrual period

This questionnaire is about how you feel about your quality of life during menstruation. Please answer all the questions and choose among the alternatives that seem most appropriate to you.

You should mark the number that best corresponds to how much you have worried about your period in the last menstrual cycles.

Please read each question and put an X in the number that seems the best answer for you. If you wish, please comment on the lines below each question group.

Thank you very much for your participation.

Questions 1 and 2 are about a general assessment of your menstruation period.

General perception of menstrual period	Very good Good		Neither good or bad	Bad	Very bad	
	5	4	3	2	1	
Q1. For you, menstruation is:						

Impact of menstruation on daily life	Nothing	A few	More or less	A lot	Extremelly
	5	4	3	2	1
Q2. Does menstruation affect your daily life?					

Mobility. During your period, you:	Never	Rarelly	Sometimes	Repeatedly	Always
	5	4	3	2	1
1. Do you stop travelling?					
2. Stop going to church/worship?					
3. Stop going to the club, pool or beach?					
4. Stop goingtoparties?					
5. Will you stop making appointments?					
6. Stop relaxing, enjoyingandenjoyingyourmomentsofleisure?					
7.Do you have difficulties with transportation (bus, subway, train, car) during menstruation?					
8. Do you miss work?					

Humor	No	Very little	More or less	Very	Extremely
	5	4	3	2	1
9. Do you feel you have mood changes during menstruation?					
10. Do you feel sad during menstruation?					
11. Do you cry more during menstruation?					
12. Do you feel nervous during menstruation?					
13. Does menstruation affect living with your family members?					
14. Is it more difficult for you to live with co-workers and superiors					

during your period?			

Menstrual cramps	No	Very little	More or less	Very much	Completely
	5	4	3	2	1
15. Do youhave menstrual cramps?					
16. Do you need medication for cramps and/or menstrual symptoms?					
17. Do you use a birth control method to relieve menstrual symptoms?					
18. Do you wake up at night due to pain?					

Discomfort	No	Very little	More or less	Verymuch	Completely
	5	4	3	2	1
19. Do you dislike the smell of blood or dirty tampons?					
20. Do you feel "disgust" from the blood of menstruation?					
21. Do you feel discomfort with the blood from menstruation?					
22. Are you ashamed or embarrassed to talk abou tmenstruation?					

Body Image&Appearance	No	Very little	More or less	Very much	Completely
	5	4	3	2	1
23. During your period your appearance bothers you?					
24. Are you unhappy with the swelling of your belly during menstruation?					
25. During menstruation your belly gets enlarged?					

Safety	Never	Rarely	Sometimes	Almost always	Always
	5	4	3	2	1
26.At night, I					
worryaboutgettingthebeddirty					
27.At night I					
needtochangetheabsorbent					
28. I					
feeldiscomfortwiththeamountofblood					
29. Do you worry about wearing					
some clothes for fear of marking the					
pad or staining with blood?					

Pain	No	Very little	More or less	Very	Extremely
	5	4	3	2	1
30. Do you feel pain in your legs during menstruation?					
31. Do you get swollen legs during					

menstruation?			
32. Do you feel back pain during menstruation?			
33. Do you feel pain all over your body during menstruation?			

Beliefs	No	Very little	More or less	Very much	Completely
	5	4	3	2	1
34. Do you believe that menstruation is the woman's health?					
35.Do you believe that not menstruating can cause health problems?					
36. Você acredita que menstruar eliminates as impuritiesdo body?					

Sexual activity	No	Very little	More or less	Very much	Completely
	5	4	3	2	1
37. Does menstruation bother you during intercourse?					
38. Does menstruation prevent you from satisfying yourself during sexual intercourse?					

Concentration	No	Very little	More or less	Very much	Completely
	1	2	3	4	5
39. Are you easier to concentrate and learn during menstruation?					
40. Do you think you can think more clearly during menstruation?					

Financial aspect	No	Very little	More or less	Very much	Completely
	1	2	3	4	5
41. Do you think your financial spending on absorbent is suitable?					
42. Do you think your financial expenditure on medication due to your menstruation is appropriate?					