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Brazilian version of the Profil der Lebensqualität Chronischkranker: validity and psychometric evidences for climacteric women

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ABSTRACT. The main objective of this study was to validate and examine the psychometric parameters of Profil der Lebensqualität Chronischkranker (PLC) in climacteric women. We conducted an exploratory research in Health Care and Treatment enrollment 280 participants. The data collection instruments were the PLC and the SF-36 (Medical Outcomes Study 36 - Item Short - Form Health Survey). The original German version of PLC consists of 40 items that explore the biological and psychosocial items of daily life. The questionnaire was submitted to translation into Portuguese of Brazil, back translation, review by experts and cultural adaptation. For the psychometric study, Cronbach's alpha, factor analysis and the Pearson correlation coefficient were used. In the internal consistency analysis, Cronbach's alpha coefficient ranged from 0.81 a 0.89 in all categories, indicating that the instrument has adequate internal consistency. We could verify the existence of five factors that together explained 55.85% of total variance. For criterion validity, Pearson's correlation was between 0.41 and 0.78. Therefore, the Brazilian version of the PLC is configured in valid, reliable and easy-to-use option for assessment of quality of life in climacteric women.

Keywords: quality of life, climacteric, validation studies.

Versão brasileira do Profil der Lebensqualität Chronischkranker: validade e evidências psicométricas para mulheres climatéricas

RESUMO. O objetivo deste estudo foi validar e verificar os parâmetros psicométricos da Escala Profil der Lebensqualität Chronischkranker (PLC) para uma amostra de 280 mulheres climatéricas. Realizou-se uma pesquisa exploratória, cujos instrumentos de coleta foram o PLC e o SF-36 (Medical Outcomes Study 36 - Item Short - Form Health Survey). A versão original em alemão do PLC compõe-se de 40 itens que exploram os itens biológicos e psicossociais da vida diária. Foi realizada a tradução para o português do Brasil, retrotradução, revisão por painel de especialistas e adaptação cultural. Para o estudo psicométrico foram utilizados alfa de Cronbach, análise fatorial e coeficiente de Pearson. O coeficiente alfa de Cronbach variou de 0,81 a 0,89 em todas as categorias, apontando que o instrumento apresenta adequada consistência interna. Quanto à validade de constructo, verificou-se a existência de cinco fatores (estado de ânimo negativo, capacidade física, função social, estado de ânimo positivo e bem-estar social) que juntos explicam 55,85 % da variância total. Para validade de critério, os valores da correlação de Pearson situaram-se entre 0,41 e 0,78. Sendo assim, a versão brasileira do PLC configura-se em opção válida, confiável e de fácil aplicação para avaliação da qualidade de vida em mulheres climatéricas.

Palavras-chave: qualidade de vida, climatério, estudos de validação.

Introduction

Climacteric is the time of change between the reproductive phase and the non-reproductive phase of women's life, which occurs between the ages of 35 and 65. It is a physiological phenomenon, resulting from the depletion of ovarian follicles, which happens to all middle-aged. The climacteric is followed by a

progressive decrease in estradiol secretion, reducing ovarian activity and, in turn, decreasing fertility, culminating in the definitive interruption of menstrual periods (menopause) and, concomitant with all this, the characteristic symptoms emerge in the physical, biological and psychosocial aspects of the woman (DE LORENZI et al., 2005).

Around 50 to 70% of women refer to somatic symptoms and emotional problems in climacteric, such as depression, which interfere in their welfare. This might be related to the fear of aging, feeling of uselessness and even lack of affection. This phase coincides with the growth and independence of children, widowhood and retirement, which are difficult moments for women. Other common complaints during this period are insomnia, loss of libido, headache, myalgia and arthralgia, increased anxiety and even depression (DE LORENZI, 2008).

Culturally, menopause is a milestone in determining changes in the life of women, which includes their social role. On the other hand, it promotes uncomfortable symptoms and increases the incidence of diseases. In Brazil, it generally occurs after 50 years of age, and it is estimated that women remain for approximately one third of their lives in a state of hormonal deficiency (ZAHAR et al., 2005). Particularly, the most common clinical manifestations are complaints related to vasomotor symptoms, vaginal dryness, dyspareunia and urinary urgency, the latter resulting from urogenital atrophy, possibly associated to fatigue, depression, anxiety, insomnia and forgetfulness. However, all these changes may cause an important repercussion in sexuality and the quality of life of women (MEDEIROS et al., 2006).

According to the World Health Organization (WHO), quality of life is an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, and their relationship to salient features of their environment (WHO, 1995).

The most commonly used instruments for assessing quality of life in climacteric women are the Women's Health Questionnaire (WHQ), The Menopause-Specific QoL Questionnaire (MENQOL) and Menopause Rating Scale (MRS) (ZÖLLNER et al., 2005). The WHQ was developed to assess a wide range of physical and emotional symptoms and study possible health changes in middle-aged women (HUNTER, 2003). The MENQOL is a specific instrument for assessing menopause with items that include physical, vasomotor, psychosocial and sexual factors (HILDITCH et al., 1996). MRS was originally developed and applied to a random sample of 683 german women aging between 40/60 years, and involves the analysis of three domains:

psychological, somato-vegetative and urogenital symptoms (HEINEMANN et al., 2003).

Although analyzing the quality of life during climateric, these tools do not address issues related to the chronic problems that can emerge at this stage (BLÜMEL et al., 2014). Physiologically, the progressive reduction of estrogen that occurs at climateric, promotes profound effects overall organism. In some cases, the consequence of this estrogen deficiency, long-term, provides unpleasant symptoms and serious illness. In fact, the development of some chronic and degenerative diseases is related to estrogen deficiency. Among them is osteoporosis, cardiovascular disease, dementia and atrophy of genital tissue, resulting in vaginitis, urinary incontinence, and pain on intercourse (LOBO et al., 2014).

Aiming to answer the multidimensional conception involving quality of life in climateric, the Profil der Lebensqualität Chronischkranker (PLC) questionnaire intending to cover common problems of individuals whose functional capacity and wellbeing were sensibly affected by a disease or negative chronic health condition. This questionnaire was used for validation to Portuguese language of Brazil, considering that the state of menopause is closely associated with chronic degenerative diseases that impair the quality of life of women (SANTOS et al., 2012). Several studies in other countries were developed to validate this instrument, in the assessment of quality of life, in order to use it for several populations, with different health conditions (FERNANDÉZ-LÓPEZ et al., 1999; IHLE et al., 2011; SÁNCHEZ et al., 2008).

In this respect, the main objective of this study was to validate and examine the psychometric parameters of Brazilian version of Profil der Lebensqualität Chronischkranker (PLC) in climacteric women.

Material and methods

This is a cross-sectional observational research. On execution, the study followed the standards demanded by the Helsinki Statement and was approved by the Research Ethics Committee of the Institution where the study was conducted. The original author of the instrument has authorized the validation process.

To calculate the sample size was considered a minimum of 5 participants per item of questionnaire (HAIR et al., 2009). Taking into account that the PLC has 40 items, it would take at least 200 participants. Considering the possibility of sample loss throughout the study (eligibility criteria or missing date), 300 patients were enrolled in study.

Target population comprised participants in climacteric carried in Units and Municipal Care Centers focused on women's health. Participants under anticonvulsant, antidepressant, thyroid hormone and estrogen medicine, and bearers of related diseases or that were affected by cognitive deficits that could limit the interviews were excluded from the sample, in order to avoid the interference of other factors in the quality of life assessment.

All data collection instruments where individually applied through interviews, made by an interviewer adequately trained and familiarized with the questionnaire.

Results and discussion

PLC (Profil der Lebensqualitä Chronischkranker) is a generic questionnaire, with adequate validity and evidenced trustability. It was initially developed and validated by Siegrist et al. (1996) in Germany, originally created to assess the changes related to health for several chronic conditions. This questionnaire comprising 40 items, which explore the biological and psychosocial components of daily life, during the seven days prior to its application. Answers are grouped in a Likert scale, with five categories (from 0 to 4). In this module, items are distributed in positive or negative disordered series. Twelve of the items have a negative/regressive sense (questions 1, 22, 24, 26, 27, 30, 31,32, 33, 35, 38 and 40) and should therefore be recoded to Likert scale (0 = 4; 3 = 1; 2 = 2; 3 = 1; 4)= 0). The higher the score, the better the quality of life of the individual. The PLC has been tested and validated in various studies (BULLINGER; HASFORD, 1991; JEGER et al., 2007; SIEGRIST et al.,1996; 1997; SIMON et al., 2008).

PLC scales are analytically characterized by six factors which correspond to the following dimensions: I- Physical Function (questions 1,2,3,4,5,6,7 and 40), includes the body and intelectual performance ability, both for personal and professional lives; II- Psychological Function (questions 22, 24, 26, 27, 30, 31, 32 and 33), relates to the psychological regeneration ability of the individual, relaxation ability, quality of sleep, appetite and ability to overcome resentment and disappointment; III- Positive State of Mind (questions 23, 25, 28, 29 and 34), contains essential aspects of positive animosity, such as attention, good humor, emotional balance and optimism; IV-Negative State of Mind (questions 22, 24, 26, 27, 30, 31, 32 and 33), refers to the essentials of negative animosity, such as sadness, nervousness, irritability,

feelings of threat and despair; V-Social welfare (questions 35, 36, 37, 38 and 39), encompasses the feeling of 'belonging to a group', including aspects of socio-emotional support expressed as proximity to other people, in dedication and providing assistance, as well as the absence of loneliness and exclusion; VI-Social Function (questions 13, 14, 15, 16, 17 and 18), includes aspects related to the ability of relationship, i.e. the ability to establish and maintain relationships and communication with others (SIEGRIST et al.,1996).

Validation of the Brazilian version and psychometric study

Initially, the original version of the PLC was cultural adaptation including submitted to translation of the questionnaire to Portuguese language of Brazil, according to international criteria, involving translation, back translation, review by experts panel and cultural adaptation (GUILLEMIN et al., 1993). After back translation, discrepancies were discussed at a meeting with team of health care professionals with knowledge of German, with extensive experience in applying quality of life scales and care for climacteric women. After consensus, all the characteristics of the original instrument were preserved, by only applying semantic and cultural adaptations, and the final version was considered as ready for use.

For the psychometric study, the assessment of reliability and validity of the scale was conducted. The evaluation of reliability was measured by Cronbach's alpha to evidence internal consistency, i.e. to analyze the magnitude in which items of an instrument are correlated. A Cronbach's alpha greater than 0.70 indicates a good internal consistency (CRONBACH, 1951).

Exploratory factor analysis were performed aiming to evaluate the degree of representativeness of the constructs. Initially, factorability matrix generated was verified. Values of Bartlett's sphericity test (AIC) and Kaiser-Meyer-Olkin (KMO) were calculated. And for the rotation and factors extraction the Principal Axis Factoring (PAF) method was used, with oblique rotation. The initial assumption was that the instrument consist of six factors. To ensure that each item represented the construct behind the factor, a minimum factor load of 0.40 was set for accepting the item (HAIR et al., 2009).

For criterion validation, PLC was compared to SF-36 (Medical Outcomes Study 36-Item Short-Form Health Survey), which is a questionnaire measuring quality of life developed in the late '80s in

the United States, applied in several studies that provided evidence of its reliability, validity and accuracy (CICONELLI et al., 1999; MASTROPIETRO et al., 2007; PIMENTA et al., 2008). The SF-36 questionnaire consists of 36 questions, divided into seven domains: physical functioning, physical aspects, pain, general health, vitality, emotional aspects and mental health. It presents the final score from zero to one hundred, where zero corresponds to the worst overall health status and one hundred the best state of health (WARE; SHERBOURNE, 1992).

For analysis of the comparison between the PLC and SF-36, Pearson's coefficient was used in order to assess the criterion validity of the instrument studied, adopted for correlations at a statistical significance level of 0.05%.

The findings in this study were statistically analyzed using the Statistical Package for Social Sciences - SPSS Ver.20.0 (SPSS Inc., Chicago, IL, USA) software.

Results

The sample loss was small (9.3%) and related with to the number of participants belonging to one or more exclusion criteria. Thus, this study examined 280 women, aged between 35 and 65 years (45.84 ± 7.80), of which 59.4% were married, 11.7% were single, 28% were widows and 13.3% were divorced. As for labor activity, 61.1% were active and 38.9% were retired.

In the factorial analysis, the KMO index (0,868) and Bartlett's sphericity test [χ^2 (78) = 120.656, p < 0.001] are considered worthy, and the factorability matrix can be checked. According to this Kaiser criterion, we verify the existence of five factors that together explain 55.85% of the variance of the construct.

Subsequent to the rotation, we tried to obtain a satisfactory factor solution. The inspection of factor loads of the 40 items from the original scale revealed that not all of them were contributing positively in the measurement of factors. These items were excluded according to the criteria established (minimum factor load of 0.40). In total, 17 of 40 items were eliminated, leaving 23 items in the final factor solution.

Distribution of the 23 items in five factors is shown in Table 1. By inspecting this table it is seen that virtually all loads (19 of 23 items) are above 0.50. This can be considered as an indicator of the quality of the identified factor solution.

In the internal consistency analysis, Cronbach's alpha coefficient ranged from 0.81 to 0.89 in the five categories, indicating that the instrument has

adequate internal consistency. The factors were distributed as follows: the first one, negative state of mind, with seven items and Cronbach's alpha of 0.89, explained 25.67% of the variance; the second factor, physical ability, with four items and Cronbach's alpha of 0.83, explains 12.57% of the variance; the third factor, social function, with four items and Cronbach's alpha of 0.85, explained 8.67% of the variance; the fourth factor, positive state of mind, with five items and Cronbach's alpha of 0.83, explained 5.60% of the variance; and finally the fifth factor, social welfare, with three items and Cronbach's alpha of 0.81, explained 3.34% of the variance (see Table 1).

Table 1. Factorial Analysis of the Main Components (PCA) of the Brasilian version of PLC.

Item	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
22	. 881				
23	. 858				
27	. 860				
28	. 813				
25	. 792				
24	. 719				
26	. 615				
02		. 791			
04		. 693			
03		. 663			
05		. 586			
39			. 779		
38			. 579		
36			. 447		
35			. 452		
09				. 760	
10				. 687	
20				. 582	
18				. 524	
19				. 487	
31					. 695
30					. 596
33					. 466
Eigenvalue	9.01	5.77	3.37	2.90	1.91
% of Variance	25.67	12.57	8.67	5.60	3.34
Total items	7	4	4	5	3
Cronbach's Alpha	0.89	0.83	0.85	0.83	0.81

Table 2 presents data obtained from criterion validity, with the respective values of Pearson's correlation coefficients between the domains of PLC and categories of the SF-36. The highest values are found in positive correlation between pain with negative state of mind (0.781) and between social aspects and social welfare (0.764). Statistically significant negative correlations were also found, between various correlations involving the Negative State of Mind.

The Negative State of Mind item, which composes the PLC questionnaire, presents the reverse direction, where the higher the value, the worse the impact on quality of life. The same occurs with some questions that comprise the SF-36, as for pain, general health and vitality that have some negative series. This explains why the comparisons

between the Negative State of Mind field and other categories of the SF-36 present correlation coefficients sometimes negative, sometimes positive, depending on the item under comparison. The remaining items of PLC and SF-36 have scores ranging from a lower to a higher value, according to the improvement of the general state of the patient (see Table 2).

Table 2. Comparison between the fields of Brazilian version of PLC and categories of the SF-36.

SF-36			PLC		
	Negative State of Mind	Physical Capacity	Social Function	Positive State of Mind	Social Welfare
Funcional Capacity	754*	.740★	.683*	.720★	494
Physical Aspects	456*	.723*	.722*	.663*	579
Pain	.781*	659*	767*	688*	.441
General Health State	.657*	510	619*	419	.617*
Vitality	.742*	-,694	500	.645	.648*
Social Aspects	.513	523*	471	489	.764*
Emotional Aspects	653*	.632*	.413	.703*	.711*

*p < 0.05. Classification of Pearson's Correlation Coefficient: very low (r = 0.001 to 0.200); low (r = 0.201 to 0.400); moderate (r = 0.401 to 0.600); high (r > 0.601).

Discussion

The term 'quality of life' is increasingly cited in studies of evolution and therapy involving various clinical conditions. The idea of developing a universal and more sensitive parameter to detect and compare the psychosocial impact of various clinical conditions is of fundamental importance (FERNÁNDEZ-LÓPEZ et al., 1997). In this study, the negative impact of climacteric in important areas of quality of life of women was verified.

In validation process, to quantify the quality of life in countries with different culture and language, it is recommended to execute its adaptation to local conditions, where such instruments will be used (HARB et al., 2008). In this study, the PLC has been translated and adjusted to the Portuguese language of Brazil, preserving the format of the original instrument, as well as the method of application. As for semantic equivalence, the greatest difficulties in translation refer to the colloquial and idiomatic expressions used in the instrument in German, which was resolved by reaching a consensus in the process of translation and adaptation, often focusing on the adaptation to Brazilian culture, at the expense of semantic equivalence. Without this, the instrument would lose in terms of overall meaning and would be limited to the referential meaning.

One of the psychometric qualities considered important for the instruments is reliability, which assesses the consistency of a measure when applied to a population or group. The internal consistency of Brazilian version of PLC, analyzed by Cronbach's alpha index, presented adequate reliability, in agreement with the results of other studies involving the validation of the instrument in countries like Germany and Spain (FERNÁNDEZ-LÓPEZ et al., 2001; SIEGRIST et al., 1996). The Cronbach's alpha of the original instrument range from 0.86 to 0.93. These coefficients always greater than 0.76, show sufficient internal consistency of information and suggest that the items of each scale measure a unitary construct, aggregate low random error (FERNANDÉZ-LÓPEZ et al., 1999).

The validity of a measuring instrument (including construct validity, content and criterion) is established from a set of techniques that intend to evaluate the degree to which an empirical measure adequately reflects the real meaning of the concept under consideration (GRIEP et al., 2005). Factor analysis is a measure used to assess the construct validity by analyzing the dimensions or components of the adapted instrument. Performed mathematical procedures, it identifies clusters of variables from the analysis of their inter-correlations with each cluster, called factor or dimension. A factor is defined for that group of variables whose scale items correlate more strongly between themselves than with variables of other unrelated clusters (HAIR et al., 2009).

Regarding factor analysis, the instrument evaluated in this study presents five factorial distinct dimensions. Thus, in this study was change in the original structure, which is composed of six factors. It is necessary to emphasize that the five factors explain 55.85% of variance, similar to that detected by German instrument, in which the factors for each of the categories vary between 0.5 and 0.9, with the total explained variance above 60%. Therefore, these indicators prove the relevant dimensions of the health-related quality of life, defined theoretically by the instrument (SIEGRIST et al., 1996). In another study, Fernández-Lopez et al. (2007) analyzed the relationship between quality of life and work stress in physicians and nurses. The factorial validity of the PLC was confirmed, with percentage of explained variance equal to 58.09%.

Therefore, the percentage found in the Brazilian version is important and appropriate in terms of explanatory power (GARCÍA-JIMÉNEZ et al., 2000). Moreover, Amirkhan (1994) considers that factor structures are amenable to instability, so it is common differences in the field of assessment instruments, without compromising the reliability and validity of the scales.

Regarding content validity, the development model of the PLC was built by a multidisciplinary

team, establishing a consensus among experts from different fields, creating appropriate validity conditions (FERNÁNDEZ-LÓPEZ et al., 2001). However, there are no standard procedures for demonstrating content validity, and in the medical field this task is even harder. A consensus on the categories of each dimension is necessary, which implies the existence of a considerable number of examiners trained to propose and select the most significant ones (RODRIGUES, 2008).

Criterion validity is the degree in which the measurements agree with other approaches that measure the same characteristic. The process involves a second measurement of the concept, represented as a criterion so that the measurement of the tested instrument can be evaluated and its validity confirmed in future applications (BALEY, 1994). In this study, the instrument employed showed a criterion validity with values that were mostly moderate and high compared to the categories of PLC and the domains of SF-36, which is similar to the findings from other studies that simultaneously used those two instruments to evaluate the quality of life in different populations (KUGLER et al., 2004). In a study conducted by Goldbeck and Schmitz (2001), the correlations between the PLC and the SF-36 index reached levels above 0.5, indicating that the subjective and objective perspectives on health are overlapping (GOLDBECK; SCHMITZ, 2001).

Regarding limitations, this study was conducted with participants of a single state of Brazil. Thus, when applied in other regions of the country, the semantic equivalence should be analyzed by considering the possible linguistic and socio-cultural variations. In addition, the study sample was not probabilistic; however, there was homogeneity of the study group, as demonstrated by the analysis of socio-demographic factors. For climacteric condition, since the selection was performed with participants met in treatment centers specifically focused on women's health, the group maintains the characteristics of the study population, being considered representative (VAN BELLE et al., 2004).

Conclusion

We conclude that the PLC's Brazilian is similar to the German version and presents a valid, reliable and easy-to-apply option for assessing quality of life in climacteric, suggesting it as a useful tool for analyzing problems and guiding solutions. Assess the quality of life during climacteric is a preventive measure in the health care of women,

as it will allow changes in lifestyle, use of hormone therapy or adjuvant drugs for treatment of chronic disease. The decay of women's health starts many years before menopause and prevention of its consequences is necessary and essential (BLÜMEL et al., 2014).

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