

## PSYCHOMETRIC EVALUATION OF A BRAZILIAN PORTUGUESE VERSION OF THE SPITZER QUALITY OF LIFE INDEX IN PATIENTS WITH LOW BACK PAIN

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*The purpose of this study was to adapt the Spitzer Quality of Life Index and evaluate its reliability in patients with low back pain. The following steps were followed: translation, back-translation, evaluation by a committee, and pretest. The reliability was estimated through stability and homogeneity assessment. The validity was tested comparing scores of the Spitzer (QLI) with the SF-36 and the Roland-Morris. The psychometric properties were evaluated by the self-application on 120 patients. Results showed that the Cronbach's Alpha was 0.77. Intraclass correlation coefficient for test-retest reliability was 0.960 ( $p < 0.001$ ; IC95%: 0.943; 0.972). Spearman's correlation coefficient for test-retest reliability was 0.937 ( $p < 0.001$ ). There was significant correlation between the Spitzer (QLI) scores and the dimensions of the SF-36. A significant negative correlation was found between the Spitzer (QLI) and the Roland-Morris scores ( $r = -0.730$ ). The adaptation process was conducted successfully and the questionnaire presented reliable psychometric measures.*

**DESCRIPTORS:** low back pain; pain; psychometrics; quality of life; validation studies

## EVALUACIÓN DE LAS CALIDADES PSICOMÉTRICAS DE UNA VERSIÓN BRASILEÑA DEL SPITZER QUALITY OF LIFE INDEX EN PACIENTES CON DOLOR LUMBAR

*Este estudio tuvo como objetivo realizar la adaptación cultural del Spitzer Quality of Life Index y evaluar su confiabilidad en pacientes portadores de dolor lumbar crónico. Se siguieron las siguientes etapas: traducción, retrotraducción, evaluación por un comité y pre-prueba. La validez fue obtenida por medio de la correlación entre los puntajes del Spitzer (QLI), del SF-36 y del Roland-Morris. Las propiedades psicométricas fueron evaluadas en 120 pacientes. Los resultados demostraron un coeficiente alfa de Cronbach=0,77. En una nueva pre-prueba, se encontró un coeficiente de correlación intraclases ICC=0,960 ( $p < 0,001$ ; IC95%: 0,943; 0,972). El coeficiente de correlación de Spearman fue de  $r=0,937$  ( $p < 0,001$ ). Las correlaciones entre los puntajes del Spitzer (QLI) y de SF-36 fueron significativas. Correlación negativa entre los puntajes de Spitzer (QLI) y de Roland-Morris fue de ( $r = -0,730$ ). El proceso de adaptación cultural fue realizado con suceso y la versión adaptada presenta medidas psicométricas confiables.*

**DESCRIPTORES:** dolor de la región lumbar; dolor; psicometría; calidad de vida; estudios de validación

## AVALIAÇÃO DAS QUALIDADES PSICOMÉTRICAS DE UMA VERSÃO BRASILEIRA DO SPITZER QUALITY OF LIFE INDEX EM PACIENTES COM DOR LOMBAR

*Este estudo teve como objetivo realizar a adaptação cultural do Spitzer Quality of Life Index, e avaliar sua confiabilidade em pacientes portadores de dor lombar crônica. Foram seguidas as seguintes etapas: tradução, retro-tradução, avaliação por um comité e pré-teste. A confiabilidade foi avaliada por meio da consistência interna e da estabilidade. A validade foi obtida por meio da correlação entre os escores do Spitzer (QLI), do SF-36 e do Roland-Morris. As propriedades psicométricas foram avaliadas em 120 pacientes. Os resultados demonstraram coeficiente alfa de Cronbach=0,77. No teste-reteste, encontrou-se coeficiente de correlação intraclasse ICC=0,960 ( $p < 0,001$ ; IC 95%: 0,943; 0,972). Coeficiente de correlação de Spearman foi de  $r=0,937$  ( $p < 0,001$ ). As correlações entre os escores do Spitzer (QLI) e do SF-36 mostraram-se significativas. Observou-se correlação negativa significativa entre os escores do Spitzer (QLI) e do Roland-Morris ( $r = -0,730$ ). O processo de adaptação cultural foi realizado com sucesso e o questionário apresentou medidas psicométricas confiáveis.*

**DESCRITORES:** dor lombar; dor; psicometria; qualidade de vida; estudos de validação

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## INTRODUCTION

**M**usculoskeletal symptoms represent one of the principal problems in industrialized countries. There is a need for internationally standardized measurements for the analysis of musculoskeletal symptoms<sup>(1)</sup>. Low back pain is the most common of these symptoms<sup>(2)</sup>. It is one of the most common work-related injuries and is a cause of high costs both to industry and workers, negatively affecting the quality of life of its subjects. There are various reasons for evaluating the quality of life of people with back pain, including the need to establish objectives and plan treatment, to monitor the evolution of pain and to assess the outcome of the care<sup>(3)</sup>. Therefore, there are various advantages to be gained from the use of a standardized clinical protocol for the treatment of low back pain<sup>(4)</sup>.

The Spitzer Quality of Life Index – Spitzer (QLI), is a generic instrument for the evaluation of quality of life (QOL) that was initially used in patients with cancer and other chronic diseases<sup>(5-6)</sup>. The Spitzer (QLI), has been used to evaluate the quality of life in individuals with various medical conditions and also following surgical intervention<sup>(7-8)</sup>. The use of the Spitzer (QLI) has been reported in the international literature mainly in relation to the evaluation of the quality of life of elderly patients with musculoskeletal disorders<sup>(6)</sup>. In addition, Spitzer (QLI) is also being used in clinical protocols to evaluate the efficacy of treatments for low back pain<sup>(4)</sup>, and is also being used in studies as an instrument to evaluate the quality of life of patients with back pain<sup>(9)</sup>. The Spitzer (QLI) is originally intended to be filled out by healthcare professionals.

In view of the scarcity of instruments available in Brazil for the generic evaluation of quality of life, the objective of this study was to adapt the Spitzer (QLI) in a self-reported version into Brazilian Portuguese and evaluate its reliability and validity in patients suffering from back pain.

## METHODS

### Cross-Cultural Adaptation Process

To guarantee the quality of the adaptation, the steps recommended in specialized publications were followed<sup>(10-12)</sup>. The author was consulted and authorized the cultural adaptation of the instrument.

*Initial translation and Synthesis:* The original version of the Spitzer (QLI) was translated into Portuguese by two independent bilingual translators, whose native language was Portuguese. After this step, the two translated versions of the instrument were compared by the investigators, a mediator (a professional translator) and a university professor with research experience in quality of life. Discrepancies were identified and a consensus was obtained.

*Back-Translation:* The final version was translated back into English by two other independent translators who had not participated in the first stage and whose native language was English, thereby obtaining a back-translation-1 and a back-translation-2.

*Reviewer's Committee:* A committee composed of six bilingual individuals specialized in the subject area, were invited to review and compare the translations. To provide guidance to the judges on the evaluation procedure, an instrument was initially sent to each one of the members. This instrument was constructed specifically for this purpose and contained instructions for the evaluation of the topics in each section according to the semantic, idiomatic, cultural and conceptual equivalences.

After this first step, carried out individually by each one of the judges, a meeting was then organized with all the members to analyze the instructions and the questions of the instrument, and to evaluate their lay-out. All the judges participated in this meeting and the objective was to give continuity and depth to the analysis carried out previously, giving the judges the opportunity to discuss the discrepancies amongst themselves and to reach a consensus with respect to a final version of the instrument.

*Test of the prefinal version:* To evaluate the equivalence of the questionnaire within the Brazilian cultural environment, a pre-test was carried out in a sample of 40 patients with chronic low back pain. For this evaluation, it was established that a review would be carried out whenever more than 15% of the patients failed to understand the instructions for filling out the questionnaire, or the words or questions used in the instrument<sup>(13)</sup>.

### Evaluation of psychometric properties

#### Reliability

Reliability was evaluated using internal consistency and stability (test-retest). The stability

was evaluated by applying the questionnaire to the same group of patients on two different occasions.

#### Convergent Validity

The validity was analyzed using the relationship between the Spitzer (QLI) score and the Roland-Morris questionnaire and the Medical Outcome Study Short Form – 36 Health Survey (SF-36).

#### Subjects and setting

The data were collected in a physiotherapy outpatient clinic. Following referral and medical diagnosis, patients with low back pain receive care in this clinic, located in the Department of Orthopedics. Male and female adult patients over 18 years of age who had been referred with a diagnosis of low back pain were included in this study. Chronic low back pain was defined as pain localized in the lumbar region for a period of more than 12 weeks<sup>(14)</sup>. Patients who were incapable of understanding or of communicating verbally and/or who were illiterate were excluded from the study. It is suggested a minimum number of 100 subjects in studies of cultural adaptation<sup>(10)</sup>. In this study, 120 patients composed the sample group.

#### Data collection

The data were collected before the physiotherapy sessions took place. The subjects answered the questionnaires individually in a private room. The first step was to obtain the sociodemographic data, followed by the self-report Spitzer (QLI) questionnaire, the Medical Outcome Study Short Form – 36 Health Survey (SF-36) and the Roland-Morris questionnaire. The second stage was carried out 48 hours after the first. The QLI was applied to the same patient sample (120 patients), in the same private room, if pain status was maintained.

#### Data collection instruments

Data collection was performed by applying four instruments: the instrument for sociodemographic classification, the Spitzer (QLI), the Medical Outcome Study Short Form – 36 Health Survey (SF-36) and the Roland-Morris questionnaire.

The SF-36 is a generic instrument. It was adapted for the Brazilian cultural environment in

patients with rheumatoid arthritis<sup>(13)</sup>. It contains 8 health domains that may be grouped into 2 components: *Physical*, composed of functional capacity, physical aspects, pain, and general state of health; and *Mental*, which encompasses vitality, emotional aspects, social aspects and mental health. The score is given for each dimension, and these scores are transformed into a scale ranging from 0 to 100 in which 0 corresponds to the worst state of health possible and 100 to the best state of health<sup>(15)</sup>. It was decided to use the SF-36 since this instrument is easy to apply and commonly used in patients with low back pain<sup>(16)</sup>.

The Roland-Morris questionnaire is a specific instrument used to evaluate disability in patients with low back pain, having already been adapted and validated for use in the Brazilian cultural environment. It is composed of 24 items related to daily life activities, and takes an average of five minutes to complete<sup>(17)</sup>. The total score is calculated from the total number of questions marked, ranging from 0 to 24 where 0 refers to the absence of disability and 24 to severe disability<sup>(18)</sup>.

The Spitzer (QLI), developed by Spitzer, is a generic instrument for the evaluation of quality of life (QOL) that was initially used in patients with cancer and other chronic diseases<sup>(5)</sup>. The use of the Spitzer (QLI) has been reported in the international literature mainly in relation to the evaluation of the quality of life of elderly patients with musculoskeletal disorders. The Spitzer (QLI) is composed of five domains, each one representing a different aspect of the functions of life: involvement in occupational and domestic activities; activities of daily life; perception of the patient's own health; support from family and friends and perception of perspectives in life. Each domain is composed of three questions that may be awarded 0, 1 or 2 points, 2 representing the most positive response and 0 the worse response. The quality of life index is calculated from the sum of the scores obtained in each one of the domains, resulting in a score ranging from 0 to 10. Therefore, the highest possible score is 10, which represents an optimal quality of life<sup>(5)</sup>. The Spitzer (QLI) affords reliable psychometric measurements, and its content validity and construct validity have been confirmed in patients with cancer and other chronic diseases. Reliability was evaluated by internal consistency and inter-observer correlation. Internal consistency showed a high Cronbach's alpha coefficient (0.77) and the

Spearman's correlation between the data was statistically significant (0.81,  $p < 0.001$ ).

#### Statistical analyses

The data were entered into the Excel software program (Microsoft Office 2003) and into the SAS (Statistical Analysis System) software program for Windows, version 8.02 and the following analyses were performed:

- Descriptive analysis for the sociodemographic and clinical data and for the domains of the SF-36 and total scores of the Spitzer (QLI) and Roland-Morris questionnaires.
- Cronbach's coefficient alpha: to verify reliability. Cronbach alpha values  $> 0.70$  were established as constituting evidence of satisfactory internal consistency<sup>(19)</sup>.
- Spitzer (QLI) scores were considered continuous and were not normally distributed. Then, non-parametric statistics were used.
- Intraclass correlation coefficient (ICC): used to verify reliability with reference to the stability of the instrument (test-retest). ICC values  $\geq 0.90$  were considered evidence of stability<sup>(20)</sup>.
- Spearman's correlation coefficient: used to verify the test-retest and to evaluate validity, i.e. the correlation between the total scores of the Spitzer (QLI) and the Roland-Morris questionnaires and the domains of the SF-36.

The significance level of the statistical tests was established at 5%.

#### Ethical considerations

All patients who participated in this study were asked to provide written informed consent prior to enrollment. The full protocol received the approval of the university's Institutional Review Board.

## RESULTS

#### Cross-cultural adaptation process

Despite the complexity involved in the stages of the cross-cultural adaptation process, no great difficulties were found in performing these steps and all were carried out successfully. During evaluation

by the committee of judges, some alterations were suggested, with modifications that did not alter the sense of the original instrument, as well as changes related to the layout of the instrument. Although the instrument had originally been developed to be answered by healthcare professionals, it was decided to make this version a self-report questionnaire. This decision was justified since it would increase the range of use of the instrument.

In the pretest phase, the questionnaire was responded by a sample of 40 subjects. This group was characterized by the fact that the majority of subjects were female (80%, 32/40) with a mean age of 36.2 years and a mean of 10.7 years of schooling. The mean duration of low back pain was 46.2 months. A mean score of 7.8 was found for the Spitzer (QLI), indicating a moderate quality of life. Following application of the instrument, the patients were interviewed to evaluate the difficulties found in filling out the questionnaire and to identify any questions or words that were difficult to understand.

When filling out the heading of the questionnaire in which details regarding patient identification were requested, 47.5% of patients (19/40) had difficulty with the question "Problem or Principal Diagnosis", indicating a lack of comprehension with respect to the term "diagnosis". No difficulties were found in understanding the instructions for filling out the questionnaire. Based on these data, a further meeting was held with the committee members at which time it was decided to substitute "Problem or Principal Diagnosis" by "Principal Disease". Following this modification, the final version of the instrument was then considered to have been obtained.

#### Description of the sample

One hundred and twenty subjects with a mean age of 37.4 ( $\pm 18.3$ ) years participated in the test phase of this study. Almost 30% (29.2%) of subjects were in the 20-29 year old age-group and low back pain was more common among women (77.5%). The most frequent duration of low back pain was between 25 and 60 months (31.7% of participants), followed by 13-24 months (25.8%). Sociodemographic and clinical data with respect to these patients are shown in Table 1.

Table 1 - Sociodemographic characteristics (n=120)

	N	%	Mean (±SD)
Age (in years)			37.4 (±18,3)
Gender			
Male	27	22.5	
Female	93	77.5	
Years of schooling			10.7 (±4,6)
Current employment status			
Currently working	43	35.8	
Not working	36	30.0	
Housewife	06	5.0	
Unemployed	35	29.2	
Duration of low back pain (in months)			60.2 (±81,5)
4-12	22	18.3	
13-24	31	25.8	
25-60	38	31.7	
>60	29	24.2	

Quality of life and evaluation of low back pain

With respect to the QOL data obtained with the use of the Spitzer (QLI), analysis revealed a mean score of 7.3 (± 2.4) and 7.4 (± 2.4) in the retest, on a scale ranging from 0 to 10. It was found that with respect to the 8 different domains of the SF-36, the dimensions that had the lowest values were: 40.9 (± 21.2) for pain; 46.7 (± 42.2) for emotional aspects; 47.1 (± 40.8) for physical aspects and 49.0 (± 24.6) for vitality. The mean score obtained in the application of the Roland-Morris instrument was 9.5 (± 7.0) on a scale of 0-24. The measurements of quality of life as well as the measurement of low back pain, are shown in Table 2.

Table 2 - Scores of the Spitzer (QLI) questionnaire (test/retest), of the SF-36 and the Brazil-Roland-Morris questionnaire (n=120)

Instruments	Mean (±SD)	Median	Minimum	Maximum
Spitzer (QLI) (test)				
Score	7.3 (±2,4)	8.0	0.0	10.0
Spitzer (QLI) (retest)				
Score	7.4 (±2,4)	8.0	1.0	10.0
SF-36				
Physical functioning	59.6 (±31,0)	70.0	0.0	100.0
Physical role	47.1 (±40,8)	50.0	0.0	100.0
Bodily pain	40.9 (±21,2)	41.0	0.0	87.5
General health	68.3 (±23,1)	72.0	5.0	100.0
Vitality	49.0 (±24,6)	50.0	0.0	95.0
Social functioning	63.4 (±29,8)	62.5	0.0	100.0
Emotional role	46.7 (±42,2)	33.3	0.0	100.0
Mental health	59.7(±25,8)	66.0	0.0	100.0
Roland-Morris				
Score	9.5(±7,0)	7.5	0.0	24.0

Psychometric properties

Reliability

The Cronbach's alpha coefficient was calculated in the test and retest phases. Internal consistency was found to be satisfactory, as confirmed by a Cronbach's alpha coefficient of 0.76 for the test and 0.77 for the retest. A high degree of stability was found for the score of the Spitzer questionnaire in the test/retest, with an intraclass correlation coefficient (ICC) of 0.960 (p<0.001; 95%CI: 0.943-0.972). Spearman's correlation coefficient was r=0.937 (p<0.001), also indicating high agreement between the test/retest values of the Spitzer (QLI) score, as shown in Figure 1.

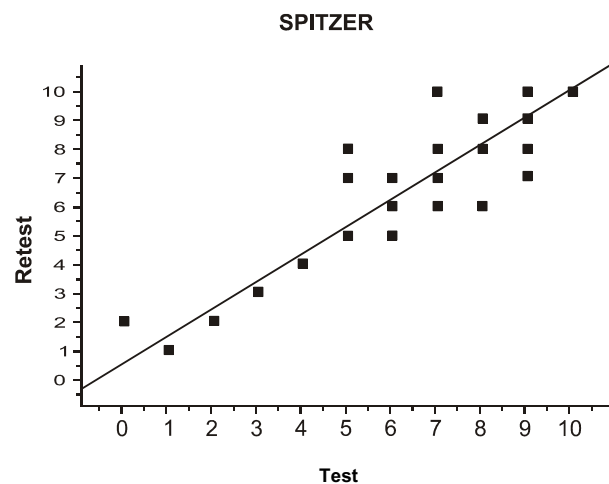


Figure 1 - Test-retest reliability of the Brazilian-Portuguese version of the Spitzer (QLI) (Spearman's coefficient)

Convergent Validity

The correlations between the Spitzer (QLI) score and the different dimensions of the SF-36 were significant, particularly with respect to the correlations between the domains of pain (r=0.699), physical aspects (r=0.687), functional capacity (r=0.682) and social aspects (r=0.680). A significant negative correlation was also found between the scores obtained in the Spitzer (QLI) and the Roland-Morris questionnaire (r= - 0.730) (Table 3).

Table 3 - Spearman's correlation coefficient (r) for the 8 domains of the SF-36 and Brazil-Roland-Morris questionnaire with the Brazilian-Portuguese version of the Spitzer (QLI)

SF-36	Spitzer (QLI) (Escore)
Physical functioning	0.682
Physical role	0.687
Bodily pain	0.699
General health	0.429
Vitality	0.674
Social functioning	0.680
Emotional role	0.612
Mental health	0.660
Roland-Morris Score	-0.730

All correlations significant at  $p = 0.0001$

## DISCUSSION

The process of cultural adaptation followed all the steps suggested in international methodology. The principal modification implemented to make the instrument more appropriate for use within the Brazilian cultural environment was to make the version a self-report questionnaire. This alteration occurred because of the conceptual perspective of quality of life, which considers the measured concept as subjective and, therefore, its evaluation must be based on the report of the subject themselves. We should point out that in studies carried out in other countries, as Australia, the instrument in its self-reported form was also used<sup>(5,21)</sup>.

The majority of subjects in this study were female, and the predominant age-groups confirm that the back pain is one that affects an economically productive population, leading to a large number of claims of disability compensation. The most frequent duration of low back pain was between 25 and 60 months (31.7%), characterizing a population with chronic symptoms, as previously reported<sup>(16)</sup>. The version of the instrument was easily understood by the patients. The average schooling was of 10,7 ( $\pm 4,6$ ) years of study, and because of this, new studies with individuals who have little schooling are required.

With respect to quality of life, the analysis of the scores of the Spitzer (QLI) test and retest showed a moderate quality of life, and this was confirmed by the results of the Roland-Morris. The dimensions of the SF-36 instrument that resulted in the lowest scores recorded were: pain, emotional aspects, physical aspects and vitality. Similar results have been reported in recent studies on musculoskeletal

disorders, specifically those on low back pain<sup>(16)</sup>. New dimensions of health are being incorporated into the traditional evaluation of clinical, laboratory and radiographic parameters for patients with chronic diseases. Studies have confirmed the negative effect of musculoskeletal symptoms on various dimensions of quality of life, particularly pain and physical aspects<sup>(22)</sup>. Therefore, it is increasingly important to measure the impact of the back pain on the quality of life of patients.

The international literature has reported that health-related quality of life instruments are being widely recommended to measure the outcome in patients with back disorders. Following up these results constitutes a systematic method of monitoring the efficacy of treatment of low back pain.

The evaluation of the reliability showed satisfactory internal consistency as indicated by a Cronbach's alpha coefficient of 0.76 for the test and 0.77 for the retest. These results are similar to those found in the original study<sup>(5)</sup> carried out in 91 patients with cancer and other chronic diseases, in which a Cronbach's alpha value of 0.77 was reported. Cronbach's alpha coefficient was also calculated for a sample of 261 patients with chronic diseases in a study on the validation of the Quality of Life Index carried out in Canada, in which a value of 0.78 was found. A sub-group of these patients with cancer had an alpha of 0.85<sup>(23)</sup>. We must point out that these studies used the original form of application. These results of the present study suggest that the Spitzer (QLI) instrument has reliable internal consistency in the self-reported form.

The test-retest stability of the Portuguese version of the Spitzer (QLI) was evaluated using an interval of 48 hours between the first and the second interview, resulting in a Spearman's correlation of 0.937 ( $p < 0.001$ ) and an intraclass correlation coefficient (ICC) of 0.960 ( $p < 0.001$ ; 95%CI: 0.943-0.972). It should be remembered that during the first step in the data collection process, four different instruments were applied. The literature states the importance of considering the time interval, in such a way that the answers of the second interview may not be influenced by the memory of the first, and also that the interval isn't long enough to produce changes in the natural evolution of the pain chart<sup>(24)</sup>.

In the original study<sup>(5)</sup>, the reliability of the questionnaire was evaluated using internal consistency and inter-observer correlation. In

Canadian patients, physicians applied the instrument independently to a group of subjects with an interval of 7 days between the test and the retest. For a sample of 64 patients, Spearman's correlation coefficient was 0.81<sup>(25)</sup>.

The correlations between the Spitzer (QLI) score and the dimensions of the SF-36 were significant, particularly the correlations of the domains of pain ( $r=0.699$ ), physical aspects ( $r=0.687$ ), functional capacity ( $r=0.682$ ) and social aspects ( $r=0.680$ ). Satisfactory negative correlation was also found between the scores obtained in the Spitzer (QLI) and those of the Roland-Morris questionnaire ( $r= -0.730$ ).

In a study carried out in patients with congestive heart failure, Spitzer's questionnaire was found to be effective in differentiating between a study group and a control group when compared with the Sickness Impact Profile (SIP) and the Quality of Well-Being (QWB)<sup>(26)</sup>. The data showed that the adapted version of this instrument may be useful since it is easily applied, particularly in clinical and interventional evaluations. Further use and psychometric evaluation should be tested in other chronic conditions within the Brazilian cultural environment.

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## CONCLUSIONS

The Brazilian version of the Spitzer (QLI) achieved good results with respect to the evaluation of its psychometric properties, and was considered reliable for use in subjects with low back pain. Internal consistency was satisfactory with a Cronbach's alpha coefficient of 0.76 for the test and 0.77 for the retest. Stability (test-retest) was confirmed by the Intraclass Correlation Coefficient (ICC) of 0.960 ( $p<0.001$ ; 95%CI: 0.943-0.972) and Spearman's correlation coefficient ( $r=0.937$ ). Validity was confirmed by the significant correlation between the Spitzer (QLI) and the Roland-Morris questionnaire ( $r= -0.730$ ) and the different dimensions of the SF-36, stronger correlations being found for the dimensions of pain ( $r=0.699$ ), physical aspects ( $r=0.687$ ), functional capacity ( $r=0.682$ ) and social aspects ( $r=0.680$ ).

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