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Enhancing the Cross-Cultural Adaptation and Validation Process of the Functional Rating Index in Spanish Patients with Low Back Pain: A Study Protocol

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Abstract

Background: Patient-orientated evaluation methods are of paramount importance in assessing treatment outcomes. The Functional Rating Index (FRI) is one of the condition-specific questionnaires recommended for use with low back pain (LBP) patients. To date, no Spanish version has been published in the peer-reviewed literature.

Objective: The aim of this study is to cross-culturally adapt and validate the FRI into Spanish in LBP population, according to established guidelines, and to evaluate its psychometric properties in different clinical settings.

Design: Cross-cultural and validation study protocol.

Setting: Five public and private physical therapy units in our area.

Methods: Patients of any gender suffering nonspecific LBP will be recruited. Three phases will be conducted through a multi methodical approach, consisting of translation and cross-cultural adaptation of the FRI into Spanish: translation and cross-cultural adaptation of the FRI into Spanish, pilot testing to assess comprehensibility, and a validation phase considering aspects of reliability, construct validity, and structure of the instrument.

Conclusion: The translation and cross-cultural adaptation of the FRI to Spanish language will be performed in a structured and evidence-based manner through a prospective, multicenter design. FRI usefulness in LBP patients in both public and private settings will be evaluated.

Keywords: Functional rating index; Cross-cultural adaptation; Validation; Psychometry; Low back pain

Introduction

Low back pain (LBP) is an enormous burden of disease globally affecting 70-80% of adults sometime during their life [1]. Most episodes are self-limiting but recurrent, being the second most frequent medical visits for chronic pain and the most common cause of work disability (60%) in the western world. Thus, LBP constitutes a major health problem in terms of volume and costs in health care, compensation, working hours and pension losses [2].

Condition-specific, patient-reported outcome (PRO) measures have become essential for clinical assessment and research of LBP-related disability [3]. A large number of self-administered questionnaires have been proposed to measure the functional capacity of patients with LBP. The most commonly used are the Roland-Morris Disability Questionnaire (RMDQ) [4], the Oswestry Disability Questionnaire (ODQ) [5], the Quebec Back Pain Disability Scale (QBPDS) [6], and the Functional Rating Index (FRI) [7], among others. All these instruments have been extensively tested, have shown similarly good psychometric properties, and are applicable in a wide variety of settings, although the number and nature of their items and their response categories differ [8,9].

The FRI is specifically designed instrument to quantitatively measure subjective perception of function and pain related to the spinal musculoskeletal system in a clinical context. It is a self-reporting tool comprised by 10 items, each with 5 possible responses, which express graduating degrees of disability. Compared to other instruments, FRI index may have the advantage of brief, concise and simple format, with short sentences, and options leading to shorter time spent on reading and completing it. The FRI has been widely used in research among several cohorts of LBP patients (e.g., athletes, elderly) [10,11] and has already been translated into Chinese [12], Iranian [13], Brazilian-Portuguese [14], with significant validity and reliability [15–18].

The aim of this study is to describe the process of translation and cultural adaptation of the FRI instrument into Spanish, assessing its reproducibility, internal consistency and external validity, and to validate its use in Spanish patients with LBP.

Methods/Design

The study will follow a multimethodical approach. Three parts will be conducted, consisting of translation and cross-cultural adaptation of the FRI into Spanish (i), a subsequent, initial evaluation of this tool in a pilot trial to assess comprehensibility (ii), and a validation phase considering aspects of reliability, construct validity, and structure of the instrument (iii).

Translation and cross-cultural adaptation

Cross-cultural adaptation will be performed in accordance with previously published guidelines [19–21]. A written authorization allowing translation into Spanish was obtained from the original authors, as recommended [22].

Stage I: Forward translation to Spanish

The forward translation of the FRI to Spanish will be carried out independently by two bilingual translators whose native language is Spanish.

Stage II: Synthesis of the Translations

After discussion, the two translators and an observer recorded will synthesize the results of the translations and will produce a consensus version of the FRI.

Stage III: Back Translation

Two new bilingual (English and Spanish) translators without a health sciences background will independently back-translate the consensus version of the Spanish FRI into English. This process is a validity check to ensure that the translated version is reflecting the content of the original items. The two translators will be blind to the original version of the questionnaire,

Stage IV: Expert Committee

An expert committee will review all translations and will discuss with the original translators possible discrepancies, and will develop the final FRI version to be tested in Spanish population. Translators must also ensure that the final questionnaire is understood by the equivalent of 12 years old (about a 6th grade level elementary) individual, as is the general recommendation for questionnaires [20,23].

Stage V: Pre-test – Pilot study

Pilot testing will take place with an incidental sample of 35 patients suffering LBP. The original English version was designed as self-applicable. It was decided that the Spanish version would be read to the illiterate patients. The interviewer will be asked to document any problems that occurred during the administration of the questionnaire. Also, each respondent will be asked at the end of the interview to provide comments about the questionnaire and identify any words or questions that are difficult to understand. The inclusion and exclusion criteria are listed in Table 1. Participants to complete the consolidated version will be requested and, using a structured interview, will be invited to comment on any aspect that has been difficult to understand. Both the meaning of the items like the answers would be considered. This ensures that the adapted version retains its equivalence to be applied. The distribution of responses will be examined to find a high

proportion of missing items or individual responses. De Soarez et al. recommends reviewing any question in the questionnaire if at least 15% of participants found the same difficulties [21].

Inclusion criteria	Aged between 18 and 80. Ability to read and speak Spanish. Presence of nonspecific acute or chronic low back with or without radiation to the lower limbs or neurological signs.
Exclusion Criteria	Spinal surgery Tumors Systemic rheumatologic disease or infection. Ankylosing spondylitis Neurological disorders. Being unable or unwilling to complete the questionnaire independently.

Table 1: Eligibility criteria.

Once the Spanish version of the FRI shows a good level of understanding and answering by all the patients and no change is proposed by the expert committee, the validation phase of our original translation will then take place.

Stage VI: Evaluation of the Adaptation process

The final step in the adaptation process is a presentation of all reports and forms to the authors of the instrument or the committee has monitored the translated version. This is an audit of all the steps taken and reports followed. It is not for the Committee to alter the content, it is supposed to follow this process has achieved a reasonable translation [19,27].

Stage VII: Validation of the questionnaire in the target language

Setting

This is a multi-center study, involving five different clinical settings in Malaga, Spain. The selected centers will be outpatient physical therapy clinics and units (public and private), all chosen to represent different social and cultural contexts within different areas of our region.

Study Population

The study includes outpatient patients aged between 18 and 80 years with a primary complaint of nonspecific acute/chronic LBP with or without lower extremity symptoms, who are able to speak and read Spanish. They should be receiving or planned to receive at least one form of treatment at the physiotherapy centers. Excluded patients will be those aged less than 18 years, those with incomplete diagnosis, those with a history of spinal surgery, tumors, infection, systemic rheumatologic disease, ankylosing spondylitis, arthritis, severe personality disorders, loco-regional tumor or metastasis, pelvic and abdominal pain and/or neurological disorders and those who were unable or unwilling to complete questionnaires independently (table 1). A group of asymptomatic subjects (healthy group) will be also recruited, and their scores will be compared to the clinical group to evaluate discriminative validity.

Study Variables

A data extraction form will be developed for the purpose of gathering the relevant sociodemographic and clinical data from the sample. Variables collected will be: patient's identification number, age, gender, weight (Kg), heigth (m), body mass index (BMI), educational status/qualification level (elementary sch, middle sch, high sch, university), employment status/occupation, self-report health status (excellent, very good, good, fair, poor), workload (no work, low, medium, high), past year-impairment (days). Information on the pathology will be: LBP duration, and stage (6wk to 3mo, 3mo to 1yr, >1yr). Pain at this moment will be assessed by use of a numeric rating scale (0-10, NRS).

Research Tools

The instruments selected for this study include Roland-Morris questionnaire (RMQ)-Spanish version [24], Global Perceived Effect Scale (GPES) [25], a global HRQL question ("I am content with the quality of my life right now"), and Numerical Pain Rating Scale (NPRS) [26]. The choice of these instruments was guided by the availability, established psychometric properties, and non-superiority of other instruments.

To accommodate the irregularities of punctuation, the following rules will be established: 1) when an individual scores two responses on the same item, responses are averaged; 2) when an individual scores response between two numbers, the answer is the average of the two numbers; and 3) when a subject did not respond to an item, that item was excluded from the study (4,5).

Functional Rating Index (FRI)

FRI is a patient self-report measure that uses both pain and function for a wider view of a patient's disability. This questionnaire derived from a combination of NDI (7) and OLBDQ (14). This instrument has proven satisfactory reliability, validity and responsiveness among LBP patients. It consists of 10 items that measure both pain and function of the spine. Of these 10 items, 8 refer to activities of daily living that can be adversely affected by a disease of the spinal system, and 2 refer to two different attributes of pain. Using a five-point scale for each item (0 = no pain or full ability to function; and 4 = worst possible pain and/or unable to perform this function), the patient ranks his or her perceived disability to perform a function and/or the severity of pain at the present time. The range of scores is 0% (no disability) to 100% (severe disability). An example calculation is as follows: 1) when all 10 items are completed, the score is calculated as follows: (total score / 40) x 100%; and 2) when you have completed only 9 items, the score is calculated as follows: (total score / 36) x 100%) (4,5).

Since many spinal disabilities combined loss of function and pain and/or fear of pain, the use of both allows a broader view of the patient's disability (4,5). It also reduces the administrative burden of other common spine PROs.

Roland Morris Disability Questionnaire (RMDQ)

RMDQ is a 24-item, self-administered questionnaire, derived from the Sickness Impact Profile[27], a 136-item outcome assessment tool covering aspects of both physical and mental health. It's simple, fast and can be filled out by the patient. Each item in the RMDQ can be answered "yes" or "no." The RMDQ is scored by adding up the number of items checked by the patient. The score can therefore vary from 0 to 24. If patients indicate in any way that an item is not applicable to them, the item is scored 'No', i.e. the denominator remains 24.

The range of scores is zero percent (no disability) to one hundred percent (severe disability). Higher the number and greater the perceived pain and dysfunction; lower the number and lower the perceived pain and dysfunction.

Global Perceived Effect Scale (GPES)

A 11-point Likert-type scale evaluating "global perceived effect" (GPE) of the physical therapy treatment will be also completed as the external criterion of clinically important change. The response options are +5 (completely recovered), 0 (no change), and -5 (vastly worse).

Sample Size Estimation

Sample size calculation will be based on the "rule of 10" patients per item. According to Terwee et al., a minimum number of 100 subjects are necessary for internal consistency analysis and 50 for appropriate analysis of other tests [28]. As a consequence, the final expected sample will be higher than 100 subjects. Due to the potential for loss to follow-up and missing data, a sample of 120 subjects will be recruited.

Pilot study: Patient selection was based on the recommendations made by Beaton et al. [20], who suggest that at least 30-40 patients should be evaluated.

Validation: For a multivariate analysis technique to gain reliable estimates, the number of subjects' observations should be 10 times the number of variables in the model [29]. Therefore, the sample size was estimated based on this recommendation as follows; EORTC QLQ-CR29: There are 10 items in the FRI. Thus, the minimum number of subject required is 100. In our study, we will recruit 120 subjects due to the potential for loss to follow-up and missing data.

Ethical and Legal Considerations

The FRI authors [7] were contacted, and they provided authorization to conduct this work. The study will be conducted in accordance with medical professional codex and the Helsinki Declaration. Study participation by patients will be voluntary and could be cancelled at any time without provision of reasons and without negative consequences to any participant or their future medical care.

Written informed consent and verbal assent will be given by all participants or their surrogate prior to the interview. Previous to study participation patients will receive written and oral information about the content and extent of the study. No financial incentives will be provided to any study participant.

After the completion of questionnaires and documents –provided with a special code– they will be stripped of personal data (e.g. names, date of birth). Personal data will be eliminated. All electronical data of the complete, coded documents will be saved on a protected server. Only members of the internal study team can access the respective files.

Procedure

Patient's selection

Prospective patients will be identified using the above mentioned eligibility criteria. The patients will be recruited non-selectively and consecutively in the period from October 2015 till July 2016 from different Physical Therapy units (public and private) in Malaga, Spain.

Baseline data and Questionnaire administration

Baseline data for all prospective patients will be obtained through personal, guided interview. Questionnaires will be presented by research assistants to each participant, who will be ensured that his or her physical therapist will be blinded to the results. Questionnaires will be administered before a session of treatment, excluding the first session, and in a separate room, ensuring privacy. Items will be presented to each participant in written form. Participants will answer each question verbally, and research assistants will fill in the answers for them. A data extraction form will be completed for every patient. Specific characteristics regarding pathology will be collected parallely at the same meeting. The data collection method will be interviewer delivered: research administrators (research assistants and the researcher) will present the instruments, answer questions from respondents and will be present throughout every session. Among the advantages of this method are further patients´ motivation and encouragement to answer every item, increase reliability and quality in the answer.

Statistical Analysis

Data preparation

Questionnaires will be checked and data will be entered into an Excel database file and transferred to SPSS version 21.0 for Windows (SPSS Inc., Chicago, IL, USA) for analysis. Data will be coded based on the guidelines as contained in the FRI scoring manual [7].

Descriptive statistics

All statistical analyses will be performed using SPSS (v.21). Descriptive statistical analysis will be performed for all demographic variables. A confirmatory factor analysis will be performed. Quantitative variables will be described using mean, standard deviation (SD) and range. Qualitative variables will be described using frequency and percentages. To assess central position, dispersion and distribution of variables, the Kolmogorov-Smirnov test will be used. Correlations will be calculated between scores and continuous variables using Pearson correlation coefficient (i.e. correlation between FRI and RMQ, or FRI and NRS). A p-value of ≤ 0.05 will be considered statistically significant.

Psychometric properties

Reliability

Reliability is the degree to which an instrument is capable of measuring error. Measures the proportion of variation in the measurements is due to the diversity of values that the variable takes and not the possible systematic or random error. Reliability determines the proportion of the total variance attributable to true differences between subjects. This psychometric property will be performed by means of internal consistency and test-retest reliability.

Internal consistency

The internal consistency will be assessed using the Cronbach's alpha coefficient. Coefficients between 0.70 and 0.95 will be considered adequate [30]. As FRI is comprised of distinct subscales, Cronbach´s alpha coefficient should be calculated for items with respect to the overall score (item-total correlation) and the items of each subscale of the value of the same (correlation item-subscale).

Reproducibility (Test-retest reliability)

Patients will be asked to complete the questionnaire twice within an interval of 1 to 2 days to avoid variations in clinical status. The initial questionnaire will be completed in an outpatient room at the clinical setting, and the retest data will be collected via phone. Intraclass correlation coefficient (ICC) will be calculated to quantify the reproducibility. ICC will be interpreted as follows: <0.40, poor reliability; 0.40 to 0.75, moderate reliability; 0.75 to 0.90, substantial reliability; and >0.90, excellent reliability. A score of one indicates perfectly reliable, zero perfectly unreliable test [31].

Validity

Content validity will be addressed during the translation and cross-cultural adaptation stage by testing the prefinal Sp-FRI with patients and incorporating expert opinion.

Construct validity will be assessed by correlating the Spanish FRI, the Spanish RMDQ, and the Pain Numerical Rating Scale (Pain NRS) at baseline using Pearson's coefficient. A score of 0.70 is widely accepted for instruments that measure the same construct. When similar constructs are compared, scores lower than 0.70 should be accepted.

Score distribution

Ceiling effects occur when subjects produce a high score on an instrument at baseline, making it impossible for the measure to detect improvement. Floor effects occur when subjects produce the lowest possible score, making it impossible to detect any deterioration. Ceiling and floor effects are considered to be present if more than 15% of respondents achieved the lowest or highest possible total score. Potential ceiling and floor effects will be estimated by assessing the distribution of answers across categories and calculating the percentage of patients indicating the minimum and maximum possible scores in both questionnaires [28].

Feasibility

Feasibility measures whether the questionnaire is available for use in the field you want to use. The aspects that are usually evaluated: the time required to complete it, the simplicity and readability of the format, brevity and clarity of the questions and the recording, coding and interpretation of results [32,33]. It can also be measured by assessing the patient's perception about the ease of using the questionnaire as well as the perception of professional respect to their usefulness in clinical practice.

Discussion

With the globalization of clinical research, self-reported outcomes assessed by valid instrument are attracting increasing attention from clinician's worldwide. Region-specific tools have been cross-culturally adapted to Spanish in recent years. However, no current "gold standard" exists, regarding LBP patients. The rationale for this study is to provide detailed information on the clinimetric quality, including test-retest reliability, of the FRI in patients with LBP. To the best of our knowledge, this is the first prospective study to gain further insight into the validity of the FRI in Spanish LBP patient. We hypothesize that the resulting FRI-Spanish version will prove to be reliable for use in Spain, thus contributing to the treatment of individuals with LBP in the selected setting. Once validated, such FRI-administered questionnaires can serve as effective tools for evaluating and screening large populations for this common condition.

Reliability, validity and responsiveness are specific attributes that depend on context, and although FRI has demonstrated satisfactory psychometric properties in diverse populations may not necessarily be suitable for Spain. A process of translation and adaptation into Spanish followed by a validation process is widely recommended, to minimize information bias that could be associated with the administration of the questionnaire in another country and different culture. Validation of the Spanish FRI will provide expansion of the questionnaire and the comparison of research results between countries. We propose to conduct an adaptation and validation study to validate FRI among Spanish population and to evaluate its psychometric properties.

Trial Status

This study is ongoing. The expected end date of patient recruitment in this study is July 2016.

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