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ORIGINAL ARTICLE

Content validity and responsiveness of a Finnish version of the Patient-Specific Functional Scale

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Abstract

Background: The Patient-Specific Functional Scale (PSFS) questionnaire was developed by Stratford and colleagues to provide a method for eliciting, measuring and recording descriptions of patients' disabilities. It can be used to guide treatment and assess patient outcome. The aim of the study was to translate and validate a Finnish version of the internationally used PSFS questionnaire, by testing its content validity and responsiveness, and to conduct a cross-cultural adaptation of the measure. *Methods:* The final version of the Finnish questionnaire underwent a cross-cultural adaptation before the validation study. The subjects of the study were patients receiving physiotherapy for low back pain ($n = 78$). They completed the PSFS questionnaire prior to physiotherapy treatment and after treatment series. Roland–Morris Disability Questionnaire (RMDQ) and the visual analogue scale (VAS) were recorded before and after the treatment series. *Results:* For content validity, a good correlation of the scores between baseline measures of PSFS and RMDQ were 0.65 (Pearson's rho) ($p < 0.01$). For responsiveness, moderate to good correlation among the measures between changes of the PSFS, RMDQ and VAS (0–100 mm) scores were analysed. *Conclusions:* The Finnish translation of the PSFS questionnaire performs as the original, is proven to have adequate content validity and responsiveness, and could be recommended as an assessment tool for clinical and research use.

Key words: *Finnish, low back pain, physiotherapy, PSFS, validity*

Introduction

The Patient-Specific Functional Scale (PSFS) was developed to provide a method for eliciting, measuring and recording descriptions of patients' disabilities (1). It can be used to guide treatment and assess patient outcome. The PSFS is intended to complement the findings of generic or condition-specific measures. The shortcoming of such measures is that they are limited in detecting small but important disabilities and changes in disability over time (1).

The PSFS is administered at the initial assessment, during the history taking, and prior to the assessment of any impairment measures. The rationale for administration prior to the physical examination is to maximize the patient's focus on activity limitation. ("I have difficulty walking down stairs") rather than impairment ("I can't flex my knee"). Patients are asked to identify up to five important activities that they are having difficulty with or are unable to perform. In addition to specifying the activities, patients are asked to rate, on an 11-point scale, the current level of difficulty associated with each activity. The scale anchors are 0 ("unable to perform activity") to 10 ("able to perform activity at same level as before injury or problem"). The clinician's role is to read the script (instructions) to the patient

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and record the activities, the corresponding numerical difficulty ratings and the assessment date. At subsequent reassessments, the clinician reads the follow-up script, which reminds the patients of the activities that they identified previously. Because patients identify between one and five activities and this activity set is unique to each patient, the PSFS is not a comprehensive measure of disability and was not designed to compare disabilities between patients (1–3).

The PSFS has been studied on patients with low back pain (LBP) and evidence proofs it to be reliable [intraclass correlation coefficient (ICC) = 0.97], valid (individual activity-specific correlations with the Roland–Morris Disability Questionnaire (RMDQ), a condition-specific measure, varied from $r = 0.55$ to 0.74), and sensitive to change over time (Norman's 0.70–0.81) (1). The PSFS has been applied also to the patients with knee dysfunction. In comparison with the Short Form-36 it was found that test–retest reliability (ICC = 0.84) and sensitivity to change (Pearson's $r = 0.78$) were excellent. Validity was also confirmed (3). The results of a cohort study provide construct and predictive validity evidence for the PSFS as an indicator of functional limitation in workers' compensation claimants (4). Excellent reliability (ICC = 0.92), validity ($r = 0.73$–0.83 compared with the Neck Disability Index (NDI), and $r = 0.52$–0.64 compared with the prognosis rating) and sensitivity to change ($r = 0.79$–0.83 compared with NDI change scores, and $r = 0.46$–0.53 compared with the prognosis rating) are demonstrated (5). PSFS and NDI were similar in their ability to detect change over time (5). So far, PSFS has been translated and validated to Brazilian-Portuguese. These language versions of the RMDQ, the Functional Rating Index (FRI) and the PSFS have been shown to have similar clinimetric properties to each other and to the original English versions. Of all the measures tested in this study, the PSFS seemed the most responsive (6). According to previous study, the RMDQ and PSFS both demonstrate good responsiveness according to the definitions given in previous guidelines (7). The PSFS is more sensitive than the RMDQ for patients with low levels of activity limitation but not for patients with high levels of activity limitation (7). The PSFS exhibited poor reliability in patients with cervical radiculopathy and it showed adequate responsiveness in this patient population (8). The PSFS demonstrated good responsiveness, moderate reliability and good construct validity for patients attending a musculoskeletal physiotherapy clinic with upper extremity problems (9). One study investigated the extent to which patient-generated PSFS items reflect The International Classification of Functioning, Disability and Health (ICF) domains. The ICF activity component was most commonly represented by patient-nominated PSFS items, the participation component was moderately represented, but impairment was least represented. Hence, the PSFS would complement impairment-based clinical outcome measures (10). In an extensive search through medical databases (PubMed, Pedro, Cinahl), eight randomized controlled trials were found to use PSFS as a primary outcome measure (11–18).

The original English version has been translated in many languages, but validated only in English and Brazilian-Portuguese. The validation process of a translated questionnaire is required to test its adaptability in a new linguistic and cultural environment. The translated version should perform as the original to enable cross-cultural exchange and interpretation of study results.

The aim of the study was to translate and validate a Finnish version of the PSFS questionnaire, by testing its content validity and responsiveness, and to conduct a cross-cultural adaptation of the measure.

Materials and methods

To be eligible for inclusion patients had to have acute, sub-acute or chronic LBP, aged between 16 and 65 years, and had given written informed consent. The ethics committee of the Kymenlaakso Hospital District approved the study design on 31 January 2009.

Translation and cross-cultural adaptation

The Finnish version of the PSFS was tested for face validity in a sample of LBP patients attending two physiotherapy clinics. These two clinics were located in different dialectical areas of Finland. Thus, the final version of the Finnish questionnaire underwent a cross-cultural adaptation before the validation study (19). During the adaptation process of the final version of the translated questionnaire, there were no minor or significant problems.

A Finnish PSFS Likert version was constructed by a repeated back-and-forth translation process of the original English version at an independent translation agency. Translation/retranslation of the English version of the PSFS was done blindly and independently by two different individuals and adapted by an expert team. The team checked the questionnaire for linguistic clearness and went through consensus process to come up with a pre-final version of the questionnaire. The consensus process was done by three experienced physiotherapy teachers. They followed the instructions given in

ISPOR Task Force for Translation and Cultural Adaptation (19).

Participants

Participants were patients seeking treatment for LBP and had Finnish as domestic language. They were referred from seven outpatient physiotherapy clinics for treatment by their local GPs and occupational health physicians during the period March 2009 to August 2010. They were briefed regarding the study and agreed to participate.

Procedures

During the first visit, each patient was interviewed and they completed the Finnish versions on PSFS, RMDQ (20) and the 0–100-mm visual analogue scale (VAS) (21). The measurements were repeated during the last session of physiotherapy. Of the clinics involved, two were public and four were private. Because of the variability of the seven different clinics, the number of treatments varied from one to 15 within different patients and clinics.

Content validity

Content validity was defined to be similarity within PSFS and RMDQ baseline measurements. The PSFS and RMDQ are constructed to determine the level of disability and VAS is a measurement for pain intensity. With the PSFS questionnaire, the score ranges from 0 to 30, a higher score indicating higher functional ability (1,6). The RMDQ is a 24-item questionnaire with a range of scores of 0 to 24, a higher score indicating higher disability (20).

Responsiveness

Responsiveness was defined to be similarity within the change scores of PSFS, RMDQ and VAS between the baseline and final measurements. Ideally, responsiveness should be tested in a follow-up study using pre-validated instruments and a global assessment scheme as an external criterion of change (21). Within this study, the VAS measurement was used as an external validation tool. The VAS is widely used as asking patients to show their pain intensity level on a 100-mm scale (ranging from 0 "no pain" to 100 "pain as bad as could be" (21,22).

Statistical analyses

Statistical analyses were performed with SPSS for Windows 17.0 (SPSS Inc., Chicago, IL). External content validity was evaluated by correlating the Finnish versions of PSFS and RMDQ scores for the patients at baseline using Pearson's *r*, a score of 0.70 being recommended for instruments that measure the same construct. When similar constructs are compared, scores lower than 0.70 are acceptable. Very high correlation is defined being over 0.80 (23). To test external responsiveness, the change of the PSFS, RMDQ and VAS scores at baseline and after the last treatment were analysed using Pearson's *r*, a score of 0.70 being recommended for instruments that measure the same construct. When similar constructs are compared, scores lower than 0.70 are acceptable (23).

Results

The study included of 78 subjects (25 male and 53 female) with mean age (± SD) of 45.4 ± 12.2 years. The baseline characteristics of the study participants are shown in Table I.

Ninety-one patients completed the questionnaires only at baseline, and 13 subjects dropped out (14.3%). With eight subjects, that was due to a misunderstanding of the way two clinics were meant to undertake the final PSFS measurement with three new expressions of discomfort. Five subjects did not complete the questionnaires at the final measurement at all or they had forgotten to complete all the questionnaires. The results of the Total scores of PSFS, RMDQ and VAS at baseline and final measure are shown in Table II.

A test of normality showed the data was normally distributed and therefore the Pearson's *r* was used.

Table I. Characteristics of study participants at baseline ($n = 78$).

Variable at baseline	
Gender: Female (%)	53 (67.9)
Age (years)	45.4 (12.2)
Symptom onset: 1–14 days (%)	9 (11.5)
Symptom onset: 2 weeks–3 months (%)	29 (37.2)
Symptom onset: over 3 months (%)	40 (51.3)
Medication: none (%)	22 (38.5)
Medication: pain med. (%)	31 (28.2)
Medication: other (%)	26 (33.3)
Weight (kg)	75.6 (15.8)
Height (m)	171.9 (9.0)
Physical activity: very active (%)	7 (9.0)
Physical activity: moderate (%)	55 (70.8)
Physical activity: low (%)	16 (20.5)
PSFS (0–30)	14.1 (6.2)
RMDQ (0–24)	7.5 (4.6)
VAS (0–100)	46.3 (22.0)

Continuous data are mean (SD), categorical data are *n* (%). PSFS, Patient-Specific Functional Scale; RMDQ, Roland–Morris Disability Questionnaire; VAS, visual analogue scale.

Table II. Total scores of Patient-Specific Functional Scale (PSFS), Roland–Morris Disability Questionnaire (RMDQ) and visual analogue scale (VAS) at baseline and final measure ($n = 78$).

Variable	At baseline	At final measure
PSFS (0–30)	14.1 (6.2)	20.4 (6.7)
RMDQ (0–24)	7.5 (4.6)	4.1 (4.4)
VAS (0–100)	46.3 (22.0)	25.4 (22.0)

Content validity: correlations of the scores between baseline measures of PSFS and RMDQ were 0.65 (Pearson's *r*) ($p < 0.01$).

To test responsiveness, the change of the PSFS, RMDQ and VAS scores at baseline and after the last treatment were used. Correlations of the change scores between baseline and final measures of PSFS and RMDQ were 0.63 (Pearson's *r*) ($p < 0.01$). A scatterplot of these changes is shown in Figure 1. Correlations of the change scores between baseline and final measures of PSFS and VAS were 0.59 (Pearson's *r*) ($p < 0.01$). A scatterplot of these changes is shown in Figure 2.

Discussion

The aim of the study was to translate and validate a Finnish version of the PSFS questionnaire, by testing its content validity and responsiveness, and to conduct a cross-cultural adaptation of the measure. Overall, the results indicate good content validity and responsiveness of the Finnish version of the PSFS and there were no significant problems involved during the cross-cultural adaptation process. The content validity was analysed by correlating the baseline scores of PSFS and RMDQ. Satisfactory correlations among the measures between the baseline scores of

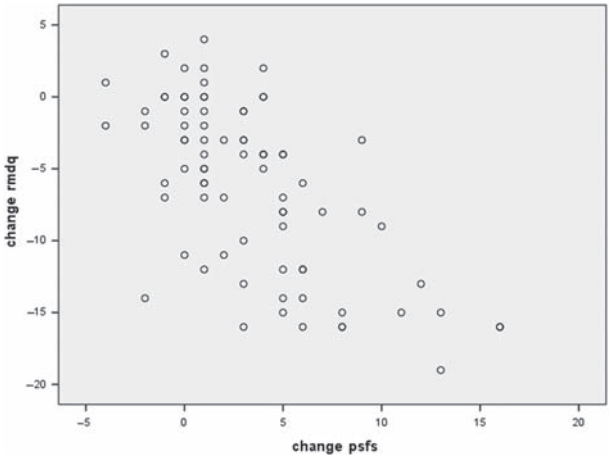

Figure 1. Change scores of Patient-Specific Functional Scale (PSFS; *x*-axis) and Roland–Morris Disability Questionnaire (RMDQ; *y*-axis).

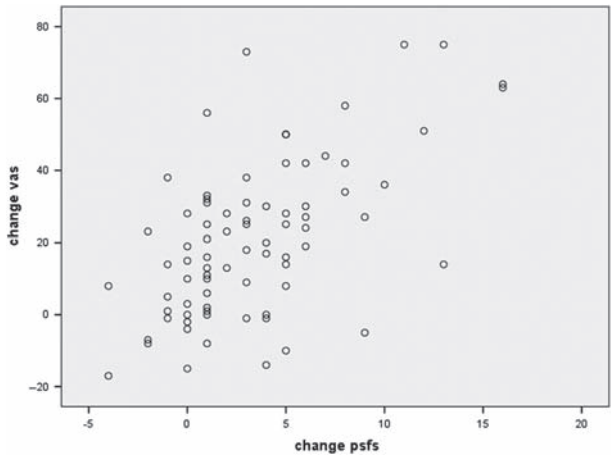

Figure 2. Change scores of Patient-Specific Functional Scale (PSFS; *x*-axis) and visual analogue scale (VAS; *y*-axis).

PSFS and RMDQ were observed with Pearson's $r = 0.63$. With LBP patients, similar results have been shown in earlier studies both in English (varying from 0.55 to 0.74) and Brazilian-Portuguese (0.51) versions of PSFS and RMDQ (2,6).

The responsiveness analysis was done by correlating the change scores of PSFS, RMDQ and VAS. The results of this study implicate that both the PSFS and RMDQ change scores and PSFS and VAS change scores have a good correlation (0.63 and 0.59, respectively). In an earlier study of the clinimetric properties, the PSFS has been shown to have a higher external responsiveness than the FRI and the RMDQ when analysed with effect sizes (6). The Brazilian research group analysed internal responsiveness with calculating the area under the curve from the receiver operating characteristics curves and concluded that the FRI and the RMDQ are less useful than the PSFS in measuring small improvements in a patient's condition.

Terwee et al. (24) suggested that at least 50 patients should be necessary to analyse the relevant clinimetric properties: internal consistency (by Cronbach's alpha), reproducibility, construct validity, ceiling and floor effects, and responsiveness. The 91 patients of this study at the baseline measurements and the 78 patients at the follow-up are enough to assess the reliability of the Finnish version of PSFS. The high drop-out rate was due to a misunderstanding of the way the two clinics were meant to undertake the final PSFS measurement with three new expressions of discomfort. Those questionnaires had to be excluded and this is one weakness of this study.

This study lacks a reproducibility analyses. The test–retest analyses of the PSFS should have been within the study design. It was in fact done by the research group, but the interval between the two

measurements was too short, 15 min, to obtain reliable answers from the subjects. In the study of the Brazilian-Portuguese version of the PSFS, the interval time was 24 h and the results showed a good reproducibility evidenced by ICC (2,1) values higher than 0.80 (6).

When integrated in the International Classification of Functioning, Disability and Health (ICF) category, the PSFS measures numerically the participation level of the patient. The PSFS indicates the unique to each patient change in disability at subsequent reassessment. Further studies are needed to understand better the use and clinical implications of the PSFS.

Conclusion

The Finnish translation of the PSFS questionnaire performs as the original, is proven to have adequate content validity and responsiveness, and could be recommended as the assessment tool for clinical and research use.

Declaration of interest The authors report no conflicts of interest.

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