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Development and testing of a new instrument for measuring quality of life in osteoporosis after a non-vertebral fracture: The Quality of Life Osteoporosis Scale—Non-vertebral Fractures (QoLOS-NVFX)

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Conflict of Interest

Emanuela Basilici Zannetti, Daniela D'angelo, Noemi Cittadini, Monica Celi, Annalisa Pennini, Gennaro Rocco, Ercole Vellone, Rosaria Alvaro, Umberto Tarantino declare that they have no conflict of interest.

Development and testing of a new instrument for measuring quality of life in osteoporosis after a non-vertebral fracture: The Quality of Life Osteoporosis Scale—Non-vertebral Fractures (QoLOS-NVFX)

Abstract

Purpose The aim of this study was developing and testing a new tool for measuring quality of life (QoL) in patients with osteoporosis who had experienced non-vertebral fractures (NVFX).

Methods Two main phases were carried out. Firstly, the tool was developed based on expert opinions through three focus groups. Secondly, the tool was tested with exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) in a sample of 458 postmenopausal women. The reliability of the developed QoL Osteoporosis Scale—NVFX (QoLOS-NVFX) was measured using Cronbach's alpha (α), maximal reliability (MR), composite reliability (CR), and average variance extracted (AVE).

Results The QoLOS-NVFX resulted in a unidimensional scale with 23 items and showed good reliability, with a Cronbach's α of .94, MR of .96, CR of .96, and AVE of .70.

Conclusions The QoLOS-NVFX shows good psychometric properties and can be used to assess the impact of NVFX on QoL in osteoporotic women. Furthermore, it can be easily used in clinical practice and research.

Introduction

Osteoporosis is defined as a systematic skeletal disorder characterized by low bone mass and microarchitectural deterioration of the bone tissue, with a consequent increase in bone fragility (Lin et al., 2015). The prevalence of osteoporosis is approximately 6% in men and 21% in women aged 50–84 years. Since women have more severe bone loss and experience falls more frequently than men do, the prevalence of osteoporosis in women over the age of 50 years is 3–4 times greater than that in men. The prevalence of osteoporosis in the European Union was estimated as 27.6 million people in 2010 (Hernlund et al., 2013).

The most important consequences of osteoporosis are fragility fractures, which can be divided into vertebral fractures (VFX) and non-vertebral fractures (NVFX) (Wilson, Sharp, & Davie, 2012). Among the fragility fractures, while VFX represent only 14.85%, NVFX make up 85.15% of all fractures (*Broken Bones, Broken Lives*, n.d.). Although VFX are the main cause of morbidity and mortality, NVFX are equally important. These fractures include, most frequently, fractures of the hip, forearm and humerus (Tsuda, 2017), rib, tibia, pelvis, and femur (Pisani et al., 2016), and they have an important influence on the quality of life (QoL) of osteoporotic patients. In fact, NVFX also cause losses of physical functioning for patients and reduce their mobility and self-care. For example, half the patients who can walk before an NVFX need a mobility aid for the rest of their lives or lose their independent walking ability afterwards (Pisani et al., 2016); up to one-third of people who experience a hip fracture become totally dependent (Panula et al., 2011); the 15–20% of osteoporotic patients with femoral fracture experience a reduction in their life expectancy by 4% per year (Edelmuth, Sorio, Sprovieri, Gali, & Peron, 2018); and finally, NVFX are associated with important decreases in physical and mental QoL ("The World Health Organization Quality of Life assessment (WHOQOL): position paper from the World Health Organization.," 1995; Yilmaz, Doğu, Sahin, Sirzai, & Kuran, 2014).

Considering that all fractures affect osteoporosis patients' QoL enormously, investigators have developed several instruments for measuring QoL in this specific population. However, while several investigators have developed a number of instruments to measure QoL for VFX [11–25], far fewer have developed instruments to measure QoL in patients with NVFX. In fact, to our knowledge, only one instrument has been developed for NVFX, specifically for wrist fracture. This instrument, called the International Osteoporosis Foundation—Wrist Fracture Questionnaire (Lips et al., 2010), measures QoL considering pain, upper limb symptoms (wrist or forearm), physical function, and general health, but it cannot be used for other NVFX, such as the hip and femur, as it does not consider lower limb fractures; furthermore, it does not assess individuals' emotional states or even all the

abilities to perform specific activities of daily life (ADL). Considering this, the aim of this study was to develop and test a new tool for measuring QoL in patients with osteoporosis who had experienced an NVFX.

Methods

The QoLOS-NVFX was developed in the phases described below.

Phase I: Scale development

The item development first included a literature review to search for existing instruments measuring QoL in osteoporosis patients with fragility fractures. Afterward, three focus groups were organized with the aim of developing QoLOS-NVFX items. After the focus group meetings, the QoLOS-NVFX comprised 23 items. The responses to each IT were developed with a 3-point Likert scale format with the following options: insufficient (score 1), good (2), and excellent (3) or never (1), sometimes (2), and every day (3). With this response format, a higher score indicates better QoL. The total score of the QoLOS-NVFX ranged between 23 and 69, with higher scores meaning better QoL, as for each single IT. A list of the QoLOS-NVFX items is reported in Table 2.

Phase II: Psychometric testing

QoLOS-NVFX psychometric testing was performed in a cross-sectional multicenter validation study. The study was conducted in outpatient clinics of several healthcare institutions throughout Italy, including 1 in the north, 11 in the center, and 13 in the south. The data collection was performed between January 2013 and December 2016 in two cohorts of patients: the first cohort included 195 women enrolled in 2013 and 2014, while the second cohort included 263 women enrolled in 2015 and 2016.

The patients were recruited for the study if they met the following inclusion criteria: women in menopause, history of previous or current fracture other than vertebral fracture, willingness to participate in the study and sign the informed consent form, and ability to read and write Italian. The exclusion criteria were the presence of severe renal failure or pre-existing/ongoing neoplastic diseases and the presence of vertebral fractures. Nurses trained on the study protocol recruited the participants and administered the questionnaires. Each patient completed the self-reported questionnaire in a private room. Furthermore, women were asked to respond to the SF36 general question on their health status (Jenkinson, Coulter, & Wright, 1993).

Ethical Considerations

The study was approved by the ethics committee of the Policlinico Tor Vergata of Rome in April 2013 (Prot. No. 0008650 of 17.04.2013). All the patients voluntarily agreed to participate in this study and gave their written consent. Before collecting their written consent, all the participants were fully informed by the research assistants that they could withdraw from the study at any time without giving a reason and their data would remain confidential.

Statistical Analysis

Descriptive statistics (e.g., mean and standard deviation [SD]) were used for describing the sociodemographic and clinical characteristics of the sample. Moreover, statistics (e.g., skewness and kurtosis) were also used for describing the QoLOS-NVFX items, as well as the frequency of the IT answer categories.

The factorial structure of QoLOS-NVFX was tested with both exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). Specifically, EFA was used on the first cohort of patients (195 women enrolled in 2013 and 2014; calibration sample), while CFA was used on the second cohort of patients (women enrolled in 2015 and 2016; validation sample) (Byrne, 2012). The EFA on the calibration sample was used for studying the factorial structure of the QoLOS-NVFX. With the EFA, we identified the final factor solution by scrutinizing the scree plot of eigenvalues and evaluating the interpretability of the solution (Brown, 2015). In this regard, when the scree plot suggests a substantial plateau, no other factors should be retained in the final solution after the first evident peak. In contrast, the CFA on the validation sample was used for replicating the factor structure identified in the EFA. Since the items were ordered categorically, weighted least squares means and variance-adjusted (WLSMV) estimators were used for the model estimation, both for the EFA and CFA (Muthén, L. K., & Muthén, n.d.), with the full-information maximum likelihood (FIML) used for handling missing data (Arbuckle, 1996). EFA was implemented using the oblique geomin rotation (Muthén, L. K., & Muthén, n.d.). Both EFA and CFA were assessed by adopting a multifaceted approach for fit evaluation, using the following indices and criteria: chi-square significance (if chi-square was not significant, the model reached a perfect fit with the observed data); root mean square error of approximation (RMSEA) (Steiger, 1990): values $\leq$ .08, or better, $\leq$.05 indicate a good fit, as well as to not rejected of the null hypothesis (for p <.05) associated with its 90% confidence interval (CI) (Hu & Bentler, 1999); and comparative fit index (CFI) (Bentler, 1990) and Tucker–Lewis index (TLI) or non-normed fit index (Tucker & Lewis, 1973): values $\geq$ .95 indicate a good fit.

Convergent validity was assessed by means of polyserial correlations of the QoLOS-NVFX total scores with the overall health status question in both samples. The QoLOS-NVFX's reliability in the calibration sample was estimated with the nonlinear structural equation modeling (SEM) coefficient (NSC), a statistic for ordered categorical indicators (Green & Yang, 2009). The values for this coefficient are interpreted comparably to those of Cronbach's alpha (α) (Nunnally, J. C. and Bernstein, 1994). Since CFA in the confirmation sample was performed with IT parceling, and the NSC is not meaningful for testing reliability, the QoLOS-NVFX's reliability in the confirmation sample was computed with other estimates, as follows: Cronbach's alpha (α), maximal reliability (MR), composite reliability (CR), and average variance extracted (AVE). All these indices ranged from 0 to 1, with values closer to 1 suggesting a higher reliability of the overall scale. The analyses were carried out using SPSS 22.0 (IBM, 2013) and MPlus 7.1. (Muthén, L. K., & Muthén, n.d.).

Results

Patient characteristics and scale scores

The sample included 458 postmenopausal osteoporotic women with a mean age of 75 years (SD 58.18). Most (52.6%) had a low level of education and more than three-quarters (76.8%) were either unemployed or retired. Most of the participants had a normal weight or were slightly overweight, with a body mass index (BMI) ranging from 20 to 29.9.

The mean age of the women's menopause occurrence was 49 years and the type of fractures recorded at the time of the interview can be consulted in Table 1.

The presence of other comorbidities, such as thyroid pathologies (34.13%), diabetes (10.64%), chronic inflammatory diseases of the intestine (16.46%), celiac disease (2.03%), and rheumatoid arthritis (36.74%), was also evaluated.

Concerning lifestyle and habits, 47.37% of the sample declared that they neither smoked nor used alcohol (93.66%). Physical activity was performed by 61.57% of the patients, and most (81%) of the women spent at least 10 minutes per day outdoors on sunny days.

In terms of medication, 51.09% of the patients were being treated for osteoporosis; specifically, 74.78% took teriparatide, 22.22% took bisphosphonates, 2.13% took denosumab, and 2.99% took strontium ranelate. Of the 51.09% of the sample taking medications, 83.76% were using vitamin D and calcium supplements. All the patients' characteristics are reported in Table 1.

The QoLOS-NVFX IT analysis is reported in Table 2. All the items had a score below 2, from a minimum of 1.32 for IT 9 (lift a heavy object and carry it for at least 10 m) to a maximum of 1.87 for IT 22 (downhearted).

Psychometric validation

Figure 1 shows the scree plot of the eigenvalues resulting from the EFA, suggesting the extraction of a single dimension. As can be observed in Table 3, all the factor loadings were high, ranging from .80 (IT 23) to .99 (IT 12). The fit indices of this model were satisfactory [$\chi^2_{(df = 230,\ N = 195)} = 552.551$, $p < .001$, RMSEA = .085 (90% CI .076–.094), CFI = .991, TLI = .990]. The overall NSC for this model was .98, suggesting high reliability.

The single-factor model resulting from the EFA was replicated on the calibration sample with the CFA, yielding a satisfactory overall fit for the fit indices, with the exception of RMSEA, which was > .08, and a test of close fit that was statistically significant [$\chi^2_{(df = 230,\ N = 263)} = 905.75$, $p < .001$, RMSEA = .106 (90% CI .076–.094), CFI = .953, TLI = .949]. Relying on these considerations, we created six parcels by generating five composites of four items and one composite of three items, balancing them for the total corrected item–total correlations (Little, Rhemtulla, Gibson, & Schoemann, 2013). The new CFA posited the same single latent dimension as above with the six parcels as observed indicators. Since the skewness and kurtosis of the parcels were not problematic (Tabachnick, B.G. & Fidell, 2013), this model was tested with maximum likelihood (ML) estimators (Muthén, L. K., & Muthén, n.d.) that fitted with the data very well [$\chi^2_{(df = 9,\ N = 263)} = 11.78$, $p < .001$, RMSEA = .034 (90% CI .00–.082), CFI = .998, TLI = .997]. A diagrammatic representation of this model is depicted in Figure 2, along with completely standardized estimates of factor loadings and residual variances. The reliability of the confirmation sample resulted in the following indices: Cronbach's $\alpha = .94$, MR = .96, CR = .96, AVE = .70.

Finally, the overall total score of the QoLOS-NVFX was correlated in both samples with the general health status indicator illustrated in previous sections. Since the total QoLOS-NVFX score was continuous and the general health status indicator had three ordered categories for the answer format, polyserial correlations were used. In both cases, this correlation was high (validation sample: $r = .88$, $p < .001$; calibration sample: $r = .78$, $p < .001$), supporting the convergent validity of the QoLOS-NVFX.

Discussion

The present study was performed for developing and testing the psychometric properties of a new self-reported scale to measure QoL among postmenopausal osteoporotic women who had experienced fragility fractures other than vertebral ones, namely the Quality of Life Osteoporosis Scale—Non-vertebral Fractures (QoLOS-NVFX). The focal point of the QoLOS-NVFX is its unidimensional measure of ADL, with high reliability and high validity for assessing QoL in this specific population. The construct validity of the QoLOS-NVFX was supported with EFA and CFA;

the EFA strongly indicated that one single factor was satisfactory for explaining most of the variance of the data, and this was supported by the CFA and other fit indices. After this first deep understanding of the nature and dimensionality of the scale, for a better fitting solution and to minimize potential pitfalls, the parceling technique was employed. Specifically, six parcels were created that included five composites of four items and one composite of three items with good factor loadings ranging from .922 to .895 (Figure 2).

The derived unidimensionality of the QoLOS-NVFX seems to be in contrast with other QoL tools that outline the multidimensionality of the construct (de la Loge et al., 2005; Marquis et al., 2001). It is known that items on a scale are the manifestations of latent variables, and the differences observed in the answers are considered to represent the differences on the latent construct. Given that the items on the scale derive from the construct intended to be measured, the unidimensionality of QoLOS-NVFX is probably related to its tailored items, which were specifically developed to be used by a well-defined population. Furthermore, the QoLOS-NVFX has demonstrated good psychometric criteria for reliability, as patients with osteoporosis without VFX were asked about their ability to perform their ADL.

The QoLOS-NVFX score ranged from 23 to 69, with a mean of 35.66. Especially, most patients answered "insufficient" for items IT 1, IT 2, IT 5, IT 7, IT 8, IT 9, IT 14, IT 16, IT 17, and IT18; "good" for items IT 3, IT 4, IT 6, IT 15, IT 19, and IT 20; and "sometimes" for items IT 21, IT 22, and IT 23. Responses of "excellent" or "never" were provided by an extremely small percentage of women compared with the three types of answers stated above probably due to the recent fracture.

The women's general state of health exhibited an average of 1.5, maintaining the majority values attributed to QoLOS-NVFX, which tended to be "insufficient" for most of the items. In addition, the responses given to the single items on the scale were compared with the type of fracture suffered by the women, and it was seen that those who had suffered fractures in the upper limbs had better QoLs than those who had suffered fractures of the lower limbs, which was presumably more disabling. To our knowledge, no previous studies have developed a specific instrument for measuring QoL in postmenopausal osteoporotic women who suffer from minor fractures.

Limitations

Our study had several limitations. First, the content validity of the QoLOS-NVFX was established in a specific population, consisting of postmenopausal women enrolled in outpatient clinics of various health institutions in Italy, with a history of at least one previous fracture other than a vertebral one and no presence of severe renal failure or pre-existing/ongoing neoplastic diseases.

Therefore, validity may not necessarily be assumed for all patients. Nevertheless, the strength of our study was that we validated our tool in the population in which the instrument was to be used and further validation study in other osteoporosis populations, such as men or women that are not in postmenopause, would be required to confirm the strong psychometric properties of this scale.

Second, we considered only the answers given to the questions at T0, and given that the study had a longer effective duration of 6 months, it would be interesting to investigate how the QoL changed over time by measuring the same item at various follow-up visits. Then, we would be able to deduce whether it is normal to have a QoL at T0 that reaches the worst level directly after the traumatic event.

Thirdly, we used a 3-point Likert scale that may have increased the possibility of losing some valuable information. Therefore, it would be appropriate to conduct a study that takes into account responses on a 5-point Likert scale to better discriminate the concept and to enhance the accuracy of participants' responses.

Conclusion

In summary, the tool developed in this study was found to be a potentially useful measure that is reliable and valid for evaluating QoL in postmenopausal osteoporotic women after fragility fractures other than VFX to help patients and clinicians in clinical practice. The construct validity was supported with adequate EFA and CFA results, while the model fit and reliability were supported by the four NSC indices. To enable the QoLOS-NVFX to be used worldwide, further studies should be carried out to validate other versions of the instrument.

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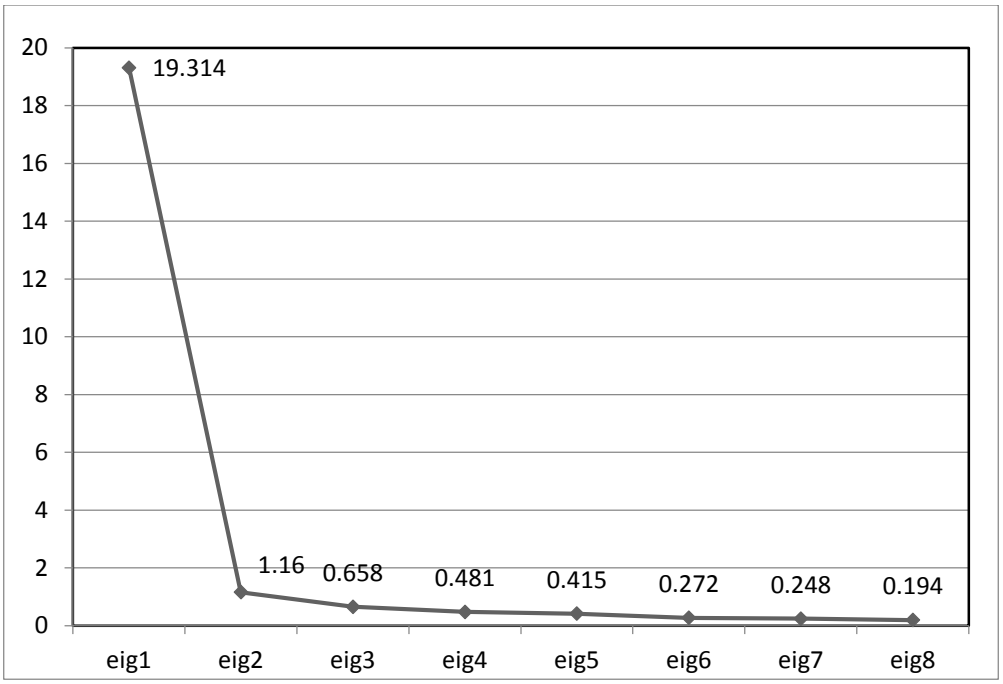

Figure 1. Scree plot of eigenvalues for the calibration (EFA) sample.

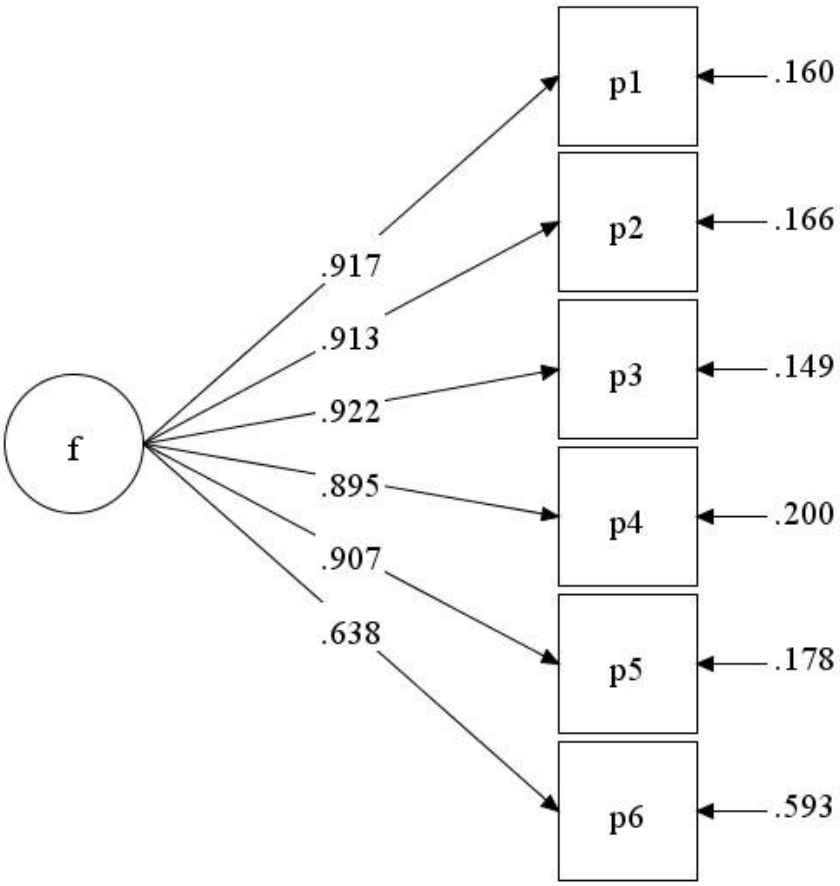

Figure 2. Estimates of the CFA model fitted with parcels on the validation sample. F = Latent variable; P1–P6 = Parcels. Factor loadings and residual variances are presented in a completely standardized solution.

Table 1. Characteristics of the Sample (*N* = 458)

AGE (mean, SD)	75 (10.12)		
		N	%
EDUCATION	None	87	18.55
	Elementary school	154	34.06
	Junior high school	123	27.07
	High school	79	18.77
	Degree	7	1.55
EMPLOYMENT	Employed	92	20.09
	Unemployed	352	76.85
	Other	14	3.06
BMI	Underweight	46	10.05
	Normal weight	194	42.35
	Overweight/Pre-obesity	152	33.19
	Class I Obesity	49	10.69
	Class II Obesity	14	3.06
	Class III Obesity	3	0.66
Menopause occurrence (mean, SD)	48.56 (5.00)		
Menopause type	Spontaneous	391	85.37
	Induced	67	14.63
FRACTURE	Previous fracture	148	32.31
	Arm/shoulder	69	46.63
	Femur	26	17.56
	Leg/foot	20	13.52
	Other	33	22.29
	Current fracture	329	71.83
	Arm/shoulder	77	23.42
	Femur	193	58.66
	Leg/foot	48	14.58
	Other	11	3.34
	Current fracture with previous experience	172	48.45
	Trivial trauma	285	80.28
LIFESTYLE	Smoking	217	47.37
	Alcohol	429	93.66
	Physical activity	282	61.57
	Outdoors during sunny day	371	81
COMORBIDITY	Thyroid diseases	170	34.13
	Diabetes	53	10.64
	Chronic inflammatory diseases of the intestine	82	16.46
	Celiac disease	10	2.03
	Rheumatoid arthritis	183	36.74
PHARMACOTHERAPY	Medication use	234	51.09
	Type of medication		
	Teriparatide	175	74.78
	Bisphosphonate	52	22.22
	Denosumab	5	2.13
	Strontium ranelate	7	2.99
	Vitamin D	196	83.76
	Calcium	196	83.76

Table 2. Item Descriptive Analysis of the QoLOS-NVFX (*N* = 458)

How do you currently evaluate your ability to ...?	Mean (SD)	Excellent %	Good %	Insufficient %
IT 1. Dress	1.59 (0.61)	7.01	45.95	47.04
IT 2. Take a bath or shower	1.52 (0.56)	3.72	44.85	51.43
IT 3. Sit down and using the toilet	1.62 (0.57)	4.82	52.95	42.23
IT 4. Rest at night	1.65 (0.57)	5.25	54.92	39.83
IT 5. Clean the house	1.39 (0.57)	1.98	35.24	62.78
IT 6. Prepare meals	1.56 (0.52)	3.09	50.01	46.90
IT 7. Do shopping	1.42 (0.55)	2.66	37.03	60.31
IT 8. Wash dishes	1.51 (0.55)	3.32	44.92	51.76
IT 9. Lift a heavy object and carry it for at least 10 m	1.32 (0.56)	2.21	27.87	69.92
IT 10. Stand up from a chair	1.52 (0.51)	4.82	42.67	52.51
IT 11. Bend at the trunk	1.39 (0.58)	2.86	34.21	62.93
IT 12. Kneel	1.36 (0.54)	2.42	32.09	65.49
IT 13. Climb a staircase	1.51 (0.53)	3.08	44.94	51.98
IT 14. Walk 100 m	1.54 (0.55)	4.01	46.44	49.55
IT 15. Go outside the house during the week	1.60 (0.57)	4.03	52.34	43.63
IT 16. Use public transport	1.47 (0.56)	2.51	42.72	54.77
IT 17. Garden, look after an animal, etc	1.48 (0.54)	2.74	43.24	54.02
IT 18. Perform any hobby	1.51 (0.55)	2.72	45.92	51.36
IT 19. Visit a cinema, theatre	1.54 (0.55)	2.29	50.01	47.70
IT 20. Visit friends or relatives	1.60 (0.54)	3.38	53.95	42.67
Do you have a tendency to feel …?		Never %	Sometimes%	Every day %
IT 21. Tired	1.64 (0.54)	6.69	50.67	42.64
IT 22. Downhearted	1.87 (0.55)	11.34	64.54	24.12
IT 23. Lonely	1.86 (0.60)	10.86	64.02	25.12

Table 3. Factor Loadings of the EFA conducted on the Calibration Sample (n = 195)

Items	Factor Loadings
IT 1. Dressing	.89
IT 2. Taking a bath or shower	.94
IT 3. Sitting down and using the toilet	.90
IT 4. Resting at night	.85
IT 5. Cleaning the house	.96
IT 6. Preparing meals	.97
IT 7. Doing shopping	.95
IT 8. Washing dishes	.93
IT 9. Lifting a heavy object and carrying it for at least 10 m	.94
IT 10. Standing up from a chair	.92
IT 11. Bending at the trunk	.94
IT 12. Kneeling	.99
IT 13. Climbing a staircase	.94
IT 14. Walking 100 m	.96
IT 15. Going outside the house during the week	.91
IT 16. Using public transport	.98
IT 17. Gardening, looking after an animal, etc	.97
IT 18. Performing any hobby	.96
IT 19. Visiting a cinema, theatre	.97
IT 20. Visiting friends or relatives	.94
IT 21. Tendency to feel tired	.85
IT 22. Tendency to feel downhearted	.82
IT 23. Tendency to feel lonely	.80