

# The culturally adapted Italian version of the Barthel Index (IcaBI): assessment of structural validity, inter-rater reliability and responsiveness to clinically relevant improvements in patients admitted to inpatient rehabilitation centers

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## Summary

The Barthel Index (BI) is widely used to determine eligibility criteria for inpatient rehabilitation and to monitor patients' recovery, irrespective of the illnesses that affect them. The culturally adapted Italian version of the Barthel Index (IcaBI) was recently validated. This paper reports the structural validity and inter-rater reliability of the IcaBI and its responsiveness to the results of inpatient rehabilitation.

The IcaBI was administered to a cohort of 264 patients hospitalized in two rehabilitation centers in Rome, Italy. Factor analysis using principal component analysis revealed a monofactorial structure for neurological patients and, after removal of item 1 “feeding”, also for orthopedic patients. Substantial to optimal inter-rater reliability was found (0.74 > intraclass correlation coefficient < 0.96). The IcaBI was found to be accurate (area under the curve = 0.72) with a minimal clinically important change score of 35 points.

This work confirms that IcaBI is a useful tool for measuring disability in health and social care settings along the continuum of care. Further studies are needed to assess its criterion validity, interpretability and responsiveness in other specific disease conditions.

**KEY WORDS:** activities of daily, living classification, Barthel Index, movement disorders, outcome assessment (health care), patient care management, rehabilitation.

## Introduction

Independence in self-care activities is a common outcome measure used in the assessment of disability. The Barthel Index (BI) is one of the most widely used measures of self-care performances, mainly for its high sensitivity, simplicity, communicability and ease of scoring (Granger et al., 1979; Wade et al., 1983; Sha et al., 1992; Bentur et al., 1993; Campbell et al., 2005). The BI was first developed by Mahoney and Barthel (1965), and later modified by Collin et al. (1988) and Shah et al. (1989). The original 10-item form of the BI consists of 10 common activities of daily living (ADL): “feeding”, “bathing”, “grooming”, “dressing”, “bowel” and “bladder control”, “toilet use”, “transfers (bed to chair and back)”, “mobility” and “stair climbing”. Items are rated in terms of whether patients can perform the activities independently, with assistance or are totally dependent (scored as 10, 5 or 0 respectively, or from 15 to 0 for transfers and mobility). It is usually administered by clinicians at the bedside, but telephone assessment has shown good reliability when compared with face-to-face assessment (Della Pietra et al., 2011). The total score is calculated by adding up the individual item scores, and it ranges from 0 (total dependence) to 100 (total independence). There is little consensus over which of the versions should be considered definitive, but the original 10-item version is the most commonly used (Wade et al., 1988). The BI has been translated and validated in Turkish (Küçükdeveci et al., 2000), German (Heuschmann et al., 2005), Persian (Oveisgharan et al., 2006), Chinese (Leung et al., 2007), Brazilian (Cincura et al., 2009), Dutch (Post et al., 1995) and Japanese (Ohura et al., 2014). It has also recently been translated into Italian and culturally adapted to Italian people (Galeoto et al., 2015).

Disability at the time of admission to a rehabilitation hospital is a major predictor of disability, both at discharge (Ween et al., 1996; Inouye et al., 2000; Stein et al., 2015) and following the patient's return home. It has been estimated that more than 3 million people in Italy were affected by functional impairment in 2011 (ISTAT, 2012). Given the burden that this represents, it is of great importance to apply evidence-based, validated and comprehensive instruments able to quantify disabili-

ity and document whether patients fulfill the criteria to access rehabilitation. As rehabilitation became integrated into the processes of care delivered to disabled people in Italy, the need for objective measures of both disability and recovery was met by developing many different versions of the BI but, until now, none of them was submitted to a cross-cultural adaptation process (Galeoto et al., 2015). Even though the BI has been found to reveal structural differences in the assessment of disability between stroke patients and chronic or orthopedic patients (Laake et al., 1995), in Italy it is widely used to determine whether the eligibility criteria for inpatient rehabilitation are satisfied, irrespective of the illness affecting a patient, as well as to monitor recovery, even though the responsiveness of the scale has not yet been evaluated.

The development of the Italian culturally adapted Barthel Index (IcaBI), i.e. the translation process, cultural adaptation and assessment of its cross-cultural validity, internal consistency, test-retest and intra-rater reliability, is reported elsewhere (Galeoto et al., 2015). The present paper instead reports the instrument's structural validity, inter-rater reliability and responsiveness in patients hospitalized for rehabilitation care according to consensus-based standards for the selection of health measurement instruments (COSMIN) (Mokkink et al., 2010 a,b).

## Materials and methods

### Patients and procedures

The IcaBI was administered to a cohort of patients who were hospitalized in two different rehabilitation centers, in Rome, Italy, providing care for patients with internal, neurological and orthopedic disorders. All the cases admitted, between May 2014 and March 2015, to the inpatient rehabilitation centers of the Israelite Hospital and the San Giovanni Battista Hospital, run by the Order of Malta, were screened for inclusion in the study, irrespective of their particular illness. All patients were informed about the study and their interest in taking part in it was recorded; those who took part in the study gave their informed consent before inclusion (Galeoto et al., 2015, 2016). The study was approved by the ethics committees of the participating hospitals. Post-comatose patients were excluded, as were cases aged <18 years, those affected by spinal cord injuries, cognitive impairment or psychiatric illnesses, and those who did not consent to enter the study. Eleven physical therapists and one occupational therapist working in the rehabilitation units of each hospital participated voluntarily in the study. Assessments were made by observing patients' performances directly at the bedside. The therapists were trained in administration of the IcaBI by the first author of this paper. As each of the participating therapists had his/her own clinical load, the matching between the patients and the raters was done by a convenience method, but the number of assessments conducted was nevertheless evenly distributed among the raters. Structural validity, inter-rater reliability and responsiveness were calculated according to the COSMIN criteria (Mokkink et al. 2010a). Statistical analyses were performed using the IBM Statistical Package for the Social Sciences (SPSS) version 20.0 for Windows,

carrying out descriptive analysis, factor analysis and calculation of intraclass correlation coefficient (ICC) values, and NCSS 11 software, performing receiver operating characteristic (ROC) curve and minimal clinically important change (MCIC) analysis. The variables were described using frequency tables, means and standard deviations.

### Structural validity

Structural validity was established using Hotelling's T-square and exploratory factor analysis; principal component analysis with quartimax rotation and Kaiser's normalization (PCA) was performed to identify parallelism and the latent factors underlying the 10 IcaBI items (Leung et al., 2007). Item analysis was also conducted to obtain the item difficulty and discrimination indices. The item difficulty index is the ratio between the average scores obtained for each item and the maximum score obtainable in each item. The item discrimination index is represented by the item-to-total Pearson's product moment correlation coefficient, for which coefficients greater than 0.28 are considered as having satisfactory discrimination property (Nunnally, 1994). Cronbach's  $\alpha$  coefficient was calculated, with a value of >0.70 being considered acceptable for the test (Mokkink et al., 2010a).

### Inter-rater reliability

A sample size of 50 subjects was considered sufficient to estimate inter-rater reliability (Mokkink et al., 2010b). Patients were consecutively recruited from the San Giovanni Battista Hospital. The scale was administered, independently, by three physical therapists and one occupational therapist during the same day. Inter-rater reliability was estimated using two-way random ICC for absolute agreement ( $p < 0.05$ ) (Hallgren, 2012). The ICC value ranges from 0.00 to 1.00, with higher values reflecting higher reliability. An ICC value >0.60 reflects good agreement, and a value >0.75 excellent agreement. In this study, good to excellent reliability for IcaBI was hypothesized.

### Responsiveness

Responsiveness in this study was defined as the ability of the IcaBI to detect clinically relevant changes over time (Mokkink et al., 2010a). A sample size larger than 50 subjects was chosen to estimate it (Mokkink et al., 2010b). Patients from the San Giovanni Battista Hospital were included randomly. In accordance with other Authors (Rollnik, 2011), the scale was administered at the beginning of hospitalization and at discharge. Sensitivity and specificity for change were plotted by ROC curve, and areas under the curves (AUCs) were calculated. The AUC corresponds to the probability of correctly discriminating between improved and non-improved patients. When the AUC was more than 0.70, responsiveness was considered sufficient (Mokkink et al., 2010a). In order to assess the MCIC, criteria are needed to identify whether patients have significantly changed over time. The objective of this study was to differentiate between improved and non-improved patients. We chose a score higher than 75 as anchor, i.e. the reference value for deciding access to inpatient or outpatient rehabilitation services in the Italian region of Lazio. The criteria for accessing rehabilitation in Lazio

stipulate that subjects with a BI score greater than 75 cannot access rehabilitation units as they are not considered disabled. On this basis, subjects with an IcaBI score >75 at discharge were considered improved and compared to those with a score <75, who were considered non-improved. MCIC was determined by the optimal cut-off point (OCP). This is the point on the ROC curve where the sum of sensitivity and 1-specificity is maximal (Mokkink et al., 2010b).

## Results

### Structural validity

Structural validity was tested on a cohort of 264 hospitalized patients, 148 from the Israelite Hospital in Rome and 116 from San Giovanni Battista Hospital. They had a mean age of 73.84±13.3 years (range 21-101). 148 subjects were females and 116 males (Table I). The interval from hospitalization to the first survey was 8.9±11.3 days (range 0–66). The total scores were not influenced by age ( $\chi^2=21.825$   $p=0.350$ ), gender ( $\chi^2=75.856$   $p=0.081$ ) or pathology ( $\chi^2=113.079$   $p=0.175$ ). One hundred and fifteen subjects (43.6%) were affected by internal diseases (65 cardiorespiratory disorders, 17 metabolic disorders, 25 oncological diseases, 8 urological diseases), 83 (31.4%) by neurological diseases [43 Parkinson's disease (PD), 16 stroke], and 66 (25%) by orthopedic pathologies (43 hip or femur surgery, 10 knee surgery, 13 vertebral problems without neurological sequelae). Cronbach's  $\alpha$  was 0.94 ( $p<0.001$ ). On excluding item 1, Cronbach's  $\alpha$  increased ( $\alpha=0.95$ ). No missing items were found. The items were not parallel (Hotelling's T-square = 2490.000  $F=268.251$   $p=0.000$ ). Factor analysis using PCA for extracting the latent factors revealed a monofactorial structure, which explained 70.78% of the total variance. The Kaiser-Meier-Olkin measure was 0.938, suggesting sample ad-

equacy, and Bartlett's test for sphericity was significant at  $p<0.000$ . Even though the scale revealed a monofactorial structure, there was a less than satisfactory fit between the IcaBI and the unidimensional model, as tested with Rasch analysis (De Morton et al., 2008), therefore item analysis was conducted according to classic theory (Nunnally, 1994). Subgroup factor analysis was performed in order to identify structural differences between evaluation of neurological patients and orthopedic ones. The model expressed a monofactorial structure for neurological patients, which explained 69.66% of the total variance. A two-factor structure was found for orthopedic patients, explaining 68.1% of the total variance: the first component explained 58.77% of the total variance, the second component explained 9.31%. Nine items were grouped under factor 1, their content being more related to self-care and motor functioning. Item 1, "feeding", was classed under factor 2, its content being more related to patients' physiological needs. On excluding item 1 "feeding", factor analysis revealed a monofactorial structure, which explained 60% of the total variance (Table II). The results of the item-item analyses (Table III) revealed, for the 10 items, difficulty indices ranging between 0.37 and 0.83. The most difficult was item number 10 "steps" (0.37), while the easiest was "grooming" (0.83). The discrimination indices of the IcaBI items ranged from 0.57 to 0.88. The most discriminative were "transfers" (item n.8) and "mobility" (item n. 9) ( $r=0.88$ ), whilst the least discriminative one was "grooming" (item n.1) ( $r=0.57$ ).

### Inter-rater reliability

Fifty-one patients were submitted to inter-rater reliability assessment procedures (mean age 73.79±9.9 years, 24 males, 27 females). Twenty-two of them were affected by orthopedic diseases, and 26 by stroke or PD. The scale was independently and simultaneously administered by three physical therapists and one occupational

Table I - Sample characteristics.

Pathology	N° of subjects	Age (mean ± SD)	Sex	Time from admission to first administration in days (mean ± SD)
Total sample	264	73.84±13.3	F = 148 M = 116	8.9 ± 11.3
Neurological	83 (PD = 43 Stroke =16)	75.13 ± 12.02	F = 50 M = 33	
Orthopedic	12.55 ± 14.77 66 (Hip/femur surgery = 43 Knee surgery =10 Vertebral problems= 13) 11.66 ± 12.38	75.13 ± 12.02	F = 45 M = 21	
Internal diseases	115 (Cardiorespiratory = 65 Metabolic = 17 Oncological = 25 Urological = 8)	75.58 ± 15.11	F = 52 M = 63	4.75 ± 4.82

Abbreviations: PD=Parkinson's disease; SD=standard deviation; F=female; M=male

Table II – Factor loading of IcaBI items.

Original BI items	IcaBI items	Neurological patients	Orthopedic patients	Orthopedic patients after excluding item	
		Factor 1*	Factor 1*	Factor 2*	Factor 1*
Feeding	Alimentazione	0.68	0.430	0.616	
Bathing	Capacità di farsi il bagno e la doccia	0.85	0.755	-0.053	0.763
Grooming	Cura dell'aspetto esteriore	0.823	0.719	0.386	0.718
Dressing	Capacità di vestirsi	0.882	0.788	0.034	0.788
Bowels	Transito intestinale	0.812	0.700	-0.215	0.708
Bladder	Vescica	0.804	0.819	0.029	0.818
Toilet use	utilizzo del WC	0.874	0.878	-0.142	0.884
Transfers (bed to chair and back)	Trasferimenti	0.857	0.852	0.055	0.854
Mobility (on levelsurfaces)	Mobilità	0.853	0.873	0.010	0.871
Stairs	Scale	0.702	0.381	-0.650	0.375

\*Factor Analysis (principal component Analysis, with quartimax rotation and Kaiser's normalization)  
Abbreviations: BI=Barthel Index; IcaBI=culturally adapted Italian version of the Barthel Index

Table III – Item-item analysis

Original BI items	IcaBI items	Difficulty index	Discrimination index
Feeding	Alimentazione	0.83	0.57
Bathing	Capacità di farsi il bagno e la doccia	0.51	0.8
Grooming	Cura dell'aspetto esteriore	0.63	0.77
Dressing	Capacità di vestirsi	0.61	0.88
Bowels	Transito intestinale	0.7	0.79
Bladder	Vescica	0.61	0.79
Toilet use	Utilizzo del WC	0.58	0.88
Transfers (Bed to chair and back)	Trasferimenti	0.67	0.88
Mobility (on levelsurfaces)	Mobilità	0.63	0.88
Stairs	Scale	0.37	0.74
Difficulty Index = ratio of average scores for each item to maximum score obtainable in each item	Discrimination Index = the item-to-total Pearson's product moment correlation coefficient		

Abbreviations: BI=Barthel Index; IcaBI=culturally adapted Italian version of the Barthel Index

therapist. No missing items were found. ICC values revealed substantial to optimal inter-rater reliability ( $0.74 > ICC < 0.96$ ). Light's K values revealed moderate to substantial inter-rater agreement ( $0.74 > K < 0.85$ ). Table IV shows the ICC and Cohen's K values for each item.

### Responsiveness

Responsiveness was estimated on 53 subjects (mean age  $72.71 \pm 12.79$  years; 21 males, 32 females). Twenty-one patients were affected by orthopedic diseases and the other 32 by PD or stroke. The scale was administered at admission and at discharge. The mean duration of hospitalization was  $45.11 \pm 16.53$  days. The mean total scores at admission and at discharge were respectively  $43.7 \pm 22.9$  (range 5-100; median value 40) and  $80.5 \pm 21.5$  (range 25-100; median value 90). The mean change in score values between the two administrations was  $36.8 \pm 23.7$  points. No missing items were found. At discharge, 37 patients recorded a total score  $> 75$  and

were considered functionally improved, 16 were considered non-improved. IcaBI was found to be able to discriminate between improved and non-improved patients according to criteria for accessing Italian in-hospital rehabilitation services (AUC= 0.72). The MCIC determined by the OCP for the ROC curve was 35 points, with a sensitivity of 0.65 and a specificity of 0.75 (Table V, Figure 1).

### Discussion

The aim of this study was to estimate the structural validity, inter-rater reliability and responsiveness of the IcaBI in two inpatient rehabilitation centers in Rome, Italy. The results have been reported according to COSMIN.

In general, IcaBI was found to have good structural validity and internal consistency, comparable with those of

the original version. It showed good to excellent inter-rater reliability too, and acceptable responsiveness according to the ROC AUC results.

In line with what has already been reported by other Authors (Laake et al., 1995), exploratory factor analysis confirmed the unidimensional model in patients affected by stroke or PD, but not in orthopedic patients, in particular for item 1 “feeding”. After excluding this item, the scale revealed a monofactorial structure, similarly to what was found in PD and stroke patients, and the internal consistency of the scale was increased. Furthermore, the item-item analysis showed it to be the least difficult and discriminative item of the scale. This may be attributable to the clinical features of the illnesses considered. In neurological disorders, such as stroke or PD, swallowing deficits are frequent and they are among the common causes of disability (Geeganage et al., 2012).

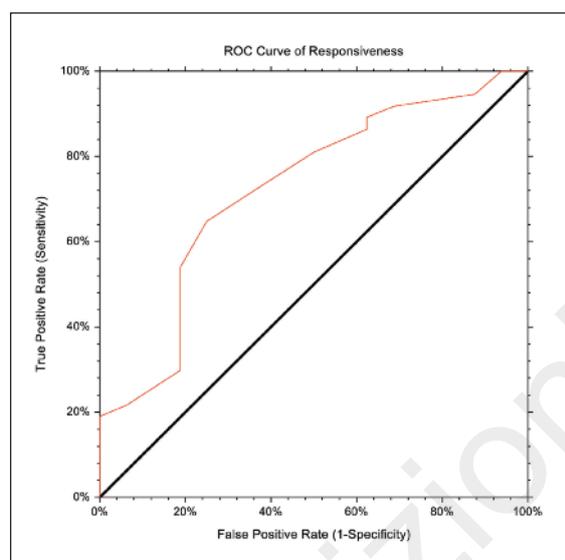


Figure 1 - ROC curve of responsiveness.

Legend: Area under the curve = 0.72

— = IcaBI ROC curve identifying improved and non-improved patients

----- = Non significance line for AUC = 0.50

By contrast, in orthopedic conditions, swallowing deficits are not so prominent, therefore item 1 is not a major cause of disability in these patients. Orthopedic patients who have no swallowing deficits and only lower limb impairments can use their upper limbs and hands for eating, so it might be useful to avoid considering the item 1 score in the calculation of total scores in orthopedic patients without involvement of the upper trunk or arms. The IcaBI was shown to be capable of detecting the proportion of the total variance in the measurement due to true differences between patients. Scores attributed to the same subject by different raters on the same occasion were found to be very similar. Two-way random ICC revealed substantial to optimal inter-rater reliability. Because the IcaBI is an ordinal scale, Light's Kappa value was also calculated, reporting similar values of inter-rater agreement. Responsiveness is defined as the ability of the IcaBI to detect clinically relevant changes over time. It was calculated through ROC curves, with the AUC indicating the probability of correctly discriminating between improved and non-improved patients. The responsiveness of the BI has previously been investigated by calculating the standard error of measurement, minimal detectable change, and minimal clinically important difference (Hsieh et al., 2007). The Authors used a distribution-based study and an anchor-based study, but they referred to a modified version of the BI with a total score of 20. In that study responsiveness was not calculated by ROC curves, as suggested by COSMIN, but by the mean change score corresponding to patients' self-ratings on a Likert scale. Other Authors (Uytenboogaart et al., 2005) investigated the optimal cut-off scores for the BI in a stroke population. They calculated sensitivity and specificity using the Modified Rankin Scale as an anchor, in order to define outcome in acute stroke patients. This study did not apply a longitudinal design and did not establish the responsiveness of the BI. To the best of the Authors' knowledge, the present study is the first to use the AUC and the optimal cut-off point to assess responsiveness and MCIC. The responsiveness analysis showed that the IcaBI was able to detect clinically significant improvements in hospital rehabilitation inpatients (AUC >0.70). An MCIC score of 35 points was found to be necessary to determine an improvement in patients' disability, with a sen-

Table IV - Inter-rater reliability.

Original BI items	IcaBI items	ICC	K
Feeding	Alimentazione	0.84	0.82
Bathing	Capacità di farsi il bagno e la doccia	0.88	0.85
Grooming	Cura dell'aspetto esteriore	0.81	0.78
Dressing	Capacità di vestirsi	0.88	0.84
Bowels	Transito intestinale	0.85	0.81
Bladder	Vescica	0.85	0.74
Toilet use	Utilizzo del WC	0.9	0.81
Transfers (Bed to chair and back)	Trasferimenti	0.86	0.77
Mobility (on levelsurfaces)	Mobilità	0.92	0.8
Stairs	Scale	0.74	0.64
Total	Totale	0.96	0.76

Abbreviations: BI=Barthel Index; IcaBI=Culturally adapted Italian version of the Barthel Index; ICC=intra-class correlation coefficient; K= Cohen's K value

Table V - Responsiveness and MCIC, sensibility and specificity.

MCIC	TPs	FPs	FNs	TNs	TPR	TNR	FNR	FPR	Sens. +
Value	A	B	C	D	(Sens.)	(Spec.)	(Miss)	(Fall-out)	Spec.
≥ -5	37	16	0	0	1	0	0	1	1
≥ 0	37	15	0	1	1	0.0625	0	0.9375	1.0625
≥ 5	35	14	2	2	0.9459	0.125	0.0541	0.875	1.0709
≥ 10	34	11	3	5	0.9189	0.3125	0.0811	0.6875	1.2314
≥ 15	33	10	4	6	0.8919	0.375	0.1081	0.625	1.2669
≥ 20	32	10	5	6	0.8649	0.375	0.1351	0.625	1.2399
≥ 25	30	8	7	8	0.8108	0.5	0.1892	0.5	1.3108
≥ 30	27	6	10	10	0.7297	0.625	0.2703	0.375	1.3547
≥ 35	24	4	13	12	0.6486	0.75	0.3514	0.25	1.3986
≥ 40	20	3	17	13	0.5405	0.8125	0.4595	0.1875	1.353
≥ 45	17	3	20	13	0.4595	0.8125	0.5405	0.1875	1.272
≥ 50	16	3	21	13	0.4324	0.8125	0.5676	0.1875	1.2449
≥ 55	13	3	24	13	0.3514	0.8125	0.6486	0.1875	1.1639
≥ 60	11	3	26	13	0.2973	0.8125	0.7027	0.1875	1.1098
≥ 65	8	1	29	15	0.2162	0.9375	0.7838	0.0625	1.1537
≥ 70	7	0	30	16	0.1892	1	0.8108	0	1.1892
≥ 75	2	0	35	16	0.0541	1	0.9459	0	1.0541
≥ 90	1	0	36	16	0.027	1	0.973	0	1.027

Abbreviations and definitions: MCIC= minimal clinically important change value; TPs=true positives; FPs=false positives; FNs=false negatives; TNs=true negatives; A= the number of true positives; B=the number of false positives; C=the number of false negatives; D=the number of true negatives; TPR=true positive rate or sensitivity:  $A / (A + C)$ ; TNR=true negative rate or specificity:  $D / (B + D)$ ; FNR=false negative rate or miss rate:  $C / (A + C)$ ; FPR=false positive rate or fall-out:  $B / (B + D)$ ; Sens. + Spec =sensitivity + specificity, i.e. the true positive rate plus the true negative rate.

sitivity of 0.65 and specificity of 0.75. According to the COSMIN statement, comparator instruments should have been assessed in the same language version as the studied scale. The IcaBI is the only validated scale measuring ADL in Italian language, therefore eligibility criteria for admission to inpatient rehabilitation centers were used to assess its responsiveness. In Italy, the BI is used to assess patients' eligibility to access these centers irrespective of their baseline conditions, so this study focused on the inpatient rehabilitation population as a whole. The responsiveness of IcaBI was calculated in a sample affected by different conditions. This approach can provide useful information on improvements in general inpatient rehabilitation populations, in order to better define the effectiveness of admission to these centers; however, it was not possible to perform a subgroup analysis, considering each condition separately, since no subgroup reached the minimum sample size of 50 subjects required by the COSMIN statement.

Further studies are needed to identify predictive outcome values and responsiveness in other pathological conditions.

In conclusion, the IcaBI, as a whole, revealed optimal internal consistency and a monofactorial structure, optimal inter-rater reliability, and the ability to detect clinically significant improvements in the status of both neurological and orthopedic patients over time. This work confirms that the IcaBI is a useful tool for measuring disability when appraising Italian speaking patients in health and social care settings along the continuum of care. Further studies are needed to assess its criterion validity, interpretability and responsiveness to other specific disease conditions.

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