

Validity and Reliability Evidence of the Functional Independence Measurement (FIM) for individuals with Neurological Disorders in Greece

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ABSTRACT

Background: The Functional Independence Measurement (FIM) is a valid and reliable instrument of examining the patients' functional independence (FI) in daily activities. The FIM reliability and validity, to date has not been established by Greek clinicians. The aim of the study therefore was to provide reliability and validity evidence of the FIM in a sample of Greek patients with neurological disorders (ND).

Methods: The sample was consisted from inpatients with stroke (N=50) and traumatic brain injury (N=24), who had been admitted to Greek hospitals and rehabilitation centers and healthy individuals (N=33) with corresponding demographic characteristics. Inpatients were evaluated by the lead researcher. Thirty inpatients were evaluated by two researchers to determine the inter-rater reliability. The FIM structural validity was determined by the differences between (i) inpatients and healthy individuals and (ii) inpatients of varying severity. The synchronic validity was determined with the WHODAS 2.0, the Sit-to-Stand-Test, the Time-Up-and-Go-Test and the 10Meter-Walking-Test. The FIM sensitivity of change in the patients' clinical condition was evaluated through the differences between admission and discharge.

Results: The results revealed sufficient evidence of validity (synchronic & structural), reliability (inter-rater & intra-rater) and sensitivity (admission- discharge) of the FIM in Greece.

Conclusion: The FIM may be used in the future for ND inpatients assessment in Greece.

Keywords

FIM, Functional independence, Neurological disorders, Reliability, Validity.

Clinical messages

- Sufficient evidence of validity, reliability and sensitivity of the FIM in Greece
- FIM may be used in the future for ND inpatients assessment in Greece

Introduction

Neurological disorders (ND) refer to central and peripheral nervous

system diseases, causing almost 5 million deaths in low and middle income countries each year [1]. The WHO classified the NDs into categories of neuropsychiatric etiology and other causes such as infections and injuries [2]. Examples of neuropsychiatric etiology incorporate epilepsy, Alzheimer's disease and other types of dementia, Parkinson's disease, multiple sclerosis and migraine. Other NDs, apart from neuropsychiatric etiology, incorporate vascular stroke (acute or chronic), polio, tetanus, meningitis, Japanese encephalitis, syphilis, pertussis, malaria, Hansen disease, diabetes mellitus, poor diet and low protein intake, iodine deficiency, etc and anything else that can damage a skull, spinal cord, or nerves [2].

Patients with ND experience several daily symptoms causing limitations in their activities of daily living (ADL) [3,4]. Changes in sensory reception, locomotion (gait speed, bizarre gait pattern and/ or asymmetrically reduced arm swing), balance or posture, recurrent falls, hypokinesia, rigidity features, trunk or hip weakness etc. are frequent earliest symptoms [4,5]. According to Maestri et al. [3], further symptoms incorporate fatigue and sleepiness in ND patients. All these symptoms presented above often lead to functional decrements and have an impact upon the patient's quality of life [3,4].

Mlinac and Feng emphasized that several functional abilities, such as eating, grooming, bathing, dressing, personal hygiene, toileting/continence and transferring/ambulating and generally the ability to engage in personal care, have to be assessed to individuals with NDs [6]. The assessment helps clinicians and experts to work effectively and enhance the patient's independence in self-care activities, improve quality of life and help to relieve caregiver burden. Our literature review suggested that several assessment measures have been reported so far in the field [6-11]. These measures mainly assess the limitations in ADL, described by the ICF [9,12]. Researchers and clinicians have promoted utilization and implementation of the ICF framework in transition research and practice [13]. Essentially, the ICF defines functioning and disability in terms of the interaction among five components: body structures/functions, activities, participation, environmental factors, and personal factors [13,14]. The ICF scope is to establish a common language and enable communication across countries, health conditions, health disciplines, experts and patients alike. It provides a coding scheme for health information systems [14,15] and, according to Madden and Bundy it offers "a conceptualization of functioning and disability that can underpin assessment and documentation in rehabilitation, with a growing body of experience to draw on for guidance" [14].

Concerning functionality measures for patients with NDs, the most frequent reported in the literature are the: a) WHO Disability Assessment Schedule 2.0 – WHODAS 2.0 [7,11,16-18] b) Functional Status Examination – FSE [19-21], c) Gross Motor Function Measure – GMFM [22-24], d) Disability Rating Scale – DRS [25-29], e) Barthel Index – BI [8,30-32] and the f) Functional Independence Measurement – FIM [9,10,33-38]. Other field measures reported are the: Time Up and Go test – TUG [39-41], Sit To Stand test – STS [39,42-46], 10 Meter Walking Test – 10MWT [47-49].

The FIM in particular is used worldwide for measuring 18 areas of independence in everyday activities [37,50]. It has been used in patients with neurological disorders [10,34-38,51-60], but also in different groups of healthy people, mainly elderly [61,62], patients with musculoskeletal injuries [54,63,64], burns [65], respiratory disorders [66]. It consists two sub-scales: a) the motor subscale (FIM - Motor) (13 areas related to self-service, clamps, transfers and movements) and b) the cognitive subscale (FIM - Cognitive) (5 areas related to communication and social cognitive functions)

[9,37,50,67]. The range of scores in each of the two areas ranges from 1 (complete dependence) to 7 (complete independence) [9,68]. The FIM has been utilized to detect changes in clinical status, the outcome of rehabilitation [9,68], and predict the functional status of patients with stroke after their departure from rehabilitation [69-73].

The literature review revealed several studies evaluating the psychometric properties of the FIM worldwide, across separate samples, including patients with NDs. Validity and reliability evidence, for example, were reported in the UK [60], Sweden (Swedish version) [53] and several USA cities such as Baltimore [64], Washington [63], Chicago [61] and Texas [65]. In addition, the instrument has been translated into other languages and has shown similar validity and reliability evidence in Iran (Persian version) [58], Canada (French version) [52], Japan (Japanese version) [57] and Turkey [55]. However, our literature revealed no studies evaluating the validity and reliability evidence of the FIM with neurologic patients in Greece.

Brosseau and Wolfson [52] found high inter-rater reliability in FIM motor items, through interview in Multiple Sclerosis patients, but questionable agreements on the social and cognitive items. The researchers reported high internal consistency and concurrent validity with the Expanded Disability Status Scale [52]. Daving et al. [53] reported high inter-rater reliability in FIM motor and cognitive-social items respectively, through interview, in stroke patients. Nevertheless, intraclass coefficients were not stable in locomotion, transfers and social – cognition. Masedo et al. found high and moderate intra-rater reliability indexes in spinal cord injury (SCI) and amputation patients alike [63]. Masedo et al however reported moderate and low convergent validity evidence in SCI and amputation patients respectively [63], through the Craig Handicap Assessment and Reporting Technique (CHART) measure. Naghdi et al. [58] reported high internal consistency of the Persian FIM (PFIM) items, excellent inter-rater and intra-rater reliability of the PFIM total score, motor and cognitive subscale, in a sample of stroke patients. The researchers stated that the FIM showed high concurrent validity, through the use of Barthel index [58]. Küçükdeveci et al. found acceptable to high internal consistency, intra-rater and inter-rater reliability of the FIM items in separate groups of patients with SCI and stroke [55]. The concurrent validity was satisfactory through the correlation of the FIM with ASIA and Brunnstrom motor scales [55]. Pollak et al. found high construct validity, in seniors and elderly groups, through differences detection between independent, assisted, and fully assisted living [61]. Intra-rater reliability was also high both in FIM motor and cognitive subscales [61].

Based on the above evidence, the present study was designed to examine the validity and reliability evidence of the FIM in a group of patients with NDs in Greece. It was anticipated that the FIM assessment would: a) differentiate patients with and without NDs, and patients who differed according to severity of ND (mild, moderate, and severe) (construct validity evidence), b)

be related to other functionality measures (WHODAS 2.0, STS, TUG, 10MWT) (concurrent validity evidence), c) differentiate scores between admission and discharge (detect clinical changes) and d) exhibit high internal consistency and test-retest reliability scores.

Materials and Methods

Participants

A total of 107 individuals were assessed for the purposes of the present study. Their mean age was 69.1 years (SD: +15.0) and they were approached through purposive sampling selection. The total sample was classified to adult ND inpatients (men and women), who were admitted for hospitalization and/ or rehabilitation in hospitals and rehabilitation centers in the Attica basin (N=74) and healthy controls, with similar age and gender (N=33). Their demographic characteristics are presented in table 1.

Table 1: Participants' demographics.

Variable	M	SD	N
GENDER			107
Male			56
Female			51
DISORDER			107
Stroke			50
TBI			24
CG			33
AGE	69.09	15	107
Stroke	71.34	10.31	50
TBI	58.42	23.56	24
CG	73.45	8.39	33
SEVERITY			74
Severe			23
Moderate			24
Mild			27

M: Mean, SD: Standard Deviation, N: Number of participants, Stroke: Patients with stroke, TBI: Patients with traumatic brain injury, CG: Control group, healthy participants.

The inpatient group consisted from individuals who met the following criteria:

a) diagnosed stroke episode or traumatic brain injury (TBI) b) assessment 2-3 days after admission to the hospital or rehabilitation center, and c) able to understand simple instructions in Greek (along with their respective relatives/ guardians). In turn, exclusion criteria incorporated: a) comorbidity with other neurological disorder as dementia, other stroke episode or TBI in the past, b) inability to follow and/ or understand simple instructions in Greek (along with their respective relatives/ guardians), and c) presence of any neurological, orthopaedic or cardiovascular disease. The participants in the control group were expected to follow simple instructions in Greek, and experience no neurologic, orthopaedic or cardiovascular diseases.

Procedures

The primary researcher contacted UDS (Uniform Data System for Medical Rehabilitation) and asked for permission to use

the FIM. The UDS requested a) the translation of the FIM scale form and FIM clinical guide (version 5.2.1.) and b) the certification of 2 raters with online examinations for adequate grading knowledge of the scale characteristics. Accordingly, the primary researcher in collaboration with an independent researcher, both graduate P.T students, studied the FIM clinical guide (version 5.2.1.) and were evaluated online by the UDS. The two researchers fulfilled successfully the UDS evaluations and they were certificated as able to use the FIM for the purposes of the present study. In an attempt to further familiarize themselves with the clinical use of the FIM, they evaluated a pilot sample of 10 patients before the study. The two researchers assessed the pilot sample separately, consulted each other afterwards, and a final 99% of agreement was obtained between them during the pilot phase.

Accordingly, the primary researcher contacted hospitals and rehabilitation centers around Attica – Athens, during November of 2018. Following a brief presentation explaining the purposes of the study, the primary researcher submitted the necessary documentation (summary, informed consent) and awaited 2 months to receive acceptance from the respective administrations. Acceptance was granted from five major hospitals and one rehabilitation center and permission was granted to visit, meet with the patients, explain the purposes of the study and administer the assessments (January & February, 2019).

During the same period (February & March 2019), the primary researcher visited several adult day care centers for senior citizens, in the wider area of Attica- Athens. The researcher explained the purposes of the study, and asked the administration office and the senior citizens for permission to visit in a predetermined date and administrate the assessments. A total of four centers responded positively, and forty individuals were enrolled to participate. However, seven individuals were absent during the predetermined visits, limiting therefore the total number of the participants in the control group to 33. The assessments were held during March and April of 2019.

The standardized forward-backward translation method described in the literature was used for the purposes of the study. Specifically, the following steps were followed to translate the FIM in the Greek language: forward translation from the source to target language; back translation from the target to the source language; review and finalization of the source and translated versions; and pre-testing of the translated version [74-77]. The translation strategy was selected based on minimal criteria developed by the Committee for Translations and Protocols International RDC/TMD Consortium Network [74], as well as by the Scientific Advisory Committee of the Medical Outcomes Trust [78].

Measuring Instruments

The measuring instruments used were the: a) FIM, b) WHODAS 2.0 (12 – item version), and the c) TUG, STS & 10MW functional tests.

Data Collection

The FIM and the WHODAS 2.0 were assessed during the morning (9-11 a.m.), through interviews mainly from the patients. Twenty patients were unable to respond and the respective data was provided through interviews with their relatives and/or the medical team. Prior to each assessment, permission was always obtained from the physician in charge. Simultaneously, the physicians reported to the primary researcher the patient's severity (mild, moderate, high) according to the ICF framework, the respected tomography scan and clinical status.

In addition, 30 patients from the total sample were assessed from the second independent researcher, to assess the inter-rater reliability of the FIM. The remaining ND patients and the controls were assessed exclusively by the primary researcher. In accordance to the FIM, the Greek WHODAS 2.0 (short 12-item version) and the functional tests were administered from the primary researcher. The assessments were repeated during the patients' discharge from the hospital or rehabilitation center for assessing the sensitivity of the FIM to detect changes of the patient's clinical status. The assessment, for each individual separate, did not exceed 30-40 minutes in total.

With respect to the functionality measures, they were conducted during morning hours (9 – 11 a.m.) through the following, step by step, order: 1) the timed walk 3 meters from and 3 meters to the sitting position (Time Up and Go test, TUG), 2) the repeated transitions from the sitting position in the standing position (Sit To Stand test, STS), 3) the timed walk at a distance of 10 meters (10 Meter Walking Test, 10MWT). The TUG and STS tests for the patients were performed in the wards of the hospitals and/ or rehabilitation center, while the 10MWT test was performed in a corridor of the respective clinic as described in previous studies [39,42,43,48,79,80]. Patients of moderate and high severity could not participate in the functional assessments, because getting out of bed was not medically indicated. Concerning the healthy population, the above tests were performed in familiar spaces and corridors of each Day Care Center for seniors. Before the assessments, the defined distance was measured with a tape measure and marks were also placed to each corridor with adhesive tape. During the TUG and STS assessments, a chair from the respective center was provided. The primary researcher notified all participants that their participation was voluntarily, they could withdraw at any time during the assessments, and was standing on their side during the assessments, mainly for encouragement and safety reasons (fall risk).

Statistical Analysis

The Statistical Package for the Social Science (SPSS 18.0) was used for the data analyses. MANOVAs were performed for examining differences between groups and confirm the construct validity hypothesis [81]. Univariate LSD post hoc analyses were performed to identify differences between patients with mild, moderate, and high severity in the FIM subscales (motor and cognitive). Respectively, the differences between patients and

non-patients in the two FIM subscales were evaluated with a MANOVA and LSD control. The Intraclass Correlation Coefficient was used to assess intra rater reliability. Pearson coefficients were used to assess inter rater reliability and concurrent validity. Significant correlation coefficients were expected between a) the assessments from the two Physiotherapists above .80 [82] and b) the FIM and the other functional measures (STS, TUG, 10MWT and WHODAS 2.0). The change of clinical status was performed with ANOVAs for repeated measures and post hoc LSD control. The alpha level of significance was set to 0.05.

Results

The results of the functional assessments (FIM, WHODAS 2.0., TUG, STS, 10MWT) are presented in Tables 2 and 3. The data met the skewness ($> \pm 2.0$) and kurtosis (± 3.2) criteria and provided the ground for parametric analysis [83,84].

Table 2: Means (M) and Standard Deviations (SD) of functional independence and functional tests in patients with stroke and traumatic brain injury (TBI) on admission and discharge from the hospital or rehabilitation center, as well as control group (CG).

VARIABLE	ADMISSION			DISCHARGE		
	M	SD	N	M	SD	N
STROKE						
FIM Motor score	32.66	23.15	50	44.20	26.24	15
FIM Cognitive score	24.94	9.09	50	28.33	10.31	15
FIM Total score	57.60	29.33	50	72.53	33.59	15
WHODAS 2.0.	46.06	9.82	50			
Time Up & Go Test	13.86	2.54	11			
Sit To Stand Test	7.91	2.51	11			
10 Meter Walking Test	10.91	1.79	11			
TBI						
FIM Motor score	24.25	14.39	24	30.33	23.18	9
FIM Cognitive score	23.54	10.92	24	27.11	8.27	9
FIM Total score	47.79	22.11	24	57.44	28.88	9
WHODAS 2.0.	48.50	9.07	24			
Time Up & Go Test	13.32	1.40	4			
Sit To Stand Test	8.25	0.96	4			
10 Meter Walking Test	9.74	0.91	4			
CG						
FIM Motor score	89.70	1.24	33			
FIM Cognitive score	34.94	0.24	33			
FIM Total score	124.64	1.30	33			
WHODAS 2.0.	13.94	2.14	33			
Time Up & Go Test (s)	9.82	1.87	33			
Sit To Stand Test (n/30s)	11.73	2.36	33			
10 Meter Walking Test (s)	7.55	1.28	33			

FIM: Functional Independence Measurement, WHODAS 2.0: World Health Organization Disability Assessment 2.0, N: Number of participants, n/30s: Trials' number / 30 seconds.

Reliability Results

The inter-rater reliability ranged from .93 to .97, while the intra rater was .99 for the motor, cognitive and total FIM score. The Cronbach alpha coefficients were .97 and .95 respectively for the motor and cognitive scores, and the overall findings are presented in Table 4.

Table 3: Means (M) and Standard Deviations (SD) of functional independence and functional tests depending on the severity of the condition of inpatients with stroke and traumatic brain injury upon admission and discharge from the hospital or rehabilitation center.

VARIABLE	ADMISSION			DISCHARGE		
	M	SD	N	M	SD	N
SEVERE						
FIM Motor score	13.39	1.31	23	13.00	.00	5
FIM Cognitive score	12.87	7.40	23	11.80	8.11	5
FIM Total score	26.26	7.92	23	24.80	8.11	5
WHODAS 2.0.	56.43	4.76	23			
Time Up & Go Test	-	-				
Sit To Stand Test	-	-				
10 Meter Walking Test	-	-				
MODERATE						
FIM Motor score	21.42	9.34	24	25.86	11.41	7
FIM Cognitive score	27.75	5.70	24	30.71	3.5	7
FIM Total score	49.17	11.12	24	56.57	12.87	7
WHODAS 2.0.	47.54	7.01	24			
Time Up & Go Test	-	-				
Sit To Stand Test	-	-				
10 Meter Walking Test	-	-				
MILD						
FIM Motor score	51.59	19.05	27	57.50	22.45	12
FIM Cognitive score	31.48	2.68	27	32.92	2.19	12
FIM Total score	83.07	19.28	27	90.42	23.83	12
WHODAS 2.0.	38.07	5.81	27			
Time Up & Go Test	13.71	2.25	15			
Sit To Stand Test	8.00	2.17	15			
10 Meter Walking Test	10.60	1.66	15			

FIM: Functional Independence Measurement, WHODAS 2.0: World Health Organization Disability Assessment 2.0, N: Number of participants.

Table 4: Reliability analyses.

VARIABLE	Interrater ICC	Cronbach A	Intrarater ICC
FIM Motor	.96	.97	.99
FIM Cognitive	.93	.95	.99
FIM Total	.97		.99

ICC = Intraclass Correlation Coefficient, FIM = Functional Independence Measurement.

Validity Results Construct Validity

Difference between groups: The differences between Stroke, TBI inpatients and the CG were examined with respect to the motor, cognitive and FIM total score. The multivariate results were significant ($\Lambda = .266$, $F = 48.342$, $p = .000$, $\eta^2 = .484$). The univariate analyses showed significant differences in the FIM motor ($F = 38.311$, $p = .000$ and $\eta^2 = .727$), in the FIM cognitive ($F = 19.334$, $p = .000$ and $\eta^2 = .271$), and in the FIM total score ($F = 110.99$, $p = .000$ and $\eta^2 = .681$) respectively. The LSD post hoc method revealed significant differences between a) the stroke group and the CG ($MD = -57.037$, $p = .000$) and b) the TBI group and the CG ($MD = -65.447$, $p = .000$ with respect

to the FIM motor. There were no significant differences between the stroke and TBI groups in the FIM motor ($MD = -8.410$, $p = .053$). With respect to the cognitive subscale, significant post hoc LSD differences were found between a) the stroke vs the CG ($MD = -10.00$, $p = .000$) and b) the TBI vs the CG ($MD = -11.40$, $p = .000$). In contrast, no significant differences were found between stroke and TBI patients ($MD = 1.40$, $p = .487$). Regarding the total FIM score, significant post hoc LSD differences were found between a) the stroke vs the CG ($MD = -67.036$, $p = .000$) and b) the TBI vs the CG ($MD = -76.85$, $p = .000$), while no significant differences were found between the stroke vs TBI inpatients ($MD = 9.808$, $p = .08$). These findings are presented graphically in Figure 1.

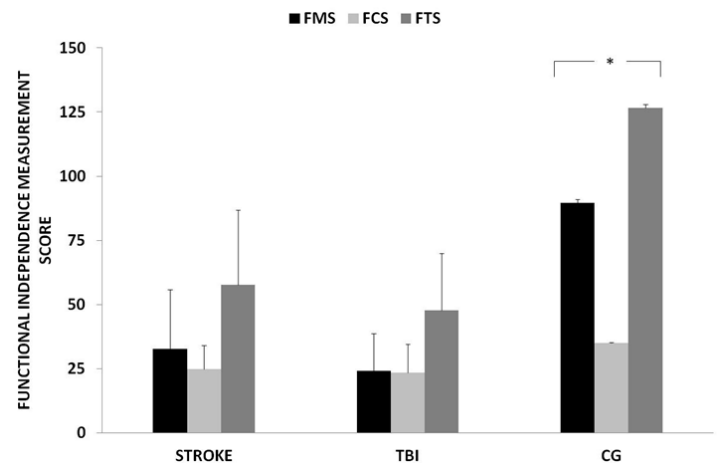


Figure 1: Means and standard deviations (error lines) of the functional independence of inpatients with stroke traumatic brain injury (TBI) and control group (CG) based on the Motor domain (FMS), the Cognitive domain (FCS) and the Total Score (FTS) of the Functional Independence Measurement (FIM) scale.

* Significant differences between CG and patients with STROKE ($p < .001$) and TBI ($p < .001$).

Differences between severity groups: Differences between the ND severity groups (mild, moderate, severe) were examined with respect to the motor subscale, cognitive subscale and the FIM total score. The multivariate results were significant ($\Lambda = .157$, $F = 53.204$, $p = .000$) and the univariate analyses showed significant differences in the FIM motor ($F = 64.037$, $p = .000$, $\eta^2 = .643$), in the FIM cognitive ($F = 77.724$, $p = .000$, $\eta^2 = .686$) and in FIM total score ($F = 104.965$, $p = .0002 = .747$). Concerning the FIM motor subscale, significant differences between the groups (severe vs moderate: $MD = -8.025$, $p = .034$), (moderate vs mild: $MD = -30.176$, $p = .000$), (severe vs mild: $MD = -38.201$, $p = .000$) were found through the LSD post hoc tests. Regarding the FIM cognitive subscale, significant differences between the three groups (severe vs moderate: $MD = -14.88$, $p = .000$), (moderate vs mild: $MD = -3.731$, $p = .000$), (severe vs mild: $MD = -18.612$, $p = .000$) were found through the LSD tests. With respect to the FIM total score, significant differences between the three groups were found through the LSD post hoc tests (severe vs moderate: $MD = -22.906$, $p = .000$), (moderate vs mild: $MD = -33.907$, $p =$

.000), (severe vs mild: MD = -56.813, p = .000) and the results are presented in Figure 2.

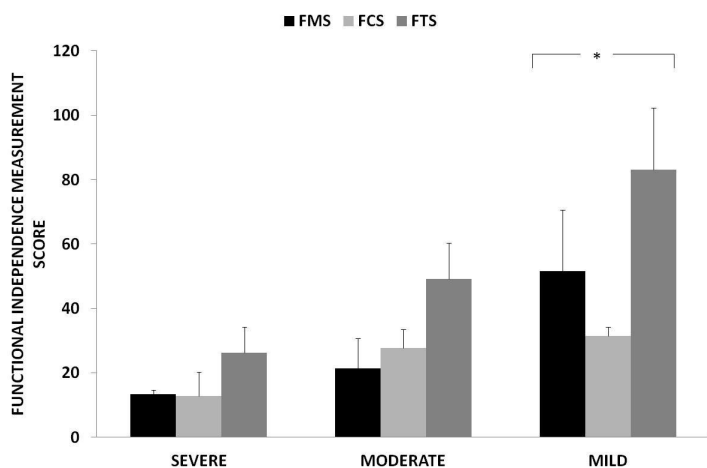


Figure 2: Means and standard deviations (error lines) of patients' functional independence according to the severity of neurological disorder (Severe, Moderate, Mild) based on the Motor domain (FMS), the Cognitive domain (FCS) and the Total Score (FTS) of the Functional Independence Measurement (FIM) scale.

* Significant differences between patients with Mild, Moderate and Severe disorders (p < .01).

Concurrent Validity

The correlations between the FIM during admission, the WHODAS 2.0 and the functional assessments were examined. The results demonstrated Pearson correlation coefficients ranging from - .608 to .985, and are presented in Table 5.

Table 5: Correlations & Examination of synchronic validity (A = FIM Motor upon Admission, B = FIM Cognitive upon Admission, C = FIM Total Score upon Admission, D = WHODAS 2.0., E = Time Up and Go test, F = Sit To Stand test, G = 10 Meter Walking test).

VARIABLES	PEARSON CORRELATION COEFFICIENTS						
	A	B	C	D	E	F	G
FIM Motor upon Admission (A)	1						
FIM Cognitive upon Admission (B)	.683**	1					
FIM Total Score upon Admission (C)	.985**	.799**	1				
WHODAS 2.0. (D)	-.784**	-.774**	-.871**	1			
Time Up and Go test (E)	-.700**	-.658**	-.714**	.612*	1		
Sit To Stand test (F)	.631**	.617**	.647**	-.608*	-.803**	1	
10 Meter Walking test (G)	-.727**	-.676**	-.741**	.706**	.749**	-.751**	1

* Significant differences between variables (p < .05).

** Significant differences between variables (p < .01).

FIM: Functional Independence Measurement, WHODAS 2.0: World Health Organization Disability Assessment.

Sensitivity of change

The differences between the admission and discharge scores upon the motor, cognitive and the total FIM score were examined. The repeated multivariate results were significant ($\Lambda = .577$, $F = 8.065$, $p = .002$, $\eta^2 = .423$) and the univariate analyses showed significant differences, between admission and discharge, in the a) motor ($F = 10.886$, $p = .003$, $\eta^2 = .321$), b) cognitive ($F = 8.337$, $p = .008$, $\eta^2 = .267$) and c) total FIM score ($F = 16.354$, $p = .001$, $\eta^2 = .416$). The results are presented graphically in Figure 3.

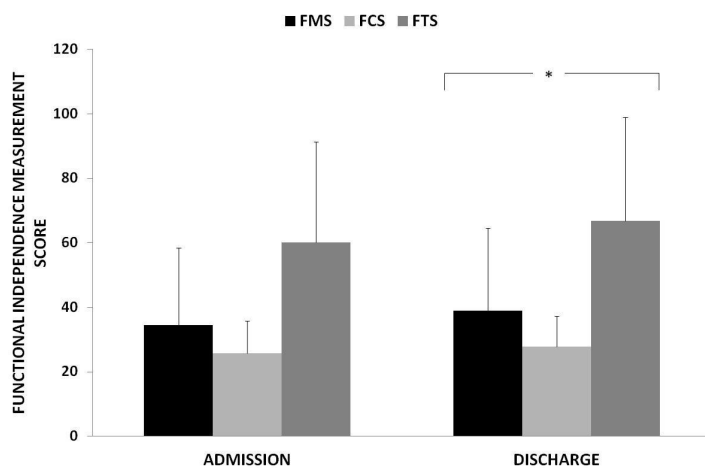


Figure 3: Means and standard deviations (error lines) of functional independence in patients with stroke and traumatic brain injury during admission and discharge from the hospital or Rehabilitation Center based on the Motor domain (FMS), the Cognitive domain (FCS) and the Total Score (FTS) of the Functional Independence Measurement (FIM) scale.

* Significant differences between admission & discharge measurements (p < .01).

Discussion

The present study examined the validity and reliability evidence of the FIM for individuals with Neurological Disorders (ND) in Greece. The results were promising with respect to the inter rater and intra rater reliability hypotheses. Further, the FIM scores a) differentiated ND patients vs no patients, and patients according to severity (mild, moderate and severe) (construct validity hypotheses), b) exhibited moderate to high intercorrelations with several functionality measures (concurrent validity hypothesis) and c) detected changes of clinical condition due to hospitalized treatment (admission vs discharge scores).

Inter rater Reliability

Regarding inter rater reliability, the present findings are partially in agreement with similar studies with ND patients [52,53,55,58] and elderly with orthopedic injury [64]. More specifically, Young et al. [64] found coefficients ranging from .74 to .76, between telephone interview and personal evaluation in the patient's ward. In the present study, the intra rater coefficients were higher than those presented by Young et al. [64]. The difference may be due to the different methods employed. In the present study the assessments were held by two independent researchers, who received the same exact training simultaneously, and assessed each patient in their clinical ward, while in the study of Young et al. the evaluations

were held under two different conditions (phone interview and ward) [64].

Previous studies in Turkey [55], Sweden [53] and Iran [58], have reported acceptable and sometimes low inter-rater reliability coefficients. Naghdi et al. [58] for example re-reported coefficients ranging from .88 to .97, similar to those reported in the present study. Küçükdeveci et al. [55] on the other hand reported coefficients ranging from .44 to .89 from two independent researchers assessing upon patient admission. Daving et al. recruited four assessors and reported higher coefficients in the motor subscale (ranging from .6 to .9) compared to the cognitive subscale (ranging from -.26 to -.61) [53]. Daving et al. claimed that the above discrepancy was probably explained from the fact that each inpatient's evaluation was carried out at different times during the hospitalization day, according to the assessor's daily schedule [53]. Further, each rater may have had a different perception of each inpatient's clinical condition, a fact that may have led to a large discrepancy among raters' assessments [53].

The present findings are in agreement with those reported by Brosseau and Wolfson [52], in patients with Multiple Sclerosis from Canada. Specifically, Brosseau and Wolfson found an inter-rater reliability coefficient of .83 for the total FIM score [52], while lower coefficients were reported for the motor and cognitive subscales. The researchers attributed this finding to the fact that patients with cognitive and communication deficits were excluded from their sample [52].

Intra rater Reliability

Regarding intra rater reliability, the present findings are partially in agreement with similar studies with elderly patients reporting coefficients ranging from .8 to .9 [61], and stroke patients with coefficients ranging from .9 to .98 [57]. Nevertheless, the high intra rater reliability of the present study is not in line with other studies. For example, Young et al. reported intra rater reliability coefficients ranging from .74 to .76 in hip fracture patients [64] and Masedo et al. reported coefficients ranging from .2 to .47 in spinal cord injury patients [63]. The low coefficients reported above may be due to the non-certified raters recruited and the self-assessment from the patients themselves regarding the percentage of the assistance needed.

Internal Consistency

Regarding internal consistency, the present findings revealed high Cronbach alpha values for the FIM subscales. These results are in line with similar studies with patients with multiple sclerosis (.94) [52], stroke patients (values ranging from .95 to .97 [57], from .70 to .96 [58], from .93 to .98, [55]), and burn patients with Cronbach alpha ranging from .96 to .97 [65]. In addition, Turner-Strokes and Siegert reported high internal consistency coefficients of the FIM+FAM in ND patients (values ranging from .96 to .97) [60]. Only Masedo et al. reported lower coefficients in spinal cord injury patients [63]. More specifically, Masedo et al. reported moderate coefficient (.63) in the FIM cognitive subscale. This may be due to the self-assessments from the patients and the written instructions

regarding the percentage of the help needed described above [63].

Construct Validity

Regarding the construct validity hypothesis, the present findings are in line with Erkin et al. [34] and Pollak et al. [61]. Specifically, Erkin et al. found differences in the FIM scores between children with and without cerebral palsy [34]. Also, Pollak et al. found differences between seniors and elderly individuals classified into independent, assisted, and fully assisted living groups [61]. The above two studies differ from the present study in terms of the sample characteristics, but confirm our research hypotheses and support the construct validity evidence of the FIM.

Concurrent Validity

The FIM scale was associated with the WHODAS 2.0 (short form) and the functional tests (TUG, STS & 10MWT) used in the present study. The literature suggested that the FIM has exhibited high intercorrelations with a variety of scales assessing functionality, such as the Barthel Index [57,58]. Brosseau and Wolfson also found concurrent validity evidence of the FIM total score through the application of Expanded Disability Status Scale in multiple sclerosis patients (coefficient indexes ranging from .7 to .9) [52]. Moderate and poor concurrent validity evidence of FIM was shown in the study of Masedo et al. [63], through the application of Craig Handicap Assessment and Reporting Technique in spinal cord injury (SCI) and amputation patients respectively. Specifically, the coefficients in SCI patients were moderate, ranging from .13 to .52 (.13 was a senior poor coefficient for locomotion). With respect to the amputation group, the concurrent validity coefficients were poor, ranging from .04 to .39 [63]. On the contrary, Young et al. findings showed high concurrent validity evidence of the FIM in hip fracture patients [64]. In particular, the intercorrelation coefficients between interview and health care assessments (golden standard) were high, both in patients' discharge (.76) and patients' admission (.74) [64]. The study of Küçükdeveci et al. further demonstrated satisfactory concurrent validity evidence for the FIM motor subscale through the application of ASIA and Brunnstrom motor in SCI and stroke patients respectively [55]. More specifically, the intercorrelation coefficients (ranging from .38 to .81) were moderate to high both for the SCI and the stroke groups of patients examined. Regarding the association between FIM and WHODAS 2.0, there is only one study confirming the present findings, with stroke patients in Turkey [85]. The interpretation probably lies in the fact that the FIM evaluates a percentage of help for specific daily self-service activities, while the WHODAS 2.0 evaluates percentage of participation in daily activities in general.

Sensitivity of Change

The FIM detected the clinical change of the patients involved in the present study, between the admission and discharge from the hospital or rehabilitation center. This finding is in agreement with other studies in the past [54,60,64]. Turner-Strokes and Siegert, in their attempt to examine the sensitivity of the collapsed FIM + FAM scale in patients with neurological disorders in the UK, identified significant differences between the patients' admission

and discharge from the rehabilitation center [60]. Similarly, Grimby et al. reported significant improvement between admission and discharge from a rehabilitation center of Swedish patients [54], in the FIM motor subscale, while Young et al. detected clinical change in ND patients after hip fracture rehabilitation [64].

Detecting changes in patients' clinical status regarding their functional independence has been noted in several studies using specialized interventions for patients with ND. These interventions incorporate physiotherapy programs, occupational therapy, speech therapy [36,37,59], transcranial magnetic stimulation [51], endurance and resistance training [54], respiratory and resistance training [66] and kinesiotherapy or dance programs [10]. The aforementioned studies used specialized interventions with specific details relevant to the techniques used, the duration, frequency, etc. The detailed information presented in the above studies could not be controlled in the present research effort, since the main intervention included medical and nursing care. Other variables, such as the length of stay in the clinic or rehabilitation setting were not predetermined, and physiotherapy sessions were held until the day of discharge from the hospital. However, although no common therapeutic intervention was performed in the present study, there was an improvement in the FIM scale within a few days. This finding may be due to the fact that doctors allowed inpatients discharging when their clinical condition was improved or stabilized in terms of hemodynamic, respiratory, temperature, and even muscle strength indicators. Overall, the results of the present study are consistent with previous studies and confirm the sensitivity of the FIM to detect changes in the clinical status of patients with neurological disorders.

Limitations of the Study

Certain limitations do not allow for generalization without caution. First, the severity was assessed by the physicians. The physicians, in turn, used several criteria such as the ICF (International Classification of Functioning) disability classification system, the image of the computed tomography and the general clinical condition observed. The research team however was unable to control the physicians' assessments and future researchers may consider developing a standardized form for assessing severity of ND patients. Second, the inability of some patients and their close relatives to participate in the study, was another limitation. Essentially, when patients or attendants were unable to understand instructions, prospective inpatients were excluded from the sample. In addition, patients with comorbidity such as dementia or other mental disorders were excluded from the sample. Third, only patients with stroke and TBI were evaluated regarding their functionality and the findings may not be generalized to patients with other neurological diseases (eg MS, CKD), or patients with orthopaedic, cardiovascular or respiratory disorders, or outpatients with respective demographics. Fourth, the assessments were held in separate clinics and rehabilitation centers, and the environment may have been a limited factor unable to control. Finally, certain variables related with the recent pandemic, such as the fear of COVID-19 (pandemic had not been present during the assessment

period), anxiety due to prolonged hospitalization, etc, were not examined. Future researchers may consider the above limitations and standardize the severity assessment, incorporate wider samples with patients unable to communicate, patients with comorbid conditions, and collect qualitative in-depth evidence to support their findings.

Recommendations to practitioners

The FIM appeared to be a valid and reliable scale for assessing ND inpatients. It also appeared sensitive in detection of patients' clinical status change between admission and discharge from rehabilitation. Therefore, it could be applied in rehabilitation centers and hospitals for assessing patient's functionality and rehabilitation progress. In the future, clinicians may consider creating a database to record patients' progress. The above database may help the medical care upgrading. For example, the frequency of nursing care, or physiotherapy, occupational therapy, speech therapy sessions could be recorded and the respective outcome evaluated accordingly through the FIM. Thus, the respective budget may also be calculated and controlled in the future.

In order to achieve the above goals, working in accordance to the Greek Ministry of Health may lead to the cross-cultural validation of the FIM and use in a national level. Thus, in the future, the FIM may be applied in the majority of patients, in Greece following rehabilitation treatment, in order to record their clinical condition and respective progress. Consequently, the timely budget for the patients' care and assistance cost could be estimated as well. The planning of health care intervention services therefore may be better planned and executed in Greece.

Suggestions for future research

The FIM may be used to assess patients with other neurological disorders, such as MS, SCI, Parkinson, Myopathies etc in the future. The effect of pre-determined controlled interventions may be useful to examine as well. Specific physiotherapy, speech therapy and occupational therapy programs may be applied and assessed after controlling for patient's severity. Frequent FIM assessment as every week, may be also considered as a possible variable for future researchers. The intermediate assessments may support the health care system regarding the patient's progress and health care cost in general.

Conclusions

In conclusion, in the present study the FIM scale was applied in ND patients (Stroke & TBI) in hospitals and rehabilitation centers within the wide area of Attica. The findings showed initial validity and reliability evidence for a sample of Greek ND patients. Specifically, the present findings demonstrated sufficient construct and concurrent validity, inter-rater reliability, intra-rater reliability, internal consistency and detection of change in patient's clinical status. Therefore, the FIM may be considered as a useful measure for the assessment of ND patients in Greece.

Institutional Review Board Statement

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the National Kapodistrian University of Athens (School of Physical Education and Sport Science ethics committee) (protocol code: 1085/13/10/2018; date of approval: 13/10/2018).

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