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Levels of Cognitive Functioning Assessment Scale: Italian cross-cultural adaptation and validation

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Key words: Brain Injury, Cognitive Functioning Levels, Italian, Outcome Assessment, Validation
Parole chiave: Trauma cranico, Cognitive Functioning Levels, Italiano, Scala di valutazione, Validazione

Abstract

Study design. *Cross-sectional study.*
Objective. *To develop an Italian version of the Levels of Cognitive Functioning Assessment Scale (LOCFAS) and examine its reliability and validity.*
Subject. *Patients with acquired brain injury in an early post-coma state.*
Methods. *The original scale was translated from English to Italian using the guidelines set forth in the Translation and Cultural Adaptation of Patient Reported Outcomes Measures–Principles of Good Practice. Intra-rater reliability was examined using the intraclass correlation coefficient (ICC). Concurrent validity was evaluated using Pearson's correlation coefficients with some of the functional and disability components of the International Classification of Functioning, Disability and Health (ICF), excluding environmental factors.*
Setting. *The highly specialized neurorehabilitation department of "San Raffaele" Hospital, Cassino.*
Results. *The Italian version of the LOCFAS (LOCFAS-I) was administered to 38 subjects from May 9, 2017 to August 31, 2017. The mean ± SD of the LOCFAS-I score was 3.05 ± 1.88. All LOCFAS-I items were either identical or similar in meaning to the original version's items. Test-retest reliability (ICC) was 0.996 ($p < 0.01$). The Pearson correlation coefficient of the LOCFAS-I scores with some of the functional and disability components of the ICF was > 0.536 ($p < 0.01$).*
Conclusions. *The LOCFAS-I was found to be reliable and a valid measurement tool for the assessment of cognitive functioning post-coma in the Italian population.*

Introduction

Acquired brain injury (ABI) is an important public health problem with a significant global impact. In the European Union, brain injury (BI) accounts for one million hospital admissions per year. In Italy, the prevalence is about 100,000 people/y-with BI.

The clinical, social, and economic implications of ABI are huge; the social costs caused by the patients' deaths or acquired disabilities are very high. The importance of the evaluation phase in taking charge of a patient is evident, as is the early assessment of patient's cognitive functioning, in order to develop an appropriate early rehabilitation program to maximize recovery (2). For this

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type of evaluation to be administered, the patient has to have the ability to comprehend, cooperate, and participate, but it may take many weeks after the trauma before the patient reaches this level. Early intervention provides greater success in helping patients to achieve their maximum potential than later intervention does (3).

The Levels of Cognitive Functioning Assessment Scale (LOCFAS) is a behavioral rating scale. It was developed as a useful and valid tool for the assessment of cognitive functioning in patients within the earliest phases of the post-coma state. Flannery (2, 4) developed the LOCFAS on the basis of the Rancho Level of Cognitive Functioning Scale (LCFS) (5, 6), which was used to assess cognitive functioning in post-coma patients. The LCFS was intended to provide a way of systematically describing and categorizing a patient's present level of consciousness and cognitive and behavioral functioning into one of eight levels through which individuals with brain injuries typically progress during their stay in hospitals submitted to acute rehabilitative care (5, 6). The LOCFAS (2, 4) was developed by adapting and modifying Levels I through V of the eight original levels of the Rancho scale (7). These selected levels include behaviors that are seen more commonly in the earliest stages of recovery, when a BI patient is more likely to be in an inpatient acute care setting. Flannery transformed the narrative for each of the first five levels of the LOCFS into a behavioral checklist of 41 individual behaviors. This helps a care team understand and focus on the patient's abilities and design an appropriate treatment program.

The simplicity and clinical utility of a measurement instrument can be important in deciding which measurement instrument to use, the LOCFAS is a quick and simple way to describe an individual's level of recovery and to make quick comparisons between groups. Its simplicity and utility have contributed to its widespread use, particularly in the United States (8), Spain (9), Netherland (10) and Italy, where it is commonly used to classify patients in acute and post-acute rehabilitation settings (11, 12).

According to the Italian Society of Physical and Rehabilitation Medicine (SIMFER), the LOCFAS has been used to assess cognitive functioning nationwide for the past 20 years by all disciplines concerned with rehabilitation (13). The tool is commonly used with the Rehabilitation Assessment Protocol from SIMFER, with ABI patients to provide criteria for admission into rehabilitative facilities and to monitor a patient's progress in recovery. The instrument also provides a common interdisciplinary language for describing a patient's progress during recovery (14).

During the National Consensus Conference in Italy (15), a jury agreed that for patients who are ready to be transferred from intensive care or neurological units to rehabilitative facilities, the choice of a rehabilitative program should be guided by a comprehensive evaluation, that includes an assessment of responsiveness, general medical condition, type and severity of complications, and prognosis of recovery. The outcome measures adopted according to the jury to assess patients were scales of clinical impairment, disability, and handicap before and after a rehabilitative program (16). For this purpose, the Glasgow Outcome Scale (GOS) (17), the Disability Rating Scale (DRS) (18) and the Level of Cognitive Functioning Assessment scale (LOCFAS) were adopted. Currently, the LOCFAS is the only not rigorously psychometrically tested in the Italian context. The cross-cultural adaptation process is important when an instrument is used in a different language, setting and time to reduce the risk of introducing bias into a study. In studies where a phenomenon is measured indirectly with questionnaires, comparison of results between cultures and groups may be a challenge. In particular, comparison will be

difficult if the adaptation process has been flawed. It is therefore important that each item is adapted appropriately.

The aim of our study was to enable the assessment of cognitive functioning in an Italian sample with ABI by translating the LOCFAS into Italian, creating a cross-cultural adaptation, and evaluating its psychometric properties.

Methods

The original LOCFAS was translated from English into Italian using international guidelines (19).

Translation and cultural adaptation: The first stage in the adaptation was forward translation. The original English version of the LOCFAS was translated into Italian by two native English speakers and one Italian physiatrist familiar with English. These individuals produced three independent literal translations. An English native speaker, who had not been involved in any of the forward translations, synthesized the results; after that, three Italian translators - having not seen the original version - used the temporary version of the questionnaire to translate the questionnaire back into the original language. The back-translated version of the instrument was then compared to the original. To adapt the translated version to Italian culture, one physiatrist and two Italian rehabilitation professionals (an occupational therapist and a physiotherapist), who were familiar with both English and Italian, reviewed the first translated version and then reworded and reformulated some items to minimize any differences from the original version.

Pre-test (cross-cultural validity): The pre-final translated version of the LOCFAS was administered to a small representative group of patients (20) to evaluate its cross-cultural validity. To avoid bias, each patient was tested twice by the same medical doctor. The time interval between repeated administrations should be short enough to ensure that no clinical change had occurred, a time period of 24 hours was considered appropriate. This resulted in the final Italian version of the LOCFAS (LOCFAS-I) being applied to the whole population of the study.

Subjects: In literature, sample size recommendations range from 2 to 20 subjects per item (21, 22), in the articles analyzed in a recent (2014) systematic review about sample size used to validate a scale, the mean subject to item ratio was 28, with a minimum of 1 and a maximum of 527 (23). Furthermore, Shoukri et al. (24) report that "However, in many cases, values of the reliability coefficient under the null and alternative hypotheses may be difficult to specify. Under such circumstances, one can safely recommend only two or three replications per subject". Consistent with previous studies of the LOCFAS (2, 4) and according to the recommendations available in the literature, a minimum sample size of 30 subjects was considered adequate by the authors of this study. To be included in the study, participants had to:

- Have an ABI,
- Be in the early post-coma state,
- Be at least 18 years old.

Patients who met the study inclusion criteria were scheduled for two testing sessions. Relatives of the patients who were considered eligible were informed about the study and their interest in taking part in it was recorded; all people who agreed to be in the study gave their consent before inclusion (25, 26). The reliability and validity of the culturally adapted scale was assessed by using the checklist titled of "COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) (27).

Reliability: To evaluate test-retest reliability, the LOCFAS-I was administered to the population twice by the same medical doctor. The time interval for test-retest studies needs to be sufficiently short to support the assumption that the patients remain stable. According to the original English validation of the tool (2, 4), a time interval of 3-6 days was considered appropriate for the current population. To measure intra-rater reliability, the intraclass correlation coefficient (ICC) was calculated. An ICC value of ≥ 0.70 is considered optimal to establish the degree to which repeated measurements are free from measurement error, so the scale was considered stable if the test-retest for ICC was > 0.70.

Validity: To evaluate concurrent validity, the LOCFAS-I and some of the functional and disability components of the International Classification of Functioning, Disability and Health (ICF) (28, 29), excluding environmental factors, were administered together and the Pearson correlation coefficients were calculated. We administered for impairments of body functions (b110 Consciousness; b140 Attention; b147 Psychomotor functions; b156 Perceptual functions; b160 Thought functions; b164 Higher-level cognitive functions and b167 Language), impairments of body structures (s110 Brain), and activity limitations and participation restriction (d310 Communicating with—receiving—spoken messages; d315 Communicating with—receiving—non-verbal messages; d320 Communicating with—receiving—formal sign language messages; d325 Communicating with—receiving—written messages; d329 Communicating—Receiving information; d330 Speaking; and d335 Producing non-verbal messages).

All statistical analyses were done using IBM-SPSS version 23.00.

Results

The participants were recruited in April 2017 through the intensive care unit of the highly specialized neurorehabilitation department of the "San Raffaele" Hospital, Cassino.

Pre-test (cross-cultural validity): Cross-cultural validity was evaluated with 20 subjects in April 2017. The results were strikingly similar to those found using the original English version (2, 7) and no items were modified to improve comprehensibility or applicability (See Appendix 1).

Subjects: From May 9, 2017 to August 31, 2017, 38 subjects (mean age = 56.9 ± 18.9) with ABI, who met the inclusion criteria, were enrolled in the study. The demographic characteristics of the subjects are summarized in Table 1. The mean ± SD of the LOCFAS-I score was 3.5 ± 1.8.

Table 1 - Demographic characteristics for the 38 participants in the reliability study LOCFAS-I.

	Sample n=38
Age Mean (SD)	56.97 (19.91)
Gender men n (%)	24 (63)
Diagnosis	n (%)
Cardiac arrest	3 (8)
Stroke	25 (65)
Lithium overload	1 (3)
Brain injury	3 (8)
Respiratory complications	1 (3)
Polytrauma	4 (10)
Encephalopathy	1(3)

Reliability: The LOCFAS-I was found to have a good degree of test-retest reliability. All 38 subjects underwent test-retest reliability procedures. The LOCFAS-I was reliable with respect to test-retest with an ICC of 0.996 ($p < 0.01$).

Validity: The Pearson correlation coefficient of the LOCFAS-I with some of

Table 2 - Gold standard analysis: Pearson's correlation between LOCFAS and ICF items

	Score LCF	b110*	b140*	b147*	b156*	b160*	b164*	b167*	s110*	d310*	d315*	d320*	d325*	d329*	d330*	d335*
Score LCF	1	-0.97**	-0.86**	-0.90**	-0.95**	-0.90	-0.73**	-0.77**	-0.91**	-0.81**	-0.82	-0.67**	-0.70**	-0.70**	-0.70**	-0.70

** Correlation is significant at the 00.01 level (2-tailed).

* Impairments of body functions (b110 Consciousness; b140 Attention; b147 Psychomotor functions; b156 Perceptual functions; b160 Thought functions; b164 higher-level cognitive functions and b167 Language);
Impairments of body structures (s110 Brain);
Activity limitations and participation restriction (d310 Communicating with receiving spoken messages; d315 Communicating with receiving non-verbal messages; d320 Communicating with receiving formal sign language messages; d325 Communicating with receiving written messages; d329 Communicating Receiving information; d330 Speaking; and d335 Producing non-verbal messages).

the functional and disability components of the ICF, excluding environmental factors, was > 0.536 ($p < 0.01$), indicating that the LOCFAS-I has good concurrent validity. The Pearson correlation coefficient for each item is reported in Table 2.

Discussion

This study was conducted by a research group composed of medical doctors and rehabilitation professionals from the Sapienza University of Rome and from the Rehabilitation & Outcome Measure Assessment (R.O.M.A.) association. In the last few years, the R.O.M.A. association has dealt with the validation of many outcome measures in Italy. (30-40) This study developed an Italian version of the LOCFAS-I and evaluated its reliability and validity. In this article, we have reported on the translation and cultural adaptation of LOCFAS-I for use among Italian ABI patients in an early post-coma state and the subsequent evaluation of its validity evidence. Translation and linguistic adaptation were performed according to international guidelines (19), under the supervision of a panel of experts who ensured that the original meaning of each item was retained. The reliability and validity of the culturally adapted scale were assessed by using the COSMIN checklist (27).

A number of published studies that support either the validity or the reliability of the LOCFAS exist. Three reliability studies (6-8) have been conducted on the LOCFAS. Govier et al. (6) found interrater reliability ranging from 0.87 to 0.92 and test-retest reliability of 0.92. In the second study, interrater reliability was obtained with a high mean coefficient kappa (= 1.00), and the third interrater reliability study showed a mean coefficient kappa of 0.98. Test-retest reliability yielded a mean coefficient kappa of 0.99, 0.84, and 0.86,

APPENDIX 1

Versione Italiana LOCFAS adattata culturalmente: LOCFAS-I

LIVELLO COGNITIVO 1
NESSUNA REAZIONE
Una persona a questo livello:
• non è in grado di reagire ad alcun tipo di stimolo

LIVELLO COGNITIVO 2
REAZIONE GENERALIZZATA
Una persona a questo livello:
• inizia a reagire agli stimoli sensoriali (suoni, immagini, contatti fisici, movimento)
• reagisce lentamente, debolmente o in ritardo
• reagisce allo stesso modo a qualsiasi stimolo sensoriale e sensazione. Le reazioni indifferenziate possono includere: masticazione, sudorazione, aumento della frequenza respiratoria, gemiti, movimenti e/o aumento della pressione sanguigna

LIVELLO COGNITIVO 3
REAZIONE LIMITATA/LOCALIZZATA
Una persona a questo livello:
• alterna stati di veglia e di sonno durante il giorno
• compie un maggior numero di movimenti rispetto alla fase precedente
• reagisce in modo più specifico ed appropriato a ciò che vede, sente o prova. Può, per esempio, voltare la testa verso un rumore o un suono, ritrarsi per il dolore, tentare di seguire con lo sguardo una persona che si muove nella stanza
• reagisce lentamente e debolmente
• inizia a riconoscere familiari ed amici
• segue semplici istruzioni come “guardami” o “stringi la mia mano”
• inizia a rispondere a semplici domande con “sì”, “no” e cenni del capo.

LIVELLO COGNITIVO 4
CONFUSO ED AGITATO
Una persona a questo livello:
• può essere molto confusa e spaventata
• può non comprendere ciò che prova o ciò che le accade intorno
• può reagire eccessivamente a ciò che vede, sente o prova, colpendo, urlando, usando un linguaggio offensivo o aggredendo. Tutto ciò, a causa dello stato confusionale
• può essere necessario immobilizzarla per evitare che si ferisca
• può essere focalizzata in maniera ossessiva sui suoi bisogni di base: scaldarsi, alleviare il dolore, tornare a letto, andare in bagno o tornare a casa
• può non comprendere che gli altri cercano di aiutarla
• può avere problemi di attenzione e concentrazione
• può avere difficoltà a seguire istruzioni
• può talvolta riconoscere familiari ed amici
• può compiere, se assistita, semplici azioni quotidiane come nutrirsi, vestirsi o parlare

LEVELLO COGNITIVO 5
CONFUSO E INAPPROPRIATO
Una persona a questo livello:
• può non essere in grado di prestare attenzione per più di qualche minuto
• può essere confusa ed avere difficoltà nel comprendere ciò che accade
• può non conoscere la data del giorno, né avere consapevolezza di dove si trova e perché
• può non essere in grado di iniziare né portare a termine attività quotidiane, come spazzolarsi i denti, anche se fisicamente abile. Può avere bisogno di istruzioni procedurali
• può divenire iperattiva ed irrequieta quando è stanca o quando c’è confusione; può avere scarsa memoria degli eventi quotidiani ma ricordare meglio tutto ciò che è accaduto prima del trauma

• può tentare di far fronte ai vuoti di memoria, confabulando fra sé
• può fissarsi su un'idea o un'attività ed aver bisogno di aiuto per passare ad altro
• può essere focalizzata in maniera ossessiva sui suoi bisogni di base: scaldarsi, alleviare il dolore, tornare a letto, andare in bagno o tornare a casa

LIVELLO COGNITIVO 6
CONFUSO E APPROPRIATO
Una persona a questo livello:
• può presentare uno stato confusionale a causa di problemi di memoria e di elaborazione concettuale; può ricordare il punto centrale di una conversazione ma dimenticare e confondere i dettagli. Ad esempio, può ricordare di aver ricevuto visite in mattinata ma non sapere di cosa abbiano parlato i visitatori
• può seguire un programma quotidiano, se assistita, ma si confonde se occorrono dei cambiamenti nelle attività programmate
• può conoscere mese ed anno correnti, in assenza di un serio problema di memoria
• può prestare attenzione per circa 30 minuti ma con problemi di concentrazione, in presenza di rumori di fondo o quando l'attività richiede molte procedure contemporanee. Ad esempio, ad un incrocio, può avere difficoltà a scendere dal marciapiede e, contemporaneamente, prestare attenzione alle auto, guardare il semaforo, camminare e parlare
• può spazzolarsi i denti, vestirsi, nutrirsi ecc, con assistenza
• può riconoscere il bisogno di usare il bagno
• può non riuscire a fare o dire cose velocemente, senza bisogno di pensare prima
• può avere consapevolezza di trovarsi in ospedale a causa di un trauma ma potrebbe non capire tutti i problemi relativi alla sua condizione
• può essere più consapevole delle sue difficoltà fisiche che di quelle cognitive
• può associare i suoi problemi alla permanenza in ospedale e credere che tutto si risolva tornando a casa

LIVELLO COGNITIVO 7
AUTOMATICO ED APPROPRIATO
Una persona a questo livello:
• può seguire un programma procedurale stabilito
• può curare l'igiene personale senza bisogno di aiuto, se fisicamente abile. Ad esempio, può vestirsi e nutrirsi autonomamente; può avere difficoltà nelle situazioni nuove e non strutturate ed agire in modo impulsivo, a causa della frustrazione
• può avere problemi a pianificare, iniziare e portare a termine attività
• può presentare problemi di attenzione in situazioni impegnative e stressanti. Ad esempio, riunioni familiari, eventi sportivi, scolastici, lavorativi, religiosi
• può non rendersi conto di quanto i suoi problemi di memoria possano influire su progetti ed obiettivi futuri
• può aver bisogno di supervisione a causa di una ridotta capacità di giudizio e di un'inappropriata consapevolezza del pericolo. Potrebbe non essere pienamente consapevole della gravità dei suoi deficit fisici e cognitivi
• può mostrarsi inflessibile o rigido, ai limiti della testardaggine. Il suo comportamento è, comunque, determinato dal danno cerebrale
• può essere in grado di dire di voler fare qualcosa ma può avere difficoltà a farla realmente

LIVELLO COGNITIVO 8
CONSAPEVOLE ED APPROPRIATO
Una persona a questo livello:
• può realizzare di avere disturbi mnesici e cognitivi
• può iniziare a compensare questi deficit
• può essere più flessibile e meno rigido nel pensiero. Ad esempio, può essere in grado di proporre diverse soluzioni ad un problema
• può essere pronto all'addestramento per la guida o alla valutazione per il reinserimento lavorativo
• può essere in grado di imparare lentamente cose nuove
• può ancora essere stressato da situazioni difficoltose o di emergenza
• può mostrare uno scarso grado di giudizio in situazioni nuove e richiedere assistenza
• può aver bisogno di consigli nel prendere decisioni
• può avere difficoltà cognitive che non risultano visibili a chi non conosceva la persona prima del trauma

respectively. The LOCFAS-I's ICC of 0.996 ($p < 0.01$) for test-retest reliability was very good. The high level of interrelatedness among the items shows the cross-cultural validity of the adapted scale, which reflects the performance of the previous LOCFAS studies. The high LOCFAS-I reliability indicates that the scores of the patients remained stable after repeated measurement, as in the English version.

The LOCFAS-I has shown significant positive correlations with some of the functional and disability components of the ICF, thus indicating good concurrent validity. The LOCFAS-I provides a standardized format for interdisciplinary team members to communicate about a patient's cognitive functioning across shifts. Use of such an instrument also provides the necessary information to develop and implement an appropriate plan of care specific to a patient's existing strengths and weaknesses, enabling team members to institute rehabilitation measures much earlier in the patient's recovery. Through repeated use of the instrument, staff can monitor a patient's progress and make appropriate modifications in the care plan to enhance recovery. Early assessment allows rehabilitation measures to begin much earlier post injury. Accurate diagnoses and appropriate treatments, which are critical to patient outcomes, will also help to minimize healthcare expenditures and reduce the reimbursable time allowed for hospitalization (2, 4).

The LOCFAS is used in most of the Italian regional health systems to determine the discharge placement of patients, the burden of care, and the efficiency and effectiveness of rehabilitation intervention. Unfortunately, no Italian studies have been published that evaluated the validity and reliability of the LOCFAS administered in the Italian ABI population in an early post-coma state, and no data on the translation of the scale and adaptation processes to Italian culture are available in the literature.

Limitations of the study

This study has a number of limitations. Previous studies have revealed weaknesses in discrimination among raters who were not experts, therefore since this is a behavioral scale, further studies are needed to test interrater reliability with Italian professionals. Additionally, future studies could calculate concurrent validity with the Italian version of Glasgow Outcome Scale. Lastly, despite the sample size has been recruited on the basis of international requirements (21-24), the small number of participants has obviously limited the analyses potentially performable, and further studies may consider a larger number of subjects. Finally, in using LOCFAS-I, it is important to recognize that the reliability and validity described above are limited to a sample of adults (> 18 years old). It would be interesting to test the measurement properties with a bigger sample, including children.ù

Conclusion

In conclusion, the culturally adapted LOCFAS-I shows itself to be a valid, reliable, and rapidly administrable scale for the assessment of cognitive functioning in the ABI Italian population in an early post-coma state. The literal translated LOCFAS has been used in most of the Italian regional health systems but not culturally adapted and validated prior to this work. Despite the study's limitations and the need for further investigations, our work is the first to have rigorously developed and psychometrically tested the LOCFAS in the Italian context. Clinicians and Italian professionals now have a standardized, valid, and reliable tool to measure and capture data about patients' levels of cognitive functioning in the early post-coma state for clinical and research practice.

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Statement of Human and Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed consent was obtained from all participants for being included in the study.
Statement of informed Consent: Informed consent was obtained from all individual participants included in the study.
Statement of Ethics: We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.
Support: None.

Riassunto

Levels of Cognitive Functioning Assessment Scale: adattamento culturale e validazione in lingua italiana

Disegno dello studio. Studio trasversale.

Obiettivo dello studio. Validare la Levels of Cognitive Functioning Assessment Scale (LOCFAS) in lingua italiana in un campione di individui con lesioni cerebrali acquisite in uno stato post-coma precoce.

Materiali e Metodi. La scala originale è stata tradotta dall'inglese all'italiano usando le linee guida internazionali. L'affidabilità intra-operatore è stata esaminata utilizzando il coefficiente di correlazione intraclasse (ICC). La validità concorrente è stata valutata utilizzando i coefficienti di correlazione di Pearson con le componenti funzionali della classificazione internazionale del funzionamento, disabilità e salute (ICF), escludendo i fattori ambientali**.**

Setting. Lo studio è stato condotto presso il reparto di neuroriabilitazione dell'Ospedale "San Raffaele" di Cassino**.**

Risultati. La versione italiana di LOCFAS (LOCFAS-I) è stata somministrata a 38 individui dal 9 maggio 2017 al 31 agosto 2017. Tutti gli item della LOCFAS-I sono identici o simili nel significato rispetto a quelli della versione originale. L'affidabilità test-retest (ICC) ha mostrato un valore di 0.996 ($p < 0.01$). I coefficiente di correlazione di Pearson dei punteggi LOCFAS-I con alcuni componenti funzionali dell'ICF erano tutti maggiori di 0.536 ($p < 0.01$).

Conclusioni. La LOCFAS-I risulta essere una scala affidabile e uno strumento di misurazione valido per la valutazione del funzionamento cognitivo post-coma nella popolazione italiana.

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