Cross-cultural adaptation and preliminary test-retest reliability of the Italian version of the Complexity Rehabilitation Scale - Extended (13th version)

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Background. **In Italy, the lack of appropriate use of intensive rehabilitative services is an acknowledged issue, as demonstrated by periodic epidemiological surveys. Rehabilitation activities are planned without considering the clinical complexity, known to be one of the most fundamental factors able to outline the real patients' needs on recently clinical practice rehabilitation guidelines. Alternative diagnostic systems become, therefore, necessary. For this reason, we would like to propose the Rehabilitation Complexity Scale - Extended version (RCS-E) within intensive rehabilitation units in Emilia Romagna.**
Aim. **This study aims at submitting an Italian translation, cross-cultural adaptation and preliminary reliability evaluation of the Rehabilitation Complexity Scale Extended (13th Version) (RCS-E).**
Design. **Face validity and test-retest reliability.**
Setting. **The study was conducted in three different rehabilitation units of the Emilia Romagna region, Northern Italy.**
Population. **Ten expert physicians and 51 Intensive (code 56) rehabilitation in-patients were recruited.**
Methods. **A cross-cultural adaptation of the scale was built from English into Italian, closely complying with international guidelines. Face validity and test-retest reliability were carried out to evaluate the comprehensibility and goodness of fit of the new scale.**
Results. **An overall positive judgement was obtained with the face validity test. No significant differences were observed between the original and the adapted scale scoring. Internal consistency measured on 51 patients by Cronbach's alpha was 0.702 for the scale. The estimated SEM was 1.211. ICC$_{consistency}$ was 0.702. Split-Half reliability and the Spearman–Brown proph-** ecy were 0.633 and 0.775, respectively. Test-retest reliability of the RCS-E measured with ICC$_{agreement}$ was 0.903.
Conclusion. **The adapted RCS-E provides a sensitive and reliable tool that appears to be suitable for measuring clinical complexity in Italian code 56 rehabilitation units. It is the first Italian version of the scale to be devised.**
Clinical Rehabilitation Impact. **Further statistical validation will assess the Italian RCS-E as a possible instrument for guiding the patients' assignment to the rehabilitation settings that best suit their specific needs. These preliminary data represent the first step through this purpose.**

KEY WORDS: Reproducibility of results - Rehabilitation.

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The purpose of rehabilitation is to recover some or most of a patient's physical, sensory, cognitive and socio-relational abilities that were significantly impaired after injury, illness, or disease by means of an appropriate, individualised treatment program.

In the late 1960s, Professor Robert Fetter *et al.* at the Yale University, first witnessed the necessity to

have a tool allowing to accurately define the patients real needs and encouraging an efficient delivery of appropriate cares and fair payment. The USA group first proposed the Diagnosis Related Group (DRG) system, developed in a previous version in 1973.[1] This revolutionary approach or evaluation system had a rapid impact on the international scene, being used also in Europe and Australia in the 1990s.

Nowadays, in Italy, hospital rehabilitation routines are classified using a coding system that encompasses items such as aetiology and the time elapsed since the clinical onset of the disease,[2] but that overlooks other important factors required to ascertain the effective rehabilitation and welfare needs. In addition, in compliance with the aforesaid decree[1,3], a "fixed tariff" reimbursement system is applied.

To date, this coding system has failed to provide a fair and proportionate system for the reimbursement of the resources used, and therefore requires an indepth review.

The recently published "Rehabilitation Guidelines"[4] clearly specify that the selection of an appropriate clinical setting that meets patients' specific needs must rely on three known dimensions: complexity, disability and comorbidity. Whereas instruments such as the Barthel Index (BI)[5, 6] and the Cumulative Illness Rating Scale (CIRS)[7, 8] are typically used to rate the disability and comorbidity dimensions, clinical complexity remains difficult to define. The need to determine the appropriateness of hospitalisation for rehabilitation purposes, as demonstrated in international literature,[9-18] is an important issue. It is generally considered that one possible solution could be based on the definition of clinical complexity following objective criteria. Wade[11] recently reviewed the rehabilitation literature available, suggesting the use of different instruments to effectively evaluate Complexity in the rehabilitation domain. Nevertheless, the scale that appears most able to reliably evaluate the complexity dimension is the Rehabilitation Complexity Scale (RCS), which was devised in England in 2007,[19] validated in 2010,[20] and finally revised, in an extended version (RCS-E) in 2012.[21] This scale allows us to obtain a simple and objective "clinimetric" evaluation of patients with clinically complex neurodisabilities, and, consequently, to estimate the related welfare costs.[22]

The RCS-E (13th version) provides a simple overall measurement of 5 major domains: Care or Risk (C or R), Nursing (N), Therapy (T), Medical (M) and Equipment needs (E), each of which is composed by 5 items, except for the Equipment Needs domain that consists of just 3.

Each domain can be evaluated with a related scale measuring the entity of needs (minimal= low scores, maximal= high scores): Care or Risk (0-4); Skilled Nursing Needs (0-4), Medical Needs (0-4); Therapy Needs (0-8); Equipment Needs (0-2). The total score is set at a maximum of 22 points.

Rehabilitation intervention planning would benefit greatly from the introduction of the RCS-E scale, as it provides an accurate definition of clinical complexity, which helps to evaluate effective clinical needs.[19-21] The adoption of this new method in the Italian Health Service would also have a positive impact on economic resource management, as it would help to recalibrate the different costs on the basis of the effective use of resources.

The aim of this study was to provide an Italian version of the Rehabilitation Complexity Scale-Extended (13th version), to evaluate its clinical complexity measurement properties in terms of face validity and test-retest reliability and to provide the first assessment on the use of this scale in rehabilitation units in hospitals in the Emilia-Romagna region.

A detailed description of the cross-cultural adaptation and preliminary validity procedures will be described in the method section below.

Materials and methods

The local ethical committees approved the study.

With the agreement of its developers (Turner-Stokes and colleagues), the RCS-E scale was translated and cross-cultural adaptation was carried out according to well-defined, recommended guidelines.[23, 24]

Forward translation was the first step of the adaptation procedure. Two bilingual translators (Italian-English) were chosen, one of who had a clinical and scientific background, the other with no experience in medicine. This procedure helped to identify errors and divergent interpretations of ambiguous items in the original version. The professional translators independently translated the scale into the target language. A new version consisting in a combination of the two translations was then produced.

For the second step, two English native speaker translators, with no medical background and no

knowledge of the original version, translated the combined version from Italian into the original language (back-translation).

A committee of experts was then created in order to achieve cross-cultural equivalence. The expert committee included all four translators involved in the procedure and three physicians with in-depth experience in the rehabilitation sector. Each expert was asked to examine the original version of the RCS-E and the forward and back-translations. Special care was dedicated to the semantic and idiomatic equivalence between the translated versions of the scale, by verifying both the conceptual and experiential equivalence between the cultures involved. The expert committee discussed different options for each ambiguous item in order to find a satisfying equivalence with the content of the original version.

After reaching a consensus between all members of the committee regarding each aspect of the scale, from single words to the entire Complexity domain, a pre-final version of the scale was drawn up (step three). The difficulties and translation discrepancies encountered will be detailed and discussed later. None of the original items was removed from the pre-final version.

In order to verify whether all items were understood correctly, the next step consisted in administering the pre-final version to 10 physicians, to test face validity.

Face validity constitutes a first step in determining the value of a test. It consists in a very basic form of validation that determines whether a measure appears (on the face of it) to measure what it is supposed to. In order to test the face validity of the pre-final version of the scale, rehabilitation specialists from various hospitals, meticulously reviewed its content, paying special attention to the wording, ambiguities, comprehensibility, layout, etc. It was considered necessary to evaluate the pre-final version of the scale before applying it to patients; although further review by the expert committee was planned in case the rehabilitation specialist's revision did not reach a satisfactory level.

To verify reliability, a generic term used to indicate both the homogeneity (internal consistency) of a scale and the reproducibility (test-retest reliability) of the score,[25] the scale was administered to a sample of patients. The internal consistency of the Italian RCS-E was assessed using Cronbach alpha with 95% confidence intervals and considered acceptable when Cronbach alpha exceeded 0.700.[26-28] Furthermore, the consistency of the scale was evaluated with intraclass correlation coefficient consistency ($ICC_{consistency}$) and 95% confidence intervals were calculated on the basis of a 2-way random model analysis of variance.[29, 30] Standard error of measurement (SEM) was also estimated. The $ICC_{consistency}$ value was interpreted as follows: less 0.400_poor reliability, 0.400–0.700_moderate to good reliability, and ICC exceeded 0.700_good reliability.[30] To reinforce our data, the Split-Half (odd-even) correlation supported by Spearman-Brown prophecy formula [31, 32] was computed.

Finally, test-retest reliability was defined in a preliminary group of patients undergoing intensive neurological rehabilitation using the $ICC_{agreement}$ 2-way random model with absolute agreement.

The software package "MedCalc version 12.7.4" was used for analysis.[33]

Results

The Italian version of the RCS-E (13th version) is presented in Appendix 1. The forward-back-translation process and further revisions to achieve a culturally-adapted prefinal version of the Italian RCS-E took more than one month's work. Some of the difficulties met during its adaptation and modifications concerned the following items.

Care and risk domain

In the risk instructions, the term "walking wounded" is a typical English idiomatic expression that describes a specific category of patients. This idiomatic expression does not exist in Italian, which led to ambiguous translations (for instance *codici Verdi*). The committee decided to translate "walking wounded" with *disabili deambulanti*. In the same section, it was decided that the most appropriate translation of the word "care" would be *assistenza*.

ITEM R2

English legislation authorises forced hospitalisation or police custody of persons diagnosed with mental disorders. Individuals with mental disabilities can have their disorder assessed or treated against their will. This specific clinical sector is

officially labelled as the MHA section, also unofficially known as "sectioning". In Italy, the equivalent is a specific clinical area called *Salute Mentale*. More specifically, the Psychiatric Diagnosis and Treatment Service (*Servizio Psichiatrico di Diagnosi e Cura*, SPDC) is the name given to the hospital section that is specifically assigned to the treatment and assistance of individuals presenting severe mental disorders. It provides both voluntary and forced (*Trattamento Sanitario Obbligatorio*, TSO) hospitalisation and emergency medical consultations. The MHA section of the R2 item was therefore translated as *Salute Mentale*. And, in the blue explanation, "Mental Health Act" was translated and adapted according to Italian legislation as *Legge sulla salute mentale*.

Item R3

In this case, the specification of "May also be managed under MHA section" was translated and adapted to the Italian Health Service, which assigns this specific type of patients risk to the SPDC (see above), a psychiatric unit of the Mental Health Department.

Nursing domain

The education and training of Italian nurses are fundamentally different to those of English nurses. In Italy, the nursing training program does not include any specialisation in a certain clinical area; rather their basic training is diversified according to their practical experience in different hospital units and/or the awarding of postgraduate certificates. An exception is made for training in the domain of rehabilitation nursing, which relies on practical experience only.

In the section "tick nursing disciplines required", the item "General registered nursing" was substituted with two different nursing disciplines, *personale OSS* meaning "social and health staff" and *Assistenza infermieristica di base* which is "basic nursing care".

Item N0, "skilled nursing", was translated as *infermiere qualificato*, which was considered to be more appropriate for the Italian version and "assistance" is classified as "OSS" in Italy.

Item N1, "qualified nurse", is translated as *Personale infermieristico competente*.

Item N2, "walking/standing practice", is translated as *deambulazione/passaggi posturali*.

Medical needs domain

In order to adapt the original RCS-E to the Italian Heart Service, items pertaining to the medical needs domain were significantly modified.

Item M1

The adapted version of item M1 considers the "community hospital with day time medical cover" as an Italian form of "rehabilitation day hospital". In the translated version, Item M1 was also labelled as "community hospital" but with the meaning of "local care".

Item M2

There is no Italian Health Service equivalent of the District General Hospital (DGH) used in the original English version. The instructions were translated and adapted to a generic *Richiede ricovero per necessità di supervisione medico/infermieristica nelle 24 ore* to describe an inpatient requiring around-the-clock medical and nursing supervision.

No discrepancies were found during the translation of the Therapy and Equipment Needs domains, except for a slight modification in item TI 2 "therapy in-group session", which now specifies ≥3 hours per day.

Based on their personal experience, a group of 10 physicians, working in three different Intensive Rehabilitation Units in Emilia, carried out a face validity judgment of the scale. No significant issues were raised. The doctors ascertained that the prefinal Italian version of the RCS-E (13th version) appeared to be clearly comprehensible and fit for evaluating clinical complexity in neurological code 56 rehabilitation units.

In order to confirm the scale's practicability, the Italian RCS-E was administered to a preliminary sample of patients selected from the intensive (Code 56) rehabilitation units of 3 different hospitals (Azienda Oospedaliero-Universitaria of Parma, Unità Operativa Complessa of Correggio and Casa di Cura San Giacomo, Piacenza). A total of 51 patients participated in the preliminary evaluation of the RCS-E items, 68.6% of the sample was constituted by males

- median age 61.46 (SD 15.24) years, 25th and 75th percentiles 44.25-73.00 years - and the remaining 31.4% by females with a median age of 59.56 (SD 21.34) years and the 25th and 75th percentiles 46.25-78.50 years.

The internal consistency measured by Cronbach's alpha was 0.702 (95% CI=0.550-0.814) and it yielded an $ICC_{consistency}$ (2.5) of 0.702 (95% CI=0.550-0.814), with a SEM of 1.211. The Split-Half was 0.633 and the Spearman-Brown prophecy was estimated to be 0.775.

The scale was administered twice, to a sample of 46 patients (15 women; 31 men, mean age 59.76 years, SD 17.51 years, 25th and 75th percentiles 43.75-77.00 years) and by the same physician, over a one-week period. The test-retest reliability showed very good reproducibility: $ICC_{agreement}$ 0.903 (95% CI = 0.759-0.954).

To sum up the results, the preliminary Italian Version of the RCS-E is now available for clinical practice and further psychometric studies. A multicenter study is under way to assess its psychometric validity.

Discussion

As literature suggests, early acute rehabilitation intervention may have a positive effect on reducing disability, nursing dependency, time to discharge and healthcare costs.[34, 35] When selecting the clinical setting that best meets the patient's specific needs, the "Italian Rehabilitation Guidelines" [4] recommend considering three fundamental dimensions: complexity, disability and comorbidity.

The evaluation of the patient's self-care abilities is currently routinely rated using the B.I., a disability profile scale developed by D.W. Barthel in 1965 [5] and the CIRS, which was developed in 1968 by B. S. Linn,[7] is commonly used to consider medical conditions that exist at the same time as but are independent of another (comorbidity). Difficulties are still encountered, however, when measuring the clinical complexity dimension.

This study presents the translation, cultural adaptation and primary reliability validation of the RCS-E (13th version) in order to validate its Italian version. RCS-E is a very simple objective tool for measuring the clinical complexity dimension in rehabilitation. The processes of translation and back-translation of the Italian RCS-E were carried out in strict observance of established guidelines,[23, 24] in order to obtain a final instrument that faithfully replicates the original scale.

Committee evaluations were crucial for reaching the best equivalence between the target scale and the original tool. In this part of the study, the main difficulty was constituted by discrepancies between words, conceptual meanings and health service structure in the two cultures.

In order to ensure that the translated scale was suitable for clinical use in Italian intensive rehabilitation units, 10 physicians, with no prior experience of the scale, critically evaluated it. Overall, feedback was mainly positive. The adapted scale was considered to be well-structured and easily comprehensible enough to constitute, in this preliminary phase, an instrument that is fit for routine clinical use. The scale took just a few minutes to administer and provided important information on the clinical domains that are crucial when defining the most appropriate rehabilitation profile for the patient, as reported in literature.[20, 21]

It is important to emphasise that assessing the tool with test-retest reliability was of utmost importance in improving the quality of this study and ensuring the validity of the adapted scale for measuring clinical complexity. Test-retest reliability is a statistical technique used to estimate the stability, repeatability and the precision of an instrumental measurement over time. A pilot test and re-test of the prefinal version of the Italian RCE was carried out using a small representative sample of neurological rehabilitation patients. Unfortunately, over a period of seven days, some discrepancies were observed between the sample groups, however the results supported the internal consistency and reproducibility of the scale and, therefore, its goodness of fit.

This pilot study, nevertheless, presents several limits. First, data were collected over a short period on a small sample of patients that was not followed from admission to discharge. As some patients were already hospitalised when the study started, their "initial" RCS-E scores might not reflect their scores at the time of their first admission to hospital. Moreover, by referring to the so-called "Hawthorne effect",[36] one has to consider that physicians might have been more cautious in their ratings when they were aware that their performance was being evaluated. In addition, over a one-week period, the 9.8%

attrition of the test-retest study sample could have artificially inflated (or deflated) reproducibility. Finally, the preliminary analysis performed cannot assess whether the scale actually measured the intended construct.

Nonetheless, the cross-cultural adaptation of the RCS-E appeared to be feasible and successfully reliable.

These preliminary results are part of a larger and multicentre research, supported by the Emilia Romagna Region, entitled "Appropriatezza di ricovero riabilitativo in regime di degenza nella regione emilia romagna: impatto di un sistema alternativo di codifica sull'inappropriatezza in eccesso e sui costi della Regione" and aimed to assess statistical validation of the Italian RCS-E as a possible instrument for guiding, with other appropriate criteria, the patients' assignment to the rehabilitation settings that best suit their specific needs.

Conclusions

Future longitudinal studies should be conducted using larger sample sizes and should attempt to assess whether the Italian RCS-E is able to usefully identify discrepancies between rehabilitation needs and the provision of rehabilitation services, an aspect that was not measured in this pilot study.

Nevertheless, to our knowledge, this is the first reported experience of RCS-E (13th Version) translation and preliminary examination for reliability in Italian.

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APPENDIX 1
Italian Version of the Rehabilitation Complexity Scale - Extended (13th version)

Per ogni sotto-scala, cerchiare il massimo livello applicabile

DOMINIO 1
CURA o RISCHIO
Descrive il livello di assistenza necessaria al paziente per la propria cura personale o per mantenere un'adeguata sicurezza personale.
NB: Se non sei sicuro sulla risposta da registrare, segna entrambe le opzioni "CURA e RISCHIO", ma applica un solo punteggio, quello di score maggiore tra i due.

BISOGNO DI CURE DI BASE E SOSTEGNO
Include l'assistenza per le attività di base (sia in termini di aiuto fisico che di supervisione).
Comprende: lavarsi, vestirsi, igiene, bisogni corporali, alimentazione e nutrizione, mantenimento della sicurezza personale, ecc.

C0	**Ampiamente autosufficiente**. Gestisce i compiti di cura personale in maniera ampiamente autonoma. Può necessitare di assistenza occasionale per iniziare o portare a termine alcune azioni, es. applicare ortesi, legare lacci, ecc.
C1	Richiede l'**aiuto di 1 persona** per la maggior parte dei bisogni di cura di base, ad es. lavarsi, vestirsi, bisogni corporali, ecc. Occasionalmente può richiedere l'aiuto di una 2 persona: per es. solo per un'azione specifica come fare il bagno.
C2	Richiede l'**aiuto di 2 persone** per la maggior parte dei propri bisogni di cura di base.
C3	Richiede l'**aiuto di ≥ 3 persone** per bisogni di cura di base.
C4	Richiede **supervisione costante 1:1** ad es. per gestire la confusione e per mantenere la propria sicurezza.

RISCHIO – LEGATO A BISOGNI COGNITIVO-COMPORTAMENTALI
(Un'assistenza alternativa principalmente per pazienti "Disabili Deambulanti" i quali possono essere capaci di gestire tutti/o la maggiore parte dei propri bisogni assistenziali di base, ma che presentano qualche rischio di sicurezza personale ad es., a causa di confusione, comportamento impulsivo o disturbi neuropsichiatrici).
Include la supervisione per preservare la sicurezza personale o gestire la confusione, ad es. in pazienti che hanno la tendenza a vagabondare, oppure per gestire i bisogni psichiatrici o di salute mentale.

R0	**Nessun rischio – Capace di mantenere la propria sicurezza personale** e **di uscire non accompagnato.** In grado di badare alla propria sicurezza in qualsiasi momento.
R1	**Basso rischio** – Precauzioni standard solo per monitorare la sicurezza all'interno di un ambiente strutturato, **ma richiede accompagnamento** al di fuori del reparto. Mantiene la propria sicurezza personale all'interno di un ambiente strutturato, richiedendo solamente verifiche routinarie, ma richiede accompagnamento quando si trova all'esterno del reparto.
R2	**Rischio medio – Misure di sicurezza aggiuntive** (può essere gestito sotto il controllo di una sezione di Salute Mentale). Misure di sicurezza aggiuntive anche all'interno di un ambiente strutturato, ad es. dispositivi di allarme, sistemi di controllo elettronico (ad es braccialetti di riconoscimento) o monitoraggio superiore allo standard (ad es. 1 o 2 controlli l'ora); OPPURE gestito secondo le regole della Legge sulla salute mentale (TSO, ecc.).
R3	**Rischio elevato – Osservazioni frequenti** (può essere gestito anche da un servizio di Diagnosi e cura). Richiede osservazioni frequenti perfino all'interno di un ambiente strutturato, per es. controlli ogni mezz'ora o ogni ora, oppure supervisione 1:1 per parte/i del giorno/notte.
R4	**Rischio molto elevato** – Richiede **supervisione costante 1:1.** Richiede una supervisione costante 1:1.

DOMINIO 2
BISOGNI INFERMIERISTICI SPECIALIZZATI
Descrive il livello dell'intervento infermieristico qualificato di un infermiere competente/qualificato o specializzato.

		Spuntare le discipline infermieristiche richieste e sotto indicate
N0	Nessuna necessità di cure infermieristiche qualificate – le necessità possono essere soddisfatte dai soli operatori sanitari (OSS)	❏ Personale OSS ❏ Assistenza infermieristica di base
N1	Richiede l'intervento di personale infermieristico competente (competenze di base ed esperienza) es. somministrazione di farmaci, medicazioni di ferite/stomie, monitoraggio infermieristico, nutrizione enterale con sondino nasogastrico, infusione endovenosa ecc.)	❏ Infermiere addestrato in riabilitazione ❏ Infermiere addestrato nei programmi di salute mentale
N2	Richiede l'intervento di personale infermieristico esperto in riabilitazione es. nella gestione di programmi di mantenimento della postura, della deambulazione/posizione eretta, nell'applicazione di splint, nel supporto psicologico.	❏ Assistenza infermieristica palliativa
N3	Richiede assistenza infermieristica altamente specializzata ad es. per bisogni assistenziali molto complessi quali: gestione di tracheostomia; gestione di alterazioni comportamentali (es. comportamenti provocatorio-aggressivi)/psicosi/bisogni psicologici complessi; bisogni posturali, cognitivi e di comunicazione complessi; stati vegetativi o di coscienza minimi, locked-in syndrome	❏ Infermiere specializzato in neurologia (es. morbo di Parkinson, sclerosi multipla, sclerosi laterale amiotrofica)
N4	Richiede assistenza infermieristica altamente specializzata (nursing infermieristico di alto livello e monitoraggio intensivo) es. pazienti clinicamente instabili, che richiedono interventi/monitoraggi frequenti (ogni ora o più spesso) da parte di personale infermieristico qualificato (solitamente anche con competenze specifiche nella somministrazione endovenosa di farmaci, ventilazione meccanica, ecc.).	❏ Altro