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Development of the Italian version of the Consultation and Relational Empathy (CARE) Measure: translation, internal reliability, and construct validity in patients undergoing rehabilitation after total hip and knee arthroplasty

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RUNNING HEAD: Italian CARE measure

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ABSTRACT:

Purpose. To translate and cross-culturally adapt the Consultation and Relational Empathy (CARE) Measure into Italian, examine its internal reliability, and construct validity in a rehabilitation setting.

Materials and methods. The translation process consisted of two forward translations, a pre-final version, a back translation, and a final version, in accordance with available guidelines. We administered the Italian version of the CARE measure to 101 patients hospitalised for rehabilitation after total hip or total knee arthroplasty (THA and TKA). We assessed face validity, internal reliability, and construct validity.

Results. Face validity was high. Patients answered all questions and the 'does not apply' option was never selected. Internal reliability (Cronbach's $\alpha = 0.962$) resulted in line with the original version. The exploratory factor analysis confirmed the unidimensional structure of the CARE measure with 74.82% of variance explained by the first factor.

Conclusions. The Italian version of the CARE measure showed high face validity. Internal reliability and construct validity were in line with the original version in patients undergoing rehabilitation after THA and TKA.

Keywords: empathy; translation; reliability; factor analysis; rehabilitation; arthroplasty

Background

Empathy is the ability to identify with the situation or condition of another person by placing oneself in their situation [1,2]. It is a complex, multi-dimensional concept that has moral, cognitive, emotive, and behavioural components, and has been enriched and understood over the centuries [3].

Empathy has recently emerged as a key factor in health care. It is regarded as being crucial to the development of the therapeutic relationship, which enables individuals to talk about their perceptions of need [4]. It is often referred to as “clinical empathy” and involves not only understanding the patient’s situation, perspective, and feelings, but also communicating this understanding to the patient. [2]. A higher level of empathy in a therapist is associated with better outcomes in psychotherapy [2], and recent studies have demonstrated this association in medical consultations concerning patient satisfaction, enablement, and health outcomes [2,5-7].

Clinical empathy plays an important role in creating a positive relationship between the patient and the therapist [2], and in the context of physiotherapy, a systematic review by Hall et al. [8] concluded that the patient-therapist alliance has a positive effect on treatment outcomes. Hence, the need to measure a therapist’s empathy also in the field of physiotherapy for clinical and research purposes.

The Consultation and Relational Empathy (CARE) measure is one of several instruments available to evaluate a clinician’s empathy [1,9,10]. It has good psychometric properties [1,10], it is quick and easy to use, and the patient has to answer 10 items after a single consultation with a healthcare professional, rating a personal perception of the clinician’s empathy. Each item can be rated from "Poor" (= 1) to "Excellent" (= 5) or "Does not apply" (= 0). Higher scores correspond to greater empathy of the clinician perceived by the patient [10].

The CARE measure was originally developed for use in primary care, with high internal reliability (Cronbach’s $\alpha = 0.93$). The authors evaluated concurrent validity by correlating the CARE measure with two existing empathy scales: the Barret-Lennard empathy subscale (BLESS) and the Reynolds empathy scale (RES). The CARE measure was highly correlated with both BLESS ($r = 0.85$, $p<0.001$) and RES ($r=0.84$, $p<0.001$) [10]. In the context of a second validation study, the developers of the CARE measure validated the scale in a secondary care setting, obtaining a similar internal reliability (Cronbach’s $\alpha = 0.94$). They also performed a factor analysis, which showed that the 10 items of the CARE measure were grouped under one single factor with

high factor loadings, indicating a robust internal structure [11]. Other authors obtained similar results in secondary care [12] and in nursing consultations [13,14].

The original (English) version of the CARE measure was also validated in a rehabilitation setting by Kersten et al. [15]. As their aim was to perform a Rash analysis of the CARE measure, they assessed its internal reliability, and performed a factor analysis. Their sample consisted of a group of 213 patients with hip and knee osteoarthritis undergoing acupuncture sessions while waiting for surgical replacement. The results obtained were similar to those of Mercer et al. [10,11], with a Cronbach's α of 0,97. The factor analysis revealed a strong unidimensional structure with 82% of variance attributable to the first factor and one significant eigenvalue [15].

To date, several validated translations of the CARE measure with appropriate psychometric validity and reliability [16-23] are available, but no valid and reliable measures of empathy have been published in Italian for use in rehabilitation. Hence, the first aim of this study was to translate and culturally adapt the CARE measure into Italian, while the second was to test its face validity, internal reliability, and construct validity on a sample of inpatients undergoing rehabilitation after total hip arthroplasty (THA) and total knee arthroplasty (TKA).

Materials and Methods

Translation of the CARE measure into Italian

The translation process of the CARE measure into Italian followed the guidelines for the process of translation and cross-cultural adaptation of measures [24,25]. We defined a translating committee consisting of three physiotherapists, two physicians, a behavioural researcher, and a native English-speaking language consultant fluent in Italian. Two members of the committee independently developed an Italian version of the CARE measure, thus, obtaining two different translations (T1 and T2). The two members were native Italian speakers and fluent in English with one involved in the healthcare sector. Subsequently, the two translators met to compare the T1 and T2 versions and produce a single Italian translation (T12). A bilingual translator, not involved in health care, with

English as a first language, back translated the Italian version (T12) into English (BT). The original author of the CARE measure read and approved the back-translation (BT) of the CARE measure and gave permission to proceed with the validation process. The translation committee determined the best cross-cultural adaptation and developed a pilot version based on all the Italian versions (T1, T2, T12) and the back-translation (BT).

In the next step, we gave the pilot version to a sample of 10 patients to obtain feedback on the clarity of the items. Patients were asked to write comments about language issues concerning the items. We also noted down any other verbal comments expressed by the patients. The committee developed the final Italian version of the CARE measure on the basis of all the Italian versions (T1, T2, T12), the back-translation (BT) and the patients' feedback from the pilot version.

Study design, inclusion, and exclusion criteria

We administered the CARE Measure to inpatients undergoing rehabilitation at Humanitas Hospital, Milan, Italy, after Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA). Patients began physiotherapy after THA and TKA the day after surgery, and the data were collected at the end of the third day of physiotherapy. We decided to administer the CARE measure to the patients after three days of physiotherapy in order to allow patients time to settle on the ward and overcome any initial post-operative pain or fear that might affect their emotional status. [15]. A physiotherapist involved in the translation process checked patients' eligibility and administered the CARE measure to the enrolled patients. This physiotherapist was not part of the THA and TKA rehabilitation unit of Humanitas Research Hospital, and was therefore unaware of which physiotherapists had treated the patients enrolled in the study. Humanitas Research Hospital Ethical Committee for Human Investigation approved the study protocol (ID: CLF20/05), and all participants signed an informed consent form before data collection.

Inclusion criteria were:

- patients who had undergone THA or TKA surgery four days before

- patients treated by the same physiotherapist in the previous three days
- age > 18 years
- native Italian-speaking

Exclusion criteria were:

- central and peripheral neurological disorders
- severe comorbidities (recent acute cardiac or neurological events, severe liver, kidney, or rheumatic diseases)
- inability to understand the CARE Measure items

Once the patients had signed the informed consent, the physiotherapist explained the aim of the study, asked patients to fill in the CARE measure autonomously, but was on hand for any doubts or help in completing the scale. The physiotherapist also noted down any questions that the patients asked about the CARE items comprehension.

Data analysis

In the validation section of the study, we evaluated face validity, internal reliability and homogeneity of the Italian version of the CARE measure, and performed an exploratory factor analysis to examine the internal structure of the CARE measure in Italian.

Face validity was evaluated by checking for any missing data and any “does not apply” answers. The amount of missing data and “does not apply” answers for every item, inversely correlates with face validity. Face validity was considered acceptable if at least 8 items of the CARE measure had been completed by the patients. [26].

Internal reliability was evaluated through computing Cronbach's α. A value of α between 0.70-0.90 indicates good internal reliability. Values of α higher than 0.90 indicate redundancy, which means that several items ask the same thing in different ways [20]. Homogeneity was

assessed by corrected item-total correlations with values above 0.20 predicting high homogeneity [20].

Previous studies performed factor analyses of the CARE measure and demonstrated that its internal structure is unidimensional with all items coherently grouping under a single construct [11,15]. To confirm these properties in the Italian version of the CARE measure, we performed an exploratory factor analysis (principal components analysis), according to deVet et al. [27]. Factors with eigenvalues greater than one were retained, as stated by Kaiser's rule [28]. We aimed to enrol a minimum of 100 patients, as indicated by the COSMIN recommendations [29].

IBM SPSS Statistics 20 was used to perform all analyses.

Results

One hundred and thirty-seven patients were assessed for eligibility. Of these, 101 were enrolled (Table 1) and 36 were excluded since they had been treated by two or more physiotherapists. Enrolled patients were between 36 and 84 years old (mean age and SD 64.3 ± 9.98), and after signing the informed consent, they completed the CARE measure.

Missing data and "does not apply" answers were not found, indicating excellent face validity (table 2).

Internal reliability was high, with a Cronbach's α of 0.962. When any of the items were deleted, slight reductions in Cronbach's Alpha were noted. Corrected item-total correlations were between 0.800 and 0.883, indicating good homogeneity (table 3).

According to the exploratory factor analysis, the scale showed a unidimensional structure, with 74.82 % of variance explained by a single factor (table 4) and factor loadings between 0.838 and 0.910 (table 5).

Discussion

In this study, we translated and culturally adapted the original version of CARE Measure into

Italian (appendix 1). In Italian culture, the third person singular is mostly used to address the patient. We thus decided to translate the questions of the CARE measure using the third person singular. (table S1). We also used paraphrasing when no translation equivalents were found between English and Italian. In all other cases, we chose a translation that was as close as possible to the original version to avoid adding or removing parts of the items.

Additionally, we also undertook investigation of face validity, internal reliability and construct validity of the Italian version of the CARE measure on patients undergoing in-hospital rehabilitation during the first three days after THA or TKA. Our results are in line with those obtained by the developers of the original version [10,11], with other validation studies of the original (English) version [12-15] and other existing foreign cross-cultural adaptations [19-21,23].

We obtained excellent face validity: in fact, missing data and items answered with 'does not apply' were not found. This result differs from other recent validations [15-21] where a minimal amount of missing data was reported. One possible explanation is the presence of the physiotherapist who administered the CARE measure to the patients and was available for help in case of any doubts. If the physiotherapist had not been there to help with comprehension issues, the patients may have left some items unanswered. However, it is worth noting that all patients answered on their own after having received adequate instructions. More specifically, prior to answering the questionnaire, 20% of the patients asked if they had to evaluate all the staff of the rehabilitation unit (i.e. their physiotherapist, the nurses and physicians) or just their physiotherapist. Once it was clarified that only the physiotherapist had to be evaluated for his/her level of empathy, all patients answered the questionnaire on their own without requiring any further explanation of single items. Another possible explanation is that the patients in our study completed the questionnaire after three days of rehabilitation with the same physiotherapist, while in other validation studies data were collected after a single consultation. Consequently, patients in this study may have answered all the questions as they developed a stronger therapeutic relationship and alliance with their physiotherapist during the three days of treatment.

The Italian version of CARE Measure has good internal reliability, comparable to the results obtained by the developers of the original version [10,11].

Similarly to the original version of the CARE measure [11] and to those adapted in other languages [16,18,20,21] the exploratory factor analysis confirmed that the Italian version of the CARE measure maintains its unidimensional structure, confirming a robust internal structure. Since empathy is a multi-dimensional concept, it could seem in contrast with the unidimensionality measured by factor analysis. However, the unidimensionality of the CARE measure refers to its internal structure, and means that all items are measuring the same latent construct, i.e., the therapist's empathy. The 10 items of the CARE measure do not directly measure empathy but the different behaviours of the clinician that are all correlated to the same latent construct, which is the multi-dimensional concept of empathy (moral, cognitive, emotive and behavioural dimensions).

One limitation of our study is that our sample size is smaller than in other studies of cultural-adaptation and validation of the CARE measure. Nonetheless, we ensured the participation of 100 patients to perform reliable statistical analyses, in line with COSMIN recommendations [29].

A second limitation is that we tested only face validity, internal reliability, and construct validity of the CARE measure. We did not include other psychometric proprieties in this initial study as the aim was to develop a solid Italian translation of the CARE measure by investigating the translation robustness through similarity with the original version of internal reliability and construct validity.

It may be advisable for future studies to first complete the validation testing of the Italian version of the CARE measure on patients undergoing rehabilitation after THA and TKA, adding concurrent validity and test-retest reliability testing. A second step could also be to test this Italian version of the CARE measure on more heterogeneous samples of rehabilitative inpatients and outpatients with diverse pathologies.

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Disclosure Statement

The authors report no conflicts of interest

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Appendix 1 – Italian version of the Consultation and Relational Empathy (CARE) Measure

Prego completi il seguente questionario valutando la visita di oggi.
Metta un segno sopra un solo riquadro per ogni domanda. Risponda per favore a tutte le domande

Come è stato il professionista sanitario nel...	Scarso	Accettabile	Bravo	Molto bravo	Eccellente	Non applicabile
1) Farla sentire a suo agio (Nell'essere cordiale e accogliente verso di lei, nel trattarla con rispetto, senza essere freddo e brusco)	☐	☐	☐	☐	☐	☐
2) Lasciarle raccontare la sua "storia" (Nel darle il tempo per descrivere pienamente il suo problema con parole sue; senza interrompere, senza farle fretta e senza distrarla)	☐	☐	☐	☐	☐	☐
3) Ascoltarla per davvero (Nel prestare molta attenzione a quanto stava dicendo; senza distrarsi guardando gli appunti o il computer mentre lei stava parlando)	☐	☐	☐	☐	☐	☐
4) Essere interessato a lei come persona (Nel chiedere/venire a conoscenza di importanti dettagli della sua vita, della sua situazione; senza trattarla semplicemente come un "numero")	☐	☐	☐	☐	☐	☐
5) Comprendere pienamente le sue preoccupazioni (Nel comunicare di aver pienamente compreso le sue preoccupazioni, senza ignorare o minimizzare nulla)	☐	☐	☐	☐	☐	☐
6) Dimostrare premura e vicinanza (Nel mostrarsi sinceramente interessato alla sua situazione, nel rapportarsi con lei con umanità; senza essere indifferente o "distaccato")	☐	☐	☐	☐	☐	☐
7) Avere un atteggiamento positivo (Nell'avere un comportamento positivo; essendo chiaro, senza atteggiamenti negativi circa i suoi problemi)	☐	☐	☐	☐	☐	☐
8) Spiegare le cose chiaramente (Nel rispondere pienamente alle sue domande; nel dare spiegazioni chiare; nel dare informazioni adeguate; senza essere vago)	☐	☐	☐	☐	☐	☐
9) Aiutarla ad assumere il controllo (Nell'esplorare con lei le sue capacità di migliorare autonomamente la sua salute; nell'incoraggiarla a trovare soluzioni invece di dirle cosa deve fare)	☐	☐	☐	☐	☐	☐
10) Creare un piano di azione con lei (Nel discutere le opzioni, nel coinvolgerla nelle decisioni per quanto desidera, senza ignorare il suo punto di vista)	☐	☐	☐	☐	☐	☐

Table 1. Demographic data

Characteristics of the 101 patients participating in the validation study of the Italian version of the Consultation and Relational Empathy (CARE) measure.

Gender	
n. Males	51
n. Females	50
Intervention	
n. THA (males – females)	71 (38 – 33)
n. TKA (males – females)	30 (13 – 17)
Age	
Mean (SD)	64.30 (9.97)

THA = Total Hip Arthroplasty TKA = Total Knee Arthroplasty; SD = Standard Deviation

Table 2. Distribution of response frequencies (n = 101)

CARE measure item	Poor	Fair	Good	Very good	Excellent	NA	Missing	Total
Making you feel at ease	0	2	18	35	46	0	0	101
Letting you tell your story	0	5	25	36	35	0	0	101
Really listening	0	4	25	34	38	0	0	101
Being interested in you as a whole person	0	4	25	34	38	0	0	101
Fully understanding your concerns	0	3	22	39	37	0	0	101
Showing care and compassion	0	3	15	40	43	0	0	101
Being positive	0	2	20	35	44	0	0	101
Explaining things clearly	0	3	13	33	52	0	0	101
Helping you take control	0	0	20	32	49	0	0	101
Making a plan of action with you	0	4	26	32	39	0	0	101

CARE measure = Consultation and Relational Empathy measure

Table 3. Homogeneity and internal reliability

Cronbach's α = 0.962

CARE measure item	Corrected item-total correlation	Cronbach's α if item deleted
Making you feel at ease	0.807	0.959
Letting you tell your story	0.800	0.959
Really listening	0.858	0.957
Being interested in you as a whole person	0.804	0.959
Fully understanding your concerns	0.844	0.957
Showing care and compassion	0.820	0.958
Being positive	0.883	0.956
Explaining things clearly	0.866	0.957
Helping you take control	0.814	0.959
Making a plan of action with you	0.808	0.959

CARE measure = Consultation and Relational Empathy measure

Table 4. Exploratory factor analysis (principal component analysis) – Total Variance Explained

Number of Factors	Initial Eigenvalues	
	Total	% of Variance
1	7.482	74.820
2	0.574	5.742
3	0.447	4.475
4	0.321	3.208
5	0.311	3.110
6	0.246	2.458
7	0.217	2.172
8	0.156	1.558
9	0.151	1.508
10	0.095	0.949

Table 5. Exploratory factor analysis (principal component analysis) – Factor Loadings

CARE measure item	Factor 1 Eigen value
Making you feel at ease	0.846
Letting you tell your story	0.838
Really listening	0.887
Being interested in you as a whole person	0.842
Fully understanding your concerns	0.876
Showing care and compassion	0.855
Being positive	0.910
Explaining things clearly	0.896
Helping you take control	0.851
Making a plan of action with you	0.846

CARE measure = Consultation and Relational Empathy measure