Assessment of relational empathy with simulated patients: adaptation and validation of a new instrument

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Abstract

Background: Empathy is a crucial competence in the doctor-patient relationship that can be trained to enhance health outcomes. The Consultation and Relational Empathy (CARE) measure assists patients in evaluating empathy of health care professionals. While the CARE measure has received extensive validation for application in primary and specialty care in diverse languages, no version has been adapted and validated for use in simulation contexts. This study aimed at adapting and validating a CARE measure for simulated patients (Sp-SIMCARE).

Methods: The contextual adaptation to simulation contexts was completed in four phases by a panel of five experts, in collaboration with five simulated patients to ensure clarity, relevance, and equivalence in language and content: 1) preparation of a preliminary contextual adaptation proposal; 2) first version drafting; 3) pilot evaluation of the first version with simulated patients; and 4) review and refinement of the Sp-SIMCARE final version. The validation of the new measure was conducted on typical primary care scenarios with simulated patients evaluating performance of undergraduate medical students at the International University of Catalunya (Barcelona, Spain). Simulated patients adopted four prototypical primary care patient roles: a) acute; b) chronic; c) with a high functional component; and d) difficult to deal with. The newly developed scale underwent analysis for convergent validity, acceptability and face validity, homogeneity, and internal reliability.

Results: The adaptation process ensured that the content of the Sp-SIMCARE scale was unambiguous, relevant, and presented in a comprehensive manner, with uniform meanings for all users. Validation was performed via 270 interviews involving 95 students (mean age, 23 years; 62.2% females). The final version demonstrated satisfactory convergent validity (Spearman's rho coefficient of 0.730; $p < 0.001$), high acceptability and face validity (proportion of 'Does not apply' responses/missing values at 1.96%), and strong homogeneity (corrected item-total correlations in the range 0.705 to 0.865), and reliability (Cronbach's alpha of 0.960).

Conclusions: The Sp-SIMCARE measure proved to be psychometrically valid and reliable for simulated patients to evaluate undergraduate medical students. The use of this tool could potentially assist in the design and implementation of interventions aimed at fostering empathy in future doctors throughout their training.

Introduction

Empathy is a critical aspect of the medical doctor-patient relationship to ensure patient satisfaction and adherence to treatment (1). In a clinical context, empathy has been defined as the ability of health care professionals to understand the patient's emotions, situational perspective, and viewpoint; confirm that understanding with them; and then take appropriate action (2). Empathy is also a complex construct that encompasses moral, cognitive, affective, and behavioural dimensions (3). Several studies have suggested that the cognitive aspect of empathy outweighs the affective dimension (4, 5). However, other

research has emphasized a strong correlation between both dimensions (6, 7). Over recent years, the relational dimension of empathy, which involves the objective understanding and sensitivity of medical doctors towards clinical issues raised by patients, has attracted increasing research interest (8–10).

Social neuroscience has recently progressed in identifying that empathy components are based on brain processes consolidated in later developmental stages. These components can be modified through changes in experiences (11). Therefore, empathy is a competency that can be taught and learned, especially in the early stages of medical practice. Training in this competence could enhance health care professionals' and students' ability to provide effective medical care, while improving patients' experiences and engagement (12–14).

Several instruments are available to assess medical doctors' empathy within general practice contexts (15–18). Particularly, the Consultation and Relational Empathy (CARE) measure has remarkable features for evaluating empathy from a relational perspective (19). Furthermore, the CARE scale has been widely implemented for research purposes and for general practitioners' workplace-based appraisal and revalidation in the United Kingdom (20, 21). In addition, this scale has undergone translation and validation in primary and specialized care consultations throughout Europe, North America, and Asia (22–27). Although numerous versions of CARE exist that can be implemented in various health care settings, none have been specifically tailored for application in simulation contexts. The objective of this investigation was to adapt a Spanish version of the CARE measure (Sp-CARE) (28) for use in validation with simulated patients and subsequently, to examine the psychometric properties of the resultant version, Sp-SIMCARE, among undergraduate medical students.

Methods

Design and study population

This study took place at the Faculty of Medicine and Health Sciences of the Universitat Internacional de Catalunya (UIC), located in Barcelona, Spain, during the academic course 2022–2023. The participants included fourth-year undergraduate medical students and simulated patients who were trained in the use of soft skills, such asinterpersonal, communication skills and listening skills, time management, problem-solving, leadership, and empathy, among others, measurement tools and evaluating those skills in students. The study protocol was approved by the Ethics Committee at the study centre (registration MED-2022-07).

The Consultation and Relational Empathy measure

The CARE measure was developed and validated in 2004, showing strong correlation with other empathy-related scales and high internal reliability (Cronbach's alpha, 0.93) (19). The scale consists of 10 items scored on a Likert scale from '1' (poor) to '5' (excellent), with higher scores signifying greater levels of empathy within a range from 10 to 50. Developers of the measure suggest that items 1 to 6 are primarily related to the affective aspect of empathy, whereas the remaining items are related to cognitive and

behavioural aspects (19). An option of 'Does not apply' is also available for each item and can be selected if the item is deemed irrelevant to the consultation. Thus, minimal occurrences of 'Does not apply' or missing responses demonstrate the patients' perceived relevance of the item. To ensure practical application, CARE developers recommend permitting a maximum of two 'Does not apply' or missing responses per measure and disregarding any measure with over two responses of this kind during analysis (20). For up to two non-applicable or missing responses, they suggest scoring those responses with the average score for the remaining items of the measure, a mean-item score. Validation of the CARE measure in 2004 showed strong convergent high internal reliability (Cronbach's alpha, 0.93). In 2020, the CARE measure was adapted and validated for use in primary care consultations conducted in the Spanish language (Sp-CARE) (28), demonstrating high acceptability and face validity (1% of non-applicable or missing response), strong homogeneity (corrected item-total correlations > 0.30), and robust internal reliability (Cronbach's alpha, 0.95).

Contextual adaptation of the Sp-CARE version

The adaptation of the Sp-CARE version to simulation followed a sequential process aimed at maintaining conceptual equivalence within this version and the new Sp-SIMCARE questionnaire. The process consisted of the following phases (see Fig. 1):

Phase 1: Preparation of a preliminary contextual adaptation proposal.

In Phase 1, two specialists in development and validation of competence evaluation scales prepared a proposal for preliminary contextual adaptation.

Phase 2: Sp-SIMCARE first version drafting.

At this stage, a multi-disciplinary panel of five reviewers who had experience in conducting adaptation and psychometric validation of measurement tools, all of them professors at the Faculty of Medicine and Health Sciences at UIC, reviewed all items of the Sp-CARE scale and compared it to each item of the preliminary contextual adaptation proposal. The objective of the comparison was to assess the clarity, relevance, accuracy, and equivalence of meaning of the proposal. Each item of the proposal was classified as either (a) conceptually equivalent and easily comprehensible, (b) functionally equivalent but with semantic discrepancies or comprehension difficulties, or (c) of uncertain equivalence. If an item was classified as (b) or (c), the reviewers were required to clarify the rationale for the mismatch. The first version of Sp-SIMCARE questionnaire was consolidated after resolving the mismatches that had been identified.

Phase 3: Pilot evaluation of Sp-SIMCARE first version with simulated patients

In Phase 3, five simulated patients assessed the first delivery of the Sp-SIMCARE questionnaire and provided responses to supplementary questions concerning comprehension of all items.These simulated patients also highlighted any irrelevant or offensive wording and were given the opportunity to suggest

additional items for inclusion in the questionnaire. Their consultations with simulated patients, coupled with further refinements and improvements they recommended, prompted the rewording of item 7, which was initially described inappropriately.

Phase 4: Review and refinement of the Sp-SIMCARE final version

During Phase 4, the expert panel that had participated in Phase 2 debated on the significance of the comments made by the simulated patients after the pilot evaluation until they reached a consensus, refining the final version of the SP-SIMCARE (see Supplemental Table 1).

Validation of the Sp-SIMCARE questionnaire

The Sp-SIMCARE questionnaire was validated through medical students' clinical interviews with simulated patients. The interviews were structured as a sequence of four scenarios, each portraying a common primary care situation. In these scenarios, students interacted with simulated patients who played the roles of chronic, acute, functional, and difficult-to-deal-with patients. To prevent the sharing of information among students, four different clinical cases were developed for each scenario. All clinical cases could be managed within a primary care setting without the necessity for referral to hospital care. Age and gender of undergraduates and patient simulation scenarios were assessed to identify differences in empathy between groups. Validity and reliability measures evaluated included convergent validity, acceptability and face validity, homogeneity, and internal reliability.

Acceptability and face validity

The scale's acceptability and face validity were evaluated indirectly by the percentage of unanswered non-applicable responses and unanswered items in each survey. Up to two 'Does not apply' or missing responses were considered acceptable for each survey and substituted by the mean score for the remaining items in compliance with the criteria endorsed by the developers of the CARE measure.

Convergent validity

Simulated patients scored undergraduates' level of empathy globally in response to the direct single question of "Is the student empathetic?" on a Likert scale of 1–10, with greater scores reflecting increased empathy. Convergent validity of scores between the Sp-SIMCARE questionnaire and that global score of empathy were assessed by Pearson or Spearman correlations.

Homogeneity

Homogeneity was examined by corrected item-total correlations, where values above 0.30 predict high correlation (29).

Internal reliability

Cronbach's alpha was calculated to assess internal reliability and determine whether removal of any of the 10 items affected the consistency of the Sp-SIMCARE scale. Alpha values above 0.70 were

considered satisfactory (29).

Statistical analysis

Normality of distribution of empathy scores was tested by the Shapiro-Wilk test. The Sp-SIMCARE scores were summarized as mean values and standard deviations or median and interquartile range values according to the normal or skewed distribution of data, respectively, and categorical variables were described as proportions. Comparison of scores by gender, age group, and simulated scenario was performed using the Student t or the Mann-Whitney test (two-group comparison) and the ANOVA or the Kruskal-Wallis test (multi-group comparisons). The level of significance was set at 5% ($p < 0.05$). Data analysis was performed using the statistical package Stata v. 15. All the identifying information of the students was duly anonymized.

Results

The contextual adaptation process ensured the Sp-SIMCARE items were relevant, clearly worded, understandable, and had equivalent meaning for all users. The measures of 27 (9.1%) out of the 297 interviews carried out had three or more non-applicable or missing responses and were excluded from analysis, in line with the criteria recommended by the CARE developers.

The validation procedure involved the examination of 270 interviews that produced a total of 2,700 answers. Ninety-five students with a median age of 22 years (IQR, 22–23), most of whom were female (63.2%), took part in the study. Table 1 presents an overview of the participants' demographics and Sp-SIMCARE scores. The median score was 32.5 (IQR, 29.0–37.0), with scores ranging from 10 to 50. Most of the responses to the individual items of the scale were scored as either 'good' (45.2%) or 'very good' (34.1%). There were no statistically significant in levels of empathy amongst the participants, based on age, gender or the type of simulated patient (see Table 1).

The Sp-SIMCARE questionnaire demonstrated high acceptability and face validity: only 53 (1.96%) out of the total 2,700 responses were 'Does not apply' choices or left blank (see Table 2). Out of 270 surveys, there were 21 (7.8%) with two non-applicable or blank responses, and 11 (4.1%) with one of such responses. The simulated interviews revealed that such responses were most frequent among difficult-to-deal-with patients (32/470, 6.81%), whereas the proportion was notably lower for chronic patients (19/750, 2.53%), and absent for acute or functional patients (see Supplementary Table 2). It was noted that a significant proportion of respondents either selected 'Does not apply' or left blank responses for items 9 'Assist you in taking charge' (26/270, 9.6%) and 10 'Collaborate with you to formulate a plan of action' (23/270, 8.5%). The proportion of non-applicable or missing responses to items 7 (4/270, 1.5%) and 8 (3/270, 1.0%) was much lower. Items 1 to 6 were scored in all surveys.

A significant positive correlation (Spearman's rho coefficient, 0.730; $p < 0.001$) was found between the scores provided by the simulated patients by the Sp-SIMCARE scale and in response to the query "Is the student empathetic?", after confirming the skewed distribution of scores. Corrected item-total correlations

ranged from 0.797 to 0.869, and Cronbach's alpha value for the scale was 0.960, with values for individual items falling within the range of 0.954–0.957 (see Table 3).

Discussion

This study presents evidence of high validity and reliability of a new questionnaire, adapted from the well-known CARE instrument, which standardises the assessment of relational empathy in the context of clinical situations with simulated patients. The psychometric results support this tool as suitable, valid, and potentially useful for use with medical students in such settings. To the best of our knowledge, this is the first validated instrument to assess relational empathy in a simulated setting and for academic purposes.

Based on the results of the study, the new questionnaire demonstrated high acceptability with only 1.96% of 'Not applicable or blank' responses, which is comparable to the 1% observed in the validation of the previous Sp-CARE version (28). This outcome indicates that the interactions generated in the simulation scenarios were realistic, varied, and effectively evaluated using the new questionnaire. Previous studies conducted in other primary care settings have documented a wide spectrum of acceptability and face validity of the original CARE measure and derived versions, with some works reporting similarly low rates of non-applicant or missing responses (25, 28) and others describing much higher percentages (20, 22, 26). The scenarios involving simulated patients difficult to deal with received the highest percentage of 'Not applicable or blank' responses (6.8%). These responses were concentrated in two specific items: 9 (9.6%) and 10 (8.5%). Those percentages were consistent with similar proportions of acceptability and face validity for items 9 and 10 that were reported in earlier research on the CARE measure (19, 22–25). Low acceptability and face validity for the two items was predictable since management of emotions and patient containment prevailed over the expected performance of students when dealing with conflictive patients. In this regard, a previous study even postulated that item 10 should be excluded from scoring when assessing relational empathy, as it may not be an accurate determinant of a medical doctor's empathy, but rather reflect shared decision making (30).

The median Sp-SIMCARE score obtained from our study population (32.5) was significantly lower than mean or median scores (above 40) previously published in CARE validation or implementation studies conducted in European primary care settings (20, 24–25). The notable variation in scores between our and other European studies could be explained by the different study populations under evaluation: our study assessed the performance of undergraduate medical students who had limited prior experience interacting with simulated patients, while other studies evaluated the performance of primary care medical doctors who commonly have regular and intense interactions with their patients and, as a result, are more likely to exhibit empathetic competency. Interestingly, no significant variations were found in Sp-SIMCARE scores based on the gender of undergraduate medical students. This outcome aligns with prior studies, which suggested that the scores by the CARE measure were not substantially affected by either the gender of medical professionals or consultation characteristics (20, 22, 23, 28). Furthermore, although the sample studied here (fourth-year students) may have had an initial imbalance in empathy in favour of

women on entering medical school, this difference could have been compensated for by the training received throughout the years of study, as we showed in (31).

The Sp-SIMCARE questionnaire displayed robust convergence (Spearman's rho coefficient, 0.730) with the scores provided by simulated patients in response to the explicit query "Is the student empathetic?", which were used for global evaluation of the simulation exercise. This outcome indicates that the novel scale measures students' empathy levels in a manner that aligns with the comprehensive assessment of empathy conducted by simulated patients in the four most common types of clinical patients (chronic, acute, functional, and difficult-to-deal with), giving validity to the use of the Sp-SIMCARE scale in different simulation contexts. Overall, corrected item-total correlation values (> 0.797) and Cronbach's alpha values (> 0.954) were high in our study and revealed strong homogeneity and internal reliability of the new tool, in line with values reported for these measures in other previous validation studies of CARE versions (20, 22–25, 28).

The present work logically presents some methodological strengths and limitations. Among the strengths, it is worth highlighting the meticulous sequential process followed to adapt Sp-CARE to the simulation context. Furthermore, the fact that it was tested in different pathology scenarios and by simulated patients with different profiles suggests that the tool has a good usability. In this sense, the scenarios, which had undergone a prior design and validation process by a committee of experts, considered not only different clinical situations, but also different types of patients, including a specific scenario with simulated "difficult-to-deal-with" patients characterized by lack of cooperation or high aggressiveness. One limitation of the study is the absence of an objective gold-standard of relational empathy. Therefore, to assess the convergent validity of the Sp-SIMCARE questionnaire, it was necessary to compare its results with a proxy for the gold standard. In this case, we did not use a validated survey to measure empathy, but instead relied on the simulated patient's self-reported perception of empathy during the clinical encounter. This served as our external standard or criterion. While some may consider this a limitation, it is a commonly used procedure in similar cases. On the other hand, the sample size was small, which restricted the possibility of exploratory and confirmatory factor analyses. Additionally, the origin of the sample, consisting of fourth-year student volunteers, suggests the need for caution when generalizing the results.

The Sp-SIMCARE questionnaire's focus on the relational aspects of empathy provides an advantage. It assesses how empathy translates into concrete actions during simulated interactions, offering valuable insight beyond a subjective and emotional understanding. The questionnaire is particularly sensitive to the complexities of interacting with varied scenarios and patients, including the most difficult ones. Adaptability is crucial in medical training, particularly when testing empathy in challenging clinical situations, such as with conflictive patients. To be highlighted, the use of simulated environments for questionnaire validation is a strategic choice. It provides a controlled and safe environment, ensuring a consistent and fair assessment for all students, especially those who are still learning. This methodology addresses the practical barriers associated with obtaining direct feedback from patients by providing a structured and reproducible assessment. Importantly, the validation of Sp-SIMCARE in advanced medical

students suggests its potential usefulness for assessing relational empathy in other health care professional groups, although further studies are needed to confirm this.

In summary, the Sp-SIMCARE questionnaire proved to be psychometrically valid and reliable for evaluation of undergraduate medical students by simulated patients. The questionnaire's uniqueness lies in its ability to measure the relational dimension of empathy, providing a practical tool for assessing this competence. The use of this new tool could potentially assist in the design and implementation of interventions aimed at fostering empathy in future doctors throughout their training.

Declarations

Ethics approval and consent to participate

Informed Consent was waived by the Institutional Review Board of Clinical Research Ethics Committee of the Universitat Internacional de Catalunya.

Consent for publication

Not applicable

Availability of data and materials

The dataset analysed during the current study is available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors contributions

PB (first co-author): data analysis, interpretation of results, draft manuscript preparation, final manuscript approval

MV (first co-author): study conception and design, data collection, interpretation of results, final manuscript approval

PC: interpretation of results, final manuscript approval

XM: data collection, interpretation of results, final manuscript approval

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Tables

Table 1. Medical students' demographics and Sp-SIMCARE scores by age group, gender, and simulated scenario

Variable	n (%)	Median score (IQR)	p
Age group			0.57
≤ 25 yr	79 (83.2)	32.5 (28.7–36.0)	
> 25 yr	16 (16.8)	33.0 (30.5–34.8)	
Gender			0.49
Male	35 (36.8)	32.4 (29.5–35.8)	
Female	60 (63.2)	33.5 (28.7–36.4)	
Simulation encounters			0.08
Acute patient	74 (27.4)	32.3 (28.0–38.0)	
Chronic patient	75 (27.8)	30.0 (23.0–39.0)	
Functional patient	74 (27.4)	34.0 (29.0–37.0)	
Patient difficult to deal with*	47 (17.4)	30.0 (23.0–39.0)	
* Significant differences (p ≤ 0.001) with the rest of patient groups			

Table 2. Medical students' responses to the Sp-SIMCARE questionnaire

	Poor	Fair	Good	Very Good	Excellent	Blank	Total
Item	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
1. Making you feel at ease	9 (3.3)	25 (9.3)	118 (43.7)	104 (38.5)	14 (5.2)	0 (0,0)	270 (100.0)
2. Letting tell your ´story´	1 (0.4)	20 (7.4)	120 (44.4)	117 (43.3)	12 (4.4)	0 (0,0)	270 (100.0)
3. Really listening	4 (1.5)	22 (8.1)	108 (40.0)	125 (46.3)	11 (4.1)	0 (0,0)	270 (100.0)
4. Being interested in you as a whole person	5 (1.8)	35 (13.0)	119 (44.1)	102 (37.8)	9 (3.3)	0 (0,0)	270 (100.0)
5. Fully understanding your concerns	8 (3.0)	45 (16.7)	133 (49.3)	75 (27.8)	9 (3.3)	0 (0,0)	270 (100.0)
6. Showing care and compassion	7 (2.6)	38 (14.1)	130 (48.1)	87 (32.2)	8 (3.0)	0 (0,0)	270 (100.0)
7. Being positive	7 (2.6)	26 (9.6)	124 (45.9)	100 (37.0)	9 (3.3)	4 (1.5)	270 (100.0)
8. Explaining things clearly	5 (1.8)	40 (14.8)	128 (47.4)	87 (32.2)	10 (3.7)	3 (1,0)	270 (100.0)
9. Helping you to take control	7 (2.6)	49 (18.1)	127 (47.0)	54 (20.0)	7 (2.6)	26 (9.6)	270 (100.0)
10. Making a plan of action with you	9 (3.3)	46 (17.0)	114 (42.2)	69 (25.6)	9 (3.3)	23 (8.5)	270 (100.0)

Table 3. Convergent validity, homogeneity, and internal reliability of the Sp-SIMCARE questionnaire

| Item	Convergent validity*	Scale mean if item deleted	Corrected item-total correlation	Cronbach's alpha
1. Making you feel at ease	0.735	29.00	0.884	0.955
2. Letting tell your ´story´	0.590	28.89	0.827	0.957
3. Really listening	0.590	28.90	0.871	0.955
4. Being interested in you as a whole person	0.589	29.06	0.870	0.955
5. Fully understanding your concerns	0.607	29.21	0.848	0.957
6. Showing care and compassion	0.685	29.14	0.896	0.954
7. Being positive	0.644	29.05	0.850	0.956
8. Explaining things clearly	0.611	29.12	0.856	0.956
9. Helping you to take control	0.593	29.34	0.847	0.957
10. Making a plan of action with you	0.553	29.28	0.840	0.957
* All correlations statistically significant at a p < 0.001				

Figures
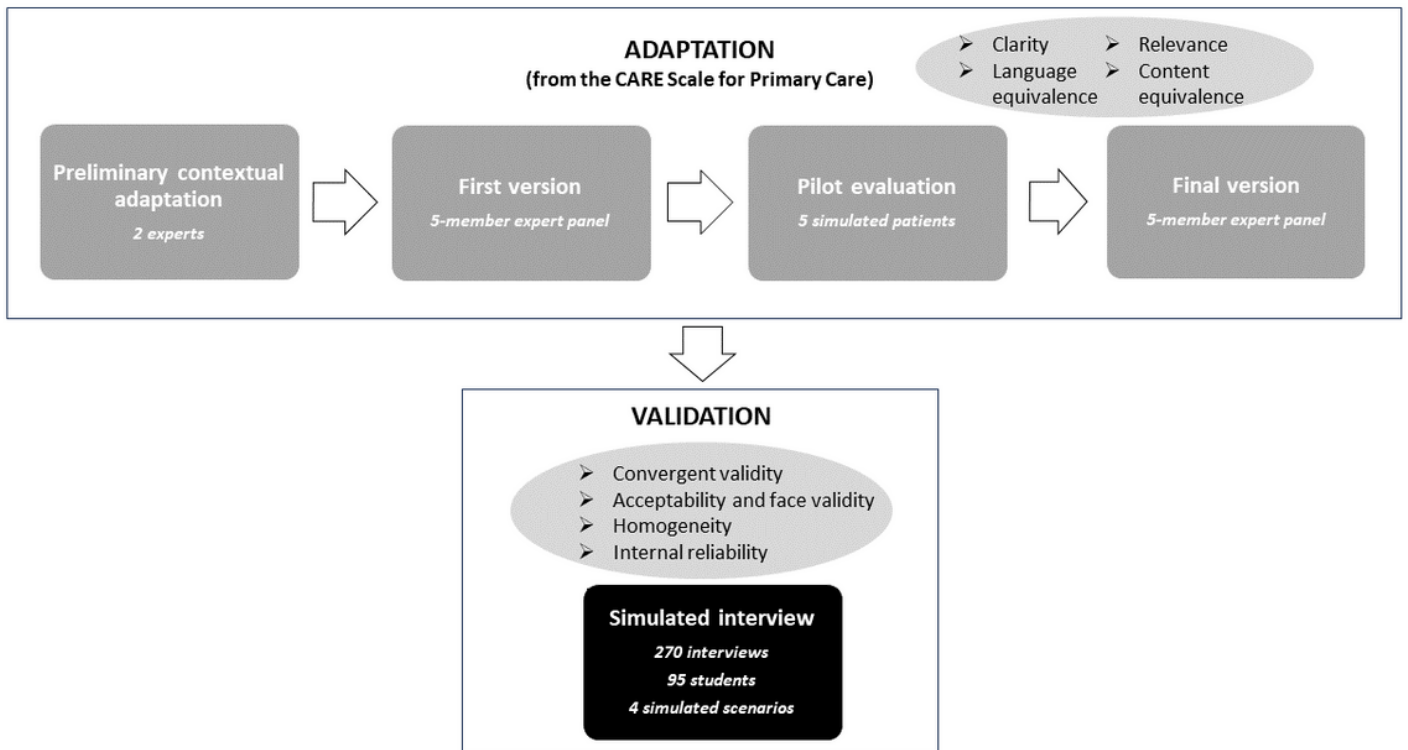
Figure 1

Diagram flow of the Sp-SIMCARE adaptation and validation process

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementalTable1.docx
- SupplementalTable2.docx