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Validity evidence of the Systematic Nutritional Clinical Assessment in individuals undergoing cancer care

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Abstract

Background: Malnutrition is highly prevalent in individuals undergoing cancer care and is associated with worse clinical outcomes, underscoring the need for accurate and standardized nutritional assessment. The Systematic Nutritional Clinical Assessment (SyNCA) was developed to standardize the Nutrition-Focused Physical Examination. **Objective:** To evaluate evidence of internal structure validity and validity based on associations with external variables of the Systematic Nutritional Clinical Assessment (SyNCA) in individuals undergoing cancer care. **Methods:** This psychometric study included individuals aged >20 years undergoing cancer care. Nutritional status was assessed using the SyNCA and the Patient-Generated Subjective Global Assessment (PG-SGA) as reference. Internal structure was examined using Exploratory Factor Analysis, and external validity was assessed through concurrent validity using the area under the ROC curve. **Results:** Among 473 participants (median age: 57 years; 60.5% female), malnutrition prevalence was 36.8% by SyNCA and 45.6% by PG-SGA. A 13-item version of the SyNCA showed a unidimensional structure, explaining 77.8% of total variance, with strong factor loadings (0.75–0.94). Reliability was excellent (Cronbach's $\alpha = 0.97$; McDonald's $\omega = 0.97$), and construct replicability was high (G-H index = 0.90). The instrument demonstrated adequate external validity, as evidenced by good discriminative ability (AUC = 0.84; 95% CI: 0.80–0.88). **Conclusion:** The 13-item SyNCA demonstrates robust internal structure and good external validity, supporting its use for malnutrition assessment in individuals undergoing cancer care.

Keywords: Cancer; Nutrition Assessment; Malnutrition; Validation Study; Psychometrics.

Abbreviations: AUC: area under the receiver operating characteristic curve; CLD: chronic liver disease; ECV: Explained Common Variance; EFA: Exploratory Factor Analysis; EAP: expected a posteriori (marginal reliability); EPTD: Expected Percentage of True Differences; FDI: Factor Determinacy Index; G-H index: Generalized H index; KMO: Kaiser–Meyer–Olkin measure; MIREAL: Mean of Item Residual Absolute Loadings; MSA: Measure of Sampling Adequacy; NFPE: Nutrition-Focused Physical Examination; PG-SGA: Patient-Generated Subjective Global Assessment; SR: Sensitivity Ratio; SyNCA: Systematic Nutritional Clinical Assessment; TVE: total variance explained; UniCo: Unidimensional Congruence.

INTRODUCTION

Malnutrition is a frequent problem among individuals undergoing cancer treatment, with an estimated global prevalence of 41% [1]. However, the occurrence of this condition may vary according to different parameters, such as tumor location and stage, clinical and nutritional history, the presence of comorbidities, as well as the method used to assess nutritional status [2,3].

Several factors contribute to the development of malnutrition in these individuals, particularly the dysregulation of systemic inflammatory mechanisms, which promotes anorexia, reduces energy intake, intensifies muscle catabolism, stimulates lipolysis, and increases the synthesis of acute-phase proteins [4]. Furthermore, malnutrition may compromise therapeutic outcomes by affecting tolerance to antineoplastic treatments, which, consequently, may result in prolonged hospital stays, treatment interruption, and reduced survival [5].

In this scenario, early nutritional assessment of individuals undergoing cancer care is essential to guide appropriate interventions. However, its implementation is often hindered by metabolic and pathophysiological alterations, such as fluid retention, inflammatory status, and increased organ and tumor mass, factors that may compromise the accuracy of traditional methods of nutritional assessment [6,7].

Given these limitations, the Nutrition-Focused Physical Examination (NFPE) stands out among subjective methods used in clinical practice, as it allows the identification of clinical signs related to nutritional deficiencies [8]. However, as a subjective method, it may present limitations and be subject to variability in interpretation among evaluators [9].

Thus, the SyNCA emerges as a proposal to minimize limitations associated with subjectivity by systematizing the NFPE, characterizing it as a low-cost and easy-to-apply instrument. By providing detailed guidance and illustrative figures that support the evaluator's decision-making, it facilitates early diagnosis of malnutrition and the implementation of appropriate nutritional therapy, with a positive impact on prognosis and quality of life [10].

According to the Standards for Educational and Psychological Testing (2014), the appropriate and safe use of an assessment instrument requires robust validity evidence to support its interpretations in the target population. Otherwise, there is a risk of imprecise or biased results that may lead to erroneous conclusions. Furthermore, investigations of such evidence must demonstrate high methodological rigor to ensure reliable interpretations regarding the adequacy of the instrument [11].

The SyNCA has already demonstrated evidence of content validity, obtained through the Delphi method [10], as well as evidence of internal structure validity, reliability, and associations with external variables in a study conducted with hospitalized individuals with chronic liver disease (CLD) [12]. However, it has not yet been tested for nutritional assessment in individuals undergoing cancer care, which limits the generalizability of its interpretations and may restrict its applicability in the oncology setting.

Therefore, this study aims to investigate evidence of internal structure validity and validity based on associations with external variables of the SyNCA in individuals undergoing cancer care, in order to support its clinical applicability for assessing nutritional status in this population.

METHODS

Study design and sample

This was a psychometric study conducted with individuals diagnosed with cancer and followed at a Brazilian philanthropic hospital recognized as a reference center in oncology, between November 2024 and November 2025. A non-probabilistic sample was used, and sample size calculation followed the psychometric recommendation of at least five individuals per instrument item [13–15]. Thus, considering the 14 items of the original version of the SyNCA, a minimum sample size of 70 participants was estimated.

Eligibility criteria

The study included individuals aged over 20 years, of both sexes, admitted to medical wards, in the preoperative period of surgical wards with up to two days of admission, as well as those receiving outpatient care.

The inclusion of individuals with different tumor sites, treated in both hospital and outpatient settings, aimed to ensure sample heterogeneity and expand the applicability of the instrument to individuals undergoing cancer care across diverse clinical contexts. In addition, hospitalized individuals were assessed within the first 48 hours of admission to minimize the effects of clinical and nutritional interventions performed during hospitalization, thereby avoiding potential interference in the diagnosis of nutritional status established by the instrument tested in this study.

Patients with physical limitations that precluded the application of nutritional assessment instruments, those under respiratory or contact isolation, and those hospitalized for graft or flap surgery were not included.

Participants with incomplete SyNCA data, and those without a defined primary cancer site were not included.

Ethical approval

This study was approved by the Research Ethics Committee of the School of Nutrition at the Federal University of Bahia, the proposing institution (approval no. 7.110.913), and by the Research Ethics Committee of the Liga Bahiana Contra o Câncer / Aristides Maltez Hospital, the participating institution (approval no. 7.125.952). All eligible participants voluntarily signed an informed consent form after receiving appropriate information about the study.

Data collection

Data collection was conducted by nutritionists and undergraduate nutrition students, previously trained to ensure standardization of the assessment procedures established in the study protocol. This process was carried out through face-to-face interviews with participants and consultation of electronic medical records, in which sociodemographic, clinical, and nutritional data were recorded using a semi-structured form.

The sociodemographic data collected included age, sex, and race/skin color. Clinical data obtained from electronic medical records included primary tumor site, time since diagnosis, and type of care. To minimize inconsistencies, clinical information from medical records was based on medical notes, prioritizing the most recent available data.

Systematic Nutritional Clinical Assessment

Initially, the SyNCA was administered using a printed questionnaire and conducted entirely by a single evaluator. This instrument examines body segments in detail, considering specific muscles, adipose tissue, bony structures, and the presence of cutaneous oedema in the lower limbs, following standardized clinical maneuvers. Inspection and palpation procedures were performed according to recommended positioning, with the aid of illustrative figures to ensure standardization and accuracy in identifying signs of muscle and subcutaneous fat depletion [10].

The scoring of each item, representing a body segment, followed a scale with possible values of 0, 2, 4, or 6 points, corresponding to no signs of depletion, mild depletion, moderate depletion, and severe depletion, respectively. The Body Depletion Index was obtained by summing the scores of all assessed regions and classified into quartiles representing different levels of nutritional depletion: none (0–21 points), mild (22–42 points), moderate (43–63 points), and severe (64–84 points). Based on this classification, the nutritional diagnosis of the evaluated individual was established [10].

The original version of the SyNCA consists of 14 items representing body segments, organized into five anatomical regions: face, frontal trunk, dorsal trunk, upper limbs, and lower limbs. This organization serves an

exclusively didactic purpose, facilitating the standardization of the clinical assessment, without implying that each anatomical region represents distinct domains within the instrument's internal structure. Despite this application structure, the instrument assesses a single dimension corresponding to the construct of malnutrition. The items included in the original version of the SyNCA are presented in **(Table 1)** [10].

Table 1. Anatomical regions and items of the original version of the SyNCA.

Anatomical region 1: Face
Item 1: Temporal (temporalis muscle)
Item 2: Masseter (chewing muscle)
Item 3: Bichat's fat pad (buccal fat pad)
Item 4: Zygomatic arch and mandible lines
Anatomical region 2: Frontal Trunk
Item 5: Trapezius and Pectoralis Major (muscles covering shoulder, clavicle, and chest)
Item 6: Intercostal muscles (muscles covering ribs and around sternum)
Anatomical region 3: Dorsal Trunk
Item 7: Deltoid muscle (muscle covering acromion, acromial angle of the scapula, and upper humerus)
Anatomical region 4: Upper limbs
Item 8: Biceps and Triceps (arm muscles)
Item 9: Adductor muscle of the thumb
Item 10: Dorsum of the hands, interosseous muscles
Anatomical region 5: Lower limbs
Item 11: Quadriceps (muscles located on the anterior thigh)
Item 12: Gastrocnemius (back of leg below knees)
Item 13: General inspection of the lower limb bone structures: hips, legs, knees and feet
Item 14: Presence of cutaneous oedema in the lower limbs

Patient-Generated Subjective Global Assessment (PG-SGA)

The PG-SGA was administered after the SyNCA by the same evaluator to avoid influencing the assessment of SyNCA items. This instrument consists of two stages. The first assesses unintentional weight loss, changes in food intake, presence of nutrition-impact symptoms, and changes in functional capacity. The second stage evaluates disease-related factors that may increase nutritional requirements and metabolic demand, including the physical examination. At the end, the total score allows classification of nutritional status as well-nourished (A), moderately malnourished (B), or severely malnourished (C) [16–18].

Statistical analysis

Sample characterization was performed through descriptive analysis of sociodemographic, clinical, and nutritional data. Categorical variables were presented as absolute (n) and relative (%) frequencies. The normality of continuous variables was assessed using the Shapiro–Wilk test and, according to data distribution, results were expressed as mean and standard deviation (SD) or median and interquartile range (IQR).

In this study, the methodological recommendations of the Standards [11], were followed, including the analysis of evidence of internal structure validity and validity based on associations with external variables, as described below.

Evidence of Internal Structure Validity

Exploratory Factor Analysis (EFA) was performed to investigate the internal structure of the SyNCA. The correlation matrix was constructed using polychoric correlations, as the instrument items are graded on ordinal data (Likert-type scale). For inspection of correlations within the matrix, values of 0.30 and 0.70 were adopted. Values below 0.30 were considered low correlations and those above 0.70 as high correlations [14].

Data extraction was performed using the robust unweighted least squares method [19]. Robust Promin rotation was considered as a methodological option for solutions with more than one dimension. However, when a unidimensional structure was indicated, the analysis was conducted without rotation [20].

Before performing EFA, tests were applied to verify whether methodological assumptions were met. For data factorability, Kaiser–Meyer–Olkin (KMO) values > 0.70 and Bartlett’s sphericity test $p < 0.05$ were considered [14]. Sample adequacy was assessed using the Measure of Sampling Adequacy (MSA), considering values ≥ 0.50 as adequate, and by the determinant of the correlation matrix, which should be < 0.00001 [21,22].

The number of factors to retain was determined using the optimized implementation of Parallel Analysis [23], and total variance explained (TVE) $\geq 60\%$ was considered adequate [14]. Once unidimensionality was indicated, confirmatory indices of unidimensionality were evaluated, including UniCO (Unidimensional Congruence) ≥ 0.95 , ECV (Explained Common Variance) ≥ 0.85 , and MIREAL (Mean of Item Residual Absolute Loadings) ≤ 0.30 [24]. Factor loadings and communalities above 0.50 were considered adequate, confirming the items retained in the model [14].

To assess instrument reliability, Cronbach's alpha (α) and McDonald's omega (ω) coefficients were used, with values > 0.70 considered adequate [14,25]. Construct replicability was evaluated using the Generalized G-H Index, with values > 0.80 considered acceptable [26].

Finally, indices of quality and effectiveness of item score estimates were evaluated considering Factor Determinacy Index (FDI) > 0.90 , EAP marginal reliability > 0.80 , Sensitivity Ratio (SR) > 2 , and Expected Percentage of True Differences (EPTD) $> 90\%$ [24].

Validity Evidence Based on Associations with External Variables

Validity based on associations with external variables was assessed through concurrent criterion validity, considering that SyNCA and PG-SGA evaluate the same construct, malnutrition, and that the PG-SGA was adopted as the reference instrument for the oncology population [6,27]. The analysis was performed using the area under the ROC curve, with dichotomization of PG-SGA classifications (A vs. B/C) and use of the continuous SyNCA score, being considered adequate when the area under the ROC curve was ≥ 0.70 [28].

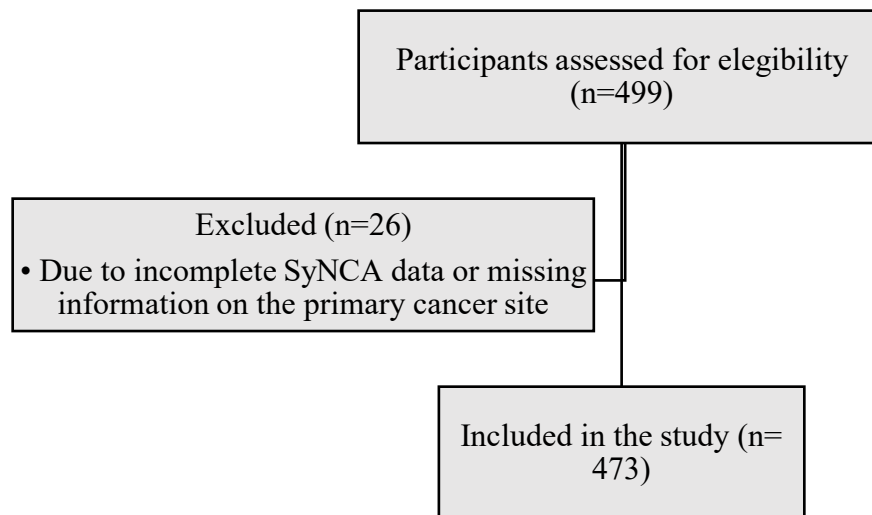
Data for descriptive analysis and validity based on associations with external variables were analyzed using JASP software (v. 0.95.3), while internal structure validity analysis was conducted using Factor software (version 12.06.08) [29–32].

RESULTS

Characteristics of the study population

The participant flow chart is presented in **(Figure 1)**, and the sociodemographic and clinical characteristics of the 473 evaluated participants are summarized in **(Table 2)**.

165 **Figure 1 – Participant flow chart of the study.**



166 The median age was 57 (IQR: 48-65) years, with a higher proportion of females (60.5%) and individuals self-
 167 identified as black/brown (84.8%). Breast cancer was the most frequent (31.1%), followed by gastrointestinal
 168 (19.5%) and head and neck cancers (18.8%). Most patients had a time since diagnosis of less than one year (50.1%)
 169 and were hospitalized in the preoperative period (52.4%).

170 **Table 2. Sample characteristics.**

	Median (IQR)	n (%)
Age (years)	57.0 (48.0 – 65.0)	
< 60 years		278 (58.8)
≥ 60 years		195 (41.2)
Sex		
Male		187 (39.5)
Female		286 (60.5)
Race/skin color		
Black/brown		401 (84.8)
White		55 (11.6)
Others*		17 (3.6)
Primary tumor site		
Breast		147 (31.0)

Gastrointestinal tract	92 (19.5)
Head and neck	89 (18.8)
Prostate	58 (12.3)
Gynecological	34 (7.2)
Hematological	9 (1.9)
Bone and soft tissue	9 (1.9)
Lung	7 (1.5)
Others**	28 (5.9)
Time since diagnosis (months)	12.0 (5.0 – 27.0)
< 1 year	231 (50.1)
≥ 1 to < 5 years	170 (36.9)
≥ 5 years	60 (13.0)
Type of care	
Medical hospitalization	34 (7.2)
Surgical hospitalization (preoperative)	248 (52.4)
Outpatient care	191 (40.4)

171 *: Indigenous and Asian; **: Kidney and urinary tract, male genital organs, peritoneum, pelvis, mediastinum
172 and unknown or unspecified primary site.

173 Measures of central tendency and dispersion for SyNCA and PG-SGA scores, as well as the frequency of patients
174 according to the classification categories established by each instrument, are presented in **(Table 3)**. The
175 prevalence of malnutrition was 36.8% according to the SyNCA and 45.6% according to the PG-SGA.

176 **Table 3. Descriptive measures and nutritional status classification according to the SyNCA and PG-SGA.**

Instrument	Mean (SD)	Median (IQR)	Min-max.	n (%)
SyNCA	19.8 (18.4)	14.0 (6.0 – 30.0)	0 – 80	
No malnutrition				299 (63.2)
Mild malnutrition				113 (23.9)
Moderate malnutrition				46 (9.7)

Severe malnutrition	15 (3.2)
PG-SGA	8.3 (6.0) 7.0 (3.0 – 12.0) 1 – 31
A	257 (54.3)
B	168 (35.5)
C	48 (10.1)

177 SyNCA: Systematic Nutritional Clinical Assessment; PG-SGA: Patient-Generated Subjective Global Assessment;

178 SD: Standard Deviation; IQR: Interquartile Range.

179 The frequency of scores assigned to each SyNCA item is presented in **(Table 4)**. All items received each of the
180 possible scores at least once, indicating that all response categories were represented in the sample.

181 The items with the highest frequencies of the minimum score (0 points), indicating absence of depletion, were
182 item 14 (82.2%) and item 10 (67.4%), while the lowest proportions were observed for items 8 (31.0%) and 1
183 (39.5%). In contrast, the maximum score (6 points), dicative of the highest degree of depletion, was most frequent
184 for items 5 (8.2%) and 8 (7.6%), whereas items 14 (0.2%) and 10 (1.0%) showed the lowest frequencies for this
185 score.

186 **Table 4. Frequency of scores assigned across SyNCA items.**

Items	Score				Total
	0	2	4	6	
Item 1	188	154	98	33	473
Item 2	244	136	79	14	473
Item 3	240	139	71	23	473
Item 4	227	147	74	25	473
Item 5	217	111	106	39	473
Item 6	272	94	80	27	473
Item 7	215	124	105	29	473
Item 8	147	179	111	36	473
Item 9	273	134	58	8	473
Item 10	319	105	44	5	473

Item 11	203	172	76	22	473
Item 12	296	107	55	15	473
Item 13	300	111	46	16	473
Item 14	389	68	15	1	473

187 SyNCA: Systematic Nutritional Clinical Assessment.

188 Evidence of Internal Structure Validity

189 Initially, an EFA was conducted on the original 14-item version of the SyNCA. The Bartlett's test of sphericity
190 ($\chi^2 = 5370.8$, $df = 91$, $p = 0.00001$) and the Kaiser-Meyer-Olkin (KMO) index = 0.93255, calculated from a
191 polychoric correlation matrix, confirmed the factorability of the data. Additionally, the determinant of the
192 correlation matrix fell within the expected range, indicating no issues of collinearity among the items (**Table 5**).

193 **Table 5. Polychoric correlation matrix of the 14-item SyNCA.**

Item s	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	1.00 0													
2	0.77 2	1.00 0												
3	0.79 0	0.79 3	1.00 0											
4	0.83 6	0.83 9	0.87 4	1.00 0										
5	0.75 3	0.77 3	0.78 0	0.80 5	1.00 0									
6	0.75 3	0.73 3	0.79 4	0.80 9	0.89 6	1.00 0								
7	0.65 9	0.72 8	0.65 6	0.71 2	0.83 8	0.80 7	1.00 0							
8	0.52 9	0.58 8	0.49 3	0.54 3	0.66 9	0.62 9	0.81 9	1.00 0						
9	0.58 7	0.58 6	0.46 3	0.54 7	0.65 7	0.57 6	0.67 1	0.66 1	1.00 0					
10	0.64 2	0.65 0	0.58 1	0.65 1	0.71 6	0.66 9	0.72 7	0.68 6	0.80 8	1.00 0				
11	0.62 0	0.68 9	0.58 1	0.66 8	0.73 3	0.74 2	0.78 2	0.75 5	0.65 5	0.72 6	1.00 0			
12	0.66 3	0.64 5	0.64 0	0.65 1	0.73 6	0.76 4	0.77 3	0.69 8	0.67 6	0.70 6	0.82 5	1.00 0		
13	0.69 7	0.73 1	0.75 2	0.78 2	0.81 7	0.85 7	0.86 0	0.75 2	0.63 8	0.76 9	0.87 1	0.87 4	1.00 0	
14	0.07 0	0.11 9	0.12 3	0.06 1	0.07 2	0.05 3	0.04 8	0.07 9	0.12 5	0.06 2	- 0.00 6	- 0.00 9	0.05 5	1.00 0

194 Determinant of the correlation matrix: < 0.000001.

Although the data from the original version of the SyNCA demonstrated satisfactory factorability, the analysis of item adequacy indices identified that item 14 (presence of cutaneous oedema in the lower limbs) had an MSA = 0.30064, a value considered inadequate, as it was below the threshold of 0.50 [21]. This result indicates that the item does not assess the same domain as the others; therefore, it was decided to remove it, since its inclusion could introduce bias into the analysis (Table 6).

Table 6. Measure of Sampling Adequacy (MSA) for the 14-item SyNCA.

Items	Normalized MSA	95% CI (bootstrap)
1	0.95343	0.845 – 0.966
2	0.95799	0.835 – 0.968
3	0.94892	0.838 – 0.961
4	0.92666	0.763 – 0.945
5	0.94175	0.851 – 0.958
6	0.94224	0.847 – 0.951
7	0.93795	0.810 – 0.950
8	0.94156	0.825 – 0.955
9	0.89063	0.711 – 0.919
10	0.92496	0.744 – 0.946
11	0.95522	0.834 – 0.963
12	0.92900	0.776 – 0.949
13	0.89959	0.739 – 0.927
14	0.30064	0.061 – 0.671

MSA: Measure of Sampling Adequacy; CI: Confidence Interval.

After the exclusion of item 14, a new EFA was conducted using the updated model, now consisting of 13 items. In this analysis, Bartlett's test of sphericity = 5374.6 (df = 78; $p = 0.000010$) and the KMO index = 0.93797, calculated from the polychoric matrix, again demonstrated adequate factorability of the data. The determinant of the correlation matrix was appropriate and did not indicate any collinearity issues, confirming suitability for conducting the EFA (Table 7).

207 **Table 7. Polychoric correlation matrix of the 13-item SyNCA model.**

Item s	1	2	3	4	5	6	7	8	9	10	11	12	13
1	1.00 0												
2	0.77 2	1.00 0											
3	0.79 0	0.79 3	1.00 0										
4	0.83 6	0.83 9	0.87 4	1.00 0									
5	0.75 3	0.77 3	0.78 0	0.80 5	1.00 0								
6	0.75 3	0.73 3	0.79 4	0.80 9	0.89 6	1.00 0							
7	0.65 9	0.72 8	0.65 6	0.71 2	0.83 8	0.80 7	1.00 0						
8	0.52 9	0.58 8	0.49 3	0.54 3	0.66 9	0.62 9	0.81 9	1.00 0					
9	0.58 7	0.58 6	0.46 3	0.54 7	0.65 7	0.57 6	0.67 1	0.66 1	1.00 0				
10	0.64 2	0.65 0	0.58 1	0.65 1	0.71 6	0.66 9	0.72 7	0.68 6	0.80 8	1.00 0			
11	0.62 0	0.68 9	0.58 1	0.66 8	0.73 3	0.74 2	0.78 2	0.75 5	0.65 5	0.72 6	1.00 0		
12	0.66 3	0.64 5	0.64 0	0.65 1	0.73 6	0.76 4	0.77 3	0.69 8	0.67 6	0.70 6	0.82 5	1.00 0	
13	0.69 7	0.73 1	0.75 2	0.78 2	0.81 7	0.85 7	0.86 0	0.75 2	0.63 8	0.76 9	0.87 1	0.87 4	1.00 0

208 Determinant of the correlation matrix: < 0.000001.

209 The polychoric correlation matrix of the new model showed no low correlations, with most correlations being
 210 high, particularly between item pairs 5 and 6 (0.896), 3 and 4 (0.874), and 12 and 13 (0.874). The lowest
 211 correlations were observed between items 3 and 9 (0.463), 3 and 8 (0.493), and 1 and 8 (0.529).

212 The parallel analysis by Timmerman and Lorenzo-Seva [23], presented in **(Table 8)**, indicated that retaining a
 213 single factor was the most appropriate solution for the data (TVE = 76.28%), demonstrating the unidimensionality
 214 of the SyNCA.

215 **Table 8. Parallel analysis of the 13-item SyNCA model.**

Factors	% Variance Explained (Real Data)	% Variance Explained (Random Data, 95% CI)
1	76.2881*	18.3111
2	8.0143	16.2613

3	4.3117	14.6064
4	2.8094	12.7126
5	2.2668	11.3054
6	1.6853	10.1055
7	1.4233	8.7969
8	1.1692	7.8253
9	0.9144	6.5835
10	0.6320	5.4679
11	0.4206	4.1712
12	0.0649	2.9531

*Note: Only one factor was retained, as it is the only factor for which the percentage of Total Variance Explained (TVE) in the real data exceeds that of the random data.

The retention of a single factor precluded the use of rotation methods, so the unrotated matrix was used. This solution confirmed the unidimensional structure of the SyNCA, with the 13 items showing factor loadings ranging from 0.752 to 0.935 and communalities between 0.565 and 0.874, indicating suitability for retaining the revised model, as shown in **(Table 9)**. The unidimensionality of the new 13-item version of the SyNCA was further confirmed by the UniCo (0.991), ECV (0.911), and MIREAL (0.246) indices, as presented in **(Table 10)**.

Table 9. Factor solution using the unrotated matrix for the new 13-item SyNCA model.

Items	Factor loading	Communality
1	0.828	0.686
2	0.848	0.720
3	0.864	0.746
4	0.904	0.818
5	0.913	0.833
6	0.913	0.833
7	0.898	0.806
8	0.788	0.622

9	0.752	0.565
10	0.825	0.681
11	0.865	0.748
12	0.862	0.744
13	0.935	0.874

224 Additionally, the instrument demonstrated excellent construct replicability (observed G-H = 0.896) and adequate
225 reliability, with high internal consistency evidenced by Cronbach's alpha ($\alpha = 0.970$) and McDonald's omega (ω
226 = 0.973). Excellent indices of quality and effectiveness of the factor score estimates were also observed, with high
227 values for FDI (0.989), EAP marginal reliability (0.978), SR (6.648), and EPTD (97.6%) (Table 10).

228 **Table 10. Indices of unidimensionality, construct replicability, reliability, and quality of the SyNCA 13-**
229 **item model.**

Total Variance Explained (%)	76.2881
Unidimensionality Indices	
UniCo (95% CI)	0.991 (0.987 – 0.995)
ECV (95% CI)	0.911 (0.897 – 0.929)
MIREAL (95% CI)	0.246 (0.216 – 0.271)
Construct Replicability	
G-H Index – latent (95% CI)	0.978 (0.973 – 0.982)
G-H Index – observed (95% CI)	0.896 (0.875 – 0.912)
Reliability Indices	
Cronbach's alpha (α)	0.970
McDonald's omega (ω)	0.973
Quality and Effectiveness of Factor Score Estimates	
FDI	0.989
EAP marginal reliability	0.978
SR	6.648
EPTD (%)	97.6

SyNCA: Systematic Nutritional Clinical Assessment; CI: Confidence Interval; UniCo: Unidimensional Congruence; ECV: Explained Common Variance; MIREAL: Mean of Item Residual Absolute Loadings; FDI: Factor Determinancy Index; EAP: EAP marginal reliability; SR: Sensitivity Ratio; EPTD: Expected Percentage of True Differences.

Validity Evidence Based on Associations with External Variables

The external association validity of the SyNCA was assessed by comparing its results with those of the Patient-Generated Subjective Global Assessment (PG-SGA). The area under the ROC curve was 0.84 (95% CI: 0.80–0.88; $p < 0.001$), indicating good concurrent validity of this instrument.

DISCUSSION

The findings of this study indicate that the 13-item version of the SyNCA exhibits a unidimensional, adequate, consistent, and reliable internal structure, in addition to robust external validity when compared to the PG-SGA, reinforcing its applicability for assessing malnutrition in individuals in the oncological context.

Evidence of Internal Structure Validity

It should be noted that the SyNCA is a novel instrument developed by our research group, and to date, there is only one study that investigated its validity evidence, conducted with hospitalized individuals with CLD [12]. However, the EFA performed in that study used a different analytical approach, which limits some comparisons with the present work. Therefore, to enhance the analyses, this study incorporated additional indicators for evaluating the internal structure, including construct replicability, indices of quality and effectiveness, and reliability estimated by McDonald's omega.

In Arruda's study [12], the reliability of the SyNCA was considered adequate according to Cronbach's alpha. However, despite its widespread use, this analysis assumes that all items contribute equally to the construct, which is not always realistic. From this perspective, McDonald's omega provides a more robust alternative, as it accounts for the actual factor loadings obtained in factor analysis, offering a more precise estimate of reliability, especially when items contribute unequally to the construct [33–35].

In the internal structure analysis of the SyNCA in individuals with CLD, the EFA indicated the presence of three factors, with a TVE of 73.31% [12]. In contrast, in the present study, parallel analysis and unidimensionality indices demonstrated that a unidimensional solution was more appropriate. This discrepancy between findings may be explained by differences in the populations studied, the analytical methods employed, and the decision criteria applied during the EFA.

In the present study, the removal of item 14 was supported by psychometric indicators. From a theoretical standpoint, the inadequacy of this item is also justifiable, as oedema does not represent a body compartment but a clinical manifestation characterized by the accumulation of interstitial fluid in the tissues, resulting from hydroelectrolytic, inflammatory, or hemodynamic alterations, and which may present locally, generally, unilaterally, or bilaterally [36]. Thus, item 14 differs from the others, which directly assess muscle or adipose tissue mass, and its retention could compromise the theoretical coherence of the model. After its exclusion, the new 13-item EFA reinforced the appropriateness of this decision, as Bartlett's test of sphericity and the KMO index indicated excellent factorability, strengthening the structural robustness of the 13-item SyNCA version.

In the original development study of the SyNCA, which analyzed content validity evidence, Jesus et al., [10] considered hospitalized patients with chronic diseases as the target population, including those with CLD, who frequently present fluid retention and oedema during hospitalization. This likely contributed to the Delphi panel expert's consideration of the item "Presence of cutaneous oedema in the lower limbs" as relevant.

Thus, although the validation study of the SyNCA in individuals with CLD found that item 14 showed low correlation with the other items, the authors justified its inclusion by arguing that it addressed the need to detect clinical manifestations common in this patient profile [12].

In contrast to patients with CLD, where oedema is a frequent clinical sign, this manifestation was rare in the oncological population assessed. In this study, item 14 exhibited the highest frequency of minimum scores and the lowest frequency of maximum scores, indicating minimal occurrence of oedema and further supporting its removal. This highlights the importance and need for studies investigating validity evidence of nutritional assessment instruments in individuals with chronic diseases across diverse clinical contexts.

Additionally, within the EFA, it was observed that the item pairs with the highest correlations in the polychoric matrix of the new SyNCA model corresponded to items positioned adjacently within the instrument and belonging to the same anatomical regions, reinforcing their theoretical-conceptual proximity. This pattern was observed

between items 5 and 6, both in the “Frontal trunk” section; items 3 and 4, in the “Face” section; and items 12 and 13, in the “Lower limbs” section.

Despite these strong correlations, the determinant of the correlation matrix remained adequate, indicating the absence of multicollinearity. In other words, these items, although conceptually close, do not measure exactly the same phenomenon, preserving sufficient variability to support the factorability of the data.

Conversely, the lowest correlations occurred among the pairs 3 and 9, 3 and 8, and 1 and 8, which represent anatomically distant regions within the structure of the instrument. This pattern suggests that anatomical proximity contributes to higher correlations between SyNCA items, while items from distinct anatomical regions tend to correlate more modestly.

It is noteworthy that in the present study, the analysis of the SyNCA’s internal structure demonstrated good construct replicability, indicating instrument stability and consistency of the latent variable. This finding shows that there is no need to conduct test-retest reliability assessments, either intra-rater or inter-rater [33].

Validity Evidence Based on Associations with External Variables

The next stage of this study addressed the external validity of the SyNCA, which demonstrated good concurrent validity when compared directly with the PG-SGA, a well-established reference method for nutritional assessment in patients undergoing oncological follow-up. To date, no studies have been identified in the literature that investigate this particular validity evidence for the SyNCA, which limits direct comparison of the results of the present study with similar investigations.

A scoping review published in 2024, which examined valid and reliable instruments for assessing the nutritional status of individuals under oncological follow-up, identified the PG-SGA as the most widely used nutritional assessment method [37]. Within this context, the literature presents several validation studies using the PG-SGA as a reference method, although most of these studies involve nutritional screening instruments rather than full nutritional assessment tools, as is the case with the SyNCA [38].

For example, the Malnutrition Screening Tool (MST) is a nutritional screening instrument with good evidence of validity for oncology patients, although it was originally developed for acutely hospitalized patients. This tool consists of only two questions regarding weight loss and reduced food intake [39]. Accordingly, Arribas et al.

[40] conducted a study with adults undergoing outpatient cancer care and observed adequate performance of the MST in identifying nutritional risk, using the PG-SGA as the reference method.

Similar results were observed by Shaw et al. [41], in hospitalized oncology patients and by Abbott et al. [42], in adults undergoing outpatient antineoplastic treatment, both demonstrating adequate performance of the MST. Conversely, in a multicenter Chinese study conducted by Kang et al. [43], the MST showed low performance when compared with the PG-SGA.

Seeking to improve the MST, Arribas et al. [40] developed the NUTRISCORE as a nutritional screening method specifically for outpatient oncology patients. In addition to questions regarding weight loss and reduced food intake, the instrument incorporated information on tumor location and type of oncological treatment. In this study, the tool demonstrated excellent performance relative to the PG-SGA. In contrast, in Kang et al.'s study [43], the NUTRISCORE showed low performance when compared with the same reference method.

More recently, a meta-analysis by Zhou et al. [44], which included 56 studies with over 55,000 individuals with cancer, demonstrated that the Global Leadership Initiative on Malnutrition (GLIM) criteria presented moderate diagnostic accuracy for identifying malnutrition when compared with the PG-SGA. In the present study, the SyNCA demonstrated higher diagnostic accuracy than that observed for the GLIM criteria in the meta-analysis, using the same reference method, indicating a promising potential of the SyNCA for assessing nutritional status in oncology contexts.

Finally, it is important to highlight that this study is pioneering in analyzing internal and external validity evidence of the SyNCA, contributing to the advancement of psychometric investigations of the instrument in individuals undergoing cancer care. In addition, the large sample size should be emphasized, as it is considered substantial within an oncological clinical context, thereby strengthening the stability of the analyses performed and the consistency of the evidence produced in this study.

Furthermore, although this article is published in English, the original version of the instrument was developed in Portuguese, which underscores the need for cross-cultural validation before its use in other languages and cultural contexts.

It should also be considered that instrument validation is a dynamic and ongoing process, involving the progressive accumulation of evidence to support the interpretation of scores in specific contexts. Therefore, further

investigations in oncology populations from different cultural backgrounds and clinical settings are warranted to expand the body of evidence available for the SyNCA.

CONCLUSIONS

The evaluation of the internal structure of the SyNCA indicated the need to remove one item to improve model fit, resulting in a version without the evaluation of oedema in the lower limbs, which is theoretically coherent for the population studied. In this new 13-item model, internal validity evidence was adequate, demonstrating stability and satisfactory internal consistency. Moreover, the analysis confirmed concurrent validity, reinforcing the instrument's capacity to consistently reflect the construct of malnutrition in oncology patients.

In conclusion, the new version of the SyNCA demonstrated a robust set of internal and external validity evidence for the assessment of malnutrition in individuals undergoing cancer care, which supports its clinical applicability.

Author contributions

The authors' responsibilities were as follow – PCTBJ: designed and conducted the research, analyzed data, and wrote the manuscript; LPMO: designed and coordinated the research project; and all authors: contributed to the writing and approved the final manuscript.

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Competing interest

355 All the authors declare no conflicts of interest.

356 **Data availability statement**

357 The datasets generated during and/or analysed during the current study are available from the corresponding
358 author on reasonable request.

359 **Declaration of generative AI in and AI-assisted technologies in the writing process**

360 During the preparation of this work, the author used “ChatGPT” to improve language. After using this tool, the
361 author reviewed and edited the content as needed and takes full responsibility for the content of the publication.

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