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RESEARCH METHODOLOGY: INSTRUMENT DEVELOPMENT

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Design and preliminarily validation of a tool to assess the impact of chronic non-cancer pain on people's daily life in Spanish-language: PAIN_Integral Scale©

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Abstract

Aim: To build and preliminarily validate a Spanish-language instrument to assess the impact that CNCP has on the daily lives of people who suffer from it.

Background: The experience of pain is multifactorial and a correct assessment of it helps to control the intensity of pain. Although there are instruments that evaluate areas on which Chronic Non-Cancer Pain impacts, it would be necessary to include other aspects that scientific literature identifies as relevant.

Design: Instrument and construct cross-sectional study for psychometric validation.

Methods: A total of 157 items based on items from validated questionnaires were evaluated by a group of 21 chronic pain experts using Delphi methodology in three evaluation rounds. A final questionnaire of 55 items with a 5-point Likert-type scale was formed. This questionnaire was piloted on a total of 30 patients to assess their understanding of the items and the psychometric validation process was carried out (January to March 2020) on a subsequent sample of 395 people, all of whom attended Pain Units and Primary Care Centres of the Public Health System in Spain.

Results: The PAIN_Integral Scale© showed acceptable internal consistency scores measured by Cronbach's alpha. Exploratory Factor Analysis indicated a structure of nine factors that explain 71.02% of the total variance, from 157 to a final total of 36 items. Confirmatory Factor Analysis showing adequate values confirmed this structure. The effect size was used to calculate the cut-off points for the overall scale, setting them at scores of 130 and 135.

Conclusion: This instrument would allow to assess other constructs and dimensions not included in the instruments previously available such as treatment compliance, proactivity, resilience, hopelessness due to pain and pain catastrophizing. However, despite the fact that the preliminary analysis shows good results, it is necessary to continue with its validation process in subsequent studies.

Impact: The PAIN_Integral Scale©, once the validation process is finished, could be a complete enough instrument to allow a comprehensive healthcare assessment of Chronic Non-Cancer Pain's impact on daily nursing clinical practice and other health-care professionals.

KEYWORDS
analogue pain scales, assessment, comprehensive healthcare, daily living, instrument development, nursing, pain, validation studies

What problem did the study address?

- A comprehensive healthcare assessment of the impact caused by Chronic Non-Cancer Pain (CNCP) would allow a specific approach, helping to improve each of the areas that are affected.
- Only 10% of healthcare professionals use validated instruments even though there are several pain assessment scales. This is due to the need to choose one as a result of the diversity of their approach.

What were the main findings?

- The PAIN_Integral Scale© was found to be a reliable and valid tool to effectively assess the impact of CNCP on daily life.
- The nine areas assessed with the PAIN_Integral Scale© consist of self-care, mobility, sleep, treatment compliance, proactivity, resilience, support network, hopelessness due to pain and pain catastrophizing.

Where and on whom will the research have an impact?

- The Pain Integral Scale© should be used by nursing professionals or professionals from other health disciplines to perform the first evaluation on patients with CNCP when the diagnosis occurs and focus on the comprehensive care plan, but it could also be used to monitor and evaluate the effectiveness of the care.
- The use of a single instrument that allows to jointly assess all impacted areas would facilitate its use by health professionals and would serve as support in their therapeutic plans.

1 | INTRODUCTION

Chronic Non-Cancer Pain (CNCP) is an unpleasant personal, sensory and emotional experience of more than 3 months' duration (Raja et al., 2020) and is not associated with an oncological condition (Cunha et al., 2016).

Pain assessment is an essential element in detecting and providing adequate treatment and should be performed systematically to ensure that patients' needs are being taken into consideration (Registered Nurses' Association of Ontario, 2013). However, the use of evaluation instruments continues to be scarce and data indicate that only 10% of health professionals use these types of instruments (Breivik et al., 2006). Among the reasons for this, literature highlights health professionals' lack of knowledge about them and the diversity of their approach about collecting all the possible altered dimensions (Ferrer-Peña et al., 2016; Registered Nurses' Association of Ontario, 2013).

1.1 | Background

CNCP affects 1.5 billion people worldwide (Global Industry Analysts, 2011). The estimated prevalence in Europe is around 19% of the population and the annual cost exceeds 300 trillion euros, about 1.5%–3% of the Gross Domestic Product (Bushnell et al., 2013). Chronic low back pain, neck pain and hip pain are the most common chronic pain conditions in the world (Flynn, 2020). In Spain, the prevalence of CNCP is 17% (23.9% women and 9.9% men; Cabrera-León et al., 2018).

In Spain, two levels of care deal with CNCP, which are Primary Care Centres and Pain Units. Primary Care Centres are the first level of care and base their approach and strategies on drug therapies and the reduction of emotional impact and inability caused by pain. Pain Units, found in most hospitals in the country, care for those who cannot achieve significant pain relief with conventional pharmacological and non-pharmacological treatment, those who are looking

for a specialized assessment or those who require an interventional analgesic technique (European Observatory on Health Care Systems, 2000).

The experience of CNCP is subjective for each person and depends on the characteristics of the pain itself and the learning process that takes place throughout their life (Ferrer-Peña et al., 2016). Due to its complexity and subjectivity, the limitations that chronic pain creates for people who suffer from it, and the high healthcare costs it causes, many researchers believe that it should be considered as a priority in health policies (Registered Nurses' Association of Ontario, 2013).

In addition, other authors and international associations such as the European Pain Federation (EFIC) or the European Federation of Neurological Associations (EFNA) are calling for a change of perspective and approach (Ferrer-Peña et al., 2016). They believe that CNCP should be assessed and managed as a disease itself in a comprehensive manner, considering it the fifth vital sign (Breivik et al., 2013; Norrefalk, 2011; Wranker et al., 2014). The authors stress the need for an efficient and simple instrument to assess CNCP in an integrative manner (Ferrer-Peña et al., 2016). The available evidence shows that a correct comprehensive assessment of CNCP improves it in terms of pain intensity control, but mainly in terms of psychological and social aspects (Cáceres-Matos, Gil-García, Barrientos-Trigo, et al., 2020). It is well-known that CNCP can impact different areas such as the ability to carry out self-care (Kovačević et al., 2018), mobility (Ferrer-Peña et al., 2016), sleep quality (Haack et al., 2020), compliance with treatment (Kipping et al., 2014), proactivity (Norrefalk, 2011), resilience (Hemington et al., 2018), social support (Cabrera-León et al., 2018; Humberto & Gerard, 2019), hopelessness (Eaves et al., 2016) and/or pain catastrophizing (Akbari et al., 2016).

There are several instruments that evaluate CNCP in a complex way such as the Brief Pain Inventory (BPI) or the Pain Disability Index (PDI), among others. BPI is a nine-item tool that assesses CNCP severity (enjoyment of life, general activity, walking ability, mood, sleep, normal work and relations with other people) with a Visual Analogue Scale from 0 (no pain) to 10 (worst possible pain; Cleeland & Ryan, 1994). On the other hand, the PDI is a 7-item scale to measure pain-related disability (family/home responsibility, recreation, social activity, occupation, sexual behaviour, self-care and life support) on a graphic rating scale ranging from 0 (no disability) to 10 (total disability; Pollard, 1984).

Despite the existence of these instruments, we think that there are other constructs and dimensions not included in the instruments available such as treatment compliance, proactivity, resilience, hopelessness due to pain and pain catastrophizing (Cáceres-Matos, Gil-García, Barrientos-Trigo, et al., 2020). These aspects are important for assessing the impact of CNCP on people's daily life from a biological, psychological and social perspective (Dansie & Turk, 2013).

2 | THE STUDY

2.1 | Aim/s

The objective of this study is to build and preliminarily validate a Spanish-language instrument to assess, from a new perspective, the impact that CNCP has on the daily lives of people who suffer from it.

2.2 | Design

The last phase was a cross-sectional study designed to test the PAIN_Integral Scale©'s internal consistency and construct validity as the preliminary validation study.

2.3 | Instrument

The study was conducted in three phases (Figure 1) following the recommendations of COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) checklist (Mokkink et al., 2019).

2.3.1 | Phase 1: Design and creation of the preliminary questionnaire

For the first phase, the research team carried out a scoping review using the methodological framework of Arskey and O'Malley (Arksey & O'Malley, 2005; The Joanna Briggs Institute, 2015) to examine and map, in a comprehensive way, the consequences that CNCP causes for adults and that may affect how they cope with it (Cáceres-Matos, Gil-García, Barrientos-Trigo, et al., 2020).

Once the affected areas were detected, a systematic review was carried out following the guidelines of PRISMA methodology to identify the European tools that measure the aspects that influence CNCP (Cáceres-Matos, Gil-García, Cabrera-León, et al., 2020). The psychometric properties of the validation studies included were analysed using the COSMIN checklist (Mokkink et al., 2010, 2012).

The items to be included were selected by the working group, which was made up of six researchers with clinical and academic profiles and who have experience in the study, assessment and treatment of people with CNCP. The working group created the preliminary questionnaire consisting of 157 items based on the items of the Spanish-language instruments selected for the quality of their psychometric properties (Pain Self-Perception Scale (PSPS-Spanish; García-Campayo et al., 2010), MOSS Social Support Questionnaire (Gómez-Campelo et al., 2014), Oviedo Sleep Questionnaire (COS; Bobes et al., 1998), Connor Davidson Resilience Scale (CD-Risc; Notario-Pacheco et al., 2014), Pain

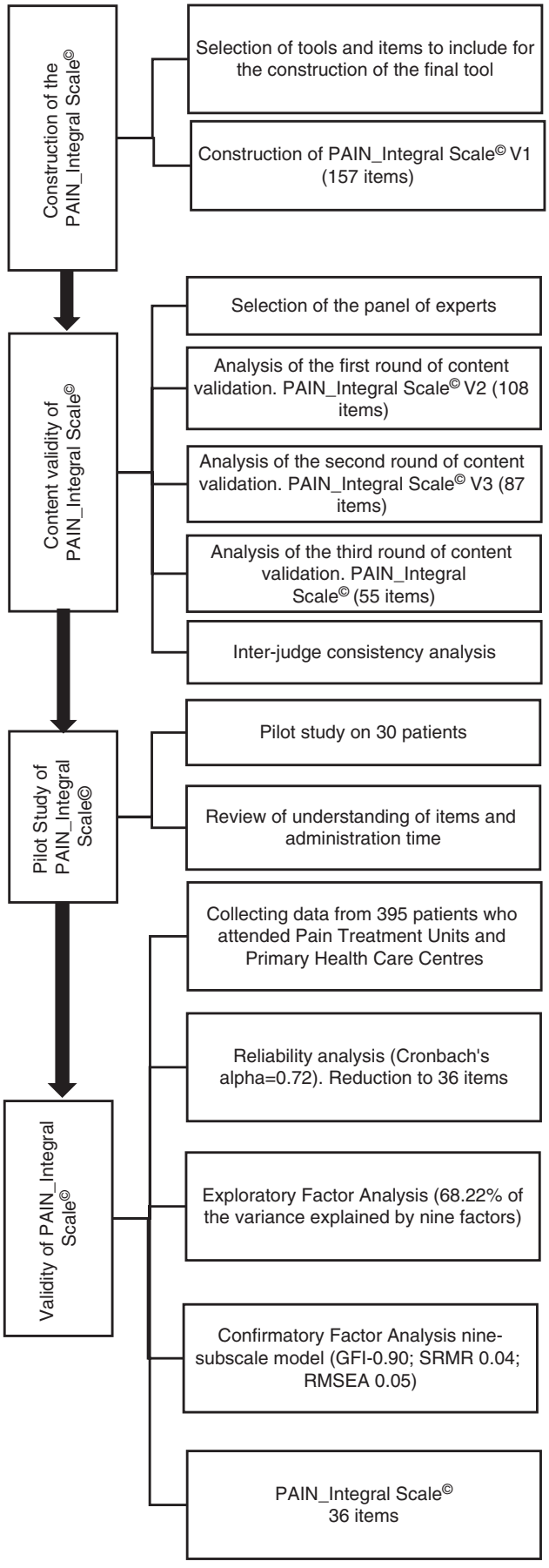

FIGURE 1 Methodological process

Catastrophizing Scale (PCS; Sullivan et al., 1995), Pain Coping Questionnaire (CAD; Soriano & Monsalve, 2002), Deterioration Inventory of Functioning (IDF; Ramírez-Maestre & Valdivia-Velasco, 2003) and Morisky-Green Questionnaire (Val Jiménez et al., 1992) and according to the recommendations provided by clinical practice guidelines (Registered Nurses' Association of Ontario, 2013). All of them are instruments that provide information on the different areas of the patient's daily life on which CNCP has an impact.

In addition, by consensus, another questionnaire was constructed to assess the clinical variables associated with CNCP (location of pain, time of pain evolution, treatment, etc.) and the sociodemographic variables (personal, anthropometric, social, labour, habits and lifestyle).

2.3.2 | Phase 2: Content validity and pilot study

The second phase involved content validity and a pilot study. Content validity was carried out between April and June 2019 following the Delphi method (Engels & Kennedy, 2007). The expert group consisted of a total of 21 experts in chronic pain with academic and clinical profiles and from different disciplines (Nursing, Anaesthesiology, Physiotherapy, Sociology, Physical Activity and Sport Sciences, Epidemiology and Public Health, and Anthropology), who responded to three rounds of evaluation items (Hsu & Sandford, 2007).

The experts rated the coherence, sufficiency, relevance and clarity of every item included on a scale from one to four. The working group deleted those items that obtained mean scores below three in any of the categories over the three rounds (1st round: 48 items deleted; 2nd round: 33 items deleted; 3rd round: 21 items deleted) finally producing a total of 55 items. At the end of the third round, the inter-judge consistency was also analysed using Aiken's *V* statistic and obtaining scores higher than 0.70 for all the 55 remaining items (Streiner et al., 2015).

Finally, to create the first version of the PAIN_Integral Scale©, the wording of each of the items was evaluated. We checked that the 55 items were all written taking into account the Morales-Vallejo recommendations (Morales-Vallejo et al., 2003). In addition, clinical characteristics of pain, sociodemographic data and habit and lifestyle questions were included in the questionnaire.

The pilot study was carried out between September and October 2019 on 30 patients (18 women and 12 men) cared for in the Pain Unit of the Virgen Macarena University Hospital and in a Primary Care Centre, both sites located in Seville and belonging to the Spanish Public Health System. Patients included in the pilot study had to be over 18 years old and suffer from any chronic pain condition not associated with an oncological procedure. Patients with some form of neurodegenerative disease, cognitive impairment or difficulties communicating in Spanish were excluded. The mean time of administration of the instrument and the understanding of the items for possible subsequent modifications

were checked and recorded. The members of the working group discussed the problems detected in understanding the items and all necessary modifications were made for the creation of the final version of the instrument.

The average age of patients included was 56.47 (±14.89) years (women: 58.47 ± 16.76 years vs. men: 53.85 ± 12.51 years). The most prevalent type of pain was low back pain in both women (58.9%) and men (72.77%); and the average pain evolution time was 120.10 (±143.85) months (women: 156.29 ± 168.00 months vs. men:72.77 ± 89.98 months).

2.3.3 | Phase 3: Preliminary validation study

The overall development of the PAIN_Integral Scale© involved a stepwise process in which the results of item analyses and conceptual considerations were used in tandem as a basis for selecting the items included in the final version of the instrument. The researcher asked all participants every question so there were no missed items. The participants' responses were entered in a google form to create the database.

To determine the final composition and structure of the PAIN_Integral Scale©, an internal consistency analysis using responses from all participants was carried out and the items were entered into an Exploratory Factor Analysis (EFA) and a Confirmatory Factor Analysis (CFA).

2.4 | Sample and data collection

The sample size calculation took into account the recommendations of McCallum (McCallum, 1993) and the COSMIN Checklist Statement (Mokkink et al., 2012), which estimate that a minimum of five and seven individuals per item, respectively, is required. Finally, the sample size of this study was 395 subjects.

Patients were recruited from January to March 2020 at four Pain Units (Virgen del Rocio University Hospital; Virgen Macarena University Hospital; Virgen de Valme University Hospital and San Juan de Dios Aljarafe Hospital) and Primary Health Centres, all of which are part of the Spanish Public Health System in the province of Seville, in southern Spain.

Inclusion criteria were patients aged over 18 years with any chronic non-cancer pain condition; and exclusion criteria were suffering from cancer pain, neurodegenerative diseases, cognitive impairment or difficulties with oral communication in Spanish.

2.5 | Data analysis

Descriptive statistics were used to map and summarise the characteristics of the sample. Continuous variables were expressed as mean values ($\bar{x}$) with a confidence interval (CI). Categorical variables were expressed as percentages (%) and CI. The comparison of the different groups' proportions was assessed using the χ^2 test. Significance was considered at 0.05 and the normality was evaluated using the Kolmogorov-Smirnov test.

Firstly, the positive and negative meaning of each item was considered. The values of the items from 11 to 17, from 24 to 31 and from 46 to 55 ranged from one, the least favourable situation, to five, the most favourable situation. The values of the items from 1 to 10, from 18 to 23 and from 32 to 45 had a negative meaning and the scores were rotated. In this case, the items' values ranged from one, the most favourable situation, to five, the least favourable situation.

The sample was divided into two randomized subsamples to perform the analysis of the EFA (n = 198) and CFA (n = 197; Izquierdo et al., 2014).

For the EFA, compliance with the three required assumptions was verified. On the one hand, the scale scores were verified as having a normal distribution. On the other hand, it was found that the analysis of the items indicated at least moderate degrees of correlation with each other. To do this, three tests were carried out. First, the correlation matrix was found to determine whether the corrected item-total correlation was greater than 0.3, indicating a moderate effect. Second, Bartlett's Sphericity Index was calculated and finally the Kaiser-Meyer-Olkin (KMO) test was carried out which had to score higher than 0.8. From the extraction methods, the main component analysis was chosen and the Varimax was used as a rotation method with Kaiser (Gaskin & Happell, 2014). For the extraction of the components, factors with eigenvalues >1 were retained, cross-loadings had to be higher than 0.4 for being assessed and an explained variance of more than 60% was required.

Internal consistency was calculated using Cronbach's alpha, which ranges from 0 to 1. Cronbach's alpha values between 0.7 and 0.8 indicate acceptable internal consistency, values between 0.8 and 0.9, good consistency, and values greater than 0.9, excellent internal consistency (Cronbach et al., 1951).

Ceiling and floor effects of up to 15% were considered acceptable for all items and each subscale (Terwee et al., 2007).

Confirmatory Factor Analysis (CFA) was performed and the acceptability of fit of the factor solutions for the CFA was evaluated based on the Goodness of Fit Index (GFI > 0.90), on the Standardized Root Mean Residuals (SRMR < 0.08), and on the Root Mean Square Error of Approximation (RMSEA < 0.10; Hu & Bentler, 1999).

To calculate the cut-off points for the overall scale and for each subscale, a different procedure was used depending on whether the data followed the normal distribution. If the data followed the normal distribution, we relied on the effect size measurement. According to Cohen, the first cut-off point would correspond to an effect size of 0.5 (mean effect size) and to the 69th percentile. The second cut-off point corresponds to the 79th percentile, that is, to an effect size of 0.8, described as good (Cohen, 1988). If the data did not follow the normal distribution, the procedure was based on the item's discriminative power, calculating the item's discriminant index and the correction factor, taking into account the weights of each item on the entire scale (Arumugam & Nagalingam, 2018; Barua et al., 2014).

TABLE 1 Descriptive analysis. Sociodemographic characteristics of the sample

Variables (*n* = 395)	Women (*n* = 249)	Men (*n* = 146)
Age	Mean (95% CI)	Mean (95% CI)
	62.0 (56.0 to 68.0)	56.2 (48.2 to 64.2)
	% (95% CI)	% (95%CI)
16–44	10.6 (6.8 to 14.4)[a]	17.8 (11.6 to 24.0)[b]
45–64	46.7 (40.5 to 43.5)	56.8 (32.3 to 81.3)
65+	42.3 (36.2 to 48.4)	24.7 (17.8 to 31.6)
Centre		
Virgen del Rocio University Hospital	77.5 (72.3 to 82.7)	74.0 (72.9 to 75.1)
Virgen Macarena University Hospital	6.4 (4.8 to 8.0)	11.0 (5.9 to 16.1)
Virgen de Valme University Hospital	3.2 (2.1 to 4.3)	7.5 (5.3 to 9.7)
San Juan de Dios Aljarafe Hospital	2.4 (0.5 to 4.3)	2.1 (0.0 to 4.4)
Primary Health Care Centres	10.5 (6.7 to 14.3)	7.4 (3.2 to 11.6)
Marital status		
Married	55.3 (48.8 to 61.5)[a]	76.0 (69.1 to 83.0)[b]
Single	12.6 (8.5 to 16.7)	12.3 (7.0 to 17.6)
Separated/Divorced	10.6 (6.8 to 14.4)	9.6 (4.8 to 14.4)
Widowed	21.1 (16.0 to 26.2)	1.4 (0.0 to 3.3)
Employment situation		
Employed	15.4 (10.9 to 19.9)	24.7 (17.8 to 31.6)
Unemployed	4.9 (2.2 to 7.6)	6.8 (2.7 to 10.9)
Retired/medical leave	60.2 (54.1 to 66.3)	66.4 (58.1 to 74.1)
Homemaker	18.7 (13.9 to 23.5)	0.7 (0.0 to 2.1)
Student	0.8 (0.0 to 1.9)	0.7 (0.0 to 2.1)
Level of education[a]		
Early childhood	15.4 (10.9 to 19.9)	5.5 (1.8 to 9.2)
Primary school	54.9 (48.7 to 61.1)	52.7 (44.6 to 60.8)
Middle school	17.1 (12.4 to 21.8)	29.5 (37.1 to 40.5)
Higher education	12.6 (8.5 to 16.7)	11.0 (5.9 to 16.1)
Type of locality		
Less than 10,000 inhabitants	17.7 (13.0 to 22.4)	20.5 (14.0 to 27.0)
From 10,000 to 50,000 inhabitants	38.2 (32.2 to 44.2)	38.4 (30.5 to 46.3)
More than 50,000 inhabitants	1.2 (0.0 to 2.6)	1.4 (0.0 to 3.3)
Capitals	43.0 (36.9 to 49.1)	39.7 (31.8 to 47.6)
Location of chronic pain		
Cervical spine	23.2 (18.0 to 28.4)	16.4 (10.4 to 22.4)
Thoracic spine	12.6 (8.5 to 16.7)	7.5 (3.2 to 11.8)
Lumbar spine	54.9 (48.7 to 61.1)	61.6 (53.7 to 69.5)
Sacral bone	25.1 (19.7 to 30.5)	26.6 (19.4 to 33.8)
Shoulder	18.3 (13.5 to 23.1)	6.8 (2.7 to 10.9)
Armpit/side/arm	15.9 (11.4 to 20.4)	11.0 (5.9 to 16.1)
Elbow	7.3 (4.1 to 10.5)	2.7 (0.1 to 5.3)
Wrist/hand	17.5 (12.8 to 22.2)	8.2 (3.8 to 12.7)
Hips	15.4 (10.9 to 19.9)	10.3 (5.4 to 15.3)
Legs	36.6 (30.6 to 42.6)	43.3 (35.3 to 51.4)
Knee	19.5 (14.6 to 24.4)	15.8 (9.9 to 21.7)

(Continues)

TABLE 1 (Continued)

Variables (*n* = 395)	Women (*n* = 249)	Men (*n* = 146)
Ankle/foot	16.7 (12.1 to 21.3)	11.0 (5.9 to 16.1)
Stomach	3.7 (1.4 to 6.0)	0.0 (0.0 to 0.0)
Abdomen	6.1 (3.1 to 9.1)	4.8 (1.3 to 8.3)
Facial	1.2 (0.0 to 2.6)	0.7 (0.0 to 2.1)
Migraine/headache	10.2 (6.4 to 14.0)	7.5 (3.2 to 11.8)
Fibromyalgia	27.6 (22.1 to 33.2)	6.2 (2.3 to 10.1)

Values < 0.05 in all the boxes from Chi-square tests.
[a]0.4 missing data.
[b]0.7 missing data.
[c]1.4 missing data.

All statistical analyses were performed using version 2.7.2 of the free software R (the R project).

2.6 | Ethical considerations

The research committee of the Virgen Macarena-Virgen del Rocio University Hospital approved the study (1373-N-20). All patients aged over 18 years with any chronic non-cancer pain condition were informed about the study, but only patients who provided written or verbal informed consent were included.

3 | RESULTS

3.1 | Sample

The study subjects represented a sample of 395 patients including 249 women (63%) and 146 men (37%). Table 1 shows data on age, marital status, employment situation, level of education, type of locality and occupational social class.

3.2 | Exploratory factor analysis and internal consistency of the PAIN_Integral Scale©

To examine the structure of the PAIN_Integral Scale© we used an EFA and extracted components with an eigenvalue greater than one. Fifty-five items were entered into the principal component analysis.

Firstly, it was verified that the distribution of the data followed the normal distribution ($p < 0.001$). Secondly, the assumption of correlation between variables was taken into account. In Table 2, the corrected item-total correlation values are shown to exceed the recommended minimum value of 0.3. The Kaiser-Meyer-Olkin (KMO) test and Bartlett's Sphericity test have also been performed. The KMO test obtained a correct score (KMO = 0.800) and in the Bartlett's Sphericity Test statistical significance ($p < 0.001$) was obtained indicating the existence of correlation between the variables. These tests have shown that EFA is feasible.

On the basis of the results of these EFA and prior research, a nine-factor solution appeared best in terms of the test score and eigenvalues. Table 3 displays the weightings for each item on the different factors. 19 items (item 1, 2, 3, 5, 6, 9, 10, 16, 19, 34, 35, 40, 41, 42, 43, 44, 45, 46 and 52) showed cross-loadings <0.4 for every factor solution. Therefore, the other 36 items were grouped into nine factors or dimensions with an explanatory power of variance of 71.02%. Table 3 shows the saturation of each factor.

Table 2 also indicates acceptable levels of floor and ceiling effects with no floor or ceiling effects on any individual item above 15%. The internal consistency of the total scale of 55 items obtained a Cronbach's alpha coefficient of 0.67. In addition, Cronbach's alpha was calculated removing each item (Table 2). The elimination of the previously mentioned 19 items was found to increase the overall Cronbach's alpha value to 0.72. A total of 36 items were proposed for confirmatory factor analysis.

3.3 | Confirmatory factor analysis subscales

The results of the CFA demonstrated a good fit for the proposed 9-subscale model (GFI = 0.93; SRMR = 0.05; RMSEA = 0.06). The path diagram analysis shows the values of the CFA (Figure 2).

No floor or ceiling effects were found on either subscale above 15% (Table 4). For each of the subscales, internal consistency was calculated using Cronbach's alpha (Table 4). Table 4 also shows good values that were obtained for all subscales (>0.70).

In addition, to name each construct that makes up the scale, the theoretical assumption previously established was taken into account, supported by the previous research (Cáceres-Matos, Gil-García, Barrientos-Trigo, et al., 2020). The nine subscales (Table 4) consist of the areas of daily life affected by CNCP, which are Self-care (3 items), mobility (3 items), sleep (3 items), treatment compliance (5 items), proactivity (3 items), resilience (5 items), support network (8 items), hopelessness due to pain (3 items) and pain catastrophizing (3 items).

TABLE 2 Internal consistency of the PAIN_Integral Scale© (55 items)[a]

Item-total statistics	Scale mean if item removed	Scale variance if item removed	Corrected item-total correlation	Cronbach's Alpha if item removed	% Floor effect[b]	% Ceiling effect[c]
Item 1. How satisfied have you been with your sleep over the last month?	**175.37**	**337.03**	**0.53**	**.695**	**13.7**	**8.4**
Item 2. Do you think the quality of your sleep has worsened due to pain?	**175.57**	**333.37**	**0.39**	**.692**	**12.9**	**14.4**
Item 3. In the last week, how many days have you had difficulty falling asleep?	**174.91**	**309.47**	**0.50**	**.681**	**8.9**	**5.3**
Item 4. In the last week, how many days have you had difficulty achieving restful sleep?	174.35	299.12	0.67	.658	10.4	7.8
Item 5. In the last week, how many days did you wake up early and not fall asleep again?	**175.55**	**318.84**	**0.40**	**.680**	**7.3**	**7.3**
Item 6. In the last week, how many days have you had difficulty waking up at the usual time?	**176.19**	**319.09**	**0.36**	**.676**	**6.3**	**8.1**
Item 7. In the last week, how many days have you been worried or noticed tiredness or a decrease in your socio-labour functioning due to not having slept well the night before?	174.46	298.24	0.69	.657	9.1	8.1
Item 8. In the last week, how many days have you felt too drowsy, falling asleep during the day or sleeping more than usual at night?	174.80	303.41	0.49	.664	6.8	8.4
Item 9. In the last week, how many days did you wake up at night?	**173.91**	**306.06**	**0.70**	**.686**	**3.8**	**6.3**
Item 10. If you woke up, how many times did you do it?	**174.26**	**308.68**	**0.73**	**.697**	**8.1**	**14.7**
Item 11. Over the past week, how many days have you visited your family or friends?	174.91	309.70	0.44	.670	7.8	3.5
Item 12. Over the last week, how many days have you gone for a walk?	174.49	314.96	0.48	.667	6.3	4.3
Item 13. Over the past week, how many days have you got dressed alone?	173.38	312.29	0.76	.670	13.4	1.3
Item 14. Over the last week, how many days have you gone shopping?	174.20	309.15	0.57	.670	10.1	5.3
Item 15. Over the past week, how many days have you carried out personal hygiene practices alone?	173.31	309.93	0.84	.667	11.1	1.3
Item 16. Over the past week, how many days have you been able to do your job correctly?	**174.51**	**313.98**	**0.50**	**.677**	**1.5**	**3.5**
Item 17. Over the past week, how many days have you made your personal grooming?	173.24	309.52	0.83	.666	9.4	1.3
Item 18. In the last week, how many days did you not take your medication?	176.23	316.77	0.64	.673	7.8	7.8
Item 19. In the last week, how many days did you forget to take your medication?"	**176.60**	**320.98**	**0.31**	**.684**	**6.3**	**0.8**
Item 20. In the last week, how many days did you not take your medication because you felt okay?	176.64	320.14	0.35	.673	1.8	1.0
Item 21. In the last week, how many days did you not take your medication because you felt bad?	176.63	320.20	0.37	.674	2.5	1.0
Item 22. In the last week, how many days did you not take your medication because you didn't want to take so many drugs?	176.53	317.98	0.49	.672	4.1	2.0
Item 23. In the last week, how many days did you not take your medication because you thought it wouldn't work?	176.64	321.57	0.36	.665	2.3	0.5
Item 24. Do you have someone you can count on when you need to talk?	173.50	305.21	0.69	.660	5.3	10.9
Item 25. Do you have someone to take you to the doctor when you need it?	173.30	313.51	0.54	.669	5.8	8.6
Item 26. Do you have someone to show you love and affection?	173.19	309.41	0.66	.663	2.3	8.4
Item 27. Do you have someone to inform you and help you understand the situation?	173.67	308.79	0.66	.666	8.9	8.4
Item 28. Do you have someone to do things with you to forget your problems?	173.65	302.58	0.81	.658	8.6	9.1

(Continues)

TABLE 2 (Continued)

Item-total statistics	Scale mean if item removed	Scale variance if item removed	Corrected item-total correlation	Cronbach's Alpha if item removed	% Floor effect[b]	% Ceiling effect[c]
Item 29. Do you have someone to help you with your household chores if you are sick?	173.48	315.89	0.48	.674	10.6	6.3
Item 30. Do you have anyone to have fun with?	173.60	302.21	0.82	.658	9.6	7.8
Item 31. Do you have someone who understands your problems?	173.64	306.60	0.68	.663	7.8	10.1
Item 32. I felt like I didn't have the strength to fight anymore.	174.59	310.83	0.64	.667	14.8	7.8
Item 33. I did not care what could happen to me anymore.	175.02	311.88	0.73	.670	11.9	6.6
Item 34. I felt defeated.	**174.85**	**313.61**	**0.72**	**.681**	**8.9**	**12.2**
Item 35. I felt like I wanted to die.	**175.60**	**316.87**	**0.64**	**.684**	**10.1**	**6.3**
Item 36. I felt I had lost my emotional stamina.	174.93	311.24	0.76	.669	10.9	9.9
Item 37. The pain is very strong and I do not think it's ever going to get better.	173.99	313.00	0.40	.670	5.3	10.9
Item 38. The pain is very unpleasant and I feel like I am out of it.	174.09	310.07	0.64	.666	4.6	8.9
Item 39. I feel like I cannot stand the pain anymore.	174.35	310.65	0.65	.668	7.1	14.2
Item 40. I am afraid the pain might increase.	**173.36**	**310.10**	**0.39**	**.675**	**6.8**	**9.9**
Item 41. Previous painful experiences come to mind.	**174.74**	**308.13**	**0.49**	**.677**	**10.1**	**13.4**
Item 42. I look forward to the pain disappearing.	**172.85**	**316.89**	**0.21**	**.680**	**1.0**	**2.0**
Item 43. I think about pain all the time.	**174.89**	**311.12**	**0.52**	**.680**	**7.6**	**11.1**
Item 44. I can do something to lessen the pain.	**175.05**	**321.48**	**0.19**	**.682**	**11.1**	**10.4**
Item 45. I wonder if something serious could happen to me.	**175.09**	**312.54**	**0.33**	**.681**	**11.9**	**13.4**
Item 46. Although it hurts, I hold back and try not to be noticed.	**174.10**	**309.54**	**0.30**	**.679**	**12.4**	**13.7**
Item 47. I am trying to get them to explain what I can do to lessen the pain.	173.96	304.76	0.44	.664	10.1	12.7
Item 48. I try to know more about my pain so I can cope.	174.59	307.88	0.53	.670	7.6	9.4
Item 49. I'm talking to someone who can do something specific about my pain.	174.32	304.68	0.47	.665	12.2	11.9
Item 50. I am able to adapt to changes.	173.77	315.46	0.45	.673	13.4	12.2
Item 51. I can overcome any challenge that is presented to me.	174.11	313.81	0.45	.672	8.2	10.0
Item 52. I get easily discouraged by the pain.	**174.26**	**313.40**	**0.37**	**.683**	**14.7**	**12.3**
Item 53. I think I am a strong person.	173.52	316.39	0.45	.673	8.6	13.4
Item 54. I can handle unpleasant feelings.	174.07	314.67	0.41	.673	14.5	14.7
Item 55. I am proud of my accomplishments.	173.50	311.03	0.51	.667	9.4	10.1

Note: Item in bold were removed after Exploratory Factor Analysis.

[a]0% missing value.

[b]% scoring worst possible value.

[c]% scoring best possible value.

TABLE 3 Rotated component matrix. PAIN_Integral Scale© (36 items)

	Factor 1 Support network	Factor 2 Self-care	Factor 3 Resilience	Factor 4 Pain Catastrophizing	Factor 5 Treatment compliance	Factor 6 Sleep	Factor 7 Proactivity	Factor 8 Mobility	Factor 9 Hopelessness due to pain
Proportion of Variance Explained	19.09%	11.47%	7.90%	7.28%	6.27%	5.21%	4.68%	3.52%	2.79%
Item 1									
Item 2									
Item 3									
Item 4						.790			
Item 5									
Item 6									
Item 7						.804			
Item 8						.775			
Item 9									
Item 10									
Item 11								.771	
Item 12								.888	
Item 13		.813							
Item 14								.646	
Item 15		.849							
Item 16									
Item 17		.812							
Item 18					.811				
Item 19									
Item 20					.788				
Item 21					.675				
Item 22					.813				
Item 23					.747				
Item 24	.815								
Item 25	.775								
Item 26	.827								
Item 27	.812								
Item 28	.843								

(Continues)

TABLE 3 (Continued)

	Factor 1 Support network	Factor 2 Self-care	Factor 3 Resilience	Factor 4 Pain Catastrophizing	Factor 5 Treatment compliance	Factor 6 Sleep	Factor 7 Proactivity	Factor 8 Mobility	Factor 9 Hopelessness due to pain
Item 29	.731								
Item 30	.837								
Item 31	.800								
Item 32				.884					
Item 33				.889					
Item 34									
Item 35									
Item 36				.798					
Item 37									.813
Item 38									.777
Item 39									.798
Item 40									
Ítem 41									
Item 42									
Item 43									
Item 44									
Item 45									
Item 46									
Item 47							.768		
Item 48							.783		
Item 49							.861		
Item 50			.699						
Item 51			.785						
Item 52									
Item 53			.737						
Item 54			.697						
Item 55			.678						

Note: Loadings <.40 were removed.

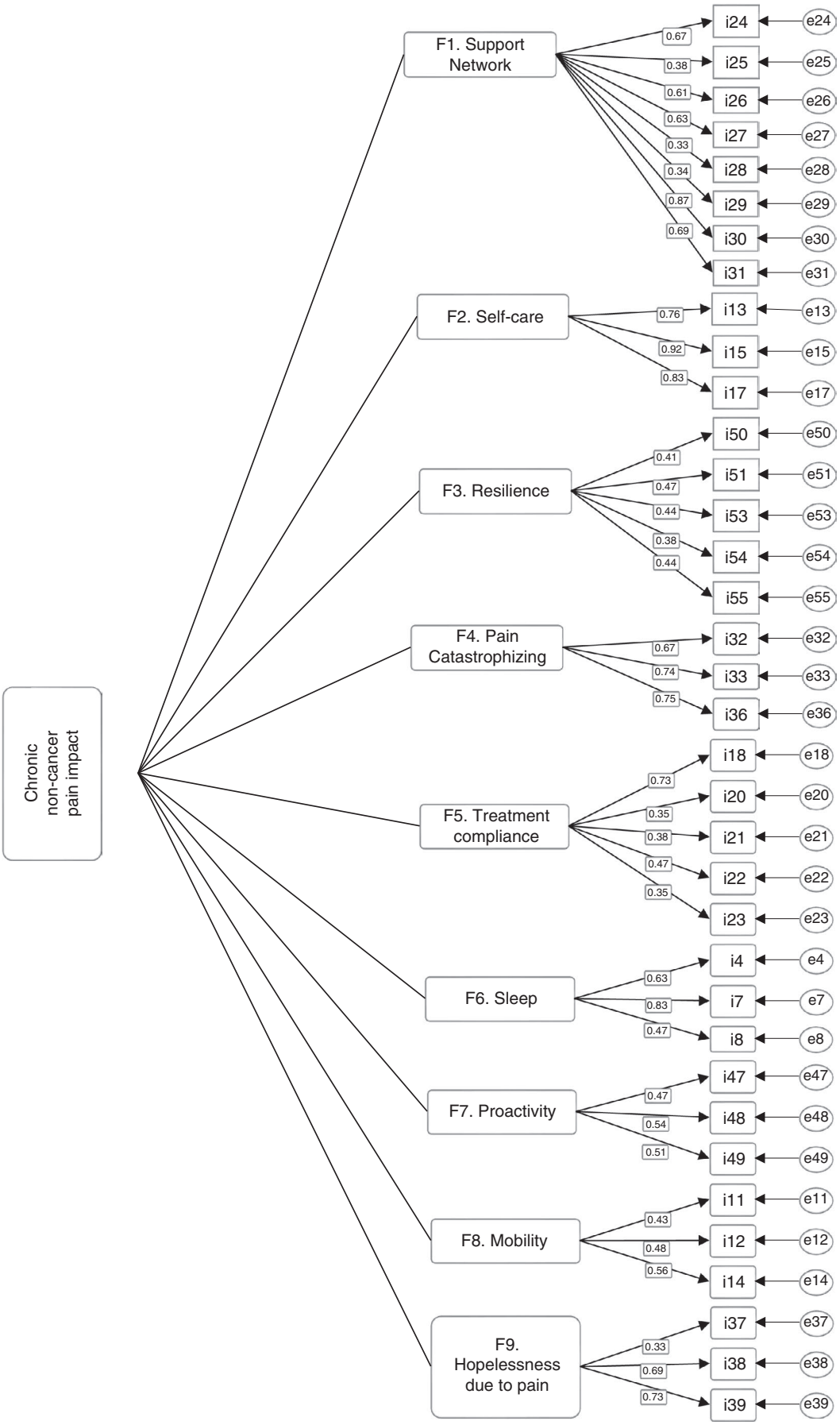

FIGURE 2 Path diagram analysis

3.4 | Cut-off points

Scores on the PAIN_Integral Scale© range from 36 to 180 with a mean of 122.22 (SD = 15.08) and a median of 124. The data were normally distributed (skewness = −0.589, kurtosis = 0.270; Figure 3). Therefore, to determine the two cut-off points of the full PAIN_ Integral Scale©, the 69th and 79th percentiles were calculated, setting the first point at 130 and the second one at 135 points.

The entire research team agreed on the name assigned to each interval of scores. The first interval would cover the least favourable situation (severe impact), the second the intermediate situation (moderate impact) and the third, the most favourable situation (mild impact).

4 | DISCUSSION

The aim of this study was to build and preliminarily validate an instrument to comprehensively assess, from a new perspective, the impact that CNCP has on the daily lives of people who suffer from it. The purpose of the instrument is to use it in clinical practice as a basis for the assessment of patients and to promote a comprehensive approach to CNCP.

We define CNCP as a disease in itself (Registered Nurses' Association of Ontario, 2013), viewing it from a biopsychosocial perspective devised by Engel in 1978. This model states that while biological aspects play a role in all the important phenomena related to health (such as CNCP), psychological, social and familiar aspects have an impact as well. In addition, cross-cultural research has

TABLE 4 Internal consistency of each subscale[a]

Subscale	Mean	SD	Minimum	Maximum	% Floor effect[b]	% Ceiling effect[c]	Cronbach's alpha
Support Network	33.94	8.12	8	40	0.8	2.3	0.92
Self-care	13.31	3.76	3	15	8.6	1.0	0.94
Resilience	19.76	4.96	5	25	1.8	6.3	0.78
Pain catastrophizing	8.70	3.68	3	15	13.4	7.6	0.88
Treatment compliance	6.06	2.87	5	25	6.1	0.3	0.76
Sleep	9.63	4.53	3	15	1.0	3.3	0.83
Proactivity	10.37	4.25	3	15	13.7	4.1	0.83
Mobility	9.64	4.26	3	15	10.9	1.5	0.75
Hopelessness due to pain	10.81	3.26	3	15	4.3	5.6	0.78
CNCP impact	122.22	15.08	69	158	0.3	0.3	0.72

Abbreviations: CNCP, chronic non-cancer pain; SD, standard deviation.

[a]0% missing value.

[b]% scoring worst possible value.

[c]% scoring best possible value.

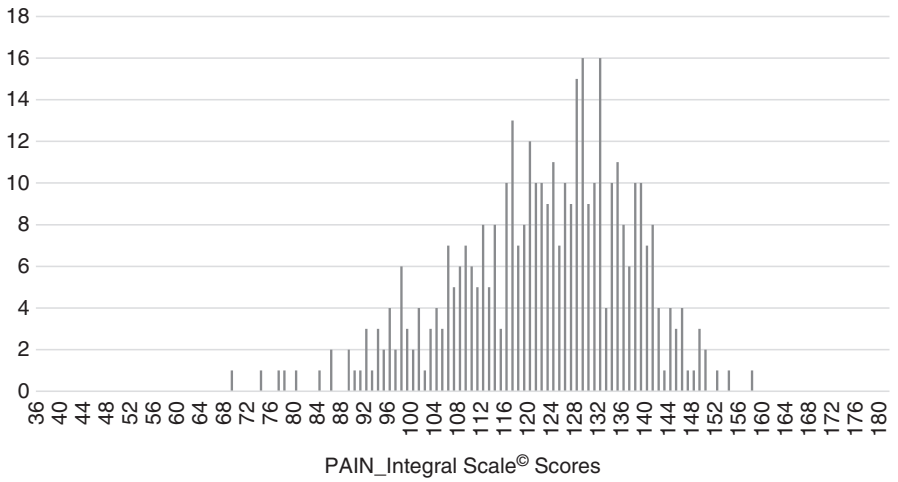

FIGURE 3 PAIN_Integral Scale© scores

demonstrated that CNCP-related perceptions and experiences are influenced by the cultural background (Shoiab et al., 2016; Torres-Cueco, 2018), attitudes, beliefs and values of those suffering from it (Brady et al., 2015). For this reason, health professionals should be encouraged to proactively assess and manage CNCP (The Joanna Briggs Institute, 2015) using simple but efficient tools that are capable of evaluating CNCP in a comprehensive way (Ferrer-Peña et al., 2016).

It is true that there are well-known validated instruments to measure pain-related disability such as the Brief Pain Inventory (BPI; De Andrés-Ares et al., 2014) or the Pain Disability Index (PDI; Pollard, 1984), among others. However, there are certain dimensions not covered by them. Therefore, to assess the impact of CNCP on people's daily life from a new and different perspective, we created a new instrument, which is the Pain_Integral Scale©. This scale includes aspects such as treatment compliance, proactivity, resilience, hopelessness due to pain and pain catastrophizing.

The dimensions that this instrument incorporates tend to be viewed as important by nurses, who are in continuous contact with the patient (Lukewich et al., 2015). However, that dimensions are not only exclusive to them as a result of the transition from biomedical care to biopsychosocial healthcare. This fact is recognized by patients themselves and seen as necessary due to the interdisciplinary nature of pain that requires the collaborative work of professionals from different areas (Registered Nurses' Association of Ontario, 2013). For this reason, the Pain_Integral Scale© is an instrument created to be used by healthcare professionals from other disciplines, in addition to Nursing, as part of a multidisciplinary team. A group of experts specialized in pain from different disciplines such as Nursing, Anesthesiology or Physiotherapy, among others, was thus composed for content validity in this study and the recommendations of considering the level of education and professional experience were followed (Hsu & Sandford, 2007). The Delphi technique was used to search for consensus on the items, which is one of the most used techniques in the Health Sciences field (Diamond et al., 2014). In the initial stages of analysis, there was a high consensus on the score for consistency, sufficiency, relevance and clarity (Streiner et al., 2015) of the proposed items and at the time of the proposal of their elimination, requiring an Aiken's *V* score >0.70 (Aiken & Groth-Marnat, 2006), which was widely surpassed by the items.

With respect to factor analyses, although there are authors who recommend a sample size greater than 200 for the analysis of EFA and CFA, in our study both subsamples are 1% and 1.5% lower than this figure, respectively (Izquierdo et al., 2014). However, other authors indicate that this rule should not be so strict because the statistical power depends on other factors in addition to the sample size. For the EFA, the authors indicated that a sample size of between 150 and 200 cases would be sufficient to achieve precise estimates under the conditions of this study (saturation close to 0.70 and a normal and homogeneous distribution of the data; Kyriazos, 2018). In this way, the EFA showed that the items on the scale can be grouped into nine factors with an acceptable exploratory power of variance (71.02%). In the CFA, the structure of nine factors was confirmed and the adjustment measures were robust (GFI = 0.93; SRMR = 0.05; RMSEA = 0.06), which allowed the sample to be somewhat smaller (Kyriazos, 2018; Tabachnick & Fidell, 2013). In addition, in this case the rule of five cases per item included in the analysis was followed.

Regarding internal consistency, the final tool, made up of 36 items, obtained an acceptable score (Cronbach's alpha = 0.72) taking into account that a value around 0.70 is considered acceptable and is also the minimum value recommended by Nunnally (Nunnally, 1978). According to various authors, the internal consistency of the items improves the closer the Cronbach's alpha value is to 1 (George & Mallery, 2013). Nevertheless, there is a current of thought that postulates that Cronbach's alpha values greater than 0.9 could indicate the existence of redundant items or constructs (De Vellis et al., 2003; Halberstadt et al., 2012).

It is important to consider that one of the most relevant aspects in clinical practice is the number of items in an instrument used by a healthcare professional. This is because the time required for each visit is limited. BPI and PDI have less than 10 items compared with the thirty-six that make up the PAIN_Integral Scale©. Although it is a longer instrument in terms of scale, it is within the range recommended by Nunnally, who suggests a maximum of forty items (Nunnally, 1978). Furthermore, the reduction of the items from 55 to 36, after factorial and internal consistency analyses, has allowed a more parsimonious structure to be found which implies achieving the highest observed correlation between variables with the fewest factors and the lowest possible residual error (Ferguson, 1954). In addition, the recommendations of Beavers et al., that each subscale should be composed of a minimum of 3 or 4 items, are met (Beavers et al., 2013). Also, regarding the response options, the 5-point Likert-type scale is considered adequate when the data follows the normal distribution as in this case (Izquierdo et al., 2014).

An aspect to consider to expedite the use of the PAIN_Integral Scale©, once validated, could be its incorporation into Electronic Medical Records or Electronic Health Records (EHR). The latter two have been shown to be useful by professionals in the clinical setting (Reis et al., 2013), however, it is the use of Personal Health Records that has shown to increase patient engagement, interest and understanding (Heart et al., 2017). Another factor to consider could be the creation of an application (app) or e-tool that allows the self-completion of the data so that it can be deposited directly into the EHR systems. Nevertheless, there is a significant generational and gender digital divide in Spain that should be considered. Studies have shown that 59.3% of people over 65 years of age do not have any digital competence (more pronounced in women as age increases; Alvarez-Galvez et al., 2020), this being precisely the age range in which CNCP is most prevalent.

Finally, this study has also made it possible to determine the cut-off points for the full scale and subscales. When other instruments that measure the same construct are available for comparison, calculating the area under the ROC curve does this. In this case, we could not use this methodology because the other instruments did not measure exactly the same concept, so we did not have a Gold

Standard instrument for comparison. We decided to determine the cut-off points using the calculation of the effect size for the full scale (Arumugam & Nagalingam, 2018; Barua et al., 2014; McCallum, 1993), as done by other authors when validating other instruments such as the Pain Catastrophizing Scale (PCS; Pedler, 2010). Two cut-off points were established because the scale is too long for just one cut-off point and this may have diminished the information obtained from it. The intervals were based on the least favourable, intermediate and most favourable situation, as has been done previously in other studies (Pedler, 2010).

In terms of the limitations, this study uses a cross-sectional methodology; therefore, the test–retest could not be applied, which would have enabled us to have results on the stability of the measurements over time, giving similar scores.

Regarding future lines of research, it would be necessary to continue with the following validation stages. One of them would be to carry out a new study to analyse the convergence of each subscale with specific validated instruments that assess the same constructs and their usability.

5 | CONCLUSIONS

The PAIN_Integral Scale© is an instrument designed to broadly assess the impact that CNCP has on a person's daily life. It is composed of 36 items, with a Likert-type scale from one to five. The results of this study indicated that the instrument is structured over nine dimensions (71.02% of the explained variance) and it also shows an acceptable internal consistency (α = 0.72). The structure was subsequently confirmed by CFA (GFI = 0.93; SRMR = 0.05; RMSEA = 0.06). The nine dimensions were named as self-care (3 items), mobility (3 items), sleep (3 items), treatment compliance (5 items), proactivity (3 items), resilience (5 items), support network (8 items), hopelessness due to pain (3 items) and pain catastrophizing (3 items). Scores on the scale range from 36 to 180 points and two cut-off points are identified that divide the scores into three intervals (36–130: Severe impact; 131–135: Moderate impact; 136–180: Mild impact). This instrument would allow to assess other constructs and dimensions not included in the instruments previously available such as treatment compliance, proactivity, resilience, hopelessness due to pain and pain catastrophizing. Despite the good results shown in the preliminary analysis, we shall ensure to continue with and improve the validation process in future studies.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTIONS

R.C.M. conceived the main idea, designed the research methodology, collected and analysed data and wrote the manuscript. E.G.G. conceived the main idea, designed the research methodology, supervised the study and wrote the manuscript. A.R.S. corrected and provided conceptual input on the manuscript. J.M.L.M. corrected and provided conceptual input on the manuscript.

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Author elects to not share data.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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