



Validity and reliability of Spanish PROMIS pediatric pain interference short form

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ABSTRACT

Background: The goal of this study was to analyze psychometric properties of the Spanish PROMIS Pediatric Pain Interference short form (PROMIS-PPI) in a sample of Spanish children and adolescents.

Methods: In a hospital pediatric sample it was studied the structure scale (exploratory and confirmatory analysis), construct validity, convergent validity, and reliability (internal consistency).

Findings: 163 children and adolescents (mean age 13.3 years; SD 2.01; 39.26% female) with and without chronic pain completed measures pertaining to their pain experience. Psychometric analysis showed the PROMIS-PPI Spanish version maintains the original one-factor model of the scale, excellent internal consistency (Cronbach's α coefficient 0.90 (95% CI 0.88–0.92)), and convergent validity (showed a positive, significant, and moderate magnitude correlation [r from 0.330 to 0.604] with pediatric quality of life, child and parent pain intensity, and showed a low correlation with the number of medical consultations in the last year).

Discussion: The Spanish PROMIS-PPI scale is a valid and reliable tool. It is recommended for research and clinical care in pediatric populations.

Application to practice: The results provide evidence that the Spanish version of PROMIS-PPI is valid and reliable tool. Health professionals who work with children in risk to develop persistent pain, will have access to short tool with highest evidence, for assess pain interference.

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Introduction

Pain in the pediatric population remains one of the major causes of disability (Datz et al., 2019; Groenewald et al., 2015; Vervoort et al., 2014; Von Baeyer, 2011). Pain directly affects physical and psychological function, family relationships, and peer relationships, as well as contributing to school absenteeism and generating a high risk of developing disability in adulthood (Datz et al., 2019; Donnelly et al., 2020; Ho et al., 2008; Vervoort et al., 2014; Walker et al., 2010). Chronic pain has a prevalence close to 10%, and the latest data show it represents a significant challenge for modernized countries (Groenewald et al., 2015; King et al., 2011; Vervoort et al., 2014). Research is focusing its efforts on understanding and responding to pain in pediatric illnesses (Eccleston et al., 2021). Recommendations provided in the Pediatric Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials in 2008 (McGrath et al., 2008) and recent expert indications (Palermo et al.,

2021) have helped to direct lines of pain study in children and adolescents. In recent years, the development of systems for measuring the components and impact of pain on children has been notable, favoring improvements in the quality of studies aimed at understanding the mechanisms underlying chronic pain in this population.

Pain interference in daily life has received attention in recent years and is a relevant component in the chronic pain process (Birnie et al., 2020; Irwin et al., 2009). Pain interference refers to the degree to which pain hinders participation in physical, cognitive, emotional, and recreational activities, as well as affects sleep and enjoyment of life (Hung et al., 2014). In the pediatric population, it is an important domain when evaluating pain impact, given it provides relevant information on the physical, mental, cognitive, and social state, and its relation to avoidance behaviors (Birnie et al., 2020; Karayannis et al., 2017; McGrath et al., 2008; Palermo et al., 2021). Assessment with specific measurement instruments that contemplate this domain accurately and validly is required (Karayannis et al., 2017; McGrath et al., 2008; Palermo et al., 2021). For pain interference evaluation, Varni et al. (2010) developed the National Institutes of Health's Patient-Reported

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Outcomes Measurement Information System–Pediatric Pain Interference (PROMIS–PPI) scale, which assesses how pain interferes with children’s physical, social, and mental activities. It is a one-dimensional self-assessment scale, developed for children from 8 to 17 years of age, that has shown interesting results in its use in children both with and without chronic pathologies. It has been used in various fields of research with application in chronic abdominal pain and kidney disease (Forrest et al., 2020), in adolescents with fibromyalgia (Fussner et al., 2019), in postsurgical chronic pain (Rosenbloom et al., 2019), and in chronic pain in sickle cell disease (Singh & Panepinto, 2019). The short 8-item version of the PROMIS–PPI has been studied in children with chronic pain, for whom it has been found to be a valid and reliable instrument (Cunningham et al., 2017). In addition, the Spanish version of 41 items for adults has been previously studied and has shown good results (Paz et al., 2017). However, there is currently no Spanish-validated self-report measure of pain interference for children and adolescents. Therefore, it is necessary to study the psychometric characteristics of the Spanish PROMIS–PPI Short Version.

Objective

The objective of this study was to evaluate the psychometric characteristics of Spanish PROMIS–PPI Short Version scale. Specifically, the construct validity, convergent validity, discriminant validity as well as the reliability of the scale were analyzed.

Methods

Participants

The convenience sample included children and adolescents with and without chronic pathology of all clinical entities. Children and their parents who attended a medical consultation were invited to participate in the study. 180 participants agreed to participate in the study, of which 17 were excluded for not meeting the inclusion criteria. A total of 163 children and their parents were included after giving their informed consent. The Hospital Ethics Committee approved this study. The procedures used in this study adhere to the tenets of the Declaration of Helsinki. The eligibility criteria for selection were (a) ability of the child and their parents/guardian to read and write in Spanish; (b) age between 8 and 17 years. This age range was chosen following the selection criteria determined in previous validations (Cunningham et al., 2017; Forrest et al., 2020; Mara et al., 2021; Varni et al., 2010), since the PROMIS–PPI Short Version scale is intended to assess pain interference in children and adolescents. Children with medical circumstances that interfered with development of the study protocol were excluded.

Outcomes

Demographic outcomes

All children and parents were asked to indicate the date of birth, sex, previous pathologies, and educational level of the children. Research’s staff measured and children’s weighed at the time of the interview and body mass index was calculated according to the National Center for Chronic Disease Prevention and Health Promotion (2021). Parents were asked to indicate their date of birth, gender, educational level, and occupational status. Occupational status of the parents was used to determine socioeconomic status in accordance with what was proposed by the Working Group of the Spanish Society of Epidemiology and the Spanish Society of Family and Community Medicine (Domingo-Salvany et al., 2000) based on Spanish Classification of Occupations (CNO-94), which is widely used to determine socioeconomic status in health problems (Chilet-Rosell et al., 2012).

Number of child’s surgeries

Parents were asked to indicate the child’s number of surgeries had undergone throughout his life.

Number of child’s medical consultation last year

Parents were asked to indicate the child’s number of medical consultations in 12 months prior to the day of the interview. Medical consultations could be both scheduled or outpatient, such as emergency or hospital admissions consultations and from any branch of health, pediatrics, nursing, speech therapy, mental health, rehabilitation, social work.

Child’s pain interference

The child’s daily pain interference was evaluated using the PROMIS–PPI Short Version scale (Varni et al., 2010), an 8-item scale in which the child is asked to evaluate the interference that pain produces in their activities of daily life (Hanssen et al., 2014) during the last 7 days (i.e., difficulties in completing daily activities, impairment in physical functioning, and socioemotional problems due to pain). Each item of the PROMIS–PPI Short Version is scored on a 5-point Likert-type scale (“Never” = 1; “Almost never” = 2; “Sometimes” = 3; “Often” = 4; “Almost always” = 5), so the total score ranges from 8 to 40. The PROMIS–PPI scale is one-dimensional, in which higher scores indicate greater pain interference in activities of daily living. This scale has been developed and calibrated successfully and has proven to be a useful tool in the pediatric population (Varni et al., 2010). For this study, the Spanish version was used, for which its validity, reliability, and psychometric qualities were not yet known. The Spanish version of the PROMIS–PPI short version used in this study can be obtained by accessing the following link: https://www.healthmeasures.net/index.php?option=com_instruments&view=measure&id=2438&Itemid=992

Child’s pain intensity

Children were asked about the most severe pain they had experienced in the past 7 days, registered with the Faces Pain Scale-Revised Spanish pediatric pain scale (Thong et al., 2018). It is a self-reported scale to assess pain intensity in the pediatric population through which the children indicate the worst pain intensity they have experienced on 6 faces that differ in their facial expression and numerical values, ranging from “0 = no pain” to “10 = a lot of pain”. This scale is recommended for assessment of pain intensity by the International Association for the Study of Pain and has adequate validity and reliability (Thong et al., 2018).

Parents’ pain intensity

Parents were asked to assess their child’s pain intensity in the past 7 days, indicating the most severe pain the child had experienced using the Spanish Parent’s Postoperative Pain Measure (PPPM) scale (Finley et al., 2003). The Spanish PPPM is a questionnaire with 15 items that refers to behaviors associated with pain in the pediatric population that allows parents to assess their children’s pain (Ullan et al., 2016). Scores range from 0 to 15 (6 = clinically significant pain). It is the only validated measure for parental reporting in research studies.

Chronic pain

The children and parents were asked if the child had had pain (FRS-R ≥ 3 or PPPM ≥ 6) for at least 3 months prior to the interview, according to the international criteria for the diagnosis of chronic pain (Nugraha et al., 2019). This outcome was coded as a dichotomous variable (“yes / no”).

Child’s health-related quality of life

All children assessed their health-related quality of life (HRQoL) using the Pediatric Quality of Life Inventory 4.0 Generic Core Scale questionnaire (PedsQL) (Varni et al., 2001). The Spanish version of 15 items (Roizen et al., 2008) is a valid a reliable questionnaire widely used, through which the children self-assessed their physical, emotional,

social, and school function. Children rated their perceived HRQoL through a Likert scale with 5 response options, ranging from “never” to “almost always”. Responses were scored inversely and were transformed into a range from 0 to 100.

Parent proxy of child's health-related quality of life

Parents assessed the child's HRQoL, also using the PedsQL and the Spanish version of 15 items (Roizen et al., 2008), in which the parents evaluated the physical, emotional, social, and school functioning of their child. Parents rated their child's perceived HRQoL with the Likert scale, as above.

Procedure

The study was performed between December 2019 and March 2020 in a first level children hospital. A research assistant met with the participants who had agreed to participate in a single session. First, an interview was conducted with the parents that lasted 1 h, during which they were informed in detail about the study, signed the informed consent document, and completed questionnaires in paper format. Second, the children were interviewed separately from their parents so that parents did not influence their response to questionnaires (also in paper format) this interview lasted half an hour.

Data analysis

SPSS software version 21 (IBM SPSS Statistics) and Mplus statistical software 7.11 were used to conduct all the statistical analyses. Statistical significance was set at 5% ($p < .05$). The procedures used to determine the theoretical construct and to examine its validity and reliability are detailed below.

Construct validity

A 2-step process was used to examine construct validity: 1) exploratory factor analysis (EFA) to identify the optimal factor structure; and 2) confirmatory factor analysis (CFA) to confirm the theoretical factor structure. The sample size was established based on the criteria of several authors, who have proposed 100 observations as the minimum required, as well as according to the proposed rule of a ratio of 20 observations per measured variable (de Winter et al., 2009; Hair et al., 2004; Kyriazos, 2018). Thus, a necessary minimum of at least 160 children were determined to analyze the validity of the construct in this study. In addition, the EFA indicators were found to be sufficiently robust to consider the determined sample size acceptable (Kyriazos, 2018).

First, to identify whether Pearson's correlation matrix was factorizable, Bartlett's test and the Kaiser-Meyer-Olkin (KMO) test were employed (Tabachnick & Fidell, 2013). The optimal number of factors was established based on Kaiser's eigenvalue criterion (eigenvalue >1 ; and the scree-plot) and the parallel analysis method, according to statistical recommendations (Lim & Jahng, 2019). In EFA, the principal axis factoring method with oblique rotation was conducted as a factor extraction method. For the item's inclusion in each factor, a factor loading >0.4 was considered necessary.

The CFA was performed using the weighted least squares mean, and variance adjusted estimation method. The following goodness of fit indices were used: comparative fit index (CFI) and Tucker Lewis index (TLI) as comparative fit indices; root mean square error of approximation (RMSEA) as a parsimony fit index; and the chi-squared and weighted root mean square residual (WRMR) as absolute fit indices. An acceptable model fit was considered according to the following criteria (TLI and CFI ≥ 0.95 , RMSEA ≤ 0.06 , and WRMR ≤ 1.0) (Brown, 2015). Furthermore, modification indices were calculated to identify local misspecified areas of the model not sensitive to the overall goodness of fit indices previously mentioned (Brown, 2015).

Convergent validity

Convergent validity was analyzed using Pearson correlations between the Spanish version of the PROMIS-PPI scale and the other pain and quality of life measures (answered by both children and parents/guardians, depending on instrument/variable): medical consultations in the last year; previous surgeries; FPS-R; PPPM; and PedsQL. A strong correlation was considered to be over 0.60; a moderate correlation between 0.30 and 0.60; and a low correlation below 0.60 (Terwee et al., 2007).

Reliability, discriminant validity (floor/ceiling effect)

The reliability of the Spanish version of PROMIS-PPI Scale was assessed employing internal consistency. The internal consistency was considered acceptable when Cronbach's alpha was >0.70 (Cronbach & Shavelson, 2004). The floor/ceiling effect was considered to be present if at least 15% of patients achieved the minimum/maximum score, respectively (Terwee et al., 2007).

Results

A total sample of 163 Caucasian children (99 boys and 64 girls) were included in the study, of whom 16% had undergone 1 surgery to date. The informed consent for participation in the study was provided principally by their parents (97.5%) or their guardians (2.5%). Table 1 presents the anthropometric and sociodemographic characteristics of the children and their parents/guardians.

Table 1

Anthropometric and sociodemographic characteristics of the children and their parents/guardians.

	Mean \pm SD	Range (min-max)
	N (%)	
Child's age (years)	13.3 \pm 2.01	8–17
Child's sex (male: female)	99 (60.73%): 64 (39.26%)	
Child's height (cm)	154.57 \pm 16.74	100–198
Child's weight (Kg)	51.74 \pm 18.52	23–121
Child's body mass index (Kg/m ²)	21.11 \pm 4.84	13.9–39.1
Child's educational level		
Primary education	73 (44.8%)	
Secondary school/high school	77 (47.2%)	
Professional training	13 (8%)	
Child's previous surgeries	0.94 \pm 1.96	0–18
Medical consultations in the last year		
1–3	76 (46.6%)	
4–6	54 (33.1%)	
7–10	20 (12.3%)	
11–14	8 (4.9%)	
15–20	2 (1.2%)	
>20	3 (1.8%)	
Medical diagnosis		
Chronic pain	40 (24.5%)	
- Migraine	4 (2.4%)	
- Orofacial pain	6 (3.7%)	
- Abdominal pain	14 (8.6%)	
- Musculoskeletal pain	16 (9.8%)	
Asthma	12 (7.4%)	
Chronic cardiovascular diseases	2 (1.2%)	
Food allergies	6 (3.7%)	
Parent/Guardian's age (years)	43.62 \pm 5.99	24–57
Parent/Guardian's sex (male: female)	26 (16%): 137 (84%)	
Parent/Guardian's educational level		
Primary education	17 (10.4%)	
Secondary education	47 (28.8%)	
Professional training	47 (28.8%)	
University education	52 (31.9%)	
Family socio-economic status		
Low	64 (39.3)	
Medium	96 (58.9)	
High	3 (1.8)	

Abbreviations: SD, Standard Deviation; N (%), total number of individuals (percentage of the total sample).

Construct validity

Exploratory factor analysis

Cronbach's α coefficient for the entire scale ($\alpha = 0.90$) and the adjusted item-total correlations (average item-total correlations = 0.692) were calculated before the EFA. No items were removed because all contributed substantially to the scale (item-total correlations >0.500 ; Cronbach's alpha decreased when any of the items were deleted).

The KMO showed an excellent data suite for factor analysis (KMO = 0.903), and Barlett's test of sphericity refused the identity matrix null hypothesis: $\chi^2 (28) = 672.68, p < .001$. According to these results, continuing with EFA could be justified. Kaiser's criteria and the parallel analysis with the polychromic correlation matrix suggested retaining 1 factor (see Fig. 1). The factor loadings of all items ranged from 0.730 to 0.772, except for item 1, which showed a factor loading of 0.610.

Confirmatory factor analysis

All items were encompassed within 1 theoretical factor and had an optimal factor loading (>0.600). Hence, we decided to fit a 1-factor CFA model with the 8 aforementioned items. Analysis of the modification indices suggested a slight correlation between item 2 and item 4 ($r = 0.341; p < .001$), which, when included in the model, improved the overall goodness of fit indices. The final model fit the data reasonably well: $\chi^2 (19) = 37.70, p = .0065$; CFI = 0.990, TLI = 0.986; RMSEA = 0.078, 95% CI 0.040–0.114; WRMR = 0.553. The observed indicators for the final 1-factor solution were reliable measures, given all standardized factor loadings were above 0.700 (except item 1, which showed a factor loading of 0.679). Fig. 2 shows the standardized factor loadings of the final 1-factor solution.

Convergent validity

The total score of the Spanish version of the PROMIS-PPI scale showed a positive, significant, and moderate magnitude correlation

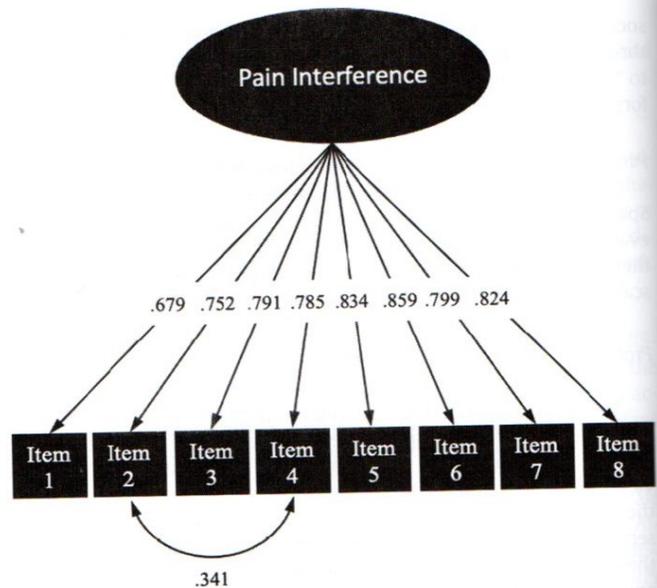


Fig. 2. Structural equation modeling for the final Spanish version of the PROMIS Pediatric Pain Interference Scale. Between paragraph "Construct Validity Confirmatory factor analysis" and "Convergent Validity".

(r from 0.330 to 0.604) with pediatric quality of life (PedsQL-child and parent/guardian responses) and with the other pain-related measures (FPS-R and PPPM). In addition, the Spanish version of the PROMIS-PPI scale was significantly, positively, and lowly correlated with the number of medical consultations in the last year. However, no scale was correlated with the number of previous surgeries. The correlations of the

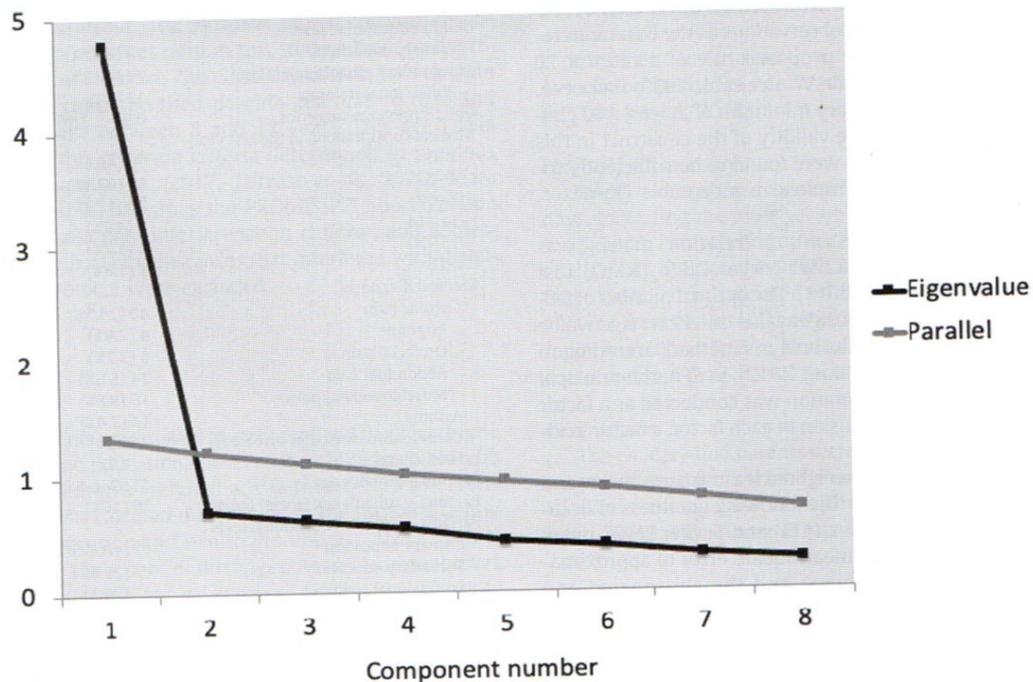


Fig. 1. Scree-plot. Between paragraph "Construct Validity- Exploratory factor analysis and "Construct Validity Confirmatory factor analysis".

Spanish version of the PROMIS-PPI scale with all the other pain and quality of life measures are shown in Table 2.

Reliability, discriminant validity (floor/ceiling effects)

The final Spanish version of the PROMIS-PPI scale consisted of a total of 8 items formulated directly/positively, and the total score could range from 8 to 40. Internal consistency of the scale was excellent, with a Cronbach's α coefficient of 0.90 (95% CI 0.88–0.92). No floor or ceiling effects were detected because only 13.5% of the children had the lowest possible score, and 0.6% obtained the highest possible score.

Discussion

According to international consensus, pain interference is a mandatory domain in pediatric pain studies (Palermo et al., 2021). Its definition has recently been suggested to be “How much pain interferes with engagement in social, physical, and recreational activities” (Karayannis et al., 2017). Given the increased interest in evaluating the pain interference domain and the absence of studies that have analyzed its behavior in other languages, our aim in this study was to analyze for the first time the psychometric properties of the Spanish version of the PROMIS-PPI Short Version. According to the results obtained, our proposed hypotheses were supported. Our results confirmed the validity and reliability of the Spanish PROMIS-PPI Short Version and provided relevant new information on the characteristics of the questionnaire.

According to exploratory and confirmatory factor analyses, the 8 items were englobed into one of the original factors, resulting in a model that fit reasonably well and obtaining an optimal factor loading (>0.600). Hence, the Spanish version of the PROMIS-PPI presented a unifactorial model, in line with the originally created version of the scale (Varni et al., 2010), as well as an adequate construct validity.

In addition, the results showed a more marked relationship between items 2 and 4. This relationship could be explained by the fact that both items refer to very similar complex cognitive tasks (“doing schoolwork when I had pain” and “pay attention when I had pain”). Thus, we considered that the pain would generate interference in both in a very similar way.

On the other hand, our findings suggest that the Spanish PROMIS-PPI Short Version could have an acceptable discriminative ability, given no floor/ceiling effect was detected in the scores obtained. In fact, less than 15% of children with pain scored a maximum and/or minimum on the scale (40 and 8 points, respectively). In addition, the internal consistency of this Spanish version was excellent, with a Cronbach's alpha of 0.90. Thus, a strong link between the different items was verified, but without obtaining a value that could reflect the presence of redundant items (Varni et al., 2010).

According to previous studies (Birnie et al., 2020; Karayannis et al., 2017), convergent validity analysis showed that there is a relationship between pain interference and HRQoL for the Spanish version, as reported by children and parents. Specifically, it was found that there

was a closer relationship between children's self-assessment of HRQoL with pain interference than with the HRQoL parental assessment. The evaluation by the parents showed a weaker relationship, possibly because it is an external evaluation; thus, although it does reflect the state of quality of life, it is not as accurate as the child's self-report. Furthermore, a relationship between pain interference and pain intensity was also found. These findings are similar to those found in samples of children and adolescents with chronic pain (Cunningham et al., 2017; Feinstein et al., 2018; Mara et al., 2021; Nelson et al., 2020). In contrast to the relationship with HRQoL, the relationship between pain interference and pain intensity established by the parents was greater than that established by the children. This small difference could be due to the fact that the measurement scales were different. The pain intensity scale assessed by the parents (PPPM) shows smaller variations than that of the children (Thong et al., 2018), leading to greater variation in the scores.

On the other hand, in line with previous studies (Datz et al., 2019), pain interference was slightly associated with the number of medical consultations in the last year. This association could be because children with more health-related problems tend to have more frequent medical check-ups. However, the poor relationship observed makes it clear that pain interference is a complex construct influenced by multiple factors. Finally, no association was found between the number of previous surgeries and pain interference. It is still unknown when and how postsurgical pain develops, and it could be that even though the children had undergone surgery they had not developed chronic postsurgical pain (Rabbitts et al., 2017).

Practice implications

The results provide evidence that the Spanish version of PROMIS-PPI is valid and reliable tool. Health professionals who work with children in risk to develop persistent pain, will have access to short tool with highest evidence, for assess pain interference.

Limitations

The present study had several limitations. First, the type of chronic pain was not considered because the purpose of the scale is to evaluate any type of chronic pain, without specifying the type of pain. However, we consider this aspect relevant, given it could assess the discriminant capacity of the scale and it could even affect the results obtained. Therefore, future studies should explore the capabilities of the scale in populations with various types of chronic pain (persistent pain, postsurgical pain, chronic musculoskeletal pain). Second, the lack of study validation in other languages made it difficult to compare our results with other previously validated PROMIS-PPI scales. Third, the sample size of our study could be considered insufficient, as some authors consider it necessary to reach samples larger than 200 subjects to perform an EFA (DeVellis, 2017). However, the results of our AFE showed a sufficiently robust model, so the sample size used could be acceptable (Kyriazos, 2018). Fourth, the age range was chosen following the selection criteria determined in previous validations (Cunningham et al., 2017; Forrest et al., 2020; Mara et al., 2021; Varni et al., 2010). However, the age range could be considered very wide, especially at these ages where you can distinguish between 8 and 12 years and 13–17 years. Future validations could assess the psychometric properties of the scale in each of these two age ranges.

Finally, the lack of validated scales in Spanish on pain fear-avoidance behaviors and evaluation of pediatric chronic pain could mean that all the capacities and relationships of the scale have not been explored (exhaustive convergent validity). The analyses were performed with all available Spanish validated instruments. However, we believe that this study provides important data that will favor research on pediatric pain in the Spanish-speaking population.

Table 2
Convergent validity of the Spanish version of the PROMIS Pediatric Pain Interference Scale.

	Spanish version PROMIS Pediatric Pain Interference Scale
	Total Score
Medical Consultations in the last year	0.204**
Previous Surgeries	−0.081
Faces Pain Scale-Revised	0.330**
PPPM (Parents Postoperative Pain Measure)	0.488**
PedsQL (Pediatrics Quality of Life Inventory)™	
Total Scale Score-Child Response	0.604**
Total Scale Score-Parent/Guardian Proxy	0.416**

** $P < .01$.

Conclusion

The results shown in this study suggest that the Spanish version of PROMIS Pediatric Pain Interference Short Form is a valid and reliable scale to identify pain interference in the pediatric population. Therefore, it should be recommended for clinical practice and research use.

Declarations of interest

None.

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CRedit authorship contribution statement

Guillermo Ceniza-Bordallo: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. **Andrés Gómez Fraile:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Project administration, Resources, Supervision, Validation, Visualization, Writing – review & editing. **Patricia Martín-Casas:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing – review & editing. **Ibai López-de-Uralde-Villanueva:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – review & editing.

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