





RESEARCH ARTICLE



## Development and Validation of a Scale for Assessing the Interference of Chronic Primary Pain Conditions in Sexual Functioning: The SEX-PAIN Questionnaire

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### ABSTRACT

Chronic pain represents one of the main health public problems worldwide and significantly affects the sexual life of patients. However, no specific instruments of evaluation have been found that address this population. This study presents the SEX-PAIN Questionnaire, developed for identifying chronic pain's interference with sexual functioning among people with chronic pain. Methods. The validation has been carried out with a sample of 303 Spanish non-hospitalized patients with chronic pain diagnosis aged between 20 and 71 years old ( $M_{age} = 49.49$ ;  $SD = 10.7$ ). Exploratory Factor Analysis (EFA) yielded 2-factor structure: Sexual and Relationship Dissatisfaction, and Chronic Pain Impact on Sexual Life. This structure was later verified through Confirmatory Factor Analysis (CFA). Internal consistency (Omega) of each factor was .72 and .96, respectively. This study presents the psychometric properties of a new measure addressed to patients with chronic pain. This 17-items self-administered instrument can be a useful measure of the chronic pain's interference with sexual functioning among chronic pain patients. It represents the first original questionnaire known in Spanish language to date. This measure could potentially help researchers and clinicians to obtain key information to design appropriate healthcare interventions.

### Introduction

One out of ten individuals of general population suffer chronic pain worldwide and an average of 27% in Europe (Andrews, Steultjens, & Riskowski, 2018; Leadley, Armstrong, Lee, Allen, & Kleijnen, 2012). The latest studies show that as many as 16.6% of Spanish adults have chronic pain (Dueñas et al., 2015). Chronic pain represents one of the main health public problems in our country, especially among females (European Health Survey in Spain, 2020; National Statistics Institute, 2021). Chronic pain significantly affects the quality of life and social and family environment. A great negative impact is observed in different aspects such as physical fatigue (Van Damme, Becker, & Van der Linden, 2018), sleep problems (Roberts & Drummond, 2016), anxiety-depressive symptoms (Velly & Mohit, 2018) or social isolation (Dueñas, Ojeda, Salazar, Micó, & Failde, 2016). This is a serious clinical problem, and, in addition, it has important health cost implications (Phillips, 2009). It is estimated that the direct and indirect costs

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associated to chronic pain in Spain represents about the 2.5% of the national Gross Domestic Product (Torralba, Miquel, & Darba, 2014).

The experience of chronic pain and the associated physical, psychological and relational factors have consequences in the sexuality (Finn, Morrison, & McGuire, 2018). These factors are interrelated and produce negative effects both in the physiological domain of sexual functioning and in the psychological domain of sexual well-being (Dorado, McDonnell, Edwards, & Lazaridou, 2018). For this reason, sexual dysfunctions are common in patients with chronic pain (Gallach et al., 2018), prevalence of sexual difficulties being almost double that found in non-clinic population of the same age (Gruenwald, Adler, Haddad, Leiba, & Eisenberg, 2017). The main problems related to sexual response are the decreasing in sexual desire, the difficulty experiencing orgasm, lubrication problems and pain during sexual intercourse (Burri, Lachance, & Williams, 2014; Finn et al., 2018). Moreover, these sexual difficulties are generated or aggravated by the effects of the pharmacological treatments received in many cases (Birke, Ekholm, Højsted, Sjøgren, & Kurita, 2019; Cassim, 2009; Nadal-Llover & Cols-Jiménez, 2017). On the other hand, the physical limitations, mobility problems and sensory difficulties characteristic of chronic pain have an impact on the sexual intimacy of patients (Rosenbaum, 2010; Sidorkewicz & McGill, 2015). All that has serious implications on the subjective assessment of quality of sexual life. For example, some studies observed greater sexual dissatisfaction, greater sexual anxiety and a decrease in the frequency of sexual intercourse (Bazzichi et al., 2013; Burri et al., 2014; Finn et al., 2018; Gallach et al., 2018; Yilmaz et al., 2012). Finally, this disease also interferes in the interpersonal level, for example, in the affection exchange or couple communication (Ayling & Ussher 2008; Cano & Williams, 2010; Paquet, Rosen, Steben, & Bergeron, 2019; Smith, Tripp, Pukall, & Nickel, 2007).

The assessment of the impact of chronic pain on sexuality should be a main aspect for the therapeutic approach to this disease. However, sexual problems are often not explored, diagnosed, or adequately treated in this population (Colson, 2016; Finn et al., 2018). The motives are related to the scarce education of healthcare professionals in the area of sexuality and to the negative emotions, such as shame, that both patients and healthcare professionals feel when they must address openly about an intimate and private topic (Nicolosi et al., 2006). For example, as showed by Bahouq, Allali, Rkain, and Hajjaj-Hassouni (2013), the 93% of patients with chronic back pain considered that addressing sexual difficulties in visits to physicians was necessary; however, 66% indicated that they had never commented about this topic with them. On the other hand, the most widely used assessment measures of quality of life do not incorporate (Vicente-Herrero, Delgado-Bueno, Bandrés-Moyá, & Capdevilla-García, 2018) or insufficiently incorporate (Tait, Chibnall, & Krause, 1990) the dimension of sexuality. Consequently, generic scales and questionnaires are usually used which are usually not adapted or validated in this population. The most used to assess sexual functioning are the Changes in Sexual Functioning Questionnaire (Clayton, McGarvey, & Clavet, 1997), and the Female Sexual Function Index (Rosen et al., 2000; Verit & Verit, 2007) or the International Index of Erectile Function (Rosen et al., 1997); and to measure sexual satisfaction are the Relationship Assessment Scale (Hendrick, Dicke, & Hendrick, 1998), the Golombok-Rust Inventory of Sexual Satisfaction (Rust & Golombok, 1985) or the New Sexual Satisfaction Scale (Štulhofer & Buško, 2008).

Given the importance of assessing the sexual experience of people living with chronic pain and the absence of specific instruments to do it, the aim of this study is to present the psychometric properties of a new instrument for the assessment of chronic pain's interference with sexual functioning. It has been developed for identifying the impact of chronic pain in sexual life and, on the other hand, for providing information to design appropriate healthcare interventions.

## Materials and methods

### Participants

In the present study there were 303 participants, all of them diagnosed with chronic primary pain. 40% have widespread chronic pain, such as fibromyalgia syndrome; and the other 60%

have localized chronic musculoskeletal pain, such as back pain. 53 participants (17.5%) were men and the other 250 (82.5%) were women. The age of the participants was between 20 and 71 years ( $M=49.49$ ;  $SD = 10.7$ ). Levene's test confirmed the homogeneity of variances regarding to gender and age ( $W=0.530$ ,  $p=0.467$ ). A 26.2% of the sample admitted having a low economic level, while 72.2% had a medium economic level, and only 1.5% achieved a high economic level. 70.3% of our sample were married, 14.2% were separated, and 11.9% were single. Most of the sample had two children. Regarding religious beliefs, more than half of the respondents were non-practicing Catholics (50.3%), 23.7% were atheists/agnostics, and 22.7% were practicing Catholics. According to the employment situation, 34.3% were working when the test was administrated, 31.7% were unemployed, 10.9% cared for the home, and 12.6% had some type of disability (7.6% suffered from a permanent disability). Finally, around 83% were following some type of pharmacological treatment to alleviate chronic pain.

### **Procedure**

After a first contact with more than 30 Spanish associations of chronic patients, we were able to contact the heads of different centers (AVAFI, ADEC, AVAFAS, APAFIMA and AFIBROSE) through email and telephone, to whom we explained in detail the objective of the study. Once the authorization was got, we obtained 50 online responses in AVAFI and ADOLOR associations after an information session attended by members of both associations. Furthermore, 94 online responses were obtained from the other associations. Finally, the rest of the participants (159) were recruited among the students at the Senior Citizens' University, a range of studies created by Jaume I University for those people who are older than 55 and are willing to continue their studies and widen their general knowledge. They completed the questionnaire in a pencil-format. Through the questionnaire, the participants declared their consent to participate in this research and were made aware that the data would be used anonymously and confidentially. The development of the study complies with the rules and ethical principles of the Declaration of Helsinki and was approved by the Ethics Committee of the Jaume I University.

### **Measures**

A questionnaire named "SEX-PAIN Questionnaire" was developed. This questionnaire was created to evaluate the chronic pain's interference with sexual functioning in people with fibromyalgia or other chronic pain. In its initial format, it consisted of 20 items, 4 of which are inverse. Format response was a four-point Likert scale (Absolutely disagree to absolutely agree).

Four steps were followed to develop this new self-report measure to assess pain's interference with sexual functioning in chronic pain patients. As a first step, an exploratory literature review on sexuality in this population was done. Scientific literature data bases (PubMed and PsycINFO) were reviewed, looking for papers published between 2000 and 2020. General descriptors were employed --i.e. (sexuality OR sexual health) AND (chronic pain). Additional criteria for selecting papers were applied (e.g., studies addressing adult samples with self-report questionnaires; including a validated sexuality questionnaire as an outcome measure; publishing in a peer reviewed journal). Selected references were compiled. The second step was to include the perspective of people with chronic pain, addressing a qualitative study with focus groups to identify relevant indicators and needs related to sexual health. In this step, 20 persons with chronic pain were selected from different associations, taking part in the focus groups. Diversity in socio-economic status, educational level, and disease status were considered to select participants. Four focus groups were planned and performed by trained psychologists and audio recorded. Before audio recording, the right to confidentiality of participants was confirmed and written permission was requested. The material collected from the focus groups consisted of transcripts for posterior qualitative approach analysis by a team of four experts in sexuality and chronic pain. The team

of experts analyzed contents and identified relevant concepts and areas to assess. Four areas were defined: Affectivity, Communication, Sexual satisfaction, and Sexual interference caused by pain. The third step included drafting a pool of potential items covering relevant topics. In order to draft elements for the questionnaire the researchers: (1) deliberated, agreed, and wrote a definition of the construct (facet) to be evaluated; (2) drew up items tapping the construct defined, and agreed on those elements which were a fit; (3) decided on the answer format scale for the questionnaire. The chosen format was a four-point Likert scale. Subsequently, the pool of items and respective answers adapted to a questionnaire format was sent to four experts in the field to rate and assess the clarity, representativeness and relevance of items using a standard form assessment tool, developed in previous published research. In addition, the revised items using experts' suggestions were submitted to the assessment of people with chronic pain. Ten participants were selected in order to assess comprehension and feasibility of the reviewed pool of items and format response. The fourth step addressed the pilot testing of the revised questionnaire elements. The goal of this step was to assess items-quality by empirical criteria. Pilot testing included 20 people with chronic pain. The pilot testing helped to deplete the elements based on empirical criteria (e.g., missing responses, floor and ceiling effects, item-total correlation, internal consistency, facets' unidimensionality). The resulting questionnaire included the following number of items by area: Affectivity (3 items), Communication (3 items), Sexual satisfaction (5 items) and Sexual interference caused by pain (9 items).

### **Data analyses**

Different software was used in this research. SPSS (version 25) was used to carry out descriptive analyses on sociodemographic data, as well as to check the homoscedasticity of the variances according to gender and age, and calculating the items' correlation with their respective scales. The exploratory factor analysis (EFA) was performed with the data of 150 participants. For this analysis, Mplus 7.4 (Muthén & Muthén, 2015) and FACTOR 11.02 (Lorenzo-Seva & Ferrando, 2006) software's were used. The main reason of using each software was complementing the wide range of indices offered by FACTOR with the statistical adjustment provided by Mplus, also checking if both programs converged in the same factorial structure.

On the one hand, Mplus allows to obtain the factorial structure based on polychoric correlations using the robust ULSMV estimator, especially indicated with categorical data and less than 200 participants (Asparouhov & Muthén, 2010). Here, the oblique method and the Quartimin rotation were used, given that it is the one that provides the best results in multifactorial models when the items saturate in several factors at the same time, rotating the solution until obtaining the simplest factorial structure (Brown, 2006). On the other side, FACTOR also has the advantage of allowing the factorial structure to be obtained from the polychoric correlation matrix. In addition, FACTOR performs parallel analyses to determine the number of factors to be extracted (Timmerman & Lorenzo-Seva, 2011). Robust DWLS (Diagonally Weighted Least Squares) estimator was used. Once again, the oblique method was selected. Concretely, the Promin rotation was used, because there are preferred for multidimensional scales, given that Promin rotation maximizes factorial simplicity (Lorenzo-Seva, 2013).

For the EFA, the number of factors was extracted from the eigenvalues, parallel analysis, the scree-plot, the absence of negative residual variances, a large sample of factor extraction indices, the goodness-of-fit test and finally the closeness to unidimensionality (UniCO and ECV should have values above .95 and 85, respectively; and MIREAL below .30; to be treated as unidimensional). Thus, the results obtained are highly definitive.

Subsequently, a Confirmatory Factor Analysis (CFA) was carried out with the data of the other 153 participants, in order to corroborate the EFA structure. With the aim of confirming the structure obtained in the CFA, invariance analyses (configural, metric and scalar) were carried out, comparing the paper-and-pencil and the online format.

For both EFA and CFA, the goodness-of-fit indices used were the following: Satorra-Bentler chi-square ( $\chi^2$ ), relative chi-square ( $\chi^2/df$ ), general model significance ( $p$ ), Root Mean Square

Error of Approximation (RMSEA), the Comparative Fit Index (CFI), the Tucker-Lewis Index (TLI), the Adjusted Goodness of Fit Index (AGFI, only available in the EFA), the Standardized Root Mean Squared Residual (SRMR, only available in the EFA), the Weighted Root Mean Square Residual (WRMR, only available in the EFA), and finally the Modification Index (MI) and the Expected Parameter Change (EPC) (Whittaker, 2012), both used in the CFA. An acceptable fit corresponds to  $p < .05$ ; RMSEA values  $< .08$ ; WRMR and SRMR  $< 1.00$ ; and AGFI, CFI and TLI values  $> .90$  (DiStefano, Liu, Jiang, & Shi, 2018; Hooper, Coughlan, & Mullen, 2008). Excellent values correspond to relative chi-square values between 1 and 2;  $p > .05$ ; AGFI, CFI and TLI  $> .95$ ; RMSEA  $< .05$ ; and SRMR and WRMR  $< .08$  (Bagozzi & Yi, 2012; DiStefano et al., 2018).

Finally, RStudio software was used to calculate the scale and their dimension's internal consistency. For that purpose, it was used the "userfriendlyscience" package (Peters, 2014), which provides hierarchical omega index. Furthermore, it provides ordinal omega index, used specifically with ordinal items (Viladrich, Angulo-Brunet, & Doval, 2017).

## Results

### Exploratory Factor Analysis (EFA)

As previously mentioned, the statistical software FACTOR 10.10 and Mplus 7.4 were used for the EFA. We carried out two EFA. The first EFA carried out with the Mplus showed that the 3-Communication items were troublesome, given that in all models, they had negative residual variance values, and their factorial loading were always above 1. When these items were examined, it was observed that participants had only selected two of their four categories, having ceiling effects. Furthermore, those items were correlated with the Sexual Satisfaction factor items. These problems were biasing the results. Thereby, the authors decided to erase those items. Once they were eliminated, a final scale of 17 items was obtained (See Appendix).

In the second EFA, both programs showed that the 2-factor structure best represented the data, giving the same item-factor structure. In contrast, other rotated solutions were not suitable. On the one hand, the unidimensional model obtained non-acceptable GOF indexes (RMSEA = .145; CFI = .731; TLI = .692; SRMR = .149). Furthermore, closeness to unidimensionality was fair to be acceptable (UniCO = .774; ECV = .735; MIREAL = .327)

On the other, models with 3 or more factors had dimensions in which some items had a factor loading below .30, also obtaining negative residual variances in several items.

Finally, the 2-factor model did not have negative residual variances, which is another evidence to support this factorial structure (Muthén & Muthén, 2015). Table 1 shows the factorial loadings matrix, in addition to the GOF indices and the overall adjustment statistics.

With an Eigenvalue of 7.17, the first factor is made up by 8 items (1 to 8). This dimension collects items related to the dissatisfaction with different aspects of the sexual life (such as the frequency or personal satisfaction) and the lack of affectivity (petting and touches). Therefore, this dimension was called "*Sexual and Relationship Dissatisfaction*".

The second factor is composed by 9 items (9 to 17), with an eigenvalue of 2.87. This factor evaluates the sexual interference originated by the chronic pain, and some consequences in different areas. Thus, this dimension was called "*Chronic Pain Impact on Sexual Life*".

### Confirmatory Factor Analysis (CFA)

In order to corroborate our structure, a CFA was performed using Mplus 7.4. Robust estimator ULSMV was used (Asparouhov & Muthén, 2010).

The first model (M1) analyzed a unifactorial structure, as a reference model, with all the items that the EFA included in the scale structure (unifactorial model). The second model (M2) exactly replicated the factor structure derived from the EFA (two correlated factors). In

**Table 1.** EFA structure loading matrix (FACTOR values).

Items	F1	F2	Communalities
1) I would change a lot of things about my sexual relationships.	<b>.480</b>	.310	.316
2) Throughout the day we share physical contacts (caresses, hugs ...) that make me feel good.	<b>.825</b>	.260	.668
3) I enjoy hugging, caressing ... my partner.	<b>.580</b>	.217	.337
4) I don't think I get all the affection I want from my partner.	<b>.619</b>	.254	.383
5) I think my partner is only interested in his/her own pleasure.	<b>.712</b>	.366	.514
6) Sometimes sexual relations do not satisfy me but I am afraid to tell my partner.	<b>.671</b>	.277	.450
7) I am satisfied with my sex life.	<b>.772</b>	.370	.600
8) I am satisfied with the amount of time my partner and I spend on foreplay / sex games.	<b>.601</b>	.228	.362
9) I feel pain when I have intercourse with my partner.	.292	<b>.592</b>	.353
10) Pain prevents me from having sex.	.411	<b>.835</b>	.703
11) Because of the pain, my sexual relations are unsatisfactory.	.467	<b>.824</b>	.669
12) If I have pain in my body when I am having sex, I cannot think of anything else.	.219	<b>.796</b>	.647
13) Because of the pain I refuse to have sex with my partner.	.290	<b>.884</b>	.787
14) Because of the pain the frequency of my sexual intercourse has decreased.	.385	<b>.948</b>	.898
15) Because of the pain the quality of my sexual relations has deteriorated.	.384	<b>.930</b>	.865
16) Because of the pain, I usually don't feel like making love.	.414	<b>.950</b>	.904
17) Because of my pain, my partner does not enjoy sex anymore.	.308	<b>.806</b>	.651
Factor Determinacy Index	.932	.992	

Note: KMO = .843; RMSEA = .078; TLI = .976; CFI = .981; AGFI = .998; SRMR = .072; WRMR = .081; Cumulative proportion of variance = .61%.

this model all variables are significant. As MI and the EPC did not suggest any statistical improvement in M2, this is the final model. Table 2 shows all the results obtained for each model.

As can be seen in Table 2, the model with the best goodness-of-fit was M2. In this model, chi-square value is significant ( $p < .001$ ). The relative chi-square achieves a perfect value, because it is found between the 1 and 2 range. CFI and TLI achieved excellent values. The RMSEA is below the acceptability limit (0.08), being close of the excellence criteria. Therefore, the final model is made up of two factors. This model is represented in Figure 1.

The next step was checking for the invariance assumption. According to invariance analysis (Table 3), results show our scale is invariant between the paper-and-pencil ( $n = 159$ ) and the online ( $n = 144$ ) format. Here, configural (C), metric (M) and scalar (S) invariance was tested, obtaining positive results. In all models, the CFI, TLI and the relative chi-square values are considered as excellent. On the other hand, RMSEA values are within the acceptability parameters.

As the evaluation of invariances is supported at all levels, the next step was to compare the nested models (Table 3) (Satorra & Bentler, 2010). For the 3 models, all the comparisons made are not significant ( $p > .05$ ), which means that our scale is structurally invariant, as well as for the factor loadings and the thresholds in both groups.

### Descriptive and internal consistency

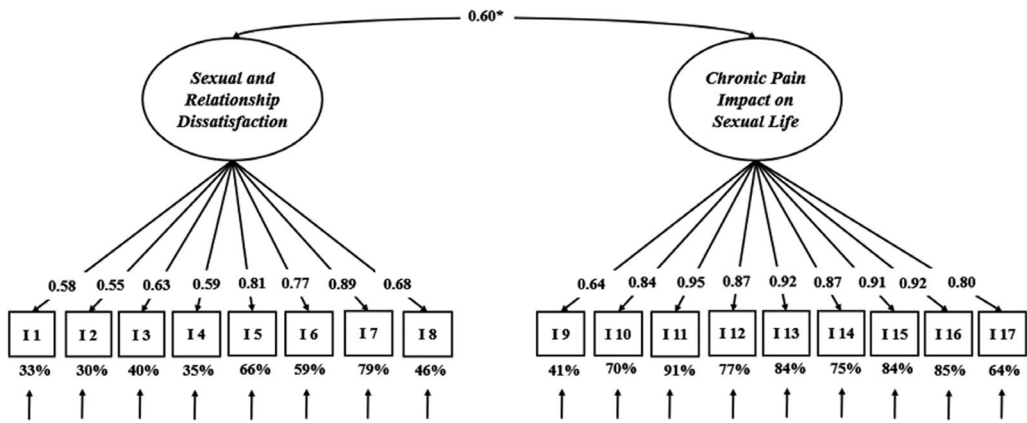
Table 4 shows the means, median, IQR, standard deviations, asymmetry, and kurtosis for each of the items and the two factors of the model, in addition to the internal consistency of each factor and for the total test.

**Table 2.** Goodness-of-fit indexes for the CFA.

	$\chi^2$	df	p	$\chi^2/df$	CFI	TLI	RMSEA (90% CI)
Model 1	391.823	119	<.001	3.29	.812	.785	.128 (.114 – .142)
<b>Model 2</b>	<b>182.907</b>	<b>118</b>	<b>&lt;.001</b>	<b>1.55</b>	<b>.955</b>	<b>.951</b>	<b>.062 (.044 – .080)</b>

Note: M1= unifactorial model; M2=EFA two-factor model.





**Figure 1.** CFA for model 2. Coefficients are reported as standardized. All endogenous variables are significant at  $p < .001$ .  $r^2$  is expressed as a percentage below variable's box. Factor correlation is significant at  $p < .001$ .

**Table 3.** Factorial invariance of CFA across groups.

	$\chi^2$	df	$p$	$\chi^2/df$	CFI	TLI	RMSEA	Comparison	$\Delta\chi^2$	$\Delta df$	$p$
C	369.269	236	<.001	1.56	.953	.946	.062	M-C	14.09	15	.519
M	379.260	251	<.001	1.51	.955	.951	.059	S-C	31.98	47	.954
S	401.247	283	<.001	1.48	.959	.960	.054	S-M	21.98	32	.908

Note: C = Configural; M = Metric; S = Scalar.

**Table 4.** Descriptive statistics and reliability indexes for items and factors.

	Range	M (SD)	IQR		Skewness	Kurtosis	$\alpha$ (CI)	Reliability indexes		
			Median	(25-50-75)				$\Omega$ (CI)	$\Omega$ (hier)	I-F r
<b>Factor 1</b>	0-24	10.20 (5.02)	NA	NA	.032	−.484	.77 (.73 – .81)	.72 (.67 – .77)	.65	NA
Item 1	0-3	1.46 (1.17)	1	0-1-3	.105	−1.469	NA	NA	NA	.529
Item 2	0-3	1.42 (1.14)	2	0-2-2	.030	−1.421	NA	NA	NA	.641
Item 3	0-3	1.01 (1.04)	1	0-1-2	.543	−1.001	NA	NA	NA	.513
Item 4	0-3	1.12 (1.17)	1	0-1-2	.519	−1.263	NA	NA	NA	.543
Item 5	0-3	.54 (.95)	0	0-0-1	1.607	1.249	NA	NA	NA	.547
Item 6	0-3	.90 (1.11)	0	0-0-2	.861	−.726	NA	NA	NA	.603
Item 7	0-3	1.94 (1.10)	2	1-2-3	−.593	−1.022	NA	NA	NA	.639
Item 8	0-3	1.81 (1.07)	2	1-2-3	−.389	−1.108	NA	NA	NA	.575
<b>Factor 2</b>	0-27	11.98 (8.59)	NA	NA	.240	−1.206	.96 (.95 – .97)	.96 (.95 – .97)	.95	NA
Item 9	0-3	1.14 (1.16)	1	0-1-2	.566	−1.144	NA	NA	NA	.620
Item 10	0-3	1.32 (1.08)	1	0-1-2	.337	−1.137	NA	NA	NA	.822
Item 11	0-3	1.16 (1.14)	1	0-1-2	.444	−1.241	NA	NA	NA	.826
Item 12	0-3	1.22 (1.14)	1	0-1-2	.421	−1.239	NA	NA	NA	.795
Item 13	0-3	1.29 (1.18)	1	0-1-2	.304	−1.419	NA	NA	NA	.864
Item 14	0-3	1.59 (1.15)	2	0-1-3	−.056	−1.444	NA	NA	NA	.885
Item 15	0-3	1.44 (1.18)	1	0-1-3	.129	−1.488	NA	NA	NA	.877
Item 16	0-3	1.39 (1.24)	1	0-1-3	.162	−1.596	NA	NA	NA	.896
Item 17	0-3	1.30 (1.21)	1	0-1-3	.285	−1.480	NA	NA	NA	.780

Note: I-F r: correlation item-factor. All correlations were significant at  $p < .001$ .

Regarding internal consistency, Table 4 shows excellent results. Either for factor 1 or factor 2, both Omega indexes exceed the criterion of .70 as a minimum value for a good internal consistency (Hunsley & Mash, 2008). About the total test internal consistency, ordinal Omega reaches a value of .89; and the hierarchical Omega coefficient reaches a value of .76, being an excellent value. Furthermore, both online and pencil format have excellent internal consistency values, reaching Ordinal Omega indexes of .91 and .92, respectively.

Additionally, the item-factor correlations were calculated for both factors, reaching values higher than 0.5 in all cases (between .513 and .896), being all correlations significant at  $p < .001$ .

## Discussion

The scientific literature and the health services and health policies have paid greater attention to chronic diseases in past decades. They account for the great proportion of these diseases in the morbidity of the population and have important health care costs. Indeed, the main health problems affecting the population are currently chronic diseases. These diseases compel the patients to live with them lifetime, have an important interference in different areas and require a process of adaptation and acceptance on the part of patients. Specifically, chronic pain constitutes one of the main public health problems, because of the prevalence and the impact that it causes on those who suffer it. Chronic pain can be caused by multiple factors but there can be no doubt that any manifestations of chronic pain seriously threaten the quality of life.

Despite the growing number of publications in past years about the quality of life of people with chronic pain, there is a dimension that has been largely forgotten, their sexuality. There is scarce scientific literature about how pain affects seriously their sexual life, reduces sexual self-esteem and impairs the couple's relationship. However, this oblivion in the scientific and professional fields has occurred in many other medical diseases too. Perhaps, it is because of two main causes. On the one hand, the belief that patients do not have sexuality because they have other major problems or concerns, or at least they do not have the right to sexual enjoyment. It is believed that sick role is incompatible with the right to continue enjoying a good sexual life. On the other hand, the lack of training of health professionals in the different aspects of human sexuality. The consequence is not only a very scarce scientific literature on the sexuality of people with chronic pain. Moreover, no one asks the patient about this aspect in the medical practice and if the health professionals wanted to ask about it, they do not have specific instruments for the evaluation.

These were the main reasons for carrying out this study in which the development and validation of the SEX-PAIN Questionnaire is presented. It is composed of 17 items and two factors that named: "Sexual and relationship dissatisfaction" and "Chronic pain impact on sexual life". These factors obtained from exploratory and confirmatory factor analysis have showed internal consistency indexes of 0.72 and 0.96, so the psychometric goodness of the SEX-PAIN Questionnaire is proven.

According to the few studies that there are about this topic, these factors are related to aspects of sexuality that may be affected in people with chronic pain. The first factor, named "Sexual and relationship dissatisfaction", describes the interpersonal dimension of pain, a central dimension (Dueñas et al., 2016). Studies such as Ayling and Ussher (2008) or Paquet et al. (2019) show the serious impact that pain has on the couple's relationship and the great relevance of active listening and empathy of the patient's partner. On the other hand, it includes the sexual satisfaction, perhaps consider the global subjective experience of these patients. It is regarding to the satisfaction with their sexual life, which is threatened by pain, as has been shown in Gallach et al. (2018), Jovaní, Martín, Fernández-Carballido, and Ibero (2010) or Yilmaz et al. (2012).

The second factor, named "Chronic pain impact on sexual life" includes difficulties associated with the physiological and psychological domains of the sexuality, such as low sexual desire, avoidance of sexual intercourse or painful intrusive thoughts during sexual intercourse. This factor is related to the previous scientific evidence that show that sexual dysfunctions are frequent in these patients and the prevalence is almost double that of people without this chronic disease, as Burri et al. (2014), Gallach et al. (2018), Gruenwald et al. (2017) or Rosenbaum (2010) showed. On the other hand, some of these dysfunctions may be associated with pharmacological treatment, as shown by the studies by Cassim (2009) regarding opioid therapy, Nadal-Llover and Cols-Jiménez (2017) or Santos, Santos, and Cendoroglo (2015) or associated to psychopathological comorbidity (Bazzichi et al., 2013).

Obviously, this study has some limitations. One of them refers to problems of social desirability and the subjective nature of the information derived from any self-report. The only source



to collect the information on partner's communication or sexual relationships has been the own patient, it has not been contrasted with the partner. The other questions evaluate highly subjective constructs. Moreover, it should be noted that the problems in sexual response mentioned do not refer to sexual dysfunctions that meet all the diagnostic criteria of the classification manuals but only the main symptom of such dysfunctions. On the other hand, may be the problems related to sexuality in these patients are greatly influenced by factors such as their medical condition and their age.

Despite these limitations, this study provides the first questionnaire developed and validated in Spanish and one of the few existing in the world to assess chronic pain's interference with sexual functioning in people with chronic pain. It can be especially useful for clinicians and researchers do not forget this important dimension of the quality of life of people with chronic pain. In addition, this questionnaire has been validated with an acceptable size sample, much than other studies. Moreover, the sample type is very valuable because it is considering as a clinical sample, that is not obtained in hospitals settings but in the general population and associations of patients. So, the results are more likely to be derived from the effects of chronic pain and are not contaminated by other factors associated to the hospitalization process.

### Data availability statement

The study data will be available by the corresponding author upon request.

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