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Development and Validation of the "Physical Functional Impact Index on Chronic Pain" (PFIICP): A Formative Model Approach

Desenvolvimento e Validação do "Índice de Impacto Funcional Físico na Dor Crónica" (IIFFDC): Uma Abordagem de Modelo Formativo

Filipe ANTUNES [1,2,3], Nuno SOUSA [1,4,5], Pedro TEIXEIRA [1,3,6]
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ABSTRACT

Introduction: The development and validation of reliable and valid instruments to assess chronic pain and its impact on daily functioning are crucial in both clinical and research settings. The aim of this study was to develop and validate the scale 'Physical Function Impact Index on Chronic Pain' – PFIICP, a novel 12-item questionnaire designed to evaluate the physical functional impact on chronic pain.

Methods: A formative measurement model was used. In comparison with other established scales that have emotional, cognitive and social considerations, PFIICP is designed to be more objective, as it focuses only on the relationship between physical performance and the subject's pain.

Results: Data were collected from n = 285 patients at baseline and n = 58 patients at follow-up (3 - 6 months later). Spearman's rho correlations between the 12 items ranged from 0.153 to 0.793, all statistically significant ($p < 0.05$), indicating that each item contributes uniquely to the construct. The intraclass correlation coefficient (ICC) for test-retest reliability was 0.788 (95% CI: 0.731 - 0.833), demonstrating good stability over time. Convergent validity was supported by strong Pearson correlations with established measures, including the Brief Pain Inventory (BPI; r = 0.739, $p < 0.05$) and the Pain Disability Index (PDI; r = 0.739, $p < 0.05$).

Conclusion: These findings suggest that the PFIICP is a robust tool for assessing the functional impact of chronic pain through a formative model approach.

Keywords: Chronic Pain; Pain Measurement; Quality of Life; Reproducibility of Results; Surveys and Questionnaires

RESUMO

Introdução: O desenvolvimento e a validação de instrumentos fiáveis e válidos para avaliar a dor crónica e o seu impacto no funcionamento diário são cruciais tanto em contextos clínicos como de investigação. Este estudo teve como objetivo desenvolver e validar a escala 'Índice de Impacto Funcional Físico da Dor Crónica' IIFFDC, um novo questionário de 12 itens concebido para avaliar o impacto funcional físico na dor crónica.

Métodos: Foi utilizado um modelo de medida formativo. Em contraste com outras escalas bem estabelecidas que apresentam considerações emocionais, cognitivas e sociais, a IIFFDC, de forma a ser objetiva, foca-se apenas na relação entre a atividade física e a dor crónica do individuo.

Resultados: Foram recolhidos dados de n = 285 doentes no início do estudo e de n = 58 doentes no seguimento (3 - 6 meses depois). As correlações rho de Spearman entre os 12 itens variaram entre 0,153 e 0,793, todas estatisticamente significativas ($p < 0,05$), indicando que cada item contribui de forma única para o constructo. O coeficiente de correlação intraclasse (ICC) para a fiabilidade teste-reteste foi de 0,788 (IC 95%: 0,731 - 0,833), demonstrando uma boa estabilidade ao longo do tempo. A validade convergente foi apoiada por fortes correlações de Pearson com medidas estabelecidas, incluindo o *Brief Pain Inventory* (BPI; r = 0,739, $p < 0,05$) e o *Pain Disability Index* (PDI; r = 0,739, $p < 0,05$).

Conclusão: Estes resultados sugerem que o IIFFDC é uma ferramenta robusta para avaliar o impacto funcional da dor crónica através de uma abordagem de modelo formativo.

Palavras-chave: Dor Crónica; Inquéritos e Questionários; Medição da Dor; Qualidade de Vida; Reprodutibilidade dos Resultados

KEY MESSAGES

- Development and validation of the Physical Function Impact Index on Chronic Pain (PFIICP), a 12-item questionnaire designed to evaluate the physical functional impact on chronic pain.
- Results suggest strong correlations between the 12 items, indicating that each item contributes uniquely to the construct.
- Strong convergent validity with the Brief Pain Inventory and the Pain Disability Index.
- Validation was done in a public general hospital; More studies are needed to validate the questionnaire in different settings.
- The PFIICP is a robust tool for assessing the functional impact of chronic pain through a formative model approach.

1. P5 Clinical Digital Center. Braga. Portugal.
2. Hospital de Braga. Unidade Local de Saúde de Braga. Portugal.
3. Life and Health Sciences Research Institute (ICVS). School of Medicine. Universidade do Minho. Braga. Portugal.
4. Centro Universitário de Jaguariúna (UniFAJ). Jaguariúna. São Paulo. Brazil.
5. Centro Universitário Max-Planck (UniMAX). Indaiatuba. São Paulo. Brazil.
6. ICVS/3B's - PT Government Associate Laboratory. Guimarães. Portugal.

✉ **Autor correspondente:** Filipe Antunes. filipe.j.antunes@gmail.com

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INTRODUCTION

Chronic pain is one of the primary reasons to seek healthcare, namely at the level of primary healthcare services. It has a prevalence rate of approximately 37% in the Portuguese population[1] and in a recent study,[2] its prevalence in primary healthcare in mainland Portugal was estimated at 33.6%. As expected, in its origin, pain was mostly musculoskeletal, located in the lower back and lower limbs.[2] It is widely recognized that the assessment of the functional consequences of chronic pain in the individual, considering both the person's organic structure (body segments) and the physical functional implications (body functions) in the individual's activities and participation in their daily environment, as defined in the International Classification of Functioning, Disability, and Health[3,4] is of great relevance. However, to quantify objectively a specific action performed by someone is inherently difficult to establish and reproduce.

The present study aimed to develop and validate a new tool, the 'Physical Function Impact Index on Chronic Pain' (PFIICP), designed to promote objectivity and practicality. This instrument was designed to be as objective as possible and it focuses on the relationship between physical performance and pain, considering only the body functionality and the limitations resulting from the subjects' chronic pain. Furthermore, as it is based on the anatomical representation of the body, its applicability is intuitive for any healthcare professional. For comparative validity, we used two validated questionnaires in Portuguese: the Brief Pain Inventory (BPI) and the Pain Disability Index (PDI). Although these questionnaires do not specifically address (in detail) the physical functional impact of pain on the individual, they do approach the interference of pain in a general set of daily activities, professional issues and quality of life.

The assumption of the measurement model – whether reflexive or formative – is critical, as it directly influences the interpretation of the results and the psychometric properties of the instrument.[5] Reflexive models assume that latent constructs cause observed variables, while formative models posit that the construct is an aggregation of specific dimensions represented by the observed variables. Clarifying the type of model used is particularly important in the field of pain research, where constructs such as 'functional impact' may be better represented as aggregations of distinct facets rather than as underlying causes of observed indicators.[6]

The PFIICP was developed to assess the physical functional activities associated with chronic pain. Unlike traditional reflective models, where latent constructs cause observed variables, the PFIICP employs a formative measurement model, wherein the latent construct ("physical functional impact of chronic pain") is defined and formed by the observed variables (12 items). This approach aligns with the understanding that the construct of interest is not an independent entity but rather an aggregation of specific dimensions based on segments of the human body and their corresponding physical functions such as upper body *versus* lower body physical limitations or walking *versus* sitting or lying down.[5]

Since daily life, professional activities, and social participation are based on the functional performance of the human body (and its different segments), it is assumed that it is this functional impact that truly weighs on an individual's daily quality of life, particularly for those who suffer from chronic pain.

The PFIICP is an intuitive tool that is easy to use in health care, particularly in Primary Health Care, as it is the translation of a set of functions that correspond to the body diagram. It leaves out psychological concepts and emotional experiences that are certainly important in those who experience pain, but it objectively translates the repercussions of pain at the present time, so that it can be properly quantified.

METHODS

Instrument development and pre-test

The development of the PFIICP results from a literature review of existing and validated metrics for functional assessment and quality of life. In addition, we consulted five experts in the chronic pain domain on the adequacy of the items that compose the scale and on whether they would fit for the purpose of developing an instrument that is not only more objective but also more user-friendly. In informal discussions, we sought to explore whether the proposed items made the appropriate correspondence between the action (function) and the body segments involved in the most common pain syndromes, namely using a body diagram of pain location. The experts agreed on the adequacy of the final version of the scale.

To test its applicability, we then performed a simple pre-test. For that purpose, 10 individuals, recruited from the general population, accepted to respond to the questionnaire to ensure comprehension and the time needed to fill in the questionnaire (the goal was less than five minutes). After very minor adjustments, the instrument proved suitable to be tested and validated.

Participants

Data were collected from n = 285 patients (91 men and 194 women; aged between 21 and 90 years old) attending their first consultation at the Pain Unit at Unidade Local de Saúde de Braga (Hospital de Braga), between March 2024 and March 2025. A subset of n = 58 patients (17 men and 41 women) completed a second evaluation, according to

the scheduled clinical appointments (generally three to six months later) and after clinical individual orientation, including any kind of analgesic treatment purposed (e.g., pharmacological, physical or psychological).

The participants were adults aged ≥ 18 years diagnosed with chronic pain lasting three or more months[7-9] followed in the consultation for that same reason, without any diagnostic restriction (assumption of chronic pain as a diagnosis for frequency of that same consultation) and who agreed to participate in the study.

Ethics committee approval was obtained from the institutional review board (ID:13_2024), and informed consent was provided by all participants.

Instruments

The PFIICP: A self-reported 12-item questionnaire designed to assess the functional impact of chronic pain. Each item evaluates a distinct aspect of daily functioning affected by pain, scored on a Likert scale (0 - 10) using the verb form to express the action. Higher scores indicate greater functional impairment.

The questionnaire uses a visual representation of the human body to facilitate self-reporting, ensuring that respondents can easily identify areas of concern.

I.

Figure 1.

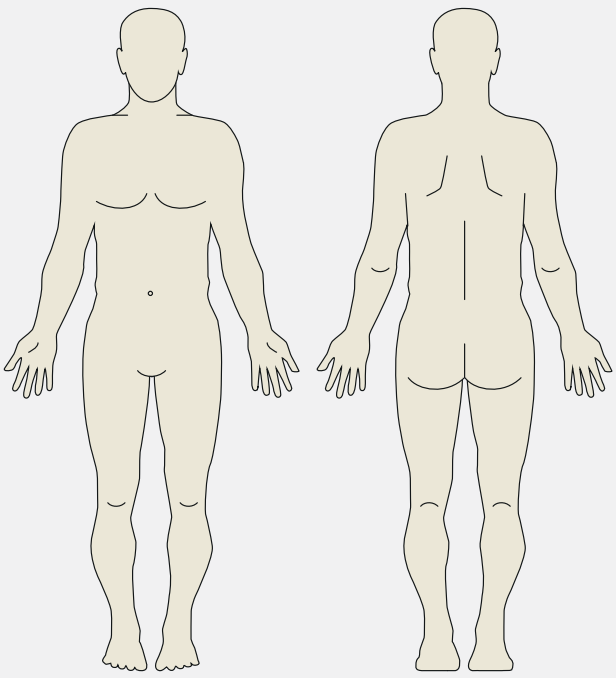

Figure 1 – Human body representation

II.

1. Personal care (washing, dressing, ...)
2. Working (or studying)
3. Sitting or lying down
4. Standing (orthostasis)
5. Changing position (getting up/sitting down; getting in and out of a vehicle/bathtub)
6. Walking
7. Going up/down (stairs)
8. Carrying loads or weights (for example, a shopping bag)
9. Handling objects (for example, writing, buttoning...)
10. Chewing/brushing teeth
11. Urinating or defecating
12. Engaging in sexual activity

The assessment of participants included the validated Portuguese versions of the following questionnaires:

- The Brief Pain Inventory.[10,11] The BPI assesses the intensity of pain at its worst, best, average, and current levels, according to an 11-point numerical rating scale (NRS), where 0 = 'no pain' and 10 = 'worst pain imaginable'. It also gathers information on pain treatments, perception of relief, and pain interference. The latter dimension includes general activity, mood, walking ability, normal work, relationships with others, sleep, and enjoyment of life, also using an 11-point NRS (0 = 'no interference'; 10 = 'completely interferes').
- The Pain Disability Index.[11,12] The PDI measures the overall impact of pain on seven activities of daily life, using an 11-point scale ranging from 0 (no disability) to 10 (total disability). The seven activities cover vital aspects (eating, sleeping, or breathing), physical (personal care), and social aspects (social activities, family and/or household responsibilities).
- The BPI and the PDI were used in clinical trials to measure the response to treatment. In a study by Azevedo *et al*,[1] the BPI and the PDI were used to evaluate the effectiveness of pharmacological and non-pharmacological therapies in pain management for patients with chronic pain. They helped monitor the reduction in pain intensity and improvement in quality of life, providing essential data for assessing treatment effectiveness.

Data collection

The PFIICP was administered via a self-reported questionnaire before entering the medical appointment without any kind of time restriction. Participants were presented with a visual representation of the human body, alongside the 12 items, allowing them to rate the specific aspects of

daily functioning on chronic pain.

No external observers influenced the responses, ensuring that the data reflected genuine patient perceptions.

The use of self-reported measures requires careful consideration of potential common methodological biases, which may arise from factors such as social desirability, mood states, or item characteristics. To minimize these biases, the PFIICP was designed with clear and concise items, avoiding ambiguity and reducing the likelihood of misinterpretation.

Statistical analysis

Spearman's rho correlations were calculated to examine the relationship between individual items and the total PFIICP score. Test-retest reliability was assessed using the intraclass correlation coefficient (ICC). Convergent validity was evaluated through Pearson correlations with the BPI and PDI. All analyses were conducted using JASP (Version 0.19.2). Statistical significance was set at $p < 0.05$.

Normality tests (Shapiro-Wilk) were performed for all items and the total PFIICP score. The results indicated moderate deviations from normality in some items, which was expected due to the ordinal nature of the scale. To mitigate possible limitations, we supplemented the analyses with nonparametric methods, such as Spearman correlations and the Wilcoxon Signed-Rank test to assess responsiveness.

To assess the relative independence between items, we performed a multicollinearity analysis using the variance inflation factor (VIF).

RESULTS

Item contribution

Spearman's rho correlations between the 12 items pairs ranged from 0.153 to 0.793, with all correlations being statistically significant ($p < 0.05$). These results indicate that each item contributes meaningfully to the construct, albeit with varying degrees of importance (Table 1). The multicollinearity analysis confirmed the independence of the items, with VIF values < 4.5 for all items, considered acceptable, ensuring that the items represent distinct dimensions without significant redundancies.

This characteristic is particularly important in formative models, where the items represent distinct dimensions of the latent construct rather than being reflections of a single underlying dimension.

Test-retest reliability

The ICC for the PFIICP scores between baseline and follow-up assessments was 0.788 (95% CI: 0.731 - 0.833), indicating good temporal stability. To further address the suitability of ICC for ordinal data, additional item-level analyses using Spearman's rank correlation coefficients were conducted between the initial and follow-up assessments. These analyses confirmed the scale's temporal stability, reinforcing its reliability as a measure of chronic pain's physical functional impact.

It is important to note that traditional internal consistency metrics, such as Cronbach's alpha coefficient, are not applicable to the PFIICP due to its formative model-based structure. In this approach, the items represent distinct and independent dimensions that contribute to the latent construct, without the expectation of high correlation between them.

Table 1 – Spearman's rho Correlations between items and PFIICP/IIFFDC global score; Variance Inflation Factor (VIF) of PFIICP/IIFFDC items.

Item	I01	I02	I03	I04	I05	I06	I07	I08	I09	I10	I11	I12	PFIICP	VIF
I01	--													2.293
I02	0.535***	--												1.676
I03	0.511***	0.384***	--											1.942
I04	0.510***	0.459***	0.526***	--										2.808
I05	0.634***	0.439***	0.625***	0.640***	--									3.083
I06	0.552***	0.462***	0.492***	0.667***	0.657***	--								3.604
I07	0.564***	0.488***	0.461***	0.701***	0.677***	0.793***	--							4.330
I08	0.534***	0.616***	0.446***	0.582***	0.555***	0.579***	0.683***	--						2.486
I09	0.538***	0.334***	0.322***	0.259***	0.376***	0.333***	0.338***	0.439***	--					1.926
I10	0.366***	0.197**	0.300***	0.234***	0.265***	0.214***	0.218***	0.211***	0.563***	--				1.849
I11	0.300***	0.153*	0.305***	0.229***	0.304***	0.208***	0.250***	0.207***	0.361***	0.533***	--			1.650
I12	0.313***	0.374***	0.375***	0.343***	0.358***	0.326***	0.309***	0.342***	0.269***	0.265***	0.411***	--		1.445
PFIICP	0.760***	0.647***	0.675***	0.705***	0.764***	0.723***	0.748***	0.726***	0.655***	0.552***	0.537***	0.603***	--	

*: $p < 0.05$; **: $p < 0.01$; ***: $p < 0.001$

The application of measures such as Cronbach's alpha, which assume high intercorrelations between items (typical of reflective models), could result in artificially low values, incorrectly suggesting a lack of reliability. Thus, methods more appropriate to the formative nature of the PFIICP were chosen, such as multicollinearity analysis (VIF) and the assessment of temporal stability through the intraclass correlation coefficient (ICC).

Convergent validity

Pearson correlations revealed strong associations between the PFIICP and the BPI ($r = 0.739$, $p < 0.05$) and PDI ($r = 0.739$, $p < 0.05$). These high correlations confirm the PFIICP's ability to capture similar constructs measured by these established instruments, providing evidence for convergent validity.

Exploratory analysis of responsiveness

An exploratory analysis of responsiveness was conducted to evaluate the PFIICP's ability to detect changes in the functional impact of chronic pain over time. This analysis was based on individual variations between baseline and follow-up assessments, conducted three to six months later. Participants who received significant interventions during the follow-up period were excluded to minimize external influences. The Wilcoxon Signed-Rank Test revealed no statistically significant changes in PFIICP scores over time ($z = 1.043$, $p = 0.299$). The effect size, measured by the matched rank biserial correlation, was small ($r = 0.166$, $SE = 0.158$), with a 95% confidence interval ranging from -0.144 to 0.446. These findings suggest minimal change in PFIICP scores over time without interventions. While the changes were not statistically significant, the small effect size indicates potential sensitivity to detect clinically meaningful changes in future studies with stricter control of interventions. The exploratory nature of this analysis highlights the need for longitudinal studies to further validate the PFIICP's responsiveness.

DISCUSSION

The present study provides initial validation evidence for the PFIICP, a novel 12-item questionnaire designed to assess the impact of physical functional activities on chronic pain. By adopting a formative measurement model, the PFIICP reflects the multidimensional nature of chronic pain's consequences, with each item contributing uniquely to the overall construct.

The wide range of Spearman's rho correlations (0.153 - 0.793) underscores the heterogeneity of the PFIICP items. While some items (e.g., I05) showed stronger associations with the total score, weaker correlations (e.g., I11) do not necessarily imply redundancy (even though this item may need further revision, namely in semantic terms). In formative models, items are not required to be highly intercorrelated, as they represent distinct facets of the construct.[5] Instead, their relevance lies in their theoretical alignment with the concept of functional disability caused by chronic pain, a functionally complex network of diverse aspects considered in these 12 different items.

The ICC value of 0.788 suggests that the PFIICP produces consistent results over time, which is crucial for longitudinal studies or clinical monitoring. This level of reliability indicates that the PFIICP can consistently track changes in patients' functional status.

Although the results of the exploratory responsiveness analysis did not reach statistical significance, the small effect size observed ($r = 0.166$) suggests that the PFIICP may have potential sensitivity to detect clinically relevant changes in future studies, especially with greater control of interventions performed during the follow-up period. It is important to note that this analysis complements the assessment of temporal consistency (stability of scores without interventions) by exploring the instrument's ability to capture individual variations in functional impact associated with changes in the clinical status of participants.

The strong correlations between the PFIICP and the BPI/PDI highlight the instrument's ability to measure constructs aligned with existing gold-standard measures. The construction and validation of this scale intends to objectify pain in clinical practice in terms of the physical repercussions on the individual's daily life. On the one hand it facilitates the interpretation of the healthcare provider who applies it, given that it is based on the affected body segments and, on the other, it allows the construction of an expected network of interactions of these same physical repercussions that result in the individual chronic pain.

The index is a practical, quick to answer (four minutes) and useful tool to objectify the real consequences of chronic pain of each person, their need for health care and ultimately, the social and economic costs that this means, mainly the need to resort to differentiated health care in hospital pain units, with increased costs of referral, use of specialized human resources and highly complex techniques. Because it is an objective, reproducible and reliable indicator of repercussion of pain, it can be assumed as a severity screening instrument and an indicator of the quality of care provided and, subsequently, a potential factor in the creation of public policies of general interest, given the scale of pain in the Portuguese society.[1,2]

Although the relatively small sample size, due and carried out in a real consultation context and respecting the regular appointments, may limit generalizability for the follow-up analysis, the inclusion criteria were very broad, particularly in terms of age and definition of chronic pain lasting

three months or more as the pathology, which minimized bias.

However, given the fact that the validation was done in a Pain Unit of a public general hospital, more studies are needed to validate the questionnaire in the general population in different settings.

Finally, the assumption of a formative model considers that the construct is defined by the unique contributions of each item rather than by their shared variance.[5] This approach reduces the risk of spurious relationships arising from methodological biases (e.g., social desirability bias, memory bias, acquiescence bias, fatigue effect),[13] as the focus is on the relevance and representativeness of the items rather than their internal consistency.

CONCLUSION

The PFIICP demonstrates promising psychometric properties as a tool for assessing the functional impact of chronic pain. Its adoption as a formative measurement model reflects the multifaceted nature of chronic pain's consequences. With promising test-retest reliability and convergent validity, the PFIICP holds potential for use in both clinical practice and research. Further studies are warranted to refine the instrument and evaluate its performance across diverse populations.

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AUTHOR CONTRIBUTIONS

FA, NS: Study design, writing of the manuscript.

PT: Data analysis and interpretation, critical review of the manuscript.

All authors approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

COMPETING INTERESTS

FA is the president of Associação Portuguesa para o Estudo da Dor (APED).

NS is the president of the Portuguese Agency for Clinical Research (AICIB).

PT has declared that no competing interests exist.

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