4-DOMAIN SPORTS PROM TRANSLATION AND CULTURAL ADAPTATION INTO PORTUGUESE



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4-DOMAIN SPORTS PROM: TRADUÇÃO E ADAPTAÇÃO CULTURAL PARA A LÍNGUA PORTUGUESA

4-DOMAIN SPORTS PROM: TRADUCCIÓN Y ADAPTACIÓN CULTURAL AL PORTUGUÉS

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ABSTRACT

Introduction: The literature presents several scientifically validated and cross-culturally adapted questionnaires in the area of orthopedics and Sports Medicine scientifically validated and cross-culturally adapted. However, they are anatomically specific, and do not consider the specific needs of athletes. The "4-Domain PROM for Orthopedic and Sports Medicine" (4-Domain Sports PROM) is the first questionnaire, in the literature (International Journal of Sports Medicine - 2021), designed to assess athletes and highly active sports practitioners, and their specificities. physical and psychological. It comprises four domains: athlete without injury, after sports injury, expectation of treatment, athlete's assessment of the treatment received. Objectives: This work aims to carry out the translation and cross-cultural adaptation (TCA) to the Portuguese language. Methods: The questionnaire was self-administered by 50 participants, regular physical and sports activities practitioners. The translation and cultural adaptation process involved six steps: translation; synthesis; back translation; pre-test; review by the Expert Committee, clinical application and author approval of the original version. The Equivalence of translation and relevance of questionnaire items were evaluated. RESULTS: The Portuguese version of the 4-DOMAIN SPORTS PROM had a translation equivalence of 0.94, and item relevance was 0.98, while the percentage of agreement between patients for understanding was 0.98. Conclusion: The translation and cross-cultural adaptation of the 4 Domain Sports PROM into the Portuguese version proved to be understandable and reproducible in all questionnaire domains (agreement above 90% and content validity index of 100%) to assess the treatment of the population of athletes and regular sports practitioners. Level of Evidence II; A cross-sectional qualitative study.

Keywords: Outcome and Process Assessment, Health Care; Patient Outcome Assessment, Patient-Reported Outcome Measures; Sports Medicine.

RESUMO

Introdução: A literatura apresenta diversos questionários cientificamente validados e adaptados transculturalmente na área de na Ortopedia e Medicina Esportiva validados cientificamente e adaptados transculturalmente. Entretanto, eles são anatomicamente específicos, e não consideram as necessidades específicas dos atletas. O "4-Domain PROM for Orthopedic and Sports Medicine" (4-Domain Sports PROM) é o primeiro questionário, na literatura (International Journal of Sports Medicine - 2021), concebido para avaliar atletas e praticantes de esportes altamente ativos, e suas especificidades físicas e psicológicas. Ele compreende quatro domínios: atleta sem lesão, após lesão esportiva, expectativa do tratamento, avaliação do atleta sobre o tratamento recebido. Objetivos: O objetivo deste trabalho é realizar a tradução e a adaptação transcultural (TCA) à língua portuguesa. Métodos: O questionário foi autoadministrado por 50 participantes, praticantes regulares de atividades físicas e esportivas. O processo de tradução e adaptação cultural envolveu seis etapas: tradução; síntese; retrotradução; pré-teste; revisão pelo comitê de experts; aplicação clínica e aprovação do autor da versão original. Foi avaliado a Equivalência da tradução e relevância de itens do questionário. RESULTADOS: A versão em português do 4-DOMAIN SPORTS PROM apresentou equivalência da tradução de 0,94 e relevância dos itens foi de 0,98, enquanto a porcentagem de concordância entre os pacientes para compreensão foi de 0,98. Conclusão: A tradução e adequação cultural do 4-DOMAIN SPORTS PROM para língua portuguesa mostrou-se compreensível e reprodutibilidade adequada em todos os domínios do questionário (concordância acima de 90% e Índice de Validade de Conteúdo de 100%) para avaliar o tratamento de população de indivíduos atletas e praticantes regulares de esportes. Nível de Evidência II; Estudo Qualitativo Transversal.

Descritores: Avaliação de Processos e Resultados em Cuidados de Saúde; Avaliação de Resultados da Assistência ao Paciente, Medidas de Resultados Relatados pelo Paciente; Medicina Esportiva.

RESUMEN

Introducción: La literatura presenta varios cuestionarios científicamente validados y transculturalmente adaptados en el área de la ortopedia y Medicina del Deporte. Sin embargo, son anatómicamente específicos y no consideran las necesidades específicas de los atletas. El "4-Domain PROM for Orthopaedic and Sports Medicine" (4-Domain Sports PROM) es el primer cuestionario, en la literatura (International Journal of Sports Medicine - 2021), diseñado para evaluar



atletas y practicantes de deportes altamente activos, y sus especificidades físicas y psicológicas. Comprende cuatro dominios: atleta sin lesión, después de una lesión deportiva, expectativa de tratamiento, evaluación del atleta sobre el tratamiento recibido. Objetivos: El objetivo de este trabajo es realizar la traducción y adaptación transcultural (TCA) a la lengua portuguesa. Métodos: El cuestionario fue autoadministrado por 50 participantes, practicantes habituales de actividades físicas y deportivas. El proceso de traducción y adaptación cultural involucró seis pasos: traducción; síntesis; traducción inversa; prueba previa; revisión por el comité de expertos; aplicación clínica y aprobación del autor de la versión original. Se evaluaron la equivalencia de traducción y la relevancia de los ítems del cuestionario. Resultados: La versión portuguesa del 4-DOMAIN SPORTS PROM tuvo una equivalencia de traducción de 0,94 y la relevancia de los ítems fue de 0,98, mientras que el porcentaje de acuerdo entre los pacientes para la comprensión fue de 0,98. Conclusión: La traducción y adaptación transcultural del 4-DOMAIN SPORTS PROM al portugués amplía las posibilidades de evaluar los diferentes momentos que involucran el tratamiento de lesiones deportivas, ya que este cuestionario fue diseñado para capturar datos sobre la percepción de los pacientes antes de la lesión, después de la lesión, expectativa y evaluación del trato recibido en deportistas y practicantes habituales de actividad física.

Descriptores: Evaluación de Procesos y Resultados en Atención de Salud; Evaluación del Resultado de la Atención

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Nivel de Evidencia II; Estudio Cualitativo Transversal.

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INTRODUCTION

Assessment of patient benefits is critical to guide the duration and treatment that best meets the proposed goal.¹⁻³ Historically, outcomes have been broadly assessed from a clinical perspective.^{4,5}

al Paciente, Medición de Resultados Informados por el Paciente; Medicina Deportiva.

However, recording patients' perceptions of the outcome of their treatment has become the focus of recent research efforts for both the medical and social sciences. Thus, measuring outcomes based on patient reports (PROMs) has become integral to the evaluation process, as decision-making should primarily benefit patients. Therefore it is essential to consider their expectations regarding treating their injury.^{6,7}

The literature presents a considerable variety of PROMs used in the field. These include IKDC (knee ligament injuries), DASH (upper extremity), FAOS (foot and ankle), EQ-5D (health-related quality of life), Lysholm (knee ligament injury and TKA), KOOS (Total Knee Replacement), HAAS (High-Activity Arthroplasty Score), and have been scientifically validated and culturally adapted. However, they are anatomically specific, focus on a particular joint or anatomical location, and do not consider the needs of athletes. 9

It is important to emphasize that the development and improvement of the treatment of sports injuries is based on the careful analysis of risks and benefits inherent in the therapeutic approach, but mainly on the voices and opinions of patients about the treatment received.^{7,9,10}

Thus, the collection of information regarding the patient's perspective, quality of life, functional capacity, pain scales, and satisfaction with the treatment received, combined with physical, functional, social, and emotional aspects, allows a more comprehensive analysis of the health situation, recovery after therapeutic approach - PROMs (Patient Reported Outcomes Mesures). 5,11,12

The application of these questionnaires (PROMs) can be made by a wide variety of electronic devices and interfaces available, such as smartphones, tablets, and web tools that optimize data collection, and currently, studies for the cross-cultural adaptation of these instruments are constantly being developed. 13,14

Although the orthopedic literature presents different PROMs validated for clinical practice, it is critical to recognize the apparent gap of a specific PROM for Sports Medicine. After all, athletes have different demands and expectations from the general population: 9.11,13

In this context, the "4-Domain Patient Reported Outcome Measures (PROM) for Orthopedic and Sports Medicine" (4-DOMAIN SPORTS PROM)¹⁵ is a specific tool for assessing this population. It is organized

into four domains, each with a specific purpose. This organization allows comparative analysis between the domains (pillars) or by selecting specific questions within each domain to compare with the others. 14,15

OBJECTIVES

The general objective of this study was to translate and culturally adapt the questionnaire "4-Domain Patient Reported Outcome Measures (PROM) for Orthopedic and Sports Medicine" (4-DOMAIN SPORTS PROM), 15 so that it can be used reliably in Brazil, proceeding to content validation, obtained by evaluating the instrument by a reliable and reproducible method. (Annex 1)

The specific objectives in validating its use in Portuguese are to apply it in developing scientific research and health protocols and contribute to improving the therapeutic approach in sports injuries.

METHODS

The process of translation and cultural adaptation of the 4-PROM questionnaire followed the methodological criteria described by Guillemin, Bombardier, *and Beat, 1993*^{16,17} and Beaton, Bombardier, and Guilemin, 2000, ¹⁸ used by the American Academy of Orthopaedic Surgeons (AAOS) and the International Quality of Life Assessment (IQOLA).

The present study was approved by the Research Ethics Committee of this University (CAAE: 52301221.0.0000.5404) and was authorized by the authors of the original version of the questionnaire. The participants signed the Informed Consent Form, which will keep their identities confidential.

Patients who met the inclusion criteria and did not meet the exclusion criteria shown in Table 1 were introduced to the project and judged whether or not they would participate in the study.

Demographic data such as age, gender, level of education, and sports practice were collected for better characterization and sample evaluation.

Table 1. Sample analysis Pre-test.

	50 interviewed individuals	
Gender	Male	38 (76%)
Gender	Femele	12 (24%)
age (mean and DP)	31,96 ± 7,55	
hMI (maan and DD)	Men	Women
bMI (mean and DP)	21,13 ± 4,21 Kg	20,41 ± 3,21
	Incomplete higher	29 (58%)
Education	Completed higher	18 (36%)
	Middle school	3 (6%)

The translation and cultural adaptation process involved six steps:
1) translation; 2) synthesis; 3) *back-translation*; 4) pre-test; 5) Expert committee:

- An orthopedic doctor and professor at a Brazilian state university whose line of research is sports medicine;
- An orthopedic physician and professor at a Brazilian state university whose line of research is musculoskeletal disorders of the shoulder;
- An orthopedic doctor graduated from a Brazilian federal university with a post-graduate degree in sports medicine;
- A physiotherapist graduated from a Brazilian federal university.
- A nurse works in the inpatient care of the orthopedic surgical center.
 6) approval of the author of the original version for publication of the final version.

Phase 1 (Initial translation) - The 4-PROM was translated into Portuguese by two sworn translators, working independently, with their mother tongue, Portuguese, and fluency in English. T1 and T2 versions were created. Phase 2 (Synthesis) - The two versions were compared, and joint adjustments were made in this phase, thus originating a new version of the instrument - S1.

Phase 3 (Backtranslation) - In the process of back-translation into English, the text is returned to the original by two certified translators with a mother tongue of English, unaware of the original questionnaire. In this way, translation problems can be amplified.

Phase 4 (Testing of pre-final version) - Testing the questionnaire to patients. Feedback will be considered for the need to reword the questionnaire for the final version.

Phase 5 (Expert Committee) - In this phase, the need for cultural adaptation, the relevance of the items, and the level of understanding of what was being asked were assessed. The sample of the expert committee (Table 2) was critically reviewed for content. The evaluation method was the Content Validity Index, normally used to analyze the extent to which a measure achieves its purpose; the instrument is considered valid if it obtains a CVI of 0.80, ideally greater than 0.90.

The experts were asked to rate each item's relevance in the instrument: 1 = item not relevant; 2 = item needs revision to assess relevance; 3 = item relevant, needs minor changes; 4 = item absolutely relevant. Being considered 3 and 4 as approved relevance. (Figure 1)

Table 2. Inicial translation.

Questionnarie item - "term"	"T1" e t2"	Modification to version consensual "s1"		
1º Domínio - "uninjured	T1 - linha de base do status ileso	linha de base		
baseline status"	T2 - linha de base sem ferimentos	antes da lesão		
Questão 4 - "the main	T1 - as principais demandas físicas	as principais		
physical demands"	T2 - a principal demanda física	demandas físicas		
Questão 8 - "did you	T1 - você realmente entendeu	você realmente entende.		
really understand"	T2 - você de fato entendeu	voce realmente entendeu		
Questão 8 - "no way"	T1 - de forma nenhuma	de forma alguma		
Questao o - 110 way	T2 - de jeito nenhum	de forma alguma		
Questão 10 - "your	T1 - seu cuidado pós operatório	seu acompanhamento		
postoperative care"	T2 - seu manejo pós operatório	pós operatório		
Questão 11 - "at the	T1 - ao fim do tratamento	ao fim do tratamento		
end of treatment"	T2 - ao final do tratamento	ao ilin do tratamento		

Similarly to translation equivalence 1 = item not equivalent; 2 = item needs revision to assess equivalence; 3 = item equivalence, needs minor changes; 4 = item absolutely equivalent.

A simple measure of inter-observer agreement was considered to assess comprehension,¹⁹ with an agreement rate of 0.9 or higher being acceptable.^{20,21} Each item was rated from 1 to 4, like a 4-point Likert scale by patients where 1" corresponds to "unclear/unintelligible" "2" corresponds to "unclear/needs adjustment" "3" corresponds to "fairly clear/easy to understand" "4" corresponds to "very clear/very good understanding". (Figure 2)

After analyzing all versions of the questionnaire, the final version of the "4-DOMAIN SPORTS PROM" questionnaire was developed. The evaluation data were organized in summary tables for better visualization and understanding.

Phase 6 (Final version) - All versions were evaluated and, together with the *backtranslation*, sent to the original authors of the "4-Domain Sports PROM". With the approval of the original authors, the final version is summarized.

RESULTS

In the translation process into Brazilian Portuguese, the two versions (T1 and T2) did not differ significantly (Table 3), all items of the versions were discussed to formulate the consensus version.

There was consensus among the committee to choose different words without changing the understanding or identification of what the questionnaire is about. The same happened with back-translation, with no problems occurring for the translation of the questions (back-translation 1 and back-translation 2).

The questions, after evaluation by the multi-professional committee of experts, were considered suitable for the pre-final version through the Likert scale; from these points, minor changes were made in grammatical structures of some items to acquire better equivalence between words, between languages, and cultural context adaptations. (Table 4)

The 4-DOMAIN SPORTS PROM (pre-final version 1) was self-administered by 50 participants, with demographic data organized in Table 5. The Content Validity Index for committee members was applied in this test, where translation equivalence was evaluated at 0.94 and item relevance at 0.98. The percentage of agreement between patients for comprehension was calculated as 0.98.

All versions and step data were emailed to the authors of the original version of the 4-DOMAIN SPORTS PROM, who did not suggest any

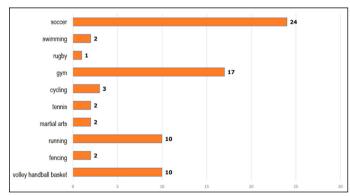


Figure 1. Sports practiced.

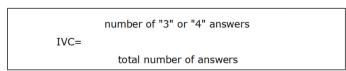


Figure 2. Calculation of the Content Validity Index (CVI).

Table 3. Modifications to facilitate understanding assessed by the committee.

Questionnarie item	Suggestion / evaluation	Pre-test version
1° DOMÍNIO- Linha de base antes da lesão (relatado do pelo paciente)	Trocar "Relatado" por "Inforrmado"	1º Domínio condição antes da lesão (informado pelo paciente)
Nada / Alta influência	Trocar "Alta influência" por "Muito"	Nada / Muito
2) Considerando sua modalidade esportiva, qual seu nível de competição?	Reformular frase	2. Considerando a modalidade do seu esporte, qual é o seu nível de competição?
 O quão motivacional (atividade positiva) é a atividade esportiva para você? 	Trocar "Motivacional" por "Estimulante"	3. O quão estimulante a atividade esportiva é para você?
2º DOMÍNIO – status com lesão (qualidade de vida e performace esportiva	Trocar "Status" por "Condição" / Trocar "Performace" por "Desempenho"	2º Domínio – condição com lesão (qualidade de vida e desempenho esportivo)
7) Quais são suas mais importantes queixas físicas (sintomas) após essa lesão?	Reformular frase	7. Quais foram suas queixas (sintomas) mais importantes após a lesão?
(1) dor (2) instabilidade articular (3) redução da amplitude de movimento (4) perda de força	Adicionar "falseio", expressão popular usada na língua portuguesa no Brasil	1) dor (2) falseio (instabilidade articular) (3) perda ou diminuição de movimento (4) perda ou diminuição
3º DOMÍNIO – Expectativas do paciente		
de forma alguma / sem dúvidas	reformular/ simplificar expressões	não / entendi completamente
não / Eu estou confiante	trocar "eu estou confiante" por "com certeza"	não / com certeza
4º DOMÍNIO – Tratamento e resultados pós operatórios		
11) Em relação à sua lesão, como está se sentindo (estado psicológico) ao fim do tratamento (resultados pós-operatórios finais)?	Reformular frase	11. Considerando a sua lesão, como você está se sentindo psicologicamente ao final do tratamento (resultado final pós-operatório)?

Table 4. Expert committee content validity index

PROM	•	Equivalence ation)	Conceptual (relev	•
questionnaire	N° of failures	IVC-I (%)	N° of failures	IVC-I (%)
1	0	100	0	100
2	0	100	0	100
3	1	80	0	100
4	0	100	0	100
5	0	100	0	100
6	1	80	1	80
7	0	100	0	100
8	0	100	0	100
9	1	80	0	100
10	0	100	0	100
11	0	100	0	100
IVC-Q(%)	94	.54	98	3.8

changes. There were no "not understood" items, which the doctor could clarify in case of need. After the result of this test, the final Brazilian version of the 4-DOMAIN SPORTS PROM was defined; in its final version, it kept the denomination "4-DOMAIN SPORTS PROM". (Annex 2)

DISCUSSION

Although the orthopedic literature presents a considerable number of PROMs developed to assess outcomes of treatment of musculoskeletal conditions,⁸ recently a systematic review showed that currently, available PROMs have not been useful to assess, for example, postoperative outcomes in athletes and highly active practicing sports. In addition, this review showed that there is no uniformity in the type of scores commonly used to assess postoperative outcomes of the same clinical problem, i.e., ACL injury.⁹

Athletes and practitioners of highly active sports cannot be considered ordinary people, as they have physical expectations and psychological goals that differ from the general population. ^{10,11,12} This fact reinforces the importance of a PROM designed "tailor-made" to more reliably capture the needs and desires inherent to this population and that, at the same time, can be applied to different sports modalities and sports injuries regardless of the anatomical site that it occurred. ^{10,12,14}

Table 5. Expert committee content validity index.

PROM questionnaire	Assessment of unde	rstanding by patients
items	N° of failures	PC-I (%)
1	5	90
2	0	100
3	3	94
4	0	100
5	0	100
6	0	100
7	0	100
8	0	100
9	0	100
10	0	100
11	0	100
PC-Q(%)	98	3.5

In this way, patient-reported independent measures (PROMs) can be analyzed in conjunction with physiological, mechanical, and imaging measures to provide a more holistic assessment of treatment.

This study developed the Portuguese translation and cultural adaptation of the 4-DOMAIN SPORTS PROM questionnaire, the first questionnaire in the literature specifically developed to capture patient-reported data (athletes and physically active individuals) on all aspects of clinical care, including surgery. In this way, global, disease-specific, and joint-specific outcomes can be explored.

Guillemin¹⁶ and Guillemim, Bombardier, and Beato,^{17,18} published a procedure for translation and cultural adaptation of instruments that follows standardized steps. Previously, the process was more difficult to carry out depending on the population studied, the type of instrument, and the authors. Although it is widely accepted and widely used in the health area,²² followed and cited in several studies, and the criteria are internationally recognized, the complexity of the steps, the long duration, and high cost are questioned points.^{23,24}

The Content Validity Index used refers to the measure of the extent to which a measure achieves its purpose. Content validity is important for all measurements, and its focus is to determine whether the items included in a tool represent the content of interest of the instrument. This validity can be measured by the Content Validity Index - CVI, which assesses the

agreement of experts regarding the representativeness/importance of the measure in relation to the content studied. It allows you to analyze each item individually and then the instrument as a whole. This method employs a Likert-type scale 25,26 with scores ranging from one to five. To assess the committee's maintenance of relevance, responses included: 1 = "not relevant or not representative", 2 = "item needs major revision to be representative", 3 = "item needs minor revision to be representative" and 4 = "relevant or representative item". Patients' understanding of the questionnaire items was assessed as 1 = "unclear/unintelligible", 2 = "unclear/needs adjustment", 3 = "quite clear/easy to understand" and 4 = "very clear/very good understanding".

By this method, the items and the instrument as a whole are considered valid if they obtain a CVI of 0.80 or greater, ideally greater than or equal to 0.9024; in this case, using the formula CVI = Number of responses "3" or "4"/Total number of responses (Figure 1 and 2), being considered valid by the evaluated if the response is 3 or 4.

Publications have presented different methods to quantify the degree of agreement among experts during the process of assessing the content validity of an instrument.^{27,28} This study used the "percentage of agreement", a method employed to calculate the percentage of agreement among participants. As it is a simple measure of interobserver agreement,¹⁹ when using this method, an acceptable rate of agreement of 90% between raters should be considered. (Figure 3)^{20,21}

Some of the answers to each question of the "4-DOMAIN SPORTS PROM" ¹⁵ are in visual analog scale (VAS) format. There was no difficulty in understanding how to answer them by the patients, as the researchers gave instructions about the questionnaire and clearly explained how to use this type of scale. There are reports of how patients may be confused when giving their answers or find the Likert scale easier in contrast to the VAS. Although better understood using the Likert scale, no significant differences were found.²³

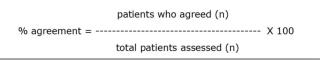


Figure 3. Calculation of the percentage of agreement between examiners.

After defining the final version of the questionnaire for the target language, it was important to apply it to a significant sample to assess validity, reproducibility, and sensitivity to change. These, statistically evaluated and approved by the CVI, we obtained agreement above 90% for both the committee and the patients evaluated, in which the CVI was evaluated in both groups as valid in all responses, being then evaluated as 1.0 (100%). Thus, determining that the questionnaire is adequately understandable and useful for its original purpose. The results themselves showed that all domains of the questionnaire had adequate reproducibility, and there were no major difficulties with translation and cultural adaptation. The use of the pre-established criteria already mentioned, associated with the exchange of information, availability, and collaboration of the authors of the original version, facilitated the steps of the process. The Brazilian version of the questionnaire is available for use in Brazil.

CONCLUSION

The translation and cultural adequacy of the 4-DOMAIN SPORTS PROM into Portuguese proved to be understandable and reproducibility adequate in all domains of the questionnaire (agreement above 90% and Content Validity Index of 100%) to assess the treatment of the population of individuals athletes and regular practitioners of sports.

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