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ASSESSMENT PROCEDURE

French translation and validation of the exercise-induced leg pain Questionnaire

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ABSTRACT

Objective: The "Exercise-Induced Leg Pain" questionnaire was developed (in German) for the evaluation of the severity of symptoms and sports ability in individuals with exercise-induced leg pain. The purpose of the present study was to translate and cross-culturally adapt this questionnaire into French and to study the reliability and validity of this French-language version.

Methods: The translation and cross-cultural adaptation of the original "Exercise-Induced Leg Pain" was performed according to established guidelines. The translation part was carried out in six stages: (i) two initial translations from German to French; (ii) synthesis of the two translations; (iii) backward translations; (iv) comparison between the backward translations and the original questionnaire by an expert committee; (v) pretest; and (vi) approval of the final version of the French-language "Exercise-Induced Leg Pain" questionnaire. To validate this questionnaire, 84 subjects were recruited (28 pathological patients with a confirmed diagnosis of chronic leg pain, 28 asymptomatic sport students, and 28 healthy control athletes). The discriminative power of the questionnaire was tested, as well as its reliability (internal consistency and test–retest reliability after a 7–10-day interval), construct validity and floor/ceiling effects.

Results: The French version of the "Exercise-Induced Leg Pain" questionnaire was generated without any major difficulties. The ability of the questionnaire to discriminate between the three groups of subjects was demonstrated with a total score of 61.0 ± 18.5 for the pathologic group; 93.9 ± 7.57 for the asymptomatic group and 94.1 ± 9.79 for the control group. A high internal consistency (Cronbach's alpha of 0.93) and an excellent test–retest reliability [intraclass coefficient correlation: 0.98 (95% confidence interval: 0.97–0.99, $p < 0.001$)] indicated that the "Exercise-Induced Leg Pain" is reliable. The questionnaire also demonstrated good construct validity against different subscales of the Short Form-36 questionnaire, a generic quality of life questionnaire, with more than 87% of the prespecified hypotheses confirmed. Finally, no floor effects or ceiling effects were observed.

Conclusion: The French version of the « Exercise-Induced Leg Pain » was successfully translated and cross-culturally adapted. The questionnaire is consistent, valid and reliable for evaluating French-speaking patients with chronic exercise-induced leg pain.

➤ IMPLICATIONS FOR REHABILITATION

- The "Exercise-Induced Leg Pain" questionnaire aims to assess the severity of symptoms that impact the function and sports ability of patients with exercise-induced leg pain;
- The French version of the « Exercise-Induced Leg Pain » was successfully translated and cross-culturally adapted. The questionnaire is consistent, valid and reliable for evaluating French-speaking patients with chronic exercise-induced leg pain.

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Psychometric validation; exercise-induced leg pain; questionnaire; translation; running

Introduction

Running has become increasingly popular in modern society. Although this activity is good for one's health, especially for the heart [1,2], it can lead to injuries such as calcaneal tendinopathies and chronic leg pain if practiced without the correct training. Among these injuries, the most frequent musculoskeletal pathologies are periostitis (shin splint), stress fractures, and chronic compartment syndromes [1]. Besides pain, patients suffering from these pathologies may complain of a variety of undesirable symptoms such as burning, cramp, muscle weakness, paresthesia, swelling and others. All these symptoms are highly susceptible to impact physical performance of both recreational and elite athletes. Unfortunately, these pathologies are often difficult to treat. Because of this, it is necessary to perform a thorough evaluation of the clinical situation of these patients. Objectively quantifying the loss of function associated with exercise-induced leg pain is essential for both clinical practice and research. For this reason, and because few patient-related and disability-specific assessments tools were available, the "Exercise-Induced Leg Pain" (EILP), a self-administered questionnaire, was developed in German

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(EILP-G) in 2015 with the aim of assessing the severity of symptoms that impact the function and athletic ability of patients with exercise-induced leg pain [3]. This instrument is composed of 10 items, ranging from moderate athletic activities to more intensive ones. Each of the 10 items is scored on a five-point Likert scale ranging from 4 (no difficulty) to 0 (unable to do). The obtained score is based on a possible score of maximum 40 points. A higher score reflects a higher level of physical function. Validation analyses of this questionnaire indicated that the questionnaire is valid and reliable and can therefore be used to measure the severity of symptoms that impact the function and athletic ability of patients with exercise-induced pain. This simple and easy-to-use questionnaire has already been translated into English and Greek [4] but not French.

French is the fifth most widely spoken language in the world and is spoken by more than 274 million people in different parts of the world (France, Belgium, Canada, Luxembourg, Switzerland, Africa, Oceania, West Indies, and Southeast Asia). Moreover, French is also one of the two languages of the Olympic Games. This language is widely used in athletic environments. Obtaining a French version of the EILP questionnaire targeted at chronic exercise-induced leg pain seems appropriate. The aim of this study was to translate and cross-culturally adapt the EILP-G into French and to study the reliability and validity of this French-language version.

Methods

Participants

Three different groups of participants, all 18 years old or older, were recruited for this study. (1) Those in the first group of subjects, recruited from the University Hospital of Liège (Belgium), had a confirmed diagnosis of chronic leg pain. The diagnosis of chronic leg pain was established by a clinical examination and a scintigraphy (a procedure to check for abnormal areas or damage of the bones) for periostitis and stress fracture or by a pressure test for chronic compartment syndrome. (2) Those in the second group were asymptomatic subjects, recruited from various athletic clubs in Liège and among students of Sport and Rehabilitation Sciences Department of the University of Liège who were practicing a discipline for which the risk for developing chronic leg pain was recognized as being high. To be eligible for inclusion into this group, the subjects had to confirm that they run at least 30 km per week. (3) Finally, the third group, which was considered as a control group, was composed of students in the Sport and Rehabilitation Sciences Department of the University of Liège. By having a sedentary lifestyle or practicing a moderate level of physical, this last group is not considered as "at risk". The exclusion criteria for all three groups were: a history of previous leg or spinal surgery and/or suffering from low back pain.

All of the participants gave informed consent for participation in the study, and the study was approved by the Ethics Committee of the University of Liège.

Procedures

This study followed, in as much as possible, the COSMIN guidelines [5].

French translation of the EILP-G

To reach linguistic and cultural equivalence between the original questionnaire (EILP-G) and the translated version (EILP-F), the validated guidelines of Beaton et al. [6] were followed for the translation methodology. Six different steps were followed: (1) two initial translations from German to French were performed by two independent bilingual translators (one active in the medical field and one not active in this area) who were native French speakers; (2) a synthesis of the two initial translations was performed to provide a consensual first translation of the EILP-F (T1); (3) two backwards translations were performed by two additional independent bilingual translators (one active in the medical field and one not active in this area) who were native German speakers and who were blinded to the original EILP-G version; (4) an expert committee review, which was composed of the four translators, a medical expert (physical and rehabilitation medicine and sports traumatology specialist) and a French linguist, was organized in order to compare the back translations with the original questionnaire and to come to a consensual agreement on a second version of the EILP-F (T2); (5) pretests of the T2 of the EILP-F were performed on five pathologic subjects with a confirmed diagnosis of chronic leg pain and on five asymptomatic subjects who were at risk for chronic leg pain to ensure a good comprehension of each question and to ensure that the translated questionnaires equivalent to the original. The final version of the EILP-F was generated after modification based on the changes deemed necessary in light of the feedback from the pretest; (6) the final version of the EILP-F was approved by the expert committee.

Psychometric validation of the EILP-F

The verification of the questionnaire's psychometric properties consisted of an analysis of its discriminative power, an assessment of its reliability (internal consistency and test–retest reliability), an analysis of its construct validity and an assessment of its potential floor and ceiling effects.

Discriminative power

The ability of the questionnaire to discriminate between the three groups was tested by comparing the scores of the different groups (total score and individual item scores). Intergroup differences were assessed by a binary logistic regression analysis to independently assess the differences in the scores between each group (pathologic versus symptomatic; pathologic versus control; symptomatic versus control) with confounding factors included as covariates.

Reliability

Internal consistency: Internal consistency reflects the estimation of homogeneity across the items of the scale. The interconnection of items is measured with Cronbach's alpha coefficient. The alpha values range from 0 to 1, with internal consistency increasing as the alpha approaches 1. However, a Cronbach's alpha close to 1 (above 0.95) is unacceptable since it indicates a redundancy of items. Therefore, a value between 0.70 and 0.95 is generally considered as indicating a high level of internal consistency [7,8]. Spearman correlations and their 95% CIs were also used to test this property by assessing correlations between the total score and each individual item. A correlation greater than 0.6 was considered as being indicative of a strong correlation between the item and total score.

Test–retest reliability: This assessment tests the stability of the scale over time. When no health change was observed among the population, the score of the EILP-F was expected to remain unchanged. For this purpose, all of the subjects were asked to complete the EILP-F a second time after an interval of 7–10 days. The intra-class coefficient correlation (ICC) was used to test the reliability between the total score of the first and second

administration of the EILP-F scale for the complete sample but also for the three subgroups (pathologic, asymptomatic, and control). An ICC greater than 0.7 was considered as being indicative of an acceptable reliability [7,8]. For individual items, as they are represented by categorical values, Cohen's Kappa coefficient was used, with values ≤ 0 indicating no agreement, values from 0.01 to 0.20 indicating no to slight agreement, those from 0.21 to 0.40 indicating fair agreement, values from 0.41 to –0.60 indicating moderate agreement, values from 0.61 to 0.80 indicating substantial agreement, and values from 0.81 to 1.00 indicating almost perfect agreement [9].

Construct validity

Convergent validity and divergent validity were measured as indicators of the construct validity of the EILP-F.

To accomplish this evaluation, subjects were also asked to complete the Short Form-36 questionnaire (SF-36) in addition to the EILP-F questionnaire. The SF-36 is composed of 36 items measuring 8 health-related quality of life domains, namely "physical functioning", "role limitation due to physical problems", "bodily pain", "general health", "vitality", "social functioning", "role limitation due to emotional problems", and "mental health"[10].

For the convergent validity, Spearman's correlations and their 95% CIs were calculated between the EILP-F and subscales of the SF-36 questionnaire that were hypothesized to have similar constructs ("physical functioning", "role limitation due to physical problems", "bodily pain", and "general health"). Strong correlations were expected from these hypotheses. Regarding the divergent validity, Spearman's correlations and their 95% CIs were calculated between the EILP-F and other subscales of the SF-36 questionnaire that were hypothesized to have different constructs ("mental health", "role limitation due to emotional problem", "social functioning", and "vitality"). Weak correlations were expected for these hypotheses. This requirement was considered fulfilled when at least 75% of the hypotheses were confirmed.

Floor and ceiling effects

Floor and ceiling effects were considered to be present when at least 15% of the population had the lowest or the highest score. When floor or ceiling effects are present, persons with the minimum or maximum score cannot be distinguished from one another, reducing the discriminative power of the questionnaire.

Statistical analysis

The normality of quantitative variables was tested with the Shapiro–Wilk test. In light of the results from this test, quantitative variables were expressed as mean ± standard deviation (SD), while categorical variables were reported as the absolute and relative frequencies (%). Analyses were performed using IBM SPSS Statistics 21.0. The results were considered statistically significant at the 5% significance level ($p < 0.05$).

Results

French translation of the EILP-G

The 10 items of the EILP-F were translated without any major difficulties.

The final version of the EILP-F was approved by the expert committee. The pretest of the final version, which was carried out with 10 subjects, 5 from the pathologic group, and 5 from the asymptomatic group, indicated that there were no difficulties related to understanding the questionnaire.

Table 1. Population characteristics.

	Pathologic $n = 28$	Asymptomatic $n = 28$	Control $n = 28$
Age (years)	25.9 ± 11.7	29.5 ± 9.51	22.8 ± 3.10
Sex Women	10 (35.7)	7 (25.0)	8 (28.6)
Weight (kg)	70.2 ± 15.1	66.9 ± 10.4	67.0 ± 10.6
Height (cm)	174.1 ± 9.49	176.1 ± 8.23	174.5 ± 9.19
Runners	13 (46.4)	28 (100.0)	9 (32.1)

Table 2. Results of the EILP-F questionnaire.

Items	Pathologic $n = 28$	Asymptoma tic $n = 28$	Control $n = 28$
Total score	61.0 ± 18.5	93.9 ± 7.57	94.1 ± 9.79
Item 1	2.75 ± 1.26	3.46 ± 0.69	3.79 ± 0.57
Item 2	2.18 ± 1.22	3.79 ± 0.42	3.79 ± 0.69
Item 3	2.12 ± 1.24	3.82 ± 0.48	3.71 ± 0.85
Item 4	1.85 ± 1.35	3.93 ± 0.26	3.54 ± 0.92
Item 5	2.73 ± 1.25	3.86 ± 0.45	3.86 ± 0.45
Item 6	2.88 ± 1.14	3.79 ± 0.50	3.82 ± 0.47
Item 7	2.50 ± 1.10	3.64 ± 0.56	3.82 ± 0.47
Item 8	2.68 ± 1.05	3.79 ± 0.50	3.68 ± 0.61
Item 9	3.43 ± 0.69	3.93 ± 0.26	4.0 ± 0
Item 10	1.46 ± 1.03	3.58 ± 0.64	3.64 ± 0.62

Psychometric validation of the EILP-F

Participants

A total of 84 subjects were recruited for the present study. Among these subjects, 28 subjects suffered from chronic leg pain (53.6% from compartment syndrome and 46.4% from periostitis), 28 were asymptomatic subjects but were considered as being high-risk and 28 were included in the control group.

The characteristics of the patient population are presented in Table 1. The mean age of the population was 25.9 ± 11.7 years in the pathologic group, 29.5 ± 9.51 in the asymptomatic group (at risk) and 22.8 ± 3.10 in the control group.

All of the subjects were involved in various sports. Running was practiced by 32.1% of the control population (mean of 16.1 ± 4.86 km per week), 46.4% of the pathologic population (mean of 30.7 ± 21.2 km per week) and 100% of the asymptomatic population (running at least 30 km per week was an inclusion criterion for this group of subjects) (mean of 51.3 ± 20 km per week).

Discriminative power

The total score of the EILP-F was 61.0 ± 18.5 for the pathologic group, 93.9 ± 7.57 for the asymptomatic group and 94.1 ± 9.79 for the control group (Table 2). Significant two-group differences were observed between the pathologic group and the asymptomatic group as well as between the pathologic group and control group. No intergroup difference was observed between the asymptomatic group and control group. Similar results were found for the individual items (Table 3).

Reliability

Internal consistency: The Cronbach's alpha of the EILP-F questionnaire was 0.93, which indicates a high level of internal consistency. When deleting one item at a time, we observed the Cronbach's alpha varying between 0.911, which was observed when deleting item 3, and 0.928, which was observed when deleting item 9. Reliability was therefore considered as stable when deleting the items one at a time. The correlation between the total score of the EILP-F questionnaire and each item was also tested. These results indicated that individual items were positively and significantly correlated with the total EILP-F score, with

Table 3. Discriminative power of the EILP-F questionnaire.

Items	Pathologic versus asymptomatic			Pathologic versus control			Asymptomatic versus control		
	OR	95% CI	*p*-value*	OR	95% CI	*p*-value*	OR	95% CI	*p*-value*
Total score	1.24	1.09–1.41	0.001	1.16	1.08–1.25	<0.001	1.02	0.95–1.09	0.63
Item 1	2.04	1.12–3.72	0.02	3.11	1.48–6.56	0.003	2.91	1.09–7.80	0.03
Item 2	8.85	2.88–27.2	<0.001	5.03	2.23–11.4	<0.001	1.17	0.42–3.27	0.76
Item 3	12.7	3.21–50.1	<0.001	4.58	1.99–10.6	<0.001	0.83	0.32–2.18	0.71
Item 4	32.2	4.70–220.5	<0.001	3.52	1.78–6.99	<0.001	0.19	0.03–1.32	0.09
Item 5	5.56	1.80–17.1	0.003	6.27	2.00–19.6	0.002	1.05	0.28–3.97	0.94
Item 6	3.94	1.56–9.97	0.004	5.37	1.86–15.5	0.002	1.36	0.40–4.66	0.62
Item 7	4.86	2.00–11.8	<0.001	6.98	2.44–19.9	<0.001	2.60	0.78–8.50	0.12
Item 8	6.19	2.25–17.0	<0.001	4.08	1.80–9.24	0.001	1.14	0.39–3.34	0.81
Item 9	8.86	1.85–42.3	0.006	/	/	/	/	/	/
Item 10	30.1	3.86–235.3	0.001	12.5	3.22–48.3	<0.001	1.08	3.67–3.18	0.89

Intergroup difference including control group was not calculable for item 9 because all values of item 9 were identical this group.
*Adjusted on age.

Table 4. Correlations with the EILP-F total score.

EILP-F vs	r_s[a]	95% CI
Internal consistency		
Item 1	0.73	0.58–0.88
Item 2	0.88	0.78–0.99
Item 3	0.83	0.68–0.91
Item 4	0.82	0.67–0.91
Item 5	0.75	0.58–0.86
Item 6	0.71	0.53–0.83
Item 7	0.79	0.66–0.93
Item 8	0.79	0.66–0.92
Item 9	0.59	0.42–0.77
Item 10	0.85	0.74–0.98
Convergent validity		
SF-36 physical functioning	0.70	0.54–0.86
SF-36 role limitation due to physical problems	0.42	0.22–0.62
SF-36 body pain	0.52	0.34–0.71
SF-36 general health	0.13	−0.09 to 0.22
Divergent validity		
SF-36 mental health	0.21	−0.004 to 0.21
SF-36 role limitation due to emotional problems	0.13	−0.08 to 0.35
SF-36 social functioning	0.17	−0.05 to 0.39
SF-36 vitality	0.14	−0.08 to 0.35

[a]Spearman's correlations used.

correlations varying from 0.59 (95% CI: 0.42–0.77) for item 9 to 0.88 (95% CI: 0.78–0.99) for item 2 (Table 4).

Test–retest reliability: All of the subjects completed the EILP-F questionnaire a second time after an interval of 7–10 days. The results showed an excellent test–retest reliability for the whole population, with an ICC of 0.98 (95% CI: 0.97–0.99; $p < 0.001$). An excellent test–retest reliability was also observed across the populations, with an ICC of 0.97 (95% CI: 0.93–0.98; $p < 0.001$) for the pathologic group, 0.94 (95% CI: 0.86–0.97; $p < 0.001$) for the asymptomatic group and 0.91 (95% CI: 0.82–0.96; $p < 0.001$) for the control group (Figure 1). For the individual items, the Kappa values indicated moderate to high agreement, with Kappa values varying from 0.58 ($p < 0.001$) for item 7 to 0.76 for item 3 ($p < 0.001$).

Construct validity

A strong correlation between the EILP-F questionnaire and "physical functioning" subscale of the SF-36 questionnaire was found ($r = 0.70$; 95% CI: 0.54–0.86) (Table 4). Moderate correlations between the EILP-F questionnaire and the "role limitation due to physical problems" and "bodily pain" subscales were also observed [$r = 0.42$ (95% CI: 0.22–0.62) and $r = 0.52$ (95% CI: 0.34–0.71)]. In contrast to what was *a priori* expected, a low and non-significant correlation was observed between the EILP-F and the "general health" subscale ($r = 0.13$; 95% CI: −0.09–0.22). With regards to the divergent validity, all of the hypotheses were confirmed given that low and non-significant correlations were observed between the EILP-F and the "mental health", "role limitation due to emotional problem", "social functioning", and "vitality" subscales.

Floor and ceiling effects

None of the subjects presented with either the lowest score or the highest score of the EILP-F questionnaire. Consequently, there were neither floor effects nor ceiling effects present.

Discussion

This study produced a French version of the Exercise-Induced Leg Pain questionnaire that has been proven to be a discriminant, valid and reliable tool for the evaluation of the severity of symptoms and athletic ability in individuals with exercise-induced leg pain after being assessed for transcultural adaptation and validation.

To provide equivalence between the French and original German version of the EILP questionnaire, a rigorous translation and cross-cultural adaptation process was followed. Proof of accuracy and equivalence between the two questionnaires was provided by the high internal consistency of the translated questionnaire, by its good construct validity and by the excellent test–retest reliability observed in the validation study.

First, the evaluation of the psychometric properties shows that the French version of the questionnaire is able to discriminate between the pathologic group of subjects and the asymptomatic group (students who were practicing a discipline for which the risk for developing chronic leg pain was recognized as being high), and from the control group (healthy students without any particular risk). Because the questionnaire was specifically developed to evaluate the severity of symptoms and athletic ability in individuals with exercise-induced leg pain, all of the questions included in the questionnaire are specific to individuals with exercise-induced leg pain. Therefore, it is not surprising that the pathologic subjects had lower results than the non-pathologic ones. Similar results have been observed for the German [3] and Greek [4] versions of the EILP questionnaire. It should be pointed out that in terms of age and anthropometric data, the subjects involved in the psychometric validation of the German, Greek and French versions were relatively similar. Second, the EILP-F questionnaire has been shown to have a high internal consistency, with a Cronbach's alpha of 0.93. A Cronbach's alpha of 0.92 was found for the German original version [3] and a Cronbach's alpha of 0.94 for the Greek version, which are very close to our result. These results highlight the fact that the different items of the

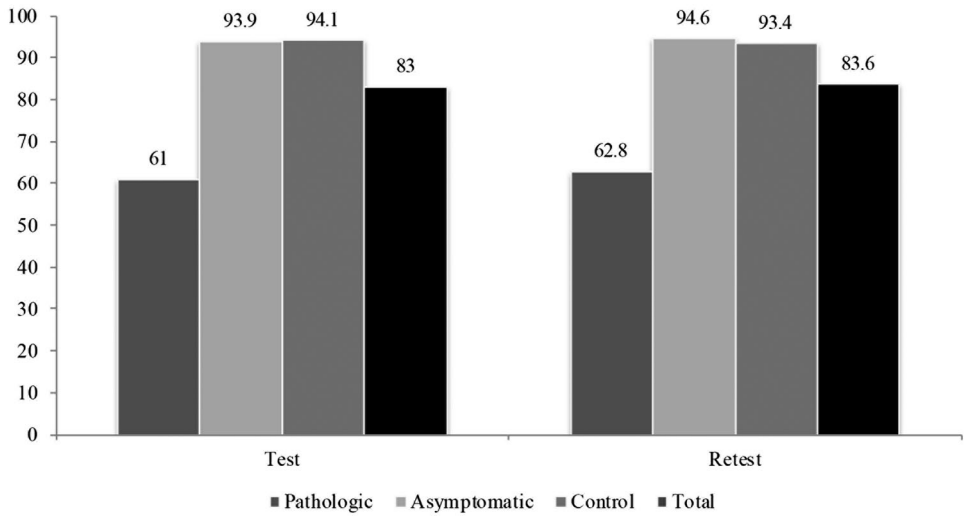

Figure 1. Test and retest values for the global score of the EILP-F across populations.

EILP questionnaire have a high level of consistency. Internal consistency is generally better for instruments measuring narrower concepts, such as this specific questionnaire, and lower when more generic, broader constructs are measured. The reliability of the scale has also been tested by test–retest reliability. In the field of clinical assessment using questionnaires, a high reliability is considered to be established when the ICC is greater than 0.90, which is the case for the translated EILP-F questionnaire for the restricted population of pathologic subjects (ICC of 0.97) and also for the asymptomatic (ICC of 0.94) and control populations (ICC of 0.91). In the original German version [3], a higher ICC for the pathologic population was observed compared with that for the two other populations (ICC of 0.98 for the pathologic population; ICC of 0.86 for the asymptomatic and control groups). This suggests that this questionnaire is specific to pathological populations and not designed for use in healthy populations. Finally, to assess the construct validity of the questionnaire, it is recommended to measure correlations with other questionnaires that are supposed to have similar or different constructs to the questionnaire being examined. For this purpose, the generic quality of life questionnaire SF-36 was used, and 7 out of 8 (87.5%) of the hypotheses made *a priori* were confirmed, indicating a good construct validity. For the original German version of the questionnaire and for the Greek translation, authors decided to use the Schepsis Chronic Exertional Compartment Syndrome Outcome Classification System [11] to measure construct validity and, more precisely, the convergent validity. This scale, which is much more specific than the SF-36 questionnaire and therefore has a much more similar construct to that of the EILP questionnaire, was not used in our study because we also included subjects suffering from periostitis, not only those suffering from compartment syndrome. However, another Patient Reported Outcome Measure (PROM) developed by Winter et al. [12] and designed to classify the severity of periostitis could have been used for the present study. Its absence is one of the limitations of this study. However, to our knowledge, none of these questionnaires have been translated and validated in French. In the same vein, a questionnaire with more specific divergent construct of the EILP could have been used for evaluating the divergent validity. Another limitation of the present study is related to the fact that the sensitivity to change has not been measured, given that the cross-sectional design made this not feasible. It is important to evaluate sensitivity to change in some circumstances, for example when assessing the impact of a pharmaceutical of non-pharmaceutical therapeutic intervention. The more sensitive a questionnaire is, the more likely it will be able to show an effect of the intervention. In both the German and the Greek versions of the EILP, a minimal clinical difference (MCD) [13] was measured through a prospective study. The results revealed that a MCD of between 3.82 points (for the Greek validation) and 4.16 points (for the German validation) is necessary before a change can be considered clinically relevant to patients. Finally, another limitation of this study is the sample size, which is considered as being too small. according to Terwee et al. [7], a sample size of at least 50 pathologic subjects is required for psychometric validation. Results should therefore be interpreted with this limitation in mind.

Nevertheless, the psychometrics analyses performed in this study revealed that the EILP-F is a reliable instrument for evaluating French-speaking patients with chronic exercise-induced leg pain. An objective quantification of the loss of function associated with exercise-induced leg pain is essential for both clinical practice and research. Indeed, when assessing the effect of any treatment, it is strongly recommended that disability-related outcome measures be obtained and also that patients undergo a subjective assessment. To extend the availability and utilization of such a questionnaire by clinicians and researchers across the world, its translation and validation in other languages is necessary, especially in French, which is one of the most widespread languages worldwide. The psychometric properties of the French version of the EILP-F confirm that the questionnaire is now ready to be used both in clinical settings and in research.

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Disclosure statement

No potential conflict of interest was reported by the authors.

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