Universidade Estadual de Londrina

WAGNER FLORENTIN AGUIAR

TRADUÇÃO, ADAPTAÇÃO TRANSCULTURAL E VALIDAÇÃO DA VERSÃO EM PORTUGUÊS DO *IPF-SPECIFIC VERSION OF SAINT GEORGE'S RESPIRATORY QUESTIONNAIRE* (SGRQ-I) PARA PACIENTES COM DOENÇA PULMONAR INTERSTICIAL

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Dissertação apresentada ao Programa de Pós-Graduação em Ciências da Reabilitação (Programa Associado entre Universidade Estadual de Londrina [UEL] e Universidade Norte do Paraná [UNOPAR]), como requisito parcial à obtenção do título de Mestre em Ciências da Reabilitação.

Orientador: Prof. Dr. Carlos Augusto Marçal Camillo

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Londrina, 30 de outubro de 2019.

Dedico este trabalho à Deus e aos meus pais, que me deram força e me conduziram dignamente ao caminho da persistência permitindo-me chegar até aqui.

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“O futuro pertence àqueles que acreditam na beleza de seus sonhos”.

Elleanor Roosevelt.

AGUIAR, Wagner Florentin. **Tradução, adaptação transcultural e validação da versão em português do *IPF-specific version of saint george's respiratory questionnaire* (SGRQ-I) para pacientes com doença intersticial pulmonar.** 2019. 81 f. Dissertação (Mestrado em Ciências da Reabilitação) – Programa Associado UEL – UNOPAR) – Universidade Estadual de Londrina, Londrina, 2019.

RESUMO

Introdução: A qualidade de vida relacionada à saúde (QVRS) está prejudicada na maioria dos pacientes com Doenças Pulmonar Intersticial (DPI) devido a sintomas como dispneia e fadiga, limitações nas atividades físicas e isolamento social. Instrumentos para a mensuração da mesma já são válidos e utilizados em outros países. No entanto, não existe uma ferramenta válida, confiável e reprodutível para avaliar a qualidade de vida específica para pacientes com DPI brasileiros. Objetivo: Desenvolver uma versão em português do Brasil do *Saint George Respiratory Questionnaire for patients with Interstitial pulmonary fibrosis* (SGRQ-I) que seja conceitualmente equivalente ao original; e avaliar a validade, confiabilidade e reprodutibilidade desse instrumento. **Métodos:** A presente dissertação foi realizada em duas etapas. A primeira consistiu na tradução do questionário e adaptação transcultural para pacientes brasileiros. Em um segundo momento, pacientes com doença intersticial pulmonar foram convidados a responder o questionário em três momentos por dois avaliadores diferentes. A avaliação da confiabilidade intra e inter-avaliador foi analisada por meio do coeficiente de correlação intraclasse (CCI). A consistência interna foi analisada pelo coeficiente α de Cronbach e as associações entre as variáveis clínicas e do SF-36 foram analisadas pelos coeficientes de correlação de Pearson ou Spearman. O software utilizado para a análise estatística foi o *Statistical Analysis System* (SAS) University Edition® e a significância estatística foi estabelecida como $p<0,05$. **Resultados:** No total, 30 pacientes com DPI responderam o SGRQ-I traduzido em três momentos, o score final do SGRQ-I apresentou excelente concordância e consistência interna no teste-reteste intra-avaliadores (CCI: 0,93 [0,85 - 0,97]; Cronbach α: 0,88) e interavaliador (CCI: 0,88 [0,77 - 0,94]; Cronbach α: 0,86). O escore total do SGRQ-I correlacionou-se moderadamente com o SF-36 nos domínios de capacidade funcional, dor, estado geral de saúde e vitalidade ($-0.66 \leq r \leq -0.40$; $p<0.05$ para todos). **Conclusão:** A versão em português do SGRQ-I é válida, confiável e possui consistência interna para uso em pacientes com DPI brasileiros.

Palavras-chave: Doenças Pulmonares Intersticiais. Qualidade de Vida. Questionário.

AGUIAR, Wagner Florentin. **Translation, cross-cultural adaptation and validation of the Portuguese version of the IPF-specific version of Saint George's Respiratory Questionnaire (SGRQ-I) for patients with interstitial lung disease.** 2019. 81 p. Dissertation (Masters in Rehabilitation Sciences) - UEL Associate Program - UNOPAR) - State University of Londrina, Londrina, 2019.

ABSTRACT

Introduction: Health-related quality of life (HRQoL) is impaired in most patients with interstitial lung disease (ILD) due to symptoms such as dyspnea and fatigue, limitations in physical activity and social isolation. However, there is no valid, reliable and reproducible tool for assessing specific quality of life for Brazilian ILD patients. Aim: To develop a Brazilian portuguese version of the Saint George Respiratory Questionnaire for Interstitial Pulmonary Fibrosis (SGRQ-I) that is conceptually equivalent to the original version and; to evaluate the validity, reliability and reproducibility of this instrument. **Methods:** This dissertation was divided in two parts. The first consisted of the translation of the questionnaire and cross-cultural adaptation for Brazilian patients. Secondly, patients with interstitial lung disease were asked to answer the questionnaire three times by two different evaluators. The assessment of intra and inter-rater reliability was analyzed using the intraclass correlation coefficient (ICC). Internal consistency was analyzed by Cronbach's α coefficient and associations between variables were analyzed by Pearson or Spearman correlation coefficients. The software used for statistical analysis was the Statistical Analysis System (SAS) University Edition® and the statistical significance was set at $p<0.05$. **Results:** Thirty patients with ILD were evaluated, the final SGRQ-I score showed excellent agreement and internal consistency in the intra-rater test-retest (ICC: 0.93 [0.85 - 0.97]; Cronbach's α: 0.88) and inter-rater (ICC: 0.88 [0.77 - 0.94]; Cronbach α: 0.86). SGRQ-I total score correlated with the domains functional capacity, pain, general health and vitality ($-0.66 \leq r \leq -0.40$; $p<0.05$ for all). **Conclusion:** The Portuguese version of SGRQ-I is valid, reliable and has internal consistency for use in Brazilian patients with ILD.

Keywords: Interstitial Lung Diseases. Quality of Life. Questionnaire.

LISTA DE TABELAS

LISTA DE ABREVIAÇÕES

AEHU	Ambulatório de Especialidades da Universidade Estadual de Londrina.
CCI	Coeficiente de correlação intraclasse
COSMIN	*Consensus-based Standards for the selection of health status Measurement Instruments*
CPT	Capacidade pulmonar total
CV	Capacidade Vital
CVF	Capacidade vital forçada
CRQ	*Chronic Respiratory Questionnaire*
DPI	Doença Intersticial Pulmonar
D_{LCO}	Capacidade de difusão de monóxido de carbono
DPOC	Doença Pulmonar Obstrutiva Crônica
FPI	Fibrose Pulmonar Idiopática
IMC	Índice de massa corporal
MRC	*Medical Research Council*
QV	Qualidade de vida
QVRS	Qualidade de vida relacionado a saúde
SAS	*Statistical Analysis System*
SF-36	*Short-Form Health Survey* – 36
SGRQ	*Saint George Respiratory Questionary*
SGRQ-I	*Saint George Respiratory Questionary* versão específica para Fibrose Pulmonar Idiopática.
TC6	Teste de caminhada de seis minutos
VEF_1	Volume expiratório forçado no primeiro segundo

SUMÁRIO

1. INTRODUÇÃO

As doenças pulmonares intersticiais DPIs são doenças raras que compartilham de características clínicas e fisiopatológicas comuns, mas também apresentam etiologias e prognósticos diversos[1,2]. A qualidade de vida relacionada à saúde (QVRS) está prejudicada na maioria dos pacientes com DPI devido a sintomas como dispneia e fadiga, limitações nas atividades físicas e isolamento social[3]. A QVRS inclui habilidades, deficiências, sintomas e resultados psicossociais devidos a uma doença[4]. Essa é quantificada por meio de questionários específicos sobre aspectos da vida que os pacientes consideram importantes. Na pesquisa clínica, a QVRS é um importante desfecho para avaliar a eficácia das intervenções terapêuticas[3,4], como iniciar, mudar ou interromper o tratamento.

Uma infinidade de instrumentos genéricos e específicos estão disponíveis para medir a QVRS em pacientes com doenças crônicas[5]. Há uma escassez de instrumentos específicos para indivíduos com DPI, assim, muitas das formas de avaliações são feitas por meio de questionários validados e específicos para outras doenças respiratórias crônicas, com a doença pulmonar obstrutiva crônica (DPOC) e a asma. Manter a qualidade e especificidade de um questionário de QVRS os tornam mais sensíveis às mudanças subjacentes do que outros instrumentos genéricos[6].

O *Saint George Respiratory Questionnaire* (SGRQ), originalmente desenvolvido e validado para uso em pacientes com DPOC,[7,8] possui validade e confiabilidade aceitáveis para uso em pacientes com fibrose pulmonar idiopática (FPI)[9]. No entanto, devido à heterogeneidade das DPI, é esperado que um questionário inespecífico à população-alvo apresente propriedades de medição pouco específicas[10].

Recentemente, uma versão modificada em inglês deste questionário específico para avaliar a QVRS em pacientes com FPI foi desenvolvida. No entanto, atualmente não existe uma ferramenta válida, confiável e reprodutível para avaliar a qualidade de vida específica para pacientes com DPI brasileiros. Uma adaptação correta requer um desenho amplo que leve em conta não apenas os aspectos linguísticos, mas técnicos e conceituais envolvidos na medição do estado de saúde[11]. Dessa forma, os principais objetivos da presente dissertação foram: 1) desenvolver uma versão em português do Brasil do *IPF-specific version of Saint George's Respiratory Questionnaire* (SGRQ-I)

que seja conceitualmente equivalente a o original; e 2) avaliar a validade, confiabilidade e reprodutibilidade desse instrumento.

2. CONTEXTUALIZAÇÃO

2.1 Doença Pulmonar Intersticial (DPI)

As doenças intersticiais pulmonares (DPIs) são doenças raras que compartilham uma série de características clínicas e fisiopatológicas comuns, mas também demonstram etiologias e prognósticos diversos, com características progressivas e geralmente fatais[1,2,12]. Para determinar o diagnóstico, é necessária uma avaliação clínica inicial, é nesse momento que são identificadas características de doença sistêmica ou fatores ambientais (e.g exposições ocupacionais ou alérgenos) que possam desencadear a DPI (e.g asbestose e pneumonite de hipersensibilidade[13,14].

Para avaliação inicial e diagnóstica das DPIs, a radiografia do tórax é frequentemente a primeira investigação a ser feita. Embora não seja suficiente para fazer um diagnóstico diferencial e confiável dentre as diversas patologias, a radiografia pode auxiliar a estabelecer a gravidade e a progressão da doença[13,15]. Já a tomografia computadorizada de alta resolução (TCAR) do tórax em muitos casos, elimina a necessidade de procedimentos diagnósticos invasivos[13,15,16]. Os principais padrões encontrados são: padrão reticular (bronquiectasias), padrão de vidro fosco e faveolamento alveolar (fibrose pulmonar idiopática [FPI]) e padrão nodular (sarcoidose).

Além dos exames de imagem, outros exames complementares são importantes para avaliar a gravidade da doença e auxiliar no manejo clínico destes pacientes. Dentre estes, podemos incluir os testes laboratoriais (hemograma, gasometria arterial, fatores autoimunes), testes de função pulmonar, incluindo a medida de difusão de monóxido de carbono (DLCO) e medida de saturação periférica de oxigênio (SpO2) no esforço[13,15.]

Determinar a epidemiologia das DPIs é uma tarefa difícil, pois esta partilha de problemas e limitantes em seu diagnóstico, como o elevado número de casos subdiagnosticados[17]. A evolução clínica da doença é muito variável e imprevisível, com alguns pacientes demonstrando estabilidade clínica em longo prazo e outros apresentando um curso mais rápido de piora da doença[12,18]. A avaliação do prognóstico desses pacientes considera a progressão e/ou estabilidade da doença, utilizando não apenas a função pulmonar, mas também critérios clínicos, radiológicos

e até sorológicos[19,20.] Embora os parâmetros clínicos permitam o estadiamento dos pacientes, eles não predizem o prognóstico com precisão[21]. Em média, a sobrevida desses pacientes, sem transplante pulmonar, é de aproximadamente três a cinco anos após o diagnóstico[18,19,23.]

As DPIs são caracterizadas por distúrbios da função pulmonar com um padrão restritivo típico definido pela diminuição da capacidade pulmonar total (CPT) ou capacidade vital (CV) juntamente com a diminuição da difusão de monóxido de carbono (*D*LCO)[24]. Pacientes com DPI apresentam troca gasosa prejudicada, decorrente da destruição do leito capilar pulmonar, que por sua vez resulta em incompatibilidade da ventilação-perfusão e limitações de difusão de oxigênio[25].

Assim como em outras doenças pulmonares pacientes com DPI sofrem com alterações extrapulmonares como a disfunção muscular periférica, capacidade de exercício reduzida, e diminuição dos níveis de atividade física[26-31]. A limitação ao exercício nos pacientes com DPI pode derivar de fatores ventilatórios, cardiovasculares e/ou musculares[12,32]. No entanto, diferente de outras doenças respiratórias, a redução da reserva ventilatória durante o exercício não é um fator limitante para atividade física nessa população[28].

A disfunção muscular periférica, observada em diferentes DPIs, aumenta a susceptibilidade dos músculos para fadiga e reduz a geração de força e resistência[28,33,34]. A redução da atividade física é uma estratégia adotada para evitar o surgimento de sintomas[28]. Porém, a redução da atividade física agrava a disfunção muscular e induz ao surgimento de sintomas em atividades de intensidades ainda mais leves, criando um ciclo vicioso de piora da função muscular e aumento de sintomas[28]. Ainda, a atividade física está relacionada com mortalidade em pacientes com fibrose pulmonar idiopática (FPI)[35-37]. Além disso, neste mesmo grupo de doentes, a AFVD apresenta correlação com capacidade de exercício[38]. Estudos prévios que avaliaram a atividade física de vida diária (AFVD) em DPI demonstraram que há uma redução nos níveis de AFVD em comparação com indivíduos saudáveis[39]. Devido a essas alterações pulmonares e sistêmicas, não é incomum que os pacientes com DPIs apresentem uma piora na percepção da qualidade de vida.

2.2 Reabilitação Pulmonar e Qualidade de Vida Relacionada a Saúde (QVRS).

Os tratamentos disponíveis para pacientes com DPI, até o momento mostraram-se pouco eficazes, não oferecendo melhora na sobrevida e demonstrando apenas um impacto limitado na qualidade de vida[27]. A reabilitação pulmonar (RP) é uma intervenção multidisciplinar e abrangente, incluindo não apenas treinamento de resistência, exercício aeróbico e treinamento muscular respiratório, mas também oxigenoterapia, intervenção nutricional, educação, autogestão, etc.[27].

Nos últimos anos, a RP tem sido amplamente utilizada na intervenção e tratamento de doenças respiratórias crônicas, desempenhando um papel importante na melhoria da capacidade de exercício, dispneia e qualidade de vida relacionada à saúde[40,41].

O SGRQ / SGRQ-I é uma medida útil da qualidade de vida relacionada à saúde em pacientes com FPI[10]. Um estudo de revisão demonstrou que a QVRS medida pelo SGRQ / SGRQ-I após a RP para pacientes com FPI foram menores em comparação a grupos controles, e isso pode indicar o efeito da RP em diferentes aspectos do estado de saúde em pacientes com FPI, e estender se estender para outras DPIs[42].

A RP pode efetivamente melhorar alguns desfechos clínicos de pacientes com FPI, como melhora da capacidade de exercício, CVF e QVRS[27,42]. No entanto as evidências são insuficientes para apoiar o potencial de melhorar de DLCO em pacientes com FPI. Mesmo que os benefícios da RP não estejam claros para todas as DPI, normalmente não são relatados efeitos adversos durante a RP, portanto, devemos considerar a importância da melhora da QVRS e estender para os demais pacientes com DPI.

2.3 Métodos de Avaliação da QVRS

A QVRS refere-se à satisfação de uma pessoa com fatores que afetam ou são afetados por seu estado de saúde[10]. Esta é cada vez mais vista como um resultado importante usado para avaliar a eficácia dos tratamentos e monitorar a trajetória da doença[3]. A avaliação da QVRS não é um conceito novo e é possível encontrar evidência de sua aplicação em doenças pulmonares crônicas já a partir da década de 1980 [9,43,44]. A QVRS pode ser avaliada por uma simples conversa com o paciente questionando fatores relacionados ao estado geral de saúde. Porém, o uso de métodos

não estruturados não permite a comparação da avaliação com o mesmo indivíduo em diferentes momentos ou ainda impede sua utilização em estudos que requeiram uma ferramenta válida. Por este motivo, diversos questionários estruturados foram desenvolvidos com o intuito de investigar o impacto de diversos aspectos de saúde na qualidade de vida.

Esses instrumentos variam no formato de acordo com o objetivo da medição. Eles podem avaliar a QVRS de um modo geral ou em aspectos específicos da saúde. Além disso, podem ainda ser desenvolvidos para aplicação na população como um todo ou em doenças específicas[10]. O *Short-Form Health Survey – 36* é um exemplo de instrumento genérico para avaliar a QVRS que foi projetado para uso na pesquisa e na prática clínica. Trata-se de um questionário multidimensional formado por 36 itens, englobados em 8 componentes: capacidade funcional, aspectos físicos, dor, estado geral de saúde, vitalidade, aspectos sociais, aspectos emocionais e saúde mental. Cada domínio apresenta um escore final de 0 a 100, no qual zero corresponde a pior estado geral de saúde e 100 a melhor estado geral de saúde[45].

Quanto às ferramentas de avaliação de QVRS para populações específicas, um exemplo bastante utilizado para pacientes com doenças respiratórias é o *Chronic Respiratory Questionnaire* (CRQ)[5,46]. O CRQ foi o primeiro questionário elaborado para avaliar a QVRS para doenças respiratórias crônicas, a princípio desenvolvido e validado para a doença pulmonar obstrutiva crônica (DPOC), e posteriormente utilizado em outras doenças respiratórias como bronquiectasias e doenças pulmonares intersticiais[6,46]. Uma limitação do CRQ é a relativa inespecificidade da ferramenta para algumas doenças respiratórias. Uma vez que o questionário foi desenvolvido para pacientes com DPOC, algumas situações avaliadas podem não ser relevantes para outras doenças (e.g. pacientes com DPIs).

Similarmente, o *Saint George Respiratory Questionnaire* (SGRQ) foi originalmente desenvolvido e validado para uso em pacientes com DPOC[7]. Além disso, o SGRQ foi validado para uso em outras doenças respiratórias crônicas e também parece possuir validade e confiabilidade aceitáveis para uso em pacientes com FPI[4,9]. No entanto, é inevitável que alguns itens do SGRQ tenham propriedades de medição pouco sensíveis do que outros quando aplicados a populações de pacientes diferentes daquela para a qual foi desenvolvido[10]. Desta forma, uma versão específica do questionário para pacientes com FPI foi desenvolvida (i.e. *Saint George Respiratory Questionnaire for patients with Idiopathic Pulmonary Fibrosis* (SGRQ-I)[5].

Assim como a versão original, o questionário SGRQ-I avalia a qualidade de vida em 3 domínios: sintomas (6 itens), atividade (10 itens) e impacto (18 itens). É importante ressaltar que a adaptação para a versão SGRQ-I sofreu uma redução importante do número de itens (i.e. de 76 para 34) o que o torna menos cansativo para sua aplicação. Um score é calculado para cada domínio individualmente. Cada item é pontuado de acordo com pesos específicos e a soma das questões produz um score final no qual maiores scores indicam pior QVRS[10].

2.4 Importância da Tradução, Adaptação Transcultural e Validade de Questionários de QVRS.

Muitas vezes o questionário não foi desenvolvido na língua que se pretende utilizá-lo. Além da importância de se ter ferramentas específicas para a população investigada, há a necessidade de que a ferramenta seja adaptada a realidade cultural e geográfica do paciente[47]. Por exemplo, um questionário desenvolvido em países com clima temperado que questione se o paciente refere desconforto ao tirar a neve da calçada não faz sentido para pacientes que habitem países tropicais. Para isso, deve-se fazer uma adaptação da ferramenta antes de utilizá-la seguindo rigorosos critérios para que a nova versão apresente resultados compatíveis com o do questionário original[47]. No entanto, enormes dificuldades são encontradas durante a fase de validação. Para que isso seja evitado, verificações das propriedades métricas, controle das traduções e equivalência metodológica rigorosa se tornam indispensáveis[47,48].

Para verificar se a ferramenta de fato mede o que se propõe, o *Consensus-based standards for the selection of health status measurement instruments* (COSMIN) foi desenvolvido visando melhorar a seleção de ferramentas para medir qualidade de vida[49]. O checklist proposto pelo COSMIN contém nove tópicos, cada um lidando com uma propriedade de medição. Cada tópico por sua vez contém 5 a 18 itens que podem ser usados para avaliar se um estudo apresenta propriedades de medida específica e se o mesmo atende ao padrão para uma boa qualidade metodológica. O COSMIN avalia ainda a consistência interna, confiabilidade, erro de medição, validade de conteúdo, validade de construto (validade estrutural, teste de hipóteses e validade transcultural), validade de critério e responsividade da ferramenta[50,51].

2.5 Qualidade de Vida em Pacientes com Doença Intersticial Pulmonar Brasileiros.

Do mesmo modo que ocorre em diferentes doenças respiratórias, há a necessidade de se avaliar a QVRS em pacientes com DPI. Até o momento apenas uma ferramenta estruturada para avaliar QVRS foi traduzida e adaptada para ser aplicada em pacientes com DPI brasileiros, ainda que essa ferramenta não tenha propriedades métricas testadas. A validação de um questionário de QVRS para pacientes com DPI permitiria uma interpretação específica da QVRS durante o curso clínico da doença, guiando a tomada de decisão na prática clínica.

Desta forma, o estudo que compõe a presente dissertação faz-se importante para que tais questões referentes à tradução, adaptação transcultural e validação do *Saint George Respiratory Questionnaire* versão específica para FPI sejam bem elucidadas, permitindo o uso para pacientes brasileiros.

3. ARTIGO ORIGINAL

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Translation, cross-cultural adaptation, and measurement properties of the Brazilian-Portuguese version of the idiopathic pulmonary fibrosis-specific version of the Saint George's Respiratory Questionnaire (SGRQ-I) for patients with interstitial lung disease

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Conflicts of interest
None of the authors have conflicts of interest to declare.

ABSTRACT

Background: The idiopathic pulmonary fibrosis-specific version of the St George's Respiratory Questionnaire (SGRQ-I) is a valid tool to assess health-related quality of life in patients with interstitial lung diseases (ILDs). **Objective:** To translate and cross-culturally adapt the SGRQ-I to Brazilian-Portuguese, and to assess its measurement properties. **Methods:** Phase one consisted of the translation and cross-cultural adaptation of the questionnaire. In phase two, intra- and inter-assessor reliability (intraclass correlation coefficient [ICC]), internal consistency (Cronbach's α), minimal detectable change (MDC), ceiling/floor effects, convergent validity (correlation with SF-36 questionnaire), and discriminative validity (according to clinical characteristics) were investigated. **Results:** No significant adaptations were needed during the translation process of the SGRQ-I. In phase two, 30 patients with ILD were included (15 men; age 59 ± 10 years; Forced Vital Capacity 73 [61–80] %predicted). The total score on the SGRQ-I presented excellent intra-assessor (ICC: 0.93; 95%CI: 0.85, 0.97]) and inter-assessor (ICC: 0.88; 95%CI: 0.77, 0.94) agreement. Internal consistency was considered adequate for the domains impact, activity, and total score ($0.79<\alpha<0.88$) but not for symptoms ($\alpha=0.43$). MDC was 12.8 points and ceiling/floor effects were found in only 3% of patients. No discriminative validity was observed, but there was adequate convergent validity. **Conclusion:** The results provide preliminary evidence of adequate measurement properties and validity of the Brazilian-Portuguese version of the SGRQ-I for patients with ILDs.

Keywords: Health-related quality of lifeInterstitial lung disease Questionnaire

INTRODUCTION

Interstitial lung diseases (ILDs) are a heterogeneous group of pathologies with similar clinical, radiological, and functional characteristics. The occurrence of ILD varies with prevalence rates ranging from $17/10^5$ to $80/10^5$ and annual incidence rates ranging from $4.1/10^5$ to $30/10^5$.[1, 2, 3] In Brazil, the incidence of interstitial pulmonary fibrosis is 0.4/10 per year, while the prevalence is 14/10.[4] In addition to respiratory problems, patients with ILD show systemic manifestations that directly impact their quality of life.[5]

Although there is a vast number of generic instruments to assess health-related quality of life, better results are obtained when valid and specific instruments are used for targeted populations.[6,7] The St George's Respiratory Questionnaire (SGRQ) was initially developed and validated to assess health-related quality of life in patients with chronic obstructive pulmonary disease (COPD).[8,9] The SGRQ has acceptable validity and reliability to use in individuals with idiopathic pulmonary fibrosis.[7] However, due to large clinical differences between patients with COPD and those with idiopathic pulmonary fibrosis, a specific English version of this questionnaire for this population, named the SGRQ-I, was developed.[6] Although the SGRQ-I was specifically developed for patients with idiopathic pulmonary fibrosis, the clinical and functional similarities among the various subtypes of ILDs allows the use of the SGRQ-I for the broad group of ILDs. In fact, the SGRQ-I has recently been used as a clinical outcome in a randomized controlled trial investigating the effect of exercise training for patients with different ILDs.[10]

The SGRQ-I has been cross-culturally adapted into Spanish with adequate internal consistency, reliability, and validity.[11] Likewise, the SGRQ-I may be valid for Brazilian patients with ILD; however, this has not been investigated. The aim of the present study was to translate and cross-culturally adapt the SGRQ-I to Brazilian-Portuguese and to test its measurement properties (i.e. reliability, validity, minimal detectable change (MDC), and ceiling/floor effects) in patients with ILDs.

METHODS

STUDY DESIGN

This methodological study was divided into two phases. In the first phase, we translated and cross-culturally adapted the SGRQ-I questionnaire to Brazilian-Portuguese. In the second phase, we investigated its measurement properties in patients with ILDs. The study was approved by the ethics committee of the Universidade Estadual de Londrina (Londrina, Paraná, Brazil) under the registry number #2.484.871. All patients provided written consent prior to participating in the study.

PARTICIPANTS

Patients diagnosed with ILD,[12,13] age between 40 and 75 years, were recruited from the outpatient clinic of the University Hospital of the State University of Londrina (Londrina, Brazil). All patients had to present clinical stability for at least four weeks before the initial assessment and during the study. Participants' medical treatment and medication were monitored over the study period to identify potential changes in health status (e.g. exacerbations). Patients were excluded if they presented with cognitive deficits as identified with the Mini-Mental State Examination14 or if they presented any change in health status that could interfere with the assessments.

SGRQ-I

The original version of the SGRQ-I questionnaire has 34 items, divided into three domains: symptoms (6 items), activity (10 items), and impact (18 items). Scores can be calculated for the total questionnaire and separately for each domain. Each item has a specific weight. Total and domain scores range from 0 to 100, with higher scores indicating a more impaired health-related quality of life.[6]

TRANSLATION AND CROSS-CULTURAL ADAPTATION

The translation of the English version of the SGRQ-I (EV1) to Brazilian-Portuguese followed the recommendations of the ISPOR Task Force for Translation and Cultural Adaptation of Patient-Reported Outcome Measures.[15] The translation was done independently by two native Brazilian-Portuguese authors, both fluent in the English language. Both versions were then compared to each other, and the first

Brazilian-Portuguese version (PV1) was created and tested in five patients with ILD. This procedure allowed the committee of experts, consisting of authors of the study (CAC and FP), and the researcher who developed the questionnaire (JY), to discuss and address any doubts or difficulties reported by the patients. The committee's role was to audit trail every step in the process of translation and cross-cultural adaptation as well as to provide solutions for problems occurring at this stage. After the analysis of PV1 by the committee of experts, the second Brazilian-Portuguese version of the questionnaire (PV2) was created. Then, PV2 was translated back into English (EV2) by a native Brazilian-Portuguese physical therapist who was fluent in English and had no prior contact with the original questionnaire. Subsequently, the original English version (EV1) and the back-translated version (EV2) were compared. Finally, small inconsistencies raised by the developer of the questionnaire were addressed in the final Brazilian-Portuguese version (PV3).

ASSESSMENT PROCEDURE

In the initial visit, all participants underwent a comprehensive clinical assessment. Lung function (whole-body plethysmography and diffusion capacity for carbon monoxide (DLCO), Vmax, CareFusion©) was evaluated following internationally accepted guidelines, and values were compared to normative data.[16, 17, 18, 19, 20] Exercise capacity was assessed with the 6-minute walk test (6MWT).21,22 The 6MWT test was performed twice, and the highest achieved walking distance was recorded. Quadriceps strength was assessed by maximal voluntary isometric contraction (MVIC) of the dominant limb using a strain gauge (EMG System®, Brazil) attached to a stationary multigym device. Participants were instructed to perform the MVIC for six seconds, with 90° of hip and knee flexion.[23] Symptoms of dyspnea were assessed using the Medical Research Council (MRC) scale (1–5 points),[24] and health-related quality of life was assessed using the 36-item Short-Form Health Survey (SF-36).[25] Physical activity in daily life was assessed using an activity monitor (Actigraph®, wGT3x-BT). Patients were instructed to use the activity monitor on their waist for six consecutive days, for 24 h, including sleeping time.[26] Acceleration data were sampled at 30 Hz and analysed in 1-minute epochs. A complete data set was considered valid if the patient wore the activity monitor for at least 8 h/day for at least four weekdays.[27] The intensities of activities were stratified according to metabolic equivalent of tasks

(METs). Light-intensity activities were those demanding ≤1.5 METs while moderate-intensity activities were those demanding 3–6 METs.27 Outcomes related to physical activity in daily life included in the analysis were: daily steps and activities of light and moderate intensity.

For the reliability analysis, the SGRQ-I (which was researcher-administered) was applied at three time-points: initial visit and two additional visits. Each time-point took place with an interval of 5–7 days. This timeframe is considered adequate for not allowing participants to remember their answers and minimizing changes in participants' health status.[28, 29, 30] The questionnaire was administered by two trained assessors, both physical therapists with at least four years of clinical experience. The use of two assessors allowed us to determine the intra- and inter-assessor reliability. The assessors were trained on how to perform interviews using verbal and non-verbal communication techniques to establish good rapport with patient. The questionnaire was always administered at the same place (a quiet and climate-controlled room) and at the same time of day to enhance standardisation of the procedure. Illiteracy is not uncommon among Brazilian patients with chronic respiratory diseases.[31] So, given that scores may vary depending on how the questionnaire is administered (ie, self- versus researcher-administered), participants in this study were interviewed by two different assessors.[30] Assessor 1 (WFA) applied the questionnaire in the first and third visits, while assessor 2 (HS) applied the questionnaire during the second visit. Misunderstandings and queries related to the questions were clarified according to the SGRQ-I application manual.[6] The scores of the SGRQ-I obtained at each visit and the time required to complete the questionnaire at each visit were compared.

Finally, the SF-36 applied during the initial visit was used in the validation of the SGRQ-I (anchor-based method). It is a generic assessment tool to assess the quality of life that is easy to understand and apply. It is a multidimensional questionnaire that comprises 36 items, divided into eight domains: physical functioning, physical role, pain index, general health perceptions, vitality, social functioning, emotional role, and mental health index. Total score ranges from 0 to 100, where zero corresponds to the worst and 100 the best overall quality of life.[25] The eight domains of the SF-36 are grouped into two major components: physical and mental. These scores vary from 0 to 50, in which the lower the score, the higher the physical and mental impairment. The SF-36 was chosen for the validation of SGRQ-I because it has been used in patients

with ILD, and present acceptable construct and criterion validity to investigate the quality of life in this population.[7,32,33]

STATISTICAL ANALYSIS

Intraclass correlation coefficient (ICC) and 95% confidence interval (CI) were used to determine the reliability of the questionnaire. The ICC selection followed the McGraw and Wong convention[34] and the "two-way mixed effects, single measurement, absolute agreement" was used to investigate intra- and inter-assessor reliability. The reliability was classified as poor (ICC<0.5), moderate (0.5≤ICC<0.75), good (0.75≤ICC<0.9), or excellent (ICC≥0.9).[35] Absolute reliability of the data was determined using the standard error of measurement (SEM). The SEM was calculated based on the intra-assessor reliability. The lower the SEM value, the more reliable the measurement.[36] Cronbach's α coefficient was used to verify the internal consistency of the SGRQ-I. Values >0.7 were deemed acceptable.[37] The MDC was calculated using the equation $MDC = z - score \times SD\sqrt{2(-1 \times r)}$ where the z-score represents the CI from a normal distribution (i.e. 1.96), SD is the standard deviation of the scores and r is the coefficient of the intra-assessor test-retest reliability (i.e. ICC).[38] Ceiling and floor effects were calculated by estimating the percentage of patients whose scores lied within the 10% best (ceiling effect) or the 10% worst scores (floor effect) of the SGRQ-I.[39]

VALIDITY ANALYSIS

Spearman's correlation coefficient was used to verify construct validity (i.e. convergent validity). For the validity analysis, we correlated the total SGRQ-I score obtained in the initial visit with the score of the Physical Health component of the SF-36. We hypothesized that the SGRQ-I would show at least moderate correlation with the Physical Health component of the SF-36. The magnitude of this correlation is expected to be at least moderate (r > 0.39).[40,41] We also conducted an exploratory analysis to investigate whether SGRQ-I score correlated with other measures, such as the Medical Research Council (MRC) scale, pulmonary function, and exercise capacity. Discriminative validity was done using a one-way ANOVA comparing groups of patients according to disease severity (i.e. i-Forced Vital Capacity, Discriminative

validity was done using a one-way ANOVA comparing groups of patients according to disease severity (i.e. i-Forced Vital Capacity, FVC<55%predicted; ii-55%<FVC<69%predicted and; iii-FVC ≥70% predicted).[42] Additionally, patients were stratified according to age, sex, educational level, and cognitive status (Mini-mental State Examination) and the SGRQ-I scores for each category were compared using student's t-test or Mann-Whitney test depending on data distribution. For the discriminative validity analysis, we hypothesized that the questionnaire would be able to detect differences according to disease severity but would not detect difference across the groups defined by age, sex, educational level, and cognitive status. A posteriori analysis was performed to assess the statistical power of the SGRQ-I validation with the score of the SF-36 physical domain. Power analysis was done using specific software (G*Power 3.1, University of Dusseldorf). Statistical significance was set at $p < 0.05$.

RESULTS

Participants' characteristics are described in **Table 1**. Thirty patients diagnosed with ILD were initially assessed and considered eligible for inclusion in the study (15 men; mean age of 59 ± 10 years; median FVC = 73% [61–80] of the predicted value). The most prevalent diagnosis was idiopathic pulmonary fibrosis (n = 18), followed by pulmonary fibrosis related to diseases of the connective tissue (n = 5), diseases related to inhalation of particles (n = 4), and non-specific interstitial pneumonia (n = 3). Most of the participants were literate (93%) but had a low education level (i.e. 50% of them had only elementary education completed). The cross-cultural adaptation and translation of the questionnaire did not undergo significant changes except for item 4 of Section 5. The original question asks, "My breathing makes it difficult to do things such… play bowls or play golf". These two activities (bowls and golf) were excluded from the item as they were not applicable to Brazilian patients (Supplemental online material).

Table 1. Characteristics of participants.

Variable	**Participants (*n* = 30)**
Sex, M (%)	15 (50%)
Age, years	59 ± 10

Body composition	
BMI, kg/m^2	27.4 ± 5.3
Literacy, yes (%)	28 (93%)
Education: Elementary/Middle-High/College, n(%)	15 (50%)/13 (43%)/2 (7%)
Pulmonary Function	
FVC,% predicted	73 [61–80]
FEV_1,% predicted	73 [62–84]
FEV_1/FVC	83 [78–87]
TLC,% predicted	72 [65–89]
D_{LCO},% predicted	49 [35–67]
Exercise Capacity	
6MWT, m	469 ± 100
6MWT,% predicted	86 ± 17
Peripheral Muscle Strength	
Quadriceps force, N	395 ± 174
Physical Activity in Daily Life	
Steps, n/day	5190 [3863–6916]
Light-intensity activity (≤1.5METs), min/day	308 ± 90
Moderate-intensity activity (3–6METs), min/day	12 ± 9
Health-related quality of life (SF-36)	
Physical functioning,% of impact	41 ± 24
Physical role,% of impact	41 ± 41
Pain index,% of impact	53 ± 28
General health perceptions,% of impact	44 ± 18
Vitality,% of impact	59 ± 16
Emotional role,% of impact	70 ± 26
Social functioning,% of impact	53 ± 41
Mental health index,% of impact	68 ± 18
Health-related quality of life (SGRQ-I)	
SGRQ-I Symptoms, score	50 [26–69]
SGRQ-I Activities, score	74 [50–89]
SGRQ-I Impact, score	44 [35–54]
SGRQ-I Total, score	50 [36–63]
Symptoms	
MRC, score	3 [2–4]

Data are presented as mean ± SD or median [interquartile range] or frequency (percentage) unless otherwise stated. Abbreviations: 6MWT, six-minute walk test; BMI, body mass index; DLCO,

carbon monoxide diffusion capacity; FEV1, forced expired volume in the first second; FVC, forced vital capacity; METs, Metabolic equivalent of task; MRC, Medical Research Council Dyspnoea scale; SF-36, Medical Outcomes Short-Form Health Survey quality of life questionnaire; SGRQ-I, Saint George Respiratory Questionnaire for patients with Interstitial Pulmonary Fibrosis; TLC, Total lung capacity.

The median length of time for completing the SGRQ-I during the initial, second, and third visits was 461 s [413–536], 476 s [430–552], and 422 s [368–470], respectively (p = 0.052). The median SGRQ-I total score for the 3 visits was 50 [36–63] points, 48 [38 −70] points, and 56 [40–68] points, respectively (p = 0.94). SGRQ-I domains and total scores for the initial visit are reported in **Table 1**. The total score of SGRQ-I had excellent intra-assessor (ICC= 0.93; 95%CI: 0.85, 0.97]) and inter-assessor (ICC = 0.88; 95%CI: 0.77, 0.94) reliability. Internal consistency analyses were deemed adequate for total score (Cronbach's α = 0.88), activity (Cronbach's α = 0.83), and impact (Cronbach's α = 0.79) domains but inadequate for symptoms domain (Cronbach's α = 0.48). The SEM for the total score was 6.5 points (or 13%) and the MDC was 12.8 points. The percentage of patients with maximum and minimum score were respectively 3% and 0%, indicating no ceiling and floor effects. Reliability date are provided in **Table 2**.

Table 2. Reliability analysis of SGRQ-I.

Assessment	**ICC (95% CI)**
Symptoms	
Intra-assessor	0.90 (0.78, 0.95)*
Inter-assessor	0.76 (0.56, 0.88)*
Activities	
Intra-assessor	0.85 (0.70, 0.93)*
Inter-assessor	0.84 (0.70, 0.92)*
Impact	
Intra-assessor	0.91 (0.80, 0.96)*
Inter-assessor	0.80 (0.63, 0.90)*
Total	
Intra-assessor	0.93 (0.85, 0.97)*
Inter-assessor	0.88 (0.77, 0.94)*

Abbreviations: 95% CI, 95% Confidence Interval; ICC, Intraclass Correlation Coefficient; SGRQ-I, Saint George Respiratory Questionnaire for patients with Interstitial Pulmonary Fibrosis; r, Spearman's correlation coefficient. *$p<0.05$.

For the validity analysis, the total SGRQ-I score showed negative moderate correlation with the physical health component of the SF-36 ($r = -0.53$; $p < 0.05$). The full set of correlations between SGRQ-I and the domains of the SF-36 is provided in **Table 3**. There was no significant correlation between any domain of the SF-36 and SGRQ-I symptoms domains ($-0.35 \leq r \leq 0.20$; $p > 0.05$ for all). The impact domain of the SGRQ-I correlated with the functional capacity, general health status, and vitality domains of the SF-36 ($-0.71 \leq r \leq -0.39$; $p < 0.05$ for all).

Table 3. Correlations between the SGRQ-I and SF-36 questionnaire (anchor-based method).

	Domains			
Variable	***Symptoms***	***Activities***	***Impact***	***Total Score***
SF-36 (Physical functioning)	−0.29	−0.71*	−0.71*	−0.66*
SF-36 (Physical role)	−0.05	−0.24	−0.28	−0.24
SF-36 (Pain index)	−0.32	−0.45*	−0.36	−0.40*
SF-36 (General health perceptions)	−0.27	−0.49*	−0.45*	−0.44*
SF-36 (vitality)	−0.35	−0.43*	−0.39*	−0.40*
SF-36 (Emotional role)	0.06	−0.25	−0.14	−0.16
SF-36 (Social functioning)	0.10	−0.03	−0.18	−0.08
SF-36 (Mental health index)	0.20	−0.07	0.09	0.08
Physical health	−0.52*	−0.32	−0.59*	−0.53*
Mental health	0.05	0.10	0.03	0.01

SF-36: *Medical Outcomes Short-Form Health Survey* quality of life questionnaire*; *p* < 0.05.

The SGRQ-I was not able to discriminate health-related quality of life according to the disease severity, age, sex, educational level, and cognitive status (discriminative validity) (**Table 4**). Finally, the power analysis of the correlation between SGRQ-I total score and physical health component of the SF-36 was 0.83.

Table 4. Discriminative validity of SGRQ-I for age, sex, educational level, cognitive status, and disease severity.

	Symptoms	**Activities**	**Impact**	**Total Score**
Age				
≥ 60 years old	51 [28–66]	67 [58–79]	46 [36–54]	49 [36–62]
< 60 years old	45 [31–71]	78 [43–89]	42 [33–54]	49 [31–65]
Sex				
Man	50 [35–66]	68 [47–79]	40 [28–50]	48 [34–62]
Woman	46 [27–84]	78 [58–89]	46 [34–57]	54 [40–67]
Educational level				

	Symptoms	Activities	Impact	Total Score
Elementary	50 [27–60]	58 [47–78]	38 [27–50]	49 [34–60]
Middle-High	51 [43–84]	78 [69–89]	44 [36–54]	54 [47–67]
College	22 [17–29]	59 [30–89]	37 [14–60]	41 [19–62]
Cognitive status				
≤ 24 points, Mini-mental	60 [27–84]	70 [39–100]	54 [15–88]	59 [23–90]
> 24 points, Mini-mental	49 [29–67]	73 [50–89]	42 [35–54]	49 [36–62]
Disease severity				
FVC<55%predicted	68 [42–68]	68 [58–89]	40 [38–45]	49 [40–50]
55%<FVC<69%predicted	50 [46–66]	78 [48–89]	43 [36–54]	61 [55–65]
FVC ≥70% predicted	44 [27–60]	70 [50–79]	48 [32–55]	49 [36–63]

Data are presented as median [interquartile range]. Abbreviations: FVC, forced vital capacity. No significant differences were found across all categories ($p > 0.05$ for all).

SGRQ-I scores significantly correlated with the MRC (symptoms r = 0.42, p = 0.02; activity r = 0.71, p < 0.0001; impact r = 0.62, p = 0.0004; total score r = 0.66, p = 0.0001). There was no significant correlation between SGRQ-I scores and exercise capacity [−0.36 ≤ r ≤ −0.25; p > 0.05 for all], pulmonary function outcomes [−0.03 ≤r ≤ 0.20; p > 0.05 for all], and daily activities of light or moderate intensities (0.16 ≤r ≤ 0.30; p > 0.05 for all). Daily steps correlated significantly with symptoms of the SGRQ-I (r = 0.37, p = 0.04).

DISCUSSION

In the present study, the translated version of the SGRQ-I demonstrated good to excellent intra- and inter-rater reliability and good to excellent internal consistency. Further, the Brazilian-Portuguese version of the SGRQ-I is valid to be used in patients with ILDs. Consistent with previous work, the reliability analysis in this study demonstrated excellent values of ICC in most domains and total score.[6,43] Yet, scores were somewhat higher in the intra-assessor analysis. The difference in total scores between assessors, however, was negligible with a clear overlap of the CIs. Also, in the intra-assessor analysis the scores of the second application were slightly higher, which suggests a learning effect. This, however, is not supported by the statistical analysis which showed adequate ICC values and no statistical difference between the assessments. The values of Cronbach's α confirmed the adequate internal consistency of the SGRQ-I except for symptoms (i.e. α < 0.7). In a systematic review of the

psychometric properties of the SGRQ in patients with idiopathic pulmonary fibrosis, Swigris et al.[33] also reported low values of internal consistency in the symptoms domain. A possible explanation for this is that questions related to symptom assess respiratory complaints that are not common in ILDs. For instance, items 4 and 5 of the first part of the questionnaire refers to "wheezing" and "respiratory crisis," symptoms more commonly reported by patients with obstructive lung diseases.

To the best of the authors' knowledge, this is the first study investigating the MDC of the SGRQ-I. This statistical approach helps clinicians to identify changes that are not merely a normal variation of the tool but instead changes in the clinical condition of the patient.[44] It, however, does not mean that changes on MDC superior to 12.8 points are considered clinically relevant for patients. Future studies are needed to determine whether this cut-off resembles clinically relevant changes in patient's quality of life.

Recently, Prior and colleagues[45] demonstrated that less than 15% of patients with ILDs reached highest (celling effect) or lowest (floor effect) deciles of possible scores on the SGRQ-I. Consistent with these results, our findings also did not identify a significant proportion of patients with maximal/minimum scores in the questionnaire (i.e. less than 5% of patients). Albeit these results should be confirmed in larger sample size, this is a good indication that the tool is not limited by construct constraints.

The analysis of the construct validity of the SGRQ-I or Brazilian-Portuguese language presented similar values to those observed in the validation of the English version.[6] These results confirm that the translation and the cross-cultural adaptation in the present study did not impact on the essence of the questionnaire. Indeed, there was no need to adapt the text during the translation process significantly. Only item 4 of the fifth section was changed due to environmental and cultural differences, as reported in the results section. Importantly, the questionnaire was designed to be applied in idiopathic pulmonary fibrosis. The present study expands the results of the reliability and validity of the SGRQ-I questionnaire for utilisation in patients with ILD.

The analysis of discriminative validity showed that it was not possible to anticipate a better or worse quality of life based on age, sex, educational level, cognitive status, and the severity of the disease. This finding, however, needs to be interpreted with caution. The sample size of the present investigation was not powered for this analysis, and these results likely change if using a larger sample size. Additional validation analyses were recently published using the English version of the SGRQ-I

and confirmed that it was good at discriminating patients with different stages of the disease.[45]

Similar to Capparelli et al.,[11] we also found a significant correlation between SGRQ-I and MRC scores. Conversely, none of the other investigated outcomes presented significant correlations. This is not particularly surprising as the SGRQ-I also failed to show strong correlations of the same outcomes in the validation study for the English language.[6] Lubin et al.[46] demonstrated that dyspnea was one of the strongest determinants of health-related quality of life in patients with idiopathic pulmonary fibrosis, being superior to disease severity. In other respiratory diseases, a reduced exercise capacity present meaningful relationship with health-related quality of life, especially in more severely affected patients.[47] The sample in the present study did not include many patients with marked reduction of exercise capacity or muscle strength. It is possible to hypothesise that the lack of correlation between SGRQ-I and 6MWT is a consequence of the preserved muscle function in the assessed patients.

The results of the present study need to be interpreted in light of some potential limitations. First, the sample size is somewhat small. The low prevalence of patients with ILD and the monocentric design of the present study have limited participant recruitment. However, other authors found acceptable results with a similar sample size.[11] But, the post-hoc power analysis of the SGRQ-I validation (power=0.83) confirmed the sample size of the present study did not hamper the interpretation of our results. Second, the questionnaire was applied in patients with different types of ILD, despite the original version being specifically developed for patients with idiopathic pulmonary fibrosis. Although 60% of the study sample was comprised of people with idiopathic pulmonary fibrosis, our results were similar to the previous study on the validity of SGRQ-I.[6] Also, investigating the validity of SGRQ-I in specific diseases was beyond the scope of the present study. Third, in the process of translation and cross-cultural adaptation of questionnaires, the backward translation should ideally be performed by two independent researchers. Finally, the SGRQ-I was initially developed to be self-administered. In the current study, questionnaires were researcher-administered. This was done as we anticipated patients with low literacy levels to be included in the present study. Given there is considerable variation of

scores when questionnaires are self- versus researcher-administered, we attempted to reduce bias by standardising the application method.[31]

CONCLUSION

The Brazilian-Portuguese version of SGRQ-I, albeit conducted in a relatively small sample, seems to have adequate measurement properties justifying its use in the Brazilian population.

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4. CONCLUSÃO GERAL

Ao traduzir uma ferramenta de medida para ser usada em um país diferente do qual foi desenvolvido, é necessário garantir a equivalência da tradução, adaptação transcultural e propriedades de medicação do instrumento. O presente estudo demonstrou que o SGRQ-I versão em português do Brasil é valido, confiável e tem consistência interna para o seu uso em pacientes com DPI no Brasil. Além disso, o questionário é capaz de refletir a qualidade de vida relacionada a saúde desses pacientes, refletindo propriedades de medidas similares ao adaptado para pacientes com FPI.

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APÊNDICES

APÊNDICE A

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Conforme a Resolução 466 de 12 de Dezembro de 2012, do Conselho Nacional de Saúde/Ministério da Saúde.

Prezado(a) Senhor(a):

O(A) Sr(a) está sendo convidado para participar de um projeto de pesquisa chamado "**Associação entre progressão da doença e desfechos clínicos em pacientes com doenças intersticiais pulmonares**", realizado no Laboratório de Pesquisa em Fisioterapia Pulmonar da Universidade Estadual de Londrina (Londrina, Brasil). O objetivo do estudo é avaliar por um período de até 2 anos o impacto de possíveis mudanças na função pulmonar em diferentes aspectos clínicos (incluindo os níveis de atividade física na vida diária) em indivíduos com doenças intersticiais pulmonares e em indivíduos sem a doença. A sua participação é muito importante e ela se daria da seguinte forma: Os participantes realizarão algumas avaliações em cinco momentos: no início do protocolo, após 6 meses, 1 ano, 18 meses e 2 anos. Em cada momento serão realizadas as seguintes avaliações:

- Avaliação da função pulmonar por meio de pletismografia/espirometria e capacidade de difusão de monóxido de carbono (D_{LCO});
- Atividade física na vida diária que será realizada durante 6 dias consecutivos pelo aparelho Actigraph® (aparelho pequeno e leve, utilizado na cintura, de manuseio extremamente simples que monitora todas as atividades físicas realizadas pelo participante, permitindo saber o quanto ativo ele é). Nos 6 dias de avaliação, o participante permanecerá durante 24 horas com o aparelho, havendo a necessidade de retirá-lo apenas durante o banho e atividades realizadas em piscina (por exemplo: natação, hidroginástica).
- Força muscular por meio de dinamometria de membros superiores e inferiores e teste de 1 repetição máxima; força muscular respiratória por meio de manovacuometria; fadiga muscular periférica por meio eletromiografia de superfície;
- Capacidade funcional de exercício por meio do teste da caminhada de 6 minutos e; capacidade máxima de exercício por meio do teste cardiopulmonar de esforço;
- Capacidade funcionais por meio dos testes: Teste de caminhada de 4 metros, teste de Sentar e levantar por 30 segundos e Teste do degrau de 6 minutos
- Composição corporal por meio do teste de bioimpedância elétrica;
- Ansiedade e depressão por meio da *Hospital Anxiety and Depression Scale (HADS);* Qualidade de vida relacionado à saúde por meio dos questionários: *Short Form Health Survey (SF-36)* e *Saint George Respiratory Questionnaire* específico para pacientes com doença intersticial pulmonar (SGRQ-I); Função congnitiva por meio do Mini Exame do Estado Mental (MEEM); sono e sonolência por meio do Índice de Qualidade de Sono de Pittsburgh (PSQI) e escala de sonolência de Epworth (ESE); Falta de ar no dia-a-dia por meio da escala do *Medical Research Council (MRC) e pelo Short of breath questionnaire do centro médico UCSD (UCSD-SOBQ).* HADS, SF-36, MRC, MEEM, PSQI, ESE e UCSD-SOBQ serão administrados a todos os pacrticipantes. SGRQ-I será administrado apenas para pacientes com doenças intersticiais pulmonares;
- Exames de sangue (marcadores inflamatórios e estresse oxidativo).

Benefícios esperados do estudo: Os resultados deste estudo ajudarão a compreender o efeito que uma possível progressão da doença (ou seja, mudanças na função pulmonar) tem sobre diferentes aspectos clínicos da doença. Isso poderá contribuir para que, no futuro, novos tratamentos surjam e ajudem pacientes com doença pulmonar intersticial. **Benefícios diretos ao participante:** Após cada avaliação, se for de seu interesse, você receberá um relatório com os resultados de todos os testes. Esses resultados podem ser entregues ao seu médico para uma avaliação mais completa do seu estado de saúde. Além disso, os participantes sem acompanhamento médico no momento da inclusão do estudo serão cadastrados no Ambulatório de Especialidades do Hospital Universitário da UEL. **Riscos:** Nenhum dos procedimentos utilizados constitui risco direto para a integridade física ou moral dos participantes. Em alguns casos, após a coleta de sangue é possível

que se forme um pequeno hematoma na região onde a coleta ocorreu. Além disso, caso algum teste gere mal estar (físico ou emocional) ele será interrompido sem que haja risco real para a saúde do participante. **Custos:** Informamos que o(a) senhor(a) não pagará nem será remunerado por sua participação. Garantimos, no entanto, que todas as despesas de transporte, por meio público, serão ressarcidas, se necessário, quando devidas e decorrentes especificamente de sua participação na pesquisa. No entanto, em caso de eventuais danos ocorridos exclusivamente por causa deste estudo, o(a) Sr(a) terá direito a tratamento médico completo oferecido pela instituição do estudo. **Participação no estudo:** Uma vez que o(a) Sr(a) aceitar participar do estudo, os pesquisadores iniciarão o agendamento das visitas e realizarão as avaliações após garantir que o(a) Sr(a) tenha compreendido o que será avaliado em cada momento. É importante que o(a) Sr(a) saiba que tem a opção de não fornecer o seu consentimento e não participar desta pesquisa. Sua decisão não interferirá no seu atendimento no Hospital Universitário Regional do Norte do Paraná da Universidade Estadual de Londrina. Além disso, os participantes poderão abandonar o estudo a qualquer momento que se achar conveniente, sem qualquer prejuízo em nenhum sentido. **Sigilo:** Embora os resultados da pesquisa possam ser divulgados em publicações e eventos científicos, a identidade dos participantes será sempre preservada de maneira sigilosa, ou seja, em segredo, conforme previsto pela lei. Quando os resultados forem analisados, não aparecerá o nome de nenhum participante e sim um código. Desse modo, a identidade não será revelada. **Acompanhamento da pesquisa:** Você poderá solicitar informações ou esclarecimentos sobre o andamento da pesquisa em qualquer momento da pesquisa. Para tanto, você poderá telefonar para (43) 3371-2490 / 3371-2477 e falar com o Professor Carlos Augusto Marçal Camilo. Se você tiver reclamações sobre a condução ética deste estudo, assim como preocupações, dúvidas ou reclamações sobre seus direitos como participante da pesquisa, você poderá entrar em contato com o Comitê de Ética em Pesquisa (CEP) do Hospital Universitário Regional do Norte do Paraná da Universidade Estadual de Londrina no endereço: LABESC - Laboratório Escola de Pós-Graduação - sala 14 - Campus Universitário - Rodovia Celso Garcia Cid, Km 380 ou pelo telefone (43) 3371-5455, de segunda a sexta, das 08:00 às 11:30hrs. O CEP trata-se de um grupo de indivíduos com conhecimentos científicos e não científicos que realizam a revisão ética inicial e continuada de propostas de pesquisas para mantê-lo seguro e proteger seus direitos. Você também tem a opção de entrar em contato diretamente com a Comissão Nacional de Ética em Pesquisa (CONEP) através do Fone de denúncia: (61) 3315-3927 ou (61) 3315-2472.

Caso o(a) Sr(a) aceite esse convite e concorde voluntariamente em participar do estudo assinando este termo de consentimento, consideramos que o(a) Sr(a) acredita que foi suficientemente informado(a) por um dos pesquisadores responsáveis sobre a pesquisa, os procedimentos envolvidos nela, assim como os possíveis riscos e benefícios decorrentes dessa participação. Ressaltamos novamente que o(a) Sr(a) pode retirar seu consentimento a qualquer momento, sem que isto leve a qualquer prejuízo em nenhum sentido.

Colocamo-nos à disposição para qualquer esclarecimento que se fizer necessário nos telefones (43) 3371-2490 / 3371-2477 ou pessoalmente no Ambulatório de Fisioterapia Respiratória do Hospital Universitário Regional Norte do Paraná: Av. Robert Koch, 60 – Vila Operária – Londrina – PR (perguntar pelo Professor Carlos Augusto Marçal Camilo).

Atenciosamente,
Prof. Dr. Carlos Augusto Marçal Camilo
Prof. Dr. Fábio de Oliveira Pitta
Prof. Dr. Marcos Ribeiro

Eu, abaixo assinado

.....,
(Nome do participante em maiúsculas)

Declaro ter sido informado verbalmente além de ser provido com as informações do estudo por escrito. Eu também tive a oportunidade de fazer perguntas e discutir o estudo com os Professores Carlos Augusto Marçal Camillo e/ou Fábio de Oliveira Pitta e/ou Marcos Ribeiro ou ainda por algum pesquisador do estudo.
Declaro que recebi respostas para todas as minhas perguntas (caso tenham ocorrido). Estou ciente de que a minha participação é completamente voluntária e que a qualquer momento posso retirar meu consentimento, sem que isto leve a qualquer prejuízo em nenhum sentido. Eu também sei que a participação no estudo não me trará vantagem ou prejuízo em nenhuma atenção médica atual ou futura oferecida pelo Sistema Único de Saúde – SUS.

Paciente ou Responsável:

___ / ___ / ___ (DD/MM/AA) _____
Assinatura (ou impressão papiloscópica)

Pesquisador:

___ / ___ / ___ (DD/MM/AA) _____
Assinatura

ANEXOS

ANEXO A

THE SAINT GEORGE'S RESPIRATORY QUESTIONNAIRE IDIOPATHIC PULMONARY FIBROSIS VERSION

The SGRQ-I

THE ST GEORGE'S RESPIRATORY QUESTIONNAIRE
IDIOPATHIC PULMONARY FIBROSIS VERSION
The SGRQ-I

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you most problem, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

Name: ..... Date: .....

ID Number: .....

Age: ..... Sex: Male/Female

Please tick in one box to show how you describe your current health:-

Item not scored

Very good	Good	Fair	Poor	Very poor
☐	☐	☐	☐	☐

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Part 1

Questions about how much chest trouble you currently have. Please tick in one box for each question.

	Almost every day	Only with chest infections	Not at all
1. I cough:	☐	☐	☐S1
2. I bring up phlegm (sputum):	☐	☐	☐S2
3. I have shortness of breath:	☐	☐	☐S3
4. I have attacks of wheezing:	☐	☐	☐S4

5. In a typical week how many attacks of chest trouble do you have? Please tick (✓) one:S5

More than 1 attack ☐

No attacks ☐

6. In a typical week how often do you have good days? Please tick (✓) one:S6

None ☐

A few days ☐

Every day is a good day ☐

Part 2

Section 1:
If you have ever had paid employment:

Please tick (✓) one:I1

My lung condition interferes or made me stop work ☐

My lung problem does not affect my job ☐

Section 2: Questions about what activities usually make you feel breathless. Please tick in each box that applies to you <u>these days</u>.

Please tick (✓) in *each box* that applies to you *these days:*

		True	False
1.	Getting washed or dressed	☐	☐A1
2.	Walking around the home	☐	☐A2
3.	Walking outside on the level	☐	☐A3
4.	Walking up a flight of stairs	☐	☐A4
5.	Playing sports or games	☐	☐A5

Section 3: Some more questions about your cough and breathlessness. Please tick in each box that applies to you <u>these days</u>.

Please tick (✓) in *each box* that applies to you *these days:*

		True	False
1.	My cough hurts	☐	☐I2
2.	My cough makes me tired	☐	☐I3
3.	I am breathless when I talk	☐	☐I4
4.	I am breathless when I bend over	☐	☐I5
5.	My cough or breathing disturbs my sleep	☐	☐I6
6.	I get exhausted easily	☐	☐I7

Section 4: Questions about other effects that your chest trouble may have on you. Please tick in each box that applies to you <u>these days</u>.

Please tick (✓) in *each box* that applies to you *these days:*

		True	False
1.	My cough or breathing is embarrassing in public	☐	☐I8
2.	My chest trouble is a nuisance to my family, friends or neighbours	☐	☐I9
3.	I get afraid or panic when I cannot get my breath	☐	☐I10
4.	I feel that I am not in control of my chest problem	☐	☐I11
5.	Exercise is not safe for me	☐	☐I12
6.	Everything seems too much of an effort	☐	☐I13

Section 5: These are questions about how your activities might be affected by your breathing. Please tick in each box which you think applies to you <u>because of your breathing</u>

	True	False
1. Jobs such as housework take a long time, or I have to stop for rests	☐	☐A6
2. If I walk up one flight of stairs, I have to go slowly or stop	☐	☐A7
3. If I hurry or walk fast, I have to stop or slow down	☐	☐A8
4. My breathing makes it difficult to do things such as walk up hills, carrying things up stairs, light gardening such as weeding, dance, play bowls or play golf	☐	☐A9
5. My breathing makes it difficult to do things such as very heavy manual work, run, cycle, swim fast or play competitive sports	☐	☐A10

Section 6: We would like to know how your chest <u>usually</u> affects your daily life. Please tick in each box that applies to you <u>because of your chest trouble</u>

	True	False
1. I cannot play sports or games	☐	☐I14
2. I cannot go out of the house to do the shopping	☐	☐I15
3. I cannot do housework	☐	☐I16
4. I cannot move far from my bed or chair	☐	☐I17

Now, would you tick in the box (one only) which you think best describes how your chest affects you:- I18

It does not stop me doing anything I would like to do	☐
It stops me doing one or two things I would like to do	☐
It stops me doing most of the things I would like to do	☐
It stops me doing everything I would like to do	☐

ANEXO B

QUESTIONÁRIO DO HOSPITAL SAINT GEORGE NA DOENÇA RESPIRATÓRIA VERSÃO PARA FIBROSE PULMONAR IDIOPÁTICA - SGRQ-I

Este questionário é desenvolvido para nos ajudar a compreender até que ponto a sua condição respiratória perturba você e como isso afeta sua vida. Nós o utilizamos para descobrir quais os aspectos da sua doença que causam mais problema. Estamos interessados em saber o que você sente e não o que os médicos, enfermeiros e fisioterapeutas pensam que você sente.

Leia atentamente as instruções com atenção e pergunte caso não entenda algo. Não gaste muito tempo em suas respostas.

Nome: …….....Data: ……

ID: ……. Idade: …… Sexo: ( ) Masculino ( ) Feminino

Marque uma das opções que mostra como você considera seu estado de saúde atual.

Muito boa ☐	Boa ☐	Regular ☐	Ruim ☐	Muito ruim ☐

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London SW17 ORE, UK. Fax +44 (0) 20 8725 5955

Parte 1

Nas questões abaixo, assinale aquela que melhor identifica seus problemas respiratórios atualmente. Por favor, assinale com um "X" em um dos quadrados de cada questão abaixo.

	A maioria dos dias da semana	Só com infecções respiratórias	Nunca
1. Eu tusso	☐	☐	☐
2. Eu tenho catarro (escarro)	☐	☐	☐
3. Eu tenho falta de ar	☐	☐	☐
4. Eu tenho chiado no peito	☐	☐	☐

5. Durante uma semana típica, quantas vezes você teve crises respiratórias: Por favor assinale uma resposta:

   ☐ Mais de uma crise ☐ Nenhuma crise

6. Durante uma semana típica, quantos dias bons você tem? (ex: sem problemas respiratórios): Por favor assinale uma resposta:

   ☐ Nenhum dia ☐ Alguns dias ☐ Todos os dias são bons dias

Parte 2

Seção 1:

Se você já teve um trabalho remunerado, assinale um dos quadrados:

Minha condição respiratória interfere ou me fez parar de trabalhar ☐

Meu problema respiratório não afeta meu trabalho ☐

Seção 2:

As perguntas abaixo referem-se às atividades que normalmente provocam falta de ar em você.

Por favor, assinale com um “X” no quadrado de cada questão abaixo, indicando se você sentiu falta de ar em alguma dessas atividades atualmente:

	VERDADEIRO	FALSO
1. Tomando banho ou vestindo-se	☐	☐
2. Caminhando dentro de casa	☐	☐
3. Caminhando em terreno plano	☐	☐
4. Subindo um lance de escadas	☐	☐
5. Praticando esportes ou jogos que impliquem esforço físico	☐	☐

Seção 3: Mais algumas perguntas sobre a sua tosse e a sua falta de ar.

Por favor, assinale com um “X” no quadrado de cada pergunta abaixo de acordo com o seu caso atualmente.

	VERDADEIRO	FALSO
1. Minha tosse me causa dor	☐	☐
2. Minha tosse me deixa cansado	☐	☐
3. Tenho falta de ar quando falo	☐	☐
4. Tenho falta de ar quando me inclino (dobro meu corpo para frente)	☐	☐
5. Minha tosse ou falta de ar perturba o meu sono	☐	☐
6. Fico exausto com facilidade	☐	☐

Seção 4: Perguntas sobre outros efeitos que o seu problema respiratório possa ter causado em você.

Por favor, assinale com um “X” no quadrado de cada pergunta abaixo de acordo com o seu caso atualmente.

	VERDADEIRO	FALSO
1. Minha tosse ou falta de ar me deixa envergonhado em publico	☐	☐
2. Meu problema respiratório é inconveniente para minha família, amigos ou vizinhos	☐	☐
3. Tenho medo ou pânico quando não consigo respirar	☐	☐
4. Sinto que não tenho controle sobre a minha doença respiratória	☐	☐
5. Fazer exercício não é seguro para mim	☐	☐
6. Tudo que eu faço parece um esforço muito grande	☐	☐

Seção 5:

As perguntas seguintes se referem às atividades que podem ser afetadas pela sua condição respiratória. *Por favor, assinale com um “X” no quadrado de cada pergunta abaixo no qual acredita se aplicar melhor a você* ***por causa da sua condição respiratória****.*

	VERDADEIRO	FALSO
1. Demoro muito tempo para realizar tarefas como trabalho de casa, ou tenho que parar para descansar	☐	☐
2. Quando subo um lance de escadas, vou muito devagar, ou tenho que parar para descansar	☐	☐
3. Se estou muito apressado ou caminho mais depressa, tenho que parar para descansar ou ir mais devagar	☐	☐

4. Minha respiração torna difícil fazer coisas como subir ladeiras, carregar objetos subindo escadas, cuidar do jardim, ou dançar.	☐	☐
5. Por causa da minha respiração tenho dificuldades para desenvolver atividades como: trabalho manual pesado, correr, nadar rápido ou praticar esportes muito cansativos	☐	☐

Seção 6:

Gostaríamos de saber o quanto sua condição respiratória <u>geralmente</u> afeta suas atividades do dia-a-dia. *Por favor, assinale com um "X" no quadrado de cada questão abaixo, indicando a que melhor se aplica a você <u>por causa da sua condição respiratória.</u>*

	VERDADEIRO	FALSO
1. Eu não consigo praticar esportes ou jogos que impliquem esforço físico	☐	☐
2. Eu não consigo sair de casa para fazer compras	☐	☐
3. Eu não consigo fazer trabalho de casa	☐	☐
4. Eu não consigo me mover para longe da minha cama ou da cadeira	☐	☐

Agora, por favor assinale com um "X" a resposta que melhor define a forma como você é afetado pela sua condição respiratória:

Não me impede de fazer nenhuma das coisas que gostaria de fazer	☐
Impede-me de fazer uma ou duas coisas que eu gostaria de fazer	☐
Impede-me de fazer a maioria das coisas que eu gostaria de fazer	☐
Impede-me de fazer tudo que eu gostaria de fazer	☐

ANEXO C

Parecer do comitê de ética em pesquisa

UNIVERSIDADE ESTADUAL DE LONDRINA - UEL

PARECER CONSUBSTANCIADO DO CEP

DADOS DA EMENDA

Título da Pesquisa: Associação entre progressão da doença e desfechos clínicos em pacientes com doenças intersticiais pulmonares

Pesquisador: CARLOS AUGUSTO MARCAL CAMILLO

Área Temática:

Versão: 3

CAAE: 69598317.5.0000.5231

Instituição Proponente: CCS - Progr. de Pós-Grad. em Ciências da Reabilitação

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.484.871

Apresentação do Projeto:

Trata-se de solicitação de emenda ao projeto.

Objetivo da Pesquisa:

Objetivo Primário:

Avaliar o impacto do declínio da função pulmonar nas mudanças nos níveis de atividade física de pacientes com doenças intersticiais pulmonares

Objetivo Secundário:

Avaliar o impacto do declínio da função pulmonar em outros desfechos clínicos: função muscular (força, resistência e fadigabilidade); capacidade de exercício (máxima e funcional), qualidade de vida relacionada à saúde e sintomas. Além disso, investigar associações entre o nível de atividade física (e suas mudanças ao longo do tempo) e hospitalizações e mortalidade em pacientes com DIP durante o período do estudo. Por último, também serão verificadas possíveis associações entre função pulmonar (e suas mudanças ao longo do tempo) com os demais desfechos investigados.

Avaliação dos Riscos e Benefícios:

Segundo o pesquisador, "nenhum dos procedimentos utilizados constitui risco direto para a integridade física ou moral dos participantes. Em alguns casos, após a coleta de sangue é possível

que se forme um pequeno hematoma na região onde a coleta ocorreu. Além disso, caso algum teste gere mal estar (físico ou emocional) ele será interrompido sem que haja risco real para a saúde do participante.
Benefícios:
Benefícios esperados do estudo: Os resultados deste estudo ajudarão a compreender o efeito que uma possível progressão da doença (ou seja, mudanças na função pulmonar) tem sobre diferentes aspectos clínicos da doença. Isso poderá contribuir para que, no futuro, novos tratamentos surjam e ajudem pacientes com doença pulmonar intersticial.

Comentários e Considerações sobre a Pesquisa:
O pesquisador solita a inclusão de realização de três testes funcionais. Estes testes apresentam relação com força de membros inferiores além de risco de quedas, sarcopenia e consequentemente hospitalizações. A realização dos testes ocorrerá nas mesmas visitas já programadas pela pesquisa e implicará em aumento de 10 - 15 minutos em cada visita.
Tendo vista que a hospitalização é um desfecho do estudo, a solicitação é pertinente.

Considerações sobre os Termos de apresentação obrigatória:
Não se aplica.

Recomendações:
Incluir a explicação dos 3 testes agregados ao estudo no TCLE.

Conclusões ou Pendências e Lista de Inadequações:
Não há.

Considerações Finais a critério do CEP:
Prezado (a) Pesquisador (a),
Este é seu parecer final de aprovação da emenda solicitada, vinculado ao Comitê de Ética em Pesquisas Envolvendo Seres Humanos da Universidade Estadual de Londrina. É sua responsabilidade imprimi-lo para apresentação aos órgãos e/ou instituições pertinentes.
Coordenação CEP/UEL.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações	PB_INFORMAÇÕES_BÁSICAS_102844	29/01/2018		Aceito

UNIVERSIDADE ESTADUAL DE LONDRINA - UEL

Continuação do Parecer: 2.484.871

Básicas do Projeto	_E1.pdf	10:36:22		Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Adendo290118.pdf	29/01/2018 10:25:44	Humberto Silva	Aceito
Recurso Anexado pelo Pesquisador	Adendo_de_projeto.pdf	29/01/2018 10:17:05	Humberto Silva	Aceito
Folha de Rosto	Folha_de_rosto_Camillo.pdf	29/01/2018 10:14:17	Humberto Silva	Aceito
Cronograma	Cronogramas_Camillo_Versao01.pdf	09/06/2017 15:38:20	CARLOS AUGUSTO MARCAL CAMILLO	Aceito
Orçamento	Orcamento_Camillo_Versao01.pdf	09/06/2017 15:35:25	CARLOS AUGUSTO MARCAL CAMILLO	Aceito
Declaração de Instituição e Infraestrutura	Declaracao_Infraestrutura_Camillo_Versao01.pdf	09/06/2017 15:32:25	CARLOS AUGUSTO MARCAL CAMILLO	Aceito
Projeto Detalhado / Brochura Investigador	Protocolo_Camillo_Versao01.pdf	09/06/2017 15:30:39	CARLOS AUGUSTO MARCAL CAMILLO	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

LONDRINA, 05 de Fevereiro de 2018

Assinado por:
Alexandrina Aparecida Maciel Cardelli
(Coordenador)

Endereço: LABESC - Sala 14
Bairro: Campus Universitário **CEP:** 86.057-970
UF: PR **Município:** LONDRINA
Telefone: (43)3371-5455 **E-mail:** cep268@uel.br

ANEXO D

Normas de submissão para revista Brazilian Journal of Physical Therapy (BJPT)

GUIDE FOR AUTHORS

INTRODUCTION

Types of article

The Brazilian Journal of Physical Therapy (BJPT) publishes original research articles, reviews, and brief communications on topics related to physical therapy and rehabilitation, including clinical, basic or applied studies on the assessment, prevention and treatment of movement disorders. Our Editorial Board is committed to disseminate high-quality research in the field of physical therapy. The BJPT follows the principle of publication ethics included in the code of conduct of the Committee on Publication Ethics (COPE).The BJPT accepts the submission of manuscripts with up to 3.500 words (excluding title page, abstract, references, tables, figures and legends). Information contained in appendices will be included in the total number of words allowed. A total of five (5) combined tables and figures is allowed.

The following types of study can be considered for publication, if directly related to the journals scope: **a) Intervention studies (clinical trials):** studies that investigate the effect(s) of one or more interventions on outcomes directly related to the BJPTs scope. The World Health Organization defines a clinical trial as any research study that prospectively allocates human participants or groups of humans to one or more health-related interventions to evaluate the effect(s) on health outcome(s). Clinical trials include single-case experimental studies, case series, nonrandomized controlled trials, and randomized controlled trials. Randomized controlled trials (RCTs) must follow the CONSORT (Consolidated Standards of Reporting Trials) recommendations, which are available at: http://www.consort-statement.org/consort-statement/overview0/. The CONSORT checklist and Statement Flow Diagram, available at http://www.consort-statement.org/consort-statement/flow-diagram, must be completed and submitted with the manuscript. Clinical trials must provide registration that satisfies the requirements of the International Committee of Medical Journal Editors (ICMJE), e.g. http://clinicaltrials.gov/ and/or http://www.anzctr.org.au. The complete list of all clinical trial registries can be found at: http://www.who.int/ictrp/network/primary/en/index.html.

We suggest that all authors register clinical trials prospectively via the website http://www.clinicaltrials.gov. Note: We do not accept single case studies and series of cases (i.e. clinical trials without a comparison group).

b) Observational studies: studies that investigate the relationship(s) between variables of interest related to the BJPTs scope. Observational studies include cross-sectional studies, cohort studies, and case-control studies. All observational studies must be reported following the recommendation from the STROBE statement (http://strobe-statement.org/index.php?id=strobe-home).

c) Qualitative studies: studies that focus on understanding needs, motivations, and human behavior. The object of a qualitative study is guided by in-depth analysis of a topic, including opinions, attitudes, motivations, and behavioral patterns without quantification. Qualitative studies include documentary and ethnographic analysis.

d) Systematic reviews: studies that analyze and/or synthesize the literature on a topic related to the scope of the BJPT. Systematic reviews that include meta-analysis will have priority over other systematic reviews. Those that have an insufficient number of articles or articles with low quality in the Methods section and do not include an assertive and valid conclusion about the topic will not be considered for peer-review analysis. The authors must follow the Preferred Reporting Items for Systematic Reviews and MetaAnalyses (PRISMA) checklist to format their systematic reviews. The checklist is available at http://www.prisma-statement.org/PRISMAStatement/Default.aspx and must be filled in and submitted with the manuscript. Potential authors are encouraged to read the following tutorial, which contains the minimum requirements for publication of systematic reviews in the BJPT: Mancini MC, Cardoso JR, Sampaio RF, Costa LCM, Cabral CMN, Costa LOP. Tutorial for writing systematic reviews for the Brazilian Journal of Physical Therapy (BJPT). Braz J Phys Ther. 2014 Nov-Dec; 18(6):471-480.

e) Studies on the translation and cross-cultural adaptation of questionnaires or assessment tools: studies that aim to translate and/or cross-culturally adapt foreign questionnaires to a language other than that of the original version of existing assessment instruments. The authors must use the checklist (Appendix) to format this type of paper and adhere to the other recommendations of the BJPT. The answers to the checklist must be submitted with the manuscript. At the time of submission, the authors must also include written permission from the authors of the original instrument that was translated and/or cross-culturally adapted.

f) Methodological studies: studies centered on the development and/or evaluation of clinimetric properties and characteristics of assessment instruments. The authors are encouraged to use the Guidelines for Reporting Reliability and Agreement Studies (GRRAS) to format methodological papers, in addition to following BJPT instructions. Important: Studies that report electromyographic results must follow the Standards for Reporting EMG Data recommended by ISEK (International Society of Electrophysiology and Kinesiology), available at http://www.isek.org/wp-content/uploads/2015/05/Standards-for-Reporting-EMG-Data.pdf.

g) Clinical trial protocols: The BJPT welcomes the publication of clinical trial protocols. We only accept trial protocols that are substantially funded, have ethics approval, have been prospectively registered and of very high quality. We expect that clinical trial protocols must be novel and with a large sample size. Finally, authors have to provide that the clinical trial is on its first stages of recruitment. Authors should use the SPIRIT statement while formatting the manuscript (http://www.spirit-statement.org).

h) Short communications: the BJPT will publish one short communication per issue (up to six a year) in a format similar to that of the original articles, containing 1200 words and up to two figures, one table, and ten references.

i) Masterclass articles: This type of article presents the state of art of any topic that is important to the field of physical therapy. All masterclass articles are invited manuscripts and the authors must be recognized experts in the field. However, authors can send e-mails to the editor in chief with an expression of interest to submit a masterclass article to the BJPT.

Submission checklist

You can use this list to carry out a final check of your submission before you send it to the journal for review. Please check the relevant section in this Guide for Authors for more details.

Ensure that the following items are present:

One author has been designated as the corresponding author with contact details:

• E-mail address

• Full postal address

All necessary files have been uploaded:

Manuscript:

• Include keywords

• All figures (include relevant captions)
• All tables (including titles, description, footnotes)
• Ensure all figure and table citations in the text match the files provided
• Indicate clearly if color should be used for any figures in print
Graphical Abstracts / *Highlights files* (where applicable)
Supplemental files (where applicable).

Further considerations
• Manuscript has been 'spell checked' and 'grammar checked'
• All references mentioned in the Reference List are cited in the text, and vice versa
• Permission has been obtained for use of copyrighted material from other sources (including the Internet)
• A competing interests statement is provided, even if the authors have no competing interests to declare
• Journal policies detailed in this guide have been reviewed
• Referee suggestions and contact details provided, based on journal requirements
For further information, visit our Support Center.

BEFORE YOU BEGIN

Ethics in publishing

Please see our information pages on Ethics in publishing and Ethical guidelines for journal publication.

Studies in humans and animals

If the work involves the use of human subjects, the author should ensure that the work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. The manuscript should be in line with the Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical
Journals and aim for the inclusion of representative human populations (sex, age and ethnicity) as per those recommendations. The terms sex and gender should be used correctly.

Authors should include a statement in the manuscript that informed consent was obtained for experimentation with human subjects. The privacy rights of human subjects must always be observed.

All animal experiments should comply with the ARRIVE guidelines and should be carried out in accordance with the U.K. Animals (Scientific Procedures) Act, 1986 and associated guidelines, EU Directive 2010/63/EU for animal experiments, or the National Institutes of Health guide for the care and use of Laboratory animals (NIH Publications No. 8023, revised 1978) and the authors should clearly indicate in the manuscript that such guidelines have been followed. The sex of animals must be indicated, and where appropriate, the influence (or association) of sex on the results of the study.

Declaration of interest

All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential competing interests include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. Authors must disclose any interests in two places: 1. A summary declaration of interest statement in the title page file (if double-blind) or the manuscript file (if single-blind). If there are no interests to declare then please state this: 'Declarations of interest: none'. This summary statement will be ultimately published if the article is accepted.

2. Detailed disclosures as part of a separate Declaration of Interest form, which forms part of the journal's official records. It is important for potential interests to be declared in both places and that the information matches. More information.

Submission declaration and verification

Submission of an article implies that the work described has not been published previously (except in the form of an abstract, a published lecture or academic thesis, see 'Multiple, redundant or concurrent publication' for more information), that it is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyrightholder. To verify originality, your article may be checked by the originality detection service Crossref Similarity Check.

Use of inclusive language

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