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Cultural adaptation and validation of the Brazilian Portuguese version of the PROactive Physical Activity in COPD–clinical visit instrument for individuals with COPD

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ABSTRACT

Objective: To adapt the PROactive Physical Activity in COPD–clinical visit (C-PPAC) instrument to the cultural setting in Brazil and to determine the criterion validity, test-retest reliability agreement, and internal consistency of this version. **Methods:** A protocol for cultural adaptation and validation was provided by the authors of the original instrument and, together with another guideline, was applied in a Portuguese-language version developed by a partner research group from Portugal. The adapted Brazilian Portuguese version was then cross-sectionally administered twice within a seven-day interval to 30 individuals with COPD (57% were men; mean age was 69 ± 6 years; and mean FEV_1 was 53 ± 18% of predicted) to evaluate internal consistency and test-retest reliability. Participants also completed the International Physical Activity Questionnaire (IPAQ), the modified Medical Research Council scale, the COPD Assessment Test, and Saint George's Respiratory Questionnaire to evaluate criterion validity. **Results:** The C-PPAC instrument showed good internal consistency and excellent test-retest reliability: "amount" domain = 0.87 (95% CI, 0.73-0.94) and "difficulty" domain = 0.90 (95% CI, 0.76-0.96). Bland & Altman plots, together with high Lin's concordance correlation coefficients, reinforced that agreement. Criterion validity showed moderate-to-strong correlations of the C-PPAC with all of the other instruments evaluated, especially with the IPAQ (rho = −0.63). **Conclusions:** The Brazilian Portuguese version of the C-PPAC is a reliable and valid instrument for evaluating the experience of Brazilian individuals with COPD with their physical activity in daily life.

Keywords: Pulmonary disease, chronic obstructive; Validation study; Activities of daily living; Psychometrics.

INTRODUCTION

Individuals with COPD have lower levels of physical activities (PAs) in daily life as compared to healthy older people,[1-4] and this reduction is associated with a higher risk of exacerbations and mortality.[5-7] In order to be able to evaluate and tackle reduced levels of PA in individuals, the use of validated instruments to quantify such levels is vital. In general, for the objective assessment of the amount of PA performed on a daily basis, PA monitors are considered more accurate than are questionnaire-based self-reported PA.[8-10] Yet, PA monitors do not capture other important PA dimensions, such as the difficulties experienced when being active and how individuals with COPD adapt or modify their activities. This concerns the particular and self-reported view of the patient (usually through standardized questionnaires) about his/her difficulty in performing PAs. This is a relevant aspect, because the adequate representation of how the patient perceives the practice of PAs should cover different dimensions that influence that performance. Therefore, quantity and difficulty are two different but

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complementary approaches for the evaluation of PA because they respectively capture the objective aspect of the amount of PA performed and the subjective difficulty in performing these activities.[11,12]

The PROactive Physical Activity in COPD (PPAC) is an innovative hybrid instrument that integrates the dimensions of PA that people with COPD consider important in two domains: amount and difficulty.[12,13] The "amount" domain integrates information obtained from an activity monitor (objective amount and intensity) and self-reported items, whereas the "difficulty" domain relies on self-report only. Two applications have been developed for the PPAC instrument, that is, one to be used during clinical visits (C-PPAC), with a seven-day recall period, and one to be completed on a daily basis (D-PPAC). The C-PPAC instrument in particular is more applicable for use in routine clinical practice. The PPAC instruments were originally published in English and were carefully planned and developed based on a modern conceptual model, using qualitative input from several European COPD populations.[11,12] These instruments were subsequently translated into several languages using a culturally-sensitive translation methodology, including be4ing translated into Portuguese by a research group from Portugal, which is a partner of the present group. However, the PPAC has yet to have a validated Brazilian Portuguese version. For its reliable use, the instrument needs adaptation and adequate investigation of its metric properties. Therefore, with the permission of the original instrument development team and the research group from Portugal, this study aimed to adapt the self-reported items of the C-PPAC to the cultural setting in Brazil and to determine the test-retest reliability, agreement, internal consistency, and criterion validity of the Brazilian Portuguese version of the instrument. We decided to focus on the clinic visit version of the PPAC only since we were not planning to use the D-PPAC as part of our routine COPD care.

METHODS

Study design and ethics

This was a cross-sectional study involving the cultural adaptation and validation of the Brazilian Portuguese version of the C-PPAC instrument, following the protocol indicated by the original authors of the instrument in English. The guidelines by Beaton et al.[14] were also considered in the cross-cultural adaptation process. The study was approved by the Research Ethics Committee of the State University of Londrina (Protocol no. 36966920.7.0000.5231). Of note, the original authors fully agreed to the cultural adaptation of the C-PPAC with no similar process regarding the D-PPAC at that moment and to the cultural adaptation not from the original instrument in English but from the adapted Portuguese-language version developed in Portugal. An informed consent form, explaining the ethical and legal aspects of the research, was signed by all participants before starting data collection.

The PPAC instrument

The PPAC[12] is an instrument for the hybrid evaluation of PA experience in daily life (i.e., subjective assessment plus objective quantification). Its clinical-visit version (C-PPAC) consists of two items derived from a validated activity monitor (steps and vector magnitude units converted into an item score) and 12 questions addressing the experienced amount of PA within the last seven days, as well as the difficulties in performing PAs. All of the questions are scored from zero to four, except for the first question, whose score ranges from zero to three. The first 2 questions compose the "amount of PA" domain, together with two separate self-reported items (at the end of the instrument) which complement the items extracted from the PA assessment using PA monitors worn during the week preceding the instrument application, which runs in parallel with the recall period for the questions. In the original study, the use of one of two PA monitors was recommended: ActiGraph wGT3X (ActiGraph, Pensacola, FL, USA) or DynaPort Activity Monitor (McRoberts, the Hague, the Netherlands).[12] The former was used in the present study by all subjects for one week (additional information on the C-PPAC and its scoring characteristics are provided in the methods section in the supplementary material). Despite the fact that the PA monitors were worn for one week by all subjects, the present study focused primarily on the validation of the questions of the instrument (i.e., the 10 questions about "experienced difficulty" and the 2 questions about "experienced amount"), although the validity of the total score and each specific domain (amount and difficulty) were also studied based on the assessment with the full instrument. In general, it is encouraged that these scores be summed up to compose the total score for the full administration of the instrument.

Cultural adaptation for the Brazilian Portuguese version

Initially, the version developed by the research group from Portugal (already translated into Portuguese and in the process of validation in that country) was adapted for Brazilian Portuguese by a panel of five Brazilian experts (further details in the methods section in the supplementary material). The Portuguese translation of the items and instructions was discussed and modified to better fit with the Portuguese language used in Brazil until consensus was reached among the experts. Next, the Brazilian Portuguese version was presented to a group of five individuals with COPD, who were asked to indicate any words that were unclear or not reflecting lay language understood by the majority of the Brazilian population. Based on their feedback, the adaptation of the C-PPAC questionnaire was further modified by the expert panel and the final version was defined (Chart S1). Then, the Brazilian Portuguese translation of the instrument was back-translated into English by a qualified professional, fluent in both English and Brazilian Portuguese, and the version generated in English was sent to the original developers of the

instrument for review. Upon minor clarifications and approval by the original authors, that version was considered adequate to be integrated in the validation study (Figure S1).

No reduction of items or significant adaptations of the instrument was necessary for the process of cross-cultural adaptation and linguistic validation from the Portuguese from Portugal version to the Brazilian Portuguese version. Furthermore, there were no items with floor or ceiling effect. Only minor adaptations were made both in the patient and the evaluator guidelines and in the "thank you" text, in addition to minimal changes in the items of the instrument that were unusual in Brazilian Portuguese (Chart S2).

The Brazilian Portuguese version of the C-PPAC is available in Chart S1. For clinical use, the tool can be used by clinicians without restrictions and with no need of authorization from the original team or from the authors of the present study. For clinical studies (i.e., scientific investigations), the original authors should be contacted and approve the use of the tool. Authorization should be asked to Professor Dr. Thierry Troosters at the following e-mail: thierry.troosters@kuleuven.be.

Establishing the psychometric properties of the C-PPAC instrument—Brazilian Portuguese version

Sample and setting

Sample size calculation was performed using G*Power, version 3.1.9.7 (Heinrich Heine University, Düsseldorf, Germany), and the minimum sample size was defined as 15 individuals (methods section in the supplementary material). However, aiming at reducing bias, a larger sample was included.

A convenience sample was formed by individuals followed up in projects developed in the Laboratory of Research in Respiratory Physiotherapy, linked to the State University of Londrina, in the city of Londrina, Brazil. A randomized list of eligible individuals was contacted by telephone using the number that appeared in their follow-up records in the abovementioned research laboratory, and, upon interest in participating in the study, the individuals were screened in accordance with the inclusion criteria. Inclusion criteria were as follows: diagnosis of COPD established according to the GOLD guidelines[15]; fluency in Brazilian Portuguese; clinical stability, that is, no acute exacerbation for at least one month prior to inclusion; no concomitant diagnosis of severe and/or unstable heart disease; and no neuromusculoskeletal dysfunction that could limit the performance of PA in daily life. Exclusion criteria were the occurrence of any clinical condition that could interfere with the level of daily PA (e.g., surgeries, orthopedic disorders, or neurological disorders) or the impossibility of readministering the instrument for any reason (e.g., refusal to continue participating in the study).

The individuals included received two home visits, one week apart. In each visit they completed the Brazilian Portuguese version of the C-PPAC in interview mode for test-retest purposes. In addition, only in the first visit, they completed self-reported instruments for assessment: the short-form International Physical Activity Questionnaire (IPAQ) for assessing the level of PA[16]; the modified Medical Research Council scale (mMRC) for the assessment of dyspnea[17]; the modified version of the Saint George's Respiratory Questionnaire (mSGRQ) for the assessment of health-related quality of life[18]; and the COPD Assessment Test (CAT) for assessing the health status of the participants.[19] All of these instruments have been validated for use in Brazil and were administered in an interview. The C-PPAC was administered twice to all individuals by the same evaluator. In addition to the instruments, the individuals wore the PA monitor ActiGraph wGT3X-BT (ActiGraph) for 8 h/day (agreed time) for seven consecutive days between the first and second evaluations (for more details, see the methods section in the supplementary material).

Statistical analysis

Statistical analyses were performed with the IBM SPSS Statistics software package, version 21.0 (IBM Corporation, Armonk, NY, USA). According to the Shapiro-Wilk normality test, continuous variables were expressed as mean ± standard deviation or median [interquartile range]. Categorical variables were expressed as absolute and/or relative frequency.

Cronbach's alpha coefficients were calculated for the two domains, (amount and difficulty) using the first and second assessments for the evaluation of internal consistency, and values above 0.70 were considered adequate. Likewise, the intraobserver test-retest reliability of the C-PPAC was calculated by the two-way mixed effects intraclass correlation coefficient (ICC) for test and retest, an ideal value being equal to or greater than 0.8. The test-retest agreement for the questions of the C-PPAC was studied using Bland & Altman plots and their 95% limits of agreement, as well as the Lin's concordance correlation coefficient.[20,21] Finally, the criterion validity of the C-PPAC (second visit) complete data, that is, including data from the one-week PA monitor assessment plus the self-reported items (encompassing the total score and the two domains) was evaluated by using the Spearman's correlation coefficient with the IPAQ, mMRC, CAT, and mSGRQ instruments. The interpretation of the correlations was as follows: weak: $0 < \text{rho} \leq 0.30$; moderate: $0.30 < \text{rho} \leq 0.60$; strong: $0.60 < \text{rho} \leq 0.90$; and very strong: $0.90 < \text{rho} \leq 1$.[22]

RESULTS

The convenience sample consisted of 30 individuals with COPD, 17 of whom (57%) were male, and the age range was between 57 and 88 years. The median C-PPAC score was 67 [58-78], and most participants presented with moderate-to-very-severe disease (mean FEV_1 = 53 ± 18% of the predicted values).

The general characteristics of the participants are described in Table 1.

Regarding the psychometric properties of the C-PPAC, there was excellent internal consistency (Cronbach's alpha for the "amount" and "difficulty" domains were 0.87 and 0.91, respectively) and excellent test-retest reliability, with an ICC(2,1) of 0.87 (95% CI, 0.73-0.94) and of 0.90 (95% CI, 0.76-0.96), respectively. Furthermore, good agreement between the data obtained in the first and second administration of the instrument was demonstrated by the Bland & Altman plots, with a test-retest difference of nearly zero and relatively narrow confidence intervals, with no signs of systematic errors for either domain (Figure 1). The excellent agreement between the two administrations of the C-PPAC was strengthened by the Lin's concordance correlation coefficient (Rc of 0.77 and of 0.81 for the "amount" and "difficulty" domains, respectively), with a test-retest difference of nearly zero (Figure 2). Criterion validity of the C-PPAC total score (i.e., including PA monitor data) was demonstrated by its moderate correlations with the IPAQ, CAT, and mSGRQ instruments ($p < 0.05$ for all), as well as with the mMRC scale ($p = 0.067$; Figure 3). Figures 4 and 5, respectively, show the correlations of the "amount" and "difficulty" domains of the C-PPAC instrument separated by the two domains with the other self-reported measures. The "amount" domain was moderately correlated with the IPAQ (Figure 4), whereas the "difficulty" domain was moderately to strongly correlated with the IPAQ, CAT, mMRC scale, and mSGRQ ($p < 0.05$ for all; Figure 5).

Table 1. Characteristics of the participants (N = 30).[a]

Variable	Result
Male sex	57%
Age, years	69 ± 6
BMI, kg/m^2	30 ± 14
FEV_1, L	1.47 ± 0.56
FEV_1, % predicted	53 ± 18
FEV_1/FVC, %	55 ± 14
Steps/day	4,355 ± 2,841
Time spent/day in MVPA, min/day	11 ± 14
C-PPAC	
Total score	67 [58-78]
Amount domain score	63 [45-77]
Difficulty domain score	78 [61-84]
IPAQ (1-4)	3 [2-3]
CAT (0-40)	13 [8-22]
mMRC scale (1-5)	3 [2-4]
mSGRQ (0-100)	37 [28-50]

MVPA: moderate-to-vigorous physical activity; C-PPAC: PROactive Physical Activity in COPD-clinical visit; IPAQ: International Physical Activity Questionnaire; CAT: COPD Assessment Test; mMRC: modified Medical Research Council; mSGRQ: modified version of Saint George's Respiratory Questionnaire. [a]Values expressed as n (%), mean ± SD, or median [IQR], except where otherwise indicated.

DISCUSSION

This study provides a novel validated C-PPAC version for use in Brazil. This C-PPAC version (self-reported portion) had high Cronbach's alpha coefficients for both domains (amount and difficulty), yielding excellent internal consistency of the instrument. There was also excellent test-retest reliability and good agreement between the two administrations of the instrument, which were revealed by Bland & Altman plots and the Lin's concordance correlation coefficients. Finally, there was a moderate correlation between C-PPAC (total score) and IPAQ, defined as a validation criterion, as well as moderate correlations with CAT, mSGRQ and mMRC scale. Scores of the two specific domains were also moderately to strongly correlated with these outcome measures. These results show that, overall, the Brazilian Portuguese version of the instrument was valid and reproducible to evaluate the experience of Brazilian individuals with COPD regarding their PA in daily life.

Instruments that assess different aspects of PA in daily life have widely been used in studies involving several populations, including individuals with

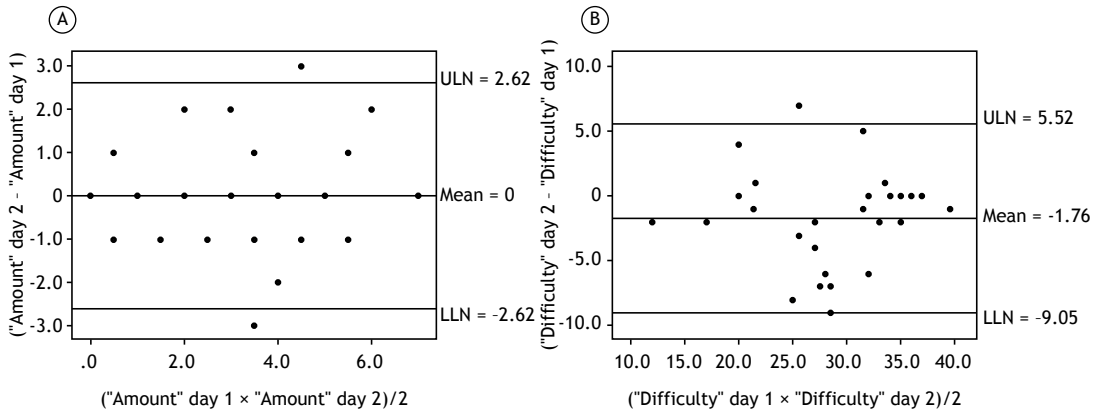

Figure 1. Bland & Altman plots comparing the first and second administration of the PROactive Physical Activity in COPD–clinical visit for the "Amount" domain (in A) and the "Difficulty" domain (in B). ULN: upper limit of normal; mean: mean difference; and LLN: lower limit of normal.

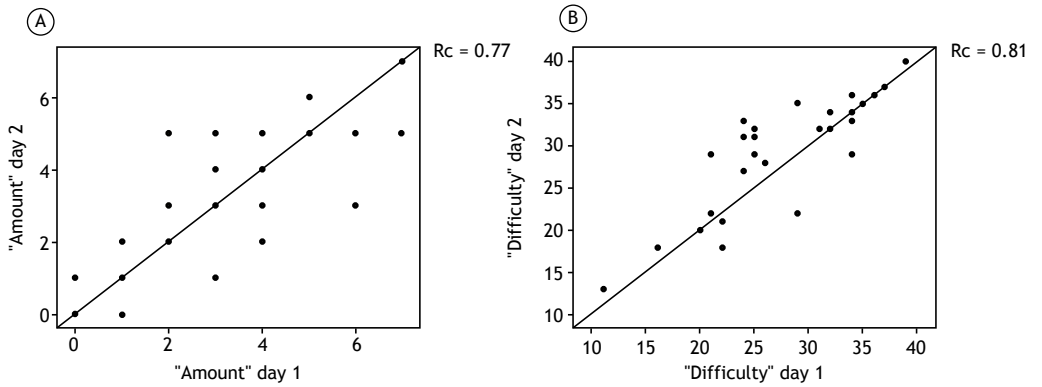

Figure 2. Plots of Lin's concordance correlation coefficient graphic dispositions between the first and second administration of the PROactive Physical Activity in COPD–clinical visit for the "Amount" domain (in A) and the "Difficulty" domain (in B).

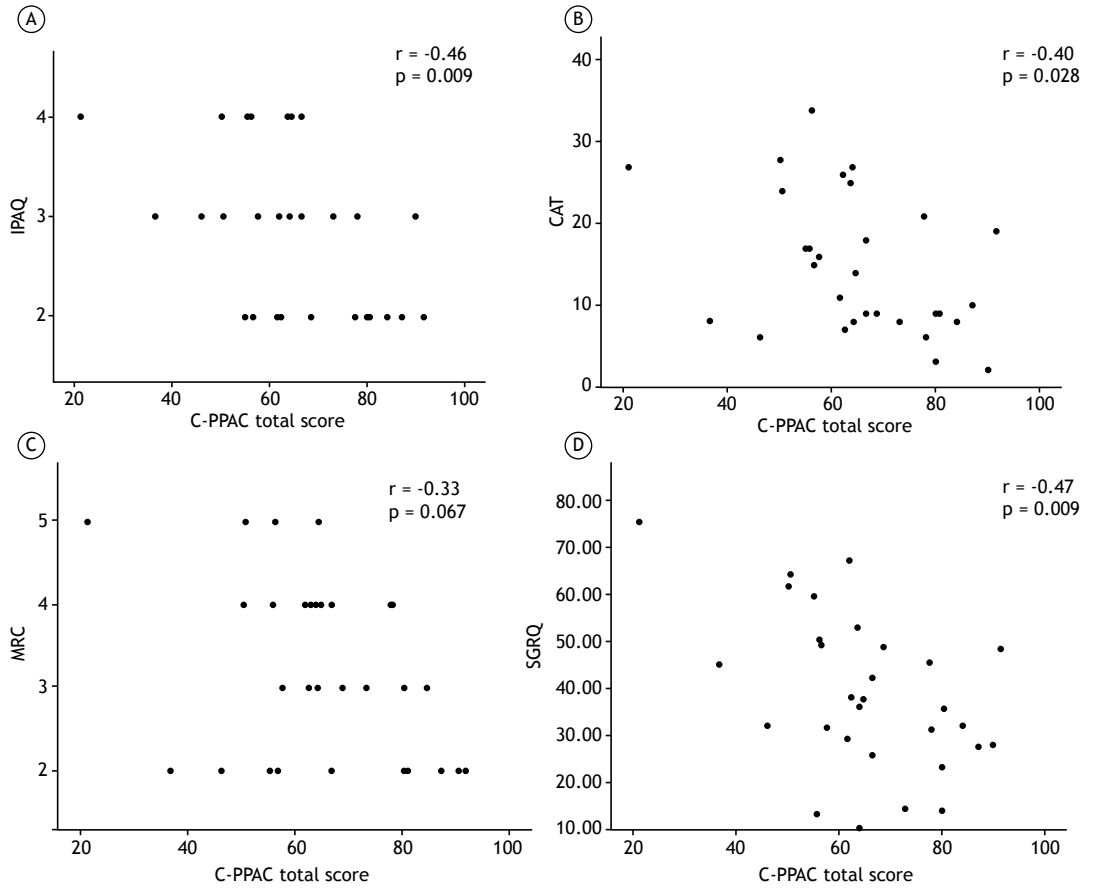

Figure 3. Correlations of the PROactive Physical Activity in COPD–clinical visit (C-PPAC) total score (i.e., including physical activity monitor data) with: A, the International Physical Activity Questionnaire (IPAQ); B, the COPD Assessment Test (CAT); C, the modified Medical Research Council (mMRC) scale; and D, the modified version of the Saint George's Respiratory Questionnaire (SGRQm).

COPD.[23,24] One of the most commonly used and cited questionnaires in the literature is the IPAQ, which provides a classification in terms of the level of PA based on international recommendations.[16] Despite the frequent use of IPAQ and other questionnaires, it is known that self-report measures are biased and not the most accurate method to quantify PA because the subjectivity of the answers makes the quantification of PA less realistic.[25] In this sense, PA monitors are more accurate and, therefore, more recommended to quantify the level of PA in daily life from a quantitative point of view. On the other hand, only quantifying PA may not fully reflect the experience that an individual has when performing such PA. PA experienced by patients includes the experienced amount as well as the experienced difficulties and adaptations needed. In

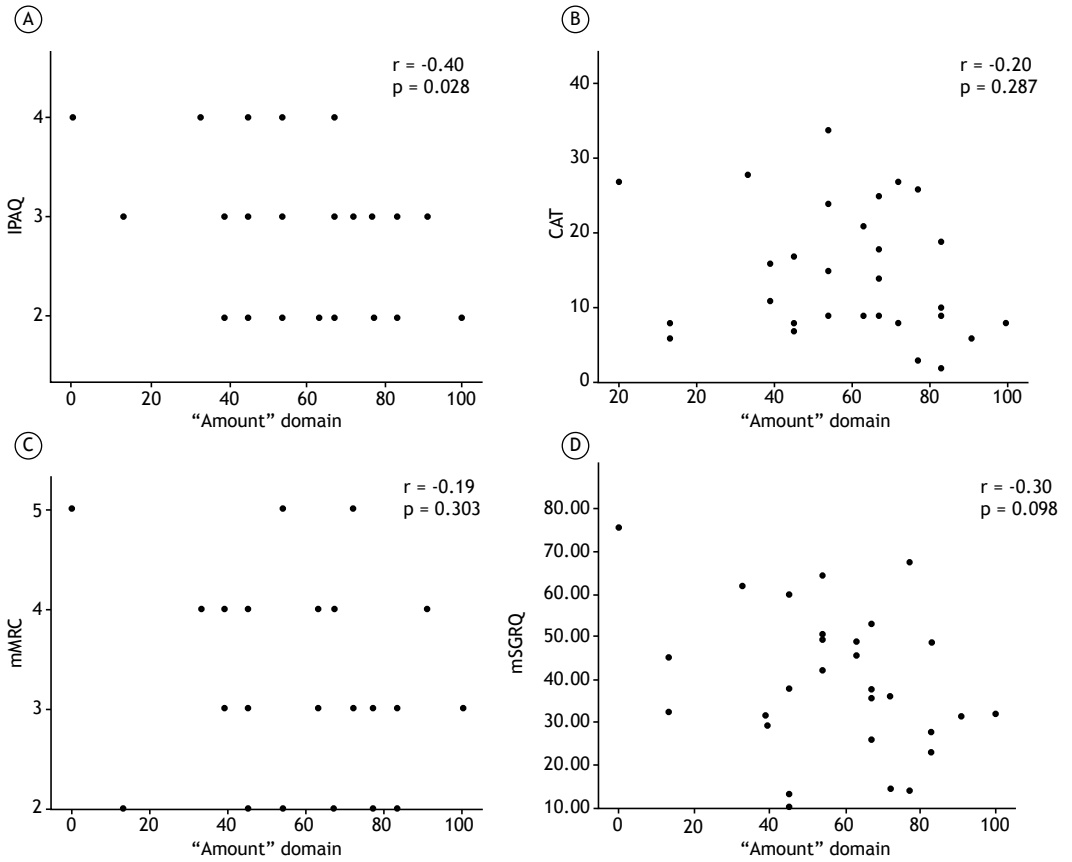

Figure 4. Correlations of the PROactive Physical Activity in COPD–clinical visit (C-PPAC) "Amount" domain (second visit) with: A, the International Physical Activity Questionnaire (IPAQ); B, the COPD Assessment Test (CAT); C, with the modified Medical Research Council (mMRC) scale; and D, the modified version of the Saint George's Respiratory Questionnaire (SGRQm).

this regard, the C-PPAC has shown to be an innovative instrument.[12] The instrument includes the use of the monitor to quantify PA in daily life broadly, as well as including items that capture the perception of patients regarding their PA. The present study did not aim to cover the validity of PA monitors in COPD since this has already been done.[8] Another advantage of the use of this instrument in individuals with COPD is that it was developed specifically for this population, in contrast to other instruments which were developed for other populations and simply validated for individuals with COPD. The items are therefore specifically tailored to individuals with COPD. Also, in the target population of the present study, individual answers spanned the complete range of answer options, showing the relevance of the questions to Brazilian patients with different COPD severity levels.

In the original C-PPAC validation studies,[12,13] strong internal consistency of the instrument was found (Cronbach's alpha coefficient > 0.9), as well as excellent test-retest reliability (ICC > 0.8), which was corroborated by the present results. Vaidya et al.[26] performed the cultural adaptation and translation of the C-PPAC into French and also showed good results (Cronbach's alpha coefficient > 0.90 and ICC ≥ 0.8). Although Brazilian individuals with COPD are known to be more active than are individuals with COPD from some other countries,[27,28] this difference did not seem to influence the performance of the C-PPAC. Of note, the present study used the same validation strategy as did the French study,[26] focusing mainly on the validation of the self-report items of the instrument.

In this study, the correlations of the C-PPAC with other criterion instruments were moderate to strong. In the study by Gimeno-Santos et al.,[12] correlation analyses were performed for each domain separately ("experienced amount" and "experienced difficulty"). For the "experienced amount" domain, there were weak to moderate correlations with the instruments used for validation, whereas for the "experienced difficulty" domain, as evaluated in the present study, there were also moderate-to-strong correlations.

It is worth remembering that the C-PPAC is a hybrid instrument,[12] in which the two dimensions complement each other. By means of the criterion validity analyses shown in Figures 3-5, we could demonstrate the ability of the C-PPAC to measure the constructs that it proposes to measure PA as a hybrid instrument. Moderate to strong correlations were observed both

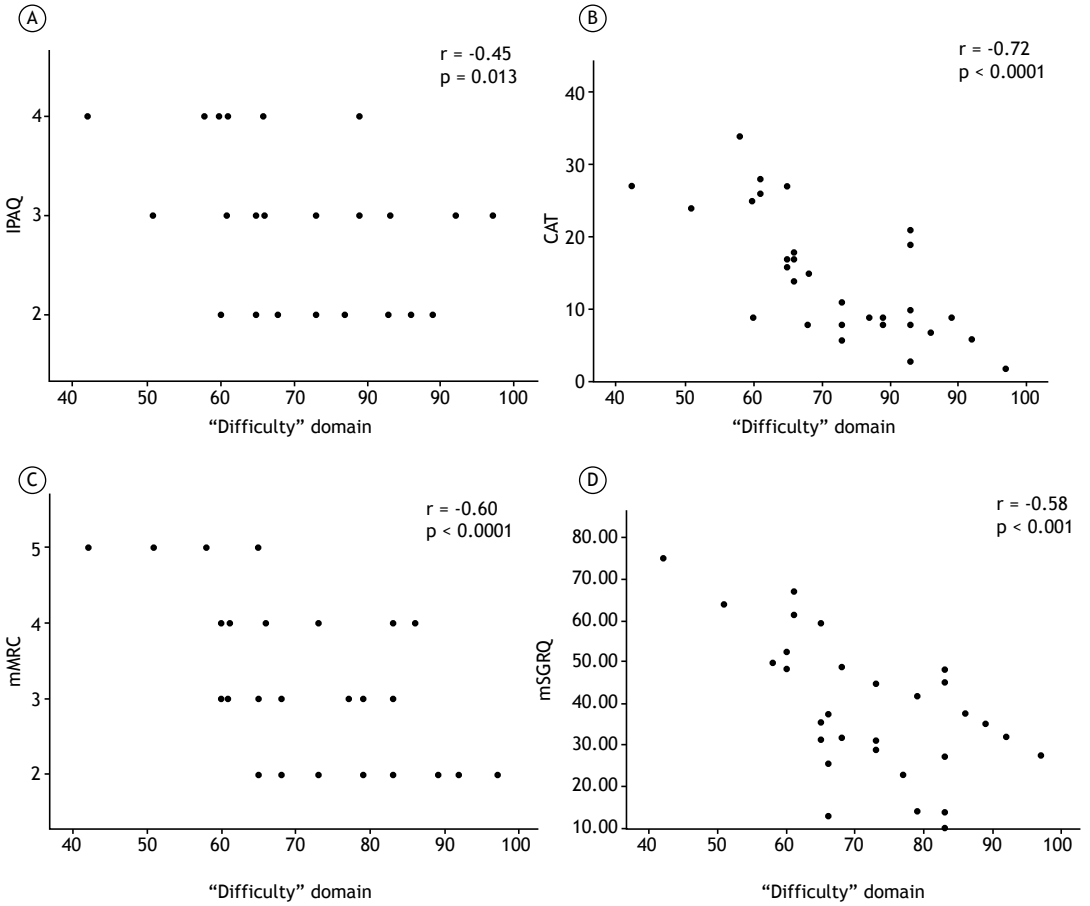

Figure 5. Correlations of the PROactive Physical Activity in COPD–clinical visit (C-PPAC) "Difficulty" domain (second visit) with: A, the International Physical Activity Questionnaire (IPAQ); B, the COPD Assessment Test (CAT); C, with the modified Medical Research Council (mMRC) scale; and D, the modified version of the Saint George's Respiratory Questionnaire (mSGRQ).

in the total score (Figure 3) and in the two domains separately (Figures 4 and 5).

The present study has some limitations: the selection of a convenience sample from a single center makes it uncertain that the sample was representative of the profile of the entire population of Brazilian individuals with COPD. However, to mitigate the selection bias, all registered individuals in the research laboratory were randomized, creating a sequence for the recruitment of participants, which was carried out consecutively. Due to the relatively small sample, it was not feasible to investigate the metric properties of the instrument in separate subgroups stratified by disease severity, although this is not necessarily a standard procedure. In this sense, future studies with larger samples may add relevant information. Additionally, further studies are needed to verify the responsiveness of the C-PPAC to interventions in individuals with COPD, in addition to confirming whether the six-point value for minimal important difference applies to the Brazilian population.[13] Furthermore, the present study focused on the C-PPAC, the most widely used of the two PROactive instruments, although future validation of the D-PPAC would be useful to provide additional insights on PA assessment in this population. Finally, the present study focused on the validation of self-reported difficulty related to PA, since the validity of the proposed PA monitors was already carefully studied and confirmed in COPD.[8] The use of PA monitors is not dependent on language adaptation; therefore, the present study enables the use of the full PROactive tool (i.e., amount [hybrid] + difficulty [self-report]) to assess Brazilian individuals with COPD by adding up the original "amount" assessment with PA monitors to this newly validated version of the self-reported "difficulty" domain.

In conclusion, according to the results of the present study, the Brazilian Portuguese version of the C-PPAC has proven to be reproducible and valid for evaluating the experience of Brazilian individuals with COPD regarding their PA in daily life.

AUTHOR CONTRIBUTIONS

AVS and ADF: study planning and design; data collection; data analysis and interpretation; and drafting of the manuscript. RCA, LCM, CAC, and KCF: data collection; and data analysis and interpretation. FR, JC, AM, CJ, HD, FD, JGA, and TT: study planning

and design; interpretation of data; and revision and approval of the final version of the manuscript. NAH: study planning and design; data collection; data analysis and interpretation; and review and approval of the final version of the manuscript. FP: study planning and design; data collection; data analysis and interpretation; drafting of the manuscript; and revision and approval of the final version of the manuscript.

CONFLICTS OF INTEREST

None declared.

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