ISSN 1413-3555

BJPT Brazilian Journal of Physical Therapy

2016 Jan/Feb; 20(1)

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ASSOCIAÇÃO BRASILEIRA DE PESQUISA
E PÓS-GRADUAÇÃO EM FISIOTERAPIA

BJPT Brazilian Journal of Physical Therapy

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ISSN 1413-3555

BJPT Brazilian Journal of Physical Therapy

Journal affiliated with the
Associação Brasileira de Editores Científicos
ABEC Brasil

COPE COMMITTEE ON PUBLICATION ETHICS

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ASSOCIAÇÃO BRASILEIRA DE PESQUISA E PÓS-GRADUAÇÃO EM FISIOTERAPIA

Braz J Phys Ther. 2016 Jan-Feb; 20(1):1-103

The Brazilian Journal of Physical Therapy is published by the Associação Brasileira de Pesquisa e Pós-Graduação em Fisioterapia – ABRAPG-Ft (Brazilian Association for Research and Graduate Studies in Physical Therapy). Published since 1996, the Brazilian Journal of Physical Therapy adopts a peer review process. Each article is only published after it is accepted by the reviewers, who are maintained anonymous during the process.

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Mission

To publish original research articles on topics related to the areas of physical therapy and rehabilitation sciences, including clinical, basic or applied studies on the assessment, prevention, and treatment of movement disorders.

Indexed in

Cataloguing Card

Brazilian Journal of Physical Therapy / Associação Brasileira de Pesquisa e Pós-Graduação em Fisioterapia. v. 1, n. 1 (1996). – São Carlos: Editora Cubo, 1996-

v. 20, n. 1 (January/February 2016).
Bimonthly
Continued Revista Brasileira de Fisioterapia
ISSN 1413-3555

1. Physical Therapy. 2. Studies. I. Associação Brasileira de Pesquisa e Pós-Graduação em Fisioterapia.

Librarian: Dormélia Pereira Cazella (CRB 8/4334)

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Editorial

Systematic Review

Original Articles

BJPT Brazilian Journal of Physical Therapy

Research productivity grants: Physical Education, Physical Therapy, Speech Pathology, and Occupational Therapy

Brasília M. Chiari[1], Débora B. Grossi[2], Fernanda D. Fernandes[2], Leslie P. Ferreira[3], Marco T. Mello[4], Pedro C. Hallal[5], Sérgio T. Fonseca[4]

The research productivity grants (PQ) distributed annually by Conselho Nacional de Desenvolvimento Científico e Tecnológico - CNPq (National Council for Scientific and Technological Development) have generated a number of concerns in the scientific community. It is the purpose of this editorial to shed light on the criteria adopted by the Multidisciplinary Health Advisory Committee (AC) for granting PQ grants.

A key point is to emphasize that the PQ grants of this AC are distributed primarily to researchers with initial training in the areas of the committee and with institutional ties to units, departments, or graduate programs of these areas. Supervision of candidates in programs that are not accredited by Coordenação de Aperfeiçoamento de Pessoal de Ensino Superior - CAPES (Coordination for the Improvement of Higher Education Personnel) are ineligible, as are scientific works not related to the areas of the committee.

It should be noted that there are minimum entry criteria for each level, which are publicly available on the CNPq website. Regrettably, the AC continues to receive numerous applications that do not meet those criteria, including applications from undergraduate or graduate students.

A diagnosis of the situation of the AC is in order at this point. Physical Education currently has 85 existing grants, Physical Therapy and Occupational Therapy have 65 grants and Speech Pathology has 51 PQ grants. The Physical Education grants are distributed among eight states of the Federation, with 40% allocated to teachers in the state of São Paulo. The Physical Therapy and Occupational Therapy grants are allocated to researchers in seven states, with 63% of grant holders working in the state of São Paulo. In Speech Pathology, the grants are concentrated in six states, with 71% allocated to researchers with ties to institutions in São Paulo.

Of the total AC grants, 62.5% are level 2, 18.5% are level 1D, 5.5% are 1C, 8.5% are 1B, and 5.0% are 1A. These percentages are at odds with CNPq standards, which recommend 10% of grants in levels 1A and 1B and 50% at level 2. The AC has forwarded documents to the senior management at CNPq requesting a review of this scenario and an increase in level 1 grants, particularly 1A and 1C. It is also worth noting that, in the last three appraisals, there was no allocation of new grants for our AC. The matter was also discussed in a recent document forwarded to senior management at CNPq.

We will now present some information about the appraisal of PQ grants in 2015. The most complex task of the assessment was to define the indicators to be included in the calculation algorithm, with respective weights. The AC has chosen to use five indicators, with the following weights: scientific production during the study period (35%), supervision (25%), H index from the Institute of Scientic Information - ISI (20%), average number of citations per paper based on data from the Scopus database (15%), and submitted research project (5%). It should be noted that these criteria were used only for the applicants who met the minimum criteria published in the CNPq website. For example, researchers with predominant activity in other areas or who did not reach the minimum criteria of supervision and scientific production were eliminated at this first stage of the assessment.

Each of these indicators has a specific algorithm with standardized calculation, and the final score ranges from 0 to 100. For the project, they are evaluated by two ad-hoc reviewers. An "excellent" rating is equivalent to a score of 5, a "good" rating is equivalent to a score of 3, a "fair" rating is equivalent to a score of 2, and

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a "poor" rating is equivalent to a score of 1. The average of the two assessments is used in the final score. In the 2015 appraisal, only 16% of the projects were rated "excellent" by both evaluators.

Regarding the H index, the 95th percentile of the distribution is calculated and this value is equivalent to the maximum score (20). The score of each researcher is determined by using a rule-of-three calculation compared to the value of the 95th percentile. In gross terms, the average H index of applicants in 2015 was 5.2, ranging from 0 to 19. The 95th percentile corresponded to 13. The average H index of the Physical Education applicants was 5.4, compared to 6.0 in Physical Therapy and Occupational Therapy, and 3.0 in Speech Pathology.

Regarding citations, the calculation is made in exactly the manner that the H index calculation is made. In gross terms, the average number of citations per paper was 5.6, with an average of 5.2 citations/paper in Physical Education, 6.6 in Physical Therapy and Occupational Therapy, and 4.0 in Speech Pathology.

The calculation of the scientific production score is complex. Each article published in journals with impact factor greater than four equals 100 points. The weight of the publications in journals with lower impact decreases gradually, reaching 50 for publications in journals with impact factor between 0 and 0.5 and 10 for publications in journals without impact factor. Articles published in journals without peer review are disregarded. Each book is equivalent to 80 points and each book chapter is equivalent to 40 points. Bonus points are awarded for publications as first or last author, and then as a second or second-to-last author. This algorithm generates a continuous score, which is then processed in the same manner as described for the H index and citation index.

In the Guidelines, three points are awarded for completed doctoral supervisions, two points for completed postdoctoral supervisions, and one point for completed master's supervisions. Half of these values is assigned to supervisions in progress. The final score is calculated with a weight of 25 in a manner similar to that performed for the other indicators. However, this indicator has a ceiling value, equivalent to the title of 0.5 doctor and 1 master per year. All lecturers who reach these values receive the maximum score in the supervision category.

The continuous score, with a weight of 100, correlates with all indicators. The strongest correlation was with the H index ($r = 0.83$), followed by scientific production ($r = 0.73$), average number of citations ($r = 0.66$), supervisions ($r = 0.58$), and research project ($r = 0.42$). The final average score was 47 points for Physical Education applicants, 48 for Physical Therapy and Occupational Therapy applicants, and 36 for Speech Pathology applicants.

Given the availability of the grant renewals in 2015, it was possible to meet 30% of the demand for Physical Education, 31% of the demand for Physical Therapy and Occupational Therapy, and 49% of the demand for Speech Therapy. These figures demonstrate the competitiveness of the system and encourage this AC to seek the constant improvement of the evaluation criteria.

The AC then carried out a number of analyses comparing the researchers who received grants to those who did not in 2015. In Physical Education, the average H index for grant recipients was 8.3, compared to 2.0 for non-recipients. The average number of citations was 8.2 for recipients and 2.7 for non-recipients. In Physio Therapy and Occupational Therapy, the differences were smaller. The average H index was 7.6 for recipients, compared to 4.8 for non-recipients. The average numbers of citations were 11.1 and 4.1, respectively. In Speech Pathology, the average H index was 3.6 for recipients, compared to 1.8 for non-recipients. The average number of citations was 4.6 for recipients and 2.0 for non-recipients.

The AC would like to take this opportunity to raise some issues related to the area. Lattes résumés need to be written appropriately. We have detected many instances of conference abstracts included as "Full Papers Published in Journals" in the applicants' résumés. Similarly, editorials and letters to the editor are not always clearly identified as such by the applicants. There is an increasing tendency by the committee to place more emphasis on the quality of the scientific production than on mere quantity. At the 2014 appraisal, production had a weight of 50 points, however this was educed to 35 points in 2015. The H index doubled in value and the weights of the citation index and supervision history have increased.

We would also like to take this opportunity to thank the ad hoc reviewers of the AC. However, some considerations should be made. The reviews are often too succinct, preventing a more adequate understanding of the submitted projects. It should also be noted that the overall assessment of the ad-hoc review for the PQ grants should focus on the submitted project, not on the applicant's résumé, which is assessed according to

the other indicators described herein. Finally, it is essential that the reviewers assess the proposals based on the criteria established by the AC.

In conclusion, the AC promises to publish the detailed results of all appraisals conducted, within the legal restrictions imposed by CNPq and by the Federal Constitution. Applicants are welcome to contact the members of the AC via email regarding any questions about the appraisal or its general and specific scores for each indicator.

This editorial is being published simultaneously in the Brazilian Journal of Physical Therapy, Cadernos de Terapia Ocupacional da UFSCar, CoDAS, and Movimento, as well as the CNPq website. The purpose of this joint publication is to reach researchers from the different areas that make up the AC. We hope that it will generate a broad scientific discussion about constant improvement of the AC's evaluation criteria.

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systematic review

BJPT Brazilian Journal of Physical Therapy

The effects of whole body vibration in patients with type 2 diabetes: a systematic review and meta-analysis of randomized controlled trials

Caroline C. Robinson[1,2], Rodrigo P. G. Barreto[1,3], Graciele Sbruzzi[4], Rodrigo D. M. Plentz[1,3]

ABSTRACT | Background: Whole body vibration (WBV) has been used to increase physical activity levels in patients with type 2 diabetes mellitus (T2DM). **Objective:** To carry out a systematic review of the effects of WBV on the glycemic control, cardiovascular risk factors, and physical and functional capacity of patients with T2DM. **Method:** MEDLINE, LILACS, PEDro, and Cochrane Central Register of Controlled Trials were searched up to June 1st, 2015. Randomized controlled trials investigating the effects of WBV, compared to control or other intervention, on blood glucose levels, blood and physical cardiovascular risk factors, and physical and functional capacity in adult individuals with T2DM. Two independent reviewers extracted the data regarding authors, year of publication, number of participants, gender, age, WBV parameters and description of intervention, type of comparison, and mean and standard deviation of pre and post assessments. **Results:** Out of 585 potentially eligible articles, two studies (reported in four manuscripts) were considered eligible. WBV interventions provided a significant reduction of 25.7 ml/dl (95% CI:–45.3 to –6.1; I^2: 19%) in 12 hours fasting blood glucose compared with no intervention. Improvements in glycated hemoglobin, cardiovascular risk factors, and physical and functional capacity were found only at 12 weeks after WBV intervention in comparison with no intervention. **Conclusion:** WBV combined with exercise seems to improve glycemic control slightly in patients with T2DM in an exposure-dependent way. Large and well-designed trials are still needed to establish the efficacy and understand whether the effects were attributed to vibration, exercise, or a combination of both.

Keywords: type 2 diabetes mellitus; exercise; physical activity; whole body vibration; blood glucose; glycemic control.

PROSPERO: CRD42014010495.

BULLET POINTS

- WBV plus exercise slightly decrease fasting blood glucose in T2DM.
- Evidence of WBV effects on glycemic control improvement is limited in T2DM.
- Isolated effect of WBV on outcomes in T2DM still has not been investigated.

HOW TO CITE THIS ARTICLE

Robinson CC, Barreto RPG, Sbruzzi G, Plentz RDM. The effects of whole body vibration in patients with type 2 diabetes: a systematic review and meta-analysis of randomized controlled trials. Braz J Phys Ther. 2016 Jan-Feb; 20(1):4-14. http://dx.doi.org/10.1590/bjpt-rbf.2014.0133

Introduction

Physical activity plays an important role in prevention and control of type 2 diabetes mellitus (T2DM) and its related complications[1]. Both aerobic and resistance training improve insulin action and can assist with the management of blood glucose levels, lipids, blood pressure, cardiovascular risk, mortality, and quality of life; however, exercise must be undertaken regularly for continued benefits[1,2]. Nevertheless, most of people with T2DM are not active, mirroring the inertia of a lifetime of habits and motivational barriers such as lack of interest, lack of time, and depression[3]. In addition, physical disabilities and perceived discomfort when exercising are challenges to adherence to physical activity[3,4].

Physical therapists are able to help people plan an individualized exercise program in order to maintain good blood glucose and achieve optimal weight[5]. To help people with diabetes improve their quality of life, physical therapists can intervene with physical

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Received: Mar. 08, 2015 Revised: Apr. 04, 2015 Accepted: June 24, 2015

treatment techniques such as manual or manipulative treatments, electrophysical agents, and mechanical agents[5,6].

Among the alternatives aimed to increase overall physical activity, whole body vibration (WBV) has been shown to be a new effective option in healthy subjects and individuals with several health conditions[7]. It is assumed that vibration activates muscle spindles and evokes muscle contractions induced by a complex spinal and supraspinal neurophysiological mechanism known as tonic vibration reflex, allowing muscular activity enhancement even in static positions[8].

Some systematic reviews[9-14] summarized the effects of WBV in some outcomes of specific populations as follows: improvements in bone mineral density in postmenopausal women[9]; leg muscle strength[10] and balance improvement in older individuals[11]; balance, gait, and proprioception improvement in individuals with neurological conditions such as Parkinson's disease, multiple sclerosis, and stroke[12]; pain intensity decrease and physical function enhancement in individuals with knee osteoarthritis[13]; and functional exercise capacity and quality of life improvement in people with chronic obstructive pulmonary disease[14]. Furthermore, WBV requires significantly less time than conventional training and, therefore, reached a satisfactory compliance in previously inactive patients[11].

Nevertheless, the effects of WBV in patients with T2DM were infrequently reported through a case report[15] and acute[16], crossover[17], or pilot[18,19] studies. In the last years, few randomized controlled trials were performed[20,21] with conflicting results. To summarize the current evidence, we aimed carry out a systematic review of the effects of WBV intervention on the blood glucose levels, blood and physical cardiovascular risk factors, and physical and functional capacity of individuals with T2DM in comparison with a control or other intervention group.

Method

This systematic review was performed in accordance with the Cochrane Handbook for Systematic Reviews of Interventions[22] and the recommendations of the Brazilian Journal of Physical Therapy tutorial[23]. The protocol of this systematic review was prospectively registered at PROSPERO under the identification CRD42014010495 and can be assessed online[24].

Data sources and searches

Comprehensive literature searches were performed on the following electronic databases (from inception to June 1st, 2015): MEDLINE (accessed by PubMed), LILACS, Physiotherapy Evidence Database (PEDro), and Cochrane Central Register of Controlled Trials (Cochrane CENTRAL). The search terms included 'Whole body vibration', 'Diabetes' MeSH and synonyms, and a string of terms to optimize randomized controlled trial searches on PubMed[25]. In order to improve sensitivity, outcomes were not included in the search strategy. The references list of the articles identified in these searches were used as an additional source to identify other potentially eligible trials. The search strategy used on PubMed database can be fully assessed online[26].

Randomized controlled trials were considered eligible if they addressed the effects of WBV on blood glucose levels, blood and physical cardiovascular risk factors, and physical and functional capacity in adult patients with T2DM, with a minimum of four weeks intervention and at least a control group not performing WBV. We considered as the primary outcome blood glucose levels, assessed by 12-hours fasting blood glucose (12-h FBG) or glycated hemoglobin (HbA1c). The secondary outcomes were blood and physical cardiovascular risk factors (blood cholesterol and triglycerides, atherogenic index, body mass index, body composition, weight, waist circumference, waist to hip ratio, blood pressure, or heart hate) and physical and functional capacity (maximal oxygen uptake, six-minute walk test (6MWT) distance, muscle strength, or static and dynamic postural balance). The exclusion criteria were studies that included individuals with stated diabetic complications (e.g. diabetic peripheral neuropathy, retinopathy, or nephropathy) and studies with an unreliable description of WBV.

Study selection

Two independent reviewers screened the titles and abstracts of all studies identified through the search strategies. A standard screening checklist based on the eligibility criteria was used for each study. Studies that did not meet the eligibility criteria, according to titles or abstracts, were excluded. The two independent reviewers retrieved full text versions of the remaining studies for a second review. There were no disagreements between reviewers.

Data extraction and quality assessment

Two reviewers independently extracted the data from the eligible studies by using a standardized data extraction form. The following data were extracted: authors; year of publication; number of individuals analyzed; gender; age; parameters of WBV and

description of intervention; type of comparison; mean and standard deviation of pre and post assessments of each outcome available. From articles referred to the same participants, the article with the larger sample was considered and the article with the smaller sample was excluded if outcome measurements were duplicated. There were no disagreements between reviewers. HbA1c and 12-h FBG mean and standard deviation values were not available in one published study[14], but the authors informed these estimates by email.

The studies were assessed regarding methodological quality and statistical reporting using the PEDro scale[27]. When methodological quality assessment was not available on the PEDro database, two reviewers performed the ratings using the Brazilian Portuguese version of the PEDro scale[27] items. In addition, the quality of each article was evaluated based on the recommendation of the International Society of Musculoskeletal and Neuronal Interactions (ISMNI)[28] for reporting WBV intervention studies, consisting of 13 minimal reporting items about the WBV parameters and participant positioning. The instruments were rated independently by two reviewers. There were no disagreements between reviewers.

Data synthesis and analysis

After data extraction, if the outcome values could not be transformed into a common numeric scale for quantitative synthesis, a descriptive synthesis was performed. For quantitative synthesis, pooled-effect estimates were obtained by comparing the change from baseline to study end for intervention and control group. The procedures for estimation of missing data[22] were performed to obtain the standard deviation difference. Results were presented as weighted mean difference (WMD) with their respective 95% confidence intervals (CI). Meta-analysis was performed using the random effects model. The statistical heterogeneity among studies was assessed using Cochran's Q test and the inconsistency I^2 test, in which values above 25% and 50% were considered as indicatives of moderate and high heterogeneity, respectively. Sensitivity analysis was not possible given the number of available studies, therefore when I^2>25%, meta-analysis was not considered. A p value lower than 0.05 was considered statistically significant. All analyses were conducted using Review Manager, version 5.2.

Results

Description of studies

The search strategy yielded 585 articles. From these, eight[16,19-21,29-32] were considered as potentially relevant and retrieved for a detailed analysis. After full-text reading, four articles were excluded. As three articles[21,31,32] referred to the same original study (clinical trial register: ACTRN12613000021774), they were considered as a single study. From this, two studies reporting outcomes on four different articles[20,21,31,32] were included in this systematic review. Figure 1

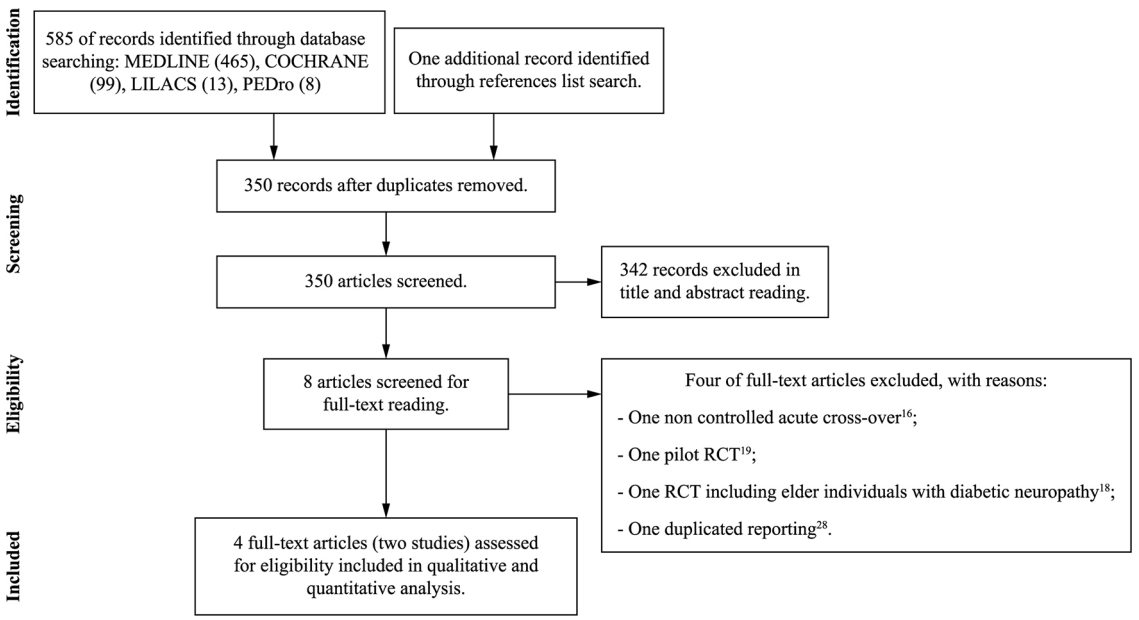

Figure 1. Flow diagram of studies included.

Table 1. Characteristics of the included studies.

Author, year	Follow up	Participants	Intervention group / Comparison group	Gender IG % /CG %	Age in years mean (sd) IG /CG	Description of intervention	Description of comparison	Outcomes	Results
Behboudi et al.[20], 2011	8-wk	T2DM diagnosis, males, < 250 mg/dl 12-h FBG, non-smoking or in regular exercise programs.	WBV + Aerobic exercise (AE): 10; / AE: 10; control (C): 10.	WBV: 100 (M) / AE: 100 (M) C:100 (M)	WBV: 49.20 (3.94); / AE: 53.10 (6.57); C: 52.30 (6.17)	30 to 60 min of increasing aerobic program plus 8 to 24 min (110° squat positioning) on a vibrator (2 mm amplitude; 30 Hz; 1 min vibration and 1 min of rest).	AE: 30 to 60 min of increasing aerobic program; C: keep routine activities.	VO_{2max} (one-mile walk test); BMI; %BFM (caliper and Sirri formula); insulin, 12-h FBG, HbA1c (cubital blood).	After 4 and 8 weeks of exercise, VO_{2max} significantly increased only in AE group. BMI, %BFM, 12h-FBG, HbA1c, and insulin did not change significantly in AE or WBV groups. 12h-FBG was significantly higher in C group than post intervention WBV and AE groups.
Del Pozo-Cruz et al.[31], 2013	12-wk	T2DM diagnosis by ADA criteria, HbA1c < 10%, not receiving physical therapy.	WBV + exercises: 19 /usual-care control group (C): 20.	WBV: 55 (M); 45 (F) / C: 50 (M); 50 (F)	WBV: 71.60 (8.54) / C: 66.80 (10.83)	Eight upper and lower limb exercises with progressive 30 to 60-s duration (30-s interval between them) on an oscillating platform (1 to 2g; 12 to 16Hz; 4mm peak to peak amplitude) in a squat position with 100° knee flexion.	C: Keep nutritional and exercise habits.	TUG; Postural sway on the Wii Balance Board (WBB): AP and ML CoP excursion with eyes open (EO) and closed (EC), feet apart (FA) and together (FT).	After 12 weeks, significant between-group differences in CoP excursions with EC (FA and FT) were found. Participants in the WBV group exhibited significantly lower CoP excursions with EC after the intervention, while participants in the control group experienced a non-significant greater excursion with EO (ML). No significant difference in the TUG values post intervention.

Wk: week; T2DM: type 2 diabetes mellitus; 12-h FBG: 12-hour fasting blood glucose; ADA: American Diabetes Association; HbA1c: glycated hemoglobin; WBV: whole body vibration; C: control group; IG: intervention group; CG: comparison group; AE: aerobic exercise; M: male; F: female; SD: standard deviation; $VO_{2max:}$ maximal oxygen uptake; BMI: body mass index; % BFM: percentage of body fat mass; TUG: timed up and go test; WBB: Wii Balance Board; AP: antero-posterior; ML: medio-lateral; CoP: center of pressure; EO: eyes open; EC: eyes closed; FA: feet apart; FT: feet together; HDL: high density lipoprotein; LDL: low density lipoprotein; 6MWT: six-minute walk test distance; 30s-STS: 30-second sit to stand.

Table 1. Continued...

Author, year	Follow up	Participants	Intervention group / Comparison group	Gender IG % /CG %	Age in years mean (sd) IG /CG	Description of intervention	Description of comparison	Outcomes	Results
Sañudo et al.[21], 2013	12-wk	The same participants of Del Pozo-Cruz et al.[31]	WBV group (WBV): 20 /usual-care control group (C): 20.	WBV: 55 (M); 45 (F) / C: 50 (M); 50 (F)	WBV: 72 (8) / C: 67 (11)	WBV: description on study Del Pozo-Cruz et al.[31]	C: Keep nutritional and exercise habits.	Body composition [waist circumference, waist-to-hip ratio, weight, height, %BFM] heart rate, and blood flow [femoral artery diameter, maximum systolic velocity, maximum diastolic velocity, time averaged mean, pulsatility index and resistance index, mean velocity, and peak blood velocities].	After a 12-wk WBV intervention, weight, waist circumference, waist-to-hip ratio, %BFM, blood flow, and maximum diastolic velocity improved significantly compared to C group. Mean velocity, maximum diastolic velocity, and peak blood velocities showed significant differences within-WBV analysis.

Wk: week; T2DM: type 2 diabetes mellitus; 12-h FBG: 12-hour fasting blood glucose; ADA: American Diabetes Association; HbA1c: glycated hemoglobin; WBV: whole body vibration; C: control group; IG: intervention group; CG: comparison group; AE: aerobic exercise; M: male; F: female; SD: standard deviation; $VO_{2max:}$ maximal oxygen uptake; BMI: body mass index; % BFM: percentage of body fat mass; TUG: timed up and go test; WBB: Wii Balance Board; AP: antero-posterior; ML: medio-lateral; CoP: center of pressure; EO: eyes open; EC: eyes closed; FA: feet apart; FT: feet together; HDL: high density lipoprotein; LDL: low density lipoprotein; 6MWT: six-minute walk test distance; 30s-STS: 30-second sit to stand.

Table 1. Continued...

Author, year	Follow up	Participants	Intervention group / Comparison group	Gender IG % /CG %	Age in years mean (sd) IG /CG	Description of intervention	Description of comparison	Outcomes	Results
Del Pozo-Cruz et al.[32], 2014	12-wk	The same participants of Del Pozo-Cruz et al.[31]	WBV group (WBV): 19 /usual-care control group (C): 20.	WBV: 55 (M); 45 (F) / C: 50 (M); 50 (F)	WBV: 71.60 (8.54) / C: 66.80 (10.83)	WBV: description on study Del Pozo-Cruz et al.[31]	C: Keep nutritional and exercise habits.	HbA1c; 12-h FBG; Cholesterol, triglycerides, atherogenic index, high density lipoprotein (HDL) and low density lipoprotein (LDL); TUG; 6MWT distance; 30s-STS test. Feasibility, adherence, compliance, and safety.	HbA1, 12-h FBG, cholesterol, triglycerides, and atherogenic index significantly decreased in WBV group compared to C group. No significant changes were detected for HDL, LDL, and LDL/HDL as well as TUG. 6MWT distance and 30-s STS test significantly improved in WBV group compared to C group. There was no report of negative effects during treatment. Drop outs were due to lack of time or interest and 76% of all participants completed the 12-wk program.

Wk: week; T2DM: type 2 diabetes mellitus; 12-h FBG: 12-hour fasting blood glucose; ADA: American Diabetes Association; HbA1c: glycated hemoglobin; WBV: whole body vibration; C: control group; IG: intervention group; CG: comparison group; AE: aerobic exercise; M: male; F: female; SD: standard deviation; $VO_{2max:}$ maximal oxygen uptake; BMI: body mass index; % BFM: percentage of body fat mass; TUG: timed up and go test; WBB: Wii Balance Board; AP: antero-posterior; ML: medio-lateral; CoP: center of pressure; EO: eyes open; EC: eyes closed; FA: feet apart; FT: feet together; HDL: high density lipoprotein; LDL: low density lipoprotein; 6MWT: six-minute walk test distance; 30s-STS: 30-second sit to stand.

shows the flow diagram of the studies and Table 1 summarizes their characteristics.

A total of 70 participants with T2DM were assessed. The year of publication of the included studies ranged from 2011 to 2014. Both the studies included individuals with T2DM diagnosis and excluded those with established diabetes complications and HbA1c>10% or fasting blood glucose >250 ml/dl. Age ranged from adult to elderly classification and only males were included by Behboudi et al.[20] while the other study[21,31,32] included both genders. All of the studies randomly allocated the individuals to a control group without additional intervention, keeping normal daily activities and medical instructions. In addition, Behboudi et al.[20] randomly allocated individuals to a third group that performed an increasing aerobic exercise (AE) program only.

Regarding WBV intervention, both studies[20,21,31,32] applied an intermittent exposure to WBV and acceleration and frequency parameters were very similar. Studies kept peak acceleration between 1 and 2 g (units of gravity; 1g=1 $m.s^{-2}$). In Behboudi et al.[20], the peak acceleration was influenced mainly by higher vibration frequencies and lower amplitude, but in Sañudo et al.[21] and Del Pozo-Cruz et al.[31,32], higher amplitude and lower vibration frequencies determined the peak acceleration.

Both the studies proposed a thrice-weekly intervention of WBV with total session duration increasing progressively from 12 (8-16) to 14 (16-24) minutes. All of the studies designed protocols in which individuals stood on the vibrating platform in a 100 to 110° squat position (considering total knee extension as 180°) and the vibratory stimulus was not isolated. Behboudi et al.[20] proposed WBV in addition to an increasing AE program (WBV+AE) with a follow-up after eight weeks. The study reported by Sañudo et al.[21] and Del Pozo-Cruz et al.[31,32] proposed a protocol of lower and upper limb exercises performed on the vibrating platform with a follow-up after 12 weeks.

No adverse effects were reported in any of the studies. Loss of follow-up occurred only in the assessment after 12 weeks[21,31,32], in which five participants from the control group dropped out because of lack of interest. Six participants from the intervention group dropped out because of lack of time (five participants) and change of home address (one participant). Participants attended more than 75% of the sessions in both trials[20,21,31,32].

Overall, the methodological quality assessed by the PEDro scale was low to moderate (Table 2). Table 3 shows the quality of each article based on the recommendation of the ISMNI[28] for reporting WBV intervention studies.

Table 2. Methodological quality assessment by the Physiotherapy Evidence Database (PEDro) Scale.

	PEDro Scale Items											
Author	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**Score**
Behboudi et al.[20]	Yes	Yes	No	Yes	No	No	No	Yes	No	Yes	No	4/10*
Del Pozo-Cruz et al.[31]	Yes	Yes	No	Yes	No	No	Yes	No	No	Yes	Yes	5/10
Sañudo et al.[21]	No	Yes	No	Yes	No	No	Yes	No	No	Yes	Yes	5/10
Del Pozo-Cruz et al.[32]	Yes	Yes	No	Yes	No	No	No	No	No	Yes	Yes	4/10

1: Eligibility criteria; 2: Random allocation; 3: Concealed allocation; 4: Baseline comparability; 5: Blind subjects; 6: Blind therapists; 7: blind assessors; 8: Adequate follow up; 9: "Intention-to-treat" analysis; 10: Between-group comparisons; 11: Point estimates and variability. Eligibility criteria item does not contribute to total score. *The methodological quality assessment was performed by the reviewers.

Table 3. Assessment of minimum items reported for whole body vibration interventions.

	International Society of Musculoskeletal and Neuronal Interactions Items												
Author	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**
Behboudi et al.[20]	Yes	No	Yes	Unclear	No	No	No	Yes	No	No	No	Yes	Unclear
Del Pozo-Cruz et al.[31]	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes
Sañudo et al.[21]	Yes	No	Yes	No	No	No	No	Yes	No	No	No	Yes	Yes
Del Pozo-Cruz et al.[32]	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No	No	Yes	Yes

1: Brand name of vibration platform; 2: Type of vibration; 3: Vibration frequency; 4: Vibration amplitude; 5: Peak acceleration; 6: Accuracy of vibration parameter; 7: Evaluation of skidding of the feet; 8: Changes of vibration parameters; 9: Rationale for choosing vibration parameters; 10: Support devices during vibration exposure; 11: Type of footwear; 12: Body position; 13: Description of exercise.

Blood glucose levels

For 12-h FBG, meta-analysis was performed and included data of two trials[20,32] with a total of 59 patients (29 of which were on WBV). The comparison groups did not perform any intervention. There was an improvement in 12-h FBG by reduction in 25.7 ml/dl (95% CI: –45.3 to –6.1; I^2: 19%), favoring WBV intervention (Figure 2A). There was no additional effect (p=0.09) of WBV to an eight-week increasing AE program regarding 12-h FBG, but both the groups (WBV+AE and AE only) presented significantly lower 12-h FBG levels (p=0.02) than the control group[20].

Regarding HbA1c, a meta-analysis was not considered given an I^2 of 80% between studies. After the 12-week program of upper and lower limb exercises performed on the vibrating platform, participants in the intervention group exhibited significantly lower levels of HbA1c (p=0.002) at the time of follow-up when compared to the control group, with a mean difference of −0.55% (95% CI: −0.15 to −0.76)[32]. The eight-week WBV+AE program was not sufficient to promote a significant difference in HbA1c levels compared to the control group. Furthermore, there was no additional effect of WBV on the eight-week AE program as no significant difference in HbA1c levels was found between WBV+AE and AE only. Both intervention groups did not differ significantly from controls.

Blood and physical cardiovascular risk factors

Regarding secondary outcomes, a meta-analysis was only possible for Body Mass Index (BMI). Data of two studies[20,31] with a total of 59 patients (29 of which were on WBV) were included and comparison groups did not perform any intervention. A non-significant decrease of 0.67 $Kg.cm^{-2}$ (95% CI:–2.21 to 0.87; I^2: 8%) in BMI was observed (Figure 2B).

After the 12-week program of upper and lower exercises performed on the vibrating platform, a significant decrease (p<0.050) was found in cholesterol, triglycerides, atherogenic index[32], weight, waist circumference, waist-to-hip ratio, and body fat percentage[21] compared to the control group. However, no statistically significant changes were detected for high-density lipoprotein (LDL), low-density lipoprotein (LDL), or LDL/HDL[32]. After the eight-week WBV+AE program, no significant differences in body fat percentage were found compared to the control group or compared to the AE group[20].

Physical and functional capacity

Improvements (p<0.05) were found in the 6MWT distance and muscle strength assessed by the 30-second Sit-to-Stand (30s-STS) test after the 12-week WBV program with upper and lower limb exercises compared with the control group. Regarding static balance, the same comparison showed a significant decrease in center of pressure excursions with eyes

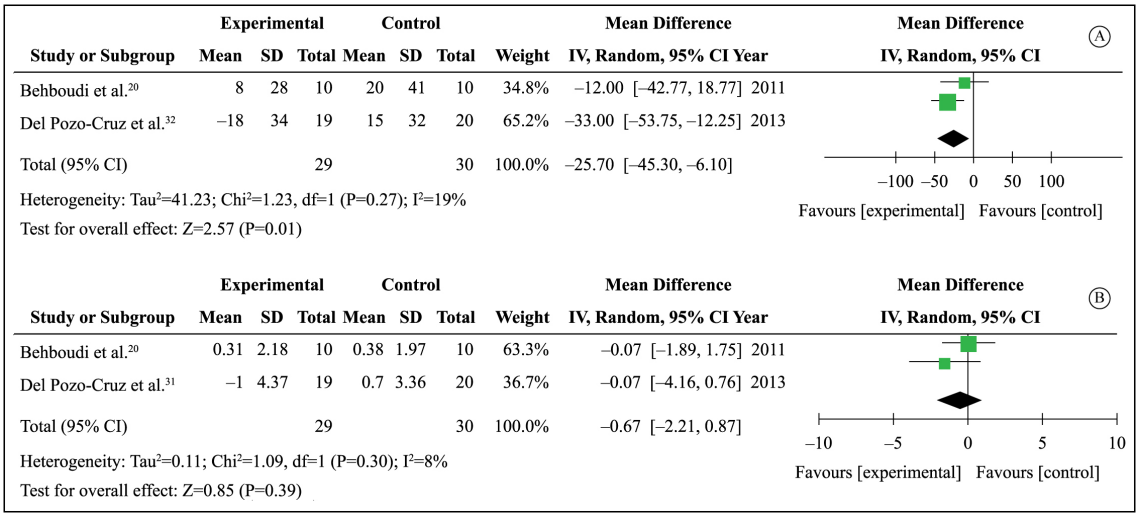

Figure 2. (A) The mean difference and 95% confidence interval (CI) of 12-hour fasting blood glucose in ml/dl for treatment with WBV (experimental) versus comparator (control); (B) Mean difference and 95% confidence interval (CI) of body mass index in Kg/cm^2 for treatment with WBV (experimental) versus comparator (control).

closed (feet apart and together), but TUG time did not improve significantly[32]. Although maximal oxygen uptake increased significantly (p=0.01) after the eight-week WBV+AE and AE only programs, WBV had no additional effect on AE (p=0.3)[20].

Discussion

Summary of evidence

It seems that the 12-week progressive intervention with WBV and exercise was sufficient for a statistically significant, but slight improvement in the 12-h FBG and HbA1c of individuals with T2DM, in comparison with no intervention. Furthermore, the eight-week intervention improved 12-h FBG, but did not improve HbA1c.

Because erythrocytes are freely permeable to glucose, the level of HbA1c in a blood sample provides a glycemic history of the previous 120 days, the average erythrocyte lifespan[33]. It is possible that a period of eight weeks was not enough to reach modifications in blood glucose profile, as no significant alterations were found in the WBV+AE or AE only programs.

The effect size for HbA1c improvement discovered after the 12-week progressive intervention with WBV and exercise was close to the one found after aerobic or resistance training reported previously in two meta-analyses[34,35]. Although the vibratory stimulation was not isolated from exercises in the proposed interventions, session duration was considerably lower in the WBV studies (8 to 24 minutes) than in the aerobic or resistance training studies (40 to 75 minutes)[34,35]. This fact corroborates other studies that found similar results in WBV application compared conventional intervention, but in a shorter time of exposure[36-38].

The meta-analysis for BMI found no significant decrease after the WBV interventions. According to Cochrane[39], although WBV has gained popularity as a modality for weight loss, it does not have the ability to generate large energy expenditure to substitute conventional aerobic exercise. However, it had positive effects on blood flow[32,40] that could indirectly improve associated diseases such as hypertension. In fact, this could be seen in some of the blood and physical markers of cardiovascular risk (cholesterol, triglycerides, atherogenic index, body weight, waist circumference, and waist-to-hip ratio) that improved after 12 weeks of progressive intervention with WBV combined with exercises[32].

It seems that an eight-week WBV intervention was not enough to reach significant improvements in the aerobic capacity[20] of patients with T2DM. In contrast, the 12-week progressive intervention with WBV and exercise improved aerobic capacity measured by the 6MWT distance, with similar values to those found in a multi-center study on fitness among healthy elderly subjects[41]. The same improvement was found in lower limb strength measured through the 30s-STS. It is possible that the time of exposure in patients with T2DM must be greater than that required for the non-diabetic population. For example, a previous meta-analysis found a significant beneficial effect of WBV on lower limb strength of elderly subjects with a treatment effect comparable to other forms of active exercises (e.g. resistance training) within six to 10 weeks[10].

Limitations and conclusions

This is the first systematic review to synthesize the effects of these outcomes in individuals with T2DM after WBV interventions. Analysis from data extraction of this systematic review was limited by the small number of available trials and duplicated articles. Furthermore, results from this systematic review must be interpreted with caution as most of the trials have some methodological limitations such as lack of concealed allocation and intention-to-treat analysis. Regarding the minimal items required for WBV intervention reproducibility, clear reporting is still necessary of the type of vibration, whether amplitude displacement was peak-to-peak, the peak acceleration, whether and how accuracy of vibration parameter were assessed, whether and how skidding of the feet were avoided, what was the rationale for choosing specific vibration parameters, whether and what support devices were used during vibration exposure and whether the type of footwear was controlled. Failing to report those items impairs protocol reproducibility as well as protocol comparison[28].

Despite the slight beneficial effect of WBV intervention on glycemic control, a paramount outcome for T2DM management, caution is required in extrapolating this result to practice. First, a significant reduction in glycemic values was found in comparison with no intervention and WBV was not investigated alone, but in addition to exercise. Similar caution must be taken regarding blood markers and functional capacity. Even if WBV parameters were very similar between studies, the combined exercises differed between studies and follow-up was also distinct, which may have influenced pooled effects and heterogeneity. It is necessary to highlight that these implications should

only be considered for patients with T2DM without reported complications or contraindications for WBV exposure as well as glycemic profile <10% for HbA1C or <250 mg/dl for 12-h FBG. Furthermore, it seems that effectiveness of WBV is exposure-related as the 12-week intervention presented the better results.

Similarly to other studies that used WBV as an intervention in sedentary or elderly individuals[10], there was good adherence and compliance in the 8-week and 12-week follow-up assessments. There was similar loss of follow-up in the intervention and control groups in the 12-week WBV program related to personal reasons[21,31,32]. Adverse effects, such as hypoglycemia, discomfort, and musculoskeletal injuries, are highly reported in studies performing exercise interventions[34], however they were not reported in the studies included in this systematic review[20,21,31,32].

WBV performed close to the parameters presented in the primary studies and combined with low-level exercises seems to be a safe, feasible, and less time-consuming intervention to help improve the glycemic control, cardiovascular risk markers, and functional capacity of individuals with T2DM in an exposure-dependent way compared to no intervention. However, given the methodological weaknesses of the primary studies and the heterogeneous protocols, confidence is limited on the decreasing effect of WBV on 12-h FBG. Further well-designed trials are still required to strengthen the current evidence and clarify whether the effect should be attributed to vibration, exercise, or the combination of both.

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original article

BJPT Brazilian Journal of Physical Therapy

Health professionals identify components of the International Classification of Functioning, Disability and Health (ICF) in questionnaires for the upper limb

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ABSTRACT | Background: Several Brazilian studies have addressed the International Classification of Functioning, Disability and Health (ICF), but few have analyzed the knowledge of the health professionals with regards to the ICF. **Objective**: To verify whether the classification of the items in the Brazilian-Portuguese versions of The Shoulder Pain and Disability Index (SPADI) and The Disabilities Arm, Shoulder and Hand (DASH) questionnaires, obtained from health professionals who worked with patients having upper limb injuries, could be related to ICF components as defined by others studies. **Method**: There were 4 participants for the group "professionals with high familiarity of the ICF (PHF)" and 19 for the group of "professionals with some or no familiarity of the ICF (PSNF)". The participants judged whether the items on the two questionnaires belonged to the ICF body function, body structure or activity-participation component, and marked a confidence level for each trial using a numerical scale ranging from zero to 10. The items were classified by the discriminant content validity method using the Student's *t*-test and the Hochberg correction. The ratings were compared to the literature by the percentage of agreement and Kappa coefficient. **Results**: The percentage of agreement of the rating from the PSNF and the PHF groups with the literature was equal to or greater than 77%. For the DASH, the agreement of the PSNF and PHF groups with the literature were, respectively, moderate (Kappa=0.46 to 0.48) and substantial (Kappa=0.62 to 0.70). **Conclusions**: Health professionals were able to correlate the three components of the ICF for most items on the 2 questionnaires, demonstrating some ease of understanding the ICF components. However, the relation of concept of pain with body function component is not clear for professional and deserves a more attentive approach.

Keywords: questionnaires; shoulder; international classification of functioning; disability and health; rehabilitation; health care.

BULLET POINTS

- The study examined whether health professionals recognize the 3 components of the ICF in 2 shoulder questionnaires – the DASH & the SPADI.
- Professionals are able to correlate the items of the 2 shoulder questionnaires with the ICF.
- Understanding the ICF is relatively easy, but the relation of pain with body function component is not clear.

HOW TO CITE THIS ARTICLE

Philbois SV, Martins J, Souza CS, Sampaio RF, Oliveira AS. Health professionals identify components of the International Classification of Functioning, Disability and Health (ICF) in questionnaires for the upper limb. Braz J Phys Ther. 2016 Jan-Feb; 20(1):15-25. http://dx.doi.org/10.1590/bjpt-rbf.2014.0135

Introduction

The International Classification of Functioning, Disability and Health (ICF) represents a perspective on incapacity and disability based on the biopsychosocial model of health care[1]. The ICF describes functionality and individual disability in relation to body function component (F), body structure (S) and activity and participation (AP), which are influenced by environmental and personal contextual factors[1].

In Brazil, studies on the ICF involved research about its conceptualization[2,3], reviews of its application[4,5] and the *Core Sets*[6], epidemiological studies[7,8] and use public policies[9] and training[10-12], with emphasis on the areas of neurology and orthopedics[4]. Some of these studies have sought to establish the relationship between different questionnaires and the components of the ICF[13-15] or its *Core Sets*[16,17]. Others either

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Received: Oct. 10, 2014 Revised: Mar. 12, 2015 Accepted: Aug. 20, 2015

evaluated the functional profile of neurological[18-20], oncological and geriatric[21,22] patients through the ICF or validated questionnaires for the classification of the components, or studied the effects of interventions on patients[23] or validated *Core Sets* for neurological[24], rheumatological[25] and orthpedic[26,27] patients.

It is noteworthy that among the research developed using the ICF in Brazil; only one study evaluated the understanding of the ICF in the educational context of graduate students[11]. Silva et al.[11] concluded that physical therapy students in the orthopedics area were unfamiliar with the ICF components because their assessments were based on the biomedical model, centered on the pathology and on the body structures and functions. This unfamiliarity may be a common reality to other health professionals as well.

Ruaro et al.[4] argued that expanding the use of the ICF could be achieved through the training of academics and professionals. However, studies investigating health professionals who had not received previous training, which aimed to analyze the ability of a professional to recognize the ICF components in assessment tools commonly used in their practice, are lacking. This assertion justifies the present study which the authors hoped could contribute to the implementation of the ICF by revealing the easiness and difficulties in identifying the ICF components: important aspects that should be considered in the training of health professionals.

Besides, there are some difficulties when applying the ICF in clinical settings[5] since it is dependent on developing evaluations that include the components of the ICF or on the availability of validated questionnaires for ICF[28-32]. Thus, one standardized way of assessing the applicability of the ICF components by various health professionals would be to examine how these professionals relate the components of the ICF classification with outcome measure questionnaires commonly used in the clinic. This process of connecting outcome measures to the ICF classification has been called *linking*[28-32].

Considering the area of orthopedic rehabilitation, some questionnaires, commonly used in clinic situations, have been linked to the ICF[30-32]. Among these are The Shoulder Pain and Disability Index (SPADI)[33], which evaluates shoulder pain and disability, and The Disabilities of the Arm, Shoulder and Hand (DASH)[34], which assesses symptoms and physical, psychological and social functions of individuals with upper limb dysfunction.

Therefore, the objective of this study was to determine whether the classification of the questionnaires SPADI, and DASH to 3 components of the ICF, when completed by health professionals who do research or treat and rehabilitate upper limb injuries, and have different levels of knowledge of the ICF, agree with the classification of the SPADI as presented by Roe et al.[30] and the DASH as presented by Dixon et al.[31] and Drummond et al.[32].

The study hypothesis was that health professionals having less familiarity with the ICF would have greater difficulty correlating the items in 2 shoulder questionnaires with the ICF classifications than those health professionals who have greater familiarity with the ICF components, when comparing to literature. It was hoped the results of this study might contribute to a better understanding of how the components of the ICF classification are recognized by health professionals with different levels of knowledge of the ICF and highlight concepts from the 2 shoulder questionnaires or ICF components that require more attention.

Method

Participants

Twenty-nine participants were recruited for this cross-sectional, observational study. The participants were contacted by telephone or directly, at public hospitals and private clinics of a city of state of São Paulo or public institutions of higher education from the southern region of Brazil.

The participants were divided into two groups according to their degree of familiarity with the ICF. Four participants composed the group of "professionals with high familiarity (PHF)" with the ICF, and 19 participants composed the group of "professionals with some or no familiarity (PSNF)" with the ICF.

The PHF group had a sample size (4) and profile of participants similar to studies investigating the content validity of several questionnaires, which had sample sizes varying from two to 20[35,36] and, about ICF, had participants with good knowledge of its components and taxonomies[30,32,37]. The authors considered the relatively small sample size of the PHF group to be acceptable, due the limited number of professionals in Brazil with this profile, and resulted in the asymmetry between the groups.

The inclusion criteria for the PHF group were being a clinician or researcher involved in the treatment or research of musculoskeletal or orthopedic

rehabilitation of the upper limb and were working or had read publications about the ICF in scientific journals, which was considered sufficient proof of their in-depth knowledge of the ICF.

For the PSNF group, inclusion criteria were "being a clinician or researcher involved in the treatment or research of musculoskeletal or orthopedic rehabilitation of the upper limb and who had no specific knowledge of the ICF. This means participants were not conducting research involving the ICF and had a level of knowledge equal to or less than five points on the numerical rating scale, where 10 points indicated that the participant fully understood the ICF and 0 indicated no knowledge of the ICF. All participants who agreed to participate in the study signed an Informed Consent form approved by the Ethics Committee of the Clinical University Hospital of the Faculdade de Medicina de Ribeirão Preto, Universidade de São Paulo (USP), Ribeirão Preto, SP, Brazil (Protocol n° 8857/2013).

Instruments

The SPADI and DASH questionnaires, are often used for functional assessment of shoulder dysfunctions, and are among the 10 questionnaires most cited in the literature[30]. Both questionnaires, including their Brazilian versions, had their psychometric properties tested[38-42].

The SPADI-Brazil[39] questionnaire has 13 items, five of which assess pain, and eight of which assess disability. Items were scored on a numerical rating scale of 10 points, with zero indicating no pain/no difficulty and 10 indicating severe pain/could not perform the activity. The scores ranged from 0 to 100 for each domain and the higher the score the more severe was the injury to the patient's shoulder.

The Brazilian version of the DASH[40] evaluates various dysfunctions of the upper limb, having 30 items, 21 of which evaluates physical function, six assess symptoms, two evaluates social functions and one evaluates psychological functions. The items were scored on a Likert scale ranging from zero to five points and the total score ranged from 0 to 100, with the maximum score indicating a lower quality of life.

The material available to the participants contained instructions and items from the SPADI and DASH questionnaires distributed randomly. Each item had three options defined by the ICF components: body function, body structure and activity-participation. For each item, the participants provided a Yes/No answer and gave a confidence percentage rating for each judgement on a numerical rating scale ranging from 0% to 100% in increments of 10%[31]. The activity-participation component was also tested to discriminate whether the questionnaire item referred to an activity itself or to participation in the activity.

Definitions of the three components of the ICF[1] were included at the top of each page, and at the end of the material, questions about the descriptive data of the sample were presented. The material omitted the identification of the participants, but posed the question "What is your level of familiarity with the ICF?" to distinguish the PHF and PSNF groups. The response options were "High familiarity" or "Some or no familiarity". The participants also answered questions about their level of knowledge of the ICF through a numerical rating scale ranging from 0 to 10, where zero indicated that the participant was unfamiliar with the ICF and 10 indicated a full understanding of the ICF.

Procedures

Participants interested in participating in the study received an email with information related to the study and with the informed consent form. After returning the signed informed consent form, each participant received the materials by post or email and had one week to return the material. To ensure the anonymity of the participants, the material returned by mail or electronically was received by a third party not linked to the research and delivered to the researchers without identification.

Participants were asked to make an individual judgment on the items without discussing their answers with any other individual, whether those other individuals were involved in the study or not. Thus, participants had to make their judgment based only on prior knowledge of the classification or on the brief definitions presented by the material.

Each item was rated three times. First, participants had to check if the item was related to the ICF component or not, and then mark the confidence level for the judgment of each response using the numerical rating scale ranging from 0-100%[31]. Thus, 43 items were rated from the 2 shoulder questionnaires, totaling 129 judgments. Finally, each participant had to respond to questions descriptively and answer questions regarding their level of knowledge of the classification.

Statistical analysis

The descriptive analyses were presented as mean and standard deviation for the quantitative data and relative frequency for the qualitative data. The classifications of the items, according to the ICF components chosen

by the participants, were analyzed with discriminant content validity and the Student's *t*-test[31,37]. In addition to establishing the content validity of the items of the questionnaire, the method also established whether the three theoretical components of the ICF could be measured discriminately from one another[31,37]. Thus, the discriminative power of the test was the result of the ratings assigned by the participants, relating each item of the two questionnaires to the components of the ICF[31,37].

The judgments of each item were scored as 1 when the professional judged that the item was related to the ICF component (marking YES) and -1 when unrelated to the ICF component (marking NO). This value was then multiplied by the level of confidence of each rating, expressed as an absolute percentage, and varied from 0 to 1. Thus, the final value obtained for each judgment ranged from –1 to +1. Data that were lost or unmarked were scored as zero[31].

The classification of the items in one of the seven possible categories – body function (F), body structure (S), activity and participation (AP), body function and body structure (F.S), body function and activity and participation (F.AP), body structure and activity and participation (S.AP) and all of them (F.S.AP) was conducted using the one sample Student's *t*-test. The item was classified as related to the ICF component when the judgment given was significantly greater than zero. The Hochberg[43] correction for multiple comparisons was performed and all procedures were conducted using the software R Core Team[44].

The classification of items from the SPADI questionnaire was compared to the study by Roe et al.[30], who associated the items to body function or activity-participation components of the ICF. The classification of the items from the DASH was compared to the study by Dixon et al.[31] and Drummond et al.[32] which classified each item specifically. The domains of physical and social function of the DASH should relate to the activity-participation component. The domain of symptoms for function and/or body structure components and item 30 of the psychological function were not considered to represent a personal factor and thus, was not classified in the study[31,32].

The agreement between the classification obtained by the PHF and PSNF groups with the literature[30-32] were conducted with the simple percentage of agreement and the Kappa coefficient with a 95% confidence interval[45]. The agreement by the Kappa coefficient was classified as follows: poor if < 0; weak if between 0.01 and 0.20; light if between 0.21 to 0.40; moderate if between 0.41 to 0.60; substantial if between 0.61 and 0.80; almost perfect if between 0.81 to 0.99 and perfect if 1[45]. In addition, if the groups could discriminate in activity or participation, the items judged as an activity-participation component were also described as performed by Dixon et al.[31].

Results

The study contacted 29 health professionals, but one refused to participate because the subject was worry about the lack of blinding. The material was sent to 28 participants and 23 returned the material. It wasn't possible to know why the subjects didn't return the material, because the researchers were blinded about assessments. Thus, data of 23 participants were analyzed and the descriptive data is presented in Table 1.

The power of the test was analyzed with the Student's *t*-test in relation to the component with which the item was correlated, and for the undefined items, the three components were considered for the power analysis. For the PSNF group, the power values were above 0.80 (beta=0.20) on 76.92% of the items of the SPADI and on 83.33% of the items of the DASH, considering an alpha of 0.05. The power of the test was not conducted for the PHF group because the sample size was small and the items judged did not present a standard deviation. However, the sample size differences between groups did not affect the analyses that were conducted only within group.

The percentage of agreement values was relatively high (above 77%), but lower for the PSNF group, mainly for the SPADI (Table 2). In relation to the Kappa values, the classifications of the PSNF group for the items of the DASH presented a moderate agreement with the literature, while the PHF group had a substantial agreement. The Kappa values were not obtained for the SPADI because the contingency table was developed only with two categories and one of them included only zero values.

Table 3 shows that the PHF group diverged from the classification from the literature only in relation to item 11 in the pain domain: "When reaching for something on a high shelf with the affected arm?" The PSNF group could not relate the components of the ICF with items 9 ("How intense was the worst pain you had last week?"), 10 ("When did you lay on top of the affected arm?"), and 12 ("When you tried to touch the back of your neck with the affected arm?") of the pain domain.

Table 1. Descriptive data of the participants in the group of "professionals with high familiarity (PHF)" (n=4), and the group of "professionals with some or no familiarity (PSNF)" (n=19) with the International Classification of Functioning, Disability and Health (ICF).

Characteristics	Values
Time after graduation	
Mean (year)±SD	11.9±9.9
Undergraduate program (%)	
Physical Therapy/Occupational Therapy	17 (73.9%) / 3 (13.0%)
Medicine – Orthopedics and Physiatrist	3 (13.0%)
Profession (%)	
Professor	9 (39.1%)
Graduate student of physical therapy	2 (8.7%)
Physical therapist/Occupational therapist	9 (39.1%) / 1 (4.3%)
Physician	2 (8.7%)
How long do you work treating the upper limb?	
Mean (year)±DP	8.5±7.6
Do you use questionnaires regularly? (%)	
Yes / No	18 (78.3%) / 5 (21.7%)
Do you know or had heard about the ICF? (%)	
Yes / No	21 (90.9%) / 2 (9.1%)
How did you know or hear about the ICF? (%)	
Courses/Lecture/Site	10 (43.5%)
Post-graduation/Academic community	10 (43.5%)
Work with people who use the ICF	5 (21.7%)
Do you consider the ICF important? (%)	
Yes / Don't know the ICF	19 (82.6%) / 4 (17.4%)
Familiarity level to the ICF (%)	
Professionals with high familiarity to ICF (PHF)	4 (17.4%)
Professionals with some or no familiarity to ICF (PSNF)	19 (82.6%)
- Do not use ICF at work	14 (73.7%)
- Use ICF at work	3 (15.8%)
- No answer	2 (10.5%)
How do you know the ICF on a scale of 0 to 10?	Mean±SD
Professionals with high familiarity to ICF (PHF)	9.25±1.8
Professionals with some or no familiarity to ICF (PSNF)	3.2±2.2

SD: standard deviation.

Table 2. Proportions of agreement and Kappa coefficient for the comparisons of the group of "professionals with high familiarity (PHF)" (n=4), and the group of "professionals with some or no familiarity (PSNF)" (n=19) with the literature.

Literature	Proportions of Agreement (%)		Kappa (95% CI)	
	PSNF	PHF	PSNF	PHF
Roe et al.[30]	77%	92%	NC	NC
Drummond et al.[32]	80%	83%	0.46 (0.29 to 0.64)	0.62 (0.39 to 0.85)
Dixon et al.[31]	80%	87%	0.48 (0.24 to 0.72)	0.70 (0.45 to 0.96)

CI: 95% confidence interval; NC: value not calculated, because contingency table included a substantial proportion of zeros.

In relation to the DASH (Table 4), the PHF group did not associate four items of distinct domains with the components of the ICF, including items 21 ("Sexual Activities"), 22 ("Over the past week, at which point did your problem with the arm, shoulder or hand affected your normal activities with family, friends, neighbors or colleagues?"), 28 ("Difficulty in moving arm, shoulder or hand"), and 29 ("Over the past week, how difficult was it to sleep because of the pain in your arm, shoulder or hand?"). The PSNF group did not associate three items of the domain symptoms: items 26 ("Discomfort in the skin (pins and needles) on your arm, shoulder or hand"), 27 ("Weakness in the arm, shoulder or hand") and 28(see above).

Table 5 illustrates the judgments of the groups and presents the classifications of Dixon et al.[31]. Both PHF

Table 3. Judgments of the group "professionals with high familiarity (PHF)", and the group of "professionals with some or no familiarity (PSNF)" for the items of The Shoulder Pain and Disability Index (SPADI-Brazil) according to International Classification of Functioning, Disability and Health (ICF) components of body function (F), body structure (S) and activity and participation (AP), and the comparisons with the literature.

	SPADI Items	PSNF			PHF			Classification of SPADI ᵀ		
		F	S	AP	F	S	AP	PSNF	PHF	Literature
		Mean	Mean	Mean	Mean	Mean	Mean			Roe et al.[30]
Items of Function	Item 1	–0.09	0.09	0.85*	–1.00*	–1.00*	1.00*	AP	AP	**Body Function** - *Sensorial and pain function (b2)* **Activity and Participation** - *Mobility (d4) and self-care (d5)*
	Item 2	0.15	0.01	0.68*	–0.98*	–0.50	1.00*	AP	AP	
	Item 3	0.05	–0.21	0.83*	–1.00*	–1.00*	1.00*	AP	AP	
	Item 4	–0.06	–0.03	0.88*	–100*	–1.00*	1.00*	AP	AP	
	Item 5	–0.21	–0.09	0.79*	–1.00*	–1.00*	1.00*	AP	AP	
	Item 6	–0.13	0.31	0.68*	–1.00*	–1.00*	1.00*	AP	AP	
	Item 7	–0.05	0.28	0.81*	–1.00*	–1.00*	1.00*	AP	AP	
	Item 8	0.05	0.21	0.79*	–1.00*	–1.00*	1.00*	AP	AP	
Items of Pain	Item 9	0.21	–0.2	–0.39	1.00*	–1.00*	–1.00*	NO	F	
	Item 10	0.11	0.14	0.03	1.00*	–1.00*	–0.50	NO	F	
	Item 11	0.29	0.18	0.60*	0.50	–0.98*	–0.50	AP	S	
	Item 12	0.07	0.15	0.07	1.00*	–1.00*	–0.50	NO	F	
	Item 13	0.17	0.32	0.43¥	1.00*	–1.00*	–0.50	AP	F	

NO: no classification. ᵀ indicates positive and negative values, respectively, associated or not associated with the ICF component. *p<0.01; ¥ p <0.05.

and PSNF groups related more frequently the items of the domain physical function of the DASH (items 1 to 16) to the component activity. The remaining items of the physical and social function domains (17 to 23), classified by the literature as activity-participation or participation, presented a frequency of judgment favoring participation, or a balance between activity and participation. The PSNF group presented a more random judgment pattern between activity and participation compared to the PHF group, which had a more consistent judgment.

Discussion

In agreement with the literature, the data showed that health professionals who research or treat upper limb injuries acknowledge the components of the ICF for most of the items of the two shoulder questionnaires studied, independent of their level of familiarity with the ICF. However, the classification of the DASH questionnaire obtained from the PSNF participants agreed moderately with the literature, while the PHF group agreed substantially, supporting our initial hypothesis.

The classifications for the SPADI were compared with the study by Roe et al[30]. They considered body function and activity-participation the correct choices for the classifications. Although the PHF and PSNF groups classified most of the items of the SPADI according to the literature, the content discriminant validity method showed that the PSNF group failed to define any of the components for the three items of pain, while the PHF group missed only one item. It was not possible to confirm that the definition of the ICF[1] for pain was insufficient for a proper classification of the items for pain since the Brazilian version of the SPADI has not been tested for content validity. However, one could consider such a possibility since the SPADI-Brazil has satisfactory construct validity, with a high (–0.78) to moderate (0.68) correlation of its pain domain with the pain domain from two other functional questionnaires - Penn Shoulder Score (PSS) and Short-Form 36 (SF-36)[46], respectively. Besides, all the test measurement properties of the SPADI-Brazil were similar to the original version in English, therefore it is likely to occur with the content validity, which showed in the original version that the SPADI has no validity problems for the pain items[47,48].

It is important to highlight the need for some specific training instead of only presenting the definitions of the components of the ICF. Therefore, health professionals could recognize the components of the pain items of the SPADI, since the questionnaire evaluates pain of the patient in the context of activities of daily living.

Table 4. Judgments of the group of "professionals with high familiarity (PHF)", and the group of "professionals with some or no familiarity (PSNF)" for the items of the Brazilian version of The Disabilities Arm, Shoulder and Hand (DASH) according to International Classification of Functioning, Disability and Health (ICF) components of body function (F), body structure (S) and activity and participation (AP), and comparisons with the literature.

	DASH Items	PSNF			PHF			Classification of DASH ᵀ			
		F	S	AP	F	S	AP	PSNF	PHF	Drummond et al.[32]	Dixon et al.[31]
Physical Function	Item 1	–0.29	–0.08	0.83*	–1.00*	–1.00*	1.00*	AP	AP	AP	A
	Item 2	–0.16	–0.11	0.83*	–0.63	–1.00*	0.95*	AP	AP	AP	A
	Item 3	0.14	–0.10	0.79*	–1.00*	–1.00*	–1.00*	AP	AP	AP	A
	Item 4	0.03	–0.03	0.87*	–1.00*	–1.00*	–1.00*	AP	AP	AP	A
	Item 5	–0.18	0.02	0.77*	–1.00*	–1.00*	–1.00*	AP	AP	AP	A
	Item 6	–0.03	–0.17	0.79*	–1.00*	–1.00*	–1.00*	AP	AP	AP	A
	Item 7	–0.04	–0.18	0.76*	–1.00*	–1.00*	–1.00*	AP	AP	AP	A
	Item 8	–0.21	–0.17	0.83*	–1.00*	–1.00*	–1.00*	AP	AP	AP	A
	Item 9	–0.09	–0.16	0.82*	–1.00*	–1.00*	–1.00*	AP	AP	AP	A
	Item 10	–0.24	–0.12	0.82*	–1.00*	–1.00*	–1.00*	AP	AP	AP	NO
	Item 11	–0.27	0.06	0.76*	–0.98	–1.00*	–1.00*	AP	AP	AP	A
	Item 12	–0.15	–0.04	0.80*	–1.00*	–1.00*	–1.00*	AP	AP	AP	A
	Item 13	–0.19	0.06	0.65*	–1.00*	–1.00*	–1.00*	AP	AP	AP	A
	Item 14	0.02	–0.08	0.76*	–1.00*	–1.00*	–1.00*	AP	AP	AP	A
	Item 15	–0.24	–0.07	0.86*	–1.00*	–1.00*	–1.00*	AP	AP	AP	A
	Item 16	–0.26	–0.01	0.88*	–1.00*	–1.00*	–1.00*	AP	AP	AP	A
	Item 17	–0.05	–0.02	0.84*	–1.00*	–1.00*	–1.00*	AP	AP	AP	AP
	Item 18	0.04	0.29	0.87*	–0.50	–1.00*	–1.00*	AP	AP	F and AP	AP
	Item 19	0.07	0.09	0.85*	–1.00*	–1.00*	–1.00*	AP	AP	F and AP	AP
	Item 20	0.05	–0.20	0.60*	–0.75	–1.00*	–1.00*	AP	AP	AP	AP
	Item 21	0.03	–0.22	0.80*	0.03	–1.00*	–0.05	AP	NO	AP	AP
Social Function	Item 22	0.30	0.05	0.55£	–1.00*	–0.50	0.50	AP	NO	AP	P
	Item 23	0.16	0.05	0.66*	–1.00*	–0.50	1.00*	AP	AP	AP	AP
Symptoms	Item 24	0.10	0.51£	–0.09	1.00*	–0.50	–0.75	S	F	F	SF
	Item 25	0.42¥	0.38	0.18	1.00*	–1.00*	–0.50	F	F	F	SF
	Item 26	0.14	0.25	–0.52*	1.00*	–0.48	–1.00*	NO	F	F	SF
	Item 27	0.36	0.34	–0.39	1.00*	–0.98*	–1.00*	NO	F	F	SF
	Item 28	0.44	0.17	0.39	0.58	–0.30	–0.60	NO	NO	F	SF
	Item 29	0.13	–0.01	0.47£	0.50	–0.50	–0.50	AP	NO	F	NO
Psychological Function	Item 30	0.49¥	–0.02	–0.07	0.45	–1.00*	–1.00*	F	NO	PF	NO

NO: no classification; A: activity; P: participation; SF: body structure and function; PF: personal factor. ᵀ indicates positive and negative values, respectively, associated or not associated with ICF component. *p<0.01; £ p=0.01; ¥ p<0.05.

Table 5. Frequency of judgments for activity (A) and participation (P) for the items of the Brazilian version of The Disabilities Arm, Shoulder and Hand (DASH) for the group of "professionals with high familiarity (PHF)", and the group of "professionals with some or no familiarity (PSNF)".

DASH items	Items	PSNF	PHF	DASH by Dixon et al.[31]
Physical Function	Item 1	A **(78.9%)**; P(21%)	A (100%)	A
	Item 2	A **(78.9%)**; P(10.5%); AP(10.5%)	A (100%)	A
	Item 3	A **(63.2%)**; P(21%); AP(5.3%)	A (100%)	A
	Item 4	A**(73.7%);** P(26.3%)	A (100%)	A
	Item 5	A **(52.6%)** ; P(26.3%); AP(15.8%)	A (100%)	A
	Item 6	A **(78.9%)**; P(10.5%); AP(5.3%)	A (100%)	A
	Item 7	A **(73.7%)**; P(15.8%); AP(5.3%)	A (100%)	A
	Item 8	A **(57.9%)**; P(36.8%); AP(5.3%)	A(50%); P(50%)	A
	Item 9	A **(57.9%)**; P(26.3%); AP(15.8%)	A (100%)	A
	Item 10	A **(73.7%)**; P(21%)	A (100%)	NO
	Item 11	A **(84.2%);** P(10.5%)	A (100%)	A
	Item 12	A **(73.7%);** P(21%)	A (100%)	A
	Item 13	A **(63.2%);** P(21%); AP(5.3%)	A (100%)	A
	Item 14	A **(68.4%);** P(21%); AP(5.3%)	A (100%)	A
	Item 15	A **(73.7%);** P(15.8%); AP(10.5%)	A (100%)	A
	Item 16	A **(78.9%);** P(21%)	A (100%)	A
	Item 17	A **(47.4%);** P**(42.1%)**	A(25%); P**(75%)**	AP
	Item 18	A **(68.4%);** P(31.6%)	A(25%); P**(75%)**	AP
	Item 19	A **(52.6%);** P**(42.1%)**; AP(5.3%)	A(50%); P(50%)	AP
	Item 20	A (36.8%); P**(47.4%);** AP(5.3%)	A (100%)	AP
	Item 21	A (31.6%); **P(52.6%);** AP(15.8%)	NO	AP
Social Function	Item 22	A (15.8%); P**(63.2%)**	NO	P
	Item 23	A (31.6%); P**(52.6%);** AP(5.3%)	P**(75%);** AP(25%)	AP
Symptoms	Items 24-28	*They were not discriminated in table because they are not classified by Dixon et al.[31] as activity or participation*		
	Item 29	A **(31.6%)**; P**(36.8%);** AP(5.3%)	NO	NO

NO: no classification.

This would give health professionals, who had little or no familiarity with the ICF, the chance to associate these items to the activity-participation component. However, pain is described in Chapter 2 (Sensory Function and Pain)[1] of the International Classification of Functioning, Disability and Health (ICF) under the body function component, and the health professionals of the PHF group who worked and/or performed research using the ICF had no difficulty identifying this classification.

The literature describes two studies that related to the items of the DASH with the components of the ICF[31,32]. Drummond et al.[32] classified each item of the DASH as belonging to the components - body function, body structure and activity-participation. Dixon et al.[31] however, considered the components function and body structure together and the components activity and participation separately.

In this study, the classifications of the PSNF and PHF groups agreed with more than 80% of the literature, considering the findings of Dixon et al.[31] and Drummond et al.[32]. Moreover, the Kappa values were moderate to substantial, indicating that the components of the ICF might easily relate to the DASH items. However, disagreements in classifications occurred for the items 21, 22 and 26 to 29 from the symptom domain.

All of the items from the DASH in which the ratings from the health professionals disagreed with the two classifications adopted by the literature[31,32] (items 21,

22 and 26 to 29), had poor content validity results. Franchignoni et al.[49] recognized some problems with the validity of the English version of the DASH questionnaire for items 21 and 26. In the Brazilian version, the factorial analysis showed that items 26, 27, 28 and 29 from the symptoms domain belonged to a different domain[50]. Therefore, it is suggested that the content validity was poorly established for these items and that it may have interfered with the ability of the health professionals from the present study to define which component of the ICF the item was related to.

The PHF group agreed relatively more in their ratings regarding the ability to distinguish activity and participation compared to the PSNF group. Thus, it appears that beyond the correct definitions of these components, other strategies were necessary to clarify that the activity component was related to the activities of daily living and the participation to social activities[1]. This differentiation is important for clinicians, since different questionnaires used in the clinical setting very often include activity components[30,31], and it is important for the health professionals to complement the evaluation with information from the participation domain.

Study limitations have occurred and are related to the sample size of the PSNF group, although the power analysis was acceptable. The PSNF group was a sample of convenience and some losses occurred. Thus, the data from the PSNF group must be extrapolated only for health professionals with similar characteristics, i.e., those who usually do not work with the ICF, or are untrained and have a limited knowledge of the ICF, or less than five points on the numerical rating scale of 10. In addition, the participants were not asked about their prior knowledge of the DASH and SPADI questionnaires, which may have lead to difficulty in the recognition of the items.

Finally, the strongest aspect of this study is the initiative to explore whether health professionals, with different levels of familiarity, are able to identify ICF components in questionnaires that have been validated for the Brazilian language and that are relatively well-known to clinicians. Thus, although the results are exploratory, it was possible to identify that professionals could relate the ICF components with most items on the questionnaires, regardless of the level of their familiarity with the ICF classification. In addition, it was also observed that the concept of pain was the most difficult to categorize. Therefore, the relation of pain with body function component of ICF deserves more attention when trying to correlate the ICF with functional outcome questionnaires.

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original article

BJPT Brazilian Journal of Physical Therapy

Cross-cultural adaptation and reproducibility of the Brazilian-Portuguese version of the modified FRESNO Test to evaluate the competence in evidence based practice by physical therapists

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ABSTRACT | Background: The *Modified Fresno Test* was developed to assess knowledge and skills of both physical therapy (PT) professionals and students to use evidence-based practice (EBP). **Objectives:** To translate the Modified Fresno Test into Brazilian-Portuguese and to evaluate the test's reproducibility. **Method:** The first step consisted of adapting the instrument into the Brazilian-Portuguese language. Then, a total of 57 participants, including PT students, PT professors and PT practitioners, completed the translated instrument. The responses from the participants were used to evaluate reproducibility of the translated instrument. Internal consistency was calculated using the Cronbach's alpha. Reliability was calculated using the intraclass correlation coefficient (ICC) for continuous variables, and the Kappa coefficient (K) for categorical variables. The agreement was assessed using the standard error of the measurement (SEM). **Results:** The cross-cultural adaptation process was appropriate, providing an adequate Brazilian-Portuguese version of the instrument. The internal consistency was good (α=0.769). The reliability for inter- and intra-rater assessment were ICC=0.89 (95% CI 0.82 to 0.93); for evaluator 1 was ICC=0.85 (95% CI 0.57 to 0.93); and for evaluator 2 was ICC=0.98 (95% CI 0.97 to 0.99). The SEM was 13.04 points for inter-rater assessment, 12.57 points for rater 1 and 4.59 points for rater 2. **Conclusion:** The Brazilian-Portuguese language version of the *Modified Fresno Test* showed satisfactory results in terms of reproducibility. The *Modified Fresno Test* will allow physical therapy professionals and students to be evaluated on the use of understanding EBP.

Keywords: evidence-based practice; modified Fresno scale; physical therapy; professional practice; professional education.

BULLET POINTS

- Evidence-based practice (EBP) is critical to clinical decision-making.
- Physical therapists should be evaluated for their knowledge and skills to use EBP.
- The Modified Fresno Test is a self-explanatory instrument designed to test the knowledge and skills of PTs.
- The results of the cross-cultural adaptation and instrument reproducibility for the Brazilian Portuguese version of the modified Fresno Test were satisfactory.

HOW TO CITE THIS ARTICLE

Silva AM, Costa LCM, Comper ML, Padula RS. Cross-cultural adaptation and reproducibility of the Brazilian-Portuguese version of the modified FRESNO Test to evaluate the competence in evidence based practice by physical therapists. Braz J Phys Ther. 2016 Jan-Feb; 20(1):26-47. http://dx.doi.org/10.1590/bjpt-rbf.2014.0140

Introduction

Evidence-Based Practice (EBP) can be defined as the use of relevant scientific evidence to guide clinical decision making and to optimize health outcomes of patients[1]. Therefore, EBP incorporates knowledge related to clinical research of high quality, professional knowledge, and patient's preferences[1-4]. This approach has been increasingly used by physical therapists. In order to be effective and applicable in clinical practice, EBP should be able to[3,5]: formulate a clinical question; drive effective searches of databases; critically assess the methodological quality of study findings; and provide the evidence for therapeutic decisions[2,6-10]. Any difficulty in performing these steps could be a barrier to the adoption of EBP[5]. To that end,

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Received: Oct. 23, 2014 Revised: Apr. 27, 2015 Accepted: Sept. 11, 2015

adequate training[11-13] and the constant evaluation of knowledge and skills acquired by the professionals during their training using reliable instruments are fundamental[14,15].

The concept of competence is broad[16], and although there is no single definition, the consensus is that integration of personal attributes to the actions carried out in specific contexts, aimed at achieving results, are key aspects[17]. In the physical therapy context, competence indicates the capacity to manipulate cognitive resources that add knowledge, information, skills, and, above all, intelligence, to effectively and with relevance, solve a number of situations in clinical practice[18,19]. The term could also incorporate the knowledge domain[2], ability to work in teams, and to be effective in verbal and written communication[2,17,20].

Although there are a number of instruments[12] that are used to assess the EBP in health professionals have been identified, few have had their validity and reliability tested or have failed to evaluate EBP in its entirety[21]. The Fresno Test[1,2,14], originally developed to assess the ability of medical professionals to evaluate medical literature, is the only instrument that evaluates all stages of EBP[2,12]. It was later adapted to evaluate other health professionals such as nurses[18], occupational therapists[22] and physical therapists[7,18]. This Modified Fresno Test[7] was developed to assess the knowledge and skills of physical therapy professionals and students to use EBP principles in their daily professional practices & classes. The instrument identifies the whether the individual has the academic and professional knowledge necessary to be able to use high methodological quality evidence for clinical decision-making.

In the absence of instruments that assess the knowledge and skills of Brazilian PT students and professionals to use EBP, the need for a cross-cultural adaptation of a suitable test instrument to be used in the Brazilian-Portuguese language becomes evident. Thus, this study aimed to translate and cross-culturally adapt the Modified Fresno Test for physical therapists, and to evaluate the reproducibility of the instrument in the Brazilian-Portuguese version.

Method

The Modified Fresno Test instrument

The Modified Fresno Test is a self-explanatory tool that evaluates competencies and skills of professionals and students to use EBP[7]. The instrument is composed of an initial text with instructions for completion and two clinical scenarios. Each participant must choose one of the scenarios provided and answer 13 questions pertaining to the chosen scenario. Questions 9 and 10 require mathematical calculations. The questionnaire must be answered within the maximum permitted time of sixty minutes.

The total score is calculated from the partial score of each question which has 4 possible answers (a to d) to choose from. For example, question 2 asks the participant to name the research databases selected to answer the clinical question, which has the following items listed: (a) different resources; (b) convenient resources; (c) clinical relevant resources; and (d) valid resources. The response or answer for each item is then scored using one of five classification categories as follows: (1) not clear; (2) limited; (3) minimum; (4) strong; and (5) excellent[7]. The sum of scores for each criterion results in a score per question that ranges from 0 to 24 points: Q1 to Q7 allow a maximum score of 24 points; Q8 and Q10 a maximum of 16 points; Q9 allows 12 points; and Q11 to Q13 a maximum of 4 points. The total test score is the sum of the points from all questions, ranging from 0 to 224 points[7] (Table 1). After the participant responded to all of the questions, two trained raters scored the responses.

Cross-cultural adaptation of the Modified Fresno Test

The first step was to cross-culturally adapt the Modified Fresno Test[7] to the Brazilian-Portuguese language. To translate and adapt the instrument, the guidelines for translation and adaptation of health care questionnaires, proposed by Beaton et al.[19], were adopted[19]. Thus, the following steps were conducted: translation, synthesis of the translation, back-translation into English, summary of the back-translation, evaluation of the new document by an expert committee followed by a pre-test.

The resulting version of the translation process was pre-tested using 30 physical therapists who had 1 to 10 years (mean=5.7; SD=3.1) experience who may or may not have had experience using EBP principles. The participants were 22 females and 8 males, between the ages of 25 and 36 years, who had graduated from public or private universities that were not involved in the first part of the study. Of those, 21 participants received the questionnaire in digital format and 9 in print format. Each participant was asked to read and answer the questionnaire and at the end of each question, there was a blank field with the text "*here, describe your suggestions and/or difficulty*

Table 1. Modified Fresno Test for physical therapists – Brazilian-Portuguese Edition: Percentage and scoring of the questions according to the steps of Evidence Based Practice.

Step/Action	Questions - Q	Scores	% and total score
Step 1: Elaboration of the question	Q1 - Formulate a clinical question	Q1 – (0 to 24)	11% (24)
Step 2: Search for the best available evidence	Q2 - Information Sources Q4 - Search (search strategy)	Q2 – (0 to 24) Q4 – (0 to 24)	21% (48)
Step 3a: Critical evaluation (qualitative evidence)	Q3 - Study design Q5 - Relevance Q6 - Internal Validity Q7 - Magnitude and significance Q12 - Best study design (diagnosis) Q13 - Best study design (prognosis)	Q3 – (0 to 24) Q5 – (0 to 24) Q6 – (0 to 24) Q7 – (0 to 24) Q12 – (0 or 4) Q13 – (0 or 4)	46% (104)
Step 3b: Critical evaluation (quantitative evidence)	Q9 - Sensitivity, positive predictive value and positive likelihood ratio Q10 - Absolute risk reduction, relative risk, NNT, and p-value Q11 - Confidence Interval	Q9 – (0 to 12) Q10 – (0 to 16) Q11 – (0 or 4)	14% (32)
Step 4: Implementation of evidence into clinical practice	Q8 - Questioning the patient/family	Q8 – (0 to 16)	7% (16)
		Total (0 to 224)	Total 100% (224)

Q: Question; NNT: Number needed to treat.

in answering this question", so that they could report any difficulties encountered when understanding the questions. Once completed, the questionnaires were scored by two investigators with experience in EBP practice, working in the areas of musculoskeletal and cardiorespiratory physical therapy for 7 years.

Measurement properties

This phase tested the measurement properties of the Modified Fresno Test for the Brazilian-Portuguese version, following the guidelines proposed by Mokkink et al.[23] for testing internal consistency and intra- and inter-rater reliability, and the guidelines of Terwee et al.[24] to test the compliance of the instrument.

Reliability measures the accuracy of an instrument to provide the same answer in repeated measurements, representing the relative error of the measurement. It can be measured when the instrument is used more than once by the same examiner (intra-rater reliability) and when the instrument is used to evaluate the same condition by different raters (inter-rater reliability)[23,25,26]. The correlation represents the degree to which the repeated analysis of the same individual provided similar responses[24,25].

The statistical tests adopted for the reliability analysis were the same ones used with the original instrument[7]. The Cronbach's alpha (α) was used to assess the internal consistency of the instrument (ranging between 0.70 and 0.95), the intraclass correlation coefficient type$_{2,1}$ (ICC$_{2,1}$) was used to test the reliability of the numeric or quantitative variables in continuous scales[27], and the Kappa coefficient (K) was used for the categorical variables. The ICC was classified according to Fleiss[27] as poor (<0.4), good (0.4 to 0.75) and excellent reliability (>0.75). The Kappa was classified according to Landis and Koch[28] as reliability being almost perfect (>0.81), substantial (0.61 to 0.80), moderate (0.41 to 0.60), low (0.21 to 0.40) and very low (0.00 to 0 20). The reliability tests were performed with a 95% confidence interval.

The agreement between the assessors was assessed using the standard measurement error (SME), which reflected the error of the instrument, expressed by the standard deviation of the differences of the test and re-test, divided by the square root of 2[24]. The relationship between the SME and the total score of the questionnaire was interpreted as proposed by Ostelo et al.[29] who considered values ≤5% as very good, >5% and ≤10% as good, >10% and ≤20% as doubtful and >20% as negative. All data collected were transferred to the software Statistical Package for Social Sciences (SPSS) version 17.0 for analysis.

Procedures

This study was approved by the Ethics Committee of the Universidade Cidade de São Paulo (UNICID), São Paulo, SP, Brazil, under the Research Protocol number 13696713/2012 and authorized by the authors who developed the original instrument. All participants signed an informed consent form.

The Modified Fresno Test was translated into Brazilian-Portuguese by two bilingual (Portuguese and English) translators, both with over 15 years of linguistics training, whose first language was Brazilian-Portuguese. Translator one had 11 years experience in higher education, was knowledgeable in health terminology and was aware of the instrument goals, while translator two had 9 years experience in higher education, but no knowledge of how EPB was used, or experience in the health area. Next, the translated versions were compared and analyzed and a consensual approach by the 2 translators to resolve any differences of interpretation and translation was conducted. Thus, the two independent translations (T_1 and T_2) were created and then synthesized into a single consensual translation, termed T_{12}.

The T_{12} version was then back translated into English by two different independent translators (back-translator 1 and back-translator 2). These translators had backgrounds in physical therapy and were knowledgeable in the EBP methodology and were fluent in Portuguese and English, with the latter being their mother tongue. In addition, these back- translators, although aware of EBP methodology, were unaware of the Modified Fresno Test. The results of the two back-translations (RT_1 and RT_2) were synthesized in a consensual manner similar to the original translations resulting in a single consensual translation called RT_{12}.

Finally, a Committee of Experts, consisting of methodologists, health professionals and professional translators (2 translators, 2 back-translators, 6 physical therapists with teaching experience in EBP), evaluated and consolidated all versions (R12 & T12). The committee compared the translations and discussed the semantic, structural, idiomatic and conceptual properties from the Brazilian-Portuguese version and developed a pre-final version. After conducting the pre-test, barely any changes were made to the final version.

To test the final version of the instrument, a convenience sample of 159 physical therapists were invited to participate. The sample size was estimated as proposed by the guidelines for reliability tests[24,30,31]. The sample consisted of: (1) physical therapy professors of public and private institutions involved in the clinical practice, (2) students enrolled on the third year of their PT program and (3) physical therapists not connected to higher education institutions, independent of the their familiarity with EBP.

The volunteers were instructed to use a notebook and a calculator to assist in answering all of the questions. They were asked to complete the task within the stipulated time (60 minutes) even though the original study had not justified the time parameters. Data collection was conducted from April to September 2013.

The evaluators received a single training, divided into three steps of one hour each. The first hour was an orientation about the criteria and scoring of the questions. The second hour was a pilot test in which each evaluator scored one sample test. The third hour was for analysis and discussion of the score results. The evaluators were blinded to avoid identification of the participants and the score of the instrument during the test and re-test.

After the training, the evaluators received the questionnaires answered by 57 participants and scored the answers to obtain the partial and total test scores of the Modified Fresno Test. Inter- and intra-rater reliability tests and inter-rater agreement of the partial and full scores of the instrument were carried out using a test/retest design with an interval of seven days between scoring sessions. The test/retest was performed by two independent evaluators who did not participate in the previous stages.

Results

Of the 159 individuals invited to participate in the study, only 32% (n=57) returned the questionnaires. Of those, 36 were PT professionals (13 were also PT teachers in the clinic) with an average working experience time of 6.6 years, (SD-3.8) and 21 were PT academics (last year program). Thirty-seven answered the questionnaire in print and 20 in the digital version. The 95 participants who did not return the questionnaires were asked about their reasons for not returning the test information. Some claimed lack of knowledge of the topic and seven expressed lack of interest in the research. None of them reported difficulty in understanding the questions, but reported a lack of knowledge for answering the topics covered. The percentage of missing items per question for the respondents of the questionnaire (n=57) is shown in Table 2. The evaluators who scored the answers of the test/re-test did not report any problems.

Table 2. Measurement properties of the Modified Fresno Test – Brazilian-Portuguese version per item and the total sum of the questions.

Questions	Inter-rater (n=57)	Inter-rater (n=57)	Intra-rater 1 (n=57)	Intra-rater 1 (n=57)	Intra-rater 2 (n=57)	Intra-rater 2 (n=57)
	$ICC_{2,1}$ (95% CI)	Agreement – (SEM)	$ICC_{2,1}$ (95% CI)	Agreement – (SEM)	$ICC_{2,1}$ (95% CI)	Agreement – (SEM)
Q1	0.75 (0.60-0.84)	3.40	0.82 (0.69-0.90)	2.80	0.98 (0.97-0.99)	0.76
Q2	0.52 (0.30-0.68)	3.81	0.47 (0.20-0.67)	4.06	0.96 (0.94-0.97)	1.07
Q3	0.89 (0.82-0.93)	2.51	0.86 (0.78-0.91)	3.01	0.97 (0.95-0.98)	1.22
Q4	0.75 (0.61-0.84)	3.11	0.80 (0.68-0.88)	2.64	0.97 (0.95-0.98)	1.05
Q5	0.66 (0.48-0.78)	2.97	0.49 (0.22-0.68)	3.70	0.91 (0.85-0.94)	4.06
Q6	0.68 (0.51-0.79)	4.44	0.79 (0.67-0.87)	3.60	0.94 (0.90-0.96)	1.84
Q7	0.58 (0.38-0.73)	4.59	0.67 (0.50-0.79)	4.10	0.94 (0.90-0.96)	4.85
Q8	0.65 (0.47-0.78)	2.53	0.64 (0.31-0.81)	2.52	0.96 (0.93-0.97)	0.83
Q9	0.90 (0.84-0.94)	1.11	0.97 (0.95-0.98)	0.65	0.99 (0.98-0.99)	0.30
Q10	0.94 (0.90-0.96)	0.94	0.94 (0.90-0.96)	0.95	0.99 (0.99-0.99)	1.96
Q11	0.92 (0.87-0.95)	0.37	0.92 (0.87-0.95)	NC	1.00 (1.00-1.00)	0.37
Q12	0.75 (0.60-0.84)	0.97	0.89 (0.83-0.93)	0.65	1.00 (1.00-1.00)	0.97
Q13	0.93 (0.88-0.95)	0.53	0.93 (0.88-0.95)	0.53	1.00 (1.00-1.00)	NC
Total	0.89 (0.82-0.93)	13.04	0.85 (0.57-0.93)	12.57	0.98 (0.97-0.99)	4.59

Missing data (n=57) – Q9=7 (12.3%); Q10=5 (8.7%); Q11=4 (7.0%); Q13=1(1.8%). NC: The statistical program did not allow the calculation of these items.

Cross-cultural adaptation of the Modified Fresno Test for Brazilian-Portuguese

When the original version was compared with the versions resulting from the translations (T_1 and T_2) and back-translations (RT_1 and RT_2), no significant differences were found for the content and meaning. Grammatical adjustments were conducted for different words but the same meaning was maintained between the two versions.

In the pre-test, participants reported no problems understanding the terms and questions. However, six of the 30 physical therapists who answered the instrument (two answered in print version and four in digital) reported difficulties understanding the instrument's instructions. Through these results, adjustments were made to facilitate understanding and the text was forwarded to the Committee of Experts, resulting in the final Modified Fresno Test – Brazilian-Portuguese version (Appendix 1 and 2).

Evaluation of reliability

The Brazilian-Portuguese version of the test showed good internal consistency (α=0.769). For evaluator 1, the ICC ranged from 0.47 to 0.97. The agreement of the SEM varied from 0.53 to 4.10 points. Evaluator 1 showed excellent reliability, except for questions 2 and 5, which showed an ICC of 0.47 and 0.49, respectively, indicating moderate reliability. In relation to questions 11, 12 and 13, the Kappa coefficient obtained was excellent and ranged from 0.89 to 0.93.

For evaluator 2, reliability was found to be higher compared to values reported for evaluator 1. The ICC ranged from 0.98 to 0.99 and the SEM agreement ranged from 0.30 to 4.85 points. These results represented excellent reliability for all questions tested in the instrument. Questions 11, 12 and 13 showed excellent reliability with a Kappa index of 1.0. The inter-rater reliability presented an ICC that ranged from 0.52 to 0.94 and an agreement by the SEM that ranged from 0.37 to 4.59 points.

The inter-rater reliability between the 2 evaluators proved to be excellent except for question 2, which resulted in an ICC of 0.52 indicating moderate reliability. Questions 11, 12 and 13 showed good to excellent reliability, with a Kappa index ranging from 0.75 to 0.93.

For the total score of the instrument, the intra-rater reliability was excellent for both evaluators. Evaluator 1 had an ICC of 0.85 (0.57 to 0.93) and evaluator 2, an ICC of 0.98 (0.97 to 0.99). The inter-rater reliability was excellent with an ICC of 0.89 (from 0.82 to 0.93). The agreement by the SEM was 13.04 points for the

inter-rater assessment, 12.57 points for evaluator 1 and 4.59 points for evaluator 2.

Discussion

The purpose of this study was to adapt and test the reliability properties and agreement of a Brazilian-Portuguese version of the Modified Fresno Test, an instrument, that to date, is considered to be the most complete and appropriate test for evaluating PT professionals and students knowledge and skills on the use of EBP[12].

The adaptation process to the Brazilian-Portuguese version of the Modified Fresno Test followed the steps indicated by the available literature[19]. The steps were completed without difficulty and adjustments were made to the content and meaning of the text. Although most of the participants failed to complete the final version of the questionnaire, the reasons were unrelated to the difficulties with the topic[10] or in understanding the questions. Therefore, it was not considered a barrier in the instrument adaptation process, since different levels of skills and competence in relation to EBP was expected, as mentioned by the authors who developed the instrument[7].

The question with the highest amount of missing data was Q9, which required statistical knowledge, followed by Q10, Q11 and Q13. The omission of EPB learning during professional training, the difficulty in dealing with statistics and conducting the databases search were the reasons for participants dropping out of this study[32]. It is possible that those reports were the major obstacles facing physical therapists, independent of their professional time in the process of adopting EBP. Difficulty in the searching process, interpretation and in translating the evidence into clinical practice is related to the competencies and skills of a professional; however, younger professionals have shown a more positive attitude to the adoption of EBP[33]. Nevertheless, other obstacles have been pointed out by other studies in the adoption of EBP, such as limited access to databases and complete manuscripts, language issues, and the time available to learn the topic[5,6,33-35].

The original version of the instrument lacked classification categories for the total score of the questions, but the higher the values, the better the participants were in answering each question or a group of questions. The results of the reliability tests for the total score of the modified instrument, obtained by using the Brazilian-Portuguese version, were considered excellent for the intra- and inter-rater assessment. The study, which validated the modified instrument for physical therapists, presented good internal consistency (α=0.769), similar to the values obtained with the original unmodified instrument (0.780). In addition, the modified English version of the instrument presented an excellent reliability inter- and intra-observer of 0.92 (95% CI 0.88 to 0.94), for evaluator 1 an ICC of 0.96 (95% CI .91-.98), and for evaluator 2 of 0.96 (95% CI from 0.91 to 0.98)[7].

The scores of the partial questions of the adapted instrument showed moderate to excellent results for intra- and inter-rater reliability of the evaluators. These results were similar to the original English version of the modified instrument which presented moderate to excellent intra-observer reliability for the evaluators for all questions (ICC ranging from 0.62-1.0) and moderate to excellent inter-rater reliability (ICC ranging from 0.61 to 0.99) for all questions of the instrument; however, differences between the two versions were observed for questions 2, 5 and 8.

Question 8 evaluated the ability of the participants to obtain information about the patient's perspective, which presented unsatisfactory reliability ($ICC_{2,1}$=0.47) in the original version and good reliability ($ICC_{2,1}$=0.65) in the Brazilian-Portuguese version for the inter-rater analysis. Question 2 evaluated the participant's knowledge and ability to search the database, and presented a moderate reliability for evaluator 1 and for the inter-rater assessment with the Brazilian-Portuguese version. In the original English version, reliability values were excellent for this question ($ICC_{2,1}$=0.83), as well as for evaluator 1 and for the inter-rater assessment ($ICC_{2,1}$=0.90). Question 5 referred to the participant's ability to determine the clinical relevance of the identified studies, and showed lower reliability values in the Brazilian-Portuguese version than in the original version for evaluator 1 ($ICC_{2,1}$=0.49). The score differences between the two versions for this question might be related to the level of knowledge acquired during their professional training[15] of EBP between participants.

The values of the inter-rater reliability and intra-rater SEM for the Brazilian-Portuguese version showed little variability in the intra- and inter-rater scores, considering that the total instrument score ranged from 0 to 224 points. These results could not be compared with the original modified version because this property was not assessed in the original version[7]. Upon completion of the translation phases and testing of the measurement properties, the Brazilian-Portuguese version of the Modified Fresno Test for physical therapists proved to be similar in terms of the language

and clearly understood by the Brazilian population (Appendix 1*). In addition, it could be a useful tool for researchers and educational institutions in assessing the ability of Brazilian professionals to adopt EBP. According to the strategy of using the Fresno Test for medical doctors and the Modified Fresno Test for physical therapists, cited in the respective studies[7,14], the authors believe that this instrument is best used for continuous evaluation, which involves a constant process of assessments and reassessments to ensure people understand EBP principles and if they do not, have taken the time or are given the opportunity to develop skills in EBP.

The difficulty in obtaining a greater number of participants to answer the questionnaire during the test and after 24 hours, ensuring that there was no time to supplement the information from websites or books, was a limitation of this study because only 11 individuals returned the questionnaire on time. Therefore, the present study only tested the reliability and agreement of the evaluators of the Modified Fresno Test version adapted to Brazilian-Portuguese. Therefore, the authors recommend the development of new studies in order to test other properties of the instrument, such as construct validity and responsiveness of the Brazilian-Portuguese version. Further studies are needed to continually assess the new learning methods and the use of scientific evidence in therapeutic decisions during students professional training, because these methods are fundamental prerequisite for the adoption of EBP principles.

Conclusion

The Modified Fresno Test for physical therapists revealed satisfactory results in the adaptation process. The Brazilian-Portuguese version of the instrument showed good internal consistency, excellent reliability and low variability in the intra-agreement test and for inter-evaluators. There are other properties that should be tested. However, the steps taken so far may contribute to the development of studies aimed at assessing comprehensively the knowledge and skills of physical therapy professionals and students in the use of EBP in their clinical practice.

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Appendix 1. Versão adaptada do Teste Modificado de Fresno para fisioterapeutas.

Instruções:

Prática Baseada em Evidências (PBE) envolve competências e habilidades relacionadas com a identificação e avaliação de evidências para informar a prática. Esta ferramenta, o Teste Modificado de Fresno é projetado para avaliar suas habilidades para a PBE.

Há oito perguntas de resposta curta, 2 perguntas que exigem uma série de cálculos matemáticos, e 3 questões de preenchimento de lacunas. Uma calculadora e papel para anotação lhe foram fornecidos. Recursos adicionais (sites da internet, livros, etc.) não são permitidos.

Por favor, preencha todo o teste de uma só vez e permita-se até 60 minutos para completar o teste.

Responda às perguntas 1 a 4 e 8 com base nos seguintes cenários clínicos:

Cenário 1: Você acabou de avaliar Maria, uma secretária, que recentemente sofreu uma lesão lombar relacionada ao trabalho, movimentando caixas de arquivos de 4,54 Kg há 3 dias. Suas radiografias são negativas e seu único sintoma é a dor na coluna lombar com intensidade 2/10, durante movimentos de flexão e ficar sentada por tempo prolongado. Ela ficou fora do trabalho por dois dias e está ansiosa para voltar, mas está também preocupada com uma nova lesão. Você está pensando em um programa de exercícios de estabilização, mas pergunta a si mesmo se a terapia manual deve ser incluída no programa de fisioterapia do paciente.

Cenário 2: Marvin é um garoto de 10 anos com hemiparesia secundária, devido a um acidente vascular cerebral associado a uma má formação artério-venosa. Ele apresenta-se à terapia ambulatorial e seus pais expressam preocupação particular sobre o braço de Marvin e fraqueza nas pernas. Você está pensando em implementar um programa intensivo de tarefa específica de fortalecimento, mas um colega adverte que tal programa é capaz de aumentar o tônus flexor e espasticidade moderada do paciente e sugere baixa intensidade de alongamento e um programa de posicionamento passivo.

Pergunta # 1: Escolha um dos cenários clínicos acima. Escreva uma pergunta clínica, focada neste cenário, que irá ajudá-lo a organizar uma busca na literatura clínica.
Resposta:

Pergunta # 2: Onde você poderia encontrar respostas para essa e outras perguntas clínicas semelhantes? Nomeie quantas fontes de informação e/ou pesquisa puder e não apenas as que você acha que são "boas" fontes. Descrever as vantagens e desvantagens de cada tipo de fonte de informação que você colocou na lista.
Resposta:

Pergunta # 3: Que tipo de estudo (projeto de estudo) melhor responderia a sua pergunta clínica descrita na pergunta 01 e por quê?
Resposta:

Pergunta # 4: Se você estivesse em uma busca no Medline, CINAHL ou qualquer outro banco de dados para a pesquisa original, para responder a sua pergunta clínica relacionada ao cenário selecionado para a pergunta 1, descreva a estratégia de busca que você pode usar. Seja o mais específico possível sobre os termos de pesquisa e campos de pesquisa que você usaria. Explique sua justificativa para esta abordagem. Descreva como você pode limitar sua pesquisa, se necessário, e explique o seu raciocínio.
Resposta:

Pergunta # 5: Quando você encontrar um artigo sobre à sua pergunta clínica ou quaisquer outras, que características do estudo você vai considerar para determinar se ele é relevante? Inclua exemplos. As questões 6 e 7 irão perguntar a você como determinar se o estudo é válido, e quão importante são os resultados. Para esta pergunta, por favor, concentre-se em como determinar se ele é realmente relevante para a sua prática.
Resposta:

Pergunta # 6: Quando você encontrar um artigo relacionado à sua pergunta clínica ou quaisquer outras, que características do estudo você vai considerar para determinar se as suas conclusões são válidas? (Você já foi abordado sobre relevância e a questão 7 vai perguntar como determinar a importância dos resultados. Para esta pergunta, por favor, concentre-se na validade do estudo).
Resposta:

Pergunta # 7: Quando você encontrar um artigo, que se relacione com a sua pergunta clínica ou quaisquer outras, que características dos resultados você vai considerar para determinar sua magnitude e significância (clínica e estatística)?
Resposta:

Pergunta # 8: Para o cenário clínico que você escolheu, liste duas questões que você gostaria de fazer ao paciente / família para obter uma melhor compreensão de suas preferências pessoais e / ou circunstâncias em relação a sua questão clínica.
Resposta:

Pergunta # 09: Um estudo sobre a precisão do diagnóstico do teste ergométrico (TE) para o diagnóstico de doença arterial coronariana (DAC) incluiu 96 mulheres com suspeita de DAC, 29 das quais foram posteriormente determinadas tendo DAC (estenose> 50% em um ou mais vasos coronarianos). Daquelas com DAC, 9 teve um TE anormal. Dos 67 pacientes determinados não tendo DAC, 32 tinham um TE anormal.

a: Com base nesses resultados, a sensibilidade do TE para DAC é?
b: Com base nesses resultados, o valor preditivo positivo de TE para DAC é?
c: Com base nesses resultados, a razão de verossimilhança positiva para um TE anormal para DAC é?

*** Caso não tenha calculadora, para facilitar os valores de freqüência utilize o texto alternativo abaixo:**
Um estudo sobre a precisão do diagnóstico do teste ergométrico (TE) para o diagnóstico de doença arterial coronariana (DAC) incluiu 120 mulheres com suspeita de DAC, 30 dos quais foram posteriormente determinadas tendo DAC (estenose> 50% em um ou mais vasos coronarianos). Daqueles com DAC, 10 tinham uma TE anormal. Dos 90 pacientes determinados não tendo DAC, 30 tiveram um TE anormal.

Resposta:

Arredondamento é aceitável (por exemplo 21,9-22 é aceitável)

Pergunta # 10: Um estudo aleatorizado recente de mulheres grávidas com incontinência descobriu que, após o treinamento do assoalho pélvico 20% tinham incontinência, comparado com 32% no grupo controle três meses após o parto. O Nível alfa para o estudo foi estabelecido ao nível de significância de 0,05.

a: A redução do risco absoluto para eventos recorrentes é?
b: A redução do risco relativo de eventos recorrentes é?
c: O número necessário para tratar (NNT) para prevenir um evento recorrente é?
d: O valor-p indicando diferença estatisticamente significativa entre os grupos seria?

*** Caso não tenha calculadora, para facilitar os valores de freqüência utilize o texto alternativo abaixo:**
Um recente estudo randomizado de gestantes com incontinência descobriu que, após o treinamento do assoalho pélvico 20% tinham incontinência em comparação com 30% no grupo controle em três meses após o parto. O Nível alfa para o estudo foi estabelecida ao nível de significância de 0,05.

Resposta:

Pergunta # 11: O mesmo estudo descrito na questão 10 revelou um risco relativo de incontinência de 0,61 para as mulheres que receberam treinamento do assoalho pélvico. Isto sugere que o tratamento com treinamento do assoalho pélvico reduz o risco para a incontinência. Gostaríamos de saber se esta diferença é estatisticamente significativa, por isso, olhe para o intervalo de confiança. Dê um exemplo de um intervalo de confiança que suporte a conclusão de que a taxa de incontinência foi realmente (estatisticamente) diferente para estes dois grupos de tratamento.

*** Caso não tenha calculadora, para facilitar os valores de freqüência utilize o texto alternativo abaixo:**
O mesmo estudo descrito na questão 11 revelou um risco relativo de incontinência de 0,66 para as mulheres que receberam treinamento do assoalho pélvico. Isto sugere que o tratamento com treinamento do assoalho pélvico reduz o risco para a incontinência. Gostaríamos de saber se esta diferença é estatisticamente significativa, por isso, olhe para o intervalo de confiança. Dê um exemplo de um intervalo de confiança que suporte a conclusão de que a taxa de incontinência foi realmente (estatisticamente) diferente para estes dois grupos de tratamento.

Resposta:

Pergunta # 12: Qual desenho do estudo é o melhor para um estudo sobre o diagnóstico?

Resposta:

Pergunta # 13: Qual desenho do estudo é o melhor para um estudo sobre o prognóstico?

Resposta:

Tempo gasto para completar o teste: _____

Appendix 2. Escore de pontuação da versão adaptada do Teste Modificado de Fresno para fisioterapeutas.

Pergunta # 1:Escolha um dos cenários clínicos acima. Escreva uma pergunta clínica, focada neste cenário, que irá ajudá-lo a organizar uma busca na literatura clínica.

	Excelente	Forte	Limitado	Mínimo	Não evidente
a: População	6: Vários descritores relevantes; por exemplo, "lesão relacionada com o trabalho", "mulher" ou "grave" ou "dor lombar", por exemplo, "menino com hemiparesia" grupo etário específico, sexo, diagnóstico, apresentação motora.	4: Um descritor apropriado como os exemplos acima, "Mulheres" ou "trabalhador" ou "dor lombar", por exemplo, "hemiparesia" "menino" "10 anos" "pós-AVC"	2: Um único descritor geral capaz de contribuir para pesquisa; por exemplo, "Paciente"		0: Nenhum dos presentes acima.
b: Intervenção	6: Inclui intervenção de interesse específico; (intervenção poderia ser uma técnica de diagnóstico); • terapia manual; • componentes específicos individuais de terapia manual; • combinação de exercício e terapia manual; • tarefas específicas de fortalecimento.		2: Menciona intervenção, mas é capaz de contribuir para pesquisa; por exemplo, "Métodos" "opções" "tratamentos".		0: Nenhum dos presentes acima.
c: Comparação	6: Identifica alternativa de interesse específico; exemplo "Nenhuma terapia manual", "alongamento de baixa intensidade".		2: Menciona comparação, mas é capaz de contribuir para pesquisa; exemplo "Métodos alternativos"		0: Nenhum dos presentes acima.
d: Resultado	6: Resultado que é objetivo e significativo para o paciente ou o caso do paciente (se a pergunta é de diagnóstico, deve estar relacionado com o que o diagnóstico está tentando detectar); exemplo, retorno ao trabalho, redução da dor, prevenção de lesões; por exemplo, controle motor seletivo ou uso funcional de extremidades paralisadas, velocidade no andar.	4: Sem resultado específico: • Recuperação • Espasticidade • Tônus • Força	2: Referência ao resultado, mas de modo geral a ser capaz de contribuir para pesquisar: • Efeitos • Alteração do resultado • Eficaz • Melhoria • Sucesso		0: Nenhum dos presentes acima.

Pergunta # 2: Onde você poderia encontrar respostas para essa e outras perguntas clínicas semelhantes? Nomeie quantas fontes de informação puder - e não apenas as que você acha que são "boas" fontes. Descrever as vantagens e desvantagens de cada tipo de fonte de informação que você colocou na lista.

	Excelente	Forte	Limitado	Min.	Não evidente
a: Variedade de fontes	6: Pelo menos quatro tipos de fontes listados. Os tipos incluem: • Bases de dados eletrônicas da literatura original [Medline (PubMed / Ovid), CINAHL]; • Bases de dados de disciplina específica (baseados em evidências, PEDro); • Periódicos (JAMA, NEJM, incluindo o acesso através da biblioteca); • Livro de texto (Merck, Harrisons, monografias); • Revisões Sistemáticas (Cochrane); • EBM publicações ou bases de dados de informação pré-avaliados (Best Evidence, InfoRetriever, DynaMed, EBM, ACPJC, EBP, Clinical Evidence); • Sites médicos (MDConsult, PraxisMD, SumSearch); • Pesquisa da Internet em Geral (google, yahoo); • Diretrizes Clínicas (Guideline Clearinghouse); • Organizações Profissionais (AAFP, La Leche League, site do NIH); • Pessoas (colega, consultor, atendendo bibliotecário,).	4: Três tipos de fontes listados.	2: Dois tipos de fontes listados.		0: Nenhuma variedade. Apenas uma fonte listada, ou todas as fontes do mesmo tipo.
b: Conveniência	6: A discussão inclui pelo menos duas questões específicas relacionadas com a conveniência, ou menciona a mesma questão ao discutir duas fontes diferentes. Problemas podem incluir: • Custo (por exemplo, "gratuito", "apenas por assinatura"); • Velocidade (por exemplo, "rápida", "leva tempo"); • Facilidade de busca (por exemplo, "deve saber como estreitar busca", "fácil de navegar"); • Facilidade de uso (por exemplo, "concisa" e "NNTs já calculado"); • Disponibilidade (por exemplo, "disponíveis online").	4:Inclui uma questão específica / explicações relativas à conveniência.	2: Menciona conveniência envolvida na utilização de uma ou mais fontes, mas sem explicação, por exemplo, "Conveniente" ou "fácil" ou "difícil".		0: Nenhuma menção de conveniência.

Pergunta # 2: Continuação...

	Excelente	Forte	Limitado	Min.	Não evidente
c: Relevância Clínica	6: A discussão inclui pelo menos duas questões específicas relacionadas com a relevância, ou menciona a mesma questão ao discutir duas fontes diferentes. Problemas podem incluir: • Resultados clinicamente relevantes; • Escrito para aplicação clínica (por exemplo, "pertinente" "informações sobre os efeitos adversos" ou "há formulários de informação do paciente"); • Foco em especialidade adequada (por exemplo, "dirigido à fisioterapeutas"); • Informação aplicável ao paciente em questão (por exemplo, "pode examinar mais detalhes deste paciente em particular" ou "a maioria dos estudos são da Europa"); • Inclui intervenções específicas em questão; • Especificidade (visão geral x alvo) (por exemplo, "pode obter informações básica" ou "mais especializada"); • Abrangência da fonte (probabilidade de encontrar uma resposta nesta fonte) (por exemplo, "ela pode encontrar qualquer coisa" ou "contém referências úteis" ou "não susceptíveis de ter resposta para esta pergunta").	4: Inclui uma questão específica / explicação relacionada com a relevância.	2: Menciona relevância do uso de uma ou mais fontes mas sem explicação, por exemplo, "Relevante".		0: Nenhuma menção de relevância.
d: Validade	6: A discussão inclui pelo menos duas questões específicas relacionadas com a validade, ou menciona a mesma questão ao discutir duas fontes diferentes. Problemas podem incluir: • Certeza de validade (por exemplo, "qualidade é incerto" ou "não foi exibido" ou "precisa ser avaliado criticamente"); • Abordagem baseada em evidências (por exemplo, "baseada em evidências" ou "Evidencia de grau 1" ou "não há referências fornecidas"); • Viés de especialista (por exemplo, "geralmente apenas a opinião de alguém"); • Abordagem sistemática; • A revisão por pares; • Capacidade para verificar; • Padrão de cuidados (por exemplo, "aceito na comunidade médica"); • Informação fornecida suficiente para uma validade crítica (por exemplo, "apenas abstrato" ou "texto completo não disponível"); • Atualizado/desatualizado (por exemplo, "a pesquisa mais recente"); • Confiabilidade - no contexto do grau de confiabilidade que pode ser colocado na fonte.	4: Inclui uma questão específica / explicação relacionada à validade.	2: Menciona validade do uso de uma ou mais fontes, mas sem explicação, por exemplo, "Bom", "lixo".		0: Nenhuma menção de validade.

Pergunta # 3: Que tipo de estudo (projeto de estudo) melhor responderia a sua pergunta clínica descrita no Q1 e por quê?

	Excelente	Forte	Limitado	Mínimo	Não evidente
a: Projeto de estudo	12: Nomeia uma das melhores fontes: • Experiência Controlada Aleatorizada; • Experiência Aleatorizada; • Revisão Sistemática; • Meta-Análise; • Experiência Aleatorizada, duplamente cego.	9: Descreve, mas não chama pelo nome, uma das melhores fontes como acima: • Comparando dois grupos, um obtém-se o tratamento, o outro placebo; • Estudo duplamente cego.	6: Descreve ou nomeia um projeto de estudo menos desejável: • Estudo de coorte; • Ensaio clínico prospectivo; • Meta-análise de tais estudos; • Longitudinal ou prospectivo.	3: Descreve ou nomeia um projeto de estudo pobre para responder a uma pergunta de tratamento: • Controle de casos, estudo transversal, estudo de casos, "retrospectivo"; • Ou descreve um estudo com detalhe insuficiente para identificar um modelo: por exemplo, um estudo comparativo.	0: Nenhum dos presentes acima.
b: Justificativa	12: Inclui justificativa bem fundamentada, que reflete a compreensão da importância da aleatorização e / ou cegueira. Conecta explicitamente aleatorização para redução de confusão e / ou cegueira de observador ou viés de aferição. Por exemplo: "Um estudo controlado aleatorizado tentará evitar qualquer viés que possa influenciar o resultado do estudo através de aleatorização" OU "mais adequada para questões de terapia, pois reduz preconceitos e controles para fatores de confusão."	9: A justificativa está presente, e toca em questões relacionadas com a aleatorização e / ou cegueira, mas menos claramente articulada, por exemplo, "Os grupos devem ser semelhantes" ou "tentar eliminar fatores de confusão" ou "evitar viés de seleção" ou "ser objetivo" ou "eliminar o preconceito".	6: A justificativa está presente, e levanta questões legítimas não relacionados à aleatorização ou cegueira, tal como a relação custo-benefício, recolhimento de produto. Talvez mencionar aleatorização ou cegueira, mas sem explicação. (Por exemplo: "o melhor em um cenário aleatório e cego"), Por exemplo: "Opiniões de gráfico fornecem muitos dados sem muito custo"	3: Tentativa de justificativa, mas os argumentos não são específicos e não demonstram compreensão da relação entre o projeto e as várias ameaças à validade Pode mencionar aleatorização ou cegueira, mas sem explicação. (Por exemplo: "o melhor em um cenário aleatório e cego"), por exemplo, "Para garantir a qualidade" ou "para reduzir potenciais conflitos" ou "para comparar".	0: Nenhum dos presentes acima

Pergunta # 4: Se você estivesse em uma busca no Medline, CINAHL ou qualquer outro banco de dados para a pesquisa original, para responder a sua pergunta clínica relacionada ao cenário selecionado para a pergunta 1, descreva a estratégia de busca que você pode usar. Seja o mais específico possível sobre os termos de pesquisa e campos de pesquisa que você usaria. Explique sua justificativa para esta abordagem. Descreva como você pode limitar sua pesquisa, se necessário, e explique o seu raciocínio.

	Excelente	Forte	Limitado	M	Não evidente
a: Termos de busca	8: 3 ou mais termos que refletem paciente, intervenção, comparação, e resultado (PICR) sendo considerados.	6: 2 termos do PICR.	3: 1 termo do PICR.		0: Não presente
b: Instruções/ Estratégia	8: Descrição da estratégia de pesquisa reflete o entendimento de que os artigos no banco de dados são indexados por mais de um campo. Discute um ou mais campo/índice/rótulo pelo nome (MESH, Palavra do título, nome da publicação, idioma, palavras-chave, autor, título da revista, utilização de operadores booleanos, etc.) E fornece justificativa plausível para a estratégia de busca usando um ou mais destes índices, por exemplo, "Palavra-chave é menos específico do que a estrutura".	6: Nomeia um ou mais campo ou índice de categoria, mas não fornece defesa plausível de estratégia de pesquisa com base neste conhecimento, por exemplo, "Eu faria uma pesquisa por palavra... seguido por..." "Eu usaria termos... desta forma".	3: Fraca descrição da estratégia, nenhum nome dado aos rótulos, ou estratégia abertamente equivocada Por exemplo: "Gostaria de usar termos..." [nenhuma descrição da estratégia].		0: Nenhuma compreensão evidente para os artigos "marcados" por diversos campos ou índices.
c: Delimitadores	8: Descreve mais de uma abordagem para a busca de limitação (por exemplo, "limite humano" ou "Inglês" ou "adulto"), nomeia um tipo de publicação específica, ou descrição de consultas clínicas no PubMed, ou o uso de operadores booleanos ou pesquisa combinações ou inclui termos relacionados a um projeto de estudo ideal (por exemplo, ao acaso) ou sugere uso de subposições. * NOTA: Se o assunto inclui o nome do índice ao descrever um delimitador (por exemplo, "verificar a linguagem como Inglês"), então nós damos crédito para um rótulo, assim como a um método de delimitação.	6: Descreve apenas um método comum de limitar a pesquisa. Por exemplo, descreve as formas de estreitar a pesquisa usando palavras-chave, mas nenhuma outra das estratégias listadas.	3: Fornece uma explicação fraca ou descrição do uso de limitadores / estreitamento de busca.		0: Nenhuma técnicas válidas para limitar uma pesquisa listada.

Pergunta # 5: Quando você encontrar um relatório de pesquisa original sobre esta questão, ou quaisquer outras, que características do estudo você vai considerar para determinar se ele é relevante? Inclua exemplos. Questões 6 e 7 irão perguntar a você como determinar se o estudo é válido, e quão importante são os resultados. Para esta pergunta, por favor, concentre-se em como determinar se ele é realmente relevante para a sua prática.

	Excelente	Forte	Limitado	Não evidente
a: A questão	12: Discussão bem-fundamentada e refletida da relevância das variáveis dependentes e independentes utilizadas no estudo, incluindo exemplos / razões específicas. Pode discutir (bem-fundamentada e refletida): • A viabilidade do teste ou intervenção; • "O teste pode funcionar, mas se a minha prática não pode se dar ao luxo de comprar a máquina, não importa"; • O paciente ou doença orientada natureza do resultado; • "Elas medem a capacidade das crianças para usar a função melhorada em atividades lúdicas?" • A congruência entre a definição operacional e o a questão de pesquisa, por exemplo, "Se o seu método de aferição do resultado é uma representação realista do resultado que nos interessa".	9: Menos discussão reflexiva da relevância das variáveis dependentes e independentes utilizadas no estudo. Pode incluir conceitos ou exemplos específicos sem razão clara. Pode referir-se aos mesmos itens listados na "excelente", mas sem demonstrar profundidade de compreensão.	5: Resposta implica na consideração de quão bem o estudo aborda a questão em mãos, mas oferece pouca discussão sobre por que isso pode ser importante, • Por exemplo: "Quais são as variáveis?"; • "Ela respondeu à minha questão?"; • "O desfecho"; • "O propósito do estudo"; • "Impactará minha prática?"; • "Comprimento de acompanhamento".	0: Nenhuma discussão sobre a questão de pesquisa e variáveis utilizadas para respondê-la.
b: Descrição dos assuntos.	12: Inclui ambos: Uma expressão clara da importância da relação entre os sujeitos do estudo e da população alvo. E pelo menos um exemplo de uma doença ou característica demográfica pertinente. • Por exemplo: "Os pacientes eram semelhantes ao meu em termos de idade e raça?" ou • "era um amostra hospitalar ou clínica como os meus pacientes?" ou • "Os pacientes tinham mesmo nível de gravidade da doença como meu paciente?" ou • "fez seleção ou inclusão inadequado de critérios dos resultados em uma população que difere da minha em raça, idade, etc.".	9: Inclui um, mas não ambos: Uma expressão clara da importância da relação entre os sujeitos do estudo e da população alvo, ou pelo menos um exemplo de uma doença relevante ou característica demográfica Por exemplo, "O paciente é como o meu?" ou "o nível de educação da população".	5: Resposta indica a consideração dos sujeitos do estudo, mas não oferece nenhuma discussão sobre a conexão entre sujeitos do estudo e a população alvo ou características específicas da amostra • Por exemplo: "É uma amostra adequada?" ou • "qual foi à resposta ou taxa de participação?" ou • "quais foram os critérios de exclusão?" ou • "viés de seleção" ou • "ajuste" ou • "onde o estudo foi conduzido".	0: Nenhuma discussão sobre as características dos sujeitos de pesquisa.

NOTA: AS RESPOSTAS ÀS PERGUNTAS 5, 6 E 7, PODEM SER APLICADAS A QUALQUER PARTE DA RUBRICA DE CLASSIFICAÇÃO PARA ESSES ITENS

Pergunta # 6: Quando você encontrar um relatório de pesquisa original relacionado à sua pergunta clínica ou quaisquer outras, que características do estudo você vai considerar para determinar se as suas conclusões são válidas? (Você já foi abordado sobre relevância e a questão 7 vai perguntar como determinar a importância dos resultados. Para esta pergunta, por favor, concentre-se na validade do estudo).

	Excelente	Forte	Limitado	Mínimo	Não evidente
a: Validade Interna	24: Lista ou descreve pelo menos 5 questões importantes para a validade interna, tais como: • Adequação do projeto de estudo; • Adequação da cegueira; • Cancelamento de Alocação; • Aleatorização de trabalho de grupo; • Medição inválida ou tendenciosas ("seguido próprio protocolo?"); • Importância do grupo de comparação ou controle; • Intenção de tratar a análise; • Consideração de co-variáveis apropriadas ("foram outros fatores relevantes considerados?"); • Conclusões consistentes com a evidência ("Os resultados fazem sentido?"); • Importância do acompanhamento de todos os participantes do estudo; • Análise estatística apropriada; • Tamanho da amostra /Poder; • Patrocínio; • Quando o estudo foi realizado; • Confirmação com outros estudos; • Medidas de resultado válidas.	18: Identifica 3-4 questões específicas como acima.	10: Identifica duas questões específicas como acima.	5: Menciona validade interna ou um conceito específico da lista de exemplos acima.	0: Nenhum dos presentes acima.

NOTA: AS RESPOSTAS ÀS PERGUNTAS 5, 6 E 7, PODEM SER APLICADAS A QUALQUER PARTE DA RUBRICA DE CLASSIFICAÇÃO PARA ESSES ITENS

Pergunta # 7: Quando você encontrar um relatório de pesquisa original, que se relacione com a sua questão clínica ou quaisquer outras, que características dos resultados você vai considerar para determinar sua magnitude e significância (clínica e estatística)?

	Excelente	Forte	Limitado	Min	Não relevante
a: Magnitude	12: Resposta deve discutir claramente ambos: • Significado clínico ("qual é o significado clínico?" Ou "quão ampla foi à diferença encontrada", a alteração excede MCID) E • Exemplo (s) de tamanho de efeito de medições (por exemplo, especificidade, sensibilidade, razão de probabilidade de um teste, número necessário para tratar, o risco relativo, redução do risco absoluto, diferença média de resultados contínuos, positivo ou negativo, o valor preditivo).	9: Resposta discute um, mas não ambos: • Significado clínico ("qual é o significado clínico?" Ou "quão ampla foi à diferença encontrada?") OU • Exemplo (s) tamanho de efeito de medições (por exemplo, especificidade, sensibilidade, razão de probabilidade de um teste, número necessário para tratar, o risco relativo, redução do risco absoluto, diferença média de resultados contínuos, positivo ou negativo, o valor preditivo).	5: Resposta só sugere uma consideração de significado clínico ou o tamanho do efeito. • Por exemplo: "Será que isso importa?" "será que vai impactar minha prática" ou • Por exemplo: (menciona "mínima diferença clinicamente importante", mas não explica como esse valor seria usado para determinar a significância clínica).		0: Nenhum dos presentes acima.
b: Significância Estatística	12: Discussão refletida e bem-fundamentada dos índices de significância estatística, incluindo pelo menos dois exemplos específicos de importantes conceitos relacionados, tais como: • P- valores; • Intervalos de confiança; • Poder; • Precisão das estimativas; • Erro Tipo 1 ou tipo 2.	9: Lista mais do que um conceito (como acima) com a discussão insuficiente ou ausente (por exemplo, "p-valor e intervalos de confiança") OU Lista e discute apenas um conceito (por exemplo, "p-valor menor que <. 05").	5: Menciona a necessidade de avaliar a significância estatística ou nomeia somente um dos conceitos acima sem mais discussão (por exemplo, "p-valores", "estatisticamente significativos").		0: Nenhum dos presentes acima

NOTA: AS RESPOSTAS ÀS PERGUNTAS 5, 6 E 7, PODEM SER APLICADAS A QUALQUER PARTE DA RUBRICA DE CLASSIFICAÇÃO PARA ESSES ITENS

Pergunta # 8: Para o cenário clínico que você escolheu, liste duas questões que você gostaria de fazer ao paciente / família para obter uma melhor compreensão de suas preferências pessoais e / ou circunstâncias em relação a sua questão clínica.

	Excelente	Forte	Limitado	Mínimo	Não evidente
a: Questão1	8: A pergunta é apropriada para obter informações importantes sobre as preferências do paciente, os valores, as circunstâncias, as expectativas, e / ou motivações que irão impactar diretamente os cuidados clínicos.		4: A pergunta é geral, mas trata de questões relevantes para a compreensão da perspectiva do paciente.	2: A pergunta é geral e não trata de questões específicas para as perspectivas do paciente. Por exemplo: Pergunta padrão de avaliação subjetiva não específica para perspectivas do paciente. Por exemplo: Perguntas sim / não ou factual que não são susceptíveis de trazer à tona detalhes sobre perspectiva do paciente.	0: Nenhuma pergunta ou não uma questão atual • "histórico médico antigo" ou • "preferências"
b: Questão2	8: Mesmo que acima, mas traz à tona informações diferentes do que a primeira pergunta (caso contrário 0).		4: Mesmo que acima, mas traz à tona informações diferentes do que a primeira pergunta (caso contrário 0).	2: O mesmo que acima, mas traz à tona informações diferentes do que a primeira pergunta (caso contrário 0).	0: Nenhuma pergunta ou não uma questão real.

Pergunta # 09: Um estudo sobre a precisão do diagnóstico do teste ergométrico (TE) para o diagnóstico de doença arterial coronariana (DAC) incluiu 96 mulheres com suspeita de DAC, 29 dos quais foram posteriormente determinadas tendo DAC (estenose> 50% em um ou mais vasos coronarianos). Daqueles com DAC, 9 teve um TE anormal. Dos 67 pacientes determinados não tendo CAD, 32 tinham um TE anormal.

*** Texto alternativo utilizando valores de frequência naturais:**

Um estudo sobre a precisão do diagnóstico do teste ergométrico (TE) para o diagnóstico de doença arterial coronariana (DAC) incluiu 120 mulheres com suspeita de DAC, 30 dos quais foram posteriormente determinada tendo DAC (estenose> 50% em um ou mais vasos coronarianos). Daqueles com DAC, 10 tinham uma ET anormal. Dos 90 pacientes determinados não tendo DAC, 30 tiveram um TE anormal.

	Excelente	Forte	Limitado	Mínimo	Não evidente
a: Com base nesses resultados, a sensibilidade do TE para DAC é...	4: 0.31; 31%; 9/29 *4: 0.33; 33%; 10/30	3: Dentro 5%: 26-36%			0: Sem resposta ou resposta errada.
b: Com base nesses resultados, o valor preditivo positivo de TE para DAC é...	4: 0.22; 22%; 9/41 *4: 0.25; 25%; 10/40	3: Dentro 5%: 17-27%			0: Sem resposta ou resposta errada.
c: Com base nesses resultados, a razão de verossimilhança positiva para um TE anormal para DAC é...	4: 0.65; 31/47 *4: 1.0; 0.333/1-0.666	3: Dentro 5%: 0.60-0.70			0: Sem resposta ou resposta errada.

Arredondamento é aceitável (por exemplo 21,9-22 é aceitável)

Pergunta # 10: Um estudo aleatorizado recente de mulheres grávidas com incontinência descobriu que, após o treinamento do assoalho pélvico 20% tinham incontinência, comparado com 32% no grupo controle em três meses após o parto. Nível alfa para o estudo foi estabelecida ao nível de significância de 0,05.

*** Texto alternativo utilizando valores de frequência naturais:**

Um recente estudo randomizado de gestantes com incontinência descobriu que, após o treinamento do assoalho pélvico 20% tinham incontinência em comparação com 30% no grupo controle em três meses após o parto. Nível alfa para o estudo foi estabelecida ao nível de significância de 0,05.

	Excelente	Forte	Limitado	Mínimo	Não Evidente
a: A redução do risco absoluto para eventos recorrentes é...	4: 0.12; 12% *4: 0.10; 10%	3: Dentro 2%: 10-14%			0: Sem resposta ou resposta errada.
b: A redução do risco relativo de eventos recorrentes é...	4: 0.38; 38%; 12/32 *4: 0.33; 33%; 10/30	3: Dentro 2%: 36-40%			0: Sem resposta ou resposta errada.
c: O número necessário para tratar (NNT) para prevenir um evento recorrente é...	4: 9; 1/0.12 *4: 10; 1/0.10	3: Dentro 1: 8-10			0: Sem resposta ou resposta errada.
d: O valor-p indicando diferença estatisticamente significativa entre os grupos seria...	4: <0.05	3: 0.05			0: Sem resposta ou resposta errada.

Pergunta # 11: O mesmo estudo descrito na questão 11 revelou um risco relativo de incontinência de 0,61 para as mulheres que receberam treinamento do assoalho pélvico. Isto sugere que o tratamento treinamento do assoalho pélvico reduz o risco para a incontinência. Gostaríamos de saber se esta diferença é estatisticamente significativa, por isso, olhe para o intervalo de confiança. Dê um exemplo de um intervalo de confiança que suporte a conclusão de que a taxa de incontinência foi realmente (estatisticamente) diferente para estes dois grupos de tratamento.

*** Texto alternativo utilizando valores de freqüência naturais:**

O mesmo estudo descrito na questão 11 revelou um risco relativo de incontinência de 0,66 para as mulheres que receberam treinamento do assoalho pélvico. Isto sugere que o tratamento treinamento do assoalho pélvico reduz o risco para a incontinência. Gostaríamos de saber se esta diferença é estatisticamente significativa, por isso, olhe para o intervalo de confiança. Dê um exemplo de um intervalo de confiança que suporte a conclusão de que a taxa de incontinência foi realmente (estatisticamente) diferente para estes dois grupos de tratamento.

	Excelente	Forte	Limitado	Mínimo	Não evidente
A (resposta)	4: Indicação de que qualquer IC que não inclua 1 indicaria significância estatística.				0: Outros

Pergunta # 12: Qual desenho do estudo é o melhor para um estudo sobre o diagnóstico?

A (resposta)	4: Estudo de Coorte; estudo transversal; comparação com o padrão ouro; revisão sistemática.		0: Outros

Pergunta # 13: Qual desenho do estudo é o melhor para um estudo sobre o prognóstico?

A (resposta)	4: Coorte; prospectivo, longitudinal; Revisão Sistemática.		0: Outros

original article

BJPT Brazilian Journal of Physical Therapy

Analysis of isokinetic muscle function and postural control in individuals with intermittent claudication

Morgan Lanzarin[1], Patricia Parizoto[1], Gilmar M. Santos[1]

ABSTRACT | **Background:** Intermittent claudication (IC) is a debilitating condition that mostly affects elderly people. IC is manifested by a decrease in ambulatory function. Individuals with IC present with motor and sensory nerve dysfunction in the lower extremities, which may lead to deficits in balance. **Objective**: This study aimed to measure postural control and isokinetic muscle function in individuals with intermittent claudication. **Method**: The study included 32 participants of both genders, 16 IC participants (mean age: 64 years, SD=6) and 16 healthy controls (mean age: 67 years, SD=5), which were allocated into two groups: intermittent claudication group (ICG) and control group (CG). Postural control was assessed using the displacement and velocity of the center of pressure (COP) during the sensory organization test (SOT) and the motor control test (MCT). Muscle function of the flexor and extensor muscles of the knee and ankle was measured by an isokinetic dynamometer. Independent t tests were used to calculate the between-group differences. **Results**: The ICG presented greater displacement (p=0.027) and speed (p=0.033) of the COP in the anteroposterior direction (COPap) during the MCT, as well as longer latency (p=0.004). There were no between-group differences during the SOT. The ICG showed decreased muscle strength and power in the plantar flexors compared to the CG. **Conclusion**: Subjects with IC have lower values of strength and muscle power of plantiflexores, as well as changes in postural control in dynamic conditions. These individuals may be more vulnerable to falls than healthy subjects.

Keywords: intermittent claudication; postural control; muscle strength; risk of falls; rehabilitation.

BULLET POINTS

- Intermittent claudication induced decreases in muscular torque and power outputs.
- Subjects with intermittent claudication present deficits of postural control.
- Individuals with intermittent claudication may be susceptible to falls.

HOW TO CITE THIS ARTICLE

Lanzarin M, Parizoto P, Santos GM. Analysis of isokinetic muscle function and postural control in individuals with intermittent claudication. Braz J Phys Ther. 2016 Jan-Feb; 20(1):48-57. http://dx.doi.org/10.1590/bjpt-rbf.2014.0134

Introduction

Falling is a serious problem among the elderly. About a third of the people over the age of 65 years experiences at least one fall per year in developed countries[1]. Ten to twenty percent of these falls cause serious injury and the need for hospitalization[2]. A recent economic health analysis revealed that falls in the elderly represent a significant economic burden for society[3].

The etiology of falls is considered multifactorial, involving extrinsic (environmental) and intrinsic factors[4]. Among the intrinsic factors are the declines in postural control[5], muscle strength[5,6] and deficits in gait[5,7]. Costello and Edelstein[8] stated that the identification of individuals with functional decline of the lower limbs, especially those with impaired balance, might be important when identifying individuals with a higher risk of falling.

A condition typically known to cause detriment in the function of the lower limbs is intermittent claudication (IC). IC is caused by peripheral arterial obstructive problems, which reduces blood flow in the arterial veins and is characterized by pain in the lower limbs and reduced walking ability[9]. In addition, individuals with IC may have a lower functional capacity and decreased muscle strength[10]. Due to the association between circulatory failure and nerve motor dysfunction of the lower extremities[11], it is hypothesized that individuals with IC may be susceptible to balance disorders and to a higher risk of falls.

The correlation between IC and the risk of falls has been explored in the literature, but the results

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Received: Oct. 24, 2014 Revised: Mar. 24, 2015 Accepted: June 15, 2015

are still inconclusive and controversial. Gardner and Montgomery[12] demonstrated that patients with IC presented with balance disorders by demonstrating less time spent in a one-legged stance and a higher prevalence of falls compared to individuals without IC. Additionally, Mockford et al.[13] using computerized dynamic posturography (CDP) showed that IC individuals had higher body sway compared to healthy individuals.

However, Arseven et al.[14] in a prospective study of 86 subjects with IC, found no association between IC decreased postural control and the risk of falls. Moreover, to date we have not been able to find studies that verified the displacement and the average speed of the center of pressure (COP) in the population of IC, parameters traditionally used in the analysis of balance and that are associated with the risk of falls[15].

Since current studies on the topic "risk of falls and intermittent claudication in the elderly population" did not show consistent and satisfactory results, this study aims to determine whether individuals with IC are susceptible to falls through the measurement of postural control and isokinetic muscle function.

Method

Study design and Ethical Aspects

This is an observational, cross-sectional study, with a comparative base (type case and control). This study was approved by the Research Ethics Committee of the Universidade do Estado de Santa Catarina (UDESC), Florianópolis, SC, Brazil, under the number 274951, and registered in the Brazil platform under the number 06677313.0.0000.0118.

Subjects

The study included 32 subjects from both sexes: 16 with IC (average age 64 years, SD=6; average weight 76 Kg, SD=11; average height 1.66 meters, SD=0.06) and 16 healthy participants (average age 67 years, SD=5; average weight 73 Kg, SD=5; average height 1.68 meters, SD=0.11).The participants were matched by age, sex and body mass and allocated in two groups: a group with IC (ICG) and a control group (CG). The sample size was calculated based on the study by Câmara et al.[16], considering 80% of statistical power and 0.05 of significance level. The Gpower3 software (found in web site http://www.gpower.hhu.de) was used for the sample calculation.

The ICG subjects were selected by convenience and recruited at the angiology clinic of the Regional Hospital São José (HRSJ), Santa Catarina, Brazil, using the following inclusion criteria: clinical diagnosis of peripheral occlusive arterial disease (POAD), aged between 60 and 75 years and with IC during the 6 minute walking test. The clinical diagnosis was made by a physician from the angiology unit of the HRSJ using Doppler ultrasound or CT angiography. For the CG, healthy participants with no history of heart disease or peripheral vascular disease previously evaluated by one of the researchers and recruited from the seniors study (NETI) from UDESC, were included.

Asymptomatic individuals with severe POAD and pain at rest, ischemic ulcers or gangrene; clinically unstable (e.g. acute angina, arrhythmia, decompensated congestive heart failure) were excluded from the ICG; and amputees with neurological and orthopedic problems who were unable to perform the tests were excluded from both groups. All study participants were informed about the procedures and signed an informed consent form.

Procedures

The procedures were conducted in two phases. Phase 1 consisted of the application of an evaluation form which contained subject identification, anthropometric data and history of falls, the International Physical Activity Questionnaire (IPAQ)[17] and assessment of the 6-minute walking test[18]. This phase was performed by researcher "A". After this phase, subjects remained at rest for a period of 30 minutes for muscle recovery following the walking test. In phase 2 of the study, data from postural control and muscle strength and power output were collected. The order of testing was randomized by a lottery to eliminate potential bias. This phase was performed by researcher "B".

Six-minute walk test

The 6-minute walk test (6MWT) was used to assess whether subjects could walk the total distance (TD) or the distance that the initial claudication (DIC) occurred. The test was performed according to the American Thoracic Society standards[18], requiring a digital timer (VOLLO - VL-233), two cones, a sphygmomanometer (PALM HT-1500 NISSEI) and a pulse oximeter (Rossmax SB100). The test consisted of walking a route of 30 meters with turns, delimited by two cones, for a period of 6 minutes.

The subjects were instructed to walk as many laps as they could at their normal speed and to inform the evaluator of any sudden onset of pain. At the onset of pain, the distance was measured (DIC) without

interrupting the test. Each individual performed the 6-MWT twice, and the average of the TD and DIC were saved for analysis. The subjects should sit at rest in a chair, located near the starting position, for 10 minutes before the second test starts[18].

Postural control

Postural control was measured by computerized dynamic posturography (CDP), using the Smart Equitest® Neurocom (NeuroCom System Version 8.3.0., 2010 NeuroCom International Inc®, Clackamas, OR). This comprises a standing platform with dual force plates that can be rotated to tip the patient forward and backward (termed as sway-referenced support), or in some cases the force plates can be translated to move the patient toward either an anterior or a posterior direction. The patient's feet are centered on the force plates and then face a brightly colored visual surround that is capable of moving relative to the patient (termed as sway-referenced surround). The CDP included a static equilibrium test (Sensory Organization test-SOT) and a dynamic balance test (Motor Control Test-MCT), both with high sensitivity and specificity for detecting abnormalities of balance[19].

The SOT evaluated the individual's ability to use different postural control systems (i.e. somatosensory, vestibular and visual) in order to keep "in balance" during sensory conflict conditions. The sensory conflicts were produced by visual surroundings or support platform in response to the anterior posterior sway of the patient[20].

The SOT consisted of six conditions, each with duration of 20 seconds and three repetitions. The test conditions were as follows: (1) eyes open, fixed surface and visual surrounding; (2) eyes closed and fixed surface; (3) eyes open, fixed surface and sway referenced visual surrounding; (4) eyes open, sway referenced surface and fixed visual surrounding; (5) eyes closed and sway referenced surface; and (6) eyes open, sway referenced surface and visual surrounding.

The MCT evaluated the postural responses of the individuals according to the platform translations. Translation sequences were applied in small, medium and large amplitudes in an anterior - posterior direction in order to generate automatic postural responses of each individual. The test was repeated three times at each amplitude and the offset distance and exposure times were set at 5, 10 and 15 cm/s and 250, 300 and 400 ms for small, medium and large amplitudes, respectively[20].

Through the MCT, it was possible to measure the latency, which was defined as the time (ms) between the beginning of platform translation and the onset of a motor response by the subject. The motor response was defined as a sudden change in the COP position. The data were recorded from 0.5 seconds before translation until 2 seconds after the task, at an acquisition rate of 100 Hz. The system used four algorithms to calculate the latency time and to identify the quality factor which demonstrated how the four algorithms showed the same result[20].

To perform the CDP, the subjects were informed about the procedure and, with the use of a harness to prevent a fall, were positioned as follows: in the standing position, barefoot on two force platforms and arms by the side. The distance that the feet were apart was standardized by the height of each individual, according to the manufacturer's instructions[20].

Muscular strength & power output

To evaluate muscle strength and power output, the isokinetic dynamometer Biodex System 4 ™ Pro (Biodex Medical Systems, Shirley, NY, USA) was used. The isokinetic evaluation was conducted on the lower limbs, specifically, the knees and ankles. The peak torque, which is the highest peak torque output throughout the range of motion, and muscle power, which is the speed at which the muscles are able to generate work, were measured[21].

For the evaluation of the knee joint, each subject remained seated, attached to the chair of the dynamometer by stabilization straps with knees flexed at 90°. The ankle muscles were evaluated with the patient seated, attached to the chair with one knee flexed at 30° and foot secured to the platform "foot plate", according to the manufacturer's instructions[22]. The mechanical axis of the dynamometer was centralized with the physiological axis of each joint. The subjects were familiarized with the equipment performing three replications for each test position. It was observed 90 second rest periods for muscle recovery before the beginning of the evaluation.

The angular speeds and the number of repetitions of the tests were determined based on previous studies[16,23]. The speed of 60°/s was adopted, with five replications, to determine the peak torque, and the speed of 180°/s was adopted, with 10 repetitions, to measure muscle power for both knee flexors and extensors muscles and the ankle dorsiflexors & plantar flexors muscles. Both tests were conducted in a concentric-concentric reciprocal basis. All participants received verbal

encouragement from one of the trained researchers in order to encourage maximum force production.

Data reduction

The data from the CPD were obtained by the Neurocom Balance System Manager software and later treated in MATLAB (*version 8.0, Math Works, Inc*.) to calculate the total range and average speed of the COP.

The amplitude of the COP was calculated from the distance between the maximum and minimum displacement of the COP in the anteroposterior (ACOPap) and medial-lateral (ACOPml) directions. The average speed of the COP (AS) was calculated from the COP displacement divided by the total time of the trial in the anteroposterior (ASap) and medial-lateral (ASml) directions[24].

Data regarding the peak torque and muscle power were generated by the Biodex advantage software (V.4X) and normalized by the body mass of the participants. There has beenevidence[25] that body mass influences the magnitude of the parameters provided by the isokinetic test. Therefore, it is necessary to standardize the torque and power values by body mass to allow comparisons between individuals.

Statistical analysis

The data obtained from the evaluation form were analyzed using descriptive statistics. The homogeneity of the baseline characteristics between groups, such as age, mass, height and body mass index (BMI) was analyzed by an independent t test.

The dependent variables in this study were the COP displacement amplitudes (ACOPap and ACOPml), the average speeds of COP (ASap and ASml), latency time, peak torque and muscle power. First, these variables were analyzed using descriptive statistics, and normality was investigated using the Shapiro-Wilk test. Since the data showed a Gaussian distribution, the t test for independent samples was used to detect the differences between groups. The significance level was set at 0.05. The Statistical Package for Social Sciences (SPSS) 20.0 for Windows was used to perform the analyses.

Results

Anthropometric and clinical characteristics of the subjects in the study are presented in Table 1. Of note was the significant difference (p=0.001) between the 6MWT, which decreased in the IC group (362.2 m, DP=110 m) relative to the healthy group (547.9 m DP=47 m).

The SOTs showed no evidence of statistically significant differences between groups in the amplitude and average speed of the COP for the six test conditions, as shown in Figure 1. During the MCT, the two translations (anterior and posterior) were evaluated at two intensities (medium and large). There were significant differences in mean posterior translation condition with medium intensity at ACOPap (p=0.027) and at ASap (p=0.033). Additionally, there were significant differences in latency time, it was higher in the ICG (156 ms, SD=17) compared to the CG (140 ms, DP=11) in posterior translation at the larger intensity (p=0.004), as shown in Figure 2.

The ICG showed decreased levels in muscle strength and power output. The results were statistically significant for the peak torque and muscle power in the right plantar flexors (p=0.036 and p=0.037) and left plantar flexors (p=0.008 and p=0.011), respectively, and muscle power of the left dorsiflexors (p=0.025). The extensors and flexors of the knee, in turn, showed no significant differences in peak torque or muscle power, but lower values were observed in the ICG (Figure 3).

Discussion

The present study investigated postural control and muscular torque and power output in individuals with intermittent claudication, factors that may increase the risk of falls. The authors hypothesized that individuals with IC would have a greater deficit of balance and because of that, an increased risk of falls. However, the results of this study led the authors to partially reject the hypothesis. The IC participants showed dynamic postural control changes over the platform only in backward translation at the medium intensity perturbation. The ICG showed higher and faster shifts during this disruption and longer latency during the large translation.

The backward translation of the platform caused the body to oscillate forward due to the displacement of the center of mass anteriorly. To regain balance, the individual needs to reposition the body by shifting his/her center of mass back to the starting position. Research on the elderly[26,27] have shown that this population has a greater displacement of COP during the platform translation. According to Daley and Spinks[28], the largest amplitude displacement

causes slower responses in the recovery of instability, increasing the likelihood of falls.

In order to restore balance after a sudden disturbance of the COP forward (caused by backward translation of the platform), contraction of the posterior muscles of the leg and trunk are necessary. The torque applied around the ankle joint during a disturbance has been described as the first action taken to restore postural control[29]. In addition, two studies have shown that individuals with a significant weakness in their lower limbs[6,30] may show more body sway since they do not generate adequate stabilization torques at the ankles.

The results of this study are consistent with the literature, since people with IC showed decreased peak torque in the ankle plantar flexors. This finding may have contributed to the decline in postural control when balance was perturbed with the translation of the platform. The ability to generate higher torque in the ankle joint has been associated with the ability to reduce the COP excursion[29].

Furthermore, participants with greater rates of generation of muscular power may present better balance performance by having a greater reactive ability to control their center of mass[31]. Muscle power and reaction time have been described as the main parameters for fall prevention[32]. In our study, participants with IC showed statistically significant reductions in muscle power of the right plantar flexors and left dorsiflexors.

It is believed that a decrease in power of the dorsiflexors of only one limb is related to the right-hand dominance of most individuals. Studies have shown that muscle strength has a positive relationship with gait limitations in individuals with POAD[33,34]. It is

Table 1. Anthropometric and some clinical characteristics in subjects with intermittent claudication & normals.

	CI (n=16)	Controls (n=16)	P
Age	64 (6.2)	67.1 (4.9)	0.1
Mass (Kg)	76.3 (11.7)	73.7 (4.9)	0.5
Height (m)	1.66 (0.06)	1.68 (0.11)	0.4
BMI (%)	27.66 (3.7)	25.72 (3)	0.1
Men (%)	14 (87.5%)	12 (75%)	-
Right Dominant (%)	16 (100%)	14 (87.5%)	-
Affected leg			
Both	14 (87.5%)	-	-
Left	2 (12.5%)	-	-
History of Falling	0	0	
6-minute walk test (6MWT)			
DTC - 6 min (m)	362 m. SD=110	547 m. SD=47	0.001*
DCI (m)	261 m. SD=229	-	-
Physical activity level (IPAQ)			
Sedentary	8 (50%)	6 (37.5%)	-
Moderately Active	8 (50%)	5 (31.25%)	-
Active	0	5 (31.25%)	-
Risk factors			
Smokers (%)	14 (87.5%)	10 (62.5%)	-
Smoking load (pack/ year)	41. SD=19	29. SD=9	-
Hypertension (%)	16 (100%)	5 (31.25%)	-
Diabetes mellitus (%)	9 (56.25%)	2 (12.5%)	-
Heart disease (%)	8 (50%)	0	-
Stroke (%)	1 (6.25%)	0	-

*=p≤0.05.

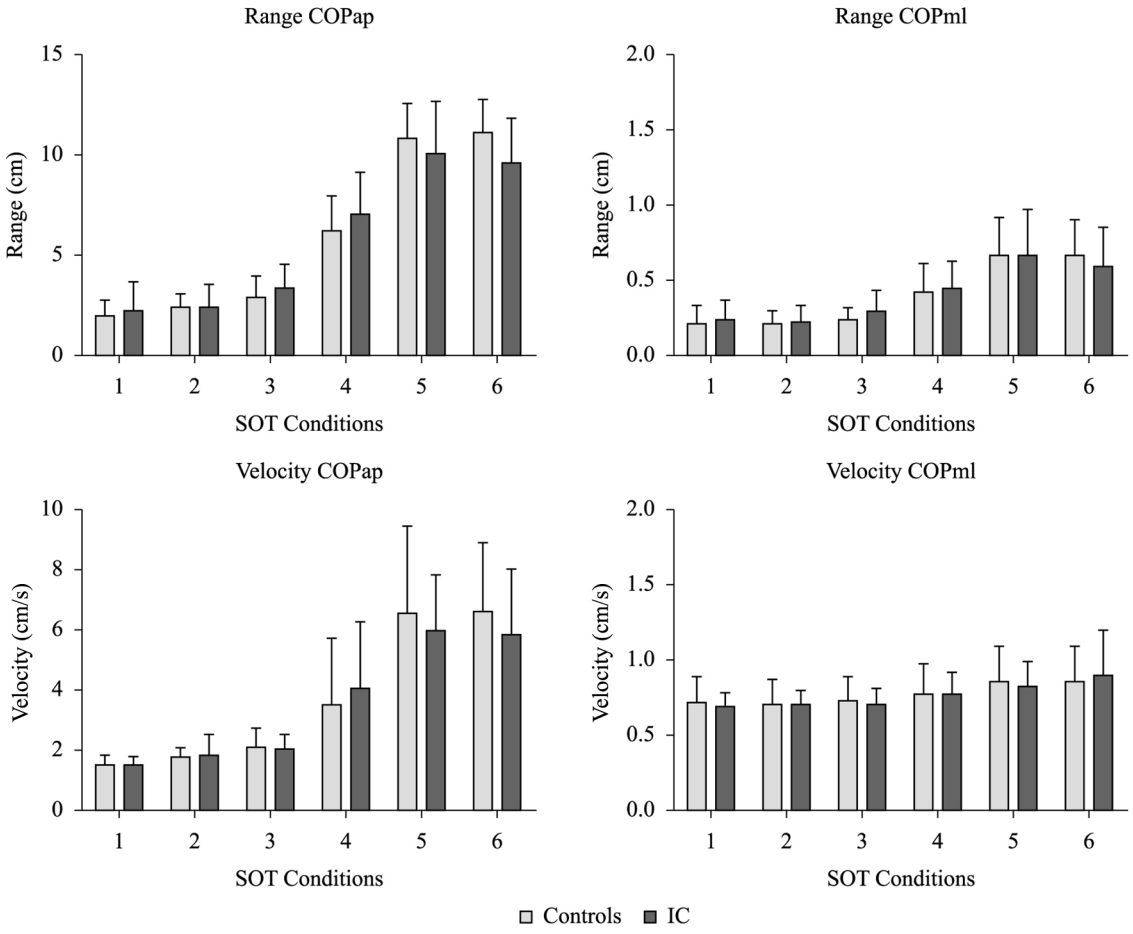

Figure 1. Sensory Organization Test (SOT) – Range and Velocity of Center of Pressure (COP) in the anteroposterior and mediolateral directions. SOT conditions: (1) eyes open, fixed surface and visual surrounding; (2) eyes closed and fixed surface; (3) eyes open, fixed surface and sway referenced visual surrounding; (4) eyes open, sway referenced surface and fixed visual surrounding; (5) eyes closed and sway referenced surface; and (6) eyes open, sway referenced surface and visual surrounding.

known that the dorsiflexors play a fundamental role in locomotion. Thus, a decreased walking speed and lower levels of physical activity could further reduce the overall performance: especially muscle strength[12] and consequently, the power of the non-dominant limb. Nevertheless, it is possible that change in the muscle phenotype may have occurred in the non-dominant limb due to neuromuscular dysfunction, such as atrophy[35]. In this context, Regensteiner et al.[36] showed that in individuals with POAD, there is a 31% reduction in peak torque of the dorsiflexors and a 43% reduction in the plantar flexors when compared to healthy individuals. Thus, it is believed that the lower percentage reduction in the peak torque of the dorsiflexors – compared to the plantar flexors – could also explain the change in muscle power only in the non-dominant leg.

Additionally, the subjects' latency time was higher in the ICG during posterior translation at a higher (large) intensity. The platform translations went from medium to large intensity. The authors believe that the lower displacement speed (10 cm/s) and the exposure time (300 ms) at the medium intensity were insufficient to promote different latency times between the groups. Longer latency times have been associated with peripheral neuropathy[37]. Studies with IC participants had shown the association of IC with peripheral nerve dysfunction[11]. The present results are in agreement with Mockford et al.[13] who assessed 54 subjects with IC using the MCT. They showed an increase in the latency by 24% in IC participants compared to a control group.

Of the six conditions evaluated with the SOT – static equilibrium test – no statistically significant differences

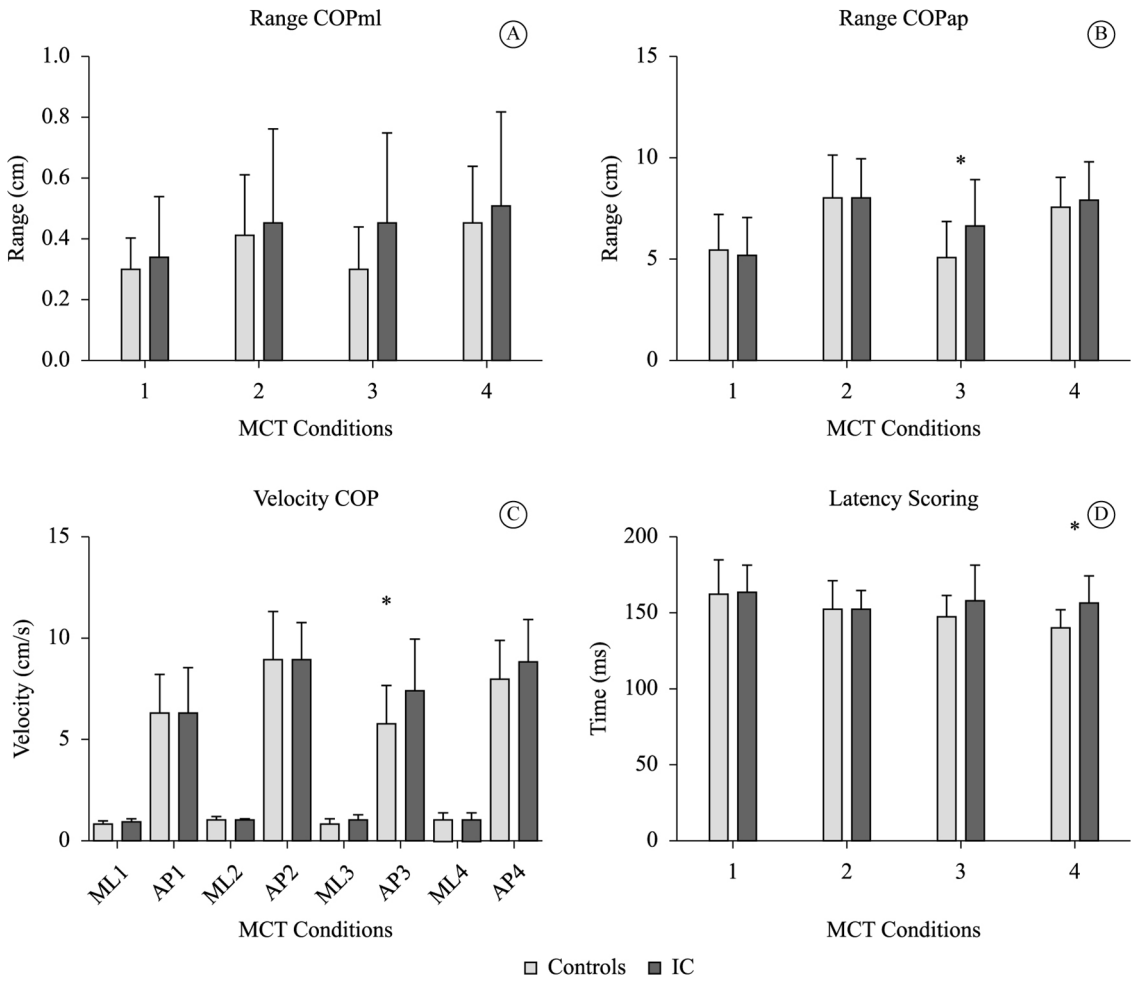

Figure 2. Control Motor Test – Range and Velocity of Center of Pressure (COP). (A) COP range in the mediolateral direction. (B) COP range in the anteroposterior direction. (C) Average velocity of the COP (ML = mediolateral; AP = anteroposterior). (D) Latency Time. Conditions of Motor Control Test (MCT): 1 = medium platform translation forward; 2 = large platform translation forward; 3 = medium platform translation backward and forward; 4 = large platform translation backward and forward. * = $p \leq 0.05$.

were observed in the amplitude and average velocity of the COP between groups. According to Horak et al.[37], dynamic tests are better when differentiating more homogeneous populations than static tests which usually do not require restoring balance. In addition, it is clear that the elderly, particularly those who had fallen, had a higher dependence on a step strategy to maintain and restore balance, (i.e., using the dynamic activity of the lower limbs to protect against falls). Thus, it is understandable that the findings of this study showed no significant difference in the static balance tests.

There are few studies using PDC in individuals with IC. Mockford et al.[13], using the SOT, found alterations in 41% of individuals with intermittent claudication compared to a healthy group. The sensory system with greater impairment was the vestibular (52%), followed by the somatosensory (22%) and the visual (17%). Horak et al.[37] suggested that the information from the somatosensory, visual and vestibular systems is dynamically redistributed to maintain balance. This information should be integrated into the central nervous system (CNS) so that the motor system is able to produce proper muscle contraction. Often, these sensory stimuli are redundant. The abundance of information is important in situations where some of the systems are deficient, so that the remaining systems may compensate for such restrictions[37].

In this study, through the evaluation of some of the risk factors for falls, such as decreased postural control and muscle weakness, it was observed that individuals with IC were more likely to fall than subjects with no

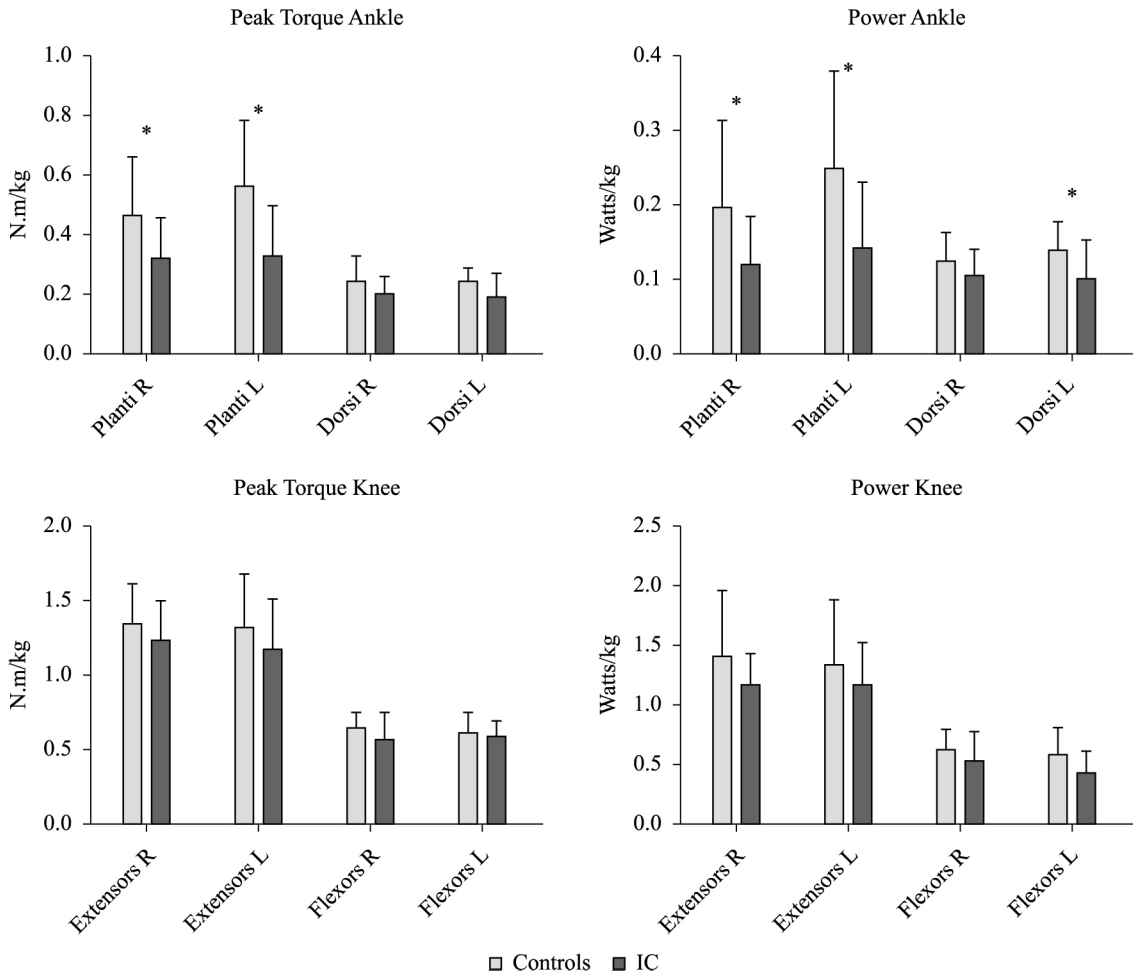

Figure 3. Muscle performance. Peak torque and muscle power of dorsiflexors and plantar flexors in the ankle and the knee flexors and extensors of both limbs (right and left). * = $p \leq 0.05$.

claudication: even for IC participants without history of previous falls. These results are relevant for clinical practice, since a fall may have a great impact on the quality of life of individuals, leading to restriction of physical activity[1] and increased hospitalizations[2]. Therefore, the development of rehabilitation strategies that include ways to minimize the potential for falls in this population is important.

It can be suggested that in addition to decreased strength and muscle power, a low level of physical activity in individuals with intermittent claudication (50% without regular physical activity) may be associated with balance disorders. A recent meta-analysis has shown that regular exercise significantly reduced the rate of falls in the elderly[38].

Finally, some limitations of this study need to be observed. The cross-sectional design does not allow causality to be established. The large proportion of males in the sample can target our findings towards to the male population. Furthermore, the sensory evaluation was not performed to prove proprioceptive deficits in individuals with IC.

For Boucher et al.[39], the sensory information, originating from cutaneous receptors in the plantar region in individuals with peripheral neuropathy, may influence postural control. However, this study showed no significant differences in postural control under conditions 1 and 2 of the SOT. Such conditions evaluated the ability of individuals to use the sensory inputs of the somatosensory system, mainly from the contact of the feet with the support surface to maintain balance. In addition, measurement of cutaneous sensitivity was not our goal in this study, since the Rutherford (gold standard)[40] and ITB (sensitivity of 95% and specificity of 99% for the diagnosis of PAD) classifications were used to categorize the sample, similar to previous studies.

Conclusion

IC is a condition that adversely affects the functional capacity of the individual, such as a decreased walking distance, changes in the level of muscle strength and power around the ankle joint and an impaired ability to regain balance after unexpected disruptions or perturbations. These results indicate that individuals with IC may become more susceptible to falls than individuals without IC.

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original article

BJPT Brazilian Journal of Physical Therapy

Early sensory re-education of the hand after peripheral nerve repair based on mirror therapy: a randomized controlled trial

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ABSTRACT | **Background:** Mirror therapy has been used as an alternative stimulus to feed the somatosensory cortex in an attempt to preserve hand cortical representation with better functional results. **Objective:** To analyze the short-term functional outcome of an early re-education program using mirror therapy compared to a late classic sensory program for hand nerve repair. **Method:** This is a randomized controlled trial. We assessed 20 patients with median and ulnar nerve and flexor tendon repair using the Rosen Score combined with the DASH questionnaire. The early phase group using mirror therapy began on the first postoperative week and lasted 5 months. The control group received classic sensory re-education when the protective sensation threshold was restored. All participants received a patient education booklet and were submitted to the modified Duran protocol for flexor tendon repair. The assessments were performed by the same investigator blinded to the allocated treatment. Mann-Whitney Test and Effect Size using Cohen's d score were used for inter-group comparisons at 3 and 6 months after intervention. **Results:** The primary outcome (Rosen score) values for the Mirror Therapy group and classic therapy control group after 3 and 6 months were 1.68 (SD=0.5); 1.96 (SD=0.56) and 1.65 (SD=0.52); 1.51 (SD=0.62), respectively. No between-group differences were observed. **Conclusion:** Although some clinical improvement was observed, mirror therapy was not shown to be more effective than late sensory re-education in an intermediate phase of nerve repair in the hand. Replication is needed to confirm these findings.

Keywords: hand injuries; peripheral nerve injuries; rehabilitation.

Clinical Trials Identifier: NCT01215760

BULLET POINTS

- Rosen Score represents a combination of motor, sensory, and pain/discomfort domains.
- DASH and Rosen Score are useful for functional assessment following nerve repair of the hand.
- Early sensory re-education after nerve repair in the hand can facilitate functional result.

HOW TO CITE THIS ARTICLE

Paula MH, Barbosa RI, Marcolino AM, Elui VMC, Rosén B, Fonseca MCR. Early sensory re-education of the hand after peripheral nerve repair based on mirror therapy: a randomized controlled trial. Braz J Phys Ther. 2016 Jan-Feb; 20(1):58-65. http://dx.doi.org/10.1590/bjpt-rbf.2014.0130

Introduction

Peripheral nerve injuries of the hand have a high incidence[1] with consequences related to loss of mobility, sensibility, and function[2]. Studies have shown that changes in the cerebral cortex begin within the first minutes after peripheral nerve injury, resulting in an overlap of adjacent cortical areas. These changes occur due to the absence of afferent stimuli in the area of cortical representation of the injured nerve[3]. In order to feed the somatosensory cortex and to preserve the cortical representation of the hand and indirectly facilitate better functional results[4,5], early alternative stimuli have been used such as tactile glove or mirror therapy during the initial sensory loss period.

Mirror therapy combined with conventional rehabilitation is a therapeutic alternative in hand rehabilitation to improve range of motion and

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Received: Nov. 17, 2014 Revised: Mar. 27, 2015 Accepted: July 22, 2015

function in both orthopedic and central nervous system injuries[6,7]. In addition, a sensory and motor re-education program in the early postoperative phase before any re-innervation hypothetically helps to preserve the somatosensory cortical representation of the hand and to reduce or inhibit the cortical reorganization that would occur without early intervention[8-10]. However, there is still a need for studies that address the effect of mirror therapy on nerve repair in the hand.

Therefore, we hypothesized that an alternative stimulus during the early phase after nerve repair in the hand would bring better functional results. Therefore, the objective of this study was to analyze the functional outcome of an early re-education program using mirror therapy compared to a late classic sensory re-education program of up to 6 months for median and ulnar nerve repair in the hand.

Method

Study design

This study was designed as a parallel randomized controlled trial. This trial report followed the CONSORT guidelines[11].

Participants

Participants were of both genders and at least 18 years old. All participants had been submitted to primary repair of the median or ulnar nerves with or without flexor tendon repair and were referred to the study through the Hand Surgery Service of a university hospital from 2009 to 2011. The exclusion criteria were the presence of associated fracture or other chronic metabolic-degenerative diseases related to the peripheral or central nervous system.

Blinding

Randomization was based on a sequence of random numbers generated by Excel®. The allocation was concealed by using sealed opaque envelopes. The treatment groups were classic sensory re-education group and mirror therapy group. All participants received the interventions by three physical therapists. The assessments were also blinded and performed by a physical therapist and an occupational therapist. Two other therapists (one physical therapist and one occupational therapist) coordinated the group, the study design, and the outcome assessment.

Sample size

We calculated that 16 participants were required per group to provide 80% power (Standard Deviation of 0.36 for Rosen score) based on Vordemvenne et al.[12]. The sample size was calculated using Graphpad Statmate (GraphPad Software Inc., San Diego, CA, USA).

Interventions

All patients with associated flexor tendon repair were submitted to early passive mobilization with the modified Duran protocol[13] in a dorsal cast for 4 weeks in a semi-flexion wrist position and fingers in extension. Both groups followed a combined standard increasing home program of active and passive exercises aimed at preventing tendon adhesion and improving passive mobility and grip strength. Desensitization and scar management were conducted in the cases where hyperesthesia and adhesion occurred.

Mirror therapy group

For the mirror therapy group, an early sensory re-education program was initiated in the first postoperative week. A mirror was placed in front of the patient on a table so that the reflected image of the healthy hand looked as if it were the injured hand. Tactile stimuli with several textures and shapes, manipulation of small objects, and active motion on the uninjured hand was performed for 30 minutes a day, 3 times a week, to give the brain the visual illusion of the injured hand. After the cast removal, the procedure was performed bilaterally (Figure 1) for 5 months, in addition to a sensory re-education program. Standard mirror training was performed at home every single day, 30 minutes a day.

Control group

For the control group, classic sensory re-education was initiated only 3 months after nerve repair to the injured hand when protective sensation returned according to the Semmes Weinstein monofilament test and up to 5 months after surgery. This was performed in the same manner by tactile stimuli with several textures and shapes in a progressive and discriminative way, adding the manipulation of small objects, all included in a similar home program.

All participants received a patient education booklet entitled *"Re-educação sensorial" após reparo nervoso,* translated and adapted from the manual *"Sensory re-education" after nerve repair* by Birgitta Rosén of Lund University, Sweden[14]. It contains an

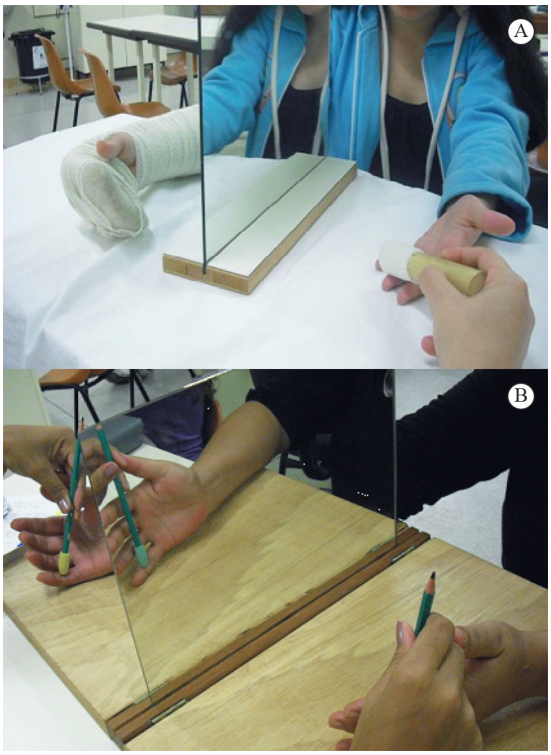


Figure 1. (A) Mirror placed in front of the patient with tactile stimuli with textures on the first post operative week for the Mirror Therapy group; (B) Mirror placed in front of the patient with tactile stimuli with textures after cast removal for the Mirror Therapy group.

illustrated instruction guide with general information about the trauma and rehabilitation process and how to stimulate hand function in daily life activities at home after nerve repair. The early re-education group received this book on the first week, and the control group received it when sensory re-education started 3 months post nerve repair.

Key outcome

The Rosen Score was defined as the primary key outcome and the Disability of the Arm, Shoulder and Hand (DASH) questionnaire as a secondary key outcome. The Rosen score[15,16], ranging from 0 to 3, was collected 3 and 6 months after surgery. The Rosen score is based on A Model Instrument for Outcome After Nerve Repair[15], a valid tool that represents a combination of selected instruments clustered in motor domain (motor innervation and grip strength), sensory domain (sensory innervation, tactile gnosis, and finger dexterity), and pain/discomfort domain (hyperesthesia and cold intolerance). In the motor domain, motor innervation was assessed using manual muscle testing and isometric grip strength was tested with a Jamar® dynamometer. In the sensory domain, sensory innervation (sensitivity threshold) was measured with Semmes-Weinstein Monofilaments SORRI®[17], tactile gnosis was tested with the Shape-Texture Identification test (STI-test™)[18,19] and the Weber DiskCriminator™[20], and finger dexterity was tested with three tasks from the Sollerman grip test (no. 4 - pick up coins, no. 8 - put nuts on bolts, and no. 10 - do up buttons)[21]. In the pain/discomfort domain, hyperesthesia and cold intolerance were assessed by a specific scale.

For function assessment, the DASH outcome measure was used, a self-report questionnaire translated and validated to Brazilian Portuguese[22]. The 30-item instrument evaluates symptoms and physical function on a 5-point Likert scale with total scores ranging from 0 to 100. The higher the score is, the worse the disability.

The present study was approved by the Research Ethics Committee of Hospital das Clínicas de Ribeirão Preto, Universidade de São Paulo (USP), Ribeirão Preto, SP, Brazil, on 03/02/2009 (process no. HCRP 13711/2008). Informed consent was obtained from each subject before participation. This trial was prospectively registered at www.ClinicalTrials.gov (Identifier: NCT01215760).

Statistical analysis

The statistics analysis was performed using SPSS Statistics® software, version 20.0. Shapiro-Wilk test denoted that the Rosen score and the DASH questionnaire deviated from normality. Therefore, the Mann-Whitney test was used for inter-group comparison at 3 and 6 months after intervention (<0.05).

Cohen's d, one of the most standardized measures of the magnitude of an observed effect, was defined for the effect size (ES) calculation using the online ES calculator from the University of Colorado at Colorado Springs: http://www.uccs.edu/~lbecker/. For this study, the benchmarks for effect size were 0.20 = small, 0.50 = moderate, and 0.80 = large[23].

Results

A total of 35 eligible patients volunteered for the trial, but 3 were considered ineligible because of associated comorbidities. Initially, 32 were randomized for Mirror Therapy group (n=16) or Control group (n=16), but 12 discontinued intervention due to transportation/ personal issues. The protocol was completed by 20 participants, whose data were analyzed (Figure 2). Most of the participants worked in heavy manual

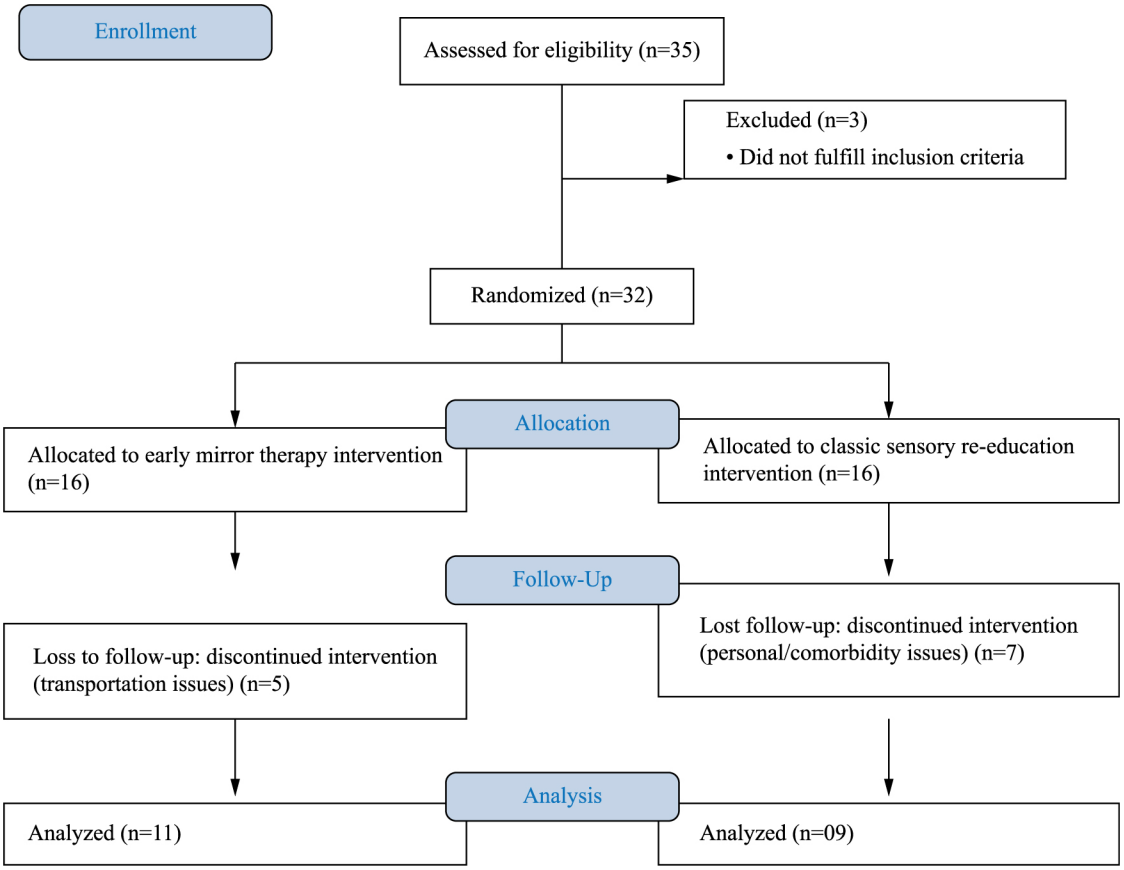


Figure 2. Flowchart of the group randomization of the RCT.

labor occupations (93.3%). Patient demographics are described in Table 1.

The mean scores for the Rosen score and DASH questionnaire at 3 and 6 months for each group are summarized in Table 2. No significant differences were observed for DASH and Rosen scores in the between-group comparison. The total Rosen score and its domains for both groups for 3 and 6 months are presented in Table 3.

Discussion

Our clinical trial did not demonstrate any advantages of Mirror Therapy over classic re-education. This early approach using visual illusion by mirror therapy was implemented in a phase before any re-innervation had occurred and assessed by the Rosen score through its subtests related to the motor, sensory, and pain/discomfort domains. For the classic re-education control group, the Rosen score was even lower for the sensory and pain/discomfort domains after 6 months (Table 3). Rosén and Lundborg[24] also found poor results for this domain after 6 months postoperative. The pain/discomfort domain includes cold sensitivity and hypersensitivity items. Cold intolerance item is often an issue following nerve injuries. To increase validity, a reference score for tropical climate conditions should be developed in comparison to countries with a colder climate.

Outcome measurements following nerve repair provide information about the patients' sensorimotor deficits and function[25,26]. In a systematic review, Jerosch-Herold[27] described a few of sensory tests for nerve repair with sufficient evidence of reliability, validity, and responsiveness. These tests range from a numerical grading scale for peripheral nerve function[28] to a model instrument for documentation after nerve repair that includes sensory, motor, and pain/discomfort outcomes, which together constitute the Rosen score[15,16] used in the present study. A reference interval[24] for recovery after median and ulnar nerve repair in adults can be easily used in clinical practice and in combination with the DASH questionnaire

for functional assessment following nerve injury and repair[27].

Sensory re-education is well established as a therapeutic method for nerve repair[29], however it is not advocated by most therapists[30] as part of early phase retraining with sensory substitution when no re-innervation has occurred. Although few studies have addressed this approach, interest has improved in the area. A study[31] reviewed 67 cases treated with classic sensory re-education and found good recovery of perception of touch but poor ability to use this capacity to identify and discriminate touch (tactile gnosis) 3 months after nerve repair in the hand. In a recent systematic review of clinical trials on the effects of re-education programs in functional hand sensibility after median and ulnar repair, the authors found just one study that investigated early phase retraining using the Model Instrument with moderate evidence in tactile gnosis but not in the composite score[32]. In a multi-center randomized controlled trial, adults with median or ulnar nerve repair at the distal forearm were randomized to mirror visual feedback intervention, and at 6 months, discriminative touch was significantly better in the early intervention group[33], corroborating the data of the present study.

Cortical plasticity is an intrinsic property of the central nervous system. Although cortical plasticity following nerve injury is still not fully understood, peripheral nerve injuries are known to result in "black holes" in somatosensory cortex in primates with changes in representation after a few weeks, depending on external input stimulation[34]. Methods such as mirror therapy[9,10] or sensory glove[5,8] allow early sensory re-education before re-innervation is detected. These concepts aim to facilitate peripheral sensory integration with the cortex area and promote interaction between tactile, visual, and auditory stimuli. Therefore, they are important tools to optimize sensory re-education strategies and maximize the preservation of the hand's cortical map representation in the early phase following injury. In addition to these new rehabilitation and surgical concepts, there is still not a single technique that ensures full recovery of tactile discrimination of the hand in adults following peripheral nerve injury[16]. Therefore, early strategies for sensory re-education, such as the mirror therapy used in this study, could be adopted into the sensory and functional rehabilitation process after nerve repair.

Although our sample was small, it was representative of the profile of this type of injury with complete transection of the median and ulnar nerves[1,2,35,36].

Table 1. Demographic data of study participants in each group.

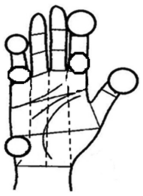
	Control (Classic sensory re-education) (n=09)	Mirror Therapy (n=11)
Age (years)	24.25 (4.8)	29.45 (12.2)
Male Gender (%)	55.5	72.7
Right-handed (%)	77.7	100
Right Affected side (%)	55.5	72.7
Injured Nerve (%)		
Ulnar	44.5	27.3
Median	22.3	54.5
Ulnar and median	33.2	18.2
Location of injury (%)		
Volar aspect of wrist	100	81.8
Palmar aspect of hand/fingers	0	18.2
Type of nerve injury (%)		
Full laceration	100	100
Mechanism of injury (%)		
Glass	88.8	81.8
Saw/knife	0	18.2
Motorcycle accident	11.2	0

Continuous variables are expressed as mean (SD), categorical variables are expressed as percentages.

Table 2. Mean scores (SD and min-max) for DASH and Rosen score for Control classic and Mirror Therapy group after 3 and 6 months.

	Control classic group		Mirror Therapy group		P value for Between-group differences	
	3 months	6 months	3 months	6 months	3 months	6 months
DASH	38.62±27.66 (3.33-100)	27.84±23.35 (2.4-70)	24.25±19.38 (5.8-58.33)	20.34±17.68 (5.8-60)	0.20	0.77
Rosen score	1.65±0.52 (1.11-2.51)	1.51±0.62 (0.71-2.76)	1.68±0.50 (0.78-2.34)	1.96±0.56 (1.00-2.80)	0.82	0.11

Table 3. Protocol for documentation of hand function after nerve repair – total Rosen-Score[15,16] filled with mean scores of domains at 3 and 6 months after nerve repair for control and mirror groups.

Domain	Subtests		Mirror group 3 months	Control group 6 months	Mirror group 3 months	Control group 6 months
Sensory Domain						
Innervation	Semmes-Weinstein Monofilament Test, mini-kit		0.61	0.48	0.81	0.76
	0 = not testable	Results: 0-15				
	1 = filament 6.65 (magenta)					
	2 = filament 4.56 (red 4g)					
	3 = filament 4.31 (violet 2.0g)					
	4 = filament 3.61 (blue 0.2g)	Normal median: 15				
	5 = filament 2.83 (green 0.05g)	Normal ulnar: 15				
Tactile gnosis	2PD (finger II and V)	Results: 0-3	0.26	0.20	0.43	0.34
	0 = ≥16 mm					
	1 = 11-15 mm					
	2 = 6-10 mm					
	3≤5 mm	Normal: 3				
	STI test (fingers II and V)	Results: 0-6 Normal: 6	0.15	0.12	0.23	0.14
Finger dexterity	Sollerman test	Results: 0-12	0.34	0.62	0.53	0.67
	(tasks 4, 8, and 10)	Normal: 12				
Mean score for Sensory Domain:			0.34	0.35	0.50	0.49
Motor Domain						
Innervation	Manual muscle test 0-5		0.57	0.41	0.70	0.50
	Median: palmar abduction	Result median: 0-5				
	Ulnar: abduction fingers II/V	Result ulnar: 0-15				
	Adduction finger V	Normal median: 5				
		Normal ulnar: 15				
Grip strength	Jamar dynamometer in second position Normal: Result uninjured hand Mean of three trials, right and left		0.39	0.34	0.62	0.44
Mean score for Motor Domain:			0.48	0.37	0.66	0.47
Pain/discomfort Domain						
Cold intolerance/ hyperesthesia	Patient's estimation of perceived problems					
	0 = Hinders function	Result: 0-3				
	1 = Disturbing					
	2 = Moderate					
	3 = None/minor	Normal: 3				
Mean score for Pain/Discomfort Domain:			0.86	0.86	0.80	0.65
TOTAL SCORE (Sensory + Motor + Pain/Discomfort):			1.68	1.58	1.96	1.61

Our sample was mostly young and male who suffered cuts from glass. The early sensory re-education group had a predominance of median nerve injuries, which could have brought better sensory and motor results and consequent superior short-term functional outcomes in comparison to ulnar injuries[12].

A limitation of this study is that the assessment was performed only during the first six months following

the nerve repair. Regeneration of the repaired nerve and recovery of function can take several years, and improvements, especially in discriminative touch, have been documented up to at least five years after the repair[37]. A longer follow-up, when touch threshold at fingertip level would be lower, might show more distinct results after early sensory re-education. Other limitations of our study include a high loss to follow-up and absence of intention-to-treat analysis. These two methodological issues are likely to overestimate our results[38,39]. Therefore, caution is needed when interpreting our results.

Conclusion

Mirror therapy combined with an early re-education program was not shown to be more effective than late sensory re-education in the intermediate phase of nerve repair to the hand, based on the functional outcome Rosen Score after traumatic injury of the median and ulnar nerves in adults. Replication is necessary to confirm these findings.

Acknowledgements

Débora Lara Zuza Scheucher and Vanessa Queiroz for helping to provide the interventions and Eula Katucha da Silva Rodrigues for collecting data. This project was supported by Fundação de Apoio ao Ensino, Pesquisa e Assistência (FAEPA) of Hospital das Clínicas, Faculdade de Medicina de Ribeirão Preto da Universidade de São Paulo (HCFMRP-USP), and Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq), Brazil.

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original article

BJPT Brazilian Journal of Physical Therapy

Performance in the 6-minute walk test and postoperative pulmonary complications in pulmonary surgery: an observational study

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ABSTRACT | Objectives: To assess functional capacity in the preoperative phase of pulmonary surgery by comparing predicted and obtained values for the six-minute walk test (6MWT) in patients with and without postoperative pulmonary complication (PPC). **Method:** Twenty-one patients in the preoperative phase of open thoracotomy were evaluated using the 6MWT, followed by monitoring of the postoperative evolution of each participant who underwent the routine treatment. Participants were then divided into two groups: the group with PPC and the group without PPC. The results were also compared with the predicted values using reference equations for the 6MWT. **Results:** Over half (57.14%) of patients developed PPC. The 6MWT was associated with the odds for PPC (*odds ratio*=22, p=0.01); the group without PPC in the postoperative period walked 422.38 (SD=72.18) meters during the 6MWT, while the group with PPC walked an average of 340.89 (SD=100.93) meters (p=0.02). The distance traveled by the group without PPC was 80% of the predicted value, whereas the group with PPC averaged less than 70% (p=0.03), with more appropriate predicted values for the reference equations. **Conclusions:** The 6MWT is an easy, safe, and feasible test for routine preoperative evaluation in pulmonary surgery and may indicate patients with a higher chance of developing PPC.

Keywords: functional capacity; six-minute walk test (6MWT); thoracotomy; pulmonary complications; physical therapy.

BULLET POINTS

- Evaluation can identify risk of postoperative pulmonary complications (PPC).
- The 6MWT is simple to perform and safe for use in the preoperative evaluation.
- Lower than expected 6MWT distance is associated with increased risk of PPC.
- Reference equations seem appropriate to compare predicted and obtained values.

HOW TO CITE THIS ARTICLE

Santos BFA, Souza HCD, Miranda APB, Cipriano FG, Gastaldi AC. Performance in the 6-minute walk test and postoperative pulmonary complications in pulmonary surgery: an observational study. Braz J Phys Ther. 2016 Jan-Feb; 20(1):66-72. http://dx.doi.org/10.1590/bjpt-rbf.2014.0119

Introduction

Postoperative pulmonary complications (PPCs) are common and are a major cause of morbidity and mortality[1]. They are defined as complications that present within 30 days after the surgical procedure and include mechanical ventilation for more than 24 hours, hypoxemia, atelectasis, hemoptysis, empyema, and death caused by heart or respiratory failure[2].

The preoperative evaluation is a fundamental step in identifying risk factors for the development of these complications, which can be related to the patient and to the planned surgical procedure. Tests such as spirometry and arterial blood gases are generally used in the preoperative evaluation of all patients eligible for lung resection, in order to assess the risk of complications and calculate the residual forced expiratory volume in one second (FEV_1) to determine surgical indication. Although FEV_1 obtained by spirometry has been widely used for this risk stratification process, cases of increased risk may require additional tests, such as lung diffusion

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Received: Dec. 16, 2014 Revised: June 08, 2015 Accepted: July 24, 2015

testing (DLCO), and methods to estimate residual postoperative lung function, such as scintigraphy and cardiopulmonary exercise tests[1,3].

Cardiopulmonary exercise testing is considered extremely important in identifying patients at greater risk of complications and mortality, and according to the European functional assessment algorithm, should be performed especially when the predicted FEV_1 or DLCO are below 80%. However, its application is restricted due to the limited availability of the test, which has stimulated the search for methods to provide similar information that is also simpler and more cost-effective[3].

Among the alternatives, the step test, the shuttle walk test, and the six-minute walk test (6MWT) have been studied[1,3]. Despite the satisfactory results found in the performance of these tests, some points related to the methods – especially the control of exercise intensity, the variability of the results, and level of evidence – require a standardization and interpretation of the results obtained by patients[3].

The 6MWT is simple to perform, practical, and does not require special equipment or facilities. The 6MWT is intended to assess, at submaximal levels, exercise walking for six minutes. The test provides an assessment of all systems involved during exercise, including the cardiopulmonary system and the peripheral muscles. As walking is a routine activity and the intensity is defined by the patient, it is usually well tolerated and can be used easily in the preoperative period[4].

The 6MWT follows a standardization proposed by the American Thoracic Society (ATS)[4], which makes it a safer and more reproducible technique, however patients may vary the intensity of exercise, which can lead to different results, even when compared with predicted values, which can be predicted by several reference equations[5-11]. Additionally, since the predicted values were established for the general population, there is no information available about the expected performance of patients in the preoperative phase, which may be compromised by the underlying disease.

The aim of this study was to optimize the care requirements of the population submitted to lung surgery via thoracotomy by evaluating functional capacity prior to surgery using the 6MWT and the predicted values obtained in the reference equations in patients with and without PPC.

Method

This is a prospective observational study, conducted in the years 2012 to 2014, with patients from the Clinical Hospital of Ribeirão Preto Medical School, Universidade de São Paulo (HC-FMRP-USP), Ribeirão Preto, SP, Brazil.

For this research, we initially recruited 69 patients, all with surgical indication of open thoracotomy with or without pulmonary resection, however only 21 were able to participate, as shown in Figure 1.

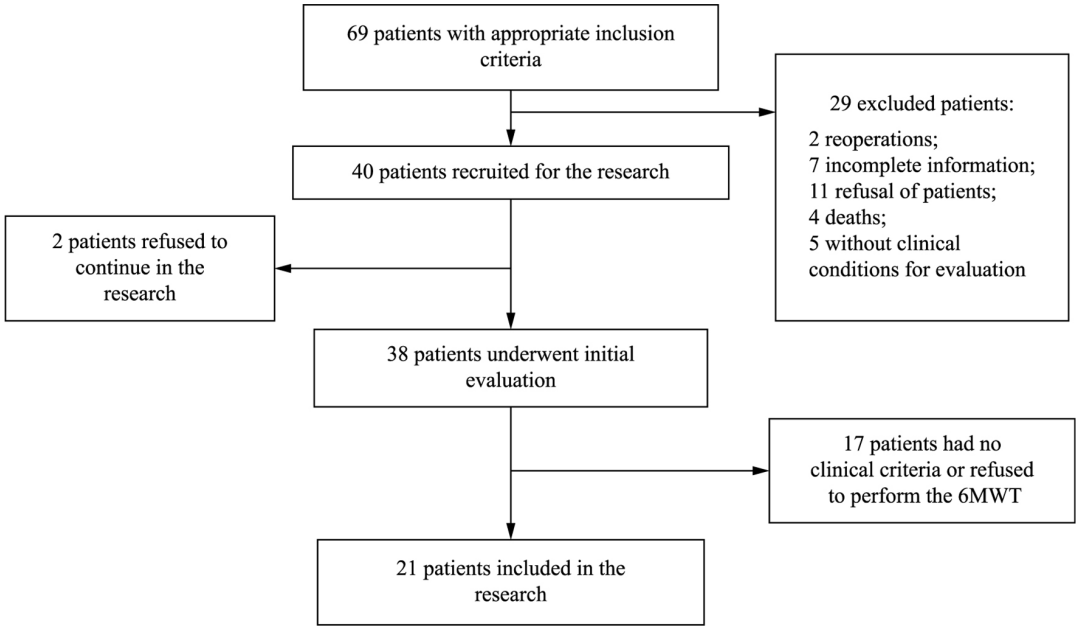

Figure 1. Study flowchart.

Patients were over 18 years old, with the ability to walk, without cognitive impairment, clinically stable, and agreed to participate and signed an informed consent form. The exclusion criteria were as follows: orthopedic disorders; balance disorders; inability to understand commands for testing; or uncontrolled pain.

The evaluation was performed in the preoperative period and included the patient's history, physical examination, and the 6MWT. Before and after the 6MWT, the following measurements were taken: blood pressure; pulse oximetry; heart rate; visual analogue scale (VAS) for pain; and dyspnea level through the Borg scale. In cases of oxygen saturation lower than 85%, the test was interrupted and restarted after the oxygen was supplemented. The 6MWT was performed in a corridor 30 meters long, following the standard established by the American Thoracic Society[4], using a stopwatch, two cones for delimitation of the circuit, one sphygmomanometer (Premium® ESFHS50 model, China), one stethoscope (adult BD®MDF727, United States), and an oximeter (Moriya® MD300C1, China).

During the postoperative hospital stay, patients received routine clinical care and physical therapy. During this period and after hospital discharge, the PPCs developed by patients were recorded. For data analysis, patients were divided into two groups according to postoperative outcome. The first group included the patients who did not develop PPCs, called the group without PPC, and the second group included the patients who developed PPCs, called the group with PPC.

PPCs were considered those complications presented by patients after surgery, such as mechanical ventilation for more than 24 hours, hypoxemia, atelectasis, hemoptysis, empyema, and death caused by heart or respiratory failure[2].

The results were also compared with different equations to predicted values of the 6MWT[5-11]. The equations used were Soares and Pereira[8], Britto et al.[11] (A = model considering heart rate; B = model not considering the heart rate), Dourado et al.[10], Iwama et al.[7], Gibbons et al.[6], and Enright and Sherrill[5], selected because they were taken in groups of the same age group.

The normal distribution of data was assessed using the Shapiro–Wilk test and the results were expressed as mean and standard deviation. The comparison between the groups with and without PPC was made with the application of the unpaired t-test, and the comparison between the values obtained and provided by the various reference equations was performed with one-way ANOVA followed by the Tukey test for multiple comparisons, using Prism software 5®, with a p-value of 0.05.

To examine a possible association with anthropometric data, 6MWT, and FEV_1 (independent variables) with the risk of PPC (dependent variable), the method of simple and multiple logistic regression was used, and the results were presented in odds ratio (OR) using PROC LOGISTIC of SAS® 9.0 software.

The design of this study was approved by the Research Ethics Committee of HCRP and FMRP, Universidade de São Paulo (USP), Ribeirão Preto, SP, Brazil, 043627/2012 process.

Results

Functional capacity was assessed by the 6MWT in 21 patients, 11 females (52.11%) and 10 males (47.61%) in the preoperative period of open thoracotomy. Patients walked an average distance of 375.81 (SD=92.92) meters and had 7.71 (SD=3.10) days of hospital stay. Among these 21 patients, 12 went on to develop PPC (57.14% of participants) after surgery, while 9 evolved without PPC (42.86% of the participants).

The group without PPC had a mean age of 59.22 (SD=8.24) years, comprised 33.33% women and remained 6.11 (SD=1.26) days in hospital after surgery. The surgical procedures were pneumonectomy (1), lobectomy (2), segmentectomy (3), nodulectomy (2), and biopsy (1). The group with CPP had a mean age of 61.41 (SD=7.93) years, comprised 41.66% women and remained 8.91 (SD=3.55) days in hospital after surgery. The surgical procedures were pneumonectomy (1), lobectomy (4), segmentectomy (5), nodulectomy (1), and biopsy (1). The comparison of age, weight, height, and body mass index (BMI) of the two groups showed no statistically significant differences, but there was a difference for the expected percentage of FEV_1 (p=0.04) (Table 1).

The group of patients without PPC walked an average of 422.38 (SD=72.18) meters, while the group with PPC walked an average of 340.89 (SD=100.93) meters. Statistical analysis showed that when comparing the 6MWT, the group without PPC traveled a greater distance than the group with PPC (p=0.02) (Tables 1 and 2 and Figure 2), with an estimated power of 95%.

In the group without PPC, the values were not different from those predicted by the equations. In this group, the percentage of predicted value

ranged 66-83% of the prediction. However, in the group with PPC, the values were different from those predicted by the equations, ranging from 51-69% (p=0.03), except for the values predicted by Gibbons et al.[6] (p=0.09) (Table 2). When the percentages of predicted value by different equations were compared in the groups with and without PPC, the percentage predicted by Gibbons et al.[6] was different from those provided by all other equations (p=0.02) (Table 2).

The evaluation of risk factors for the development of PPC was significant for FEV_1 and 6MWT, with an OR of 0.94 for FEV_1 (p=0.04), while for the performance in the 6MWT, the OR was 22 (p=0.01). Other factors, such as age, sex, and BMI did not significantly correlate with the appearance of PPC (Table 3).

Table 1. Patient characterization and 6MWT in the groups with and without PPC, expressed as a mean and standard deviation.

	Group without PPC	Group with PPC	P value
Age (years)	59.22 (8.24)	61.41 (9.93)	0.78
Gender	6F/3M	5F/7M	-
Weight (Kg)	68.42 (10.49)	73.25 (17.18)	0.69
Height (cm)	160.44 (7.55)	163.25 (10.01)	0.71
BMI (Kg/m^2)	26.70 (4.01)	27.39 (5.17)	0.86
FEV_1 (% of pred)	67.3 (12.8)	82.4 (21.8)	0.04
6MWD obtained (meters)	422.38 (2.18)	340.89 (100.93)	0.02

PPC=postoperative pulmonary complications; F=female; M=male; Kg=kilogram; cm=centimeters; BMI=body mass index; FEV_1=forced expiratory volume in one second; pred=predicted; 6MWT=six-minute walk test.

Table 2. 6MWT values obtained and percentage of the predicted values by different equations in groups with and without PPC.

	Without PPC			With PPC		
	Mean (SD)	CI95%	Obtained vs. pred	Mean (SD)	CI95%	Obtained vs. pred
Obtained (m)	422.38 (72.19)	366.89-477.87	P value	340.89 (100.93)	276.76-405.02	P value
Soares and Pereira[8] (%)	81.25 (16.71)	68.41-94.09	0.22	65.06 (16.95)	54.29-75.83	0.04
Britto et al.[11] A (%)	79.36 (16.77)	76.46-92.23	0.22	62.47 (16.44)	52.02-72.92	0.03
Britto et al.[11] B (%)	79.80 (16.17)	67.37-92.22	0.22	62.84 (17.95)	51.44-74.24	0.03
Dourado et al.[10] (%)	72.88 (16.80)	59.97-85.78	0.22	56.77 (14.68)	47.44-66.10	0.03
Iwama et al.[7] (%)	79.94 (16.70)	67.09-92.76	0.22	62.24 (16.85)	51.53-72.95	0.02
Gibbons et al.[6] (%)	66.53 (14.04)	55.72-77.31	0.22[a]	51.82 (13.87)	43.01-60.63	0.09[a]
Enright and Sherrill[5] (%)	83.74 (17.85)	70.01-77.31	0.22	68.61 (20.01)	55.90-81.32	0.04

6MWT=six-minute walk test; PPC=postoperative pulmonary complications; SD=standard deviation; [a]: Gibbons ≠ all other equations (p=0.02); Britto A and B: equations without and with heart rate, respectively; pred=predicted.

Table 3. Risk factors and development of PPC.

Effects	Odds Ratio	CI95%	P value
Without PPC vs. with PPC	2.667	0.277-25.635	0.40
FEV_1 (%)	0.94	0.89-0.99	0.04
6MWT (m)	22.00	1.86-260.65	0.01
Age	1.04	0.93-1.17	0.52
Gender (F x M)	0.36	0.06-2.16	0.26
BMI	1.04	0.86-1.27	0.69

PPC=postoperative pulmonary complications; FEV_1=forced expiratory volume in one second; 6MWT=six-minute walk test; F=female; M=male.

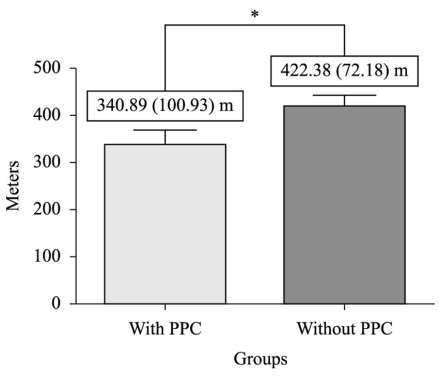

Figure 2. Distance obtained during the 6MWT in patients with and without PPC. *p=0.02; 6MWD=six-minute walk distance; PPC= postoperative pulmonary complications.

Discussion

In this study, the functional performance of 21 patients was evaluated using the 6MWT in the preoperative phase of open thoracotomy. In the postoperative follow-up, the development of PPC and performance in the 6MWT divided the volunteers into two groups. The first group included those with the best performances during the 6MWT who did not develop PPC. The second group included those who had worse performances, walked a shorter distance than that provided by the reference equations, and went on to develop PPC.

Although FEV_1 has also been linked to the PPC, the chance of developing PPC increased as the 6MWD decreased, and these data suggest that the 6MWT, which is easy and simple to execute, can help the physical therapist and the team in planning the postoperative care routine, with more intense care in the group with a lower than expected performance in the 6MWT.

It is important to note that this study did not interfere in the care of these patients, who received the routine clinical care and physical therapy during their hospital stay, and the group that developed PPC comprised 57.14% of the study participants. The definition of PPC differs among authors, but can include an incidence of up to 65% of atelectasis and 20% pneumonia[12]. This rate may be associated with the quality of postoperative care. One study found a low incidence (7.7%) of PPC after lung resection performed by a trained multidisciplinary team[13].

Although spirometry, using FEV_1 and DLCO in the lung, have been suggested since the 1950s as good predictors of PPC, some studies have shown a good correlation between FEV_1 and CPP[2,14-17]. In the study of Stanzani et al.[3], lower FEV_1 values predicted for the postoperative outcome correlated with a higher rate of PPC, although the cardiopulmonary exercise test has been important in identifying patients at high risk. In this context, it would be interesting to identify the 6MWT as a possible substitute for cardiopulmonary exercise testing, mainly due to its lower cost and simplicity.

In this study, the 6MWT and FEV_1 variables correlated with an increased chance of PPC, especially the 6MWT. Subjects who walked way below the predicted distance in the 6MWT showed an increased chance of developing PPC, with an odds ratio of 22, while the decrease in FEV_1 was related to increased PPC with an odds ratio of approximately one. These results suggest that the 6MWT was a better indicator of PPC risk in lung surgery, even considering the large amplitude of the resulting confidence interval.

PPCs are associated with increased hospital costs and greater exposure of patients to infections, in addition to the physical, emotional, and social burden. Preventing the onset of PPC requires interventions and more complex and/or frequent care, especially with regard to physical therapy services, and in this context the inclusion of the 6MWT in the preoperative evaluation could guide physical therapists and all clinical staff regarding which patients are likely to require more intensive or less intensive treatment. However, other studies found no relationship between the risk of developing PPC and performance in the incremental shuttle walk test or the endurance shuttle walk test in pulmonary surgery[2] or between the 6MWT and PPC in abdominal surgery[18].

The 6MWT is widely used in the literature for different purposes, such as measuring response to interventions in patients with heart and pulmonary diseases[4]. A systematic review of the walk test found that the 6MWT was most commonly used in patients with chronic obstructive pulmonary disease (COPD) or heart failure and, less frequently, in cases of surgery[19]. In these studies, the distance traveled was strongly correlated with maximal oxygen uptake (VO_2 max) measured on a bike or treadmill. Some researchers have shown that reduced exercise capacity is associated with a longer hospital stay and costs in patients undergoing lung resection[20-22]. Other authors have shown that when the distance was 300 meters or less, the risk of hospitalization or mortality in patients with heart failure increased[23]. It is noteworthy that the average distance traveled by the group with PPC in our study was 340.89 meters.

The use of the 6MWT for preoperative evaluation involves the use of reference values for comparison between achieved performance and expected values for each individual. According to the guidelines of ATS[4], the values for interpretation of the 6MWT should be based on sex, age, height, and weight of individuals, due to the interference of these variables on performance in the test. Even before the ATS standardization[4] for the 6MWT, Enright and Sherrill[5] published an equation that took into account the height, weight, age, and sex of individuals in relation to the 6MWT. Since then, with the popularization of the 6MWT, other equations for forecasting distance were proposed, and other variables were introduced.

In this study, it was necessary to test which one of the proposed equations to predict the 6MWT would be

better suited to this population. Of the variables used in the equations, age, gender, weight and height, and BMI were the most frequent[5,10,11]. Britto et al.[11] also proposed a second equation model with the change in heart rate between the start and end of the test, the latter equation having a greater affinity with the 6MWT, according to the authors. Soares and Pereira[8] published an equation covering only the age, height, and BMI of the participants, while Gibbons et al.[6] found only age and sex were relevant variables in their work, similarly to that found by Iwama et al.[7], who worked out an equation composed of the variables age and sex.

As for the method used in the studies that resulted in the equations, Iwama et al.[7], Soares and Pereira[8], Dourado et al.[10], and Britto et al.[11], used the standardization of ATS[4] and only Gibbons et al.[6] used a hallway which was far less than 30 meters in length (20 meters used) and held the test three times.

The results showed that the group with PPC had an average walking distance of 340.89 meters, while the group without PPC traveled a greater distance, with an average of 422.38 meters. The performance of the group without PPC was approximately 80% of the values predicted by the equations analyzed in this study (except Gibbons et al.[6]), while the group with PPC averaged less 70% of the predicted values. Comparing the different equations used, proposed by Britto et al.[11], Soares and Pereira[8], Dourado et al.[10], and Iwama et al.[7], the predicted values showed no statistically significant difference, which may suggest that the latter are more appropriate for this population because they were able to predict the expected performance in the 6MWT. Among the equations developed in international research, the equation of Enright and Sherrill[5] was the one with similar results to the Brazilian analyzed equations.

Importantly, the 6MWT requires activity at submaximal level, allowing for a greater variation of performance according to the effort employed by the patient, but the physiological variables were not examined during the test. Another limitation of the 6MWT can be attributed to the fact that equations available in the literature are not prepared based on a population such as that in this study, i.e. with prior disease and surgical indication.

In conclusion, the 6MWT is an easy, safe, and feasible test for routine preoperative evaluation in pulmonary surgery and may indicate patients with a higher chance of developing PPC. The reference equations for the Brazilian 6MWT of Britto et al.[11], Soares and Pereira[8], Dourado et al.[10], and Iwama et al.[7] seem more appropriate for this population, followed by the equation of Enright and Sherril[5].

Acknowledgements

The authors would like to thank Pró-Reitoria de Pesquisa and the Medical School of Universidade de São Paulo, Ribeirão Preto, SP, Brazil, for their support and undergraduate scholarship.

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original article

BJPT Brazilian Journal of Physical Therapy

Reliability of the Brazilian Portuguese version of the Gross Motor Function Measure in children with cerebral palsy

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ABSTRACT | **Objective:** To test the intra- and interrater reliability of the Brazilian Portuguese version of the 66-item Gross Motor Function Measure (GMFM-66). **Method**: The sample included 48 children with cerebral palsy (CP), ranging from 2-17 years old, classified at levels I to IV of the Gross Motor Function Classification System (GMFCS) and four child rehabilitation examiners. A main examiner evaluated all children using the GMFM-66 and video-recorded the assessments. The other examiners watched the video recordings and scored them independently for the assessment of interrater reliability. For the intrarater reliability evaluation, the main examiner watched the video recordings one month after the evaluation and re-scored each child. We calculated reliability by using intraclass correlation coefficients (ICC) with their respective 95% confidence intervals. **Results**: Excellent test reliability was documented. The intrarater reliability of the total sample was ICC=0.99 (95% CI 0.98-0.99), and the interrater reliability was ICC=0.97 (95% CI 0.95-0.98). The reliability across GMFCS levels ranged from ICC=0.92 (95% CI 0.72-0.98) to ICC=0.99 (95% CI 0.99-0.99); the lowest value was the interrater reliability for the GMFCS IV group. Reliability in the five GMFM dimensions varied from ICC=0.95 (95% CI 0.93-0.97) to ICC=0.99 (95% CI 0.99-0.99). **Conclusion**: The Brazilian Portuguese version of the GMFM-66 showed excellent intra- and interrater reliability when used in Brazilian children with CP levels GMFCS I to IV.

Keywords: cerebral palsy; reproducibility of results; performance evaluation; rehabilitation; physical therapy.

BULLET POINTS

- The GMFM is a very important test for the area of child motor rehabilitation.
- Every new version of a measuring instrument must be tested for reliability.
- Brazilian therapists can use the translated version of GMFM with confidence.

HOW TO CITE THIS ARTICLE

Almeida KM, Albuquerque KA, Ferreira ML, Aguiar SKB, Mancini MC. Reliability of the Brazilian Portuguese version of the gross motor function measure in children with cerebral palsy. Braz J Phys Ther. 2016 Jan-Feb; 20(1):73-80. http://dx.doi.org/10.1590/bjpt-rbf.2014.0131

Introduction

The Gross Motor Function Measure (GMFM) is a standardized, valid, reliable, and responsive tool designed to evaluate gross motor function in children with cerebral palsy (CP)[1,2]. This measure has been widely used in research and clinical practice in the field of child rehabilitation in different countries and has served as a reference for the development of other tests and classification systems[3-8].

The GMFM aims to measure gross motor function, to help define therapeutic goals, to record changes over time, to inform caregivers of the progress made in the rehabilitation process, and to enable the development of scientific research studies in the field[1,2]. Following training, the measure should be used preferably by pediatric physical therapists and occupational therapists[1].

The first version of the GMFM consisted of 88 items divided into five dimensions, namely, dimension A - lying and rolling (17 items); dimension B - sitting (20 items); dimension C - crawling and kneeling (14 items); dimension D - standing (13 items); and dimension E - walking, running, and jumping (24 items)[1]. The score of each item is based on a four-point scale, where a score of zero (i.e. "*does*

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Received: Dec. 22, 2014 Revised: June 16, 2015 Accepted: June 24, 2015

not initiate") means that the child is unable to start any activity and a score of three (i.e. *"complete"*) informs that the child completes 100% of the activity tested by the item; intermediate scores (i.e. scores of 1 and 2) describe partial performances of the item[1]. The GMFM includes two types of items, dynamic and static. In the dynamic items, the examiner observes the child's movements (e.g. item 78: *standing*, where the child must kick a ball with the right foot). In the static items, the focus is on the child maintaining the initial position for a specific period of time (e.g. item 39: *the child must maintain the weight on hands and knees for 10 seconds*). The description of the expected behavior for each score is detailed in the GMFM's manual[1]. The scores of all items are added after completing the test and are converted into a percentage performance[1]. The GMFM-88 version is also used to evaluate children with syndromes and other disorders affecting motor development[9-11].

A second version with 66 items (GMFM-66) was developed and tested using the GMFM-88 data from 537 children, making it possible to undertake Rasch analyses and extract a 66-item version[1,12]. The original 88 items were downsized mainly by excluding items from dimensions A (reduced from 17 to four items) and B (from 20 to 15 items)[1]. Rasch analysis redistributed the items over a continuous range of relative difficulty, which enables the professionals using the test to identify items within each child's specific functional range[12,13]. The testing procedures and scoring are conducted as in the longer version. After completing the test, the scores of all items are plotted using the Gross Motor Ability Estimator (GMAE) software, which converts the result into a scale ranging from zero to 100 and provides a map of tested items ranked by the degree of relative difficulty[1].

The GMFM-66 requires a shorter application time (approximately 45 minutes), enables the examiner to calculate the total score, even if some items are not tested, and is the recommended version for research purposes. This new version should only be used with children at levels I to IV of the Gross Motor Function Classification System (GMFCS). Children at level V should only be evaluated using the GMFM-88 because it includes more items of lower complexity[1,2].

The GMFM validation sample was collected in Canada and consisted of 111 children with CP, 25 with brain injury, and 34 children under five years of age with normal motor development[1,2]. Content validity was tested by a group of experts in pediatric developmental assessment, who selected items corresponding to the gross motor skills of a five-year-old child without motor impairment to integrate the test content[1]. Inter- and intrarater reliability values were tested in 12 children with CP and evaluated by six experienced therapists. The results, assessed using the intraclass correlation coefficient (ICC), showed excellent test consistency (ICC=0.99 for both)[1]. Intra- and interrater reliability values were also assessed in each test dimension, with results ranging from 0.87 to 0.99; the lowest values were detected in the interrater reliability of dimension A[1].

GMFM-66 shows psychometric characteristics similar to those of GMFM-88[1,12-14]. The reliability of the new version was tested in some studies and consistently presented excellent estimates. A study conducted by the authors of the instrument[2] on 19 children with CP, who were all evaluated by the same rater, reported an intrarater reliability of ICC=0.99. Wei et al.[15] assessed the GMFM-66 intra- and interrater reliability values of two raters in a sample including 20 children with CP aged between zero and three years and also observed excellent reliability, with ICC=0.97 and ICC=0.98, respectively.

The first requirement for a good standardized test is reliability, that is, the extent to which a measure is consistent and error-free, without which reliable data cannot be collected and inferences cannot be made from the data[16,17]. Reliability is not a fixed feature but is rather the product of interactions between instruments, raters and subjects in the evaluation context[18]. The main types of reliability reported in the literature are interrater reliability, which is the estimate of how consistent the test is when applied by different raters using the same scale to assess the same subjects or objects, and intrarater reliability, which informs on the consistency of scores when individuals are assessed on two or more occasions by the same rater, using the same scale[16-18].

The authors are responsible for providing the initial test validity and reliability data. However, those characteristics are never assessed definitively, as continuous evaluations of psychometric properties are required[17,19]. Evidence of the validity and reliability of an instrument does not guarantee that it will be used validly and reliably, particularly in a population culturally different from the population in which it was developed[17]. Thus, an instrument's psychometric properties must be tested each time a scale is used in a new context or with a different group of people.

The GMFM manual and score sheet were translated into Brazilian Portuguese[20]. To the best of our knowledge, the psychometric properties of the translated instrument have not been tested yet in the Brazilian population, though the original untranslated version is often used in research studies conducted in Brazil[21]. The assessment of GMFM reliability may show local parameters for the use of the instrument in clinical practice and research studies conducted in the country. This study aimed to assess the intra- and interrater reliability values of the Brazilian Portuguese version of the GMFM-66 in CP children with GMFCS levels ranging from I to IV.

Method

Sample

A total of 48 children diagnosed with CP were selected from clinics and rehabilitation centers between January 2013 and July 2014. The study was approved by the Human Research Ethics Committee of Universidade Federal de Minas Gerais (UFMG), Belo Horizonte, MG, Brazil (protocol no. 476.437). The parents or guardians were invited to participate and were informed about the study procedures. Those who voluntarily agreed to their child's participation in the study signed an informed consent form.

Participants were children with CP diagnosis (GMFCS levels I to IV) confirmed by medical report and with the ability to understand and follow simple verbal commands. The sample size was calculated using the equation derived from Pearson's product-moment correlation, as reported by Streiner[22], considering α=0.05, a 95% confidence interval (CI) and an expected ICC>0.90[20], which resulted in 48 children, including 12 in each GMFCS group[17,22].

Four raters also participated in this study, including three physical therapists and one occupational therapist, who work in the field of pediatric rehabilitation. Only one of these raters was experienced in using the GMFM. Three raters had neither experience in using the instrument nor prior access to the English manual, not even during the study.

Procedures

The raters were trained in the use of the GMFM by two therapists with experience using the instrument. The training consisted of reading the manual translated into Portuguese and discussing test application videos with experienced therapists for 12 hours. After training, one of the raters was selected to be the primary rater and to administer the GMFM to all of the children. The other raters watched the footage to assess interrater reliability. The primary rater had previously applied the GMFM-66 to children with normal motor development as a practical exercise to become more familiar with the score sheet and test application guidelines, as suggested by the manual[20].

The evaluations were performed in rehabilitation centers, locations well-known to the children, in spacious rooms at least five meters long, using benches, stairs, a stopwatch, sticks and drawing lines, and circles on the ground to apply specific items[20]. The primary rater evaluated each child only once and filled out the test score sheet at the time of on-site assessment, consulting the manual whenever necessary. The children were evaluated while wearing comfortable clothes and no shoes and without using any assistive devices or orthotics. The items administered to each child were those whose completion was considered feasible by the rater, who allowed three attempts toward identifying the best performance[20].

All evaluations were recorded using a digital video camera according to a predefined standardized method. For most items applied, the camera was placed on a tripod and was positioned between the frontal and sagittal planes, according to the type of movement to be recorded, so that the child's entire body or body part to be examined was visible to the camera. Items requiring a wider camera angle, namely, items including walking, were recorded with the camera on the tripod, and its digital zoom was controlled by a research assistant. Descriptive data were collected on the same day for each child, including gender, age, social class, and GMFCS level. The entire procedure lasted 50 to 60 minutes[20].

To assess intrarater reliability, the primary rater watched the footage and filled out the score sheet again four weeks after the on-site assessment. This period was necessary to avoid recall bias of the on-site assessment scoring[16]. The scores obtained in the assessments were transferred into the GMAE, wherein the final score of the GMFM-66 assessment was generated for each child. To assess interrater reliability, the other three raters received the randomized videos recorded during the assessment of each child, including information on the administered items. The blinded raters, with no access to the sample data (GMFCS and age, among others), watched the footage of the 48 children selected, filled out the GMFM score sheets independently, and entered the data in the GMAE software.

Statistical analysis

All results assessed in the data collection were entered into the Statistical Package for the Social Sciences (SPSS) version 20.0. The values for intra- and interrater reliability regarding the total sample and each GMFCS group were calculated based on the final score generated using the GMAE. The reliability of each GMFM dimension was also calculated based on the net score. A measure of consistency (ICC type 3.1) with two-way mixed analysis[23] was used to assess intrarater reliability. A measure of absolute agreement with two-way random analysis between the scores obtained in the assessments conducted by the primary rater and the other raters (ICC type 2.1)[23] was applied to assess interrater reliability.

The ICC is an estimate ranging from zero (unreliable measure) to one (perfect reliability), assessed by the ratio between inter-group variance (including random error) and total variance. The ICC is a reliability parameter appropriate for measuring the agreement or consistency between two or more interval measures[24]. The results of correlation coefficients are interpreted as follows: weak or no correlation from zero to 0.25; fair correlation from 0.25 to 0.50; moderate correlation from 0.50 to 0.75; and very good to excellent correlation for values higher than 0.75[25]. However, the interpretation of reliability based on the ICC values varies according to the specificity of each study. A more stringent criterion is recommended, considering an ICC minimum value of 0.90, when a test is used for clinical decision-making for individuals with specific health conditions[18,24].

Results

A total of 48 children with CP, aged two to 17 years old, primarily from families of lower socio-economic classes and predominantly with spastic-type of CP, participated in this study. Table 1 outlines the main descriptive characteristics of the sample according to the GMFCS level. The mean scores obtained in the first assessment performed by the primary rater in each GMFCS group indicated that the higher the group severity is, the lower the score obtained in the GMFM-66 will be.

To calculate reliability, 48 on-site assessments and 192 video reviews were performed. Table 2 shows the results of intra- and interrater reliability rates in the total sample, in the GMFCS groups, and in the five dimensions of the GMFM-66. The GMFM-66 scores showed excellent intra- and interrater reliability rates (ICC 0.99 and 0.97, respectively) when the total sample was analyzed. The reliability rates of results assessed in each GMFM-66 dimension were also considered excellent, all with ICC>0.95. The reliability remained excellent in the four GMFCS groups, with the lowest value detected for the intrarater reliability of GMFCS IV (ICC=0.92), which also showed the widest 95% CI (0.72 to 0.98).

Table 1. Descriptive characteristics of the total sample and per GMFCS group.

Description	GMFCS I	GMFCS II	GMFCS III	GMFCS IV	Total sample
Number of children	12	12	12	12	48
Age (mean)	7.75	8.58	8.42	10.41	8.8
Gender (n)					
Female	8	2	6	9	25
Male	4	10	6	3	23
Clinical Type (n)					
Spastic hemiplegia	8	2	0	0	10
Spastic diplegia	4	7	9	2	22
Spastic quadriplegia	0	1	1	9	11
Dyskinetic	0	1	1	1	3
Ataxic	0	0	1	0	1
Mixed	0	1	0	0	1
GMFM-66 mean score	78.53	63.75	53.47	41.21	-

GMFCS=Gross Motor Function Classification System; GMFM=Gross Motor Function Measure; n=frequency.

Table 2. Intra- and interrater reliability rates.

GMFM-66 structure	N	Intrarater reliability $ICC_{3,1}$ (95%CI)	Interrater reliability $ICC_{2,1}$ (95%CI)
GMFM-66 (GMAE) total score	48	0.99 (0.98-0.99)	0.97 (0.95-0.98)
Result per subscale			
Dimension A	48	0.98 (0.97-0.99)	0.95 (0.93-0.97)
Dimension B	48	0.99 (0.98-0.99)	0.96 (0.94-0.98)
Dimension C	48	0.99 (0.99-0.99)	0.99 (0.98-0.99)
Dimension D	48	0.99 (0.99-0.99)	0.99 (0.99-0.99)
Dimension E	48	0.99 (0.99-0.99)	0.99 (0.99-0.99)
GMFM-66 total score (GMAE) per GMFCS			
GMFCS I	12	0.98 (0.95-0.99)	0.93 (0.84-0.98)
GMFCS II	12	0.99 (0.97-0.99)	0.98 (0.96-0.99)
GMFCS III	12	0.99 (0.99-0.99)	0.99 (0.99-0.99)
GMFCS IV	12	0.92 (0.72-0.98)	0.94 (0.84-0.98)

N=number of subjects; GMFM=Gross Motor Function Measure; GMAE=Gross Motor Ability Estimator; GMFCS=Gross Motor Function Classification System; ICC=Intraclass Correlation Coefficients; CI=Confidence Interval.

Discussion

The present study demonstrated that the Portuguese-translated version of the GMFM-66 has excellent intra- and interrater reliability when applied to Brazilian children with CP, GMFCS levels I to IV. This result indicated that the Brazilian version corroborates the reliability rates of the original version of the test, as assessed by Russell et al.[1,2,20].

The GMFM has been translated into different languages in various countries, and the psychometric properties of the translated versions have been consistently assessed[4,15,26]. The interrater reliability of the Korean version was assessed in 39 children with CP by two experienced raters following training to use the test[4]. The Korean version also showed excellent interrater reliability in the GMFM dimensions, with the ICC values ranging from 0.98 in dimension A to 0.99 in dimension E[4]. Subsequently, the same authors assessed the reliability in 84 children with CP through video reviews conducted by 10 therapists who were trained for 30 hours. The authors identified excellent interrater reliability in all GMFM dimensions (ICC values ranging from 0.97 to 0.99) and excellent intrarater reliability (ICC values ranging from 0.99 to 1.00)[27].

Mahasup et al.[26] assessed the intra- and interrater reliability rates of the GMFM in 10 Thai children with CP. Three raters participated in the study, including one experienced in using the GMFM and two raters who read the manual and received training. On-site assessments were performed by the experienced rater and were recorded to enable the other raters to review them and score the children independently using the footage. The study showed excellent intrarater (ICC=0.99) and interrater (ICC=0.93) reliability rates regarding the total sample score[26]. The present study is similar to the others cited above[2,4,26] regarding the sample characteristics of both children and raters and regarding the methods and results. Furthermore, consistency between the literature studies and the present study was also observed in terms of the previous training of raters and the use of the manual during the application of the test[2,4,26,27]. Such methodological consistency enables the comparison of results.

The evaluation of child development using standardized instruments is complementary to purely observational clinical evaluations because such a method is structured toward minimizing subjective interpretations and ensuring the consistency of the results by assessing the psychometric properties of the tests[19]. The reliability of a test refers to its capacity for providing consistent results. Several factors may affect the agreement of scores, including the evaluation setting, the psychological status and age of the examinee, familiarity between examinee and rater and, especially, the knowledge, experience, and skills of the raters[16,17,28]. It is important to conduct studies that evaluate different types of reliability, to cover as much as possible the sources of error[16,17,19]. According to the methodology used in the present study each child was evaluated with the GMFM only

once, this administration was video recorded, and evaluations were scored again from the videotaped assessments. The results showed that examiners trained to look at children with CP on the GMFM items can consistently score them (i.e. interpret the performances). However, our study did not test the test-retest reliability, in which the examiner's ability to apply the test and get a similar performance in the scores would be checked by applying the GMFM more than once to the same individuals under similar conditions. Future reliability studies should investigate the examiner's skill in using the test as a source of variability for the Portuguese version.

The training of raters in the administration and scoring of observational instruments is a major factor in the consistent administration of these instruments and a key strategy for helping to minimize errors[1,19,20]. Russell et al.[28] showed that raters improve the agreement of their scores after GMFM training workshops and that the training process has a greater effect on the ability to learn and administer the test than years of pediatric clinical experience. The sample of raters in the present study included four therapists; three of them, including the primary rater, had no prior experience in using the test and had worked in pediatric rehabilitation for less than one year. However, all raters were properly trained, according to instructions in the manual, by two experienced therapists, and the results indicate that the GMFM-66 can be used by new Brazilian therapists, provided they have received previous training. The study by Ko and Kim[27] assessed the interrater reliability of the GMFM Korean version between one experienced rater and one inexperienced rater and identified excellent reliability in all five GMFCS levels, which corroborates the results from the present study.

The high ICC values measured in this study may also be explained by the use of video footage to assess reliability. The videos enable the raters to watch the items as many times as necessary and to pause the videos to review the scoring guidelines in the manuals, resulting in greater reliability[4]. Video review is a rather objective form of evaluation, wherein the children's performance, rather than their ability to perform a task, is observed[20]. This strategy may be used in both clinical practice and research studies aiming to increase the reliability of assessments using the GMFM.

This study aimed to assess the reliability of the GMFM-66, which is the version that best enables the longitudinal quantification of changes in gross motor function of children with CP[12-14]. The improvement of the test as a longitudinal assessment tool was enabled by the Rasch analysis, which reorganized the items in a continuum of difficulty, showing the hierarchical structure of the instrument and providing information about the prior and emergent motor functions of each child[12]. The Rasch analysis also allowed one of the requirements for using parametric statistical tests in research studies to be met by transforming the GMFM-66 total score into an interval scale[12]. However, the GMFM-66 may only be administered in children with CP, preferably with GMFCS levels I to IV, as in this study sample. The reliability of the GMFM Brazilian version should also be tested encompassing all test items by applying the GMFM-88 to children with different health conditions to whom this version of the test may be applied.

The original GMFM version has been used in Brazilian research studies mainly aimed at assessing the effects of interventions on the motor functions of children with CP[21,29,30]. The translation of the manual and evidence of reliability in the Brazilian population of children with CP will enable the use of this test to be expanded to research and clinical practice. The raters reported no difficulties in using the translated versions, and the training sufficed to apply the test. However, some translation errors were identified by experienced examiners with prior knowledge of the original version. For example, the description of score 3 of one item is defined in the test score sheet as "incomplete" instead of "fully complete", which may confuse the inexperienced rater[20]. Another issue is the lack of translation of the GMAE software into Portuguese, despite coming with the manual, which will require therapists seeking to use the GMFM-66 to have some knowledge of the English language. These and other minor adjustments may be included in the new Portuguese edition of the manual.

Conclusion

The GMFM-66 version, translated into Portuguese, shows excellent intra- and interrater reliability values when used in children with CP between GMFCS levels I and IV and may be used in clinical practice and in research studies on Brazilian children.

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original article

BJPT Brazilian Journal of Physical Therapy

The Brief Kinesthesia test is feasible and sensitive: a study in stroke

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ABSTRACT | **Background:** Clinicians lack a quantitative measure of kinesthetic sense, an important contributor to sensorimotor control of the hand and arm. **Objectives**: The objective here was to determine the feasibility of administering the Brief Kinesthesia Test (BKT) and begin to validate it by 1) reporting BKT scores from persons with chronic stroke and a healthy comparison group and 2) examining the relationship between the BKT scores and other valid sensory and motor measures. **Method**: Adults with stroke and mild to moderate hemiparesis (N=12) and an age-, gender-, and handedness-matched healthy comparison group (N=12) completed the BKT by reproducing three targeted reaching movements per hand with vision occluded. **Other measures**: the Hand Active Sensation Test (HASTe), Touch-Test™ monofilament aesthesiometer, 6-item Wolf Motor Function Test (Wolf), the Motor Activity Log (MAL), and the Box and Blocks Test (BBT). A paired t-test compared BKT scores between groups. Pearson product-moment correlation coefficients assessed the relationship between BKT scores and other measures. **Results**: Post-stroke participants performed more poorly on the BKT than comparison participants with their contralesional and ipsilesional upper extremity. The mean difference for the contralesional upper extremity was 3.7 cm (SE=1.1, t=3.34; p<0.008). The BKT score for the contralesional limb was strongly correlated with the MAL-how much (r=0.84, p=0.001), the MAL-how well (r=0.76, p=0.007), Wolf (r=0.69, p=0.02), and the BBT (r=0.77, p=0.006). **Conclusions**: The BKT was feasible to administer and sensitive to differences in reaching accuracy between persons with stroke and a comparison group. With further refinement, The BKT may become a valuable clinical measure of post-stroke kinesthetic impairment.

Keywords: hemiparesis; upper extremity; somatosensation; proprioception; position sense; measurement.

BULLET POINTS

- Clinicians lack a quantitative measure of upper extremity kinesthetic sense.
- Brief Kinesthesia Test was validated for healthy people across the life span.
- Brief Kinesthesia Test is freely available, quantifiable, merits development.
- Brief Kinesthesia Test is practical, feasible for mild to moderate hemiparesis.
- Identification of kinesthetic impairment will inform hand/arm rehabilitation.

HOW TO CITE THIS ARTICLE

Borstad A, Nichols-Larsen DS. The Brief Kinesthesia test is feasible and sensitive: a study in stroke. Braz J Phys Ther. 2016 Jan-Feb; 20(1):81-86. http://dx.doi.org/10.1590/bjpt-rbf.2014.0132

Introduction

Stroke is a common problem worldwide[1]. More elusive than motor impairment, somatosensory impairment, in at least one modality, affects 67% of individuals with stroke[2]. Post-stroke somatosensory impairment is associated with decreased coordination in reaching and grasping[3], decreased functional mobility, and longer hospital stays[4]. Kinesthesia is the somatosensory modality that includes limb position sense and perception of movement and is a component of proprioception. Recent research using robotics suggests that 61% of individuals with acute stroke have kinesthetic impairment[5]. It is commonly accepted that somatosensation is an important contributor to sensorimotor control mechanisms and recovery from stroke[6]; however, clinicians lack a brief and inexpensive method to quantify the active, behavioral aspect of proprioception – kinesthesia. It follows that practical, quantitative tools are needed to enable clinicians to individualize stroke rehabilitation.

The Brief Kinesthesia Test (BKT) is freely available and takes approximately eight minutes to administer[7]. For this test, error in targeted reaching tasks is measured to evaluate kinesthetic impairment. The BKT was recently shown to be valid and reliable (ICC=0.71) in healthy

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Received: Jan. 26, 2015 Revised: May 21, 2015 Accepted: June 17, 2015

individuals across the lifespan[8]. The objective of this study was to determine the feasibility of administering the BKT and begin to validate it in persons with mild to moderate post-stroke hemiparesis. Here we report BKT scores from a heterogeneous group of persons with chronic stroke and a healthy comparison group and examine the relationship between the BKT scores and other valid sensory and motor measures.

Method

Design and participants

Using a cross-sectional design, we studied a heterogeneous sample of community-dwelling adults with chronic stroke (N=12) who were recruited through word of mouth and through advertisement with local stroke support groups. We also studied an age- (SD= 3 years), gender-, and handedness-matched healthy comparison group (N=12). Recruitment for the study was done via ResearchMatch, a national health volunteer registry that was created by several academic institutions and supported by the U.S. National Institutes of Health as part of the Clinical Translational Science Award (CTSA) program (Table 1). Inclusion criteria were a single diagnosed stroke greater than three months prior to enrollment; mild to moderate hemiparesis defined as greater than 10 degrees active extension in the contralesional fingers and wrist (required for manipulation of test objects); 45 degrees active elbow and shoulder flexion[9]; and communication in English. Potential participants were excluded if they scored less than 24 on the Mini-Mental State examination (MMSE), indicating potential difficulty following instructions; demonstrated severe spatial neglect on Albert's test[10]; demonstrated apraxia as determined by object naming on the MMSE; or reported another neurologic or sensory disorder such as Parkinson's disease or peripheral neuropathy. One control participant was excluded who reported a history of peripheral neuropathy. Participants provided written informed consent prior to participation. The Biomedical Institutional Review Board of The Ohio State University, Columbus, OH, USA, approved this study (approval number 2011H0029).

The Brief Kinesthesia Test and other measures

The BKT was administered with the participants seated in a standard height chair (19 inches) in front of a standard height table (29 inches) with vision

Table 1. Demographic and clinical characteristics of participants.

ID	Age	Sex	Dom. Hand	Most Affected Hand	Chronicity (Months)	Lesion vascular distribution/location	BKT (cm) contralesional/ ipsilesional	Wolf (Rate metric/60 sec.)	BBT	MAL HM/HW
011	64	M	R	R	20	Lacunar/ thalamus	10.8/11	19.8	4	0.73/0.85
012	62	M	R	L	16	Lacunar/ PLIC	5.2/7.4	35.6	29	3.16/3.76
013	39	F	L	R	4	Lacunar/ thalamus	12.4/3.2	18.34	27	1.85/3.08
014	61	F	R	L	24	Lacunar/ thalamus	10.8/5.5	33.91	29	2.5/2.8
015	77	F	R	R	8	MCA/ frontal	5.8/3.4	41.88	40	4.83/4.42
016	70	M	R	L	21	Lacunar/ thalamus	4.9/7.1	53.9	52	5/5
017	60	F	R	L	94	MCA/ parietal	8/7.3	23.01	36	2.62/2.5
018	85	F	R	L	38	Lacunar/ PLIC	6/6.6	42.81	46	4.53/4.9
019	65	M	R	L	41	Lacunar/ PLIC	10.6/7.3	24.27	19	1.61/1.37
020	71	F	R	L	8	MCA/ frontal	6.6/6.9	38.5	39	3.71/3.96
021	69	M	R	R	9	MCA-ACA/ frontal	NA/5.9	1.97	0	1.83/1.33
022	48	F	R	R	13	MCA/ corona radiata	4.4/5.7	27.08	52	3.78/3.93
Mean	64	7F/ 5M	11R/1L	7L/5R	25	NA	7.8/6.4	30.09	31	3.01/3.16
Comparison (n=12)	64	7F/ 5M	11R/1L	NA	NA	NA	4.2/4.9*	NA	NA	NA

R: Right; L: Left; NA: Not Applicable; MCA: Middle Cerebral Artery; PLIC: Posterior limb of the internal capsule; ACA: Anterior cerebral artery; BKT: Brief Kinesthesia Test; Wolf: Wolf Motor Function Test; BBT: Box and Blocks Test; MAL: Motor Activity Log; HM: How much scale; HW: How well scale. *scores from the matched upper extremities of the healthy control participants.

occluded by a curtain. Participants reproduced targeted reaching movements from a starting location to a target location on a test page after being guided by the examiner (Figure 1A). The distance from the response location to the target location was recorded in centimeters. Additional equipment needed to administer the BKT includes a visual shield (Figure 1A) and a tape measure. There were three trials per hand (two longer reaches and one shorter reach) as can be seen on the test page in Figure 1A. The BKT took an average of 8 minutes to administer including set-up. Our feasibility outcome for the BKT was whether or not participants, who met our criteria, could complete the test with standard administration[7]. Our criteria for feasibility was 90% of participants completing the test. The BKT score used here was the sum of the distance from the target in centimeters for the two longest reaches for each hand, as originally published by Dunn et al.[8] (Figure 1B).

Other measures collected and the construct they measure are listed here. The Hand Active Sensation Test (HASTe), a measure of haptic performance of the hand, includes trials of weight and texture discrimination[11]. The Touch-Test™ monofilament aesthesiometer is a measure of sensitivity to touch[12], and the 6-item Wolf Motor Function Test (Wolf)[13] quantifies upper extremity motor ability through timed and functional tasks. Wolf scores are reported using the rate metric proposed by Hodics et al.[14], that is, the number of times on average a participant could perform the tasks in one minute. The Motor Activity Log (MAL) assesses daily use of the affected upper extremity and is based on subjective rating of how much and how well the extremity performs common

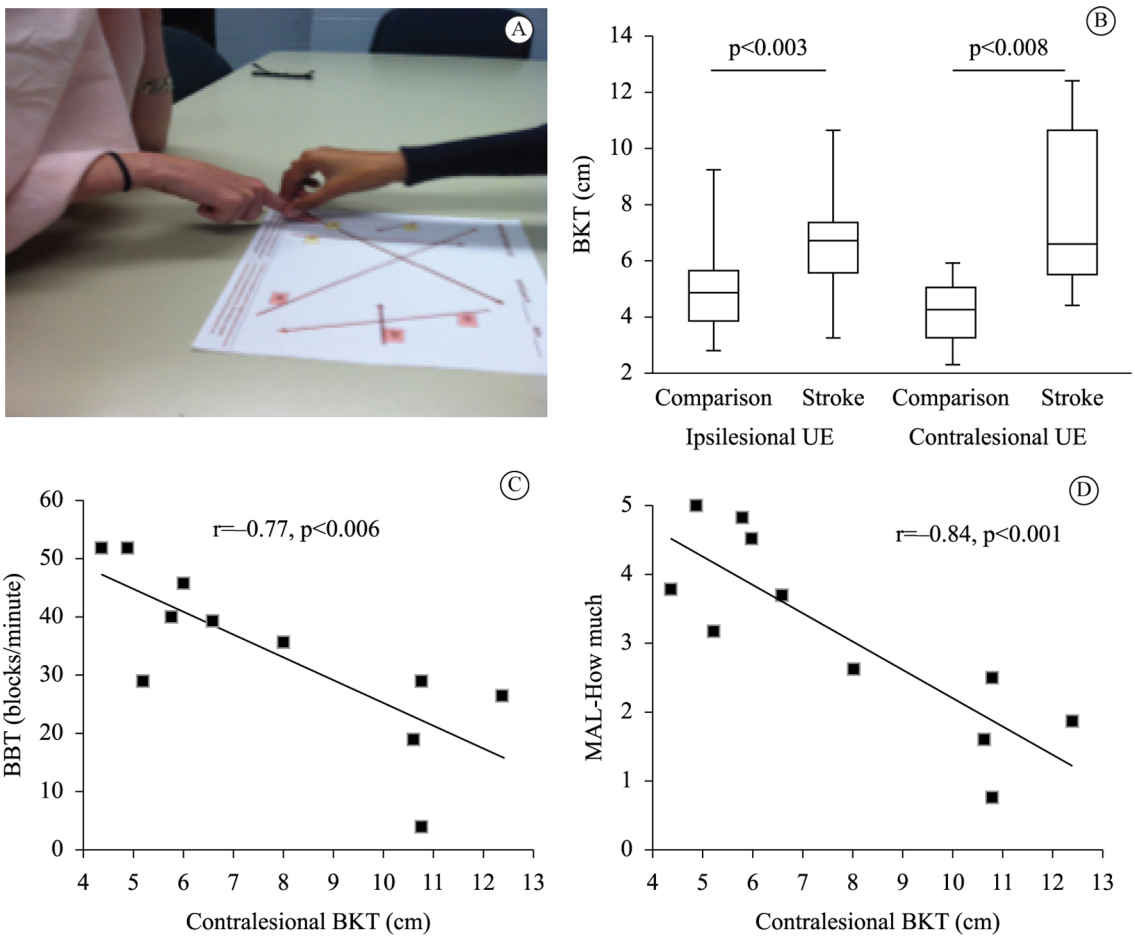

Figure 1. A: BKT set-up example. B: Box plot of BKT scores (sum of the error in centimeters for the two longest reaches) for ipsilesional and contralesional upper extremity (UE). C: Pearson correlation coefficient of 0.77 (p=0.006) indicates a strong relationship between the Box and Blocks Test (BBT) and the BKT. D: Pearson correlation coefficient of 0.84 (p=0.001) indicates a strong relationship between the Motor Activity Log (MAL)-How much scale and the BKT.

tasks[15]. The Box and Blocks Test (BBT) is a test of manual dexterity in which individuals transfer 1-inch blocks from one side of a partitioned box to another. The BBT score is the number of blocks transferred in one minute[16]. Bilateral upper extremities of participants were tested on a single occasion by one examiner. For consistency, the following order of testing was used for all participants: Touch-Test™, BKT, HASTe, BBT, Wolf, and MAL. When both hands were tested, the less affected or dominant hand were tested first.

Statistics

A paired t-test was conducted to compare BKT scores between post-stroke and comparison groups. The alpha was set at $p \leq 0.05$. Pearson product-moment correlation coefficients were computed to assess the relationship between BKT scores and sensory and motor measures. We used the Portney and Watkins criteria for interpretation[17]. The relative standard error of the mean (RSEM) was calculated to describe the variability of the BKT scores in our sample. The magnitude of difference between post-stroke and comparison groups for BKT scores for both upper extremities was calculated using effect size. All data were analyzed using JMP® Pro 11.0.0.

Results

Demographic and clinical characteristics are given in Table 1. One post-stroke participant out of 12 was unable to complete the BKT with their contralesional upper extremity (UE); therefore, the feasibility criterion of 90% was met. BKT scores for both stroke and comparison groups were normally distributed. Regarding variability in BKT scores, the RSEM for the post-stroke group contralesional and ipsilesional and for the comparison group contralesional and ipsilesional were 11%, 9%, 8%, and 10%, respectively. Contralesional UE scores for the post-stroke group (n=11, $\bar{x}$=7.8 centimeters (cm), SD=2.9, 95% CI=5.8-9.7 cm) and the comparison group (n=12, $\bar{x}$=4.2 cm, SD=1.2, 95% CI=3.4-4.9 m) were statistically different. The mean difference between groups was 3.7 cm (SE=1.1, t=3.34; p<0.008). Cohen's effect size value (d=0.96) suggests a large practical difference between groups. Ipsilesional UE scores for the post-stroke group (n=12, $\bar{x}$=6.4 cm, SD=2.0, 95% CI=5.2-7.6 cm) and the comparison group (n=12, $\bar{x}$=4.9 cm, SD=1.7, 95% CI=3.8-6.0 cm) were also statistically different. Here the mean between group difference was 1.5 cm (SE=0.6, t=2.49; p=0.03). Cohen's effect size value (d=.47) suggests a low to moderate practical difference between groups. Contralateral UE BKT scores strongly correlated with the MAL-how much (r=0.84, p=0.001), the MAL-how well (r=0.76, p=0.007), Wolf (r=0.69, p=0.02), and the BBT (r=-0.77, p=0.006) but did not correlate with HASTe (r=0.355, p=0.29) or Touch-Test (r=0.095, p=0.77). In a previous study, the 95% confidence interval for BKT scores in healthy participants in the age range of our participants was 5.0 – 5.87 cm[8]. Given this, 58% of our post-stroke participants were outside of this range with their contralesional UE, while 50% were outside of this range with their ipsilesional UE.

Discussion

Data from this preliminary study suggest the BKT is feasible to administer and may be a useful tool to identify kinesthetic impairment in individuals with mild to moderate post-stroke hemiparesis. To our knowledge, this is the first report of a clinically practical tool with the potential to quantify UE kinesthesia post-stroke. Kinesthetic awareness informs movement; therefore, it is not surprising that a strong relationship was identified between the BKT and participants' subjective rating of how well their arm performs tasks (MAL) and the objective measures (Wolf and BBT). It is also possible that a participant's ability to generate motor output affected the BKT scores in this study. Determining the discrete somatosensory and motor contributions to this sensorimotor task is an area for future research.

Post-stroke somatosensory impairment is difficult to recognize unless the loss is profound. The nature and extent of post-stroke somatosensory impairment has been difficult to describe due to a variety of factors including: 1) stroke heterogeneity; 2) multiple somatosensory modalities; 3) multiple body areas effected; and 4) scarce quantitative measurement tools. Our finding that BKT was not related to touch perception or haptic performance is consistent with evidence that there is low agreement between modalities in post-stroke somatosensory impairment[18]. Touch perception threshold is low in the somatosensory hierarchy[19] and reflects cutaneous receptor function of the index finger without a movement requirement. The HASTe is a measure of haptic performance, which requires cutaneous receptors of the hand, proprioceptive receptors of the UE, and active movement and is an example of a higher-level somatosensory process[19]. The BKT would also be considered higher level, given that scaling of distances is required with proprioception of the UE and active movement is essential to the task.

Therefore, while the BKT shares with the HASTe the requirement of UE proprioceptive information, it differs from both other somatosensory measures used here in that cutaneous input will not drive performance. As with all studies of this size, interpretation should be done with caution.

In comparison to the commonly used method of joint position matching[20], the BKT has the following advantages. First, the BKT has a ratio scale of measurement. BKT scores from this study were normally distributed and ranged from 3.2 to 12.4 cm error for post-stroke and from 2.3-9.2 cm error for comparison participants. Ratio scales of measurement are unambiguous and allow all mathematical and statistical operations[17]. Second, normative data are available by age group[8], eliminating the need to compare to the ipsilesional extremity, which may be problematic as discussed below. In comparison to robotics[5], the primary advantage of the BKT is that it is freely available and does not require special equipment to administer, therefore being practical for therapists in settings worldwide. The primary disadvantage is that the BKT scores are based on localization of the target; other metrics that may reflect kinesthesia, such as velocity of movement and smoothness of reaching trajectory and response latency, are not quantified with the BKT. Comparisons in larger studies using a gold-standard measure of kinesthetic impairment, such as robotics[5], are needed to further validate the BKT as a method of quantifying post-stroke kinesthesia.

Importantly, the exact contribution of motor and somatosensory impairment to BKT scores in this study is uncertain. This is the primary limitation of attempting to quantify kinesthetic impairment using a targeted reaching task in this population. This limitation applies to simple tests, such as the BKT, as well as to sophisticated approaches such as robotics[5]. After stroke, poor reaching accuracy may be due to limited motor output versus poor control of movement secondary to impaired kinesthetic sense, the latter being what we aim to quantify with the BKT. One participant who met the criteria for this study was unable to perform the BKT due to insufficient motor ability to reach across the test page, highlighting this circumstance. We suggest this limitation can be addressed by establishing minimum motor criteria for the BKT. Minimum motor criteria would establish that an individual possesses the motor ability to perform the reach, ideally leaving kinesthetic sense as the primary variable captured. The extent to which standardized table and chair heights affected BKT scores in this study is unknown. A limitation of this particular study is the small sample size; therefore, the results may not generalize to the population of individuals with mild and moderate stroke.

As a group, post-stroke participants in this study also performed significantly more poorly on the BKT with their *ipsilesional* UE than the comparison group suggesting that the BKT may be sensitive to subtle ipsilesional changes in kinesthetic awareness (Figure 1B). Ipsilesional impairment in sensorimotor performance[21], manual dexterity[3], ipsilesional reaching[22], and grip force modulation[23] have also been reported after unilateral stroke. While we can only speculate as to the sensorimotor processing problem that causes ipsilesional impairment, these data and other studies[5,21] suggest that bilateral hemispheres likely contribute to normal kinesthetic performance. Additionally, these data call into question the concept of an 'unaffected' UE and highlight the importance of using healthy comparison groups for normative UE performance data.

The BKT has the potential to be a useful clinical tool with some additional development. Advantages of the BKT include that it is inexpensive, standardized, quantifiable, and quick to administer. The results from this study do not suggest there is a ceiling effect, unlike the Nottingham Sensory Assessment and the Fugl-Meyer Assessment[24]. Low RSEM values suggest BKT scores may provide a relatively precise estimate of the population. The simple instructions may limit the potential for confounding by cognitive impairment seen with other somatosensory measures. Future research should be directed at establishing validity, reliability, and the minimum clinically important difference in the post-stroke population. Minimum motor criteria should be established. Also of interest is whether BKT scores would be useful to predict motor recovery from stroke and whether the measure will be sensitive to change following UE rehabilitation.

The implications for improving identification of post-stroke kinesthetic impairment include enhanced understanding of the impairments that result in disordered reaching, improved assignment of rehabilitation treatments, and possible prediction of motor recovery. The data from this preliminary study suggest that, with further refinement, the BKT may emerge as a valuable clinical measure of kinesthetic awareness post-stroke.

Clinical message

Inexpensive and quick to administer, the BKT may become a valuable clinical measure of post-stroke kinesthetic impairment.

Acknowledgements

This study was supported by the OSU CCTS grant number UL1TR001070, and OSU Neuroscience Signature program and by The Foundation for Physical Therapy through an award to Dr. Borstad.

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original article

BJPT Brazilian Journal of Physical Therapy

Relationships between static foot alignment and dynamic plantar loads in runners with acute and chronic stages of plantar fasciitis: a cross-sectional study

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ABSTRACT | **Background:** The risk factors for the development of plantar fasciitis (PF) have been associated with the medial longitudinal arch (MLA), rearfoot alignment and calcaneal overload. However, the relationships between the biomechanical variables have yet to be determined. **Objective:** The goal of this study was to investigate the relationships between the MLA, rearfoot alignment, and dynamic plantar loads in runners with unilateral PF in acute and chronic phases. **Method**: Cross-sectional study which thirty-five runners with unilateral PF were evaluated: 20 in the acute phase (with pain) and 15 with previous chronic PF (without pain). The MLA index and rearfoot alignment were calculated using digital images. The contact area, maximum force, peak pressure, and force-time integral over three plantar areas were acquired with Pedar X insoles while running at 12 km/h, and the loading rates were calculated from the vertical forces. **Results**: The multiple regression analyses indicated that both the force-time integral (R^2=0.15 for acute phase PF; R^2=0.17 for chronic PF) and maximum force (R^2=0.35 for chronic PF) over the forefoot were predicted by an elevated MLA index. The rearfoot valgus alignment predicted the maximum force over the rearfoot in both PF groups: acute (R^2=0.18) and chronic (R^2=0.45). The rearfoot valgus alignment also predicted higher loading rates in the PF groups: acute (R^2=0.19) and chronic (R^2=0.40). **Conclusion**: The MLA index and the rearfoot alignment were good predictors of plantar loads over the forefoot and rearfoot areas in runners with PF. However, rearfoot valgus was demonstrated to be an important clinical measure, since it was able to predict the maximum force and both loading rates over the rearfoot.

Keywords: plantar fasciitis; foot; plantar arch; physical therapy; overload; running.

BULLET POINTS

- Elevated arches predict higher forefoot pressures in runners with PF, regardless of its stage.
- Rearfoot valgus alignment predicts higher rearfoot dynamic loads in runners with PF.
- Conservative interventions to control rearfoot alignment and support the plantar arch may improve the plantar load distribution, independent of the PF stage.

HOW TO CITE THIS ARTICLE

Ribeiro AP, Sacco ICN, Dinato RC, João SMA. Relationships between static foot alignment and dynamic plantar loads in runners with acute and chronic stages of plantar fasciitis: a cross-sectional study. Braz J Phys Ther. 2016 Jan-Feb; 20(1):87-95. http://dx.doi.org/10.1590/bjpt-rbf.2014.0136

Introduction

Foot types and repetitive plantar loads have been commonly associated with lower limb injuries, especially running-related injuries[1], such as medial tibial stress syndrome[2], patellofemoral pain syndrome[3], and plantar fasciitis (PF)[4-6]. Among them, PF is a musculoskeletal disorder characterized by pain at the plantar fascia insertion point[7]. PF is considered to be the third most prevalent injury in runners[8-10]. Despite its high prevalence, knowledge about its pathogenesis is still limited[7]. However, specific intrinsic and extrinsic risk factors related to the foot-ankle structures have been explored in the literature[11]. The main intrinsic factors for the development of PF in runners have been explained as foot-type changes[12], rearfoot valgus posture[4,13,14], and elevated plantar arch structures[5,8,13]. Understanding the foot structure has been the main

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Received: Mar. 25, 2015 Revised: Aug. 10, 2015 Accepted: Sept. 29, 2015

focus of clinicians to prevent injuries in runners, helping them to choose the correct footwear and providing the appropriate interventions[15]. These are directed towards improving the synaptic tactile afferents from the fascia and the motor neurons supplying the leg muscles[1,16].

Studies of runners with PF have shown that changes in the medial longitudinal arch (MLA) geometry (higher[5,6] or lower[4]) and the presence of pain contribute to increasing plantar loads[4,13]. Di Caprio et al.[5] described a higher arch as a great predictor of PF in runners, because an elevated MLA could induce greater stiffness of the plantar fascia, resulting in less flexible tissue[5]. This could result in the inefficient capacity to dissipate foot impact forces, with greater mechanical stress on the calcaneus[17], interfering with the dynamic foot function[18].

Elevated MLAs in healthy runners have been associated with higher vertical loading rates[19,20] and peak pressures over the rearfoot while running[20]. However, some studies have reported a lack of association between static and dynamic elevated MLAs and the loading rates or peak pressures during running[21,22]. Recently, the combination of MLAs and rearfoot eversion angles were described as good predictors of the pressure-time integral over the rearfoot and midfoot in healthy runners[23]. The increased rearfoot pronation associated with a lower MLA could also result in greater plantar loads over the calcaneal medial area[24-27], which, in turn, induces greater stretch in the plantar fascia[10,17]. A valgus alignment of the calcaneus or pronated foot posture significantly increases the likelihood of generalized foot pain[18].

The microtrauma and microtearing potentially caused by an elevated MLA and a valgus rearfoot are the primary mechanisms of PF, resulting in the inflammation characteristic of the acute phase[28,29]. The progression of PF can lead to a symptom remission phase, with the evolution of fragmentation and degeneration of the plantar fascia, characterizing the chronic phase[29,30]. Previous gait studies in individuals with PF determined that the pain stimulus promoted changes in foot roll-over patterns, thus causing load reductions in the rearfoot and load increases in the midfoot[31], forefoot[32], and toes[32,33], possibly due to the protective mechanisms of pain. A deep comprehension of the changes in plantar pressure associated with static foot posture may provide useful information for the prescription or design of interventions, such as orthotics or motion-control shoes for runners with PF.

The purpose of this study was to investigate the relationships between the MLA index and rearfoot alignment with plantar loads in runners with PF in the acute and chronic phases. We hypothesized that (1) an elevated MLA will predict lower plantar loads over the rearfoot in runners with acute PF, due to an antalgic mechanism, and higher loads in runners with chronic PF; and (2) a valgus rearfoot alignment would predict higher plantar loads and loading rates over the rearfoot in both groups of runners.

Method

Participants

This cross-sectional study examines the relationship between PF and foot alignment. For this, thirty-five runners of both sexes with diagnoses of unilateral PF were recruited from the Rehabilitation Center of Sport Rheumatology at Hospital Universitário de São Paulo, Brazil. The mean running speed of their last 10 km competition was 11.5±0.4 km/h. The inclusion criteria were: runners must have run at least 20 km weekly for at least one year, be experienced in long-distance competitions, have a regular rearfoot strike pattern, and have a diagnosis of unilateral PF confirmed by a clinical examination. The exclusion criteria were a history of previous surgery in the lower limbs, traumas or fractures of the lower limbs in the previous six months, leg length discrepancies, or other musculoskeletal disorders such as neuropathies, rheumatoid arthritis, or calcaneal spurs. This protocol was approved by the Human Research Ethics Committee of the School of Medicine of Universidade de São Paulo (USP), São Paulo, SP, Brazil (number: 384/10; title: Support standard and impact of the feet with the ground during the running of runners with history and symptoms of plantar fasciitis and its relationship to the medial longitudinal arch). All participants provided written consent.

All of the runners had diagnoses of unilateral PF confirmed by clinical examination and ultrasound images. Twenty runners were included in the acute PF group; they had acute inflammation and perifascial fluid detected in the ultrasound images combined with pain symptoms in the calcaneus for more than four months (mean of 4.0±2.0 months), with mean intensity of 8.1 cm (measured by a 0-10 visual analog scale). The pain was present during palpation of the plantar fascia after waking up in the morning, while remaining in the standing position, when taking the first few steps, while sitting for long periods of time, and after physical activity[32,33].

Fifteen runners had previous chronic stages of PF with a mean time since the first diagnosis of 1.5±3.0 years and cycles of remission within the period between the diagnosis and the biomechanical evaluation. In this group, we only included runners with unilateral PF who showed plantar fascial thickness, fragmentation, and degeneration in the ultrasound, but no signs of acute inflammatory processes or pain complaints over the previous two months[30].

Both groups (acute and chronic) demonstrated similar anthropometric characteristics and running practices (Table 1). In addition, all of the runners with PF were asked about any interventions previously used to treat this injury. The most frequent clinical interventions described by the runners were: physical therapy combined with medication (38%); insoles (27%); medication alone (21%); and other interventions such as acupuncture and manual therapy (14%).

Static measurements of the structures of the ankle and foot

Assessment of the frontal alignment of the rearfoot (calcaneal tendon)

To evaluate the alignment of the rearfoot in the posterior view of the frontal plane, the runners stood over a 45 cm platform, keeping their feet 7.5 cm apart. With a dermatographic pen and 9 mm white markers, the following anatomical points were identified on the inferoposterior regions of both legs: 1) the posterior calcaneal tuberosity; 2) the second point above the center of the calcaneus; and 3) the lower third of the leg[13,34,35] (Figure 1). The center of each marker in the

Table 1. Descriptive statistics (mean ± standard deviation) and comparisons between acute plantar fasciitis (FP) and chronic plantar fasciitis (PF) regarding their demographic, anthropometric, and running practice characteristics.

Variables	Acute PF (n=20)	Sex (Acute PF) (n=13 M; 7 F)	Chronic PF (n=15)	Sex (Chronic PF) (n=10 M; 5 F)	p*
Age (years)	42.8±9.3	M (46.1±8.3) F (44.5±9.0)	38.3±7.3	M (37.8±6.5) F (34.6±4.3)	0.126
Body mass (Kg)	70.1±14.5	M (77.1±8.8) F (59.2±9.5)	72.3±10.0	M (75.4±8.3) F (60.0±9.8)	0.641
Height (m)	1.70±9.9	M (1.74±4.7) F (158.7±6.1)	1.76±7.8	M (1.79±5.7) F (1.6±3.6)	0.224
Body mass index (Kg/m^2)	24.6±2.7	M (25.3±1.8) F (23.4±1.9)	23.0±2.0	M (23.3±1.8) F (22.3±2.2)	0.090
Training volume (km/week)	41.0±9.0	M (42.8±7.7) F (40.1±4.6)	45.0±10.0	M (46.4±8.1) F (40.0±3.4)	0.147
Practice time (years)	8.0±5.5	M (9.7±7.0) F (5.5±1.7)	6.2±5.0	M (7.2±6.1) F (6.0±1.4)	0.382

Acronym: M for male; F for female; PF: Plantar Fasciitis. *Calculated by ANOVAs one-way between groups (Acute and Chronic of PF), post-hoc: Tukey.

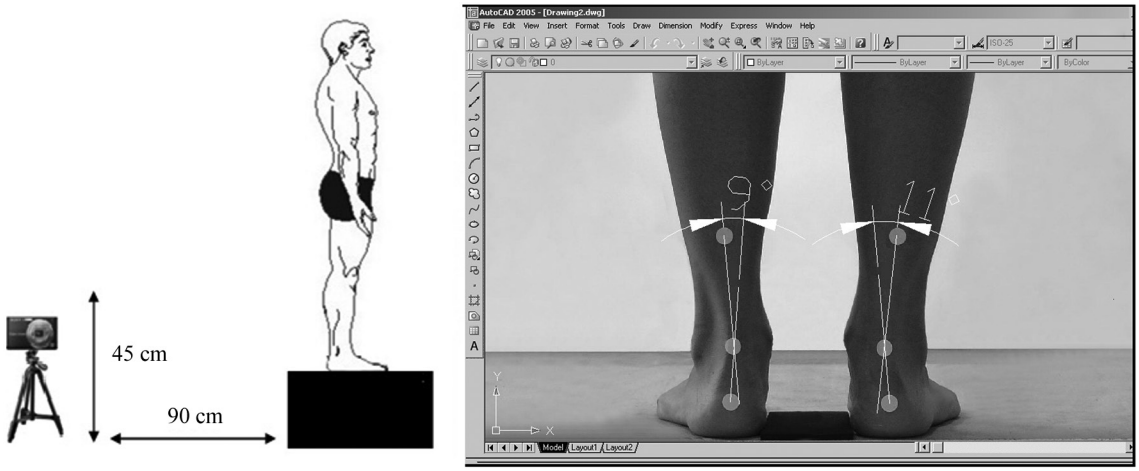

Figure 1. Position of individual and digital camera to capture digital image of rearfoot angle and measurement of the frontal alignment of the rearfoot in AutoCAD software.

medial-lateral axis was obtained with a digital caliper that was used to measure the distances between the two symmetrically opposing sides with a ruler[13]. The images were then obtained with a digital camera positioned anterior and perpendicular to the subjects at a distance of 90 cm and at a height of 45 cm. The images obtained (with a minimum size of 768 pixels) were analyzed on a 96-ppi screen, due the good inter-examiner reliability for the photogrammetric measurements of the rearfoot static angles[35] (Figure 1).

AutoCAD software 2005® was used to quantify the alignment of the rearfoot. For this, a line was drawn from the first marker (posterior calcaneal tuberosity) to the second marker (calcaneal center). A second straight line was then drawn, which originated from the lower third of the leg marker and passed through the second marker (calcaneal center)[13,35] (Figure 1). The intersection of the extensions of both straight lines resulted in angles, which were classified as normal foot (0° to 5°), varus (< 0°), or valgus (> 5°)[34].

Assessment of the medial longitudinal arch (MLA)

The footprint was acquired using a Carci® podoscope. For the barefoot assessments, the subjects were positioned on the podoscope with 7.5 cm of ethylene vinyl acetate (EVA) placed between the feet. The footprint image was obtained with a digital camera, which was placed in front of the podoscope at a distance of 24 cm and a height of 45 cm (Figure 2). The EVA measurement was taken as a reference for the AutoCAD software 2005® image scale. In AutoCAD, a vertical line (L) was drawn from the second metatarsus to the center of the calcaneus. Then, the L line was divided into three parts for the delineation of the forefoot, midfoot, and rearfoot areas[13,34].

To classify the MLA, the Arch Index[36] was calculated in the footprint image corresponding to the foot injured by PF. This index is the result of the ratio between the midfoot area and the total area of the foot (Figure 2). Index values between 0.22 and 0.25 correspond to a normal MLA, values smaller than 0.21 correspond to a cavus MLA, and values greater than 0.26 were classified a planus MLA. Footprint analyses via digital imaging were chosen because of the advantages of having the reliability and validity previously confirmed[37,38].

Procedures and instruments for the assessment of plantar loads while running

The plantar pressure distribution while running was obtained using the Pedar X system (Novel, Munich, Germany) at 100 Hz. All of the runners wore standard athletic shoes, which were considered to have neutral support (RAINHA SYSTEM, RAINHA, Alpargatas, São Paulo, Brazil). The shoe characteristics included a midsole made up of ethylene vinyl acetate (EVA, with compression set at 56%, hardness: 57 Asker C, and density = 0.21 g/cm^3) throughout the entire sole of the shoe. The insoles were placed between the socks and the shoe, and were connected to equipment inside a backpack (about 1.5 Kg).

After a period of adaptation with the shoes, insoles, and backpack, the runners ran a distance of 40 meters on

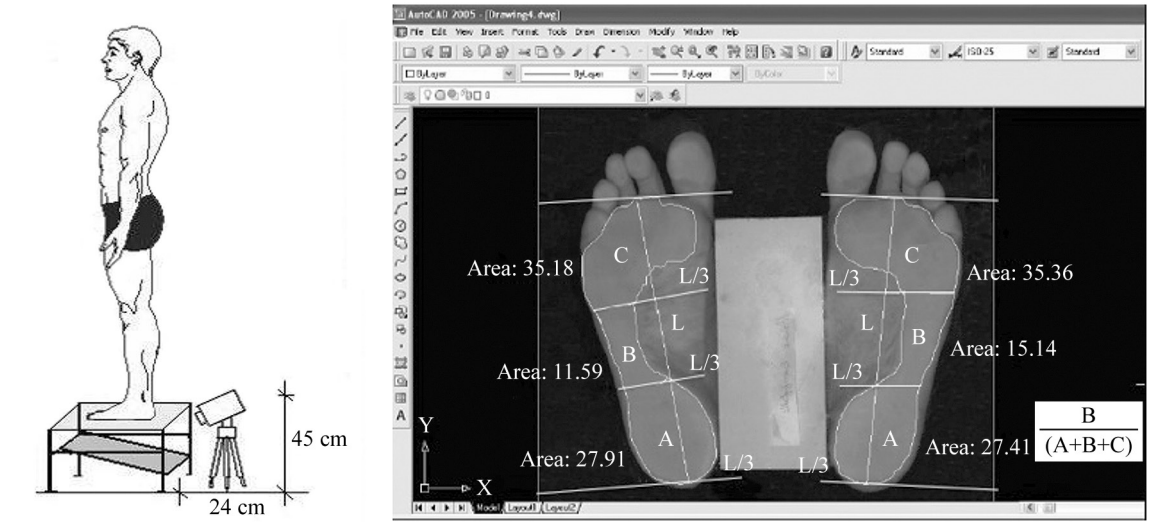

Figure 2. Image obtained by podoscope (A) and illustration of the areas of the feet to calculate the longitudinal plantar arch index (MLA), where L: vertical line and areas A: rearfoot, B: midfoot and C: forefoot (B).

a smooth and regular asphalt track in good conditions at 12 km/h. The speed of the intermediate 20 meters of the track was controlled by two evaluators using a digital chronometer[6]. Two observers used a digital stopwatch to control the speed simultaneously, and the inter-examiner reliability of the speed measurements was calculated using Intra-Class Correlation Coefficients (ICCs). The inter-examiner reliability was excellent ($ICC_{2,1}$=0.96; 95% CI=0.88–0.73), with a standard error of prediction of 0.04.

A mean value of 30 steps per subject was used for statistical purposes, and the variables were calculated using a MATLAB function: contact area (cm), maximum force (N), force-time integral (N.s), and peak pressure (kPa) over the three plantar areas of the rearfoot (30% of the foot length), midfoot (30% of the foot length), and forefoot and toes (40% of the foot length)[6]. Two plantar loading rates were calculated from the vertical force: 1) loading rate of 80% [$BW.s^{-1}$], defined as the force rate between 20 and 80% of the first peak, and 2) loading rate of 100% [$BW.s^{-1}$], as determined by the force rate between 0 and 100% of the first peak. All of the force variables were normalized by the body weight (BW).

Statistical analysis

The sample size calculation of the 35 runners with unilateral plantar fasciitis, based upon the maximal force variable, was carried out using G-Power 3.0 software, considering a moderate effect size (F=0.25), a statistical power of 80%, and a significance level of 5%. Since all of the outcome variables showed normal distributions (Shapiro-Wilk's test), ANOVAs followed by Tukey's post-hoc tests were used to compare the groups.

To verify our hypothesis that the MLA and rearfoot alignment variables could predict the plantar loads on the foot, we first checked the correlations between these biomechanical variables. Pearson's correlation coefficients were calculated to investigate the relationships between the MLA index and rearfoot alignment and the 20 dependent biomechanical variables: 18 plantar pressure variables over the rearfoot, midfoot, and forefoot (maximum force, force-time integral, maximum mean pressure, peak pressure, pressure-time integral, and contact area), and two loading rates (20 to 80% and 0 to 100% of the first peak [$BW.s^{-1}$]).

Forward step-wise multiple regression analyses were used to predict the biomechanical dependent variables (plantar pressure and loading rates) via the MLA index and rearfoot alignment. The biomechanical dependent variables were sequentially included in the model in three consecutive blocks: variables of contact area, force, and pressure. The 20 biomechanical variables were reduced, and only those whose correlation coefficients were higher than 0.20 were entered into the model. For all of the analyses, we adopted $p<0.05$.

The Pearson correlation analyses between the 20 dependent variables and the MLA index and rearfoot alignment resulted in 11 variables of interest for the regression analyses. The force-time integral, maximum force, and contact area over the rearfoot, midfoot, and forefoot, as well as the loading rates (20 to 80% and 0 to 100%), were included in the model. Nine variables were removed from the model due to low correlation coefficients ($r<0.20$): maximum mean pressure, peak pressure, and pressure-time integral over the foot areas.

To analyze the intra-rater reliability of the MLA index and rearfoot alignment, the measurements were obtained by the same examiner in two evaluation moments, with a one-week interval, and the intraclass correlation coefficients ($ICC_{3,1}$) were calculated. To investigate the inter-rater reliability, $ICC_{2,1}$ were calculated using the data collected during the first week by two independent examiners[39]. The intra- and inter-rater reliability analyses for the anatomical marker data were performed only by the first examiner, following previously recommended procedures[37,38]. Both evaluations were performed for both of the PF groups, without separating the phase of the injury.

In order to determine the systematic error of the MLA and rearfoot angle measurements for each examiner (intra- and inter-examiner reliability), the standard error of measurement (SEM) and standard error of prediction (SEP) were calculated. The intra-examiner reliability SEM was calculated as the ratio between the variability (standard deviation, SD) of the mean difference scores between the two repeated measurements, and the $\sqrt{2}$. The inter-examiner reliability SEP was calculated as: the product of the variability (SD) of the measurements obtained by each examiner and the $\sqrt{1-ICC2}$[35,39].

Results

The means and standard deviations of the medial longitudinal arches for the acute and chronic PF groups were 0.15±0.05 and 0.17±0.09, respectively. With regards to the rearfoot angles, the values were

6.4±4.5 and 7.8±3.4 for the acute and chronic PF groups, respectively.

In the final regression model, the MLA index predicted a higher force-time integral over the forefoot for both PF groups and a higher maximum force over the forefoot in the chronic PF group (Table 2). However, the MLA index could not predict any loading rate variables for either PF group. The rearfoot valgus alignment predicted a higher maximum force over the rearfoot for both PF groups, in addition to predicting higher loading rates (20-80% and 0-100%) and higher force-time integrals over the rearfoot in the chronic PF group (Table 2).

High intra-examiner (pre: 0.178±0.09 cm; post: 0.177±0.08 cm; SEM=0.10; ICC=0.92; 95% CI=0.84-0.78) and inter-examiner (examiner 1: 0.178±0.09 cm, SEP=0.02; examiner 2: 0.186±0.05 cm, SEP=0.01; ICC=0.90 95% CI=0.89-0.80) reliability levels were found for the MLA index. The rearfoot alignment reliability levels were also high for the intra-examiner (pre: 6.7±2.3 degrees; post: 6.5±2.7 degrees; SEM=0.7; ICC=0.95; 95%CI=0.87-0.78) and inter-examiner (examiner 1: 6.7±2.3 degrees, SEP=0.7; examiner 2: 6.3±2.9 degrees, SEP=0.9; ICC=0.90; 95% CI=0.83-0.77) measurements.

Discussion

To the best of our knowledge, this is the first study to investigate the relationship between static foot alignment and plantar pressure patterns in runners with different stages of PF, as main risk factors for PF[23,26]. In contrast to what we hypothesized, an elevated MLA predicted higher plantar loads (higher force-time integral) over the forefoot while running in both PF groups and a higher maximum force over the forefoot in chronic PF (not only in runners with acute PF). This last finding suggests that higher loads over the forefoot, particularly during the propulsion of running, are strongly associated with elevated MLAs in runners with PF. This combination of the arch structure and loading pattern could indirectly result in higher tension in the plantar fascia around the metatarsal heads[40], contributing to the progression of PF, regardless of its phase. Another important result allowed us to confirm our second hypothesis, which states that static valgus rearfoot alignment predicts higher plantar loads (higher maximum force and force-time integral) and higher loading rates (20-80% and 0-100%) over the rearfoot in both groups of PF.

During gait, some authors observed positive correlations between elevated MLAs and higher forefoot impulses[41], and between elevated MLAs with foot pain symptoms and higher pressure-time integrals over the forefoot[42]. Although the present study evaluated the relationship between the foot posture and pressure while running, our results are similar to the gait findings[41,42], demonstrating the predictive association between an elevated MLA and increased plantar load over the forefoot. One possible explanation for the positive relationship between an elevated MLA and higher maximum force over the forefoot

Table 2. The multiple regression models of the longitudinal plantar arch index (MLA) and rearfoot valgus alignment (REARFOOT) to predict the biomechanical dependent variables of runners with plantar fasciitis (PF): acute and chronic.

Variables	Group	Beta Coefficient	Standard deviation	t	p[&]	Equation*	R, R^2
Force-Time Integral (N.s) (FTIF)	Acute PF	0.350	0.16	3.0	0.031	FTIF=0.211+0.350*^{MLA}	r=0.35; R^2=0.15
	Chronic PF	0.165	0.12	3.2	0.020	FTIF=6.096+0.165*^{MLA}	r=0.41; R^2=0.17
Maximal Force forefoot (N) (MFF)	Chronic PF	1.850	0.81	2.2	0.043	MFF=1.580+1.850*^{MLA}	r=0.59; R^2=0.35
Maximal Force rearfoot (N) (MFR)	Acute PF	2.012	0.17	2.8	0.048	MFR=1.400+2.012*^{REARFOOT}	r=0.42; R^2=0.18
	Chronic PF	0.056	0.02	2.7	0.017	MFR=2.140+0.056*^{REARFOOT}	r=0.67; R^2=0.45
Force-Time Integral rearfoot (N.s) (FTIR)	Chronic PF	0.103	0.12	3.8	0.041	FTIR=2.840+0.103*^{REARFOOT}	r=0.41; R^2=0.17
Loading rate 20-80% ($BW.s^{-1}$)	Chronic PF	0.278	0.01	1.6	0.013	Loading rate (20-80%) =0.645+0.278*^{REARFOOT}	r=0.44, R^2=0.19
Loading rate 0-100% ($BW.s^{-1}$)	Chronic PF	1.238	0.14	1.8	0.012	Loading rate (0-100%) =7.54+1.238*^{REARFOOT}	r=0.63, R^2=0.40

Acronyms: PF: Plantar Fasciitis; MLA: Medial Longitudinal Arch; REARFOOT: rearfoot valgus alignment; FTIF: Force-Time Integral; MFF: Maximal Force Forefoot; MFR: Maximal Force Rearfoot; FTIR: Force-Time Integral Rearfoot. [&] p-value of the multiple regression analyses. *Equations of the multiple regression analyses. The t-value and resulting p-value are used to test the hypothesis that the intercept is equal to 0.

in the group with chronic PF may be attributed to the foot's passive tissue and muscle changes[30,31], such as reduced thickness of the plantar fascia and atrophy of the intrinsic musculature[43], which, in turn, would affect the function of the MLA while running. In this study, the altered function resulted in reduced loads over the rearfoot and higher loads over the forefoot.

Other studies have reported positive correlations between elevated MLAs and higher loading rates, measured by force plates in healthy individuals while running[32,33]. Contrarily, Ramskov et al.[44] observed that the static foot posture, quantified by the Foot Posture Index, did not seem to affect the risk of injury among novice runners. However, these results should be interpreted with caution due to the small sample size. The advantage of our study was to prove that static foot alignment (elevated MLA) in runners with PF, a more prevalent injury in runners[8,9], predicted a higher plantar load over the forefoot while running, depending on the stage of PF (acute or chronic). However, the absence of a control group is one limitation of the present study.

One important finding was the non-confirmed relationship between an elevated MLA and higher plantar loads, or loading rates, while running, over the rearfoot in runners with PF (acute and chronic phases), since the rearfoot area is the region most associated with the physiopathology and etiology of PF[7]. A possible explanation for this finding is that runners in the acute phase of PF, with inflammation present in the calcaneal region, may have increased thickness of the plantar fascia (perifascial and cellular fluid collection), resulting in the reduced capacity of this tissue to support mechanical loads over the rearfoot area[23,45]. The consequence of this reduced capacity of the attenuating loads in the plantar fascia can lead to the adoption of an antalgic strategy to reduce the plantar load over the rearfoot, resulting in an increase in the plantar load over the forefoot. These results were also observed in studies that evaluated the gait task[7,33]. In addition, Sullivan et al.[46] showed that people with heel pain had reduced maximum force, peak pressures, and force–time integrals over the heel while walking.

We hypothesized that the structure of an elevated MLA and valgus rearfoot alignment would predict higher plantar loads and loading rates over the rearfoot in both groups of runners. However, only the static valgus rearfoot alignment was a significant predictor of the maximum force and the force–time integrals, as well as the higher loading rates over the rearfoot in both PF groups. Our results agreed with the study by Pohl et al.[4], who found increases in the vertical force in female runners with histories of PF, compared with control runners, although these authors did not show a statistical model demonstrating a direct relationship between these two parameters (MLA and plantar loads).

Higher and repetitive plantar loads over the rearfoot while running, due to valgus rearfoot alignment, can indirectly induce the tensile force and micro-failure of the plantar fascia throughout the medial calcaneal tuberosity while running[23], contributing to the progression of PF. Lee and Hertel[26] showed that valgus rearfoot alignment was a significant predictor of the peak and pressure-time integrals over the medial rearfoot and midfoot in healthy runners running on a treadmill. In the current study, we confirmed that runners with PF presented positive relationships between the valgus rearfoot alignment and maximum force, time-integral forces, and load rates over the rearfoot while running in a natural environment. Therefore, we can conclude that controlling the valgus alignment of the rearfoot may help prevent PF (acute and chronic). These findings may help health care professionals to choose more appropriate mechanical treatment strategies for runners with PF, such as orthoses, insoles, and physical therapy interventions, for better controlling rearfoot valgus and reducing the loading rates over the rearfoot.

One of the limitations of this study was that the loading rates were estimated using equipment with a maximal sampling rate of 100 Hz. We suggest that further studies examine the rearfoot valgus alignment and MLA dynamically to clearly elucidate the underlying mechanism of the increased maximum force, time-integral force, and loading rate over the rearfoot, as well as the maximum pressure and time-integral pressure over the forefoot, and relationships between these clinical measurements of the foot.

Conclusions

An elevated MLA was shown to predict higher plantar loads over the forefoot in both groups of runners with PF (acute and chronic). The rearfoot valgus alignment was determined to be a good clinical measurement for predicting increases in the maximum force, force-time integral, and loading rates over the rearfoot in runners in both acute and chronic PF. Both clinical measurements showed relationships with the plantar loads and may contribute to the progression of PF, regardless of its phase.

Acknowledgements

The authors would like to thank Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES) for one scholarship (2011/03069-6) and Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP) for three scholarships (2014/081190, 2015/20042-5, and 2010/14044-1).

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original article

BJPT Brazilian Journal of Physical Therapy

Effects of diaphragmatic control on the assessment of sniff nasal inspiratory pressure and maximum relaxation rate

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ABSTRACT | Objective: To assess the influence of diaphragmatic activation control (diaphC) on Sniff Nasal-Inspiratory Pressure (SNIP) and Maximum Relaxation Rate of inspiratory muscles (MRR) in healthy subjects. **Method**: Twenty subjects (9 male; age: 23 (SD=2.9) years; BMI: 23.8 (SD=3) kg/m^2; FEV_1/FVC: 0.9 (SD=0.1)] performed 5 sniff maneuvers in two different moments: with or without instruction on diaphC. Before the first maneuver, a brief explanation was given to the subjects on how to perform the sniff test. For sniff test with diaphC, subjects were instructed to perform intense diaphragm activation. The best SNIP and MRR values were used for analysis. MRR was calculated as the ratio of first derivative of pressure over time (dP/dt_{max}) and were normalized by dividing it by peak pressure (SNIP) from the same maneuver. **Results**: SNIP values were significantly different in maneuvers with and without diaphC [without diaphC: –100 (SD=27.1) cmH_2O/ with diaphC: –72.8 (SD=22.3) cmH_2O; p<0.0001], normalized MRR values were not statistically different [without diaphC: –9.7 (SD=2.6); with diaphC: –8.9 (SD=1.5); p=0.19]. Without diaphC, 40% of the sample did not reach the appropriate sniff criteria found in the literature. **Conclusion**: Diaphragmatic control performed during SNIP test influences obtained inspiratory pressure, being lower when diaphC is performed. However, there was no influence on normalized MRR.

Keywords: respiratory muscles; nasal inspiratory pressure; physical therapy.

BULLET POINTS

- Diaphragmatic activation control reduced Sniff Nasal-Inspiratory Pressure due to a possible use of accessory inspiratory muscles.
- The Maximum Relaxation Rate of inspiratory muscles does not change when diaphragmatic activation control is used.
- Diaphragmatic activation control increased the number of technically acceptable tests.

HOW TO CITE THIS ARTICLE

Benício K, Dias FAL, Gualdi LP, Aliverti A, Resqueti VR, Fregonezi GAF. Effects of diaphragmatic control on the assessment of sniff nasal inspiratory pressure and maximum relaxation rate. Braz J Phys Ther. 2016 Jan-Feb; 20(1):96-103. http://dx.doi.org/10.1590/bjpt-rbf.2014.0101

Introduction

The evaluation of respiratory muscle strength is an important method for early detection of weakness in these muscles. This evaluation also aims to monitor their function in respiratory, cardiac, and neuromuscular diseases[1,2] and provides prognostic and predictive information on survival in different patients[1,2]. Respiratory muscle strength is estimated using Maximal Expiratory Pressure (MEP) and Maximal Inspiratory Pressure (MIP), which are obtained noninvasively through the mouth and sustained for 2 to 3 seconds with an occluded airway[3,4]. Despite its usefulness as a diagnostic test, this assessment is difficult for patients with neuromuscular disease, since it requires coordination, collaboration, and facial muscle integrity[4,5].

A test has been developed recently to assess inspiratory muscle strength during a sniff (Sniff Nasal Inspiratory Pressure - SNIP). Given that this new method is a natural maneuver performed primarily by the diaphragm in a ballistic as opposed to isometric contraction, it is easily executed when compared

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Received: Apr. 09, 2015 Revised: Aug. 05, 2015 Accepted: Aug. 17, 2015

to MIP, a maximal sustained static effort. Previous studies consider SNIP a complementary maneuver to MIP because it is a simpler technique that does not require a mouthpiece, since pressure is measured via the nasal airway with a nose clip, making it easier to assess children and patients with neuromuscular disorders[3,4].

SNIP has gained clinical importance in recent years, with reference values published for different populations (adults and children)[5-8]. Studies suggest intense activation of the diaphragm muscle during a maximal sniff[9,10]. The diaphragm is one of the main inspiratory muscles active during this maneuver, which raises the question of whether to emphasize its action when measuring SNIP. Although the SNIP test is noninvasive, research indicates a high correlation ($r=0.99$, $p<0.001$) between this maneuver and invasive techniques measuring esophageal pressure with an esophageal balloon catheter[11-13]. In addition to assessing muscular strength, SNIP has been used as a predictor of respiratory muscle fatigue by analyzing the Maximum Relaxation Rate (MRR) of inspiratory muscles, calculated based on test kinetics[13]. Previous studies evaluated the MRR in healthy subjects and patients with neuromuscular disorders and chronic obstructive pulmonary disease (COPD)[11-13].

The SNIP test is considered a predictor of mortality in patients with COPD and is compared with predictors obtained in more complex assessments related to lung hyperinflation, such as the IC/TLC ratio (Inspiratory Capacity/Total Lung Capacity)[14]. There are a number of studies on SNIP, its clinical importance in cardiorespiratory physical therapy assessment, and methodological description in important guides for respiratory diseases published by scientific institutions[15-17]. However, there is no information on the need (or not) to stimulate diaphragm contraction by visible abdominal movement. Therefore, the precise technical procedure for the maneuver remains unclear. The aim of this study was to assess the influence of diaphragmatic control (DiaphCtrl) on SNIP and MRR in healthy subjects.

Method

Subjects

Twenty healthy subjects aged between 18 and 30 years of both sexes were recruited. Inclusion criteria were: no history of smoking; any neuromuscular, cardiovascular, or respiratory disease that might result in lung dysfunction with spirometric changes; influenza and/or a cold in the week preceding assessment; no regular use of medication to treat respiratory allergies, central nervous system (CNS) depressants, barbiturates, or muscle relaxants; not pregnant; and exhibiting spirometric variables of forced vital capacity (FVC) higher than 80% and the ratio of forced expiratory volume in one second to forced vital volume (FEV_1/FVC) greater than 85% of the predicted value[14]. Individuals unable to understand and/or correctly perform the required maneuvers or diagnosed with a deviated septum were excluded. All subjects gave their written informed consent in accordance with Resolution 466/12 of the Brazilian National Health Council. The Research Ethics Committee (CEP) of Hospital Universitário Onofre Lopes, Universidade Federal do Rio Grande do Norte (HUOL/UFRN), Natal, RN, Brazil, approved the study under protocol number 185/10.

Study design

This is a cross-sectional, quasi-experimental study. Subjects were submitted to outpatient assessment at the PneumoCardioVascular Performance Laboratory and the PneumoCardioVascular Lab/HUOL/EBSERH, UFRN. After selection, individuals were assessed on the same day for collection of anthropometric and spirometric data to determine their eligibility. SNIP tests were conducted after a 20-minute rest, with a minimum 60-minute interval between the two assessments, followed by MIP measurement. SNIP assessment was conducted twice. On both occasions, the examiner carefully demonstrated the maneuver and then asked the subject to repeat it for familiarization purposes[18,19]. In assessment A, subjects received only the basic instructions recommended by the American Thoracic Society/European Respiratory Society (ATS/ERS)[16], which suggests that the sniff maneuver requires little explanation and practice. Subjects executed 5 sniff maneuvers without activating the diaphragm muscle. They were instructed to sniff with maximum effort, followed by a slow, sustained expiration without holding their breath. In assessment B, individuals were trained to breathe in a slow diaphragmatic breathing pattern. They were asked to breathe deeply through their nose, while simultaneously moving the abdominal wall outwards. A period of 5 to 10 minutes was established for training to ensure patients could correctly execute the maneuver. Success was evaluated visually, with maneuvers considered satisfactory when the abdomen clearly expanded on inspiration[20]. After being trained in diaphragmatic breathing, subjects were asked to perform ballistic stomach movements

to familiarize themselves with the speed required during the sniff. Next, participants were instructed to perform five consecutive sniffs concomitant to abdominal motion (DiaphCtrl) following the same instructions applied in assessment A (rapid maximum effort, followed by slow and sustained expiration), but emphasizing diaphragm control during execution. In both assessments, the subjects were prompted by being asked to take a "hard sniff". MIP was measured at the end of the test after a 30-minute rest to prevent the static effort required from interfering in obtaining SNIP values. The sequence of measurements was not randomized because, once a maneuver has been taught, it is impossible to ask individuals to execute it without applying the pattern learned and be certain they are performing it as they would have done before training, which could hamper result interpretation. The flow chart is shown in Figure 1.

Lung function assessment

Spirometry

Spirometry was performed using a DATOSPIR 120C spirometer (Sibelmed, Barcelona, Spain). Acceptability and reproducibility criteria followed the recommendations of the ATS/ERS[21] and the guidelines of the Brazilian Pulmonology and Thoracic Society (SBPT)[15]. Assessment was considered complete when three acceptable curves were produced, of which the best two are reproducible (with variation equal to or lower than 5% to 200 ml). The following variables were evaluated during spirometry: forced vital capacity (FVC), and forced expiratory volume in the first second (FEV_1) and the FEV_1/FVC ratio. The results were compared to reference values for the Brazilian population[22].

Inspiratory muscle strength (MIP and SNIP)

A MicroRPM digital manometer (MICRO medical, Rochester, Kent, United Kingdom) was used to measure the inspiratory pressures MIP and SNIP. Before the start of each test, individuals were instructed on the maneuver, which was then demonstrated by the examiner. The results obtained were compared to reference values for the Brazilian population[22]. Technical criteria of acceptability and reproducibility followed the standards and guidelines of the Brazilian Pulmonology and Thoracic Society (SBPT)[15].

MIP was measured while participants were seated, with their heads in a neutral position and wearing a nose

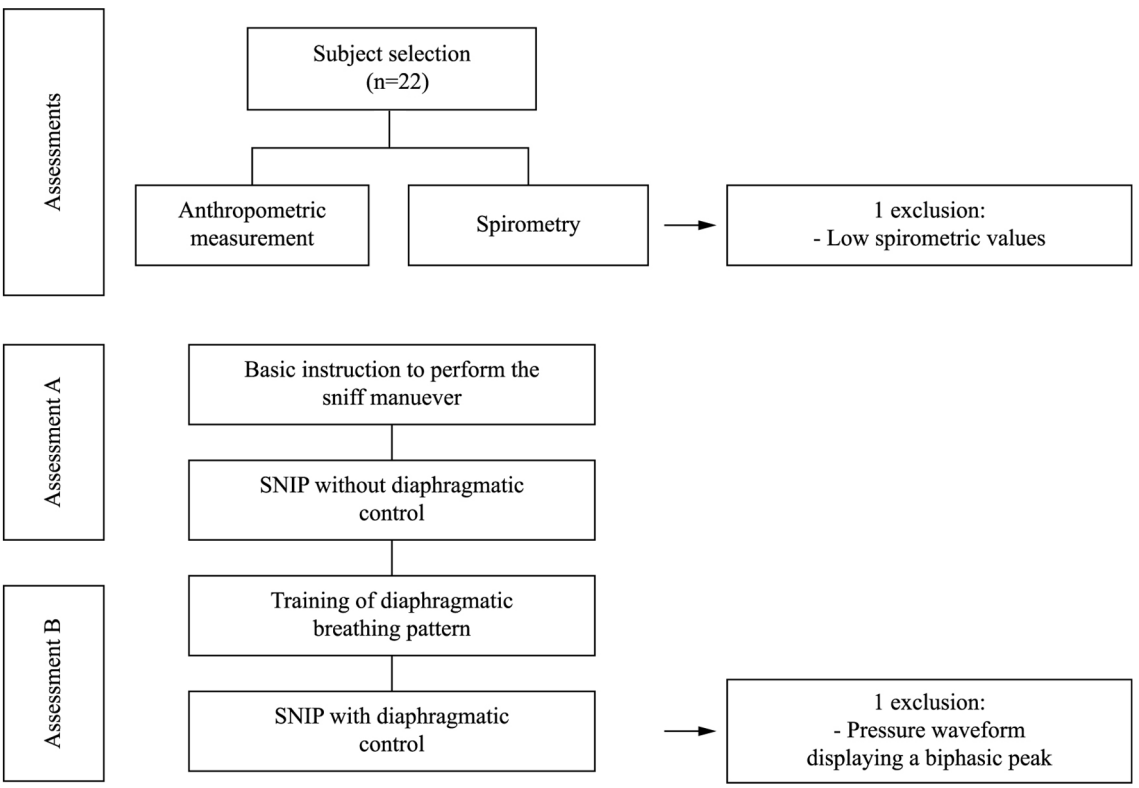

Figure 1. Study design.

clip. A disposable cylindrical mouthpiece was coupled to the manometer and positioned firmly between their lips to prevent leakage. Participants were instructed to execute a maneuver for training purposes[19], and the evaluation was considered complete when three acceptable maneuvers were performed, of which two were reproducible (with variation equal to or lower than 10% of the highest value). A one-minute rest was allowed between tests and the highest value of the two reproducible measures obtained was considered for analysis. MIP measurement was based on residual volume (RV), with subjects performing a maximum inspiration.

SNIP assessment was conducted with one nostril occluded by a nose clip, selected according to the size of the subject's nostril and connected to the manometer via a catheter measuring approximately 1 mm. The maneuver was performed from Functional Residual Capacity (FRC), whereby participants executed a maximum sniff through the contralateral (unobstructed) nostril at the end of a slow and sustained expiration[5]. The SNIP test was performed with subjects seated upright, their backs against a chair, knees and hips flexed to 90° and their heads in a neutral position.

Testing was considered complete when 5 acceptable maneuvers had been performed in each assessment (A and B) with a 30-second interval between them[5]. The three best curves for each individual in each assessment were plotted. The test with the highest value was used for statistical analysis, provided it met the criteria described in the literature as suitable for data quantification, namely: peak pressure sustained for less than 50 ms; total sniff duration (T_{total}) less than 500 ms; gentle, descending, exponential curve with no biphasic peak[11].

Statistical analysis

The three best tests from each individual with the highest absolute SNIP value in each assessment (A and B) were chosen for analysis using the LabChart 7 Pro software program (ADInstruments 2009). MRRs were calculated from the ratio between the first derivatives of pressure and time (dP/dt_{max}), normalized by the pressure peak of the same test and expressed as percentage pressure fall per 10 ms[12,13] (Figure 2). For subjects whose T_{total} in their best test was higher than 500 ms, their second or third highest SNIP values were used for quantification, whereas those who did not meet this criteria in any of their three best tests were excluded and statistics were recalculated for analysis. The Shapiro-Wilk test was used to verify the normality of variables. SNIP and MRR and their absolute and normalized values were compared using a paired Student's t-test. Statistical significance was set at $p>0.05$. Statistical analysis was performed using GraphPad Prism®, version 5.0 (GraphPad Software, San Diego, CA, USA).

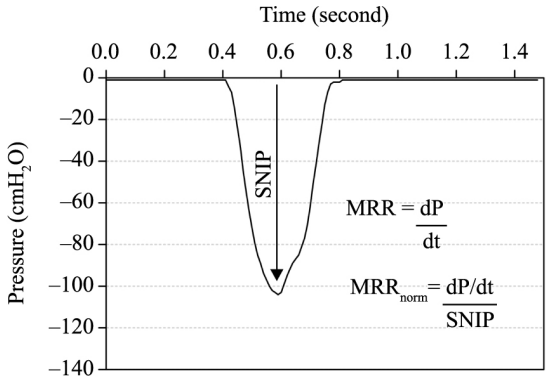

Figure 2. Example of measurement and calculation of Maximum Relaxation Rate of inspiratory muscles (MRR) from Sniff Nasal-Inspiratory Pressure (SNIP).

Results

A total of 22 individuals were recruited. Of these, one was excluded for exhibiting FVC and FEV_1 less than 80% of the predicted value and another because the SNIP curves obtained after complete assessment were not suitable for graph analysis, since the tests did not produce gentle, descending curves and displayed a biphasic peak. Anthropometric and lung function data are shown in Table 1. Mean SNIP values, absolute and normalized MRR, and T_{total} are displayed in Table 2.

A significant reduction was observed in SNIP values obtained for maneuvers performed using DiaphCtrl ($p<0.0001$) and in absolute MRR calculated from the same maneuvers ($p<0.0001$). There was no significant difference between MRRs when normalized (Table 2).

Figure 3 illustrates the kinetic pattern of SNIP tests for a single individual with and without DiaphCtrl, showing the shape of the SNIP curve and T_{total} for the maneuver. Maneuvers with DiaphCtrl exhibited a lower T_{total} than those executed without DiaphCtrl. In maneuvers without DiaphCtrl, 40% (n=8) of subjects obtained a T_{total} higher than 500 ms. However, in maneuvers with DiaphCtrl (assessment B), 100% (n=20) of subjects achieved a T_{total} lower than 500 ms, as shown in Table 2.

Table 1. Descriptive analysis of anthropometric measurements and spirometry.

	Male (N=9)	Female (N=11)	N=20
Age (years)	23.2 (2.8)	22.8 (3.1)	23.0 (2.9)
Weight (Kg)	82 (9.0)	60.4 (7.9)	70.2 (13.6)
Height (cm)	177.9 (4.2)	164.8 (5.9)	170.7 (8.4)
BMI (Kg/m²)	25.9 (2.5)	22.2 (2.1)	23.8 (3.0)
FVC (L) [$\%_{predicted}$]	5.3 (0.6) [96 (9.2)]	3.7 (0.5) [92.8 (9.7)]	4.4 (1.0) [94.2 (9.4)]
FEV_1(L) [$\%_{predicted}$]	4.4 (0.4) [94.4 (7.4)]	3.2 (0.5) [96.5 (9.7)]	3.8 (0.7) [95.4 (8.6)]
FEV_1/FVC	0.8 (0.04)	0.9 (0.1)	0.9 (0.1)
MIP (cmH_2O)	156.4 (55.1)	109.1 (22.1)	131.0 (48.0)

Data are presented as mean and standard deviation. BMI: body mass index; FVC: forced vital capacity; %predicted: percentage of predicted value; FEV_1: forced expiratory volume in one second; MIP: maximal inspiratory pressure.

Table 2. Sniff nasal inspiratory pressure, maximum relaxation rate, and sniff total duration time.

	Without DiaphC	With DiaphC	p	Mean Difference	95% CI
SNIP (cmH_2O)	–100 (27.1)	–72.8 (22.3)*	< 0.0001	–27.15	–32.84 –21.46
MRR (cmH_2O/s)	962.3 (326.5)	647.3 (218.6)*	< 0.0001	315.0	+195.5 +434.5
MRR normalized	–9.7 (2.6)	–8.9 (1.5)	0.19	–0.7750	–1.97 +0.42
T_{TOTAL} *sniff* < 500 ms	12 (60%)	20 (100%)	-		-
T_{TOTAL} *sniff* > 500 ms	8 (40%)	-	-		-

Data are presented as mean and standard deviation. SNIP: sniff nasal inspiratory pressure; MRR: maximum relaxation rate; diaphC: diaphragmatic activation control. *p<0.05.

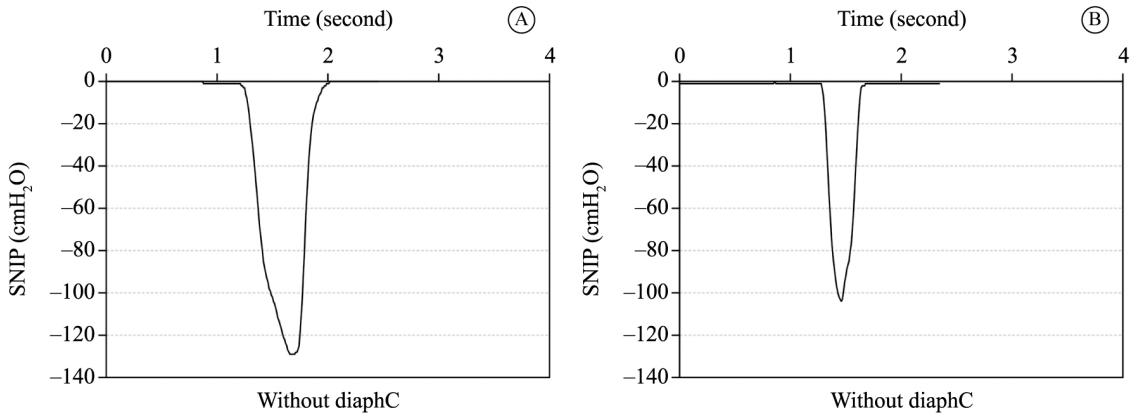

Figure 3. Graphic representation of Sniff Nasal-Inspiratory Pressure (SNIP) kinetics. Figure (A) without diaphragmatic control and (B) with diaphragmatic control in the same subject. On the left, there is a peak pressure of ~130 cmH_2O and a total duration time of sniff ~630 milliseconds; on the right, there is a peak pressure of ~103 cmH_2O and a total duration time of ~350 milliseconds. diaphC: diaphragmatic activation control.

Discussion

The aim of this study was to assess the influence of diaphragmatic control (DiaphCtrl) on SNIP and MRR in healthy subjects. It was found that T_{total} was lower in tests with DiaphCtrl; the SNIP value was significantly lower compared to tests in which DiaphCtrl was not applied; and absolute MRR also declined, since it is directly proportional to the pressure obtained ($MRR=dP/dt_{max}$). However, when normalized by the

pressure peak of the same test, MRR exhibited similar behavior in all the situations proposed.

Based on these results, it can be hypothesized that DiaphCtrl enables subjects to perform a SNIP test exhibiting ballistic characteristics, as described in the literature. Moreover, despite producing lower SNIP values than tests without DiaphCtrl, all tests with diaphragmatic control met the requirements previously described to be deemed technically acceptable.

Regarding the higher values measured in tests executed without DiaphCtrl, a significant proportion (40%) were not considered technically acceptable, since the T_{total} obtained was greater than 500 ms. In maneuvers without instruction on DiaphCtrl, longer test times may be due to greater recruitment of (accessory) inspiratory muscles in the rib cage, which is not considered suitable for the SNIP test. The same logic can be applied to the decline in SNIP value. In other words, since diaphragmatic control results in lower recruitment of accessory muscles, there are fewer muscle fibers generating force during the maneuver and the peak value is therefore lower, but still reflects that the technique was executed correctly.

The relationship between the force generated by the diaphragm and other respiratory muscles, as well as the pressure obtained, may vary depending on the maneuver executed as a result of the chest wall movements prompted by specific respiratory muscle recruitment patterns. As such, it is suggested that the different SNIP values observed in the two assessments (A and B) of this study may be due to lower recruitment of the accessory muscles of respiration.

Previous studies using electromyography[10] have shown that the diaphragm is the most active muscle during the sniff maneuver, which also recruits the scalene[23], sternomastoid[10,23], and intercostal muscles[9,10]. Nava et al.[10] assessed three different breathing muscle recruitment maneuvers and demonstrated that sniffing exhibits greater diaphragm activation. The authors[10] also suggest that the inspiratory muscle recruitment pattern in the sniff and Müller's maneuver are similar, but differ in terms of diaphragm activation. Katagiri et al.[23] studied the activation of accessory muscles during sniffs and found that the scalene muscles were active during low- and high-intensity sniffs, whereas the sternomastoid muscle was only recruited during high-intensity sniffs ($\geq$40 cmH_2O).

Based on observation of the sniff maneuver performed by the individuals in this study, we found that muscles other than the respiratory muscles were recruited when insufficient instructions were given on diaphragm control, including the use of paraspinal muscles noted in a brief chest extension performed by the subject when executing the sniff.

The visible recruitment of accessory muscles in assessment A decreased after subjects were trained in diaphragmatic breathing (DiaphCtrl), evaluated by abdominal movement paired with sniff execution. Thus, when the maneuver was performed with DiaphCtrl, the SNIP value declines, likely due to reduced activity by other breathing muscles and the recruitment of more fibers, characterizing isometric muscle contraction.

Despite this qualitative observation, it is important to note that there are no clear reports on executing the technique. According to American Thoracic Society/European Respiratory Society (ATS/ERS)[16] guidelines, subjects are asked to perform a maximal sniff followed by a slow, sustained expiration. It is also suggested that the sniff maneuver requires little instruction and practice and was performed this way in assessment A. Although the SNIP technique is entirely noninvasive, previous studies have shown a strong relationship between nasal airway and esophageal pressure, measured during sniffs by a balloon catheter in healthy subjects ($r=0.99$, $p<0.001$) and those with neuromuscular dysfunction ($r=0.96$, $p<0.001$)[24]. Given this behavior, the SNIP test is widely used in clinical practice, largely because it is easily executed by children and patients with neuromuscular diseases[3,5,25].

As previously mentioned, SNIP values were considerably higher during the test performed without DiaphCtrl than those recorded after instruction on diaphragmatic breathing. However, a significant proportion of individuals in the DiaphCtrl test exceeded the time of 500 ms recommended in the literature[11]. Without instruction on applying diaphragmatic contraction during the SNIP tests, 40% of the subjects assessed were excluded from the study. The subtle change in execution provided by diaphragmatic control reduced T_{total} in 100% of subjects, and all tests complied with the acceptability criteria of duration of up to 500 ms. Thus, reducing test times by applying DiaphCtrl during the sniff maneuver means more subjects meet the inclusion criteria for data quantification described in previous studies[12,13,26].

Kyroussis et al.[11,12] and García-Rio et al.[13] found that the MRR of respiratory muscles measured by the SNIP is highly correlated (healthy subjects: $r=0.99$, $p<0.001$; patients with neuromuscular diseases: $r=0.98$, $p<0.001$) with measurement of this rate by esophageal pressure and has been reported as a predictor of muscle fatigue. Thus, the decline in

this rate represents muscle fatigue resulting from a reduction in force generation and/or increase in T_{total} for the test (MRR=dP/dt).

The MRR represents the kinetics involved in relaxation in the SNIP test. When normalized by the peak pressure obtained in the same maneuver, the rate behaved similarly in all the situations applied in this study, with and without DiaphCtrl. In other words, instruction on executing diaphragmatic control during the sniff did not change the kinetics of relaxation, but increased the number of technically acceptable tests. This is because, despite the significant decrease in test time with DiaphCtrl, the peak pressure obtained also declined, meaning the relationship between these two measurements (normalized MRR) remained relatively unchanged in static terms. Therefore, it is important to highlight that, notwithstanding the similarity between the normalized MRRs obtained with and without DiaphCtrl, 40% of the tests would not be acceptable for quantification according to current criteria. In order to remove any doubt regarding changes to test kinetics, the second or third best test for each individual whose T_{total} exceeded 500 ms was selected in an attempt to include them according to criteria. Nevertheless, 10% of subjects were still above the cutoff time applied. As such, these were excluded and all data reanalyzed, with no significant changes in the results, i.e. the normalized MRR of respiratory muscles remained unchanged.

The study exhibited limitations in its assessment format. Since subjects were assessed in a single session, the protocol adopted involved executing 5 SNIP maneuvers with and without DiaphCtrl, despite previous studies suggesting a minimum of 10 maneuvers to achieve the maximum SNIP value[27]. Lofaso et al.[27] observed an intrasession learning effect in the sniff maneuver after the tenth repetition (between the 10^{th} and 20^{th} repetitions) when several maneuvers are repeated in the same session. In the present study, there was a subtle difference in execution of the sniff maneuver between assessments A and B. Thus, we opted for only 5 repetitions to avoid, as much as possible, the likelihood of an intrasession learning effect. However, it is important to note that the same conditions were applied in both assessments to enable comparison. Additionally, as a result of the study design adopted, it is impossible to prove that some of the subjects assessed did not voluntarily apply diaphragmatic breathing before being instructed to do so. However, a post-hoc analysis demonstrated that a significant proportion of the sample did not spontaneously use visual diaphragm contraction. As such, we feel that simply applying this technique can improve the results of the maneuver.

Conclusions

Encouraging diaphragm contraction during the SNIP test influences the inspiratory pressure obtained, which is lower when diaphragmatic breathing is applied, but does not affect normalized MRR. As such, diaphragmatic control should be used, since it ensures that the values obtained in testing conform to the guidelines described in the literature.

Acknowledgements

This study was funded in part by Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES); Programa Nacional de Cooperação Acadêmica (PROCAD), process no. 764/2010-UFRN/UFPE/UFMG; Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq), process no. 311712/2012-6; and Ciência sem Fronteiras (CsF), PVE 400316/2012-9.

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Our thanks to the referees,

The Brazilian Journal of Physical Therapy acknowledges the individuals who, during this past year, reviewed one or more manuscripts. They generously devoted their time to our peer review process. This process has been fundamental to the Journal's growth and has contributed towards the quality of the work that is demonstrated on our pages.

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PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS DA REABILITAÇÃO MESTRADO E DOUTORADO

Recomendado pela CAPES – Conceito 5

O Programa de Pós-graduação em Ciências da Reabilitação tem como base a perspectiva apresentada no modelo proposto pela Organização Mundial de Saúde e propõe que as dissertações e trabalhos científicos desenvolvidos estejam relacionados com o desempenho funcional humano. Com a utilização de um modelo internacional, espera-se estimular o desenvolvimento de pesquisas que possam contribuir para uma melhor compreensão do processo de função e disfunção humana, contribuir para a organização da informação e estimular a produção científica numa estrutura conceitual mundialmente reconhecida. O Programa de Pós-graduação em Ciências da Reabilitação tem como objetivo tanto formar como aprofundar o conhecimento profissional e acadêmico, possibilitando ao aluno desenvolver habilidades para a condução de pesquisas na área de desempenho funcional humano.

O programa conta com parcerias nacionais e internacionais sedimentadas, e os seus laboratórios de pesquisa contam com equipamentos de ponta para o desenvolvimento de estudos na área de Ciências da Reabilitação.

Mais informações

Fone/Fax: (31) 3409-4781
www.eef.ufmg.br/mreab

Universidade Federal de São Carlos

Programa de Pós-Graduação em Fisioterapia

O Programa de Pós-Graduação em Fisioterapia tem como área de concentração: "Processos de Avaliação e Intervenção em Fisioterapia". Nosso objetivo é oferecer condições acadêmicas necessárias para que o aluno adquira um repertório teórico e metodológico, tornando-se apto a exercer as atividades de docente de nível universitário e iniciá-lo na carreira de pesquisador.

Os cursos de mestrado e doutorado (stricto sensu) foram os primeiros criados na área de fisioterapia do país.

Linhas de pesquisa do programa são:

- ☐ Instrumentação e Análise Cinesiológica e Biomecânica do Movimento
- ☐ Processos de Avaliação e Intervenção em Fisioterapia do Sistema Músculo-Esquelético
- ☐ Processos Básicos, Desenvolvimento e Recuperação Funcional do Sistema Nervoso Central
- ☐ Processos de Avaliação e Intervenção em Fisioterapia Cardiovascular e Respiratória

Recomendado pela CAPES – Conceito 6

Mais informações
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O que é PEDro?

PEDro, Physiotherapy Evidence Database, é uma base de dados eletrônica gratuita de evidências relevantes em fisioterapia. PEDro permite acesso rápido a mais de 17.000 estudos clínicos aleatorizados, revisões sistemáticas e diretrizes de prática clínica em fisioterapia, fornecendo, quando possível, resumo e link para o texto completo de cada documento indexado.

Todos os estudos clínicos na PEDro são avaliados para fins de classificação de qualidade. Esses critérios de qualidade permitem aos usuários identificar de forma rápida os estudos que mais possivelmente contenham informações válidas e úteis para guiar a prática clínica.

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BJPT Brazilian Journal of Physical Therapy

ISSN 1413-3555

2016 Jan/Feb; 20(1)