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HEALTH SERVICES RESEARCH

Responsiveness and Interpretability of the Portuguese Version of the Quebec Back Pain Disability Scale in Patients With Chronic Low Back Pain

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Study Design. A prospective cohort study with a 6-week follow-up of patients with chronic low back pain undergoing physiotherapy.
Objective. To examine the responsiveness of the Portuguese version of the Quebec Back Pain Disability Scale (QBPDS-PT), and to determine the minimal clinically important difference, minimal detectable change (MDC), and floor/ceiling effects.
Summary of Background Data. Measuring change over time is critical to assess the effectiveness of a physiotherapy intervention or to distinguish individual differences in response to treatment.
Methods. One hundred thirty-two patients were recruited from 16 outpatient clinics in 7 different regions of Portugal. A final sample of 120 patients completed the QBPDS-PT twice: at the baseline and after 6 weeks of physiotherapy treatment. The patient global impression of change scale was used as an external criterion measure to distinguish between improved or nonimproved patients' scores between baseline and follow-up. The responsiveness of the QBPDS-PT was assessed through correlation coefficient and receiver operating characteristics curves. The minimal clinically important difference was estimated by the receiver operating characteristics curve method and the MDC through the standard error of measurement.
Results. The scale revealed moderate responsiveness ($\rho = 0.426$ and area under the curve = 0.741; 95% confidence interval:
0.645–0.837). The MDC achieved 19 points, whereas the minimal clinically important difference was found to be 6.5 points (area under the curve = 0.741, sensitivity = 72%, specificity = 71%). A floor effect was founded with 15.8% of the participants reporting values within the MDC at the lower end of the available range of scores. For the highest baseline scores of QBPDS-PT (≥ 34 points) the optimal cutoff point was found to be 10.5 points (area under the curve = 0.738, sensitivity = 73%, specificity = 67%).
Conclusion. The QBPDS-PT demonstrated moderate levels of responsiveness, and is recommended to measure change in disability in patients with chronic low back pain after physiotherapy intervention.
Key words: QBPDS, responsiveness, interpretability, activity limitation, patient-reported outcome measure, CLBP.
Level of Evidence: N/A
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Improving functional capacity is a common goal when providing physiotherapy treatment to patients with chronic low back pain (CLBP).[1–4] In a clinical setting, clinicians and researchers are often interested in measuring change in a patient's condition as a result of an intervention or to distinguish individual differences in response to treatment.[5,6] To address change accurately in health-related outcomes, such as functional disability, clinicians need measurement tools that show responsiveness and are able to detect minimal changes in performance over time.[6] This change must be large enough to be considered a "real" change and precise enough to detect small but important clinical changes over time considered to be important by patients and/or clinicians.[7–9] The concepts of "minimal detectable change" (MDC) and "minimal clinically important difference" (MCID) have been introduced to help clinicians and researchers in assessing and interpreting patient changes. The MDC has been defined as the minimal amount of change that can be considered above the threshold of error expected in the measurement,[7,9] whereas the MCID has been defined as the smallest change in an outcome measure that is

perceived as beneficial by the patient and that would lead to a change in the patient's management, assuming an absence of excessive side effects and costs.[10,11]

The Quebec Back Pain Disability Scale (QBPDS) is a well established functional self-report questionnaire to assess changes in function in patients with CLBP participating in rehabilitation programs.[3,9,12–14] Several studies have evaluated its reliability and validity and have had good results.[15–20] However, studies addressing its responsiveness are scarce, especially in samples of patients with CLBP, and there is little agreement in their findings.[3,9,14,21–23] In those studies the MDC was in the range 11.04[23] to 24.6 (95% confidence interval [CI]: 19.9–32.4)[14] and the MCID was in the range from 5[9] to 8.5 points.[14] Moreover, and in what concerns its interpretability, there are only a few studies that have considered the MCID in relation to the MDC.[3,9,14] Therefore, the purpose of this study was to examine the responsiveness of the QBPDS-Portuguese version (PT) and to determine the MCID, MDC, and the floor/ceiling effects, in patients with CLBP.

MATERIALS AND METHODS

A prospective multisite cohort study design with a follow-up at 6 weeks was conducted. This clinical retest interval was chosen because it is commonly used in clinical practice as a time for comprehensive reassessment of patients with low back pain,[3,24,25] and because the variability in scores over this typical clinical retest period is more likely to reflect true variability in scores than that found with very short retest periods.[3,11,26]

The study sample consisted of 132 consecutive patients with CLBP referred to physiotherapy treatment at 16 different clinical settings in Portugal. Participants were considered eligible if they had low back pain, with or without leg pain, for at least 3 months, and were aged between 18 and 65 years and able to read and speak the Portuguese language. They were excluded if they had "red flags" indicative of possible serious spinal pathology or if they had undergone back surgery or conservative treatment in the prior 6 and 3 months, respectively. The study was approved by the Ethics Committee of the School of Health Care, Institute Polytechnic of Setúbal.

All the patients underwent a multimodal physiotherapy treatment. However, it is important to note that the physiotherapy treatment applied to the patients was neither of interest nor under investigation. These interventions, as well as the interval between assessments, assisted as a construct for achieving a change.[11]

At baseline, all the participants completed a sociodemographic and clinical questionnaire and the QBPDS-PT.[27] At the end of the follow-up, the participants completed the QBPDS-PT and the Portuguese version of the patient global improvement change scale (PGIC-PT).[28]

The QBPDS is a self-administered Likert questionnaire measuring functional status in patients with low back pain with reference to "today" on a 10-item scale with 6 response categories each. Each item scores from 0 to 5 and the total score is calculated by a summation of the scores for each item. The scale score ranges from 0 (no disability) to 100 (severe disability).

The PGIC is a 7-point transition scale described by Hurst and Bolton,[29] designed to assess the patient's perception of their overall change in their back condition. The PGIC is scored as follows: 1 (no change, or condition has got worse), 2 (almost the same, hardly any change at all), 3 (a little better, but no noticeable change), 4 (somewhat better, but the change has not made any real difference), 5 (moderately better, and a slight but noticeable change), 6 (better, and a definite improvement that has made a real and worthwhile difference), and 7 (a great deal better, and a considerable improvement that has made all the difference). Both instruments have been cross-culturally adapted and validated in European Portuguese.[27,28]

After 6 weeks of physiotherapy treatment, the patients completed the QBPDS-PT and were asked to grade their overall change in LBP status using the PGIC-PT scale to rate the question: "How important is the change you have experienced in your pain-related disability in daily living activities compared with the beginning of the treatment?"

DATA ANALYSIS

The data analysis was conducted using SPSS (version 20.0; IBM, Chicago, IL). The levels of the PGIC-PT scale were collapsed in 2 subgroups: "clinically stable" and "clinically improved." On the basis of previous research,[3,11,30] this study used a conservative approach to classify patients' improvement. That is, participants who rated themselves as only a "little better" are unlikely to have experienced clinically meaningful change. Therefore, participants with ratings between 1 and 4 were considered to have remained stable in their pain-related functional status and classified as "clinically stable." The remaining participants were classified as "clinically improved" (5–7).

After the dichotomization of the group, normality tests were carried out for each subgroup. Given the non-normality of the data, nonparametric tests were chosen. The raw change score for each subgroup on the QBPDS-PT was calculated by subtracting the follow-up scores from the baseline scores. Thus a positive change score indicated a reduction of the functional disability. The percentage change score was calculated as follows: (raw change score/baseline score) × 100.[31]

The Wilcoxon test was used to test the assumption that the QBPDS-PT scores for the "clinically stable" subgroup in both administrations were not statistically different ($P > 0.05$). The equivalence of the 2 subgroups was also tested at the baseline for sociodemographic and clinical variables using the Pearson χ^2 test and the Mann-Whitney test for QBPDS-PT.

To examine the responsiveness of the QBPDS-PT, the relationship between the QBPDS-PT and the PGIC-PT score changes was tested using the Spearman rank-order correlation. The ability of the QBPDS-PT to discriminate between participants who have improved from participants who remained the same was examined using the receiver operating characteristics (ROC) method.[32] The area under the curve (AUC) was interpreted as the probability of correctly discriminating between "clinically stable" and "clinically improvement" patient's outcome, based on the change in the PGIC-PT score (score ≥5).

The MCID was estimated for raw and percent scores by identifying the point closest to the upper left corner on the ROC curve. This point indicates the change score that best fits the sensitivity and specificity.[33] On the basis of the QBPDS-PT median score at the baseline, the sample was divided into 2 subgroups (highest and lowest scores) and optimal cutoff points were estimated.

The MDC established with a confidence level of 90%, was defined as the error associated with the repeated measurements.[11] First, differences in the scores from baseline to follow-up from the "clinically stable subgroup" were used to estimate the intraclass correlation coefficient (2, 1; 2-way random effects) and to calculate the standard error of measurement (SEM) for repeated measures, using the following formula: $SEM = \text{standard deviation}_{average} \times \sqrt{1-r}$, where "$r$" corresponds to the intraclass correlation coefficient value.[11]

Then, the SEM value was used to estimate the MDC using the following formula: $MDC_{90} = 1.65 \times \sqrt{2} \times SEM$, where 1.65 is the 90th percentile of the standardized normal distribution, whereas 2 is equal to the number of measurements.[34,35]

The MDC was also used to obtain the scale width, defined as the capacity of a scale to have initial scores that are far enough onto the scale to allow detection of change in scores over time,[3] and to examine its floor and ceiling effects[36] by calculating the number of patients obtaining the lowest or the highest possible QBPDS-PT scores. Floor and ceilings effects are considered to be present if more than 15% of the participants have achieved the lowest or highest possible score, respectively.[37]

Finally, the MDC and MCID values were combined to illustrate the clinical interpretation of the QBPDS-PT results. Statistical significance was set for $P < 0.05$ level.

TABLE 1. Sample Characteristics of "Clinically Stable" and "Clinically Improved" Subgroups and Results of the Pearson χ^2 Test

	Clinically Stable	Clinically Improved		
	(n = 44), No. (%)	(n = 76), No. (%)	Pearson χ^2 Score	P
Age (median)			0.107	0.849
≤49 yr	22 (50)	39 (51.3)		
>49 yr	22 (50)	37 (48.7)		
Sex			1.451	0.288
Male	9 (20.5)	24 (31.6)		
Female	35 (79.5)	52 (68.4)		
Body mass index			2.094	0.168
Normal weight	13 (31)	32 (42.1)		
Overweight	29 (69)	44 (57.9)		
Working situation			1.783	0.410
Active	31 (70.5)	45 (59.2)		
Not active	10 (27.7)	20 (26.3)		
Domestic	3 (6.8)	11 (14.5)		
Current complaints of pain			0.015	1.000
≤24 mo	15 (34.1)	26 (34.2)		
>24 mo	29 (65.9)	50 (65.8)		
Pain location			0.855	0.446
Without leg pain	18 (40.9)	39 (51.3)		
With leg pain	26 (59.1)	37 (48.7)		
Medication			0.166	0.707
No	33 (75)	40 (52.6)		
Yes	11 (25)	36 (47.4)		
Sick leave (last year)			0.202	0.815
No	36 (81.8)	59 (77.6)		
Yes	8 (18.2)	17 (22.4)		

TABLE 2. Scores Parameters of the QBPDS-PT at Baseline and Follow-up for Each PGIC-PT Score and for Each Subgroup

PGIC (Follow-up)	QBPDS-PT Baseline Mean ± SD (Me)	QBPDS-PT Follow-up Mean ± SD (Me)	QBPDS-PT Changes Baseline Follow-up Mean ± SD (Me)	Relative QBPDS-PT Changes Baseline Follow-up Mean (%)
1 (n = 1)	55 ± 0	80 ± 0	−25 ± 0	45.5
2 (n = 8)	27.9 ± 19.3 (20.5)	29.3 ± 21.4 (24.5)	−1.4 ± 5.6 (−1.0)	−1
3 (n = 22)	32.4 ± 17 (28.0)	30.7 ± 18.7 (29.3)	1.7 ± 11.1 (−1.9)	−1.9
4 (n = 13)	42.2 ± 21.2 (36.0)	34.6 ± 16.4 (39.0)	7.5 ± 11.2 (6.0)	11.9
5 (n = 35)	37.9 ± 15.4 (35.0)	27.5 ± 15.5 (24.0)	10.3 ± 9.3 (10.0)	27.9
6 (n = 31)	40.3 ± 21.3 (40.0)	24.1 ± 13.8 (23.0)	16.2 ± 15.9 (15.0)	38
7 (n = 10)	28 ± 12.9 (25.0)	17.5 ± 15.4 (9.5)	10.5 ± 13.0 (14.5)	33.9
Total (n = 120)	36.6 (±18.4)	27.7 (±17.1)	8.9 (±13.4)	
Clinically stable (n = 44)	35 ± 19.1 (33.0)	32.7 ± 19.4 (33.5)	2.3 ± 11.3 (0.0)*	3.3
Clinically improved (n = 76)	37.5 ± 18 (34.0)	24.8 ± 15.0 (22.0)	12.7 ± 13.0 (11.0)†	32.8

*Results of the Wilcoxon test (comparing baseline and follow-up scores): *P < 0.05.*
†P < 0.01.
QBPDS-PT indicates Portuguese version of the Quebec Back Pain Disability Scale; PGIC, patient global improvement change; SD, standard deviation; Me, Median.

RESULTS

Of the 132 patients included in the trial, 12 patients failed to complete the follow-up set of questionnaires. Of those, 11 abandoned the physiotherapy treatments and 1 did not complete the QBPDS-PT after the 6 weeks of treatment. The remaining 120 patients were allocated on the basis of the PGIC-PT scores into: "clinically stable" subgroup (n = 44; 36.7%) and "clinically improved" subgroup (n = 76; 63.3%). Table 1 presents the main characteristics of the patients in the 2 subgroups. The mean age of the total patients was 47.18 years (standard deviation = 12.35) and the majority of the patients (72.5%) were female (87 patients). The duration of the complaints was predominantly "more than 24 months" (65.8%).

The results of the Wilcoxon test (Table 2) validated that the QBPDS-PT scores, concerning the "clinically stable" subgroup, did not change significantly between the baseline and the follow-up. The results of the Pearson χ^2 test (Table 1) and Mann-Whitney test confirmed ($U = 1517.000$, $P = 0.398$) the equivalence of the 2 subgroups at baseline.

RESPONSIVENESS

The Spearman ρ coefficient obtained was 0.426 ($P \leq 0.05$), suggesting a positive, moderate and statistically significant correlation between the QBPDS-PT individual changes and the PGIC-PT reported scores. Through the ROC curve method (Figure 1) the AUC showed the value of 0.741 (95% CI: 0.645–0.837) indicating a moderate capability of the scale in discriminating the patients with a successful improvement from those who remained stable.

A MDC_{90} of approximately 19 points was estimated for the QBPDS-PT. Therefore, it was determined that the QBPDS-PT

scale width is between 19 and 81. Table 3 shows the absolute and the relative frequency of the participants that had reported baseline scores below and above the MDC_{90} value.
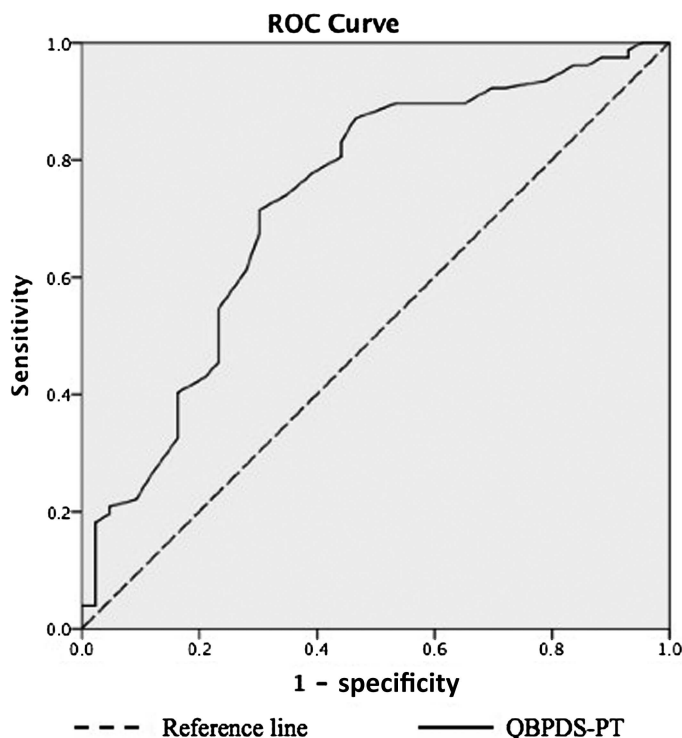
Figure 1. Receiver operating characteristics analysis of the QBPDS-PT: AUC and optimal cutoff point. QBPDS-PT indicates Portuguese version of the Quebec Back Pain Disability Scale; AUC, area under the curve; ROC, receiver operating characteristics.

TABLE 3. QBPDS-PT Scale With at Baseline		
QBPDS-PT$_{baseline}$ (n = 120)	No. of Participants	Proportion of Participants
<19	19	15.8
19–81	100	83.3
>81	1	0.8
QBPDS-PT indicates Portuguese version of the Quebec Back Pain Disability Scale.		

The lower end of the scale was a slightly more than the 15% criteria,[37] with 15.8% of the participants reporting an initial score too low to allow improvement to be detected. Accordingly, in this study sample, a marginally "floor" effect for the QBPDS-PT change score should be reported.

According to the ROC curve method (Figure 1), the optimal cutoff value of the QBPDS-PT, which minimizes the overall classification error, was 6.5 points (AUC = 0.741 [95% CI: 0.633–0.827], sensitivity of 72.4%, and specificity of 70.5%). A complementary ROC analysis based on the QBPDS-PT relative score change (expressed in percentage) from baseline revealed an optimal cutoff point of 24% (AUC = 0.737 [95% CI: 0.641–0.833], sensitivity of 71%, and specificity of 71%). An additional ROC analysis based on the QBPDS-PT baseline scores (created from the median and expressed in absolute values) showed that for patients with low scores at baseline (QBPDS-PT <34) (n = 58) an optimal cutoff point of 6.5 (AUC = 0.736 [95% CI: 0.601–0.871], sensitivity of 71.1%, and specificity of 70.5%). For patients with higher baseline scores (QBPDS-PT ≥34) (n = 62), the optimal cutoff point was 10.5 (AUC = 0.738 [95% CI: 0.597–0.878], sensitivity of 73.2%, and specificity of 66.7%).
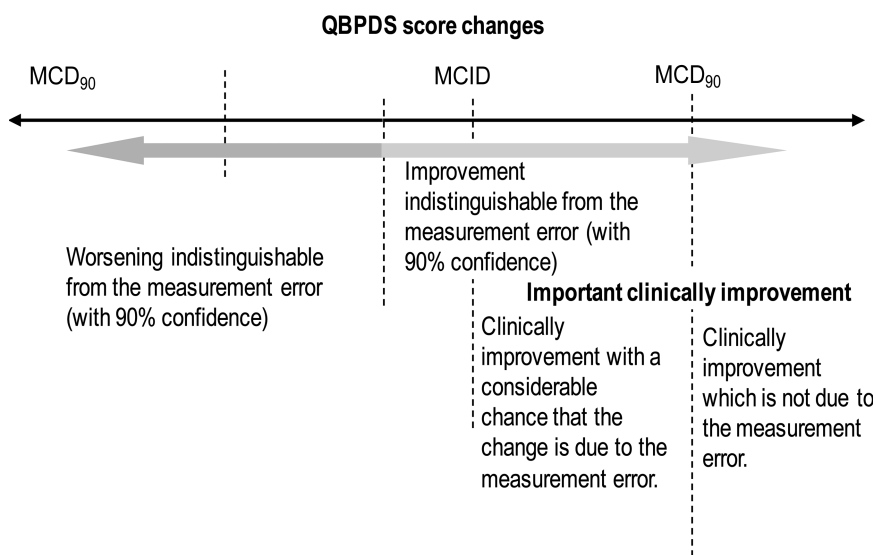
DISCUSSION

This study aimed to examine the responsiveness and determine the interpretability of the QBPDS-PT in patients with CLBP undergoing multimodal physiotherapy treatment. The results showed a moderate responsiveness that was consistent among the anchor methods used. These results were slightly lower than those reported by Fritz and Irgang[21] and Demoulin et al[9] but comparable with those reported by Davidson and Keating.[3] The MDC$_{90}$ derived from the subgroup classified as "clinically stable" was slightly higher than the values reported by Demoulin et al[9] (15.8 points) and Fritz and Irrgang[21] (13.1), identical to the value obtained in the study of Davidson and Keating[3] (19 points), and lower than the observed value reported by van de Roer et al[14] (24.6). Because the MDC is highly dependent on the reliability estimated, differences in the sample characteristics, such as the more or less variability in the baseline scores of the QBPDS, and differences in retest periods or in the global transition scales used to classify the "stable" patients, could have an important impact on the MDC value obtained.[38]

The ROC analysis based on the QBPDS-PT score changes revealed an absolute optimal cutoff value of 6.5 points and a relative cutoff value of 24%. These MCID values indicate that if a change scores smaller than its values it should be regarded as irrelevant for the patient, whereas change scores beyond the range indicate that the patient has benefited from the treatment.[14] Considering the studies with CLBP samples, the absolute value is lower than the value reported by van der Roer et al,[14] (8.5 points) but higher than the optimal cutoff point found by Demoulin et al[3] (5 points, with the AUC being 0.850 [95% confidence interval: 0.786–0.914]; 18.1%). Despite being small, these estimates differences could be related to the definition of "important change" and the type of anchor used among the studies or the baseline characteristics of the participants.[34]

This study's results also confirmed the influence of baseline functional disability scores on the optimal cutoff points identified, as reported in previous studies.[3,14] The MCID increases from 6.5, in participants with low scores at baseline (QBPDS-PT <34, n = 58), up to 11 points in participants with higher baseline scores (QBPDS-PT ≥ 34 points, n = 62).

QBPDS score changes

MCD$_{90}$ MCID   MCD$_{90}$

Worsening indistinguishable from the measurement error (with 90% confidence)

Improvement indistinguishable from the measurement error (with 90% confidence)

Important clinically improvement

Clinically improvement with a considerable chance that the change is due to the measurement error.

Clinically improvement which is not due to the measurement error.

Figure 2. Clinical interpretation of QBPDS-PT score changes using the estimated MDC and MDIC. QBPDS-PT indicates Portuguese version of the Quebec Back Pain Disability Scale; MCID, minimal clinically important difference; MDC, minimal detectable change.

Similar to previous studies,[3,9,14] the MCID of 6.5 points illustrates that the amount of change in questionnaire scores perceived by the patient to be meaningful is smaller than the amount of change required to be statistically 90% confident that score change is not just measurement error (MDC value of 19 points). Thus, it may be difficult to distinguish observed score changes either of or above the MCID value from the measurement error because there is a considerable chance that the observed score change is due to the measurement error (Figure 2). However, this result could also indicate that patients with a longer duration of complaints might assume lower values as important improvements because they not expect a very significant change in their condition.[9]

Finally, the MDC_{90} of 19 points estimated for QBPDS-PT in this study determined a valid scale width of 19 to 81 points. In this study, 15.8% of the participants reported baseline values below 19 points and 0.8% above 81 points. The lower limit of the scale could have important clinical implications because the expectation and the most likely change in the patients' condition is to experience a reduction on their functional disability level over time, which means a reduction of QBPDS-PT total score.

This study has certain limitations that need to be taken into account. First, a study with more participants can provide better information about the responsiveness and interpretability of the QBPDS-PT. Second, this study used a transition scale (PGIC-PT) to assess change. Criticisms about the reliability and recalling bias of the transition scales have been reported in the literature.[39]

CONCLUSION

The Portuguese version of the QBPDS-PT showed moderate responsiveness in assessing changes in the functional status of patients with CLBP undergoing a multimodal physiotherapy treatment. The MDC achieved 19 points, whereas the MCID was found to be 6.5 points. This study's results also confirmed the influence of baseline functional disability scores on the optimal cutoff points identified, as reported in previous studies.

➤ **Key Points**

❑ The QBPDS-PT demonstrated moderate responsiveness, and is recommended to measure change in disability in patients with CLBP after physiotherapy intervention.

❑ The minimal clinical important difference for the QBPDS-PT was established to improvements in functional disability above 6.5 points. Improvements below this change were perceived as irrelevant in chronic low back patients undergoing physiotherapy.

❑ The amount of change in questionnaire scores perceived by the patient to be meaningful is smaller than the amount of change required to be

statistically 90% confident that score change is not just measurement error.

❑ Estimation of MCID was dependent on baseline level of disability with those having more disability requiring a larger change (10.5 *vs.* 6.5).

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