



The minimal important change for the seven-item disability of the arm, shoulder, and hand (DASH 7) questionnaire – Assessing shoulder function in patients with subacromial pain



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Background: The DASH 7 is a recently published activity-related 7-item short form of the disability of the arm, shoulder, and hand (DASH) questionnaire developed to assess shoulder function in patients with subacromial pain. Before implementation in both intervention studies and in clinical practice, it is essential to evaluate its responsiveness. The objective of this study was to determine the minimal important change (MIC) in the DASH 7 questionnaire for patients with subacromial pain after a 3 months exercise intervention in a primary care context.

Methods: In this psychometric study the anchor-based MIC-distribution method was used to establish the MIC. The Patient Global Impression of Change (PGIC) was used as external criterion. Data from a clinical implementation study, aimed to implement a specific exercise strategy for patients with subacromial pain among physiotherapists in primary care, were used. Data from 70 patients were included in the analyses.

Results: The correlation coefficient between Patient Global Impression of Change and the DASH 7 score change was 0.67 and the area under the curve was 0.94 (95% confidence interval: 0.88–1.0). The MIC_{ROC} for improvement was detected at a mean change in 6.5 points with the sensitivity at 0.98 (98%) and the specificity at 0.78 (78%), and the MIC_{95%} limit for improvement was detected at a mean change of 25.7 points. There were 77% of the patients who reached at least this MIC_{ROC} and 51% who reached at least the MIC_{95%} limit after 3 months of exercise intervention.

Conclusion: The DASH 7 is responsive to change over time and can discriminate between patients considered to be improved and patients considered not improved. These MIC values for patients with subacromial pain in the primary care setting can be used in clinical practice and in intervention studies as an indication on the patients clinically important level of score change for improvement.

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The 7-item disability of the arm, shoulder, and hand (DASH 7) questionnaire is a recently developed and published patient-reported outcome measure (PROM)³⁴ for patients with subacromial pain. The development of DASH 7 was based on a study investigating which of the items in the original DASH were the most relevant for patients with subacromial pain.³⁴ The DASH 7 is an activity-related 7-item short form of the disability of the arm,

shoulder, and hand (DASH) questionnaire,¹⁷ developed to assess shoulder function in patients with subacromial pain.³⁴ PROMs are commonly used instruments in both intervention studies and in clinical practice to capture patients self-reported function, disability, and perceived health to determine patients response to treatment.³⁹ The use of PROMs in clinical practice can improve patient-clinician communication^{11,44} and enhance patient care and outcomes,⁴⁴ and it is essential that PROMs demonstrate acceptable psychometric properties.⁴² A prerequisite for a PROM to be used in both clinical practice and in research is the instrument responsiveness that can be measured in multiple ways.^{1,10,24,38} There are methodological guidelines, the Consensus-based Standards for development of Measurement Instruments (COSMIN), which describe recommendations for how measurement properties are to

The present analyses have been performed on patient data from a clinical implementation study with ethical approval from the Swedish Ethical Review (authority reference number 2014/343-31) and with additional approval for the analyses in the present study (2017/492-32).

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be defined and tested.^{29,31} As per an international consensus, responsiveness is defined as “the ability of an instrument to detect change over time in the construct to be measured” and is considered an aspect of validity.³¹ A measure known as the “minimal important change” (MIC) is commonly used to interpret a score change in a PROM. Many different terms are used for this measure, for example “minimal clinical important difference,” “minimal important difference,” and “subjectively significant difference.”^{10,23} The MIC can be defined as “the smallest change in score in the construct to be measured which the patients perceive as important.”⁹ In both research and clinical practice, it is important to be able to detect a patient response to an intervention and correctly classify someone as improved, not improved, or worsened.¹⁰

MIC has been reported for several standardized PROMs measuring shoulder function^{3,5,24,26,28,35} and the MIC values seems to vary related to patient population, baseline data, given intervention, and method used for calculation.^{5,6,38} To this date, there are no MIC values reported for the DASH 7 questionnaire.

Therefore, this study aimed to determine the MIC in the DASH 7 questionnaire after a 3-month exercise intervention for patients with subacromial pain in a primary care context.

Materials and methods

Study design and population

In this psychometric study, data from a clinical implementation study were used. The clinical study aimed to implement a specific exercise strategy for patients with subacromial pain among physiotherapists in primary care (not yet published). The patients were recruited when seeking a physiotherapist at some of the thirteen participating primary healthcare units in the County of Östergötland, Sweden. Inclusion was performed by physiotherapists who had participated in a 1-day prestudy education session designed for the study. Eligibility for the study was patients aged 30–67 years describing pain in the lateral upper arm, especially during elevation, with positive signs for a minimum of 3 of the following 5 clinical tests: impingement sign according to Neer and Welsh,³³ impingement test according to Hawkins and Kennedy,¹⁴ Pattes maneuver²⁵ (a resisted external rotation test), Jobe’s supraspinatus test,¹⁹ and painful arc.²² Exclusion criteria are presented in Table I. Data were collected between January 2015 and June 2016. The implementation study received ethical approval from the Swedish Ethical Review Authority reference number 2014/343-31, with additional approval for analyses in the present study: 2017/492-32.

A total of 121 patients were initially included, but 74 patients completed the 3-month follow-up. Inclusion criteria for the present study were that the patient had completed the DASH questionnaire¹⁷ at baseline and after 3 months of exercise intervention, with a minimum 6 of the 7 items extracted to compute the DASH 7³⁴ (missing rule). Furthermore, the patient had to have completed the Patient Global impression of Change scale¹⁵ (PGIC) at the 3-

month follow-up. Four patients had missing data in DASH 7 at baseline or at the follow-up, and 70 patients fulfilled the inclusion criteria.

Intervention

The intervention for all patients was a specific exercise strategy including information about the probable cause of subacromial pain, advice about ergonomics and daily activities, recommended corrections in posture, and a home-based specific exercise program to perform daily. The used exercises are described in an earlier publication¹⁵ and were focusing on strength and endurance of the rotator cuff muscles and the scapula stabilizers with progressive load using a pain monitoring scale.^{15,43}

Measurements

The DASH 7 is an activity-related 7-item short form of the DASH,¹⁷ a PROM developed to assess shoulder function in patients with subacromial pain.³⁴ The patient is asked to rate their ability to perform 7 different activities, related to the last week, on a scale from 1 to 5 where 1 represents “no difficulty/not limited at all” and 5 represents “unable.” The total score is calculated to a scale from 0 to 100 (as per the same formula as the original DASH¹⁷ where 0 indicates “no difficulty” and 100 indicates “severe disability.”³⁴ The original DASH contains 30 items measuring upper extremity symptoms and function in general. The DASH is reported being valid, reliable, and responsive for patients with shoulder pain.^{2,13,40,41} The DASH 7 is reported responsive for patients with subacromial pain with an effect size (Cohens *d*) of 0.93.³⁴

The PGIC scale is a PROM in which the patient is asked to assess their perceived change of symptoms compared with before start of an intervention. In the implementation study, the following question was asked to the patient: “Since the beginning of the treatment in this study, how would you describe the changes (if any) in activity limitations and symptoms related to your shoulder?” The scale used was a 5-point Likert scale with alternative answers: recovered (1), large improvement (2), small improvement (3), unchanged (4), and worse (5).¹⁵ To define improvement in this study, the scale was dichotomized into “importantly improved” (patients reporting being recovered or largely improved) and “not importantly improved” (patients reporting small improvement, unchanged, or worse).¹⁶

Data analyses

Descriptive statistics were calculated and presented for baseline characteristics. A comparison of baseline characteristics between completers and noncompleters regarding the 3-month follow-up was calculated with the independent-samples *t*-test for normally distributed variables with continuous data, the Mann-Whitney U-test for non-normally distributed continuous data, and the Chi-square for categorical data.

To establish the MIC, the anchor-based MIC-distribution method was used as per COSMIN guidelines that include both an anchor-based and a distribution-based approach.⁷ For the analyses, the PGIC was dichotomized into “importantly improved” (PGIC 1-2) and “not importantly improved” (PGIC 3-5) and used as the external criterion to determine the most optimal anchor in the receiver operating characteristic (ROC) curve. The Spearman rho was used to determine the correlation between the change score in the DASH 7 questionnaire and the external criterion (PGIC). To be adequate, a correlation coefficient at 0.50 or higher is recommended for the external criterion.⁷ The individual changes in the DASH 7 score, from baseline to 3 months follow-up, were compared

Table I
Exclusion criteria in the implementation study.

Frozen shoulder
Instability of any joint in the shoulder girdle
Symptoms from the cervical spine
A diagnosis of malignancy
Osteoarthritis in the glenohumeral joint
Symptomatic acromioclavicular arthritis
Earlier fractures or surgery in the shoulder girdle
Clinically verified polyarthritis, rheumatoid arthritis, or fibromyalgia.
Inability to understand spoken and written Swedish

Table II
Baseline characteristics, a comparison of included and excluded patients in the present study.

Patient characteristics	Included (n = 70)	Excluded (n = 51)	P value
Age in yr, mean (SD)	52.9 (9.7)	50.6 (9.8)	t-test .2
Duration of pain in mo, mean (SD)	2.5(0.7)	2.5 (0.7)	t-test .97
Women, n (%)	39 (56)	34 (67)	Chi ² .22
Heavy load occupation*, n (%)	24 (34)	9 (18)	Chi ² .07
Expectations of treatment: recovery, n (%)	59 (84)	43(84)	Chi ² .68
Corticoid injection before start, n (%)	12 (17)	5 (10)	Chi ² .31
HAD Anxiety, mean (SD)	3.6 (3.1)	4.2 (3.7)	t-test .39
HAD Depression, mean (SD)	1.7 (1.8)	2.5 (2.5)	t-test .053
VAS at rest, mean (SD)	19.8 (21)	35.8 (24.9)	t-test .002
VAS in activity, mean (SD)	68.8 (19.9)	69.7 (22.8)	t-test .86
VAS at night, mean (SD)	44.9 (28.5)	47 (36.1)	t-test .77
DASH 30, mean (SD)	33.4 (14.2)	34.5 (15.3)	t-test .70
DASH 7, mean (SD)	48.5(18.3)	48(22.1)	t-test .90
EQ-5D index, mean (SD)	0.633 (0.148)	0.589 (0.180)	t-test .15
EQ VAS, mean (SD)	70.9 (16.6)	68.6 (16.5)	t-test .45

HAD, Hospital Anxiety and Depression scale; VAS, visual analog scale; DASH, the disability of the arm, shoulder, and hand questionnaire; DASH 7, a short version of the DASH developed for patients with subacromial pain; EQ-5D, the EuroQol 5-Dimension index; EQ VAS, The EuroQol visual Analog scale.

* Heavy load is defined as minimum 50 percent of working hours with arms in or above shoulder height.

with the reported PGIC for all patients. The distribution of changes in the DASH 7 score from baseline to 3-month follow-up was plotted related to the external criterion (PGIC).

The anchor function of the PGIC was to discriminate between patients who experienced a clinical important change from those who did not. The ROC cutoff point for each change in the DASH 7 score was determined by calculating the sensitivity and specificity. The value decided as the anchor was the point on the ROC curve nearest the upper left corner, which is the point representing the lowest number of misclassified patients, with the highest level of sensitivity and specificity.⁷ The sensitivity reflects the proportion of patients correctly classified as “importantly improved” and specificity reflects the proportion of patients correctly classified as “not importantly improved” by the DASH 7 score. The area under the ROC curve (AUC) was used as an indicator of the ability to discriminate between the 2 groups (importantly improved/not importantly improved) as per the anchor. The AUC is recommended to be greater than 0.70 to be considered adequate.⁴² The MIC is presented with 2 values; one is the MIC_{ROC} which is the optimal cutoff point of the ROC curve (with sensitivity and specificity equally weighted and percentage of misclassifications the smallest) and the other is the MIC_{95% limit} which is the 95% limit cutoff point (based on the distribution of patients reporting “not importantly improved” on the external criterion and corresponds with 95% specificity).⁷ The MIC_{95% limit} was calculated by the formula: $\text{Mean}_{\text{change}} + 1.645 * \text{SD}_{\text{change}}$ for the group of patients classified as “not importantly improved.”⁷

Results

Baseline characteristics for the patients included (n = 70) vs. excluded (n = 51) are presented in Table II. At the 3-month follow-up, 74% of the included patients reported their PGIC as recovered or largely improved and 26% reported little improved or unchanged in their shoulder condition, no patient reported being worse (Table III). The reported PGIC and the DASH 7 scores for the patients included in the analysis are presented in Tables III and IV.

The correlation coefficient between the external criterion (PGIC) and the score change in the DASH 7 was 0.67 and thereby considered sufficient (>0.5) for further analysis.⁷

The MIC_{ROC} for improvement was detected at a mean change in 6.5 points in the DASH 7 score (Fig. 1) with the sensitivity at 0.98 (98%) and the specificity at 0.78 (78%) (Fig. 2). This indicate that a

patient reporting a positive score change of 7 points in the DASH 7 questionnaire has been “importantly improved” in their shoulder function, with a 24% risk of misclassification (Fig. 2). There were 54 of 70 patients (77%) who reached at least this MIC_{ROC} value as their DASH 7 score change at the 3-month follow-up. No patients reported “worse” in the PGIC as the calculation of the MIC_{ROC} for deterioration was impossible to execute. The AUC was 0.94 (95% confidence interval: 0.88-1.0) which indicate that the DASH 7 questionnaire can distinguish between the improved patients and those not improved (AUC >0.7).⁴²

The MIC_{95% limit} for improvement was detected at a mean change of 25.7 points calculated as per $-4.134 + 1.645 * 18.1057$ ($\text{Mean}_{\text{change}} + 1.645 * \text{SD}_{\text{change}}$ for the group of patients classified as “not importantly improved”) and correlated with a specificity at 95% (Fig. 1). In this study, there were 36 patients (51%) who reached at least the MIC_{95% limit} in their DASH 7 score change.

Discussion

This study shows that the DASH 7 questionnaire is responsive to change over time in patients with subacromial pain in a primary care context and has the ability to discriminate between patients considered to be improved and patients considered not improved after a 3 months exercise intervention. With a correlation coefficient at 0.7 between the external criterion and the score change in the DASH 7, the MIC_{ROC} was detected at a mean score of 6.5 points with a 24% risk of misclassification (sensitivity 0.98 and specificity 0.78).

Because the DASH 7 questionnaire is a newly developed PROM, it is essential to explore the smallest change in the score to be considered as important for patients with subacromial pain. The evaluation of measurement properties for the DASH 7 questionnaire is important before implementation of the instrument as a useful tool in clinical practice as well as in future intervention studies. The present study followed the requirements in the COSMIN checklist³² with an appropriate sample size and design. Description of missing items, used intervention, measurements, and proportions of patient-reported change is covered. By following these, requirements bias was limited and study quality enhanced.^{30,32}

Both the MIC_{ROC} (at 6.5 points) and the MIC_{95% limit} (at 25.7 points) were presented to describe the variation in the score. These MIC values can provide some help to interpret the effect of an

Table III
Reported DASH 7 score range 0-100 points, mean (SD), in relation to perceived change in the patient global impression of change (PGIC) scale.

Reported PGIC at 3 mo	No. of patients (n = 70)	Baseline DASH 7 score: mean (SD)	3-mo DASH 7 score: mean (SD)	DASH 7 score change baseline to 3 mo: mean (SD)
Recovered	15	49.3 (17.3)	3.8 (7.4)	45.5 (16.2)
Large improvement	37	50 (19.5)	18.3 (15.8)	31.9 (19.1)
Small improvement	14	43.9 (19.1)	46.2 (22.7)	-2.3 (19.8)
Unchanged	4	40.2 (7.4)	50.9 (16.3)	-10.7 (9.2)
Worse	0	0	0	0

Table IV
Perceived change in the patient global impression of change (PGIC) scale when dichotomized into “not importantly improved” and “importantly improved” in relation to reported DASH 7 score range 0-100 points, mean (SD), included in ROC analyses.

Reported DASH 7 score	Not importantly improved (small improvement, unchanged) n = 18	Importantly improved (recovered, large improvement) n = 52	P value
Mean score at baseline (SD)	43.1 (17)	49.8 (18.7)	.183
Mean score at 3-mo follow-up (SD)	47.2 (21.1)	14 (15.5)	.000
Mean change from baseline to 3-mo follow-up (SD)	-4.1 (18.1)	35.8 (19.2)	.000

DASH 7, 7-item disability of the arm, shoulder, and hand questionnaire; ROC, receiver operating characteristic.

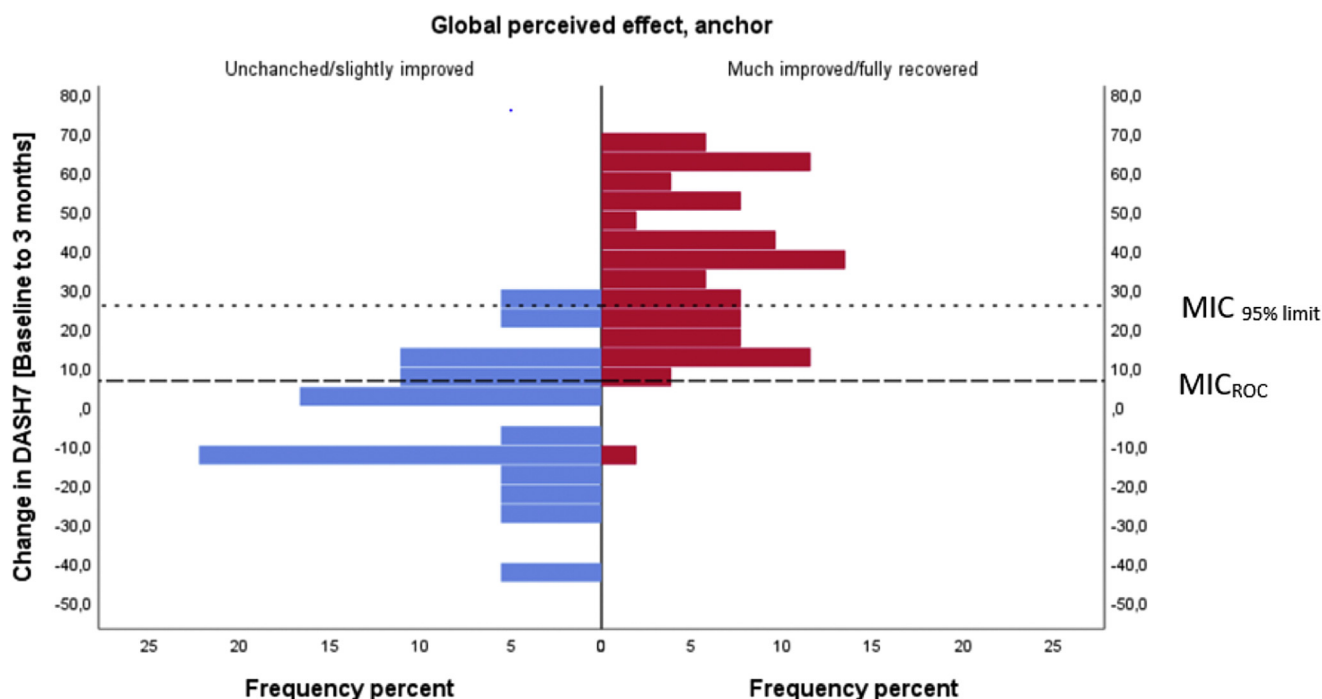


Figure 1 The anchor-based distribution of the score change in the DASH 7 for the groups “importantly improved” (n = 52) and “not importantly improved” (n = 18) presented with the optimal ROC (MIC_{ROC}) and 95% limit (MIC_{95% limit}) cutoff points. DASH 7, 7-item disability of the arm, shoulder, and hand questionnaire; ROC, receiver operating characteristic.

intervention for a patient in clinical practice or in intervention studies. Which MIC value to use depends on the specific situation. The MIC_{ROC} is based on equally weighted sensitivity and specificity to get the sum of minimum number of misclassified patients. This cutoff value would be the one to use if no reason is given for a priori among the true positives or the true negatives. The MIC_{95% limit}, based on the 95% level of specificity, would be a preferable choice if the priority is to avoid the risk of classifying a patient as “importantly improved” when the score change falls within the measurement error of the DASH 7 questionnaire. To make an evidence-based classification on a patient’s response to treatment, these MIC values can preferably be used in combination with evaluation of patient treatment goals and the score end point reached.¹

The results of this study, with the AUC at 0.94, confidence interval: 0.88-1.0, exceed the AUC reported in earlier studies evaluating responsiveness for the DASH in patients with subacromial pain (AUC 0.77-0.79, confidence interval 0.63-0.92).^{27,35} An AUC greater than 0.7 indicates an adequate ability to distinguish between the improved patients and those not improved,⁴² as this result is considered as evidence for good responsiveness of the DASH 7.

As mentioned in the introduction, MIC values are reported to possibly differ depending on patient population,^{5,6,8} context,⁵ and also on the method used for calculation.^{1,5,8} Rysstad et al (2017)³⁵ reported an MIC value at 4.4 points for the original 30-item DASH in patients with subacromial pain which can be considered in line with 6.5 for the DASH 7. The similarities in patient population, the primary care context, and the combined anchor- and distribution-

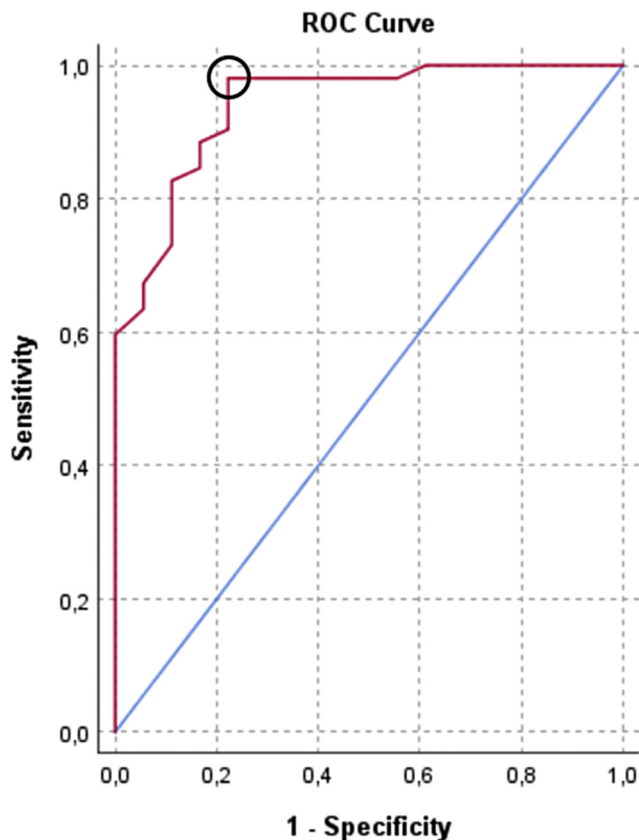


Figure 2 Receiver operating characteristic (ROC) curve for different cut-off points of changes in the DASH 7 score. The curve-point, nearest the left-upper corner represents the best cut-off as an anchor, indicating the lowest amount of misclassifications with the highest sensitivity and the lowest 1 specificity.

based method for calculating the MIC, between the present study and the study by Rysstad et al,³⁵ enable comparison of the results. Earlier research has reported a larger score change in the DASH 7 in comparison with the original DASH for patients with subacromial pain with 19.4 points compared with 13.6 in mean score change,³⁴ which support the larger MIC_{ROC} in the DASH 7 compared with 30-item DASH in patients with subacromial pain.

The chosen method in this study was the anchor-based MIC-distribution method which includes both an anchor-based and a distribution-based approach.⁷ Each approach has been criticized owing to inherent limitations. One limitation with the distribution-based approach is that it does not aid in appreciating the clinical importance of the observed change.⁷ Because the main purpose of the MIC is to identify the patient-related clinical importance from the statistical significance, that seems an appropriate criticism. The distribution-based approach also depends on the sample specific variation which can be criticized when it comes to generalizability.⁷ The anchor-based approach on the other hand misses out on taking the sample specific variation in the score into account.⁷ Therefore, by using a combined method including both an external criterion with the patient perceived change in focus together with a variability measure with the patient distribution of change presented in graphs, the results should better display the adequateness of the anchor and the consequences of choosing a specific MIC.

The MIC depends on the external criterion used to set the anchor. In this study, a 5-point Likert scale was used to assess patients' perceived change. The global assessment scales have been criticized by questioning the patient's ability to truly remember an earlier state of health^{36,37} but reported to be valid by others as a

score uniquely relevant to the patient.^{12,18,20,21} Unfortunately, there is no consensus agreement on the best anchor to use when calculating the MIC, but most often, the anchor is a global assessment scale.⁴ When using a global assessment scale as an external criterion for an MIC, it is important that the question asked is related to the same specific construct as the one measured in the score.⁷ In the present study, the patients were asked to assess their perceived change (if any) in activity limitations and symptoms related to their shoulder at the 3-month follow-up in comparison with before the intervention started. This question in the PGIC is hereby considered adequately related to what is measured with the DASH 7 questionnaire where the items focus on activity-related shoulder function. The low number of patients (n = 4) reported themselves as "unchanged" and therefore could be considered stable, eliminated the possibility to execute calculations of the minimal detectable change and the standard error of measurement. To secure interpretation of the score change and rely on the MIC value as true change, it is recommended that the MIC should exceed the minimal detectable change and the standard error of measurement.⁷ Therefore, further research is required to determine the minimal detectable change and standard error of measurement for the DASH 7. Another limitation was that only 70 of the 121 patients included in the implementation study could be included in this current analysis. However, because the baseline characteristics were similar (Table II), except for a higher pain intensity at rest among those not included, the reported MIC values are thought to be generalizable for patients with subacromial pain in a primary care context.

Conclusion

The DASH 7 questionnaire is responsive to change over time and has the ability to discriminate between patients perceived improved and not improved with an MIC_{ROC} at a score change of 6.5 points, an MIC_{95% limit} at a score change of 25.7 points, and the AUC at 0.94. These MIC values for patients with subacromial pain in the primary care setting can be used in clinical practice and in intervention studies as an indication on the patients' clinically important level of score change.

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