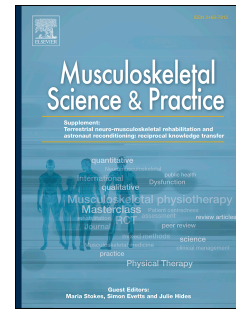


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**MANUSCRIPT FOR SUBMISSION TO**  
**MUSCULOSKELETAL SCIENCE AND PRACTICE**

**Title**

**Estimating the Minimal Important Difference for the Western Ontario Rotator Cuff Index (WORC) in adults with shoulder pain associated with partial-thickness rotator cuff tears**

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**Estimating the Minimal Important Difference for the Western Ontario Rotator Cuff Index (WORC) in adults with shoulder pain associated with partial-thickness rotator cuff tears**

**ABSTRACT**

*Background:* Knowledge about Minimal Important Differences (MIDs) is essential for the interpretation of continuous outcomes, especially patient-reported outcome measures (PROMS).

*Objective:* The aim of this study was to estimate the MID for the Western Ontario Rotator Cuff Index (WORC: score 0 (best) to 2100 (worst disability)) in adults with shoulder pain associated with partial-thickness rotator cuff tears, ‘symptomatic PTTs’, undergoing conservative treatment with physiotherapy.

*Design:* A prospectively-designed anchor-based MID analysis using data from a prospective prognostic study with a three-month follow-up conducted within an outpatient care setting in Germany.

*Methods:* The MID was estimated using data from 64 adults with atraumatic symptomatic PTTs who underwent three months of conservative treatment with physiotherapy. The anchor was a seven-point Global Perceived Change (GPC) scale.

*Results:* Based on a definition of the MID being the threshold of “being (at least slightly) improved” with a probability nearest to 0.90 (i.e. 9 of 10 patients achieving the MID), the MID for the WORC was estimated as -300 for ‘improved’ shoulder-related disability in 9 out

of 10 patients (95% CI 8 out of 10 patients to everyone) undergoing three months of exercise-based physiotherapy for symptomatic PTTs.

*Conclusions:* This is the first published MID estimate for the WORC in adults with symptomatic PTTs of the rotator cuff undergoing typical treatment comprising conservative treatment with physiotherapy. The conceptual framework for interpretation facilitates its use in similar clinical contexts.

#### **KEY WORDS**

Shoulder Pain; Physical Therapy Modalities; Patient Reported Outcome Measures; Minimal Clinically Important Difference

## INTRODUCTION

The “Minimal Important Difference” (MID) has been defined as “the smallest difference in score in the outcome of interest that informed patients or proxies perceive as important, either beneficial or harmful, and which would lead the patient or clinician to consider a change in the management.”<sup>1, p.594</sup> MIDs (alternative terms include “Minimal Clinically Important Difference”, MICD, and “Minimal Important Change”, MIC) are increasingly considered essential for the interpretation of continuous data from patient-reported outcome measures (PROMs), hence going beyond the determination of “statistical significance”.<sup>2-5</sup> MID estimates are dependent on the specific context within which they were established (e.g. populations, interventions, setting).<sup>6,7</sup>

The various approaches for estimating MIDs are commonly broadly categorized into anchor-based approaches, where the MID is estimated by linking the observed outcome to an external criterion (the anchor, which should preferably be a patient-reported measure such as a global perceived change (GPC) scale), and distribution-based approaches, where the MID is derived relying on the statistical properties of the sample (e.g. the standard error of the estimate).<sup>2,7-9</sup> These different analytical approaches usually yield different MID estimates. Although the optimal approach is yet to be determined, anchor-based methods are generally considered the preferable strategy, particularly because they define the MID based on the patients’ ratings of perceived difference.<sup>5,10,11</sup>

The purpose of this study was to derive an MID estimate for the Western Ontario Rotator Cuff Index (WORC),<sup>12</sup> a PROM developed specifically and validated for use in people with rotator cuff related shoulder complaints,<sup>13,14</sup> in a population of adults with shoulder pain

associated with partial-thickness rotator cuff tears; labelled 'symptomatic PTTs' in the following. Prior to this research, a systematic literature search failed to identify any MID estimates for this distinct subcategory of adults with shoulder disorders.<sup>15</sup>

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## METHODS

We derived the estimate of the MID for the WORC for adults with symptomatic PTTs alongside and integral to a prospective prognostic study, conducted in an outpatient setting in X, Germany. The main study was an observational study designed to develop a multivariable prognostic model for predicting the outcome of a three-month period of conservative treatment with physiotherapy, with or without adjunctive medical treatment, in adults ( $\geq 18$  years) with rotator cuff related shoulder pain in the presence of an atraumatic ultrasonographically diagnosed PTT (publication in preparation<sup>16</sup>). Clinically, attribution of the shoulder pain to the rotator cuff was based on a presentation of shoulder pain provoked or aggravated with movements or activities at or above shoulder level in the absence of a significant restriction of range of movement, and positive findings of clinical signs and tests such as a painful arc, “impingement” signs or resistance tests of the rotator cuff muscles. Patients were excluded if there was evidence of other relevant potential sources of the shoulder pain, such as previous substantial shoulder trauma, clinically relevant glenohumeral joint degeneration or disease (e.g. frozen shoulder), inflammatory conditions or previous surgery at the affected shoulder. Participants were consecutively recruited by an experienced medical shoulder specialist at an orthopedic specialist practice between December 2012 and September 2014; follow-up ended in January 2015. The mean (SD) duration between the baseline assessment and the completion of the follow-up questionnaires (see further) was 97 (17) days.

Patients were followed over a three-month period of treatment with exercise-based physiotherapy; adjunctive medical treatment (e.g. local steroid injections) was provided if considered necessary. The physiotherapy treatment followed a broad evidence-based protocol,<sup>15</sup> but was tailored to the individual patient and delivered in compliance with German

national healthcare regulations. The physiotherapy took place in collaborating physical therapy practices.

The primary outcome of the study, which was assessed after the end of the three-month treatment period, was the change in (shoulder-related) disability, assessed by a validated German-language version of the Western Ontario Rotator Cuff Index WORC.<sup>17</sup> The WORC comprises 21 items (questions), which are subdivided into five domains. Single items are evaluated by 100 mm visual analogue scales (VAS). The total WORC score can range between 0 (best) and 2100 (worst). As the WORC is patient-reported, the assessment could not be blinded.

The sample size of the main (prognostic) study was based on an a priori sample size estimation (primary outcome: WORC); no separate estimation was done for the MID analysis.

The study protocol was approved by the X Ethics Committee and the Ethics Commission of the X. the study was registered in the X.

#### MID analysis

The MID was estimated through an anchor-based approach. A seven-point Global Perceived Change (GPC) scale, i.e. a patient-based anchor, was used to determine the participants' perception of the overall change of their shoulder problem from baseline to follow-up (Fig. 1). The study participants' GPC ratings were then correlated with the change of their WORC scores (WORC change) from baseline to 'three-month' follow-up at a mean (SD) of 97 (17) days.



**Global Perceived Change (GPC)**

**We are interested to learn how you perceive the overall change of your shoulder problem since your first assessment with the doctor. Please make your rating by ticking (i.e. entering an “X” in) the box you consider appropriate:**

"Since my first assessment with the doctor, I rate my shoulder problem as..."

-3	-2	-1	0	1	2	3
Worse than ever	Much deteriorated	Slightly deteriorated	Unchanged	Slightly improved	Much improved	Completely recovered

**Figure 1: Global Perceived Change (GPC) Scale**

For the MID estimation, the GPC scale was dichotomized into “improved” and “unimproved”. The “improved” category comprised all positive GPC ratings (+1, +2, +3) and thereby represented a change of “at least slightly improved”. The “unimproved” category comprised all GPC ratings of 0, -1, -2 or -3, i.e. all “unchanged” and “deteriorated” ratings. The MID was derived from the “improved” category.

The statistical analysis was conducted in STATA (StataCorp, version 13.1). Prior to the analysis, the WORC change scores were adjusted for regression to the mean RTM.<sup>18</sup> The analysis involved two steps: the first step was a logistic regression analysis with the dichotomized GPC scale as the dependent variable and the WORC change as the independent variable<sup>8</sup>. The analysis was adjusted also for age and sex. In the second analysis step, we calculated the predicted probability of “being improved” for different WORC change thresholds, namely -100, -200, -300, -400, and obtained the 95% confidence intervals (CIs) for these probabilities. We chose these thresholds as starting positions, with the expectation of subsequent iterations to obtain the best match. The question posed was: “What is the probability of being “improved” if the WORC change is -100, -200, -300 or -400?” We

considered a probability of 90% (the WORC change threshold at which nine out of 10 patients would be “improved”) as an intuitive and reasonable target for defining the MID as the threshold for “being improved” with a probability nearest to 90%.

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**RESULTS**

The main study included 65 adults (mean age 50 (SD 12) years; 25 (38%) female; mean symptom duration at baseline 36 (SD 49) weeks; mean baseline WORC score 897 (SD 380)). All participants completed the three-month treatment period. The mean number of physiotherapy treatment sessions was 12 (SD 6). Adjunctive medical modalities included the provision of a subacromial steroid injection in 27 participants (42%). The mean duration of follow-up was 97 (SD 17) days. The mean change in the WORC score from baseline to follow-up (adjusted for regression to the mean) was -363 (SD 341; range -1102 to 387). As GPC data were missing from one participant, the MID analysis was based on data from 64 study participants.

The study participants' GPC ratings are shown in Table 1. Overall, 55 of the 64 participants (86%) rated their shoulder problem as improved (positive GPC ratings), five (8%) as unchanged (GPC = 0), and four (6%) as deteriorated (negative GPC ratings). The probabilities of being "improved" for the four WORC change thresholds are shown in Table 2. The threshold of -300 precisely matched the pre-specified probability of 0.90. It was therefore determined as the MID estimate, no further iteration being required.

GPC category	N	%
+3	5	8
+2	32	50
+1	18	28
± 0	5	8
-1	3	5
-2	1	2
-3	0	0

**Table 1: GPC ratings (n = 64)**

Level of WORC_change <sub>ADJ</sub>	Probability	95% CI	
		Lower limit	Upper limit
-100	0.78	0.65	0.92
-200	0.85	0.74	0.96
-300	0.90	0.81	0.99
-400	0.94	0.86	1.01

**Table 2: Probabilities of being improved at different WORC\_change thresholds (n = 64)**

Applying this estimate to the observed WORC change scores, 39 (61%) of 64 participants had an improvement in the WORC score that was greater than -300. The mean WORC change score (-363) exceeded the estimated MID.

## DISCUSSION

Based on a definition of the MID being the threshold of “being (at least slightly) improved” with a probability nearest to 0.90 (i.e. 9 of 10 patients achieving the MID), we estimated an MID of the WORC of -300 for ‘improved’ shoulder-related disability in 9 out of 10 patients (95% CI 8 out of 10 patients to everyone) undergoing a three-month period of exercise-based physiotherapy for symptomatic PTTs of the rotator cuff.

We applied a rigorous design that was informed by methodological guidance from the literature. We acknowledge that our approach, specifically the use of (logistic) regression to estimate an MID, is relatively novel.<sup>8</sup> In their recent review of methods for determining MIDs, Angst et al<sup>8</sup> point to another advantage of using (logistic) regression for estimating MIDs in that it allows the analysis to be adjusted by confounding variables (such as age and sex as in our analysis).

The specific statistical approach we applied represents a particular strength of our study: by calculating the probabilities (with 95% CIs) of the dependent variable (“being improved”) at different threshold of magnitude of the outcome (the WORC change), we considered the uncertainty around the true MID value. Furthermore, the framing of our findings makes these easy to interpret: the probability that a patient with a WORC change score of  $\geq -300$  was (clinically) “improved” was 0.81 to 0.99 translates to a WORC change score of -300 would signify “improvement” of the shoulder problem in between 8 out of 10 patients and everyone (10 out of 10).

As described with the methods, we derived the MID estimate from a perceived change of the patients' shoulder problem of "at least slightly improved". It may seem intuitive to some to derive the MID exclusively from the smallest GPC category ("slightly improved"); however, by including all three categories of improvement in our derivation, we increased both robustness and relevance as the MID threshold also represented greater improvement (e.g. 'much improved'). A caveat of the approach, which is commonplace in the anchor-based MID estimates, is that although patients provide their ratings of perceived change, the decision which ratings (here "at least slightly improved") are ultimately used to define the MID is still made by the researchers<sup>19</sup>. Definitions of the MID based on GPC categories vary across the literature.<sup>10</sup>

#### Study limitations

Although GPC scales represent the most commonly used patient-based anchor in MID research,<sup>7,10</sup> they have some limitations. These include the insufficient knowledge of their validity and reliability, the possible influence of recall bias on patients' ratings and the concern that GPC scales may not adequately reflect change over time.<sup>7,20,21</sup> A caveat related to our MID analysis was that the two GPC categories ("improved" and "unimproved") were unbalanced, as 86% (55/64) were in the "improved" category, whereas only 14% (9/64) were in the "unimproved" category. It is crucial to note the context-dependence of MID estimates.<sup>6,7</sup> Lastly, no MID estimate should be viewed as *the definitive MID* that is valid for all applications without confirmation.

#### Comparison with other studies

We have identified two studies providing MID estimates for the WORC for people with rotator cuff related shoulder pain.<sup>22,23</sup> One study<sup>22</sup>, using a mixed anchor and distribution approach, estimated an MID of 275 for ‘rotator cuff disease’. The other study<sup>23</sup>, using an anchor-based approach, estimated an MID of 245 for ‘chronic cuff tendinitis without tear’. While the proximity of the three MID estimates suggests convergent validity, the differences in study design and population do not support the unconditional substitution of these MIDs for adults with symptomatic PTTs. A similar consideration applies to the extension of use of our estimate to people with rotator cuff related shoulder pain.

## **CONCLUSIONS**

### Implications for clinical practice

Our study provides an estimate for the MID of the WORC, which indicates an overall change of the shoulder problem of “at least slightly improved”, for adults with symptomatic PTTs of the rotator cuff undergoing typical treatment comprising a phase of conservative treatment with physiotherapy. The conceptual framework for interpretation facilitates its use in similar contexts.

### Implications for research

Further investigations are needed for the construction of a robust evidence base for the MID of the WORC in people with symptomatic PTTs. Further methodological research is needed to determine the optimal MID analysis methods. Efforts should be undertaken to increase homogeneity of conceptual aspects as well as of terminology in MID research.



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**Highlights:**

- The Western Ontario Rotator Cuff Index (WORC) assesses shoulder-related disability
- Minimal Important Differences (MIDs) for outcome scores are context specific
- Patients had physiotherapy for symptomatic partial thickness rotator cuff tears
- The estimated MID for the WORC was -300 for 'improved' disability in 9/10 patients