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The minimal clinically important difference of the PROMIS and qDASH instruments in a non-shoulder hand and upper extremity patient population

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Abstract

Purpose—The minimal clinically important difference (MCID) is used in research and clinical settings as a benchmark to gauge response to treatment. The purpose of this study was to provide anchor-based MCID estimates for PROMIS and legacy instruments in a non-shoulder hand and upper extremity population.

Methods—Adult patients (≥ 18 years) seeking care at a tertiary academic outpatient hand surgery clinic completed patient-reported outcome measures on tablet computers between January 2015 and August 2017. Data were collected at baseline and at six ± two weeks of follow-up. The PROMIS Upper Extremity (UE), Physical Function (PF), and Pain Interference (PI) Computer Adaptive Test (CAT) instruments were administered, along with the qDASH. A mean-change anchor-based method was used to estimate MCIDs by comparing scores between anchor groups reporting ‘no change’ versus ‘slightly improved’ in terms of function and pain.

Results—Scores for each instrument significantly improved over the study period. With significant differences in scores between groups reporting ‘no change’ and ‘slightly improved’ function, anchor-based MCID estimates were calculated as follows: 2.1 for the PROMIS UE CAT, 1.7 for the PROMIS PF CAT, and 6.8 for the qDASH. There was no significant difference in PROMIS PI CAT scores between anchor groups when queried for level of pain improvement, precluding estimation of the MCID.

Conclusions—We have provided anchor-based MCID estimates for the PROMIS UE CAT, PROMIS PF CAT, and the qDASH for a general non-shoulder hand and upper extremity population. These values may be useful in future research for informing power calculations and

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when interpreting whether the magnitude of change on these instruments are clinically-significant at a population level.

Statement of Clinical Relevance—This study provides clinicians with a reference for values that may reflect clinically meaningful changes in scores for patient-reported outcome instruments commonly utilized in the current literature.

Keywords

Hand surgery; Minimal clinically important difference (MCID); PROMIS; Upper extremity (UE) CAT; Physical Function (PF) CAT; QuickDASH/qDASH

INTRODUCTION

In recent decades, there has been an effort to include the patient perspective into the assessment of treatment outcomes, and the development of patient-reported outcome (PRO) instruments has become an important adjunct to physical and radiologic evaluations. PRO instruments are useful for measuring patient improvement while offering reliability, validity, and interpretability of scores.[1] Advancements in test development using item-response theory have created instruments with individually calibrated items that can be administered electronically, reduce redundancy, shorten test administration time, and reduce respondent burden. Recently, there has been an increased focus upon tools developed with the National Institutes of Health, specifically the Patient-Reported Outcomes Measurement Information System (PROMIS). By using computer adaptive testing (CAT), responder burden, or the number of questions asked, may be lower than for traditional legacy scales.[2] However, floor and ceiling effects have been described which may be negative trade-offs resulting from scale brevity.[3,4]

Useful PROs allow meaningful interpretations of scores.[5] In clinical research, determining statistical significance is relatively straightforward, whereas understanding the clinical significance of differing or changing outcome scores may be less clear. One measure intended to help clarify clinical significance in score interpretation is the minimal clinically important difference (MCID), which reflects the minimal amount of change in an outcome score that may be meaningful to the patient.[6] There are two primary ways to determine MCID scores. The first method is the distribution-based approach, which relies on statistical methods and probability sampling. This method can detect change that falls beyond what might be considered random variation for the specific patient population, but it does not factor in patient input regarding their perceived change in their condition.[5] Distribution methods focus on how scores vary between patients, and involve calculating a magnitude of change that is beyond random fluctuation.[7] Anchor-based methods, by contrast, tie scores to another measure of improvement that is supplied directly by the patient.[7] The anchor could be a clinical evaluation of change, a score change on another PRO that is considered a reference standard in clinical care, or a question that asks the patient about their level of change.

Although the development of PROMIS began in 2004,[2] there remains a paucity of studies reporting the responsiveness, ability to detect meaningful change, or MCID in orthopaedic

populations. Additionally, elucidation of MCID values in the hand and upper extremity population for PROMIS instruments is also limited, with recent published reports that are specific to carpal tunnel release or distal radius fracture[10] patient populations. Therefore, the purpose of our study was to establish the MCID values of three PROMIS instruments (UE CAT, PF CAT, and PI CAT) and one legacy instrument (qDASH) using a mean-change anchor-based approach for an orthopaedic non-shoulder hand and upper extremity patient population.

METHODS

Data Collection

Institutional Review Board approval was obtained prior to the start of data collection. Patients seeking care at a university orthopaedic clinic for non-shoulder hand and upper extremity conditions were prospectively asked to complete demographic and physical function questionnaires on handheld tablet computers prior to seeing one of four fellowship-trained orthopaedic hand surgeons. All patients were aged 18 years or older, and sought care for their baseline visit between January 2015 and August 2017. Follow-up outcomes data was again collected at return clinic visits 6 ± 2 weeks following the baseline visit. Participants completed PRO assessments as part of standard and customary clinic care and were not required to complete informed consent documentation.

Patient-Reported Outcome Instruments

Four PRO instruments were administered, including the PROMIS Upper Extremity (UE) CAT v1.2, the PROMIS Physical Function (PF) CAT v1.2, the PROMIS Pain Interference (PI) CAT v1.1, and the qDASH. The PROMIS UE v1.2 has a 16-item test bank (Appendix I). The PROMIS PF v1.2 draws from a 121-item test bank and contains both upper extremity and lower extremity items (Appendix II). The PROMIS PI v1.1 has a 40-item bank (Appendix III). The qDASH is an 11-item shorted version of the 30-item DASH (Appendix IV).[11] Each item of the qDASH was administered to every patient. The PROMIS instruments were administered with computer adaptive testing (CAT) formats made available through the Assessment Center, a web-based portal established by PROMIS developers.[12] The CAT administration minimizes patient burden by structuring question selection from the item bank that adjusts based on prior patient answers. For example, patients would not be asked, ‘Are you able to run or jog for two miles (3 km)?’ if they had previously answered ‘Unable to Do’ to the question, ‘Are you able to stand for one hour?’. Therefore, different questions were administered to different patients.

PROMIS instruments are calculated as standardized T-scores and calibrated in the general population to a mean of 50 and a standard deviation (SD) of 10.[13] Higher scores on the PROMIS PF and UE indicate better patient function, whereas higher scores on the PROMS PI indicate greater levels of pain interference. Scores on the qDASH range from 0 to 100, in which higher scores represent greater levels of self-reported disability. The four instruments were administered at the baseline clinic visit, and again in follow-up within 6 ± 2 weeks of the baseline visit. Patients were included if at least one instrument assessing function (UE

CAT, PF CAT, or qDASH) was collected at both baseline and follow-up, and if the anchor questions for function was answered at the follow-up visit.

Statistical Analysis

Statistical analysis included descriptive information regarding patient characteristics and demographics. Scores for each instrument were measured at follow-up, then compared individually to their respective baseline scores. Changes in scores were calculated as the absolute value difference between the baseline score and the follow-up scores for all four PROs. Differences in scores were assessed using the Wilcoxon rank sum test or Student's t-test, as indicated. Categorical data were compared using the Fisher exact or Chi-square tests, as indicted.

The anchor question assessing change in function was a global rating of change: 'Compared to your FIRST EVALUATION at the xxx: how would you describe your physical function now?'(much worse, worse, slightly worse, no change, slightly improved, improved, much improved). Another anchor question assessed a global rating of change in pain ('Compared to your FIRST EVALUATION at the xxx: how would you describe your episodes of PAIN now?') using the same responses. For each instrument, the anchor-based MCID was determined through a calculation of mean change in scores between groups of patients reporting 'no change' and 'slightly improved' on the anchor question. The change in PF, UE and qDASH scores were anchored against the anchor question for physical function. The PROMIS PI score change was anchored against the anchor question for pain. For both function and pain instruments, the anchor-based MCID was calculated as the mean difference between the 'no change' group and 'slightly improved' group. The MCID estimations were anchored to patient responses to the questions above, which provided a global rating of change (GRC), between baseline and a follow-up encounters. As a patient-reported anchor, the GRC is related to the patient perceptions, thus can be interpreted as a meaningful level of change.[6] GRC's are the most common approach to anchoring change scores in MCID studies[14,15], though they have also been criticized for relying on recall which introduces variability.[5,14]

Spearman correlation coefficients were calculated to evaluate the following associations: 1) to compare the Likert scale anchor question responses to the follow-up scores, and 2) to compare the Likert scale anchor question responses to the change in scores for each instrument. Absolute values of resulting r-values were interpreted as follows in terms of strength of the association: negligible ($r < 0.3$), low ($0.3 \leq r < 0.5$), moderate ($0.5 \leq r < 0.7$), high ($0.7 \leq r < 0.9$), and very high (≥ 0.9).[16,17] All pertinent tests were 2-sided, and a significance level of 0.05 was used throughout.

RESULTS

A total of 847 patients were included in the study with an average age of 45.4 ± 18 years, in which 420 (50%) were male and 427 (50%) were female. For patients that completed at least one of the three instruments assessing function (UE CAT, PF CAT, QuickDASH), comparisons in baseline patient characteristics between groups reporting 'no change' and 'slightly improved' are depicted in Table 1. There were no significant differences in basic

demographic factors between groups reporting ‘no change’ and ‘slightly improved’ on the function anchor question with the exception of provider ($p < 0.05$).

The majority of the cohort was recovering from a surgical intervention (n = 429, 50.6%): 323 (38.1%) of patients had surgery between the baseline and the follow-up visit, and 106 (12.5%) had surgery within 1 year prior to the baseline visit. Most patients were recovering from one surgery, whereas 39 (4.6%) patients had more than one procedure performed during their surgery. The most common surgical procedures included carpal tunnel release (13.3%), mass excision (6.4%) and distal radius fracture open reduction internal fixation (3.9%). Additional procedures performed on the study cohort are illustrated in Table 2. Of the non-operative patients, 81 (9.5%) received an injection and 302 (35.7%) were treated by hand therapy at the baseline visit.

Scores for each instrument significantly improved over the study period ($p < 0.05$ for each instrument; Table 3).

For the anchor question addressing physical function, correlation with the follow-up score and anchor response level was low (coefficient 0.37; $p < 0.05$) for the PROMIS UE CAT, low (0.33; $p < 0.05$) for the PROMIS PF CAT, and low (−0.45; $p < 0.05$) for the qDASH. For the pain anchor question, correlation with the follow-up PI CAT score and anchor response level was also low (−0.48; $p < 0.05$).

For the anchor question addressing physical function, correlation with the change in score (follow-up minus baseline) and anchor response level was low (0.48; $p < 0.05$) for the PROMIS UE CAT, low (0.36; $p < 0.05$) for the PROMIS PF CAT, and moderate (−0.51; $p < 0.05$) for the qDASH. For the pain anchor question, correlation with the change in the PI CAT score and anchor response level was low (−0.48; $p < 0.05$).

Based upon differences in scores between patient groups reporting ‘no change’ and those reporting ‘slightly improved’ to the anchor questions, the following anchor-based MCID values were determined for each instrument: 2.1 for the PROMIS UE CAT, 1.7 for the PROMIS PF CAT, and 6.8 for the qDASH (Table 4). Sample sizes for ‘no change’ and ‘slightly improved’ groups were 306 and 343 for the PROMIS UE CAT, 258 and 309 for the PROMIS PF CAT, and 340 and 370 for the qDASH, respectively. There was no significant difference in PROMIS PI CAT scores between ‘no change’ (n = 265) and ‘slightly improved’ (n =275) groups for the PROMIS PI CAT ($p = 0.74$). This precluded the calculation of a meaningful anchor-based MCID estimate for this instrument (estimate −0.2). Note that the difference in mean scores between the ‘no change’ and ‘slightly improved’ groups for the qDASH is a negative value, but that by convention MCID is reported as the magnitude of difference between these two groups.

DISCUSSION

As patient-reported outcome measures are increasingly integrated into clinical care,[18] the interpretability of scores becomes increasingly important. The use of PROMIS instruments can make important contributions to clinical practice,[19] but it is important to understand how patients perceive changes in scores. The present study expands the evaluation of MCIDs for

the PROMIS UE CAT and PROMIS PF CAT to a non-shoulder hand and upper extremity patient population.

Our MCID estimate for the PROMIS UE CAT was 2.1. Compared to an MCID estimate of 5.0 as a rough estimate for the MCID of PROMIS instruments, which can be calculated using the 1/2 standard deviation method given their standard deviation is designed to be 10 in a normative population,[20] we note that our anchor-based value is subjectively smaller. For a carpal tunnel release patient population, Bernstein et al calculated anchor-based MCID values for the PROMIS UE CAT of 6.3 and 8.0 based upon Michigan Hand Questionnaire and Boston Carpal Tunnel Questionnaire anchors, respectively.[8] The authors derived a value of 4.2 using the 1/2 SD method, and Kazmers et al derived a value of 3.6 in a similar patient population using the same calculation method.[8,9] These values are also subjectively larger than that in the current study. We speculate this could relate to the paucity of nerve-specific questions in the UE CAT question bank, which in turn could reduce the responsiveness of this instrument for carpal tunnel release, and therefore lead to a given patient noting clinical improvement only with relatively larger score changes. Based on our findings, it is possible that treatments that afford improvements as low as 2.1 points on the PROMIS UE CAT may be clinically beneficial at a population level.

Our MCID value of 1.7 for the PROMIS PF CAT is subjectively smaller than the anchor-based values derived by Sandvall et al for a distal radius fracture population (3.6 to 4.6), but similar to the value of 2.3 obtained using the minimal detectable change method.[10] As in the current study, the authors used the most stringent MCID definition by compared groups experiencing no improvement to those with only mild improvement for their anchor-based calculations. It is possible that differences in the anchor question wording or responses, follow-up duration, or diagnosis of included patients contributed to subjectively differing estimates. Our calculated value is also subjectively similar to the 2–3 point MCID range reported in a pediatric population for the mobility subscale,[21] but is subjectively lower than the values identified in a cancer population for the PROMIS PF CAT (range 4 to 6, depending on the method of calculation)[22] and the value of 4.6 calculated by Kazmers et al for a carpal tunnel release population using the 1/2 SD method.[9] Using the ½ SD method, Ho et al calculated an MCID value of 4.2 in an orthopaedic foot and ankle population, which is also subjectively greater than our estimate.[23] Despite these differences, it is notable that the 1/2 SD method does not incorporate patient input into the calculations, and perhaps the smaller MCID estimates derived from stringent anchor-based calculations may be more clinically relevant.

Although the MCID of the qDASH has been previously reported, we provided an estimate in the current investigation to serve as a reference point when interpreting the MCID values obtained for PROMIS instruments. Our estimate of the qDASH MCID of 6.8 falls slightly below the range reported in prior studies on upper extremity patients (8 to 19).[24–27] Specifically, two studies on a physical therapy population calculated qDASH MCID estimates of 8 points[26] and 11 points,[27] and an estimate of 14 was determined by Sorensen et al in a hand surgery population.[24] These differences between our results and prior reports are likely due to our use of a stringent anchor-based calculation: Sorensen et al included patients with more than minimal change in their calculation,[24] Mintken et al used a receiver

operating curve method and did not confine the calculation to a comparison of ‘no change’ and ‘minimal change’ groups,[26] and Polson et al compared groups reporting ‘no change’ to the group reporting that they had ‘much improved’.[27] Therefore, we conclude that our value of 6.8 truly represents minimal change for a hand surgery population.

Limitations of the study deserve mention. We were unable to calculate an anchor-based MCID value for the PROMIS PI CAT, although prior reports range from 3.4 to 9.7 among carpal tunnel release patients, and 2–6 in other populations.[21,22,28–30] Perhaps use of a different anchor question, inclusion of patients that improved beyond a minimal amount, or a different follow-up time frame would change our findings. Also, the study sample was comprised of individuals with upper extremity hand conditions, but there was not a sufficient sample size to stratify the analysis by procedure codes or diagnosis so we were unable to determine if variability related to diagnosis or treatment exists or not. In addition, there have been updates to wordings of the questions and responses of the PROMIS PF and UE CAT instruments, thus the MCID values determined in this study may not reflect MCIDs for the updated versions of these instruments. However, it is likely that the MCIDs for the updated instruments are the same or similar to what we have established in this study as the general methodologies for developing, refining, scaling and scoring the PROMIS instruments has not changed. There is not yet a standardized or generally agreed upon method for establishing the most clinically useful MCID,[14] and other studies have shown only moderate agreement between MCID methods.[31] However, use of an anchor-based MCID calculation approach may be favored from the clinical perspective, given that patient input is factored into the calculation. Although prior research suggests that MCID determination is not overly dependent on disease severity,[32,33] our study was limited in that we did not attempt to evaluate for this possibility in a hand surgery population.

In summary, we have calculated the MCID for the PROMIS Upper Extremity CAT (2.1), PROMIS Physical Function CAT (1.7), and the qDASH (6.8) in a general non-shoulder hand and upper extremity population using a stringent anchor-based approach. These values may be useful when determining whether changes in outcomes scores are clinically significant at a population level, and for powering prospective clinical studies.

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Appendix

Appendix I.

PROMIS v1.2 Upper Extremity item bank.

Item	ID	Question
1	PFA16r1	Are you able to dress yourself, including tying shoelaces and buttoning your clothes?
2	PFA17	Are you able to reach into a high cupboard?
3	PFA18	Are you able to use a hammer to pound a nail?

Item	ID	Question
4	PFA20	Are you able to cut your food using eating utensils?
5	PFA28	Are you able to open a can with a hand can opener?
6	PFA29r1	Are you able to pull heavy objects (10 pounds/5 kg) towards yourself?
7	PFA35	Are you able to open and close a zipper?
8	PFA38	Are you able to dry your back with a towel?
9	PFA44	Are you able to put on a shirt or blouse?
10	PFA48	Are you able to peel fruit?
11	PFA54	Are you able to button your shirt?
12	PFB21	Are you able to pick up coins from a table top?
13	PFB22	Are you able to hold a plate full of food?
14	PFB30	Are you able to open a new milk carton?
15	PFB33	Are you able to remove something from your back pocket?
16	PFB36	Are you able to put on a pullover sweater?

Note: Response options for questions 1–16 are 1 = Unable to do; 2 = With much difficulty; 3 = With some difficulty; 4 = With a little difficulty; or 5 = Without any difficulty.

Appendix II.

PROMIS v1.2 Physical Function item bank.

Item	ID	Questions
1	PFA10	Are you able to stand for one hour? *
2	PFA11	Are you able to do chores such as vacuuming or yard work?
3	PFA12	Are you able to push open a heavy door?
4	PFA13	Are you able to exercise for an hour?
5	PFA14r1	Are you able to carry a heavy object (over 10 pounds/ 5kg)?
6	PFA15	Are you able to stand up from an armless straight chair?
7	PFA16r1	Are you able to dress yourself, including tying shoelaces and buttoning up your clothes?
8	PFA17	Are you able to reach into a high cupboard?
9	PFA18	Are you able to use a hammer to pound a nail?
10	PFA19r1	Are you able to run or jog for two miles (3 km)?
11	PFA20	Are you able to cut your food using eating utensils?
12	PFA21	Are you able to go up and down stairs at a normal pace?
13	PFA22	Are you able to open previously opened jars?
14	PFA23	Are you able to go for a walk of at least 15 minutes?
15	PFA25	Are you able to do yard work like raking leaves, weeding, or pushing a lawn mower?
16	PFA28	Are you able to open a can with a hand can opener?
17	PFA29r1	Are you able to pull heavy objects (10 pounds/5kg) towards yourself?
18	PFA30	Are you able to step up and down curbs?
19	PFA31r1	Are you able to get up from the floor from lying on your back without help?
20	PFA32	Are you able to stand with your knees straight?
21	PFA33	Are you able to exercise hard for half an hour?
22	PFA34	Are you able to wash your back?
23	PFA35	Are you able to open and close a zipper?

Item	ID	Questions
24	PFA36	Are you able to put on and take off a coat or jacket?
25	PFA37	Are you able to stand for short periods of time?
26	PFA38	Are you able to dry your back with a towel?
27	PFA39r1	Are you able to run at a fast pace for two miles (3 km)?
28	PFA40	Are you able to turn a key in a lock?
29	PFA41	Are you able to squat and get up?
30	PFA42	Are you able to carry a laundry basket up a flight of stairs?
31	PFA43	Are you able to write with a pen or pencil?
32	PFA44	Are you able to put on a shirt or blouse?
33	PFA45	Are you able to get out of bed into a chair?
34	PFA47	Are you able to pull on trousers?
35	PFA48	Are you able to peel fruit?
36	PFA49	Are you able to bend or twist your back?
37	PFA50	Are you able to brush your teeth?
38	PFA51	Are you able to sit on the edge of a bed?
39	PFA52	Are you able to tie your shoelaces?
40	PFA53	Are you able to run errands and shop?
41	PFA54	Are you able to button your shirt?
42	PFA55	Are you able to wash and dry your body?
43	PFA56	Are you able to get in and out of a car?
44	PFA8	Are you able to move a chair from one room to another?
45	PFA9	Are you able to bend down and pick up clothing from the floor?
46	PFB10	Are you able to climb up five steps?
47	PFB11	Are you able to wash dishes, pots, and utensils by hand while standing at a sink?
48	PFB12	Are you able to make a bed, including spreading and tucking in bed sheets?
49	PFB13	Are you able to carry a shopping bag or briefcase?
50	PFB14	Are you able to take a tub bath?
51	PFB15	Are you able to change the bulb in a table lamp?
52	PFB16	Are you able to press with your index finger (for example ringing a doorbell)?
53	PFB17	Are you able to put on and take off your socks?
54	PFB18	Are you able to shave your face or apply makeup?
55	PFB19	Are you able to squeeze a new tube of toothpaste?
56	PFB20	Are you able to cut a piece of paper with scissors?
57	PFB21	Are you able to pick up coins from a table top?
58	PFB22	Are you able to hold a plate full of food?
59	PFB23	Are you able to pour liquid from a bottle into a glass?
60	PFB24	Are you able to run a short distance, such as to catch a bus?
61	PFB25	Are you able to push open a door after turning the knob?
62	PFB26	Are you able to shampoo your hair?
63	PFB27	Are you able to tie a knot or a bow?
64	PFB28r1	Are you able to lift 10 pounds (5 kg) above your shoulder?
65	PFB29	Are you able to lift a full cup or glass to your mouth?

Item	ID	Questions
66	PFB30	Are you able to open a new milk carton?
67	PFB31	Are you able to open car doors?
68	PFB32	Are you able to stand unsupported for 10 minutes?
69	PFB33	Are you able to remove something from your back pocket?
70	PFB34	Are you able to change a light bulb overhead?
71	PFB36	Are you able to put on a pullover sweater?
72	PFB37	Are you able to turn faucets on and off?
73	PFB39r1	Are you able to reach and get down a 5 pound (2 kg) object from above your head?
74	PFB40	Are you able to stand up on tiptoes?
75	PFB41	Are you able to trim your fingernails?
76	PFB42	Are you able to stand unsupported for 30 minutes?
77	PFB56r1	Are you able to lift one pound (0.5 kg) to shoulder level without bending your elbow?
78	PFB8r1	Are you able to carry two bags filled with groceries 100 yards (100 m)?
79	PFB9	Are you able to jump up and down?
80	PFC13r1	Are you able to run 100 yards (100 m)?
81	PFC29	Are you able to walk up and down two steps?
82	PFC31	Are you able to reach into a low cupboard?
83	PFC32	Are you able to climb up 5 flights of stairs?
84	PFC33r1	Are you able to run ten miles (16 km)?
85	PFC38	Are you able to walk at a normal speed?
86	PFC39	Are you able to stand without losing your balance for several minutes?
87	PFC40	Are you able to kneel on the floor?
88	PFC41	Are you able to sit down in and stand up from a low, soft couch?
89	PFC43	Are you able to use your hands, such as for turning faucets, using kitchen gadgets, or sewing?
90	PFC45r1	Are you able to sit on and get up from the toilet?
91	PFC46	Are you able to transfer from a bed to a chair and back?
92	PFC47	Are you able to be out of bed most of the day?
93	PFC49	Are you able to water a house plant?
94	PFC51	Are you able to wipe yourself after using the toilet?
95	PFC52	Are you able to turn from side to side in bed?
96	PFC53	Are you able to get in and out of bed?
97	PFC6r1	Are you able to walk a block (100 m) on flat ground?
98	PFC7r1	Are you able to run five miles (8 km)?
99	PFA1	Does your health now limit you in doing vigorous activities, such as running, lifting heavy objects, participating in strenuous sports? **
100	PFA3	Does your health now limit you in bending, kneeling, or stooping?
101	PFA4	Does your health now limit you in doing heavy work around the house like scrubbing floors, or lifting or moving heavy furniture?
102	PFA5	Does your health now limit you in lifting or carrying groceries?
103	PFA6	Does your health now limit you in bathing or dressing yourself?
104	PFB1	Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or carrying in groceries?
105	PFB3	Does your health now limit you in putting a trash bag outside?

Item	ID	Questions
106	PFB43	Does your health now limit you in taking care of your personal needs (dress, comb hair, toilet, eat, bathe)?
107	PFB44	Does your health now limit you in doing moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?
108	PFB48	Does your health now limit you in taking a shower?
109	PFB49	Does your health now limit you in going for a short walk (less than 15 minutes)?
110	PFB5r1	Does your health now limit you in hiking a couple of miles (3 km) on uneven surfaces, including hills?
111	PFB51	Does your health now limit you in participating in active sports such as swimming, tennis, or basketball?
112	PFB54	Does your health now limit you in going OUTSIDE the home, for example to shop or visit a doctor's office?
113	PFB7	Does your health now limit you in doing strenuous activities such as backpacking, skiing, playing tennis, bicycling or jogging?
114	PFC10	Does your health now limit you in climbing several flights of stairs?
115	PFC12	Does your health now limit you in doing two hours of physical labor?
116	PFC35	Does your health now limit you in doing eight hours of physical labor?
117	PFC36r1	Does your health now limit you in walking more than a mile (1.6 km)?
118	PFC37	Does your health now limit you in climbing one flight of stairs?
119	PFC54	Does your health now limit you in getting in and out of the bathtub?
120	PFC56	Does your health now limit you in walking about the house?
121	PFB50	How much difficulty do you have doing your daily physical activities, because of your health? ***

Note:

* Response options for questions 1–98 are 1=Unable to do; 2=With much difficulty; 3=With some difficulty; 4=With a little difficulty; 5=Without any difficulty.

** Response options for questions 99–123 are 1=Cannot do; 2=Quite a lot; 3=Somewhat; 4=Very little; 5=Not at all

*** Response options for question 121 are 1=Can't do because of health, 2=A lot of difficulty; 3=Some difficulty; 4=A little bit of difficulty; 5=No difficulty at all

Appendix III.

PROMIS v1.1 Pain Interference item bank

Item	ID	Question
1	PAININ1	In the past 7 days, how difficult was it for you to take in new information because of pain? *
2	PAININ3	In the past 7 days, how much did pain interfere with your enjoyment of life? *
3	PAININ5	In the past 7 days, how much did pain interfere with your ability to participate in leisure activities? *
4	PAININ6	In the past 7 days, how much did pain interfere with your close personal relationships? *
5	PAININ8	In the past 7 days, how much did pain interfere with your ability to concentrate? *
6	PAININ9	In the past 7 days, how much did pain interfere with your day to day activities? *
7	PAININ10	In the past 7 days, how much did pain interfere with your enjoyment of recreational activities? *
8	PAININ11	In the past 7 days, how often did you feel emotionally tense because of your pain? *
9	PAININ12	In the past 7 days, how much did pain interfere with the things you usually do for fun? *
10	PAININ13	In the past 7 days, how much did pain interfere with your family life? *
11	PAININ17	In the past 7 days, how much did pain interfere with your relationships with other people? *
12	PAININ18	In the past 7 days, how much did pain interfere with your ability to work (included work at home)? *

Item	ID	Question
13	PAININ19	In the past 7 days, how much did pain make it difficult to fall asleep? *
14	PAININ20	In the past 7 days, how much did pain feel like a burden to you? *
15	PAININ22	In the past 7 days, how much did pain interfere with work around the home? *
16	PAININ31	In the past 7 days, how much did pain interfere with your ability to participate in social activities? *
17	PAININ34	In the past 7 days, how much did pain interfere with your household chores? *
18	PAININ35	In the past 7 days, how much did pain interfere with your ability to make trips from home that kept you gone for more than 2 hours? *
19	PAININ36	In the past 7 days, how much did pain interfere with your enjoyment of social activities? *
20	PAININ48	In the past 7 days, how much did pain interfere with your ability to do household chores? *
21	PAININ49	In the past 7 days, how much did pain interfere with your ability to remember things? *
22	PAININ56	In the past 7 days, how irritable did you feel because of pain? *
23	PAININ14	In the past 7 days, how much did pain interfere with doing your tasks away from home (e.g., getting groceries, running errands)? *
24	PAININ16	In the past 7 days, how often did pain make you feel depressed? **
25	PAININ24	In the past 7 days, how often was pain distressing to you? **
26	PAININ26	In the past 7 days, how often did pain keep you from socializing with others? **
27	PAININ29	In the past 7 days, how often was your pain so severe you could think of nothing else? **
28	PAININ32	In the past 7 days, how often did pain make you feel discouraged? **
29	PAININ37	In the past 7 days, how often did pain make you feel anxious? **
30	PAININ38	In the past 7 days, how often did you avoid social activities because it might make you hurt more? **
31	PAININ40	In the past 7 days, how often did pain prevent you from walking more than 1 mile?
32	PAININ42	In the past 7 days, how often did pain prevent you from standing for more than one hour? **
33	PAININ46	In the past 7 days, how often did pain make it difficult for you to plan social activities? **
34	PAININ47	In the past 7 days, how often did pain prevent you from standing for more than 30 minutes? **
35	PAININ50	In the past 7 days, how often did pain prevent you from sitting for more than 30 minutes? **
36	PAININ51	In the past 7 days, how often did pain prevent you from sitting for more than 10 minutes? **
37	PAININ52	In the past 7 days, how often was it hard to plan social activities because you didn't know if you would be in pain? **
38	PAININ53	In the past 7 days, how often did pain restrict your social life to your home? **
39	PAININ55	In the past 7 days, how often did pain prevent you from sitting for more than one hour? **
40	PAININ54	In the past 7 days, how often did pain keep you from getting into a standing position? **

Note:

* Response options for questions 1–23 are 1=Not at all; 2 = A little bit; 3 = Somewhat; 4 = Quite a bit; 5 = Very Much

** Response options for questions 24–40 are 1 = Never; 2 = Rarely; 3 = Sometimes; 4 = Often; 5 = Always

Appendix IV.

qDASH item bank.

Item	Question
	Please rate your ability to do the following activities in the last week.
1	Open a tight or new jar. *
2	Do heavy household chores (e.g., wash walls, floors). *
3	Carry a shopping bag or briefcase. *

Item	Question
4	Wash your back. *
5	Use a knife to cut food. *
6	Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.). *
7	During the past week, to what extent has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbors or groups? **
8	During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? ***
	Please rate the severity of the following symptoms in the last week.
9	Arm, shoulder or hand pain. ****
10	Tingling (pins and needles) in your arm, shoulder or hand. ****
11	During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *

Note:

* Response options for questions 1–6, 11 are 1 = No difficulty; 2 = Mild difficulty; 3 = Moderate difficulty; 4 = Severe difficulty; 5 = So much difficulty that I can't sleep

** Response options for question 7 are 1 = Not at all; 2 = Slightly; 3 = Moderately; 4 = Quite a bit; 5 = Extremely

*** Response options for question 8 are 1 = Not limited at all; 2 = Slightly limited; 3 = Moderately limited; 4 = Very limited; 5 = Unable

**** Response options for questions 9–10 are 1 = None; 2 = Mild; 3 = Moderate; 4 = Severe; 5 = Extreme

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Table 1 –

Baseline patient characteristics

Variable	Levels/Statistics	All	2.Slightly improved (N=377)	1.No change (N=348)	P-value	Test
Age at Admission	Mean (SD)	45.5 (18.1)	44.3 (18.4)	46.8 (17.7)	-	-
	Median (IQR)	46 (31, 59)	45 (28, 58)	46 (33, 60.2)	0.09	Wilcox
	Range	(1, 92)	(1, 92)	(8, 88)	-	-
Gender	Female	375 (52%)	194 (51.5%)	181 (52%)	0.88	Chi-square
	Male	350 (48%)	183 (48.5%)	167 (48%)	-	-
Ethnicity	Hispanic	63 (9%)	36 (9.5%)	27 (7.8%)	0.88	Fisher
	Non-Hispanic	652 (90%)	336 (89.1%)	316 (90.8%)	-	-
	Patient Opts Ou	6 (1%)	3 (0.8%)	3 (0.9%)	-	-
	Unknown/Missing	4 (1%)	2 (0.5%)	2 (0.6%)	-	-
Race	White or Caucasian	608 (84%)	310 (82.2%)	298 (85.6%)	0.80	Fisher
	Asian	15 (2%)	9 (2.4%)	6 (1.7%)	-	-
	American Indian/Alaska Native	7 (1%)	3 (0.8%)	4 (1.1%)	-	-
	Black/African American	11 (2%)	6 (1.6%)	5 (1.4%)	-	-
	Native Hawaiian/Other Pacific Islander	7 (1%)	4 (1.1%)	3 (0.9%)	-	-
	Other	70 (10%)	42 (11.1%)	28 (8%)	-	-
	Unknown/Patient Refused	7 (1%)	3 (0.8%)	4 (1.1%)	-	-
Provider	Provider A	190 (26%)	107 (28.4%)	83 (23.9%)	< 0.05	Chi-square
	Provider B	186 (26%)	111 (29.4%)	75 (21.6%)	-	-
	Provider C	221 (30%)	98 (26%)	123 (35.3%)	-	-
	Provider D	93 (13%)	45 (11.9%)	48 (13.8%)	-	-
	Provider E	35 (5%)	16 (4.2%)	19 (5.5%)	-	-
Marital Status	Married/Life Partner/Domestic Partner	404 (56%)	201 (53.3%)	203 (58.3%)	0.32	Fisher
	Single	228 (31%)	129 (34.2%)	99 (28.4%)	-	-
	Divorced/WidowedLegally Separated	79 (11%)	39 (10.3%)	40 (11.5%)	-	-
	Other	1 (0%)	0 (0%)	1 (0.3%)	-	-
	Unknown/Missing	13 (2%)	8 (2.1%)	5 (1.4%)	-	-
Alcohol Use	Yes	227 (31%)	119 (31.6%)	108 (31%)	0.25	Chi-square
	No	322 (44%)	158 (41.9%)	164 (47.1%)	-	-
	Unknown/Missing	176 (24%)	100 (26.5%)	76 (21.8%)	-	-
Tobacco Use	Yes	90 (12%)	49 (13%)	41 (11.8%)	0.78	Chi-square
	No	601 (83%)	309 (82%)	292 (83.9%)	-	-
	Unknown/Missing	34 (5%)	19 (5%)	15 (4.3%)	-	-

Table 2:

Summary of surgeries performed on the study cohort.

Procedure	n	Percent
Carpal Tunnel Release	113	13.3
Mass Excision	54	6.4
Distal Radius Fracture Open Reduction Internal Fixation	33	3.9
Ligament Reconstruction Tendon Interposition	20	2.4
Scaphoid Open Reduction Internal Fixation	18	2.1
Tendon Repair	18	2.1
Trigger Finger Release	18	2.1
Cubital Tunnel Release	17	2.0
Phalanx Open Reduction Internal Fixation	14	1.7
Intercarpal Open Reduction Internal Fixation	13	1.5
Ligament Repair	13	1.5
Amputation Revision	9	1.1
Incision and Debridement	9	1.1
Distal Interphalangeal Fusion	7	0.8
Intercarpal Fusion	7	0.8
Dupuytren’s Release	6	0.7
Phalanx Pinning	6	0.7
Dequervain’s release	5	0.6
Extensor Tendon Centralization	5	0.6
Nerve Repair	5	0.6
Biceps Tendon Repair	4	0.5
Hardware Removal	4	0.5
Intercarpal Pinning	4	0.5
Radius Open Reduction Internal Fixation	4	0.5
Ulnar Nerve Transposition	4	0.5
Darrach	3	0.4
Radial Head Open Reduction Internal Fixation	3	0.4
Reimplantation	3	0.4
Ulnar Open Reduction Internal Fixation	3	0.4
Wrist Fusion	3	0.4
Biopsy	2	0.2
Thumb Carpal Metacarpal Pinning	2	0.2
Fasciotomy	2	0.2
Elbow Arthroplasty	2	0.2
Extensor Indicis Proprius Transfer	2	0.2
Distal Radius Fracture External Fixation Placement	2	0.2
Finger Arthroplasty	2	0.2
Humeral Shaft Open Reduction Internal Fixation	2	0.2
Lateral Epicondyle Debridement	2	0.2

Procedure	n	Percent
Nerve Exploration	2	0.2
Pronator Release	2	0.2
Radial Head Excision	2	0.2
Scaphoid Excision	2	0.2
Vascular Re-anastamosis	2	0.2
Proximal Row Carpectomy	2	0.2
Closed Reduction	1	0.1
Closed Wedge Dorsal Osteotomy	1	0.1
Distal Radius Fracture Pinning	1	0.1
Elbow Manipulation	1	0.1
Finger Avulsion Repair	1	0.1
Hemi-hamate Reconstruction of Proximal Interphalangeal	1	0.1
Mallet Pinning	1	0.1
Olecranon Bursate Excision	1	0.1
Olecranon Open Reduction Internal Fixation	1	0.1
Neurectomy	1	0.1
Phalanx External Fixation	1	0.1
Pisiform Excision	1	0.1
Radial Head Replacement	1	0.1
Radial Shortening	1	0.1
Radial Tunnel Release	1	0.1
Synovectomy	1	0.1
Tenosynovitis Debridement	1	0.1
Triangular Fibrocartilage Complex Debridement	1	0.1
Total Shoulder	1	0.1
Ulnar Debridement	1	0.1
Blood Vessel Repair	1	0.1
Radial Styloidectomy	1	0.1
None/ Non-operative	418	49.3

Table 3 -

Change in scores over the study period

Instrument	Baseline		Follow-Up		p-value
	Mean Score (SD)	Median Baseline Score (IQR)	Mean Score (SD)	Median Baseline Score (IQR)	
PROMIS UE CAT	33.9 (10)	32.9 (27.1, 38.4)	34.7 (9.5)	34.8 (28.2, 38.9)	< 0.05
PROMIS PF CAT	43.1 (10.4)	44 (35.6, 50.0)	45.3 (10.2)	46.1 (37.4, 51.3)	< 0.05
qDASH	47.2 (22.8)	47.7 (29.5, 65.9)	39.9 (22.7)	38.6 (22.7, 59.1)	< 0.05
PROMIS PI CAT	59.1 (8.1)	59.0 (52.8, 64.4)	56.3 (8.8)	56.1 (52.6, 61.6)	< 0.05

IQR - interquartile range

p-values per Wilcoxon signed-rank test comparing median scores.

Table 4 –

Anchor-based MCID Calculation Summary.

Instrument	Baseline Score: Mean (SD)		Follow-Up Score: Mean (SD)		Change in Scores: Mean (SD)		MCID Value	p-value
	Slight Improvement Group	No Change Group	Slight Improvement Group	No Change Group	Slight Improvement Group	No Change Group		
PROMIS UE CAT	32.22 (9.6)	35.78 (10.14)	33.99 (8.46)	35.44 (10.55)	1.77 (8.07)	−0.34 (7.67)	2.1	< 0.05
PROMIS PF CAT	42.30 (10.67)	44.06 (10.07)	45.29 (9.98)	45.38 (10.55)	2.98 (9.18)	1.32 (7.66)	1.7	< 0.05
qDASH	50.40 (22.79)	43.70 (22.4)	39.84 (21.87)	39.97 (23.51)	−10.56 (20.92)	−3.73 (18.38)	6.8	< 0.05
PROMIS PI CAT	60.81 (7.04)	57.31 (8.73)	57.90 (7.14)	54.61 (10.06)	−2.90 (6.8)	−2.70 (7.57)	N/A (−0.2)	0.74

SD - standard deviation

p-values per Student’s t-test comparing change in scores between ‘no change’ and ‘slight change’ groups