



Published in final edited form as:

*Osteoarthritis Cartilage*. 2017 May ; 25(5): 667–675. doi:10.1016/j.joca.2016.12.013.

## The association of pre-operative body pain diagram scores with pain outcomes following total knee arthroplasty

Amish J. Dave, M.D., M.P.H, Faith Selzer, Ph.D., Elena Losina, Ph.D., M.S., Ilana Usiskin, B.S., Jamie E. Collins, Ph.D., Yvonne C. Lee, M.D., M.M.Sc., Philip Band, Ph.D., David F. Dalury, M.D., Richard Iorio, M.D., Kirk Kindsfater, M.D., and Jeffrey N. Katz, M.D., M.Sc.

Orthopaedic and Arthritis Center for Outcomes Research (OrACORe), Department of Orthopedic Surgery and Division of Rheumatology, Immunology and Allergy, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA

### Abstract

**Objective**—Approximately 20% of total knee arthroplasty (TKA) recipients have suboptimal pain relief. We evaluated the association between pre-surgical widespread body pain and incomplete pain relief following TKA.

**Method**—This prospective analysis included 241 patients with knee OA undergoing unilateral TKA who completed questionnaires preoperatively and up to 12 months post-operatively. Questionnaires included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain scale and a body pain diagram. We derived the number of non-index painful body regions from the diagram. We used Poisson regression to determine the association between painful body regions identified preoperatively and both WOMAC pain at follow-up and improvement in pain as defined by the minimal clinically important difference (MCID).

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Correspondence: Jeffrey N. Katz, M.D., M.Sc., Director, Orthopaedic and Arthritis Center for Outcomes Research (OrACORe), Division of Rheumatology, Immunology and Allergy, Brigham and Women's Hospital, 75 Francis Street, PBB-B3, Boston, MA 02115, Telephone: 617-732-5338, Fax: 617-525-7900, jnkatz@partners.org.

**Competing Interests:**

None

**Author contributions**

Conception and design: AJD, EL, JNK

Analysis: FS, EL, JEC

Interpretation of the data: All authors

Drafting of the article: AJD, FS, YCL

Critical revision of the article for important intellectual content: All authors

Final approval of the article: All authors

Provision of study materials or patients: PB, DFD, RI, KK

Statistical expertise: FS, EL, JEC

Obtaining of funding: JNK, EL

Administrative, technical, or logistic support: IU

Collection and assembly of data: FS, JEC, IU

**Role of Funding Source:**

The work was funded in part by the National Institute of Arthritis and Musculoskeletal and Skin Diseases. The funding agency had no role in the design, implementation, interpretation, or reporting of this work.

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**Results**—Mean subject age was 66 years (SD 9), and 61% were females. Adjusting for age, sex, co-morbid conditions, baseline pain, pain catastrophizing, and mental health, we found that more widespread body pain was associated with a higher likelihood of reporting 12-month WOMAC pain score >15 (relative risk [RR] per painful body region 1.39, 95% CI 1.18–1.63) and a greater likelihood of failing to achieve the MCID (RR 1.47, 95% CI 1.16–1.86). Pain catastrophizing was an independent predictor of persistent pain and failure to improve by the MCID (RR 3.57, 95% CI 1.73–7.31).

**Conclusions**—Pre-operative widespread pain was associated with greater pain at 12-months and failure to reach the MCID. Widespread pain as captured by the pain diagram, along with the pain catastrophizing score, may help identify persons with suboptimal TKA outcome.

### Keywords

widespread pain; total knee arthroplasty; catastrophizing; pain diagram

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### Introduction

Research on predictors of poor outcome from total knee arthroplasty (TKA) has shown that individuals with greater pre-operative levels of pain, pain catastrophizing, anxiety and depression, more diffuse body pain, lower educational attainment, and other psychological and social factors tend to have worse surgical outcomes.<sup>1–6</sup> Prior research on identifying at-risk individuals has relied upon validated measures including the Pain Catastrophizing Scale,<sup>7</sup> the Mental Health Inventory-5,<sup>8</sup> and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain and physical function subscales.<sup>9</sup> While such measures are useful for research purposes, they may be difficult to administer in a busy clinic. A simple tool that can identify those patients most at risk of poor TKA outcome may be helpful in clinical settings.

We have begun to examine such a tool – a total body pain diagram that captures patient-reported pain in 19 different body sites.<sup>10</sup> In a pre-surgical cohort of subjects with knee osteoarthritis (OA) undergoing elective unilateral TKA, widespread body pain as depicted by the whole body pain diagram was associated cross-sectionally with validated measures of OA-related pain, mental health, and pain catastrophizing.<sup>11</sup> These associations between widespread pain and OA-related pain, mental health, and pain catastrophizing persisted after adjustment for age, sex, and comorbid medical conditions. We did not include review of pre-operative knee imaging in our study. It has been established that lower radiographic severity is associated with worse TKR pain outcome.<sup>12</sup>

Despite the common use of pain diagrams to depict widespread pain in research involving other musculoskeletal conditions (e.g., chronic low back pain, Ehlers-Danlos disease, and carpal tunnel syndrome),<sup>13–17</sup> the association between widespread pain as depicted by whole body pain diagrams and TKA outcome has received little study.<sup>18</sup> We sought to evaluate the association between pre-surgical pain diagram scores and follow-up WOMAC pain scores up to 12 months post-operatively. Furthermore, we evaluated the association between pre-surgical pain diagram scores and improvement in pain by the estimated minimal clinically important difference (MCID) for WOMAC pain. We hypothesized that those participants

who reported more widespread body pain would continue to experience more pain up to 12 months postoperatively and would be less likely to improve by the MCID.

## Methods

The Study of Total Knee Arthroplasty Responses (STARs), a prospective cohort study of participants with knee OA undergoing elective unilateral TKA at three clinical sites, was designed to evaluate risk factors for suboptimal TKA outcome. The STARs study enrolled participants at one academic center (NYU Langone Medical Center, New York, NY, USA) and two community orthopedic centers (Orthopaedic Center of the Rockies, Fort Collins, CO, USA, and University of Maryland St. Joseph Medical Center, Towson, MD, USA) from September 2012 to April 2014. Institutional Review Board approval was obtained at all clinical sites and at Brigham and Women's Hospital, Boston, MA, USA.

## Participants

Participants were English-speaking community-dwelling persons, at least 40 years of age at study entry, undergoing TKA with a primary diagnosis of knee OA. Subjects with inflammatory knee arthritis or other underlying diagnoses leading to TKA were excluded. Staff at each center identified potentially eligible subjects and provided the subjects' contact information to the Brigham and Women's Hospital research coordinator, who in turn contacted all potential subjects to confirm eligibility, explain the study, and ascertain interest in participation. Study subjects were asked to complete questionnaires pre-operatively and at 6 and 12 months post-operatively to capture changes following surgery. Questionnaires included demographic information, co-morbid medical conditions, the whole body pain diagram, WOMAC pain and function sub-scales,<sup>9</sup> Pain Catastrophizing Scale (PCS),<sup>7</sup> and the Mental Health Inventory-5 (MHI-5).<sup>19</sup> Subjects were reimbursed (USD 25) for returning a questionnaire at each time-point.

While the follow-up data were derived primarily from the one-year questionnaire (n=219), we used data from 6-month questionnaires for 22 subjects in a last value carried forward fashion to maximize sample size and cohort generalizability. To evaluate the validity of the six-month data as a proxy for one year outcomes, we compared mean six-month and 24-month WOMAC scores in 18 subjects who provided both six and 24-month data but no 12-month data. These values were similar (mean [SD] WOMAC pain at 6- and 24-months, respectively: 11 [10.8] and 8 [9.3]), supporting the validity of the substitution.

## Baseline data

The pre-operative questionnaire included a self-reported body pain diagram completed within 6 weeks of surgery. Subjects were directed to report current pain using checkboxes at nineteen separate pre-defined body sites. Subjects indicated whether they had pain in each of these areas with a 'check.' The number of painful body sites is the sum of the number of sites (0 to 19) reported by the study subject on the pain diagram. The index joint was removed from this sum and thus the lowest score would be 0 and the highest would be 18. From the number and location of painful areas reported on the body pain diagram, we derived both the total number of painful sites and the number of painful body regions.

Similar to our previously reported technique,<sup>11</sup> we established eight different body regions but excluded the surgically-treated or index region so as to best capture widespread pain; thus, possible scores ranged from 0 to 7. The eight body regions were defined as follows: right upper extremity (shoulder girdle, upper arm, and lower arm), left upper extremity (shoulder girdle, upper arm, and lower arm), right lower extremity (upper leg and lower leg), left lower extremity (upper leg and lower leg), right hip (hip and buttock), left hip (hip and buttock), back/neck (upper back, lower back, and neck), and chest (abdomen and chest). In our analyses, the index joint was removed from both the body regions and from the painful sites as we anticipated that the vast majority of study participants would experience pain at the index joint. The extent of widespread body pain was analyzed as both a continuous and a categorical variable (0 versus 1–2 versus 3 painful regions). However, the modeling was performed with the continuous form of the widespread body pain regions because models using the categorical form of the variable demonstrated some instability due to small cell sizes. We assessed pre-operative pain catastrophizing utilizing the 13-item PCS<sup>7</sup> and pre-operative anxiety and depression with the five-item MHI-5.<sup>8,19</sup> Responses to questions were summed and scaled from 0 to 100. PCS scores were dichotomized at 20 with scores of  $\geq 20$  indicating high catastrophizing based on an assessment of sample distribution and published clinical studies on knee OA.<sup>7,13,17,20</sup> MHI-5 score was dichotomized at 68 with scores  $< 68$  indicating poor mental health as previously reported.<sup>21</sup> The WOMAC pain score was calculated as the sum of the responses to the five items, each of which had a five-item scale,<sup>9</sup> scaled from 0 to 100 with 100 representing the worst possible score.<sup>22</sup> Baseline WOMAC pain was categorized as 0–39, 40–69, and  $\geq 70$ .

### Outcome measures

The outcome measures for this analysis included a 1) dichotomized variable for the final WOMAC pain score at follow-up; and 2) the determination of estimated MCID (yes/no) based on pre- and post-surgical WOMAC pain scores. A dichotomous outcome variable for WOMAC pain at follow-up was created using a threshold of 15. This cut-point implies at least mild pain on 3 of 5 items or at least moderate pain on at least one item, representing persistence of pain and suggesting a suboptimal outcome. The MCID was calculated based on the methodology used by Escobar and Riddle<sup>22</sup> which takes baseline WOMAC pain into account in determining MCID. Thus, higher or worse baseline scores require a larger gain in pain scores in order to meet the MCID.

### Statistical analysis

Descriptive statistics of baseline demographic, clinical, psychosocial measures, and OA-related pain and function measured at both baseline and at follow-up were either summarized as medians (25<sup>th</sup> and 75<sup>th</sup> percentiles) or means (standard deviation) for continuous variables based on normality or as percentages for categorical variables. Similar methods were used for WOMAC pain measured at follow-up and for the difference between baseline and follow-up WOMAC pain. Participants were first stratified by follow-up participation status (Appendix Table 1) to examine factors associated with drop-out, and then by number of painful body regions (0, 1–2, and  $\geq 3$ ) among those who provided follow-up data. Differences between proportions for both follow-up participation status and painful body region category groups were assessed by the Chi-square test, and trend was assessed

by the Cochran-Mantel-Haenszel statistic. For continuous variables, the difference between two groups was compared by Student's t-test or Wilcoxon nonparametric test based on assessment of normality, and three group comparisons were made via the Kruskal-Wallis test. The test for trend for continuous variables was assessed using the Jonckheere-Terpstra test.<sup>23</sup>

We utilized Poisson regression to estimate the adjusted relative risk for each covariate.<sup>24</sup> We used this approach rather than logistic regression because odds ratios are often an overestimation of the risk ratio for common outcomes. Our regression models were used to (1) determine the crude associations between baseline measures (of pain, widespread pain depicted by a whole body pain diagram, pain catastrophizing, and MHI-5) and the dichotomous outcome for WOMAC pain at follow-up; and (2) to evaluate the independent association between baseline painful body regions and dichotomous WOMAC pain at follow-up after adjustment for age, body mass index, number of co-morbid conditions, and baseline levels of WOMAC pain, MHI-5, and pain catastrophizing. The final model is the most parsimonious model, inclusive of age, sex, and co-morbid conditions, as determined by a p-value approach.

Similar methods as above were employed for assessing the associations with attainment of estimated MCID. Poisson regression methods were used to evaluate the crude associations between number of painful body regions, WOMAC pain, pain catastrophizing, and MHI-5 measured at baseline and attainment of the estimated MCID for WOMAC pain. The independent association between body pain regions and attainment of estimated MCID was assessed again after adjusting for select baseline measures including age, body mass index, number of co-morbid conditions, WOMAC pain, MHI-5, and pain catastrophizing (full model). The final model included all covariates that were statistically significant in the full model. The final model again is the most parsimonious model as determined by assessing p-values and collinearity among psychosocial variables.

Only missing WOMAC pain data at 12-months were imputed. Our approach to addressing missing one year WOMAC pain outcome data was guided by the observation that the majority of subjects who were missing outcome data at one-year provided data at 6 and 24 months and there was no appreciable difference between 6-month and 24-month outcome. Consequently, we opted to carry the 6-month data forward rather than perform a more complex imputation. To assess the impact of this approach to missing data on our analyses, we performed several sensitivity analyses. Specifically, we excluded patients with missing outcome data at one year in one analysis. In another analysis, we used 24-month data (instead of 6-month data) in cases where 12-month data were missing. These sensitivity analyses yielded very similar results and identical interpretation as the primary analysis.

Analyses were conducted using SAS version 9.4 (SAS Institute Inc, Cary, NC). All reported p-values are two-sided, and p-values less than 0.05 were considered to be statistically significant.

## Results

### Cohort characteristics

At three clinical enrollment sites, 385 patients were eligible and agreed to participate. Of these, 267 subjects returned questionnaires prior to TKA surgery. The median number of days from data collection to surgery was 5 days (25<sup>th</sup> and 75<sup>th</sup> percentiles: 2 and 9 days prior to surgery). Follow-up questionnaire data were completed by 241 subjects (90%); this sample was the basis for this analysis. The 26 individuals who did not return questionnaires beyond 3 months were more likely to be female, non-white, and have more co-morbid medical conditions (Appendix Table 1). In addition, participants with higher baseline WOMAC pain scores ( $p=0.002$ ) were less likely to complete follow-up surveys.

Among the 241 individuals with follow-up data, age, sex, body mass index, race, and clinical site were similar across body pain region groups (0, 1–2, and 3 painful regions) (Table 1). Study subjects reporting higher levels of preoperative widespread pain were more likely to report more co-morbid medical conditions, use of supportive devices, and worse pre-operative ability to straighten their knees. Median values for WOMAC pain at baseline were significantly higher among subjects with a higher number of painful body regions. There was a significant inverse association between MHI-5 scores and preoperative number of painful body regions (Table 1).

### WOMAC pain at 12 months

At follow-up, participants in all three levels of painful body regions benefited considerably from TKA, with improvement in median WOMAC pain scores of approximately 30 points (Figure 1a, Table 2). The subjects reporting more painful body regions at baseline experienced similar change in WOMAC pain scores from baseline to follow-up (Figure 1b) -- but more pain at follow-up -- compared to those reporting pain in fewer body regions (Table 2). Participants with pre-operative pain in 3–6 body regions reported higher WOMAC scores at follow-up compared to study subjects with no painful body regions (median 10 versus 0) and were also less likely to achieve MCID (77% versus 98%).

### Associations between pain diagram scores and 12-month WOMAC pain score

We found bivariate associations between baseline measures of widespread body pain (painful body regions), WOMAC pain, pain catastrophizing, and mental health with follow-up WOMAC pain score dichotomized at 15 (Table 3a). After adjusting for baseline WOMAC pain, pain catastrophizing, MHI-5, age, sex, and number of co-morbid conditions, widespread pain (measured by number of painful body regions per 1 region) remained associated with follow-up WOMAC pain in multivariable models (Table 3a; full model). In the final model, subjects reporting pain in 1 additional body region were 1.37 times more likely (95% CI: 1.16–1.61) to continue to experience pain at follow-up (WOMAC pain score >15).

### Association between pain diagram score and estimated MCID

Bivariate analyses of baseline pain and psychosocial measures and attainment of estimated MCID for WOMAC pain revealed significant associations with number of painful body

regions, pain catastrophizing, and MHI-5 (Table 3b). A statistically significant association between painful body regions and estimated MCID persisted after adjusting for all covariates. In the final model, each additional painful body region was associated with a higher likelihood of not achieving an estimated MCID for WOMAC pain (RR 1.50, 95% CI 1.19–1.88).

## Discussion

In our initial study on the association of widespread body pain with known predictors of TKA outcome,<sup>11</sup> we found that widespread preoperative body pain as measured by a whole body pain diagram was associated cross-sectionally with preoperative pain catastrophizing. In this paper, we found that measures of widespread preoperative body pain were associated prospectively with a WOMAC pain score > 15 at 12-months follow-up as well as with failure to achieve the estimated MCID. These associations persisted after adjustment for baseline WOMAC pain, pain catastrophizing, and mental health (including anxiety and depression).

A large body of research has suggested that up to 20% of persons undergoing TKA have persistent pain.<sup>6,25,26</sup> We represented the outcome of persistent pain with a WOMAC pain score > 15. These participants have, on average, mild to moderate pain, suggesting a suboptimal outcome. While participants in all three painful body region groups had significant improvement in WOMAC pain pre- and post-operatively, our findings suggest that widespread pain is a risk factor for suboptimal outcome following TKA. Similarly, 88% of individuals in the cohort achieved the MCID, suggesting a highly favorable outcome overall. However, the proportion reaching the MCID ranged from 98% in those subjects with no reported areas of preoperative pain other than the index joint to 77% in those subjects with 3 or more painful areas.

The pain diagram score and pain catastrophizing score each contributed independently to suboptimal outcome in this study. This finding suggests that the effect of the pain diagram score on outcome is not entirely explained by its documented association with pain catastrophizing.<sup>11</sup> Participants with widespread body pain might have additional musculoskeletal conditions aside from knee OA that do not respond to TKA (such as contralateral knee OA, hip OA, spinal stenosis, foot problems, etc.). A recent carefully-done study by Brummett and colleagues assessed the association between outcomes from knee and hip arthroplasty with pre-operative scores on a fibromyalgia survey.<sup>18</sup> The researchers reported that worse pre-operative survey scores were associated with worse post-TKA and post-hip arthroplasty WOMAC pain subscale outcomes six months after surgery. The Brummett study has many similarities to ours in both design and in study findings, reinforcing the robustness of the conclusion that total body pain is associated with worse pain outcomes following joint replacement. Our study has important distinctions and thus builds upon these findings. We conducted our study in three different settings across the US, including both academic and community practices. The pain diagram used in our study differed somewhat from that used by Brummett and colleagues. We had access to extensive information on medical co-morbidities in our patient population. The fact that our findings were similar despite these differences in design, measures and setting speaks to the

robustness of the association between widespread pain and TKA outcome. Further, the 19 sites in the Michigan Body Map are validated for fibromyalgia and are commonly referred to clinically as tender points.<sup>27</sup> Although these sites differ from the body sites in our whole body pain diagram, the similarity in the results suggest that the pain diagram score may reflect, in at least some individuals, fibromyalgia symptoms and severity.

In our study, it is also noteworthy that the association between pre-operative widespread pain and TKA outcome was observed both with an outcome expressed as the pain score achieved within one year (the ‘destination’) and with an outcome expressed as the improvement in pain score (‘the journey’).<sup>28</sup> This observation speaks to the robustness of the association. We chose an estimate of the MCID as the measure of improvement because the MCID is generally regarded as a clinically relevant metric.<sup>29</sup> We note, though, that the MCID was derived using data from Escobar and Riddle<sup>22</sup> and not from our subjects. Thus, we cannot state with certainty that the individual subjects who achieved the MCID in our cohort regarded their improvement as clinically important.

An important strength of our study was the minimal (~10%) overall loss to follow-up. We note, however, that the small proportion lost to follow up at 12 months had more pre-surgical widespread body pain. As such, we might be overestimating post-surgical improvement. Other limitations of our study include that the body regions delineated on our body pain diagram do not directly correspond to joints. It is unclear whether the association between widespread pain in muscles (perhaps more representative of fibromyalgia) and TKA outcome differs from the association between widespread pain in joints (perhaps more indicative of multi-site OA) and TKA outcome. Additionally, there might be underreporting of joint pain. Prior research has shown that lower radiographic severity of osteoarthritis is an independent predictor of greater postsurgical pain outcome.<sup>12</sup> We did not have access to pre-operative imaging for all subjects and thus could not include radiographic osteoarthritis severity to our models. Further, participants were primarily white (Appendix Table 1) and were not allowed to record out-of-body or external sites of pain on the pain diagrams.

Research on the role of pain sensitization in the development of persistent knee osteoarthritis-related pain may provide further avenues for treatment of widespread pain. Widespread pain and pain sensitization appear to arise from a constellation of factors, including muscle nociceptor communication with neurons and neuronal sensitization by persistent nociceptor activation, impaired descending modulation by inhibitory neurons in the development of chronic pain, pressure hyperalgesia, thermal hyperalgesia, and spinal hyperexcitability.<sup>30,31</sup> The roles of specific cytokines, nerve growth factor, and sodium channel blockers in osteoarthritis-related pain are additionally being actively investigated<sup>32</sup> and may yield further insight into which patients are more likely to have successful outcomes from knee replacement. Translational research that bridges these pathways with the clinical phenotyping of widespread pain on a pain diagram would help to advance the field.

Our data suggest that a pre-operative whole body pain diagram, which can be readily and easily completed by participants, as well as a measure of catastrophizing, might be used to identify persons at risk for suboptimal outcome following TKA. Clinicians might consider



using these tools in their practices. Further research should determine whether or not patients with both high pain diagram scores and high catastrophizing scores might benefit from additional pre-surgical care. This care could include detailed discussions about likely surgical outcomes in order to align expectations, as well as psychological interventions such as cognitive behavioral therapy for patients with catastrophizing.<sup>28</sup>

## Acknowledgments

**Support:** The authors have no potential conflicts of interest relevant to this manuscript and have not received support or benefits from commercial sources for the work reported. The work was supported in part by National Institute of Arthritis and Musculoskeletal and Skin Diseases: T32 AR055885 and T32AR007530

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Figure 1a.

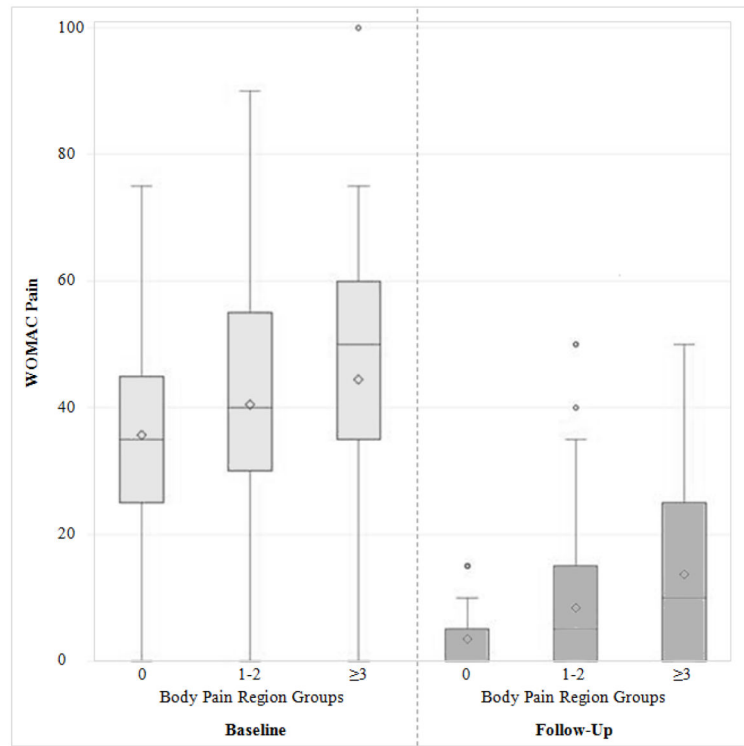
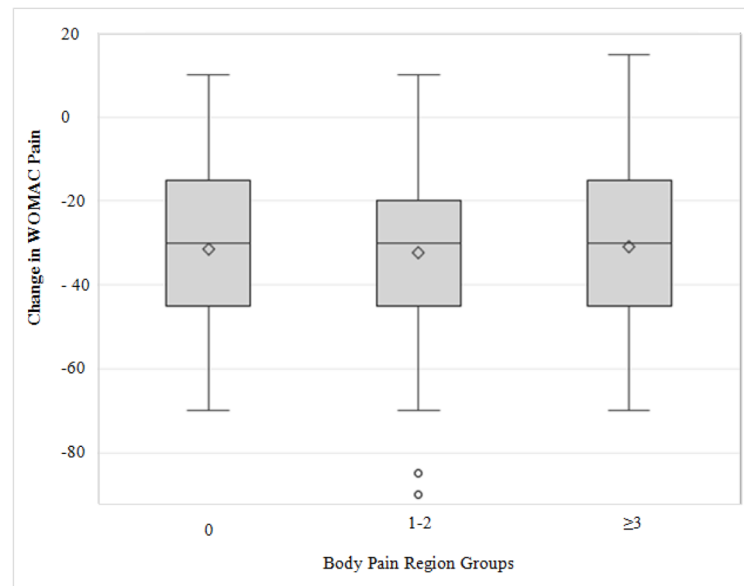


Figure 1b.



**Figure 1.** Figure 1a. WOMAC pain scores at baseline and at 12-months (Follow-up) by body pain region group

Figure 1b. Change in WOMAC pain scores by body pain region group

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Table 1 Baseline demographic, clinical, and resource utilization characteristics by regional body pain groups in STARS participants with one-year data

Characteristic	Regional Body Pain Diagram Groups						P-value				
	0 N=53	1-2 N=121	3-6 N=67	Overall	Trend						
	N	%	mean (SD)	N	%	mean (SD)					
Age – yrs	53	66.5	(7.8)	120	65.6	(9.1)	67	67.2	(8.7)	0.49	0.64
Female	19	35.8		54	44.6		22	32.8		0.24	0.64
Yes	34	64.1		67	55.4		45	67.2			
BMI (kg/m <sup>2</sup> )	52	30.5	(7.5)	116	30.3	(6.2)	64	30.8	(6.6)	0.80	0.51
White race	6	11.3		10	8.3		6	9.0		0.81	0.68
Yes	47	88.7		111	91.7		61	91.0			
Surgical site	25	47.2		41	33.9		18	26.9		0.10	0.23
Maryland	15	28.3		54	44.6		35	52.2			
Colorado	13	24.5		26	21.5		14	20.9			
NYU-Langone											
Number of co-morbid conditions <sup>f</sup>	18	35.3		31	25.6		13	19.4		0.06	0.001
0	19	37.2		47	38.8		18	26.9			
1	11	21.6		28	23.1		21	31.4			
2	3	5.9		15	12.4		15	22.4			
3											
Use of supportive device	41	78.8		85	72.6		31	52.5		0.005	0.002
No	11	21.1		32	27.3		28	47.5			
Yes											
Limp without support device										0.60	0.06

Characteristic	Regional Body Pain Diagram Groups						P-value
	0 N=53		1-2 N=121		3-6 N=67		
	N	%, mean (SD)	N	%, mean (SD)	N	%, mean (SD)	
None	7	13.2	15	12.6	6	9.0	
Slight	22	41.5	39	32.8	21	31.3	
Moderate	18	34.0	45	37.8	24	35.8	
Severe/unable to walk without support	6	11.3	20	16.8	16	23.9	
Ability to straighten knee							0.002
Completely straight	28	52.8	56	46.7	27	40.9	
Between 5-10° from straight	20	37.7	36	30.0	17	25.8	
Between 11-20° from straight	5	9.4	20	16.7	10	15.1	
More than 20° from straight	0	0	8	6.7	12	18.2	
Number of pain sites <sup>§,‡</sup>	53	0 (0, 0)	121	2 (1, 2)	67	5 (4, 7)	<0.001
Range		0 - 1		1 - 6		3 - 15	
Median WOMAC pain <sup>‡</sup>	53	35 (25, 45)	121	40 (30, 55)	65	50 (35, 60)	0.009
Pain catastrophizing categories							
<20	38	82.6	84	83.2	41	74.6	0.28
20	8	17.4	17	16.8	14	25.5	
MHI-5 score categories <sup>*</sup>							
0-67	10	19.2	34	28.3	29	43.9	0.003
68-100	42	80.8	86	71.7	37	56.1	

\* Unlike WOMAC pain and Pain Catastrophizing Scale where higher values are indicative for worse pain and catastrophizing, respectively, MHI-5 scores of lower value indicate poorer mental health

‡ Co-morbid conditions are comprised of diabetes mellitus, depression, stomach ulcers, cancer, chronic kidney disease, liver disease, cardiovascular disease, and hypertension

§ Index leg sites have been removed.

‡ Median reported (25th and 75th percentiles).

Body regions include the following painful body sites as follows:

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Upper extremity=shoulder girdle, upper arm and lower arm

Lower extremity= upper leg and lower leg

Hip = hip and buttock Back/neck=upper back, lower back, and neck

Abdomen/chest=abdomen and chest

Upper extremity, lower extremity, and hip body regions include both left and right sides.



**Table 2**

WOMAC pain outcomes by regional body pain groups in STARS participants

Outcome	Regional Body Pain Diagram Groups						P-value
	0 N=53	1-2 N=121	3-6 N=67	Trend			
	N	median (25 <sup>th</sup> , 75 <sup>th</sup> %ile)	N	median (25 <sup>th</sup> , 75 <sup>th</sup> %ile)	N	median (25 <sup>th</sup> , 75 <sup>th</sup> %ile)	
WOMAC pain Score	51	0 (0, 5)	120	5 (0, 15)	66	10 (0, 25)	<0.001
WOMAC pain categories							
0-14	47	92.2	84	70.0	37	56.1	<0.001
15-39	4	7.8	33	27.5	23	34.8	
40	0	0	3	2.5	6	9.1	
WOMAC pain change *	51	-30 (-45, -15)	120	-30 (-45, -20)	64	-30 (-45, -15)	0.82
% change in WOMAC pain	51	-99.5% (-99.9%, -76.9%)	120	-89.3% (-99.8%, -59.9%)	64	-69.6% (-99.6%, -50%)	0.008
Achieved MCID							
No	1	2.0	10	8.3	15	23.4	<0.001
Yes	50	98.0	110	91.7	49	76.6	

\* Change score calculated as follow-up – baseline

Percent change in WOMAC pain contains two outliers. Two subjects reported no pain at baseline but pain at the follow-up visit. Their change in pain has been truncated to 100%.

**Table 3a**

Crude and adjusted models for 12-month WOMAC pain >15

	Crude Models*			Fully Adjusted <sup>†</sup>			Final Model <sup>‡</sup>		
	RR	95% CI	P-value	RR	95% CI	P-value	RR	95% CI	P-value
<b>Pain and psychosocial measures</b>									
Painful body regions, per 1 region	1.40	1.21–1.62	<0.001	1.39	1.18–1.63	<0.001	1.37	1.16–1.61	<0.001
Baseline WOMAC pain									
40–69 vs 0–39	2.13	1.08–4.21	0.03	2.66	1.15–6.15	0.02	2.57	1.12–5.89	0.03
70+ vs 0–39	3.85	1.56–9.50	0.003	3.28	1.17–9.23	0.02	2.91	1.06–7.94	0.04
Pain catastrophizing >20	2.81	1.58–5.00	<0.001	2.37	1.28–4.39	0.006	2.04	1.15–3.61	0.01
MHI-5 <68	1.76	1.02–3.05	0.04	0.69	0.36–1.31	0.26	--	--	--

\*The crude models columns presents separate bivariate models with follow-up WOMAC Pain > 15 as the outcome and each row variable (eg painful body regions; baseline WOMAC pain) as the independent variable

<sup>†</sup>The fully adjusted and final model columns present a single model; each is adjusted for age, sex, and number of co-morbid conditions

**Table 3b**

Crude and adjusted models for not achieving MCID for WOMAC pain

	Crude Models*			Fully Adjusted <sup>†</sup>			Final Model <sup>†</sup>		
	RR	95% CI	P-value	RR	95% CI	P-value	RR	95% CI	P-value
<b>Pain and psychosocial measures</b>									
Painful body regions, per 1 region	1.49	1.22–1.82	<0.001	1.47	1.16–1.86	0.001	1.50	1.19–1.88	<0.001
WOMAC pain									
40–69 vs 0–39	1.28	0.58–2.82	0.55	1.64	0.57–4.74	0.36	--	--	--
70+ vs 0–39	2.56	0.79–8.28	0.12	1.76	0.43–7.26	0.43	--	--	--
Pain catastrophizing >20	4.16	1.86–9.27	<0.001	2.76	1.16–6.59	0.02	3.57	1.73–7.36	<0.001
MHI-5 <68	2.83	1.35–5.92	0.006	1.36	0.58–3.21	0.48	--	--	--

\*The crude models columns presents separate bivariate models with follow-up WOMAC Pain > 15 as the outcome and each row variable (eg painful body regions; baseline WOMAC pain) as the independent variable

<sup>†</sup>The fully adjusted and final model columns present a single model; each is adjusted for age, sex, and number of co-morbid conditions

**Appendix Table 1**

The association between baseline demographic and clinical characteristics and participation up to 1-year

Baseline characteristics	No N=26		Yes N=241		P-value
	N	% or Mean (SD)	N	% or Mean (SD)	
Age (years)	26	62.8 (8.3)	240	66.2 (8.7)	0.10
Female					0.02
No	4	15.4	95	39.4	
Yes	22	84.6	146	60.6	
Body mass index (kg/m <sup>2</sup> )	25	33.1 (7.3)	232	30.5 (6.6)	0.07
White race					<0.001
No	9	34.6	22	9.1	
Yes	17	65.4	219	90.9	
Education					0.26
High school or less	9	34.6	49	20.6	
Some college, vocational, or technical education	6	23.1	62	26.0	
Undergraduate or technical school degree	11	42.3	127	53.4	
Surgical site					0.08
Maryland	10	38.5	84	34.8	
Colorado	6	23.1	104	43.1	
NYU-Langone	10	38.5	53	22.0	
Living arrangement					0.31
Alone	8	30.8	51	21.4	
Married or with partner	15	57.7	171	71.8	
Other	3	11.5	16	6.7	
Number of co-morbid conditions <sup>†</sup>					0.09
0	4	16.0	62	25.9	

Baseline characteristics	No N=26		Yes N=241		P-value
	N	% or Mean (SD)	N	% or Mean (SD)	
1	12	48.0	84	35.1	
2	9	36.0	60	25.1	
3	0	0	33	13.8	
WOMAC function categories					
0-39	7	28.0	98	40.8	<0.001
40-69	11	44.0	129	53.7	
70	7	28.0	13	5.4	
WOMAC pain categories					
0-39	6	23.1	102	42.7	0.002
40-69	14	53.8	124	51.9	
70	6	23.1	13	5.4	
Number of painful body regions					
0	2	7.7	53	22.0	0.13
1-2	13	50.0	121	50.2	
3	11	42.3	67	27.8	
Number pain sites, <sup>§</sup>					
Median (25 <sup>th</sup> , 75 <sup>th</sup> percentiles)	26	3.3 (2.6)	241	2.5 (2.5)	0.05
Range		3 (1, 5) 0-10		2 (1, 4) 0-15	

<sup>‡</sup> Co-morbid conditions are comprised of diabetes mellitus, depression, stomach ulcers, cancer, chronic kidney disease, liver disease, cardiovascular disease, and hypertension

<sup>§</sup> Index leg sites have been removed