Pain Coping Skills Training for Patients Who Catastrophize About Pain Prior to Knee Arthroplasty

A Multisite Randomized Clinical Trial

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Background: Pain catastrophizing has been identified as a prognostic indicator of poor outcome following knee arthroplasty. Interventions to address pain catastrophizing, to our knowledge, have not been tested in patients undergoing knee arthroplasty. The purpose of this study was to determine whether pain coping skills training in persons with moderate to high pain catastrophizing undergoing knee arthroplasty improves outcomes 12 months postoperatively compared with usual care or arthritis education.

Methods: A multicenter, 3-arm, single-blinded, randomized comparative effectiveness trial was performed involving 5 university-based medical centers in the United States. There were 402 randomized participants. The primary outcome was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Pain Scale, measured at baseline, 2 months, 6 months, and 12 months following the surgical procedure.

Results: Participants were recruited from January 2013 to June 2016. In 402 participants, 66% were women and the mean age of the participants (and standard deviation) was 63.2 ± 8.0 years. Three hundred and forty-six participants (90% of those who underwent a surgical procedure) completed a 12-month follow-up. All 3 treatment groups had large improvements in 12-month WOMAC pain scores with no significant differences ($p > 0.05$) among the 3 treatment arms. No differences were found between WOMAC pain scores at 12 months for the pain coping skills and arthritis education groups (adjusted mean difference, 0.3 [95% confidence interval (CI), −0.9 to 1.5]) or between the pain coping and usual-care groups (adjusted mean difference, 0.4 [95% CI, −0.7 to 1.5]). Secondary outcomes also showed no significant differences ($p > 0.05$) among the 3 groups.

Conclusions: Among adults with pain catastrophizing undergoing knee arthroplasty, cognitive behaviorally based pain coping skills training did not confer pain or functional benefit beyond the large improvements achieved with usual surgical and postoperative care. Future research should develop interventions for the approximately 20% of patients undergoing knee arthroplasty who experience persistent function-limiting pain.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Knee arthroplasty is the most common major orthopaedic procedure conducted in the United States[1], with an estimated 1 million procedures performed in 2015[2]. Although knee arthroplasty is effective at reducing pain and improving function, approximately 20% (that is, approximately 200,000 patients in 2015) report persistent function-limiting pain following recovery from a technically sound procedure[3]. Persistent pain following knee arthroplasty is associated with patient dissatisfaction[3,4] and an increased health-care and socioeconomic burden[5].

Prognostic research in knee arthroplasty has focused on modifiable variables associated with poor pain and function outcomes and among the most powerful of these are psychological health indicators, including pain catastrophizing[6,7]. Pain catastrophizing is a maladaptive approach to coping with pain and is characterized by negative thoughts about pain, rumination about pain, and helplessness in coping with pain[8]. Many trials of cognitive behavioral treatments for pain have been conducted on patients with a variety of chronic musculoskeletal pain conditions[9,10] including knee osteoarthritis[11]. Although some trials

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have shown benefits associated with the delivery of pain coping skills training for medically treated knee osteoarthritis[12,13], to our knowledge, no study has examined patients who catastrophize about the pain prior to knee arthroplasty.

The primary aim of this randomized controlled trial (RCT) was to compare the effectiveness of pain coping skills training with arthritis education and usual surgical care in patients who were scheduled for knee arthroplasty and reported moderate to high levels of pain catastrophizing. We hypothesized that pain coping skills training would lead to better pain and function outcomes relative to arthritis education or usual surgical care.

Materials and Methods

Study Design, Setting, and Participants

The protocol for our Knee Arthroplasty Pain Coping Skills Training (KASTPain) trial has been published[14]. The study was a 3-arm RCT conducted at 5 sites (Duke University, New York University Medical Center, Virginia Commonwealth University, Wake Forest University, and Southern Illinois University). The institutional review boards from all sites approved the study. The study was registered at clinicaltrials.gov (NCT01620983).

Potential participants were ≥45 years of age, were diagnosed with osteoarthritis by the treating surgeon, had a knee arthroplasty scheduled 1 to 8 weeks after their consent, scored ≥16 points on the Pain Catastrophizing Scale (PCS)[15], and read and spoke English. Patients were excluded if they were scheduled for a revision surgical procedure, had undergone hip or knee arthroplasty within 6 months of the surgical procedure of interest, had a self-reported diagnosis of inflammatory arthritis (for example, rheumatoid arthritis), were scheduled for bilateral knee arthroplasty, planned to undergo hip or knee arthroplasty within 6 months after the currently planned knee arthroplasty, scored ≥20 points on a depression screener (indicating severe clinical depression)[16], or scored ≤2 points on a cognitive screener (indicating cognitive deficit)[17].

Randomization and Blinding

Following consent and baseline data collection, participants were randomized to usual care, pain coping skills training, or arthritis education. A study statistician generated a random numbers table to permit randomization in permuted block sizes of 3 or 6, stratified by surgeon. This randomization approach ensures that variation attributed to surgeon and site in a variety of known and unknown factors (for example, operative and postoperative anesthesia, pain control, and surgical technique) and not easily controlled would not bias the estimated treatment effects. To avoid potential selection bias, site coordinators used a REDCap (Research Electronic Data Capture) web interface[18] to reveal randomized group assignments after baseline data collection. Participants and interventionists were not blinded, but data collectors, surgeons, and investigators were blinded to group assignment.

Interventions

Participants randomized to either pain coping skills training or arthritis education received eight 50-minute sessions of 1-on-1 instruction delivered over an approximate 2-month period beginning approximately 2 weeks preoperatively and ending approximately 6 weeks postoperatively. The first session was an in-person appointment and the remaining sessions occurred via telephone. Behavioral interventions for pain management via telephone have been effective[19,20]. Pain coping skills training was delivered by local physical therapists with at least 2 years of clinical experience treating patients with knee arthroplasty. Physical therapists attended a 2-day training session conducted by clinical psychologists highly experienced in the delivery of pain coping skills training. Additionally, physical therapists received a detailed training manual to guide treatment delivery, and all treatment sessions were audio-recorded. Local clinical psychologists held monthly conference calls with physical therapists and monitored treatment delivery by listening to audiotapes throughout the study.

Arthritis education was taught by registered nurses with at least 2 years of experience in the care of patients with osteoarthritis. One author trained all nurses using a detailed manual. This treatment arm accounts for treatment effects attributable to substantial time and attention from a caring provider[21]. By comparing treatment effects in the arthritis education arm with those in the pain coping arm, we were able to determine effects attributable to the presumed active ingredient under study, pain coping skills. All arthritis education treatment sessions were audiotaped and were assessed to confirm fidelity. The arthritis education sessions used a presentation-and-discussion format similar to the approach used by Lorig et al. in their early work on arthritis education[22]. The usual-care arm was used to estimate real-world effects of knee arthroplasty. For more details, see the protocol[14] and the participant and interventionist pain coping and arthritis education training manuals (see Appendix).

Follow-up

Trained data collectors, blinded to treatment group, obtained follow-up data by telephone (using up to 8 attempts) at 2, 6, and 12 months following the surgical procedure; the 12-month data collection session was the primary end point. Participants were compensated $50 at baseline and $80 for completing all follow-up assessments.

Outcome Measures

The primary outcome was the highly reliable and valid Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Pain Scale, 3.1 Likert version, ranging from 0 (no pain with activity) to 20 (extreme pain with activity)[23]. Secondary outcome measures were the WOMAC Physical Function Scale (ranging from 0 to 68, with higher scores indicating greater functional difficulty), the Pain Catastrophizing Scale (PCS, ranging from 0, indicating no catastrophizing, to 52, indicating high catastrophizing)[15], a 4-item knee pain intensity scale ranging from 0 to 10[24], and a global rating-of-change scale from −5 (vastly worse) to +5 (completely recovered)[25]. Performance-based outcome measures were the Short Physical Performance Battery (SPPB) and the 6-minute walk test. The SPPB is a composite measure (ranging from 0 to 12, with higher scores equating to better physical

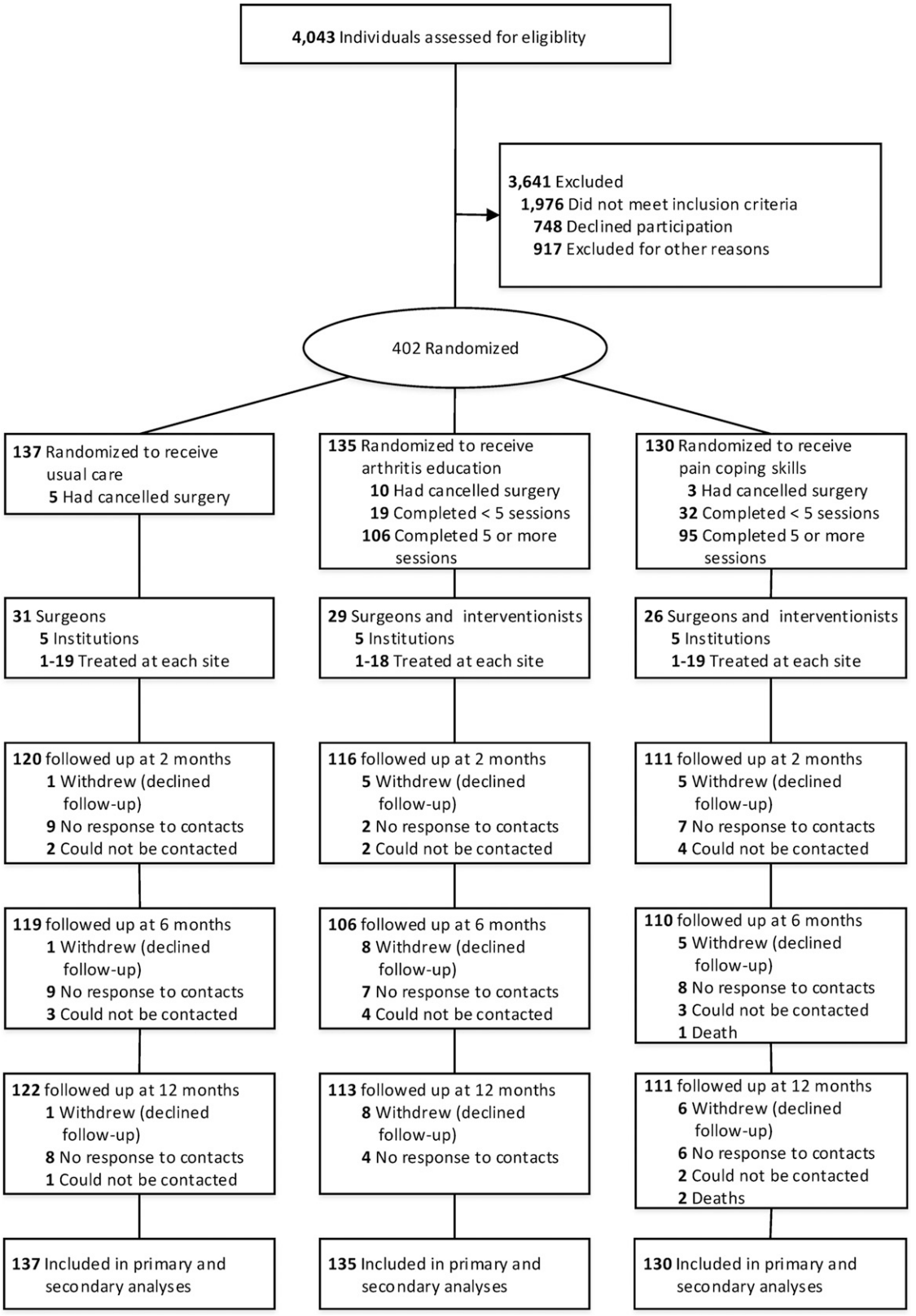

Fig. 1

CONSORT (Consolidated Standards of Reporting Trials) flowchart of participants comparing pain coping skills training with arthritis education and usual surgical care for recovery following knee arthroplasty.

TABLE I Baseline Sample Characteristics (N = 402)

Baseline Characteristics	All (N = 402)	Usual Care (N = 137)	Arthritis Education (N = 135)	Pain Coping Skills (N = 130)
Age* *(yr)*	63.2 ± 8.0	62.7 ± 7.7	64.2 ± 8.5	62.6 ± 7.9
Female sex†	267 (66%)	88 (64%)	85 (63%)	94 (72%)
Body mass index* *(kg/m²)*	32.3 ± 6.2	32.6 ± 6.5	31.7 ± 6.0	32.4 ± 6.1
Race or ethnic group†‡				
White	249 (59%)	86 (60%)	83 (59%)	80 (59%)
African American	143 (34%)	48 (34%)	45 (32%)	50 (37%)
Hispanic	13 (3%)	5 (3%)	5 (4%)	3 (2%)
Asian	8 (2%)	2 (1%)	4 (3%)	2 (1%)
Declined to answer§	6 (1%)	2 (1%)	4 (3%)	—
Current income†				
<$10,000	42 (10%)	14 (10%)	12 (9%)	16 (12%)
$10,000 to $24,999	84 (21%)	28 (20%)	30 (22%)	26 (20%)
$25,000 to $49,999	91 (23%)	27 (20%)	31 (23%)	33 (25%)
$50,000 to $99,999	94 (23%)	35 (26%)	33 (24%)	26 (20%)
≥$100,000	53 (13%)	18 (13%)	16 (12%)	19 (15%)
Declined to answer§	38 (10%)	15 (11%)	13 (10%)	10 (8%)
Current work status†				
Employed	132 (33%)	45 (33%)	42 (31%)	45 (35%)
Not working in part due to health problems	102 (25%)	36 (26%)	32 (24%)	34 (26%)
Not working for other reasons	167 (42%)	56 (41%)	60 (44%)	51 (39%)
Declined to answer§	1 (0.2%)	—	1 (1%)	—
Education†				
Less than high school	26 (7%)	10 (7%)	8 (6%)	8 (6%)
High school graduate	91 (23%)	35 (26%)	33 (24%)	23 (18%)
Some college	103 (26%)	40 (29%)	31 (23%)	32 (25%)
College degree or higher	182 (45%)	52 (38%)	63 (47%)	67 (52%)
Marital status†				
Married	197 (49%)	70 (51%)	64 (47%)	63 (49%)
Divorced	80 (20%)	26 (19%)	26 (19%)	28 (22%)
Never married	49 (12%)	19 (14%)	10 (7%)	20 (15%)
Widowed	47 (12%)	15 (11%)	18 (13%)	14 (11%)
Separated	20 (5%)	5 (4%)	13 (10%)	2 (2%)
Member of an unmarried couple	7 (2%)	1 (1%)	3 (2%)	3 (2%)
Declined to answer§	2 (1%)	1 (1%)	1 (1%)	—
Current smoker (yes)†	47 (12%)	19 (14%)	12 (9%)	16 (12%)
Health history				
Modified Charlson Comorbidity Index*#	8.7 ± 4.1	8.8 ± 4.2	8.7 ± 4.0	8.7 ± 4.1
Knee pain duration** *(yr)*	6 (3 to 15)	8 (3 to 20)	6 (3 to 12)	6 (3 to 12)
Opioid use at baseline†	121 (30%)	48 (35%)	37 (27%)	36 (28%)
Unicompartmental knee arthroplasty (yes)†	17 (4%)	8 (6%)	5 (4%)	4 (3%)
Psychological health*				
Patient Health Questionnaire (PHQ-8)††	6.0 ± 5.0	5.9 ± 5.2	6.1 ± 5.0	5.8 ± 4.8
Generalized Anxiety Disorder Scale (GAD-7)‡‡	5.4 ± 4.9	5.6 ± 4.9	5.2 ± 5.1	5.3 ± 4.8
Arthritis Self-Efficacy Scale*§§	49.1 ± 17.8	51.6 ± 18.5	50.4 ± 17.7	45.1 ± 16.7
Primary outcome scores*				
WOMAC Pain Scale## *(points)*	11.4 ± 3.4	11.4 ± 3.5	11.3 ± 3.5	11.6 ± 3.1

continued

TABLE I (*continued*)

Baseline Characteristics	All (N = 402)	Usual Care (N = 137)	Arthritis Education (N = 135)	Pain Coping Skills (N = 130)
Secondary outcome scores*				
WOMAC physical function***	37.2 ± 11.6	36.0 ± 11.1	37.1 ± 11.8	38.6 ± 11.8
Numeric pain rating*	6.1 ± 1.9	6.2 ± 1.9	6.0 ± 2.0	6.0 ± 1.8
SPPB†††	9.3 ± 2.9	9.7 ± 2.6	9.1 ± 2.9	9.1 ± 3.2
6-minute walk test *(m)*	297 ± 120	309 ± 106	279 ± 132	305 ± 121
PCS‡‡‡ *(points)*	30.0 ± 9.3	29.7 ± 9.2	30.0 ± 9.2	30.4 ± 9.6

*The values are given as the mean and the standard deviation. †The values are given as the number of patients, with the percentage in parentheses. ‡In the race or ethnic group category, the sums are greater than the total sample (n = 402) because some subjects marked >1 category. The sum may equal >100% because of multiple categories. §This category indicates not specified or missing. #The modified Charlson Comorbidity Index score range is 0 to 45 points; higher scores indicate greater comorbidity burden. **The values are given as the median, with the interquartile range in parentheses. ††The PHQ-8 score range is 0 to 24 points; higher scores indicate more depressive symptoms. ‡‡The GAD-7 score range is 0 to 21 points; higher scores indicate more anxiety. §§The Arthritis Self-Efficacy Scale score range is 0 to 80 points; higher scores indicate more self-efficacy. ##The WOMAC Pain Scale score range is 0 to 20 points; higher scores indicate more function-limiting pain. ***The WOMAC Physical Function Scale range is 0 to 68 points; higher scores indicate more difficulty with functional activities. †††The Short Physical Performance Battery (SPPB) score range is 0 to 12 points; higher scores indicate better performance. ‡‡‡The Pain Catastrophizing Scale (PCS) range is 0 to 52 points; higher scores indicate more pain catastrophizing.

performance)[26], and the 6-minute walk test assesses walking endurance and speed[27].

Adverse Events

Adverse events were identified either during data collection or via medical record review completed at 12 months postoperatively. Emphasis was placed on psychologically based adverse events because of the cognitive behavioral emphasis of the pain coping skills training.

Sample Size

The required sample size of 321 participants (107 per arm) with 12-month follow-up provided adequate power to detect meaningful differences between pain coping skills training and arthritis education or usual care. Calculations were based on a difference of ≥2 points in the 20-point WOMAC Pain Scale indicating a clinically important difference between groups[28]. Recruiting a sample size of 107 in each group provided 91% power to detect this difference, assuming an alpha of 0.05 and a common standard deviation of 4.34 (based on pilot work). This effect corresponds to a moderate effect size of 0.46, consistent with the effect of other behavioral interventions for knee arthritis[12,29]. Accounting for a 20% loss to follow-up, 402 participants were enrolled.

Statistical Analysis

Statistical analyses were completed using an intention-to-treat approach, including all participants[14]. To test for differences

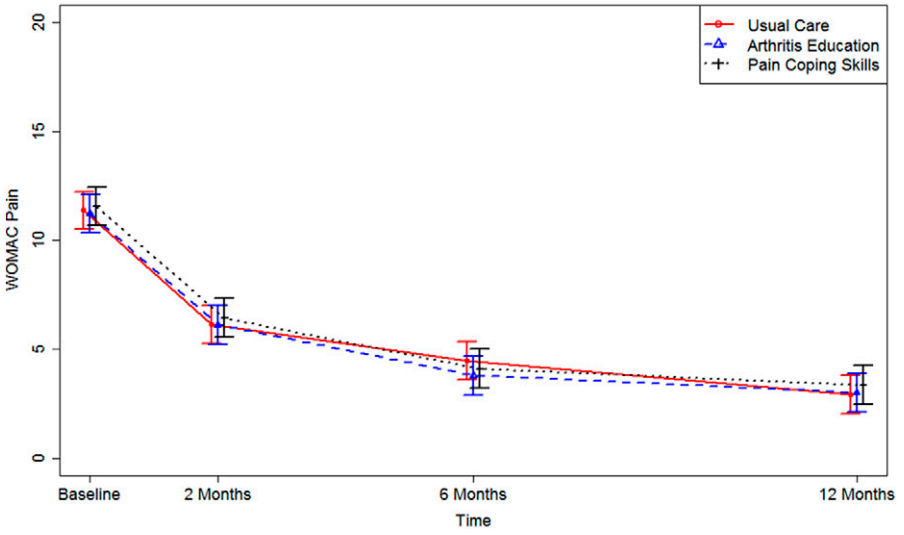

Fig. 2

Adjusted mean WOMAC pain scores for the 3 treatment groups over the study period. The bars for each line indicate the 95% CIs.

TABLE II Outcomes for the 3 Treatment Conditions for All Time Points

Outcome	Usual Care*	Arthritis Education*	Pain Coping Skills*
Primary outcome			
WOMAC Pain Scale			
Baseline	11.4 (10.5 to 12.2)	11.2 (10.4 to 12.1)	11.6 (10.7 to 12.4)
2 months	6.1 (5.3 to 7.0)	6.1 (5.2 to 7.0)	6.4 (5.5 to 7.3)
6 months	4.4 (3.6 to 5.3)	3.8 (2.9 to 4.7)	4.1 (3.2 to 5.0)
12 months	2.9 (2.0 to 3.8)	3.0 (2.1 to 3.8)	3.3 (2.5 to 4.2)
Secondary outcomes			
WOMAC physical function			
Baseline	36.0 (32.9 to 39.1)	37.1 (34.0 to 40.2)	38.6 (35.5 to 41.7)
2 months	21.2 (18.1 to 24.4)	19.5 (16.3 to 22.7)	22.5 (19.2 to 25.7)
6 months	15.4 (12.3 to 18.6)	14.7 (11.5 to 17.9)	15.2 (12.0 to 18.4)
12 months	10.5 (7.4 to 13.6)	11.7 (8.6 to 14.9)	12.2 (9.0 to 15.4)
Numeric pain rating			
Baseline	6.1 (5.6 to 6.7)	5.9 (5.4 to 6.5)	6.0 (5.4 to 6.6)
2 months	3.4 (2.8 to 4.0)	3.1 (2.5 to 3.7)	3.1 (2.6 to 3.7)
6 months	2.3 (1.8 to 2.9)	2.2 (1.6 to 2.8)	2.2 (1.6 to 2.8)
12 months	1.7 (1.1 to 2.2)	2.0 (1.3 to 2.6)	1.8 (1.2 to 2.4)
SPPB			
Baseline	7.9 (7.0 to 8.9)	7.5 (6.6 to 8.5)	7.6 (6.7 to 8.5)
12 months	8.6 (7.8 to 9.4)	8.0 (7.2 to 8.7)	8.4 (7.6 to 9.1)
6-minute walk test *(m)*			
Baseline	304 (282 to 325)	274 (252 to 296)	301 (279 to 324)
12 months	363 (340 to 387)	337 (313 to 362)	366 (341 to 391)
Pain catastrophizing			
Baseline	29.5 (26.7 to 32.2)	29.8 (27.1 to 32.6)	30.2 (27.5 to 33.0)
2 months	9.5 (6.8 to 12.3)	9.8 (7.0 to 12.6)	9.3 (6.5 to 12.1)
6 months	7.2 (4.5 to 10.0)	6.3 (3.5 to 9.1)	6.9 (4.1 to 9.7)
12 months	6.1 (3.4 to 8.9)	7.2 (4.4 to 10.0)	6.8 (4.0 to 9.6)
Global rating of change			
2 months	2.9 (2.3 to 3.4)	2.9 (2.4 to 3.5)	2.8 (2.3 to 3.3)
6 months	3.6 (3.0 to 4.1)	3.7 (3.1 to 4.2)	3.0 (2.5 to 3.6)
12 months	4.1 (3.6 to 4.6)	3.8 (3.3 to 4.3)	3.6 (3.1 to 4.2)

*The values are given as the mean estimate (from the linear mixed effect model), with the 95% CI in parentheses.

between study groups on each outcome, linear mixed effects models were used. For each outcome, a Gaussian link function was used for all outcomes with the exception of the dichotomous outcome of ≥50% change in WOMAC pain scores, which used a logistic link. These models include the between-subjects group effect, the within-subjects time effect, the group-by-time interaction, and a random intercept term. These models account for the nesting of patients within surgeon and surgeons within site, as well as the within-subjects nature of the data. To account for missing data when analyzing the binary outcome, multiple imputation was used. Predictive mean matching was used to generate 5 imputed data sets whose estimates were combined to provide final model results via the mice package in R (R Foundation for Statistical Computing)[30]. Imputed variables used in the logistic model were sex, race, age, and baseline WOMAC pain. Both methods account for data missing at random[31]. An alpha of 0.05 was used for all tests.

Prespecified moderators (depressive symptoms, surgical expectations, self-efficacy, social support) and a post hoc moderator (pain catastrophizing) of the treatment effect on the primary outcome were examined by testing for a moderator

by treatment interaction in individual models. To control for the familywise type-I error, follow-up comparisons of treatment differences were only made if appropriate omnibus tests were significant. The lme4 package in the R statistical software was used to fit all models[32].

Results

Participant flow is reported in Figure 1. From January 2013 to June 2016, 4,043 patients were considered for screening. Of 402 participants who consented, 18 had the surgical procedure canceled. A total of 367 participants underwent total knee arthroplasty, and 17 participants had unicompartmental knee arthroplasty. Thirty-two surgeons performed knee arthroplasties, with the number of patients treated by each surgeon ranging from 1 to 54. Unicompartmental knee arthroplasty was added to the protocol approximately 6 months after recruitment began.

Four sites each received consent from 94 to 108 participants, and 1 site received consent from 5 participants. Of the 130 participants assigned to pain coping skills training, 73% (95 participants) received ≥5 of 8 treatment sessions, an a priori indicator of good adherence. Of the 135 participants randomized to the arthritis education arm, 79% (106 participants) received ≥5 treatment sessions. The overall follow-up response rates were 86% (347 participants) at 2 months, 83% (335 participants) at 6 months, and 86% (346 participants) at 12 months. Among the 384 participants who had knee arthroplasty, the 12-month follow-up was 90%.

The median knee pain duration was 6 years (interquartile range, 3 to 12 years), and the mean WOMAC pain score (and standard deviation) was 11.4 ± 3.4 points, indicating moderate to severe function-limiting knee pain (Table I). Surgical methods and implant type were similar across sites (see Appendix). No significant differences between baseline characteristics were found (all $p > 0.05$), allowing for the linear mixed effects models to be fit without covariates.

Effects on Primary Outcome

No significant treatment ($p = 0.60$) or group-by-time interaction ($p = 0.73$) was found, indicating no significant difference between groups (collapsed over time) or in the trajectories of the WOMAC pain score over time (Fig. 2). There was a significant effect of time ($p < 0.001$) indicating improvement in pain for each group. Notably, the effect size ([pooled baseline – 12-month WOMAC pain score]/pooled baseline standard deviation of the difference score) was very large (2.0). The adjusted mean WOMAC pain scores for the 3 groups at the primary end point of 12 months postoperatively were not significantly different ($p > 0.05$) (adjusted score of 3.4 points for the pain coping group, 3.1 points for the arthritis education group, and 2.9 points for the usual care group). The adjusted mean differences were 0.3 (95% confidence interval [CI], −0.9 to 1.5) between pain coping skills and arthritis education and 0.4 (95% CI, −0.7 to 1.5) between pain coping skills and usual surgical care. As stated in our protocol[14], we compared the results for the full analysis with those for patients who actually underwent the surgical procedure, and no differences were found (data not shown). Likewise, when WOMAC pain scores were dichotomized on the basis of whether improvement at 12 months was ≥50% or <50%, the analysis revealed no significant differences ($p > 0.05$) (see Appendix).

Effects on Secondary Outcomes and Potential Moderators

No significant group or group-by-time interactions ($p > 0.05$) were found among WOMAC physical function, pain catastrophizing, composite pain, or SPPB scores (Table II). Substantial improvements over 12 months were noted for WOMAC physical function scores (pooled effect size, 1.8) and pain catastrophizing (pooled effect size, 2.0) (Fig. 3). There was a significant group effect on 6-minute walk scores ($p = 0.04$) but no significant interaction ($p = 0.96$). Prespecified and post hoc potential moderators (that is, treatment expectations, self-efficacy,

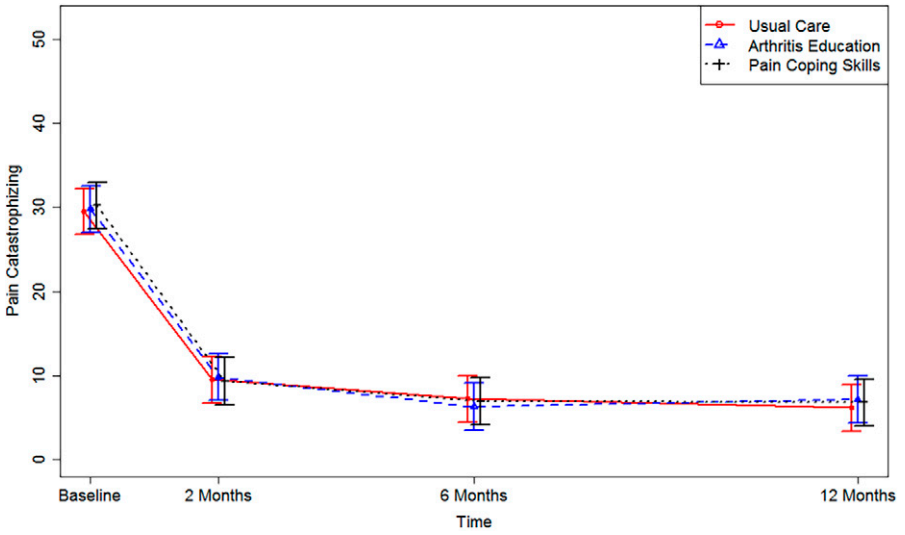

Fig. 3

Adjusted mean PCS scores for the 3 treatment groups over the study period. The bars for each line indicate the 95% CIs.

TABLE III Serious Adverse Events and Adverse Events at 12 Months Postoperatively in Participants Who Underwent Knee Arthroplasty (N = 384)

	All* (N = 384)	Usual Care* (N = 132)	Arthritis Education* (N = 125)	Pain Coping Skills* (N = 127)
Serious adverse events†	100	28	36	36
Venous thromboembolism	8	3	2	3
Infection of index knee	4	1	1	2
Other non-knee orthopaedic surgery†	7	5	2	0
Hospitalization (psychological distress)	2	1	1	0
Hospitalization (other)§	20	7	6	7
Urinary tract infection	1	0	1	0
Revision or other surgery of index knee	7	1	3	3
Manipulation of index knee	17	3	7	7
Contralateral knee replacement	32	7	13	12
Death	2	0	0	2
Adverse events#	20	9	3	8
Patient Health Questionnaire (PHQ-8) score >19	10	6	1	3
Verbal report of psychological distress	5	2	1	2
Shortness of breath	1	0	0	1
Twisted knee	1	1	0	0
Fractured patella	1	0	0	1
Emergency room visit for knee pain	2	0	1	1

*The values are given as the number of participants. †These values were not significant at p = 0.330, determined with use of the Fisher exact test. ‡Other orthopaedic surgical procedures were lumbar fusion (n = 1) and to treat hip fracture (n = 1), malleolar fracture (n = 1), tibial fracture (n = 1), and shoulder injury (n = 1). §Other hospitalization reasons included heart failure, anemia, cellulitis, angioplasty, pacemaker, and cyst removal, among others. #These values were not significant at p = 0.190, determined with use of the Fisher exact test.

social support, depressive symptoms, and pain catastrophizing, all measured at baseline)[14] were not significant predictors ($p > 0.05$) of treatment effect for 1-year WOMAC pain (data not shown).

Intervention Fidelity

After study completion, a pain psychologist not involved with the study reviewed a random set of 5% of pain coping skills training audiotapes and rated proficiency of care delivery, based on the treatment manual, on a 5-point scale (1 = poor to 5 = excellent). A joint arthroplasty nurse not affiliated with the study used a similar rating for arthritis education audiotapes. The mean quality rating was 4.0 (range, 3.5 to 4.5) for pain coping skills training and 3.8 (range, 2.0 to 5.0) for arthritis education training. These data support intervention treatment fidelity.

Adverse Events

Serious adverse events and other adverse events associated with knee replacement and other hospitalizations were not significantly different ($p > 0.05$) across treatment arms (Table III). Two deaths occurred in participants assigned to the pain coping skills group. In 1 case, the cause of death was reported by the family to be due to natural causes, and in the other case, the cause of death could not be determined. The National Institutes of Health (NIH)-appointed Data and Safety Monitoring Board adjudicated these deaths and found them to be unrelated to the intervention.

Discussion

No significant differences between treatment groups were found for any outcome. The unadjusted mean WOMAC pain scores at 12 months following the surgical procedure for all participants were 73% lower (improved) compared with preoperative scores, indicating that knee arthroplasty was associated with a substantial reduction in function-limiting pain. Beneficial effects associated with a surgical procedure were so substantial (effect sizes of 2.0 for WOMAC pain scores and 1.8 for WOMAC physical function scores) that, despite several hours of contact with a caring practitioner in both treatment groups and, in the case of pain coping skills, an intervention with known beneficial effects for patients with chronic pain[12], these treatment groups demonstrated no beneficial effects beyond those experienced by the usual care group. Beneficial effects attributed to knee arthroplasty appeared to preclude even placebo responses associated with treatment delivery and caring-practitioner interaction[21].

Approximately 20% of patients who undergo knee arthroplasty experience poor outcome[3], and some of these cases are attributed to preoperative psychological distress including pain catastrophizing[7]. In our study, all groups improved on the WOMAC Pain Scale to the extent that, at 12 months following the surgical procedure, the mean score for all 3 groups was 3.1 ± 3.7 points. A score of 3 on the WOMAC Pain Scale is equivalent to a report of mild pain with standing, walking, and climbing

steps and is consistent with 12-month outcomes from several large U.S.-based and international cohort studies of patients undergoing knee arthroplasty[33-35]. Our data run counter to prior evidence[6,7,36,37] and suggest that preoperative knee arthroplasty pain catastrophizing, using PCS cutoff scores of ≥16, is likely not a viable therapeutic target for improving knee arthroplasty outcomes. Alternatively, all 3 groups had such large improvements in pain catastrophizing that the cognitive behaviorally based intervention could not generate further benefits beyond that provided by the surgical procedure and usual care.

In 2 post hoc analyses, we compared 12-month outcomes of the 3 treatment groups for participants completing >4 treatment sessions (that is, per-protocol analysis) and with unicompartmental arthroplasty excluded (n = 17). No differences in the primary outcome were found for either analysis (see Appendix). Adverse events occurred at a rate that was expected[38], with no significant differences among the 3 treatment groups.

The limitations of our study warrant discussion. First, our participants had moderate to high levels of pain catastrophizing and were recruited from academic medical centers. Results may not generalize to individuals with low levels of pain catastrophizing or patients treated by community-based orthopaedic surgeons. Second, pain coping skills treatment sessions were delivered primarily by telephone. Although telephone-based delivery of cognitive behavioral treatment has been shown to be effective[12,39], study findings may not generalize to in-person pain coping skills training. Third, pain coping skills training was not delivered by the same physical therapists providing physical therapy following participants' surgical procedures. It is possible that physical therapists providing physical rehabilitation following knee arthroplasty will more effectively deliver pain coping skills. Finally, interventionists were not blinded to treatment group.

In conclusion, we found that pain coping skills training was not an effective perioperative treatment for patients who are undergoing knee arthroplasty and catastrophize about pain. Pain catastrophizing scores of ≥16 points, as measured with the PCS, are not prognostic of poor outcome following knee arthroplasty. Future study is needed both to identify prognostic variables that predict poor outcome following knee arthroplasty and to design and test interventions to improve outcomes for those at risk for poor outcome.

Appendix

eA Tables showing the summary of surgical data from the KASTPain sample, the dichotomous outcome of ≥50% improvement in WOMAC pain scores over the study period, post hoc analysis comparing the 3 treatment groups after excluding participants with ≤4 treatment sessions (per-protocol analysis), and post hoc analysis comparing the 3 treatment groups after excluding participants with unicompartmental arthroplasty are available with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/F122). Arthritis education manuals for nurses and patients are also available with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/F123). ■

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