A Training Program on Pain Coping Skills for African Americans With Hip or Knee Arthritis

Kelli D. Allen, PhD[1,2,3]; Tamara J. Somers, PhD[4]; Lisa C. Campbell, PhD[5]; Liubov Arbeeva, MS[1,2]; Cynthia J. Coffman, PhD[3,6]; Crystal W. Cené, MD, MPH[2]; Eugene Z. Oddone, MD, MHSc[3,7]; Francis J. Keefe, PhD[4]

[1]Thurston Arthritis Research Center, University of North Carolina at Chapel Hill, Chapel Hill
[2]Department of Medicine, University of North Carolina at Chapel Hill, Chapel Hill
[3]Health Services Research and Development Service, Durham VA Medical Center, Durham, North Carolina
[4]Department of Psychiatry and Behavioral Science, Duke University; Durham, North Carolina
[5]Department of Psychology, East Carolina University, Greenville, North Carolina
[6]Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, North Carolina
[7]Department of Medicine, Duke University Medical Center, Durham, North Carolina

Institution Receiving the PCORI Award: University of North Carolina at Chapel Hill
Original Project Title: Pain Coping Skills Training for African Americans With Osteoarthritis (STAART)
PCORI Award Number: AD-1408-19519
HSRProj ID: HSRP20153358
ClinicalTrials.gov ID: NCT02560922

To cite this document, please use: Allen KD, Somers TJ, Campbell LC, et al. (2019). *A Training Program on Pain Coping Skills for African-Americans With Hip or Knee Arthritis.* Washington, DC: Patient-Centered Outcomes Research Institute (PCORI). https://doi.org/10.25302/03.2020.AD.140819519

Table of Contents

ABSTRACT

Background: African Americans bear a disproportionate burden of osteoarthritis (OA), with greater pain and disability compared with non-Hispanic whites. Pain coping skills training (CST) is a promising intervention to improve outcomes among African Americans with OA, but there has been little study of pain CST among this population.

Objective: This project engaged African Americans with OA and other stakeholders (caregivers, clinicians) to culturally tailor a CST program for African Americans and then evaluated the CST program in a multisite randomized controlled trial.

Methods: We randomized 248 African Americans (51% male, mean age = 59 years) with knee OA, with equal allocation to CST and wait list (WL) control groups. The CST program involved 11 telephone-based sessions over 12 weeks, delivered by a counselor. We assessed outcomes at baseline, 3 months, and 9 months and included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale (primary outcome); WOMAC total score and function subscale; Patient-Reported Outcomes Measurement Information System (PROMIS) Pain Interference; Short Form-12 (SF-12) Mental and Physical Composite Subscales; Coping Strategies Questionnaire (CSQ)—Total Coping Attempts; Pain Catastrophizing Scale (PCS); Patient Health Questionnaire-8 (PHQ-8), Arthritis Self-efficacy Scale; and Patient Global Impression of Arthritis Symptom Change. We fit linear mixed models for all outcomes.

Results: Of participants, 92% and 85% completed 3- and 9-month follow-up assessments, respectively, and approximately 20% of participants attended < 2 CST sessions. We found no significant between-group differences in WOMAC pain scores at 3 months (–0.63; 95% CI, −1.45 to 0.18; $p = 0.128$) or 9 months (–0.84; 95% CI, –1.73 to 0.06; $p = 0.068$).

Among secondary outcomes, at 3 months we found significant differences, in favor of the CST group, for CSQ–Total Coping Attempts, PCS, Arthritis Self-efficacy, and Patient Global Impression of Arthritis Symptom Change (all $p < 0.01$). CSQ–Total Coping Attempts, Arthritis Self-efficacy, and Patient Global Assessment of Pain Change were also significantly improved at 9 months in the CST group, compared with WL (all $p < 0.01$).

Conclusions: The culturally tailored pain CST program did not significantly reduce pain severity but did improve key measures of pain coping and perceived ability to manage pain among African Americans with OA. The suboptimal intervention attendance illustrates the real-world challenges of identifying individuals who are most likely to engage with the intervention as well as the need to further evaluate intervention design to help participants complete pain CST, even in the face of many competing life responsibilities.

Limitations: Limitations include the lack of de novo radiographs to confirm OA status, inclusion of patients in only one geographic region, and inclusion of a relatively well-educated sample.

BACKGROUND

African Americans bear a greater burden of osteoarthritis (OA) than non-Hispanic whites, including higher prevalence and more severe pain and functional limitations.[1-5] This is consistent with the greater levels of chronic pain observed generally among African Americans.[6] Although these disparities are well documented, efforts to develop interventions to improve pain-related outcomes among African Americans have been limited.[7,8]

Pain coping skills training (CST) may be a promising intervention approach for African Americans with OA. First, prior studies have shown that pain CST can improve outcomes among individuals with OA in general,[9-15] though study samples have included primarily non-Hispanic whites. In particular, a meta-analysis shows that psychological interventions including cognitive behavioral therapy (which underlies pain CST) were associated with improved pain severity and psychological outcomes among individuals with arthritis.[10] Second, African Americans report higher levels of pain catastrophizing,[16-19] lower perceived ability to cope with and control pain,[20] and more frequent use of maladaptive coping strategies[3,18,20-22] compared with non-Hispanic whites. Pain CST uses cognitive and behavioral approaches that can modify maladaptive coping behaviors and enhance the use and perceived effectiveness of pain coping strategies.[11,12,23-25] Third, prior research suggests pain coping and other psychological variables are key factors underlying racial differences in OA-related pain.[2,3] Therefore, these factors are logical targets for interventions that aim to improve pain-related outcomes among African Americans with OA.

Although pain CST programs have empirical support, there have been no studies of pain CST specifically among African Americans with OA, and most participants in previous studies have been non-Hispanic whites.[13-15,26-32] Further, there has been limited engagement of African Americans to obtain perspectives on cultural appropriateness of behavioral interventions for pain, such as CST. It is critical that these interventions consider the cultural values and pain experiences of African Americans, which may differ from other demographic groups.[33,34] For example, African Americans often experience more and different stressful events than non-Hispanic whites, and these can contribute to the pain experience.[35] Also, one cultural value of

many African Americans is religion or spirituality, and African Americans tend to employ more religious coping strategies than non-Hispanic whites.[35,36] Attention to these experiences and values is particularly important, because pain CST programs weave coping skills into contexts, activities, and relationships. In addition, the broader literature illustrates the importance of culturally tailoring interventions to improve potential for success when focusing on minority populations.[37]

The overall goal of the Pain Coping **S**kills **T**raining for **A**frican Americans with Osteoa**ART**hritis (STAART) study was to examine the effectiveness of a culturally tailored pain CST program among African Americans with OA.[38] The specific aims and hypotheses of this study were the following:

Aim 1: Engage African American patients with OA, their support partners, health care providers, clinic administrators, and public health representatives to evaluate and refine a pain CST program for culturally appropriate content and dissemination potential (eg, cultural tailoring).

Aim 2: Examine the effectiveness of a 12-session, culturally enhanced, telephone-based pain CST program among African Americans with hip or knee OA.

Hypothesis 1: African Americans with symptomatic OA who receive the pain CST intervention will have clinically relevant improvements in pain (Western Ontario and McMasters Universities Osteoarthritis Index [WOMAC]: primary outcome) and secondary related outcomes at 3-month follow-up, compared with a wait list (WL) control group.

Hypothesis 2: African Americans with symptomatic OA who receive the pain CST intervention will have clinically relevant improvements in WOMAC pain score and secondary related outcomes at 9-month follow-up, compared with a WL control group.

Aim 3: Examine whether individual patient characteristics (particularly baseline pain catastrophizing score, comorbidity, and duration of OA symptoms) are associated with differential improvement in WOMAC pain score following the CST program.

PATIENT AND STAKEHOLDER ENGAGEMENT

Types and Numbers of Stakeholders Involved

Our stakeholder panel comprised 3 patients with knee OA, 4 representatives of national organizations seeking to improve outcomes for people with OA (Arthritis Foundation, Centers for Disease Control and Prevention [CDC] Arthritis Program, Movement Is Life), and 1 primary care clinician.

Overview of Stakeholder Panel and Recruitment

We developed the stakeholder panel to reflect different "key voices" related to experiences of living with and managing OA, health disparities, and disseminating behavioral interventions related to OA and within African American communities. Our stakeholder panel included the following:

1. **Three African American patients with knee OA (2 female, 1 male):** One patient stakeholder had participated in a prior study of a pain CST intervention, led by a study co-investigator who invited her to participate on our panel. The other 2 patient stakeholders had worked with our team on a stakeholder panel for a prior study (also involving a behavioral intervention for OA) and continued to work with us on this project.
2. **Two representatives from federal public health organizations:** We invited representatives from the CDC Arthritis Program and the Arthritis Foundation to participate on the stakeholder panel (1 from each organization); they focused on emphasizing the patient-centeredness of the intervention as well as its future dissemination. Our study team had previously worked with these 2 organizations (including in stakeholder roles on a prior PCORI study and in the contexts of professional societies, including the American College of Rheumatology), and we asked if they would appoint an appropriate representative to our stakeholder panel. These representatives were white; African American representatives were not available from these organizations at the time of the study.

3. **Two representatives from the Movement Is Life national caucus, which addresses musculoskeletal health disparities:** This organization focuses on reducing racial and gender disparities in musculoskeletal conditions, including OA, with an emphasis on tailoring and disseminating behavioral interventions. We had also worked with this organization before (Dr. Allen was a member of the steering committee) and requested their representation on our panel to share ideas on strategies they have found successful in their work relevant to this study. These representatives were African American.
4. **One African American primary care physician with health disparity expertise:** We invited a local clinician, who runs an organization that focuses on improving health outcomes for African Americans, to provide expertise in patient-centered approaches and dissemination strategies.

Overview of Stakeholder Panel Activities

Because of the geographic range of our stakeholder panel, we held meetings via teleconference. Although the frequency of contact varied throughout the study period, we held a monthly meeting or had some other form of monthly communication (eg, email update with invitation for further input). Prior to proposal submission, stakeholders provided us with feedback on the study design and intervention, and we held individual meetings with patient stakeholders. We held a kickoff call with the full study team and stakeholder panel at the beginning of the funding period. During this call, we revisited the overall study design, measures, and intervention, inviting the panel's input on all aspects of the study. Future calls addressed relevant issues for various study stages, including recruitment strategies and participant retention.

Impact of Engagement on the Study

The following are key contributions of our stakeholder panel across the study phases:

1. **Measures:** During the start-up phase, the stakeholder panel advised against using an extended-period pain diary because of participant burden; as a result, we omitted this

measure. The panel recommended we include brief measures related to physical activity and weight management as these were included in the intervention. The panel also advised on strategies and wording related to asking patients to bring their arthritis medications to study assessment visits.

2. **Participant Recruitment:** Stakeholders (particularly local ones) provided suggestions on mechanisms and locations for advertising the study and reaching out to potentially eligible patients. Examples included convenience stores, community centers, and additional clinic locations.
3. **Participant Engagement in the Pain CST Intervention:** We faced challenges engaging some study participants in the intervention (eg, despite consenting and completing outcome assessments, they failed to respond to calls from the study interventionist). The stakeholder panel worked with the study team to help boost engagement among enrolled participants. A key part of this effort was enhancing the scripts for our initial recruitment call to help ensure that potential participants fully understood the nature of the intervention (eg, emphasizing the number of sessions and duration) and were truly interested in participating (eg, giving a specific verbal opportunity to opt out). Following these changes, we noted a substantial improvement in intervention engagement/participation.
4. **Results Dissemination:** Stakeholder panel members contributed to discussions about content and framework for a baseline characteristics paper and various ideas for other papers (eg, description of participant feedback on the intervention, relationship of comorbidities to pain coping). As we work through submitting our main outcomes paper to a scientific journal, the stakeholder panel will continue to advise about avenues and strategies for disseminating results to patients and other relevant communities.

METHODS

Study Overview

The STAART trial was a parallel-group design, randomized controlled trial with 248 participants assigned with equal allocation to a pain CST group and a usual care, wait list control group. Following completion of final follow-up assessments (9 months from baseline), participants in the WL control group were offered the pain CST program. All study participants continued with their usual medical care for OA during the study period. Enrollment began on May 2, 2016, and follow-up assessments were completed on May 2, 2018.

Specific aims and associated hypotheses for this project were the following:

Aim 1: Engage African American patients with OA, their support partners, health care providers, clinic administrators, and public health representatives to evaluate and refine a pain CST program for culturally appropriate content and dissemination potential (eg, cultural tailoring).

Aim 2: Examine the effectiveness of a 12-session, culturally enhanced, telephone-based pain CST program among African Americans with hip or knee OA.

Hypothesis 1: African Americans with symptomatic OA who receive the pain CST intervention will have clinically relevant improvements in pain (WOMAC: primary outcome) and secondary related outcomes at 3-month follow-up, compared with a WL control group.

Hypothesis 2: African Americans with symptomatic OA who receive the pain CST intervention will have clinically relevant improvements in WOMAC pain score and secondary related outcomes at 9-month follow-up, compared with a WL control group.

Aim 3: Examine whether individual patient characteristics (particularly baseline pain catastrophizing score, comorbidity, and duration of OA symptoms) are associated with differential improvement in WOMAC pain score following the CST program.

Study Setting

We enrolled participants from the Durham Veterans Affairs Health Care System (DVAHCS) and the University of North Carolina (UNC) Health Care System (n = 124 at each site). We selected these sites because they serve a substantial proportion of African Americans with OA. In addition, we selected the VA site because veterans are disproportionately affected by OA.

Participants

Study inclusion criteria were self-reported black or African American race; diagnosis of knee or hip OA (identified from DVAHCS or UNC electronic medical records or based on participant self-report at screening); and self-report of pain, aching, stiffness, or swelling in or around a hip or knee with OA on most days for the past month. Exclusion criteria are shown in Table 1.

We recruited participants using 3 methods: (1) proactive recruitment of patients with evidence of knee or hip OA in DVAHCS and UNC medical records (these individuals were mailed an introductory letter); (2) advertisements at study sites and surrounding communities; and (3) referrals from health care providers at both study sites. We screened all potentially eligible individuals via telephone; we invited those who met eligibility criteria to an in-person visit to complete consent and baseline assessments. We used a culturally enhanced informed consent process that included materials developed by the National Medical Association as part of Project IMPACT – Increase Minority Participation and Awareness of Clinical Trials.[39] Specifically, prior to study enrollment we mailed potential participants the "You've Got the Power!" booklet, and at the baseline visit we showed them the "What You Should Know About Clinical Trials" video, which includes basic information about clinical trials and perspectives from African Americans who have participated. Following baseline assessments, the study coordinator or CST counselor gave participants their randomization assignment over the telephone, since they were not blinded to treatment assignment. Randomization was stratified according to enrollment site and gender with a block size of 4; randomization schedules were computer generated by the statistician and were stored in a study database; the database was

configured so that only unblinded research team members (eg, study coordinator, interventionist) could ascertain participants' group assignments.

Table 1. Exclusion Criteria

- Diagnosis of gout (in knee or hip), rheumatoid arthritis, fibromyalgia, or other systemic rheumatic disease (telephone screener and electronic medical record [EMR])
- Dementia or other memory loss condition (telephone screener and EMR)
- Active diagnosis of psychosis, serious personality disorder, or current uncontrolled substance abuse disorder (telephone screener and EMR)
- Total hip/knee replacement surgery, other hip/knee surgery, anterior cruciate ligament (ACL) tear, or other significant knee/hip injury in the past 6 months (telephone screener)
- Scheduled for or on a waiting list for joint replacement surgery (telephone screener)
- Severely impaired hearing or speech (patients must be able to participate in telephone sessions) (telephone screener)
- Unable to speak English (telephone screener)
- Participating in another osteoarthritis intervention or coping skills training study (telephone screener)
- Unwilling to be randomized to either study group (telephone screener)
- Lower extremity paralysis (telephone screener and EMR)

Interventions and Comparators or Controls

We based the pain CST program on prior clinical trials among patients with various chronic pain conditions,[11-13,15] as well as African American men with prostate cancer.[40] For aim 1 of this project, we engaged our stakeholder panel (African Americans with OA, public health representatives, and health care providers) in a process of culturally tailoring the CST program, in which we sought to incorporate the cultural values, pain experiences, and life experiences of African Americans into both the content and delivery process. We conducted sessions with African American patients with OA, in which we presented CST modules and then solicited

patients' input about aspects they liked and did not like, concepts that were difficult to understand, potential barriers to incorporating the skills into daily life, and ways in which skills related or did not relate to their cultural, spiritual, or other values. These patients, as well as other key stakeholders, also provided input on the CST handbook. Appendix 1 describes the input we received from stakeholders and the corresponding adaptations made to the CST program.

The CST program involved 11 weekly individual sessions, approximately 30 to 45 minutes each, delivered via telephone by a trained counselor. The content for each session is shown in Table 2 and details of each topic are included in Appendix 2.[38]

Table 2. Content of Pain CST Sessions

Session	Topic(s) and Skills
1	CST program introduction, education in rationale for CST, progressive muscle relaxation
2	Mini-relaxation practices, communication with significant others about pain and coping
3	Managing unhelpful mood (cognitive restructuring)—Part I
4	Managing unhelpful mood (cognitive restructuring)—Part II
5	Activity pacing
6	Pleasant activities
7	Pleasant imagery and other distraction techniques
8	Physical activity and osteoarthritis
9	Weight management and osteoarthritis
10	Skills review and problem solving
11	Relapse prevention and maintenance

During intervention phone calls, a counselor provided instruction in cognitive and behavioral pain coping skills and led participants in guided rehearsals of these skills. Participants were asked to engage in home-based practice of the skills to enhance their application in pain-related situations. During each phone call, the counselor reviewed participants' home practice, including successes and barriers, encouraged problem solving, and worked to set goals for application of skills. Participants were given handouts to facilitate each session, along with an audio recording to guide progressive muscle relaxation. For all participants in the intervention group, we tracked the number of completed calls.

CST counselors received training in the pain CST protocol, including role play sessions, by experienced co-investigators. Prior to delivering the CST protocol, study counselors received certification in the protocol from the experienced investigators. Counselor certification included delivering each of the 11 study sessions to a confederate participant. An experienced co-investigator audio-recorded and rated these practice sessions; to certify, counselors were required to receive at least a 4 out of 5 on a 5-point scale for both quality of intervention delivery and adherence to the study protocol. Counselor training also included issues related to cultural sensitivity. In particular, counselors were encouraged to use active listening to identify opportunities to demonstrate that pain coping skills are compatible with cultural, spiritual, religious, or other values. CST sessions were audio-recorded; study counselors had hour-long weekly sessions with experienced investigators to review recorded sessions, and experienced co-investigators reviewed a subset of intervention calls for quality and adherence.

The control group was usual care/WL. All participants in the study were patients under care for OA (and other health conditions) at a clinic within their study site and therefore receiving usual care for OA. At each assessment, we also asked participants to self-report medications being taken for knee OA.

Study Outcomes

Trained research assistants who were blinded to participants' randomization assignments conducted assessments at baseline, 3-month follow-up (following completion of the pain CST

program), and 9-month follow-up. The research assistants conducted baseline and 3-month assessments in person and conducted 9-month assessments via telephone. When participants could not complete 3-month assessments in person, we allowed for these to be conducted via telephone. Participants received $50 for completing baseline assessments, $50 for completing 3-month assessments, and $25 for completing 9-month assessments. We selected the primary and secondary outcomes with the goal of capturing domains that commonly affect people with OA. In addition, we selected outcomes with prior data on reliability and validity in the context of OA.

Primary Outcome

WOMAC Pain Subscale

The WOMAC pain subscale, a commonly used and well-validated measure among patients with lower extremity OA,[41] includes 5 items, all rated on a Likert scale of 0 (no symptoms) to 4 (extreme symptoms), with a range of 0 to 20. The subscale refers to the severity of pain during the previous 2 weeks for different activities (eg, walking, going up or down stairs, at night while in bed, sitting or lying, and standing). When individual items were missing, we followed guidelines regarding when to impute the score. Specifically, we considered the WOMAC pain subscale invalid if more than 1 item was missing; in the event of 1 missing item, the remaining 4 items were averaged and multiplied by 5.[42] A change of about 14% is generally thought to be a clinically meaningful change in WOMAC score in the context of nonpharmacological interventions for OA.[43]

Secondary Outcomes

WOMAC Total Score and Function Subscale

In addition to the pain subscale, the WOMAC includes stiffness (2 items) and function (17 items) subscales. All items are listed rated on a Likert scale of 0 (no symptoms) to 4 (extreme symptoms), with ranges of 0 to 96 for the total score (pain, stiffness, and function subscales) and 0 to 68 for the function subscale. If more than 4 items were missing for function

subscale, or more than 1 item was missing for stiffness subscale, we considered the corresponding subscale invalid; otherwise, missing items were replaced with the mean of the nonmissing items.[42] The total score was invalid if at least 1 subscale was missing.

PROMIS Pain Interference Instrument (Short Form 6a)

This instrument measures the self-reported consequences of pain, over the previous 7 days, across aspects of life including social, cognitive, emotional, physical, and recreational activities.[44] This validated scale has 6 items with 5 response options, with a Likert scale of 1 to 5; the raw score (sum of all 6 items, range 6-30) is converted to a *T* score. We replaced missing items with the mean of nonmissing items if at least 4 items were answered, following the guidelines (http://www.healthmeasures.net/images/PROMIS/manuals/PROMIS_Pain_Interference_Scoring_Manual_2.pdf).

Short Form-12 Health Survey

The SF-12 covers domains of general, physical, and emotional health, as well as work and activity limitations.[45] We computed both mental and physical health composite scores only if all items for the score were available; each ranges from 0 to 100, with lower scores indicating poorer health.

Coping Strategies Questionnaire

The CSQ, which includes 48 items, has subscales that assess 6 cognitive pain coping strategies (catastrophizing, diverting attention, ignoring sensations, coping self-statements, reinterpreting pain sensations, and praying-hoping) and 1 behavioral coping strategy (increasing behavioral activities).[46,47] Each subscale includes 6 items, and participants rate the frequency of their use of specific coping strategies on a 7-point Likert scale from 0 ("never do that") to 6 ("always do that"). We calculated all subscales if at least 5 items were nonmissing; in the event of 1 missing item, the remaining 5 items were averaged and multiplied by 6. We created a Total Coping Attempts score (range 0-216), which includes 5 cognitive subscales and 1 behavioral subscale but excludes the catastrophizing domain, similar to prior studies.[12,26,48-50]

We did not include the Catastrophizing subscale from the CSQ in these analyses; we measured catastrophizing using the Pain Catastrophizing Scale (PCS), which includes 5 of the 6 pain catastrophizing items from the CSQ.

Pain Catastrophizing Scale

This 13-item instrument asks participants to describe their thoughts and feelings when in pain, assessing domains of rumination (range 0-16), magnification (range 0-12), and helplessness (range 0-24); all items are rated on a scale of 0 to 4 (total score is computed by summing responses to all items, range 0-52), with higher scores indicating more pain catastrophizing.[51] We calculated the total score and the subscales if the participant provided responses to all items.

Patient Health Questionnaire-8

This 8-item survey of depressive symptoms includes items corresponding to the depression criteria listed in the *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition).[52] All items are scored as 0 ("not at all") to 3 ("nearly every day"), referring to symptoms during the previous 2 weeks, with higher scores indicating more depressive symptoms (total score range 0-24). We considered PHQ-8 missing if more than 1 item was missing; in the event of 1 missing item, the remaining 7 items were averaged and multiplied by 8.

Arthritis Self-efficacy Scale

This scale includes 8 items asking respondents how certain they are that they can manage arthritis pain and keep it from interfering with specific activities.[53,54] All items are scored on a scale of 1 (very uncertain) to 10 (very certain). The score for the scale is the mean of the 8 items (total score range 1-10), with higher scores indicating greater self-efficacy for managing arthritis symptoms. We considered the scale invalid if more than 2 items were missing.

Yale Physical Activity Survey

This scale was developed to assess physical activity in older adults and includes common activities (eg, housework, yardwork, leisure activity, moderate-intensity physical activity, caretaking, and recreational activity) performed during a typical week in the previous month; higher scores are associated with greater activity level.[55] We analyzed the first section of the tool, in which the time for each checklist activity (work, exercise, and recreational activities) is multiplied by an intensity code and then summed for all activities to create an energy summary index. If the time for particular activity was missing, we considered the participant's score invalid.

Patient Global Impression of Arthritis Symptom Change

This single-item measure asks participants to describe their change in arthritis symptoms on a 7-point rating scale with the following options: 1 = "very much improved," 2 = "much improved," 3 = "minimally improved," 4 = "no change," 5 = "minimally worse," 6 = "much worse," and 7 = "very much worse": lower scores indicate more improvement. At both follow-up times, this item was asked relative to change since baseline.

Demographic and Clinical Characteristics

Participant characteristics include age, race/ethnicity, gender, marital status, household financial state (with low income defined as self-report of "just meeting basic expenses" or "don't even have enough to meet basic expenses" vs "meet basic expenses with a little left over for extras" or "live comfortably"), education level, work status, duration of OA symptoms, comorbid illnesses (Self-administered Comorbidity Questionnaire[56]), and the Duke University Religion Index (DUREL), which includes 3 subscales of intrinsic religiosity, attendance of religious services, and frequency of private religious activities.[57]

Sample Size Calculations and Power

We based the sample size estimate of n = 124 per group on the primary research question and the 9-month follow-up assessment, because that is the most conservative test

due to higher attrition at 9 months vs 3 months. Sample size calculations used methods appropriate for analysis of covariance (ANCOVA)-type analyses,[58] which are equivalent in terms of efficiency to our proposed linear models in randomized trials.[59] Based on previous data, we assumed a correlation of 0.6 between baseline and follow-up WOMAC pain scores and an SD of 3.9. With 80% power, $\alpha = 0.05$, SD = 3.9, $\rho = 0.60$, and a conservative 20% attrition rate by 9 months, we needed to enroll 124 patients per group to detect a 1.3-point difference in mean WOMAC pain scores at 9 months between the CST group and the WL control group. Based on a mean baseline WOMAC pain score of 9.2 (based on our prior studies in similar patient groups),[60,61] this corresponds to approximately a 14% improvement or 0.33 (medium) Cohen effect size difference in WOMAC pain, which is a clinically relevant improvement.[43,62] Similarly, for the remaining secondary outcomes, we were powered to detect a 0.33 effect size difference for the CST group compared with the WL control group. We had greater than 80% power to detect a 1.3-point difference in pain scores between CST and WL at 3 months.

Time Frame for the Study

The CST program lasted 11 weeks, or approximately 3 months. Therefore, the first follow-up assessment was scheduled for 3 months after baseline. The 9-month follow-up assessment allowed an additional 6 months to assess whether any intervention effects were maintained.

Data Collection and Sources

We called participants to schedule follow-up assessments; multiple attempts were made when needed, including calling at different times of day. We used several processes to maximize retention. First, we offered the WL group treatment after completing the final follow-up. Second, we provided compensation adequate to support participants' time and travel for study assessments. Third, we made reasonable accommodations for participants to complete their baseline and follow-up assessments. If participants were unable to come to a study location for a follow-up visit, we allowed for telephone-based assessments in order to minimize loss to follow-up. Information on withdrawals, loss to follow-up, and exclusion was entered into

the study database, which included automated functions to minimize and monitor for missing data.

Analytical and Statistical Approaches

Our primary hypothesis was that participants who received the pain CST intervention would have greater improvement in mean WOMAC pain score than participants in the WL group at 3-month follow-up. Analyses involved all randomly assigned participants, using all data collected for each participant.[63] Observations were not deleted due to missing follow-up data.[64] The estimation procedure for our analytic technique (linear mixed models) implicitly accommodates missingness when related to prior outcome or to other baseline covariates included in the model (missing at random [MAR]). To assess the model's robustness to missing observations and strengthen the MAR assumption, we multiply imputed missing WOMAC pain follow-up scores using a Markov chain Monte Carlo algorithm incorporating additional baseline variables that were related to missing outcomes: gender, body mass index (BMI), occupational status, education level, and baseline score for PHQ-8, Arthritis Self-efficacy, PCS, CSQ pain catastrophizing score and its rumination and magnification subscales, and CSQ reinterpreting pain sensation subscale.

For continuous outcomes, we fit linear mixed models using the SAS procedure PROC MIXED with unstructured covariance structure to account for the repeated measures over time. We used a square root transformation for the Yale Physical Activity Survey score, and we used the SF-12 mental health component score change from baseline to 3-month and baseline to 9-month follow-up as the outcomes, due to normality assumptions.

The predictors in all models, unless otherwise noted, included dummy coded follow-up time effect(s) and indicator variables for the intervention interacting with the follow-up time effect(s).[59] We assumed equal baseline means across study groups, as is generally appropriate for a randomized controlled trial.[59,65] Final models also included stratification, variables, site, and gender. For the SFS-12 mental health component change score outcome (as described above), model fixed-effects terms included baseline Yale score along with indicators for

intervention and 9-month follow-up as well as interaction of intervention indicator by 9-month follow-up. Since Patient Global Impression of Arthritis Symptom Change was assessed only at 3- and 9-month follow-up, predictors included indicators for intervention and 3-month follow-up and interaction of intervention indicator by 9-month follow-up.

To address aim 3 (evaluation of whether individual patient characteristics are associated with differential improvement in WOMAC pain score following the CST program), we performed analyses to examine whether a priori–selected variables were associated with differential improvement in WOMAC pain score following the intervention: number of self-reported comorbid health conditions at baseline, self-reported duration of arthritis symptoms, and baseline pain catastrophizing score. In separate models for each variable, we added the characteristic and associated interaction variables with treatment group and follow-up time (2- and 3-way interactions) to the linear mixed model as described previously for the primary outcome (WOMAC pain score). We examined parameter estimates and 95% confidence intervals for 3-way interactions (eg, treatment group x time x patient characteristic) to determine whether there was evidence of heterogeneity of treatment effects (HTE) based on that characteristic. In exploratory HTE analyses to identify multidimensional subgroups from a priori–defined patient characteristics, we used multivariable logistic regression and recursive partitioning methods.[66-70] For the outcome for these exploratory analyses, we constructed a summary of each participant's repeated measures profile using empirical Bayes estimates from linear mixed-effects models to generate individual-level estimates of improvement in WOMAC pain score at 9 months.[71] From the change in WOMAC pain scores between baseline and 9 months, we created a dichotomous variable to indicate whether improvement in WOMAC pain was greater than 14%, which is indicative of clinically meaningful change in WOMAC pain in the context of this type of intervention.[72]

For the risk prediction models used to identify heterogeneous multidimensional subgroups, multivariable logistic regression models to predict improvement in WOMAC pain score included the following a priori–selected covariates: age, gender, BMI, baseline WOMAC pain, catastrophizing, and PHQ-8. Due to lack of an externally validated risk/benefit outcome,

limited sample size, and the exploratory nature of this analysis, we followed standard procedures for developing an internal model to risk stratify our sample. Following standard procedures to prevent overfitting in risk prediction models has shown that bias is not created in estimation of HTEs.[73,74] Based on the distribution of the dichotomous improvement outcome, to prevent overfitting, we were limited to the number of covariates we could include.[75] We fit restricted cubic splines for all continuous covariates to examine linearity in log odds assumption. To create heterogeneous subgroups (eg, men and women with ranges of BMI could be in one quartile), we used estimated individual predicted improvement probabilities from this model to divide participants into quartiles based on these probabilities and then fit logistic regression models to each quartile subgroup to examine whether HTEs existed in these subgroups.

For recursive partitioning methods used to identify homogeneous multidimensional subgroups (eg, men with high school education) with HTEs, we used model-based recursive partitioning (MOB) to identify subgroups (partykit package in R). The set of covariates used for MOB were age, gender, education level, marital status, financial security, BMI, baseline WOMAC pain and function, pain interference, coping, pain catastrophizing, PHQ-8, Arthritis Self-efficacy, and the 3 DUREL subscales. We used a logistic model to predict improvement in MOB with default parameter settings with no Bonferroni correction of *P* values and minimum node size of 20.

Because 35% of participants completed < 7 of the 11 CST sessions, we conducted a post hoc sensitivity analysis for the primary outcome to estimate the effect of receiving a more complete "dose" of the intervention, known as the complier average causal effect (CACE).[76] We defined compliance a priori as completing at least 7 intervention calls because all of the "core" content of pain CST was covered during these sessions. (See Table 2; Sessions 8 and 9 covered physical activity and weight management, which are not routinely part of pain CST programs but were added here for more of a comprehensive behavioral approach. Sessions 10 and 11 focused on skills review and maintenance.) Because noncompliers were also more likely to drop out, we first multiply imputed missing 3- and 9-month outcomes using the same procedures as

described for aim 2. Twenty multiple imputations were generated via the MCMC option in PROC MI. We calculated the change between baseline and month 3 and baseline and month 9 for each outcome and imputed data set. We then calculated the CACE on these change scores following the formulas presented in Liang et al and averaged across the 20 imputed data sets.[76] We computed confidence intervals (95%) for the CACE estimates via 1000 bootstrapped samples of the 20 multiply imputed data sets.[77]

Data Management

Trained research assistants collected and entered data directly into a secure, web-based database accessible only to research team members based on their duties and blinding status. Following completion of data collection, we exported outcome data and participant tracking information from the study database into an SAS database, where data were cleaned prior to analyses. Data will continue to be housed on a secure UNC server for the duration required by PCORI and/or UNC. Deidentified data can be shared, following a request to the study team and proper regulatory approvals.

Changes to the Original Study Protocol

There were no major changes to the study protocol. As noted previously, prior to study start-up we made minor changes in collection of some secondary outcomes. Protocol modifications are shown in Table 3.

Table 3. Summary of Modifications Submitted to the Institutional Review Boards

Date Approved	Notes
8/20/2015	• Added information about engaging patient stakeholders. In particular, UNC providers at UNC Family Medicine and Internal Medicine would identify potential patient stakeholders and provide them with information using the "STAART Summary for Providers" information sheet. Interested patients would be contacted by study staff.
9/30/2015	• Extended UNC IRB oversight to an external group. • Requested Reliance Agreement addition of East Carolina University and Duke.
11/2/2015	• Added a letter to be sent from UNC providers to potential patient stakeholders, as well as addition of a clinical and translational research center (CTRC) addendum, since the CTRC would be used for study visits at UNC.
12/2/2015	• Updated study protocol so that we could recruit patient partners using a flyer as well as a mass email to UNC staff.
3/3/2016	• Updated the subject payment details to reflect the correct compensation amounts to subjects: Subjects will receive up to $125 ($50 for each of the 2 in-person visits and $25 for the 9-month telephone assessment). • Edited study materials to provide clarity that the 9-month assessment is conducted via telephone. • Added the co-investigators to the adult consent form. • Added specific language to the IRB application regarding administering a feedback questionnaire to subjects. • Removal of pain medication diary from study protocol. • Added department mailing address to the top of the HIPAA Authorization. • Added some additional recruitment methods to the protocol, to include a variety of methods to advertise the study to potential participants. • Added a question for the phone screener to ask potential participants if they identify as black or African American (since the study enrolled only individuals in this racial category). Also added this question to the demographic information we collected at baseline. • Added a paragraph to the consent form to ask participants to give consent (or decline consent) to allow us to keep their contact information on file in case they may qualify for future studies with our research center. • Updated phone screener to better reflect our inclusion criteria as it related to osteoarthritis (OA) diagnosis and symptoms.

Date Approved	Notes
	• Removed coping skills training (CST) 12th session, the "feedback session," since we asked for feedback as part of the 3-month follow-up assessments. • Updated recruitment flyer with formatting changes as well as study contact information. • Updated recruitment flyer and phone screener for potential participants to indicate if they are a patient at either UNC Health Care or the Durham VA Medical Center. • Added visit confirmation letters. • Updated electronic medical record notification to participant's physician. • Added a question asking participants if they have had a total joint replacement (knee or hip) surgery, other significant knee or hip surgery, or anterior cruciate ligament (ACL) tear, to be asked prior to their 3- and 9-month assessments. • Updated study measures. • Added a copy of the booklet sent to subjects prior to enrollment. • Added script of progressive muscle relaxation CD for CST participants.
3/21/2016	• Added Self-administered Comorbidity Questionnaire to measures document. • Edited the exclusion criterion of participating in another OA intervention study to also include participation in another CST study.
4/28/2016	• Edited the frequency of counselor phone call review from 30% to approximately 15%, or more as deemed necessary. • Added the following participant characteristics to the written protocol: age, race/ethnicity, gender, general self-rated health. • Removed the formal consideration of comorbid illnesses by the CST counselor from our protocol. • Added a section on consent form for participants to initial as to whether they consent or do not consent to being audio-recorded during the CST sessions. • Deleted "physical therapists" and added "CST counselor" to the list of approved personnel in the privacy section of the consent form. • Added the Johnston County Osteoarthritis Project site in Smithfield, North Carolina, as a location where research visits may be conducted. • Edited the recruitment materials and phone screener to delete the language "to enhance accessibility and reach" regarding the CST program. • Edited the CST manual to include addition of handouts and a list of physical activity resources (web links) available to participants.
5/11/2016	• Changed exclusion criteria regarding meniscus tears.

Date Approved	Notes
5/18/2016	• Added an exclusion criterion of lower extremity paralysis to our protocol.
6/7/2016	• Updated study measures taken at baseline by adding questions regarding joints affected by arthritis.
6/23/2016	• Added the exclusion criterion "Other health problem that would prohibit participation in the study (at the discretion of the principal investigator)." We already have a question in the phone screener to cover this "other" category.
7/18/2016	• Added a measure to the 3-month follow-up assessment on duration of OA symptoms.
9/17/2016	• Edited the feedback questions we ask at the 3-month follow-up assessment.
12/22/2016	• Added an additional question on phone screener reminding participants of the time commitment involved for the intervention and confirming desire to participate in the study.
3/16/2017	• Added Perceived Discrimination, Multi-item measure to the 9-month follow-up assessment.
3/29/2017	• Updated contact information on recruitment form that will allow us to send an email to UNC employees.
4/5/2017	• Updated contact information on correspondence sent to providers to notify them that their patient has enrolled in this study.
6/5/2017	• Added language to the master study protocol to reflect additional exploratory analyses that may be conducted.
10/15/2018	• Sent study participants a letter informing them of study findings.

RESULTS

Participants, Retention, and Intervention Delivery

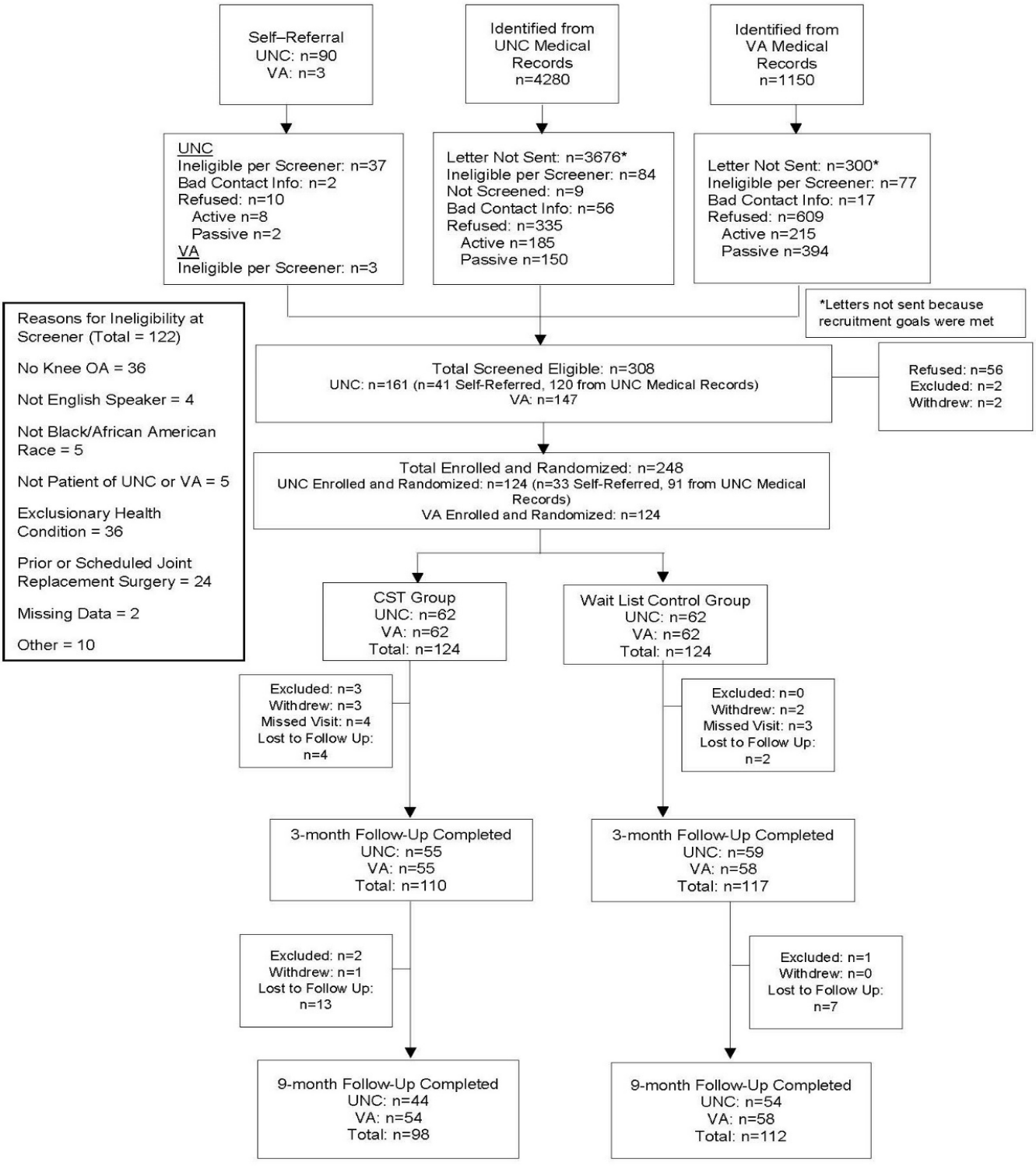
We identified 5430 potentially eligible patients from electronic medical records (4280 UNC, 1150 DVAHCS; Figure 1). An additional 93 participants self-referred to the study (90 UNC, 3 DVAHCS). Among 1547 patients who were mailed a letter or self-referred to the study, 248 were eligible, enrolled, and randomized. At 3-month follow-up, 92% of participants completed assessments (89% CST group, 94% WL group). At 9-month follow-up, 85% of participants completed assessments (79% CST group, 90% WL group). Participant characteristics are shown in Table 4.

The mean number of pain CST sessions completed was 8.0 (SD = 4.3); 20% of participants completed 0 or 1 session and 61% completed 9 to 11 sessions. There were no study-related adverse events in either the CST or WL groups.

Primary Outcome

At 3-month follow-up, WOMAC pain scores did not differ significantly between the pain CST group and the WL group (estimated treatment difference = –0.63; 95% CI, –1.45 to 0.128; Table 5), with the CST group having lower estimated pain at 3 months than the WL group. At 9-month follow-up, WOMAC pain scores in the pain CST group continued to decrease (signifying lower pain) from 3 months but were not statistically different from the WL group (estimated treatment difference = –0.84; 95% CI, –1.73 to 0.068). Results were similar in multiple imputation analyses of loss to follow-up WOMAC pain scores. At 3-month follow-up, the estimated treatment difference was –0.63 (95% CI, –1.46 to 0.20; p = 0.137). At 9-month follow-up, the estimated treatment difference was –0.92 (95% CI, –1.81 to –0.04; p = 0.042). The CACE analysis showed that receipt of at least 7 intervention sessions resulted in larger improvements, though not statistically different from the control group at either 3 or 9 months (difference in CACE estimated mean change = –1.2; 95% CI, –2.4 to 0.2 for 3 months and = –1.4; 95% CI, –2.8 to 0.1 for 9 months).

Figure 1. Participant flow: CONSORT diagram



Abbreviations: CST, coping skills training; OA, osteoarthritis; UNC, University of North Carolina; VA, Department of Veterans Affairs.

Table 4. Characteristics of STAART Participants, Overall and By Group

Characteristic	Total Sample (N = 248) Mean ± SD or N (%)	Pain CST (n = 124) Mean ± SD or N (%)	WL Control (n = 124) Mean ± SD or N (%)
Demographic and Clinical Characteristics			
Age	59.0 ± 10.3	59.2 ± 9.8	58.9 ± 10.9
Female	122 (49.2%)	61 (49.2%)	61 (49.2%)
Hispanic	7 (2.9%)	3 (2.5%)	4 (3.3%)
Some education above high school	187 (75.4%)	92 (74.2%)	95 (76.6%)
Working	86 (34.7%)	43 (34.7%)	43 (34.7%)
Married or living with partner	103 (41.5%)	51 (41.1%)	52 (41.9%)
Low perceived income[a]	83 (33.6%)	48 (38.7%)	35 (28.5%)
Body mass index (kg/m^2)	35.2 ± 8.2	35.6 ± 8.4	34.8 ± 7.9
Number of self-reported comorbidities	8.5 ± 3.9	8.2 ± 3.9	8.8 ± 4.0
Total self-reported duration of arthritis symptoms	13.0 ± 10.0	12.4 ± 9.6	13.6 ± 10.3
Currently taking non-steroidal anti-inflammatory drug	134 (54.0%)	70 (56.5%)	64 (51.6%)
Currently taking COX-2 inhibitor	6 (2.4%)	3 (2.4%)	3 (2.4%)
Currently taking opioid analgesic	60 (24.2%)	30 (24.2%)	30 (24.2%)
Primary and Secondary Outcomes			
WOMAC pain	11.0 ± 3.9	11.2 ± 4	10.8 ± 3.8
WOMAC total	53.0 ± 17.8	52.9 ± 16.4	53.0 ± 19.1
WOMAC function	37.0 ± 13.2	37.1 ± 12.2	36.9 ± 14.2
PROMIS Pain Interference score	63.8 ± 6.9	64.0 ± 6.3	63.5 ± 7.5

Characteristic	Total Sample (N = 248) Mean ± SD or N (%)	Pain CST (n = 124) Mean ± SD or N (%)	WL Control (n = 124) Mean ± SD or N (%)
SF-12–physical health component score	33.1 ± 9.1	33.1 ± 8.9	33.0 ± 9.2
SF-12–mental health component score	50.7 ± 11.1	51.0 ± 10.4	50.4 ± 11.8
CSQ–Total Coping Attempts	93.9 ± 36.6	94.3 ± 37.5	93.5 ± 35.9
PCS	19.8 ± 12.3	19.9 ± 12.8	19.6 ± 11.8
PHQ-8	6.2 ± 5.3	6.0 ± 5.1	6.4 ± 5.6
Arthritis Self-Efficacy Scale	5.9 ± 2.0	5.6 ± 1.9	5.8 ± 2.0
Yale Physical Activity Survey	4020.1 ± 3472.5	4318.0 ± 3905.5	3725.1 ± 2971.9

Abbreviations: COX-2, cyclooxygenase 2; CSQ, Coping Strategies Questionnaire; CST, coping skills training; PCS, Pain Catastrophizing Scale; PHQ-8, Patient Health Questionnaire-8; PROMIS, Patient-Reported Outcomes Measurement Information System; SF-12, Short Form-12; WL, wait list; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

[a] Self-report of "just meet basic expenses" or "don't even have enough to meet basic expenses."

Missing data: Hispanic = 9; low perceived income = 1; body mass index = 6; number of self-reported comorbidities = 7; duration of arthritis symptoms = 20; WOMAC total = 1; WOMAC pain = 1; SF-12–physical health = 4; SF-12–mental health = 4; CSQ–Total Coping Attempts= 1; PCS = 1; Arthritis Self-efficacy Scale = 1; Yale Physical Activity Survey = 37.

Table 5. Estimated Means and 95% Confidence Intervals From Linear Mixed Models (Primary ITT Analysis)

Outcome	Assessment	Pain CST (N = 124) Mean (95% CI)	WL Control (N = 124) Mean (95% CI)	Treatment Difference: Pain CST vs WL Mean (95% CI)	*P* Value
WOMAC pain subscale	Baseline	11.01 (10.52-11.49)			
	3 months	9.42 (8.77-10.06)	10.05 (9.42-10.68)	–0.63 (–1.45-0.18)	0.128
	9 months	8.77 (8.04-9.50)	9.61 (8.91-10.30)	–0.84 (–1.73-0.06)	0.068
WOMAC total subscale	Baseline	52.99 (50.79-55.19)			
	3 months	46.39 (43.49-49.29)	49.01 (46.16-51.86)	–2.62 (–6.01-0.77)	0.129
	9 months	44.18 (40.96-47.40)	47.49 (44.39-50.59)	–3.31 (–7.07-0.44)	0.084
WOMAC function	Baseline	37.00 (35.37-38.64)			
	3 months	32.93 (30.76-35.10)	35.54 (32.41-36.67)	–1.61 (–4.14-0.91)	0.209
	9 months	31.40 (29.00-33.80)	33.60 (31.29-35.90)	–2.20 (5.03-0.63)	0.128
PROMIS Pain Interference	Baseline	63.75 (62.89-64.62)			
	3 months	61.12 (60.04-62.21)	61.96 (60.90-63.01)	–0.83 (–2.18-0.51)	0.222
	9 months	61.00 (59.74-62.27)	62.14 (60.92-63.36)	–1.14 (–2.60-0.33)	0.128
SF-12–physical health component score	Baseline	33.08 (31.95-34.2)			
	3 months	35.67 (33.99-37.36)	33.96 (32.31-35.61)	1.71 (–0.40-3.82)	0.111
	9 months	35.55 (33.82-37.27)	34.81 (33.17-36.45)	0.73 (–1.42-2.88)	0.502

Outcome	Assessment	Pain CST (N = 124) Mean (95% CI)	WL Control (N = 124) Mean (95% CI)	Treatment Difference: Pain CST vs WL Mean (95% CI)	*P* Value
SF-12–mental health component score[a]	3 months	–0.72 (–2.08-0.64)	–1.48 (-2.82 to –0.15)	0.76 (–1.15-2.66)	0.433
	9 months	–0.57 (–2.13-0.99)	–2.28 (-3.76 to –0.79)	1.71 (–0.45-3.86)	0.120
CSQ–Total Coping Attempts	Baseline	105.38 (100.62-110.13)			
	3 months	121.84 (116.48-127.19)	106.53 (101.28-111.78)	15.31 (9.09-21.53)	0.001
	9 months	114.65 (108.88-120.41)	102.97 (97.42-108.52)	11.67 (5.08-18.27)	<0.001
PCS	Baseline	19.73 (18.19-21.28)			
	3 months	17.81 (15.81-19.81)	20.84 (18.87-22.81)	–3.03 (–5.25 to –0.8)	0.008
	9 months	16.98 (14.86-19.09)	18.35 (16.33-20.38)	–1.38 (–3.85 to 1.09)	0.273
Depressive symptoms (PHQ-8)	Baseline	6.19 (5.53-6.85)			
	3 months	5.87 (4.99-6.75)	6.37 (5.51-7.23)	–0.50 (–1.57-0.57)	0.356
	9 months	5.30 (4.36-6.23)	6.31 (5.43-7.20)	–1.02 (–2.19-0.15)	0.087
Arthritis Self-efficacy Scale	Baseline	5.87 (5.62-6.11)			
	3 months	6.67 (6.35-6.99)	5.66 (5.35-5.98)	1.01 (0.61-1.41)	<0.001
	9 months	6.33 (5.99-6.67)	5.66 (5.33-5.99)	0.67 (0.24-1.09)	0.002
Yale Physical Activity Survey[b]	Baseline	58.55 (55.09-62.01)			
	3 months	60.72 (56.16-65.28)	55.72 (51.29-60.15)	5.00 (–0.93-10.93)	0.078
	9 months	56.66 (51.85-61.46)	53.80 (49.38-58.22)	2.85 (–3.05-8.75)	0.727

Outcome	Assessment	Pain CST (N = 124) Mean (95% CI)	WL Control (N = 124) Mean (95% CI)	Treatment Difference: Pain CST vs WL Mean (95% CI)	*P* Value
Patient Global Assessment of Pain Change[c]	3 months	2.91 (2.67-3.14)	4.18 (3.95-4.40)	–1.27 (–1.60 to –0.95)	<0.001
	9 months	3.25 (2.99-3.52)	4.13 (3.87-4.38)	–0.87 (–1.24 to –0.51)	<0.001

Abbreviations: CSQ, Coping Strategies Questionnaire; CST, coping skills training; ITT, intention to treat; PCS, Pain Catastrophizing Scale; PHQ-8, Patient Health Questionnaire-8; PROMIS, Patient-Reported Outcomes Measurement Information System; SF-12, Short Form-12; WL, wait list; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

[a] Analyzed as score change from baseline to follow-up.

[b] Square root transformed variable.

[c] Assessed at 3 and 9 months only and reported as change from baseline.

Missing data baseline: WOMAC pain = 1; WOMAC total = 1; SF-12–physical health = 4; SF-12–mental health = 4 ; CSQ–Total Coping Attempts = 1; PCS = 1; Arthritis Self-efficacy Scale= 1; Yale Physical Activity Survey = 37.

Missing data 3 months: WOMAC pain = 21; WOMAC total = 22; WOMAC function = 22; PROMIS Pain Interference = 21; SF-12–physical health = 24; SF-12–mental health = 24; CSQ–Total Coping Attempts = 21; PCS = 22; PHQ-8 = 21; Arthritis Self-efficacy Scale = 21; Yale Physical Activity Survey = 54; Patient Global Assessment of Pain Change = 22.

Missing data 9 months: WOMAC pain = 38; WOMAC total = 41; WOMAC function = 41; PROMIS Pain Interference = 38; SF-12–physical health = 44; SF-12–mental health = 44; CSQ–Total Coping Attempts = 39; PCS = 40; PHQ-8 = 41; Arthritis Self-efficacy Scale = 39; Yale Physical Activity Survey = 59; Patient Global Assessment of Pain Change = 38.

Secondary Outcomes

WOMAC total and function scores, PROMIS Pain Interference, and SF-12 mental and physical health component scores did not differ significantly between pain CST and WL groups at either 3 or 9 months (Table 5). The CSQ–Total Coping Attempts score (reflecting all types of coping strategies except pain catastrophizing) increased more in the pain CST group than the WL control group at both 3 months (estimated treatment difference = 15.31; 95% CI, 9.09-21.53) and 9 months (estimated treatment difference = 11.67; 95% CI, 5.08-18.27). PCS scores decreased more in the pain CST group than the WL group at 3 months (estimated treatment difference = –3.03; 95% CI, –5.25 to –0.80; $p = 0.008$); at 9 months, PCS scores continued to decline in the pain CST group, but the difference compared with the WL control group was smaller and no longer statistically significant ($p = 0.273$). PHQ-8 scores did not differ between pain CST and WL control groups at either assessment. Arthritis Self-efficacy scores improved more in the pain CST group than the WL control group at both 3 months (estimated treatment difference = 1.01; 95% CI, 0.61-1.41) and 9 months (estimated treatment difference = 0.67; 95% CI, 0.24-1.09). Yale Physical Activity Survey scores did not differ between groups at either 3 or 9 months. Patient Global Impression of Arthritis Symptom Change scores (patient rating of how much symptoms changed since the beginning of the study) were lower (indicating more improvement since baseline) in the pain CST group than the WL control group at both 3 months (estimated difference = –1.27; 95% CI, –1.60 to –0.95; $p < 0.001$) and 9 months (estimated difference = –0.87; 95% CI, –1.24 to –0.51; $p < 0.001$).

Aim 3 Analyses

In analyses of our primary outcome, we found no evidence of HTEs for any of our a priori–specified patient characteristics (baseline comorbidity, duration of arthritis symptoms, or pain catastrophizing scores), at either 3- or 9-month follow-up. Specifically, none of the 3-way interaction terms were statistically significant, with all 95% confidence intervals including 0 (for number of comorbidities, 3-way interaction is –0.04; 95% CI, –0.28 to 0.21; $p = 0.77$; see Table 6).

Table 6. Estimated Means and 95% Confidence Intervals for WOMAC Pain From Linear Mixed Models

Baseline Characteristic	Pain CST: Mean difference of change from baseline to 9 months for unit change in characteristic	WL Control: Mean difference of change from baseline to 9 months for unit change in characteristic	Pain CST–WL: Mean treatment difference of change from baseline to 9 months for unit change in characteristic; *P* value of 3-way interaction
Number of comorbidities	0.24 (0.04-0.44)	0.27 (0.10-0.45)	–0.04 (–0.28 to 0.21); *p* = 0.77
Duration of symptoms (years)	0.02 (–0.06 to 0.10)	0.01 (–0.06 to 0.08)	0.01 (–0.08 to 0.12); *p* = 0.80
Pain catastrophizing score[a]	0.63 (0.35-0.92)	0.52 (0.22-0.81)	0.12 (–0.26 to 0.49); *p* = 0.54

Abbreviations: CST, coping skills training; WL, wait list; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

[a] Mean change calculated for a 5-point increase.

In exploratory HTE analysis with risk prediction models, all continuous covariates met linear assumptions except for BMI, so the final risk prediction model included restricted cubic splines for BMI (see Table 7 for risk prediction model results). Observed improvement of 14% or more in WOMAC pain score between baseline and 9 months was higher in the pain CST group than the WL control group in all except the highest quartile of predicted improvement (Table 8); however, all 95% confidence intervals for the odds ratio comparing improvement rates between groups included 1 and were wide, due partly to small sample sizes within quartiles. Participants with the highest predicted rates of improvement were younger and had higher baseline WOMAC pain, higher pain catastrophizing, and lower PHQ-8 scores (Table 9). While these analyses are exploratory, limited by small sample sizes, and should be interpreted with caution, pain CST treatment effects appear to be stronger for those with less-severe baseline pain and pain catastrophizing.

Table 7. Logistic Regression Risk Prediction Model for Dichotomous Outcome[a] Used to Generate Prediction Probabilities (C-index = 0.70)

Parameter	Estimate	Standard Error	Wald Chi-square	*P* Value
Intercept	–3.17	1.88	2.84	0.092
BMI	0.07	0.05	1.80	0.18
BMI spline	–0.01	0.01	3.02	0.08
Baseline WOMAC pain	0.17	0.04	14.26	<0.001
Depressive symptoms (PHQ-8)	–0.09	0.03	6.65	<0.001
Age	–0.01	0.01	0.20	0.66
Pain catastrophizing score	0.01	0.01	0.13	0.71
Gender	–0.04	0.15	0.07	0.79

Abbreviations: BMI, body mass index; PHQ-8, Patient Health Questionnaire-8; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

[a] Improved 14% in WOMAC pain score between baseline and 3 months or not.

Table 8. Heterogeneous Treatment Effects on Improvement of 14% or More in WOMAC Pain From Logistic Regression Models by Quartiles of Estimated Predicted Improvement Probabilities From Risk Prediction Models[a]

Strata	N	% (N) Improved Overall	% (N) Improved Pain CST	% (N) Improved WL Control	Pain CST vs WL Control OR (95% CI)
Quartile 1 (lowest predicted improvement)	59	22 (13 of 59)	27 (8 of 29)	17 (5 of 30)	1.7 (0.5-6.1)
Quartile 2	58	36 (21 of 58)	40 (10 of 33)	33 (11 of 25)	1.3 (0.5-3.9)
Quartile 3	58	48 (28 of 58)	55 (18 of 25)	40 (10 of 33)	1.8 (0.6-5.2)
Quartile 4 (highest predicted improvement)	59	69 (41 of 59)	66 (20 of 29)	72 (21 of 30)	0.8 (0.3-2.3)

Abbreviations: CST, coping skills training; WL, wait list; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

[a] Odds ratio > 1 indicates higher odds of improvement between baseline and 3 months in pain CST compared with WL control.

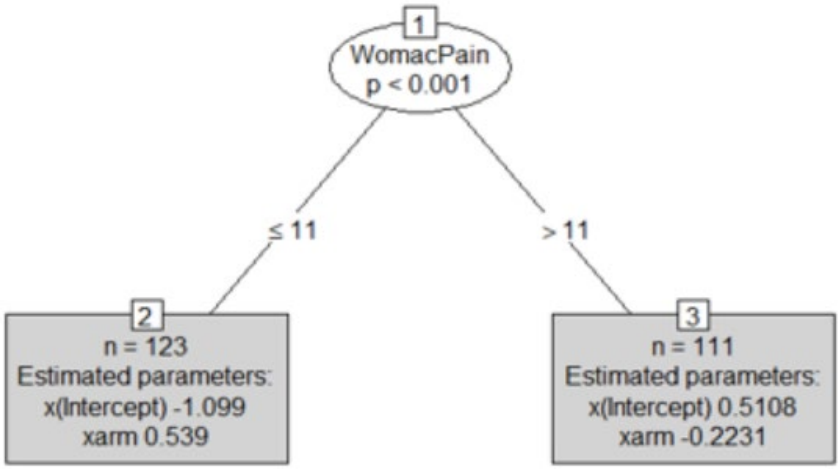
Table 9. Patient Characteristics by Risk Prediction Quartiles

	Overall N = 234	Quartile 1 N = 59	Quartile 2 N = 58	Quartile 3 N = 58	Quartile 4 N = 59
Age, mean (SD)	58.9 (10.3)	58.7 (11.1)	59.1 (11.2)	62.0 (9.4)	55.6 (8.7)
Female, % (N)	48.7 (114)	55.9 (33)	48.3 (28)	48.3 (28)	42.4 (25)
BMI, kg/m2	35.2 (8.2)	37.4 (11.0)	33.6 (7.1)	35.2 (7.5)	34.4 (5.7)
WOMAC pain	11.0 (3.9)	8.1 (4.0)	9.8 (2.9)	11.6 (2.2)	14.6 (2.7)
Pain catastrophizing score	19.8 (12.3)	19.1 (11.6)	18.5 (12.6)	19.1 (12.2)	22.4 (12.9)
PHQ-8	6.3 (5.4)	8.9 (6.8)	6.4 (5.3)	5.0 (4.0)	4.7 (3.7)

Abbreviations: BMI, body mass index; PHQ-8, Patient Health Questionnaire-8; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

In exploratory analysis using MOB, our sample size was reduced to n = 234 participants due to missing data in covariates. Only 1 subgroup was identified based on a split of baseline WOMAC pain at 11 points (Figure 2). In the subgroup with baseline WOMAC pain scores ≤ 11, 36% in the pain CST group met the threshold of 14% improvement from baseline compared with 25% in the WL control group. In the subgroup with baseline pain > 11, 57% met the threshold improvement in the pain CST group compared with 63% in the WL control group.

Figure 2. Subgroup tree from model-based recursive partitioning (MOB) analysis



DISCUSSION

Summary of Findings

We found that, among African Americans with OA, a culturally tailored, telephone-based pain CST program did not result in statistically different or clinically meaningful changes in WOMAC pain score (the primary outcome) compared with a WL control group. Although the between-group difference in WOMAC pain scores at 9-month follow-up was statistically significant in the multiple imputation analysis, this difference was still modest, with most values in the 95% confidence interval of the difference below the threshold for a clinically meaningful between-group difference (14%).[43] For secondary outcomes, including WOMAC total and function, PROMIS Pain Interference, SF-12, PHQ-8, and Yale Physical Activity Survey, observed patterns were similar to WOMAC pain scores, with somewhat more favorable changes in the pain CST group but no significant between-group differences at either 3 months or 9 months. However, the pain CST program did improve key measures of pain coping and perceived ability to manage pain among African Americans with OA. In particular, CST participants increased their total coping attempts, decreased pain catastrophizing, and increased arthritis self-efficacy relative to the WL group; however, reductions in pain catastrophizing were not sustained at 9 months. These are important outcomes, particularly given prior research showing that African Americans tend to use pain coping efforts less frequently, are more prone to engage in pain catastrophizing, and report lower self-efficacy for managing arthritis compared with non-Hispanic whites.[3,16-22] Following treatment, participants in the CST group also perceived changes in their arthritis symptoms more favorably than the WL group. Overall, results suggest that the CST intervention improved pain coping but did not seem to affect pain severity.

Comparison With Other Studies

Regarding the effects of pain CST for improving pain severity in patients with OA, prior studies have been mixed, with some reporting significant improvement in pain severity[15,32] but others reporting no difference relative to a usual care control group.[13,29,30,78] Meta-analyses of cognitive behavioral interventions (including pain CST) have concluded that there are small

effect sizes for pain severity among patients with arthritis and other chronic pain conditions.[10,79] Findings of this study among African Americans with OA therefore concur with prior research, as there was some improvement in WOMAC pain scores following the CST intervention, but the changes were relatively small and not significantly different from those in the WL control group. There is increasing recognition that patients with chronic pain vary in their response to psychological and other treatments, and one recent study found that, among participants with OA who completed a pain CST intervention, effects on a composite variable (including pain severity) varied based on several demographic and clinical variables.[80,81]

Findings of this study regarding secondary outcomes also align with prior research.[13,15,29,30,32,78] Of particular importance were the significant improvements in pain coping–related variables (total coping attempts and pain catastrophizing) and arthritis self-efficacy in the pain CST group. Prior studies of pain CST for OA have consistently shown increases in the use of overall coping attempts and arthritis self-efficacy[15,26,28,29,32]; results have been mixed regarding pain catastrophizing, with some studies showing no effect.[15,29] African Americans in this study varied considerably from participants in prior studies of CST for OA, having worse pain and function, less favorable pain coping patterns, and more risk factors for negative pain-related outcomes.[82] Therefore, findings of this study illustrate that a culturally tailored pain CST can improve perceived ability to manage pain and maintain activities in a racial minority group that is at high risk for poor pain-related outcomes. The findings regarding changes in pain catastrophizing are particularly important, because multiple studies have shown higher catastrophizing among African Americans.[16-19] African Americans in this study had significant improvements in pain catastrophizing immediately following the CST intervention, and although there was no significant difference at 9 months compared with the WL group, pain catastrophizing scores continued to decrease in the CST group between 3- and 9- month follow-up. This suggests CST participants continued to improve in this key coping-related construct even after the intervention ended.

Another interesting finding was the significant difference in the Patient Global Assessment of Arthritis Symptom Change, despite the lack of difference in WOMAC pain scores.

It is possible that CST affected how participants viewed their symptoms more generally, resulting in a more positive perception even though pain severity did not change substantially. A recent study of internet-delivered pain CST and exercise regimens for patients with hip OA also found improvements in Patient Global Impression of Arthritis Symptom Change despite a lack of significant change in pain severity.[83] It is also possible that responses to the Patient Global Assessment of Change items were influenced by social desirability, particularly in the CST group.

Subpopulation Considerations

Our aim 3 analyses first examined whether there was heterogeneity in effects of pain CST for 3 specific patient characteristics: baseline level of comorbidity, duration of arthritis symptoms, and pain catastrophizing. We found no evidence of heterogeneity based on these participant characteristics. With exploratory HTE analyses to examine multidimensional subgroups, we did not find strong evidence of baseline characteristics identifying groups that benefited from the CST program more than others. In both risk prediction models and MOB, there was some evidence that participants' treatment response varied by baseline WOMAC pain score; however, implications of these findings are not clear. Specifically, the proportion of responders was greater overall among individuals with higher baseline WOMAC pain scores (compared with participants who had baseline scores ≤ 11), but this was true for both the CST and WL groups (and, in fact, a higher proportion of WL group participants were categorized as responders). Among those with lower baseline WOMAC pain scores (≤ 11), there was a higher proportion of responders in the CST group than in the WL group. These exploratory analyses should be interpreted cautiously due to the small sample size of this trial and lack of externally validated risk/benefit outcome, but they signal that more research is needed relative to the impact of baseline pain level on response to pain CST.

Study Limitations

Limitations of this study include the lack of de novo radiographs to confirm OA status, inclusion of patients limited to a single geographic region, and inclusion of a relatively well-educated sample (75% had some education above high school). Although we aimed for our stakeholder panel to include an array of perspectives, we might not have fully captured all of the important aspects of tailoring the CST intervention for African Americans with chronic pain. In addition, although we had low rates of attrition, there were some limitations in the level of intervention adherence, particularly that approximately 20% of participants attended < 2 CST sessions. Given that the mean number of sessions completed was 8 out of 11, and because our exploratory analyses suggested that completion of at least 7 sessions was associated with greater improvement, a future intervention may need to be reconfigured to provide the most critical skills in fewer sessions. Reducing the number of sessions may also help ensure sustainability of delivery. We believe the suboptimal intervention attendance illustrates the real-world challenges of identifying individuals who are most likely to engage with the intervention as well as the need to further evaluate intervention design to help participants complete pain CST despite their competing life responsibilities.

CONCLUSIONS

We found no significant effect of pain CST on the primary outcome of pain severity in African Americans with osteoarthritis; however, participants experienced improvements in other key outcomes related to the pain experience. Based on the mixed findings (eg, no significant between-group differences in the primary outcome but significant differences for secondary, pain-related outcomes), it may be helpful for future research efforts to (1) examine strategies for enhancing engagement in pain CST programs (including different delivery models), particularly given the results of our CACE analysis, suggesting that effects of CST are more pronounced the more sessions are attended; (2) identify factors associated with treatment response; and (3) explore practical strategies to proactively identify individuals who are most likely to engage with the intervention. Finally, since there are also pain disparities based on socioeconomic status, education, urban/rural geography, and occupational status, it would also be useful for future studies to explore appropriate adaptations, as well as effectiveness of pain CST in other groups with a greater burden of chronic pain.[84]

REFERENCES

1. Allen KD. Racial and ethnic disparities in osteoarthritis phenotypes. *Curr Opin Rheumatol.* 2010;22(5):528-532.

2. Allen KD, Helmick CG, Schwartz TA, DeVellis B, Renner JB, Jordan JM. Racial differences in self-reported pain and function among individuals with radiographic hip and knee osteoarthritis: The Johnston County Osteoarthritis Project. *Osteoarthritis Cartilage.* 2009;17(9):1132-1136.

3. Allen KD, Oddone EZ, Coffman CJ, Keefe FJ, Lindquist JH, Bosworth HB. Racial differences in osteoarthritis pain and function: potential explanatory factors. *Osteoarthritis Cartilage.* 2010;18:160-167.

4. Smith DM, Parmelee PA. Within-day variability of fatigue and pain among African Americans and non-Hispanic whites with osteoarthritis of the knee. *Arthritis Care Res (Hoboken).* 2016;68(1):115-122.

5. Vina ER, Ran D, Ashbeck EL, Kwoh CK. Natural history of pain and disability among African-Americans and whites with or at risk for knee osteoarthritis: a longitudinal study. *Osteoarthritis Cartilage.* 2018;26(4):471-479.

6. Kim HJ, Yang GS, Greenspan JD, et al. Racial and ethnic differences in experimental pain sensitivity: systematic review and meta-analysis. *Pain.* 2017;158(2):194-211.

7. Anderson KO, Green CR, Payne R. Racial and ethnic disparities in pain: causes and consequences of unequal care. *J Pain.* 2009;10(12):1187-1204.

8. Dzau VJ, Pizzo PA. Relieving pain in America: insights from an Institute of Medicine committee. *JAMA.* 2014;312(15):1507-1508.

9. Carson JW, Keefe FJ, Affleck G, et al. A comparison of conventional pain coping skills training and pain coping skills training with a maintenance training component: a daily diary analysis of short- and long-term treatment effects. *J Pain.* 2006;7(9):615-625.

10. Dixon KE, Keefe FJ, Scipio CD, Perri LM, Abernethy AP. Psychological interventions for arthritis pain management in adults: a meta-analysis. *Health Psychol.* 2007;26(3):241-250.

11. Keefe FJ, Caldwell D, Williams DA, et al. Pain coping skills training in the management of osteoarthritic knee pain-II: follow-up results. *Behav Ther.* 1990;21(4):435-447.

12. Keefe FJ, Caldwell DS, Baucom D, et al. Spouse-assisted coping skills training in the management of knee pain in osteoarthritis: long-term follow-up results. *Arthritis Care Res.* 1999;12(2):101-111.

13. Keefe FJ, Caldwell DS, Williams DA, et al. Pain coping skills training in the management of osteoarthritic knee pain: a comparative study. *Behav Ther.* 1990;21:49-62.

14. Hurley MV, Walsh NE, Mitchell HL, et al. Clinical effectiveness of a rehabilitation program integrating exercise, self-management, and active coping strategies for chronic knee pain: a cluster randomized trial. *Arthritis Care Res.* 2007;57(7):1211-1219.

15. Somers TJ, Blumenthal JA, Guilak F, et al. Pain coping skills training and lifestyle behavioral weight management in patients with knee osteoarthritis: a randomized controlled study. *Pain.* 2012;153(6):1199-1209.

16. Edwards RR, Moric M, Husfeldt B, Buvanendran A, Ivankovich O. Ethnic similarities and differences in the chronic pain experience: a comparison of African American, Hispanic, and white patients. *Pain Med.* 2005;6(1):88-98.

17. Ruehlman LS, Karoly P, Newton C. Comparing the experiential and psychosocial dimensions of chronic pain in African Americans and Caucasians: findings from a national community sample. *Pain Med.* 2005;6(1):49-60.

18. Meints SM, Miller MM, Hirsh AT. Differences in pain coping between black and white Americans: a meta-analysis. *J Pain.* 2016;17(6):642-653.

19. Meints SM, Stout M, Abplanalp S, Hirsh AT. Pain-related rumination, but not magnification or helplessness, mediates race and sex differences in experimental pain. *J Pain.* 2017;18(3):332-339.

20. Tan G, Jensen MP, Thornby J, Anderson KO. Ethnicity, control appraisal, coping, and adjustment to chronic pain among black and white Americans. *Pain Med.* 2005;6(1):18-28.

21. Jones AC, Kwoh CK, Groeneveld PW, Mor M, Geng M, Ibrahim SA. Investigating racial differences in coping with chronic osteoarthritis pain. *J Cross Cult Gerontol.* 2008;23:339-347.

22. Allen KD, Golightly YM, Olsen MK. Pilot study of pain and coping among patients with osteoarthritis: a daily diary analysis. *J Clin Rheumatol.* 2006;12(3):118-123.

23. Keefe FJ, Caldwell DS. Cognitive behavioral control of arthritis pain. *Adv Rheumatol.* 1997;81(1):277-290.

24. Keefe FJ, Blumenthal J, Baucom D, et al. Effects of spouse-assisted coping skills training and exercise training in patients with osteoarthritic knee pain: a randomized controlled study. *Pain.* 2004;110:539-549.

25. Riddle DL, Keefe FJ, Nay WT, McKee D, Attarian DE, Jensen MP. Pain coping skills training for patients with elevated pain catastrophizing who are scheduled for knee arthroplasty: a quasi-experimental study. *Arch Phys Med Rehabil.* 2011;92(6):859-865.

26. Bennell KL, Nelligan R, Dobson F, et al. Effectiveness of an internet-delivered exercise and pain-coping skills training intervention for persons with chronic knee pain: a randomized trial. *Ann Intern Med.* 2017;166(7):453-462.

27. Bennell KL, Ahamed Y, Jull G, et al. Physical therapist-delivered pain coping skills training and exercise for knee osteoarthritis: randomized controlled trial. *Arthritis Care Res (Hoboken).* 2016;68(5):590-602.

28. Rini C, Porter LS, Somers TJ, et al. Automated internet-based pain coping skills training to manage osteoarthritis pain: a randomized controlled trial. *Pain.* 2015;156(5):837-848.

29. Broderick JE, Keefe FJ, Bruckenthal P, et al. Nurse practitioners can effectively deliver pain coping skills training to osteoarthritis patients with chronic pain: a randomized, controlled trial. *Pain.* 2014;155(9):1743-1754.

30. Helminen EE, Sinikallio SH, Valjakka AL, Vaisanen-Rouvali RH, Arokoski JP. Effectiveness of a cognitive-behavioural group intervention for knee osteoarthritis pain: a randomized controlled trial. *Clin Rehabil.* 2015;29(9):868-881.

31. Vitiello MV, McCurry SM, Shortreed SM, et al. Cognitive-behavioral treatment for comorbid insomnia and osteoarthritis pain in primary care: the lifestyles randomized controlled trial. *J Am Geriatr Soc.* 2013;61(6):947-956.

32. Keefe FJ, Caldwell DS, Baucom D, et al. Spouse-assisted coping skills training in the management of osteoarthritic knee pain. *Arthritis Care Res.* 1996;9(4):279-291.

33. Miranda J, Bernal G, Lau A, Kohn L, Hwang W-C. State of the science on psychosocial interventions for ethnic minorities. *Annu Rev Clin Psychol.* 2005;1:113-142.

34. Baker TA. Chronic pain in older black Americans: the influence of health and psychosocial factors. *Ethn Dis.* 2005;15(2):179-186.

35. Resnicow K, Braithwaite RL, Dilorio C, Glanz K. Applying theory to culturally diverse and unique populations. In: Glanz K, Rimer BK, Viswanath K, eds. *Health Behavior and Health Education: Theory, Research, and Practice*. 3rd ed. San Francisco, CA: Jossey-Bass; 2002:485-499.

36. Cochran S, Mays V. Applying social psychological models to predicting HIV-related sexual risk behaviors among African Americans. *J Black Psychol.* 1993;19:142-154.

37. Kreuter MW, Lukwago SN, Bucholtz RD, Clark EM, Sanders-Thompson V. Achieving cultural appropriateness in health promotion programs: targeted and tailored approaches. *Health Educ Behav.* 2003;30(2):133-146.

38. Schrubbe LA, Ravyts SG, Benas BC, et al. Pain coping skills training for African Americans with osteoarthritis (STAART): study protocol of a randomized controlled trial. *BMC Musculoskelet Disord.* 2016;17(1):359.

39. Project I.M.P.A.C.T.—Increase Minority Participation and Awareness of Clinical Trials. http://impact.nmanet.org/wordpress/. Accessed November 21, 2019.

40. Campbell LC, Keefe FJ, Scipio C, et al. Facilitating research participation and improving quality of life for African American prostate cancer survivors and their intimate partners: a pilot study of telephone-based coping skills training. *Cancer.* 2006;109(suppl 2):414-424.

41. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol.* 1988;15:1833-1840.

42. Bellamy N. *WOMAC Osteoarthritis Index User Guide. Version V.* Brisbane, Australia; 2002.

43. Angst F, Aeschlimann A, Stucki G. Smallest detectable and minimal clinically important differences of rehabilitation intervention with their implications for required sample sizes using WOMAC and SF-36 quality of life measurement instruments in patients with osteoarthritis of the lower extremities. *Arthritis Rheum.* 2001;45(4):384-391.

44. Amtmann D, Cook KF, Jensen MP, et al. Development of a PROMIS item bank to measure pain interference. *Pain.* 2010;150(1):173-182.

45. Ware J Jr, Kosinski M, Keller SD. A 12-item Short-form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care.* 1996;34(3):220-233.

46. Hastie BA, Riley JL, Fillingim RB. Ethnic differences in pain coping: factor structure of the coping strategies questionnaire and coping strategies questionnaire—revised. *J Pain.* 2004;5(6):304-316.

47. Rosenstiel AK, Keefe FJ. The use of coping strategies in chronic low back pain patients: relationship of patient characteristics and current adjustment. *Pain.* 1983;17:33-44.

48. Keefe FJ, Caldwell DS, Queen K, et al. Osteoarthritis knee pain: a behavioral analysis. *Pain.* 1987;28:309-321.

49. Keefe FJ, Caldwell DS, Queen KT, et al. Pain coping strategies in osteoarthritis patients. *J Consult Clin Psychol.* 1987;55:208-212.

50. Parker JC, Smarr KL, Buescher KL, et al. Pain control and rational thinking. Implications for rheumatoid arthritis. *Arthritis Rheum.* 1989;32(8):984-990.

51. Sullivan MJL, Bishop SR, Pivik J. The Pain Catastrophizing Scale: development and validation. *Psychol Assess.* 1995;7:524-532.

52. Kroenke K, Strine TW, Spitzer RL, Williams JB, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. *J Affect Disord.* 2009;114(1-3):163-173.

53. Lorig K, Chastain RL, Ung E, Shoor S, Holman HR. Development and evaluation of a scale to measure perceived self-efficacy in people with arthritis. *Arthritis Rheum.* 1989;32(1):37-44.

54. Sharma L, Cahue S, Song J, Hayes K, Pai YC, Dunlop D. Physical functioning over 3 years in knee osteoarthritis: role of psychosocial, local mechanical, and neuromuscular factors. *Arthritis Rheum.* 2003;48(12):3359-3370.

55. Dipietro L, Caspersen CJ, Ostfeld AM, Nadel ER. A survey for assessing physical activity among older adults. *Med Sci Sports Exerc.* 1993;25:628-642.

56. Sangha O, Stucki G, Liang MH, Fossel AH, Katz JN. The self-administered comorbidity questionnaire: a new method to assess comorbidity for clinical and health services research. *Arthritis Rheum.* 2003;49(2):156-163.

57. Koenig HG, Bussing A. The Duke University Religion Index (DUREL): a 5-item measure for use in epidemiological studies. *Religions.* 2010;1:78-85.

58. Borm GF, Fransen J, Lemmens W. A simple sample size formula for analysis of covariance in randomized clinical trials. *J Clin Epidemiol.* 2007;60(12):1234-1238.

59. Fitzmaurice GM, Laird NM, Ware JH. *Applied Longitudinal Analysis.* Hoboken, NJ: Wiley-Interscience; 2004.

60. Allen KD, Bongiorni D, Bosworth HB, et al. Group versus individual physical therapy for veterans with knee osteoarthritis: randomized clinical trial. *Phys Ther.* 2016;96(5):597-608.

61. Allen KD, Oddone EZ, Coffman CJ, et al. Patient, provider, and combined interventions for managing osteoarthritis in primary care: a cluster randomized trial. *Ann Intern Med.* 2017;166(6): 401-411.

62. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. 2nd ed. Hillsdale, NJ: Erlbaum; 1988.

63. ICH E9 Expert Working Group. ICH harmonised tripartite guideline—statistical principles for clinical trials. *Stat Med.* 1999;18:1905-1942.

64. Little RJA, Rubin DB. *Statistical Analysis With Missing Data.* Hoboken, NJ: John Wiley & Sons; 2002.

65. Liu GF, Lu K, Mogg R, Mallick M, Mehrotra DV. Should baseline be a covariate or dependent variable in analyses of change from baseline in clinical trials? *Stat Med.* 2009;28(20):2509-2530.

66. Hayward RA, Krumholz HM, Zulman DM, Timbie JW, Vijan S. Optimizing statin treatment for primary prevention of coronary artery disease. *Ann Intern Med.* 2010;152(2):69-77.

67. Kent DM, Hayward RA, Griffith JL, et al. An independently derived and validated predictive model for selecting patients with myocardial infarction who are likely to benefit from tissue plasminogen activator compared with streptokinase. *Am J Med.* 2002;113(2):104-111.

68. Kiernan M, Kraemer HC, Winkleby MA, King AC, Taylor CB. Do logistic regression and signal detection identify different subgroups at risk? Implications for the design of tailored interventions. *Psychol Methods.* 2001;6(1):35-48.

69. Owens EB, Hinshaw SP, Kraemer HC, et al. Which treatment for whom for ADHD? Moderators of treatment response in the MTA. *J Consult Clin Psychol.* 2003;71(3):540-552.

70. Zeileis A, Hothorn T, Hornik K. Model-based recursive partitioning. *J Comput Graph Stat.* 2008;17(2):492-514.

71. Singer JD, Willett JB. *Applied Longitudinal Data Analysis: Modeling Change and Event Occurrence.* New York, NY: Oxford University Press; 2003.

72. Angst F, Aeschlimann A, Michel BA, Stucki G. Minimal clinically important rehabilitation effects in patients with osteoarthritis of the lower extremity. *J Rheumatol.* 2002;29:131-138.

73. Burke JF, Hayward RA, Nelson JP, Kent DM. Using internally developed risk models to assess heterogeneity in treatment effects in clinical trials. *Circ Cardiovasc Qual Outcomes.* 2014;7(1):163-169.

74. Sussman JB, Kent DM, Nelson JP, Hayward RA. Improving diabetes prevention with benefit based tailored treatment: risk based reanalysis of Diabetes Prevention Program. *BMJ.* 2015;350:h454. https://www.bmj.com/content/350/bmj.h454

75. Harrell FE, Jr. *Regression Modeling Strategies.* New York, NY: Springer-Verlag; 2006.

76. Liang Y, Ehler BR, Hollenbeak CS, Turner BJ. Behavioral support intervention for uncontrolled hypertension: a complier average causal effect (CACE) analysis. *Med Care.* 2015;53(2):e9-e15. doi: 10.1097/MLR.0b013e31827da928

77. Schomaker M, Heumann C. Bootstrap inference when using multiple imputation. *Stat Med.* 2018;37(14):2252-2266.

78. Vitiello MV, Rybarczyk B, Von Korff M, Stepanski EJ. Cognitive behavioral therapy for insomnia improves sleep and decreases pain in older adults with co-morbid insomnia and osteoarthritis. *J Clin Sleep Med.* 2009;5(4):355-362.

79. Williams AC, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. *Cochrane Database Syst Rev.* 2012;11:CD007407. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6483325/

80. Broderick JE, Keefe FJ, Schneider S, et al. Cognitive behavioral therapy for chronic pain is effective, but for whom? *Pain.* 2016;157(9):2115-2123.

81. Turk DC. The potential of treatment matching for subgroups of patients with chronic pain: lumping versus splitting. *Clin J Pain.* 2005;21(1):44-55, discussion 69-72.

82. Allen KD, Arbeeva LA, Cené CW, et al. Pain coping skills training for African Americans with osteoarthritis study: baseline participant characteristics and comparison to prior studies. *BMC Musculoskelet Disord.* 2018;19(1):337. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6145122/

83. Bennell KL, Nelligan RK, Rini C, et al. Effects of internet-based pain coping skills training before home exercise for individuals with hip osteoarthritis (HOPE trial): a randomised controlled trial. *Pain.* 2018;159(9):1833-1842.

84. Goldberg DS, McGee SJ. Pain as a global public health priority. *BMC Public Health.* 2011;11:770. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3201926/

RELATED PUBLICATIONS

Schrubbe LA, Ravyts SG, Benas BC, et al. Pain coping skills training for African Americans with osteoarthritis (STAART): study protocol of a randomized controlled trial. *BMC Musculoskelet Disord*. 2016;17(1):359. doi:10.1186/s12891-016-1217-2

Allen KD, Arbeeva L, Cené CW, et al. Pain coping skills training for African Americans with osteoarthritis study: baseline participant characteristics and comparison to prior studies. *BMC Musculoskelet Disord.* 2018;19(1):337. doi: 10.1186/s12891-018-2249-6

Allen KD, Somers TJ, Campbell LC, et al. Pain coping skills training for African Americans with osteoarthritis: results of a randomized controlled trial. *Pain*. 2019;160(6):1297-1307. doi: 10.1097/j.pain.0000000000001525

ACKNOWLEDGMENTS

The authors acknowledge the contributions of study team members Kimberlea Grimm, Bernadette Benas, Ashley Gwynn, Alexander Gunn, Erin Haley, Caroline Nagle, Scott Ravyts, Leah Schrubbe, and Catherine Stanwyck. The authors express gratitude to the stakeholder panel for this project, without whom this work would not be possible: Ms. Mae Karim; Ms. Sandy Walker, LPN (Chapel Hill Children's Clinic); Mr. Ralph Brown; Dr. Yashika Watkins, PhD, MPH (Movement Is Life/University of Illinois at Chicago); Dr. Teresa J. Brady, PhD (Centers for Disease Control and Prevention); Dr. Elaine Hart-Brothers, MD, MPH (Community Health Coalition); and Ms. Laura C. Marrow (Arthritis Foundation). The authors also thank all the participants taking part in this research.

Disclaimer:

The [views, statements, opinions] presented in this report are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.

Acknowledgement:

Research reported in this report was [partially] funded through a Patient-Centered Outcomes Research Institute® (PCORI®) Award (#AD-1408-19519) Further information available at:
https://www.pcori.org/research-results/2015/training-program-pain-coping-skills-african-americans-hip-or-knee-arthritis