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Rationale and Design of the Staying Positive with Arthritis (SPA) Study: A Randomized Controlled Trial Testing the Impact of a Positive Psychology Intervention on Racial Disparities in Pain

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Abstract

Knee osteoarthritis is a painful, disabling condition that disproportionately affects African Americans. Existing arthritis treatments yield small to moderate improvements in pain and have not been effective at reducing racial disparities in the management of pain. The biopsychosocial model of pain and evidence from the positive psychology literature, suggest that increasing positive psychological skills (e.g., gratitude, kindness) could improve pain and functioning and reduce disparities in osteoarthritis pain management. Activities to cultivate positive psychological skills have been developed and validated; however, they have not been tested in patients with

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osteoarthritis, their effects on racial differences in health outcomes have not been examined, and evidence of their effects on health outcomes in patients with other chronic illnesses is of limited quality. In this article we describe the rationale and design of Staying Positive with Arthritis (SPA) study, a randomized controlled trial in which 180 African American and 180 White primary care patients with chronic pain from knee osteoarthritis will be randomized to a 6-week program of either positive skill-building activities or neutral control activities. The primary outcomes will be self-reported pain and functioning as measured by the WOMAC Osteoarthritis Index. We will assess these primary outcomes and potential, exploratory psychosocial mediating variables at an in-person baseline visit and by telephone at 1, 3, and 6 months following completion of the assigned program. If effective, the SPA program would be a novel, theoretically-informed psychosocial intervention to improve quality and equity of care in the management of chronic pain from osteoarthritis.

Keywords

Chronic pain; mind-body therapies; race disparities; Veterans; osteoarthritis; psychology

Introduction

Arthritis affects roughly 1 in 5 (22.7%) adults in the United States and is the leading cause of disability. Osteoarthritis (OA) is the most common form of arthritis and incurs substantial medical and nonmedical costs.^{1–6} Long-standing racial differences in the burden and management of OA exist, such that African American individuals with OA report more pain and functional impairment^{7–9} and lower quality of life¹⁰ than similarly-diagnosed Whites. African American individuals are also more likely than Whites to perceive complementary and alternative approaches to pain management (e.g., hopefulness/prayer) as beneficial for OA,^{11–13} and they are less willing to consider surgery as an option.^{14,15} Although several non-pharmacological and pharmacological treatments are recommended for OA pain,^{16–18} most yield modest improvements, and many have undesirable side effects.^{17–19} Furthermore, few studies have compared OA treatment efficacy for African American and White patients.^{20–24}

The biopsychosocial model of pain^{25–27} suggests that bolstering psychosocial wellbeing may be an effective strategy to improve OA pain and function. Psychosocial-oriented treatments for OA may also be well-suited to reduce racial disparities in OA symptoms, as they are aligned with preferences for non-traditional, non-pharmacological approaches to pain management.^{13,28} The field of positive psychology, which investigates how and why people flourish,^{29–32} has developed a variety of simple activities to cultivate positive psychological skills (e.g., gratitude, kindness) and positive affect, defined as the feelings experienced when one is pleasurable engaged with the environment.^{29,30,33,34} The broaden-and-build model of positive emotions explains how momentary increases in positive affect can lead to sustained benefits in wellbeing.^{35,36} According to this model, experiencing positive emotions makes us more open to new thoughts and actions that help us build cognitive and social resources (e.g., creative problem solving, strengthened social ties). In turn, those resources facilitate more opportunities to experience positive emotions, and the

process becomes a positive feedback loop that increases and sustains wellbeing. Strong evidence supporting this model indicates that positive psychological activities yield lasting improvements in overall wellbeing.^{30,34,37} Research on the effects of positive activities on pain, however, is in its infancy.^{38–42} The effect of positive activities on chronic musculoskeletal pain from OA has not been tested, and the psychosocial mechanisms by which positive activities may improve pain and functioning remain unknown. Studies examining the impact of positive activities in patients with other chronic diseases are limited by small samples, weak control groups, and short follow-up periods.^{42–49} Finally, racial differences in the effects of positive activities have not been examined. In this paper, we describe the rationale and design of the Staying Positive with Arthritis (SPA) study, a randomized controlled trial that will address these gaps. Our primary aim is to evaluate the impact of positive psychological skill-building activities, compared to structurally similar but affectively neutral activities, on pain and functional impairment in African American and White patients with chronic pain from knee OA. We hypothesize that patients randomized to a 6-week program consisting of positive (vs. neutral) activities will report greater improvements in the primary outcomes of self-reported pain and functioning from baseline to 6 months, and that improvements will be larger for African Americans than for Whites. We will also explore whether psychosocial variables mediate the effects of the positive program on pain and functioning.

Method

Study Design

In a sample of African American and White patients with symptomatic knee OA, we will use a randomized 2-arm design to compare the effects of a 6-week positive skill-building intervention program with that of a neutral control program on the primary outcomes of self-reported pain and functional impairment at 1, 3, and 6-months post-intervention (Figure). Participants will complete an in-person baseline assessment and be randomized to one of two programs. The positive intervention program will include activities from the field of positive psychology that foster positive psychological skills and produce lasting increases on measures of wellbeing. The neutral control program will include activities that are structurally comparable to activities in the positive program but are affectively neutral. Participants in both programs will receive weekly telephone calls from study staff to assess adherence and to review the next week's activity. Participants will be telephoned 1, 3, and 6 months after the program ends to complete follow-up assessments. Participants will be compensated up to \$110 for completing study assessments (Figure). This study will be overseen by the Veterans Affairs Central Institutional Review Board.

Rationale for Using a Positive Psychological Intervention to Improve OA Pain and Function

The positive intervention program is derived from the field of positive psychology, a sub-discipline of psychology that focuses on human strengths, resilience, and subjective wellbeing.^{30–32} Positive psychology's focus on wellbeing is in contrast to the traditional focus of psychological and medical research on identifying and treating human pathology. Positive psychological research has demonstrated that experiencing positive affect is associated with a variety of desirable physical and mental health outcomes, including

reduced mortality.^{29,30} Mechanisms by which positive affect has been linked to health outcomes include biological processes, such as the modulation of endogenous opioids and stress hormones,^{29,50} and psychosocial processes, such as increasing creativity, curiosity, openness to new information, and the desire to strengthen social ties.³⁶

We reasoned that a positive psychological intervention could reduce OA pain and functional impairment by improving mutable psychosocial factors that have been shown to be associated with chronic pain in general, and with OA-related pain and functioning in particular.^{25–27,51,52} Below we briefly highlight several such factors that we identified a priori as possible mechanisms by which a positive psychological intervention could improve OA-related pain and functional impairment.

Perhaps the most obvious pathway by which a positive psychological intervention could improve pain outcomes is by enhancing mental health. Depression and negative mood, two common targets of positive psychological interventions, often co-occur with OA and are associated with worse pain and functioning.^{53–57} Anxiety has also been shown to predict functional decline in individuals with symptomatic OA.⁵⁸ Similarly, perceived stress has been linked with higher pain intensity in cross-sectional analyses,⁵⁹ and stress reduction has been shown to be an important mediating variable by which pain intensity is reduced in response to an online self-management program.⁶⁰

Numerous studies have demonstrated that pain-related cognitions are associated with pain severity and functional impairment in patients with OA, with the most-often studied and robust predictors being self-efficacy and pain catastrophizing.^{26,55,61–64} Positive traits such as optimism and overall psychological resilience are associated with lower pain intensity and higher pain tolerance, operating through mechanisms that include increased positive affect, reduced negative affect, and reduced pain catastrophizing.^{40,65–67} Based on additional research showing that inducing positive affect increases creativity, curiosity, and openness to new information,³⁶ we reasoned that a positive psychological intervention could improve OA outcomes by increasing self-efficacy, reducing pain catastrophizing, and increasing the use of effective pain coping strategies in general.

Finally, in patients with OA, those with a stronger social support network report less pain and experience less functional decline over time.^{55,58,68} Although a positive psychological intervention is not designed to increase social connectedness directly, experiencing positive affect has been shown to have desirable social effects such as increasing levels of trust, closeness with others, receipt of social support, and positive relations with others.^{69–71} We therefore reasoned that a positive psychological intervention could improve OA outcomes by increasing social support.

Rationale for Using a Positive Psychological Intervention to Reduce Racial Disparities in OA Pain and Function

While there was sufficient evidence from extant literature to expect that a positive psychological intervention would reduce OA pain and functional impairment overall, we further hypothesized that it would reduce racial disparities in OA pain and functioning for three reasons. First, several of the previously identified psychosocial factors contribute to

racial disparities in pain related to OA and other chronic conditions.^{72,73} For example, negative affect, poor self-efficacy, and emotion-focused coping have been found to account for worse OA pain and functional impairment among African Americans than among Whites, with negative affect being the strongest mediator.⁷² It is therefore reasonable to expect a positive psychological intervention to have a larger effect on OA pain and functioning in African American individuals than in Whites. Second, disproportionate exposure to social stress, especially in the form of discrimination, is increasingly recognized as a major factor that contributes to racial disparities in health.⁷⁴ Studies have found that perceived racial discrimination, which is more frequently encountered by historically disadvantaged racial groups, is associated with greater bodily pain and lower pain tolerance.^{73,75} One mechanism by which discrimination impacts health is by taking a negative toll on emotional wellbeing and one's overall outlook on life.⁷⁶ Naturally-occurring positive affect, however, reduces the association between perceived discrimination and depressive symptoms, and experimentally inducing positive affect reduces perceptions of discrimination.^{77,78} We reasoned that a positive psychological intervention may be particularly beneficial to racial minority patients by guarding against the negative impact of race-based social stress. Third, studies examining racial differences in OA treatment preferences have found that African American individuals tend to prefer non-invasive, non-pharmacological, and alternative pain management strategies.^{11–15} A positive psychological intervention for pain is aligned with those preferences and may therefore be particularly appealing to African American individuals with OA. For these reasons, we adapted activities from the positive psychology literature for use among African American and White patients with OA. In addition to examining the effects of these activities on the primary outcomes of pain and functioning in the SPA study, we will assess and explore as potential mediators the previously discussed psychosocial variables that are associated with OA outcomes or racial differences in OA outcomes.

Participant Eligibility and Recruitment

The target population will be non-Hispanic African American and White patients who have symptomatic knee OA and are primary care patients at one of two large, urban, academic Veterans Affairs (VA) medical centers. The goal is to enroll 90 patients of each race from each site, for a total of 360 participants across the two sites. The main recruitment strategy will be a two-step process where we will first mail study brochures to patients who meet basic criteria based on information ascertained from VA electronic medical records, and then follow up by telephone to determine eligibility using a more in-depth screening survey. For the initial mailing pool, we will use data from the VA Corporate Data Warehouse to identify Veteran patients who are non-deceased; have a non-Hispanic African American or White race designation on file; are 50 years or older; have had a primary care appointment at a participating site in the past 12 months; have a diagnosis of OA (International Classification of Diseases, Ninth Revision, Clinical Modification code 715); and do not have diagnoses of inflammatory arthritis (rheumatoid arthritis [714.xx], lupus [695.4, 710.0], psoriatic arthritis [696.0], or ankylosing spondylitis [720.0]) or Alzheimer's disease/dementia (294.xx, 290.xx, 291.xx, 331.xx, 094.1). Patients meeting these basic criteria will be stratified by race and assigned a random number that will be used to determine the order in which they will be mailed. Patients of each race will be mailed information about the study in batches until

enrollment targets for each race are met. The number of patients from each racial stratum will be adjusted for each batch of mailings as needed to achieve equivalent numbers of enrolled patients from each group. Mailings will describe the study and will invite patients to contact the research team via telephone or postage-paid reply card to indicate whether or not they are interested in participating. Patients who express interest or do not respond within 2 weeks will be telephoned by research staff to complete the more in-depth screening survey. This recruitment strategy will be supplemented by distributing study brochures throughout participating sites.

The in-depth telephone screening survey will be used to determine eligibility of all potential participants prior to enrollment. To be eligible, patients must meet all inclusion and exclusion criteria in Table 1 based on their responses to the screening survey. We designed the eligibility criteria to include individuals with symptomatic knee pain consistent with OA who were likely to be able to complete the study protocol and follow-up assessments; therefore, those who report being unable to complete brief reading and writing exercises or telephone surveys, or who screen positive for cognitive impairment⁷⁹ will be excluded. Those who have recently had or are planning to have steroid injections or knee replacement surgery will also be excluded, due to the potential of those treatments to mask the effect of the intervention. For pragmatic reasons and to increase generalizability of the study findings, we did not exclude patients who were on other pain treatment regimens, nor did we dictate whether patients could initiate or discontinue other treatments over the course of the study.

Randomization and Masking

Eligible patients will meet with a study staff member for a baseline visit at their VA medical center, during which they will provide written informed consent, complete a staff-administered baseline assessment, and be randomized to either the positive intervention or neutral control program. Randomization will be at the patient level, stratified by study site and patient race, with a 1:1 allocation using random block sizes of 2, 4, 6, or 8. The scheme will be generated by the lead statistician prior to the initiation of enrollment. The statistician will place positive and neutral program workbooks in sealed envelopes in a sequence determined by the randomization scheme. To maintain blinding of participants and staff during the baseline assessment, study staff will take the next sealed envelope in the pre-determined sequence to each baseline visit, to be opened only after a patient has consented and completed the baseline assessment. The program workbooks will have the same cover page and introductory text; only the instructions for the weekly activities will differ. The study staff that complete the baseline visits will be familiar with both programs and will become unblinded once a participant's envelope is opened, but participants will not explicitly be told whether they are in the positive or neutral program. Study staff who conduct the weekly calls in the 6 weeks following the baseline visit will also be unblinded to assignment. To maintain blinding for the collection of outcome measures, study staff members who did not complete the baseline visit or any weekly calls during the 6-week program period for a given participant will collect the 1, 3, and 6-month follow-up assessments.

Positive Intervention Program

We designed the content and format of the positive intervention program based on research regarding how to implement positive psychological interventions to provide maximum and sustained benefits.⁸¹ Numerous activities have been developed to increase positive affect, each targeting at least one of the core components of subjective wellbeing (i.e., pleasure, engagement, and/or meaning in one's life).^{30,33,34} Specific activities focus on gratitude, kindness, optimism, mindfulness, self-affirmation, identifying and using personal strengths, reflecting on good things, forgiveness, or some combination thereof.^{33,34} A meta-analysis found that interventions using these activities yield the largest effects when they are administered individually (versus in a group), combine multiple activities, and are of longer duration (e.g., over multiple weeks versus one-time events).³⁴ Because positive activities are not "one size fits all," it is also recommended that positive interventions include a variety of activities and allow flexibility in how they are implemented by individuals.⁸² Taking into account how specific activities fit with people's lifestyle and preferences increases adherence and sustainability.^{81,83} With these principles in mind, we designed our positive intervention to be an individually-based, 6-week program in which participants would complete 5 positive activities (one each week) and repeat their favorite activity in the sixth week. We also emphasized in the instructions that not all activities will appeal to everyone, and that participants should try each one and remember the ones that work best for them personally.

Other aspects of the positive intervention program were driven by the patient population, which included African American and White Veterans aged 50 years or older who obtain VA health care. Most positive activities have been developed and tested in college undergraduates; therefore, we conducted extensive pilot testing to adapt the instructions for each activity to accommodate those with low reading ability and to ensure they could be understood by an older patient population.⁸⁴ The final instructions were written at a fourth-grade reading level. We also chose to administer the program in the form of a paper-and-pencil workbook, given the wide range of computer literacy, internet access, and smartphone utilization among VA patients.

Finally, several decisions were made to make it easier for the program to be widely implemented in the future if it is found to be beneficial in this study. First, we designed the program workbook to be self-contained, meaning that it could be entirely self-administered if necessary. The workbook cover displayed the title, "Staying Positive with Arthritis," and provided contact information for the principal investigator. The first page contained an overview of the purpose and format of the program, including a brief explanation of why building habits that help one to stay positive may be beneficial for people with arthritis and instructions to complete one program activity per week over the next 6 weeks. To further facilitate the stand-alone nature of the workbook, we selected activities from the positive psychology literature that were simple to complete, did not require extensive training or follow-up, and had worked well when self-administered. Second, we chose to limit contact with study staff during the program to weekly calls lasting 5 to 15 minutes so that the program would not require substantial staff time if adopted by a healthcare system. Third, we chose to have non-clinical, college-educated research assistants deliver the program to

demonstrate that advanced medical or behavioral health training is not necessary to administer such a program. The instructions and rationale for the specific activities included in the final positive intervention program are described below and summarized in Table 2.

Week 1: Three Good Things—This activity asks participants to write down three positive events that happen each day, completing the exercise at the end of each day for 1 week. This activity focuses attention on positive events to overcome our natural predisposition to remember negative events.⁸⁵ It has been shown to increase subjective wellbeing and reduce depressive symptoms, with effects lasting for 6 months.³⁰

Week 2: Expressing Thanks—This activity asks participants to write a thank-you letter to someone who has been kind to them but was never properly thanked, and to read the letter to that person if possible.³⁰ It is based on evidence that people who are grateful are healthier and have better subjective wellbeing than people who do not regularly experience gratitude.⁸⁶ Writing a letter of thanks provides an immediate and intense increase in gratitude.⁸⁷ Reading thank-you letters to the intended recipient produces increases in subjective wellbeing and decreases in depressive symptoms of greater magnitude than the Three Good Things activity.³⁰

Week 3: Making Good Moments Last—In this activity, participants practice prolonging the experience of one positive moment each day for a week. This activity cultivates mindfulness, which leads to more frequent positive emotion and enhanced self-regulation.⁸⁸ Research on Mindfulness-Based Stress Reduction demonstrates that mindfulness has numerous physical and psychological benefits.⁸⁹ While a full mindfulness meditation practice can be time-consuming to learn and difficult to maintain, this brief activity is an easy way to enhance mindfulness in everyday life.

Week 4: Acts of Kindness—This activity asks participants to practice acts of kindness towards others. Practicing kindness is associated with increased subjective wellbeing.⁹⁰ Based on evidence that completing 5 acts of kindness in a single day produces larger improvements in wellbeing than distributing 5 kind acts over a week,⁹⁰ this activity was structured so that participants were encouraged to complete 5 kind acts in 1 day.

Week 5: Increasing Pleasant Activity—This activity asks participants to identify from a list of pleasant activities those that they enjoy, give them a sense of achievement, or bring them closer to others. They then engage in at least 4 pleasant activities per day for a week and record them in an activity diary. Increasing pleasant activities is one of the most well-researched intervention strategies for reducing depression.³³ We include it in our positive program based on its effectiveness across different populations and its ease of administration.

Week 6: Practicing Your Favorite(s)—In week 6, participants will select an activity from previous weeks to complete again. Repeating an activity serves to engage participants in identifying positive activities that appeal to them, and to give them additional practice building positive activities into their daily lives.

Control Program

Our goal was to develop a control program that would provide the strongest possible comparison condition to the positive intervention program. Given that patients who are particularly motivated to be positive or likely to believe in the power of positive thinking may self-select into the study, we felt it was important to use a control program that would demonstrate that improvements in the positive study arm were attributable to the positive activities included in the program, and not simply due to expectations, motivation, or placebo effects. Toward that end, we designed the control program to be identical to the positive intervention program in terms of framing, reading level, format, duration, and delivery. For instance, the same title (i.e., “Staying Positive with Arthritis”) and introductory text is used for the control and positive intervention workbooks. Both programs also include instructions for 5 different activities to be completed over the course of 5 weeks, and instructions to repeat a favorite activity in the 6th week. The only difference between the positive intervention and control program workbooks is the nature of the activities included in each program. For the control program workbook, we replaced each activity from the positive program with a structurally similar but affectively neutral activity based on activities that were used in control conditions in previous studies that tested the impact of positive activities (Table 2).^{30,87,91,92} Our careful construction of the control program materials in this study will provide one of the strongest comparison conditions ever used to test the effects of a positive psychological intervention in a real world patient population.

Positive and Control Program Delivery

Prior to the start of enrollment, all study staff members will be trained on how to deliver the positive and control programs in a consistent manner. The training will cover how to describe each activity accurately and systematically, anticipate and respond to barriers to completing activities, and provide encouragement when necessary. Every staff member who will be involved in delivering the intervention will be required to deliver both programs in their entirety in a series of telephone calls with an expert on positive psychological interventions (AP). Staff members will undergo remedial training and practice until they are deemed by the expert as proficient in delivering the programs and responding to challenging scenarios. Once enrollment begins, study staff from both sites will participate in frequent huddle calls to review issues that arise and ensure that the program is delivered similarly across sites. A “how-to” guide for delivering the intervention and control programs will be developed, including instructions on how to respond to a list of likely scenarios that will arise based on pilot testing of the programs. Additional scenarios will be added to the guide as they arise and are discussed by the group.

At the end of each baseline visit, study staff will orient participants to their assigned workbook. The study staff member will then review the instructions for the first week’s activity, which will be either positive or neutral depending on the participant’s randomly assigned program (Table 2). Participants will be instructed to complete the first activity on their own over the next week. All subsequent contact with participants will be by telephone. For the 6 weeks following the baseline visit, study staff will telephone participants at an agreed-upon time to assess adherence to the previous week’s activity and to review

instructions for the next week's activity. At the conclusion of the sixth week, the staff member will encourage participants to continue using activities in the workbook.

Follow Up Procedures

Study staff members who were not involved in administering the positive intervention or control program for a given participant will conduct telephone surveys to assess outcomes and proposed mediating variables approximately 1, 3, and 6 months following completion of the 6-week program. We will collect the first post-treatment assessment at the 1-month time point, as opposed to immediately following program completion, because most prior studies of positive psychological interventions have only tested and demonstrated immediate or short-term benefits. According to the broaden-and-build model of positive emotions, however, the effects of the 6-week positive intervention program should be sustained long after the program ends because the activities in the program have activated the broaden-and-build process. Our goal in this study is to improve upon prior studies by focusing on longer-term benefits. To maximize study retention, patients will receive a card at the baseline visit to help them keep track of upcoming appointments and will be mailed reminder letters prior to the 1, 3, and 6-month follow-up calls. A blank survey will be mailed with the reminder letters for patients to refer to during the telephone call. Study staff will have up to 2 weeks to complete each follow up survey, after which the data for that time point will be considered missing.

Study Measures

Primary Outcomes: OA pain, functional impairment, and patient global assessment (baseline, 1 month, 3 months, and 6 months)—The OA Research Society International (OARSI) Standing Committee for Clinical Trials Response Criteria Initiative and the Outcome Measures in Rheumatology Committee recommend a core set of three outcomes to be used in clinical trials of OA treatments: pain, physical function, and patient global assessment.⁹³ We will use all three as primary outcomes in this study, with the study being powered to detect race differences in the effect of the intervention on pain. We will assess pain and functional impairment using the pain and functioning subscales of the Western Ontario MacMaster (WOMAC) Osteoarthritis Index.^{94,95} Designed to assess lower extremity pain and function in patients with OA, the WOMAC consists of pain (5 questions), physical function (17 questions), and stiffness (2 questions) subscales. Although we will focus on the pain and functioning subscales, we will administer the full WOMAC so we can also compute an overall score of OA symptom severity. We will measure patient global assessment of pain in the last week using an 11-point numeric rating scale.⁹³ Specifically, patients will be asked, "Considering all the ways your knee arthritis affects you, how would you rate your condition over the past week on a scale of 0 to 10, where 0 is very poor and 10 is very good?"

Hypothesized psychosocial mediators (baseline, 1 month, 3 months, and 6 months)—For exploratory purposes, we will also assess psychosocial variables that could serve as mechanisms by which a positive psychological intervention could improve OA outcomes or reduce disparities in OA outcomes. Given the number of potential mediators,

we will minimize participant burden by selecting the briefest measure of each variable for which sound psychometric properties have been demonstrated.

Depressive symptoms will be assessed by the Patient Health Questionnaire (PHQ), the brief depression scale most widely-used in clinical and research settings.⁹⁶ We will use the 8-item Patient Health Questionnaire (PHQ-8), which assesses the 9 DSM-IV criteria for the diagnosis of depressive disorders, with the exception of suicidality.⁹⁶ PHQ-8 has psychometric properties comparable to the PHQ-9 and is recommended for studies such where there is low risk of suicidality among participants, depression is not an inclusion criterion or a primary outcome, and research staff are unable to provide adequate intervention if suicidal thoughts are reported by participants (e.g., because staff are communicating with participants by telephone).⁹⁶

Positive and negative affect will be assessed using the International Positive and Negative Affect Schedule Short Form (I-PANAS-SF).⁹⁷ The I-PANAS-SF includes positive affect and negative affect subscales consisting of 5 positive (alert, inspired, determined, attentive, active) and 5 negative (upset, hostile, ashamed, nervous, afraid) states. Participants are asked to indicate the extent to which they have felt each state during the past week. The subscales have been psychometrically validated as measures of trait levels of positive and negative affect in people from a variety of cultural backgrounds.⁹⁷

Satisfaction with life will be assessed using the Satisfaction With Life Scale (SWLS).⁹⁸ The SWLS is widely used as a measure of overall subjective wellbeing and is a common outcome measure in positive psychological intervention studies.³⁴ It asks participants to indicate whether they agree with statements such as, “In most ways, the conditions of my life are excellent.” The scale is correlated with other measures of subjective wellbeing and has been used in elderly populations and national public health surveys.^{98,99}

Arthritis self-efficacy will be measured using the 20-item Arthritis Self-Efficacy Scale, which assesses patients' perceived ability to cope with consequences of chronic arthritis.¹⁰⁰ This widely-used scale includes 3 subscales that assess patients' perceived ability to cope with pain (5 items), functional limitations (9 items), and other symptoms (6 items) due to one's arthritis.

Pain catastrophizing will be assessed by the Pain Catastrophizing Scale, which measures the degree to which patients experience 13 thoughts or feelings when experiencing pain.¹⁰¹ Capturing patients' tendency to magnify the unpleasantness of pain experiences, to ruminate on pain-related thoughts, and to feel helpless in response to pain, this scale is often related to the degree of physical and emotional distress people experience in response to pain.¹⁰¹

Pain coping will be assessed by the Daily Coping Inventory adapted for pain coping, which assesses patients' use of 4 emotion-focused (e.g., sought or found spiritual support or comfort) or 3 problem-focused (e.g., did something to help you relax) pain coping strategies in the past 24 hours.^{102,103} This 2-factor scale has been used in Veterans with OA and is sensitive to racial differences in pain coping strategies.⁸

Stress will be measured using the validated Perceived Stress Scale (PSS), which assesses the extent to which people appraise their life situations as stressful.¹⁰⁴ We chose the PSS because it is a better predictor of mental and physical health outcomes than the number of stressful life events one has experienced¹⁰⁴ and because the positive psychological intervention is more likely to affect stress appraisals than the occurrence of stressful life events. We will use the 4-item PSS, which is recommended as a brief measure of global stress in studies where data are collected by telephone.¹⁰⁴

Perceived discrimination will be assessed using the widely-used Everyday Discrimination measure, which assesses how often one has encountered day-to-day unfair treatment (e.g., treated with less respect than other people) and the attributed reason for the treatment (e.g., one's race or sex).^{105,106} This scale is commonly used in studies examining the association between discrimination and health outcomes in diverse patient populations.¹⁰⁷

Social support will be assessed using an abbreviated version of the Medical Outcomes Study Social Support Survey.¹⁰⁸ The original version included 20 items that assess the availability of 4 types of social support (emotional-informational support, tangible support, positive interaction, and affection). The abbreviated version contains the items with the highest loading on each of the 4 types of social support and is highly correlated with the full survey.¹⁰⁸

Demographic and clinical covariates (baseline only, except for OA treatments)

—We will assess demographic and clinical characteristics to describe the study sample, include as covariates, and explore as potential moderators of treatment effects. Use of OA treatments will be assessed at all time points (baseline, 1 month, 3 months, and 6 months) using a comprehensive list of pharmacological and non-pharmacological treatment options based on those assessed in the OAI.⁸⁰ Pharmacological treatment categories will include acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), topical NSAIDs, COX-2 selective inhibitors, opioids, and hyaluronic acid or steroid injections. Non-pharmacological treatment categories will include acupuncture/acupressure/massage therapy, chiropractic care, homeo/naturopathy, physical therapy, water or land-based exercise, health supplements for joint pain, vitamins, herbs, topical creams/oils, copper bracelets or magnets, yoga/tai chi/chi gong/Pilates, relaxation/mind-body activities, and spiritual activities. We will assess use of these treatments so that we can track changes in self-reported pain regimens, control for differences in baseline pain treatments across racial groups and study arms, and account for changes in pain regimens over time, as needed.

All other covariates will be assessed only at baseline. A demographic survey will be used to assess participants' sex, age, income, education, employment, marital status, and general health status. Health literacy will be assessed by the item, "How confident are you filling out medical forms by yourself?" This was the best single-item measure for detecting inadequate literacy in a study of VA outpatients, demonstrating high specificity and sensitivity.^{109,110} Physical comorbid medical conditions will be assessed using an interviewer-administered version of the Charlson Comorbidity Index.¹¹¹ Mental comorbidity will be assessed using items from the 2010 Behavioral Risk Factor Surveillance System Questionnaire to assess diagnoses and treatment of depression or anxiety.¹¹²

Comorbidity will be further assessed by having research staff conduct chart reviews to extract medical diagnoses that are recorded in enrolled participants' electronic medical records. Obesity will also be determined through chart reviews by extracting the most recent height and weight measurements available in patients' electronic medical records at baseline, which will be used to calculate body mass index. Finally, we will determine whether each participant has radiographic evidence of OA in their VA medical record by looking at existing x-ray and MRI reports for signs of OA. Reports documenting osteophytes with or without joint space narrowing, bony sclerosis, or possible deformity of bone ends or simply OA will be considered radiographic confirmation of OA. Patients without existing knee x-rays or MRIs will be coded as not having radiographic evidence of OA on file.

Intervention adherence and engagement (6 weekly telephone surveys following baseline)—Adherence to and engagement with activities in the positive intervention and control programs will be assessed during weekly telephone surveys. Participants will be asked if they completed the previous week's activity.¹¹³ Participants who report completing the activity will be asked to rate how much they felt they benefited, how much they enjoyed, and how difficult they found each exercise using a 7-point Likert-type scale.¹¹³

Statistical Analyses

Analyses will be performed using SAS or Stata. We will check the outcomes for normality and use transformations if necessary. We will compute descriptive statistics to determine central tendency, data sparseness, and the existence of outliers for all other continuous variables. For categorical variables, we will examine frequency distributions and merge categories with small frequencies when appropriate. Differences in baseline variables by study arm and by race will be tested using chi-square statistics for categorical variables and t-tests for continuous variables. We will plot the unadjusted primary outcomes across the 4 study time points to determine whether to treat time as a continuous or categorical variable in the analyses. Time will be treated as continuous for outcomes that appear to have a linear change over time. For outcomes that appear to have non-linear changes, time will be treated as a 4-level categorical variable to allow flexibility in testing non-linear effects of time.

We will test study hypotheses using linear mixed models that account for repeated measures, assess change over time (baseline, 1 month, 3 months, and 6 months), and allow for missing data if data are missing at random. In separate models for the three primary measures of pain, functioning, and patient global assessment, we will include fixed effects for study arm (positive intervention vs. control), race, time, all 2-way interactions, and the 3-way interaction between study arm, race, and time. Demographic and clinical variables with a univariate association with the main outcomes ($p < 0.10$) will be considered for inclusion as covariates. Covariates will be retained in final multivariable models if significant at $p < 0.05$ and all models will be adjusted for study site. All tests will be two-sided. We will conduct intent-to-treat analyses that include all patients in the groups to which they were randomized, regardless of adherence and/or subsequent withdrawal.¹¹⁴

We will also conduct a number of exploratory analyses to take full advantage of the rich dataset that will result from this study. For instance, we will perform exploratory analyses to examine whether there is a dose-response effect of the intervention, with dose operationalized as the number or proportion of program activities that participants report completing on the 6 weekly adherence surveys. In addition, if preliminary analyses indicate that there are demographic differences in the primary outcomes at baseline, we will conduct exploratory analysis to determine whether there are also differential responses across demographic groups over time. Finally, we will conduct a number of exploratory analyses to test whether effects of the positive program are mediated by the proposed psychosocial mediators. Taking advantage of the longitudinal nature of our dataset, we will conduct the mediation models using the baseline-to-3 or 6-month difference in change between the positive and control groups (whichever time point shows the larger difference in change between study arms) in each outcome, and the baseline-to-1 month change for the mediator being tested. We will start by conducting traditional mediation analyses of each psychosocial variable.¹¹⁵ In the event that more than one psychosocial variable is found to mediate response to the positive intervention, we will then use a multiple mediation bootstrap approach to test the indirect effects of each significant mediating variable while controlling for the effects of other mediators.¹¹⁶ We will fit race-specific mediation models to assess whether mediating effects are different among African American and White patients. In the event that changes in the psychosocial mediators appear to lag behind changes in the primary outcome measures (e.g., functioning is improved at 1 month, while social support is only improved at 3 or 6 months), we will also explore mediation models that test whether changes in the primary outcomes mediate changes in the psychosocial variables. We recognize that there are several sophisticated approaches to examining mediation in longitudinal datasets (e.g., autoregressive structural equation modeling, latent growth curve analysis) that could be applied to this dataset. Due to the exploratory nature of the mediation analyses, however, we will begin with the approach described here and pursue more complex analytic techniques only if there is an obvious added benefit to doing so based on preliminary analyses.

Missing data—While we will attempt to minimize missing data, it is likely that there will be some incomplete data. We will attempt to assess the missing data mechanism for data missing due to lost-to-follow-up or withdrawal. If there are significant differences in baseline variables between participants that have complete outcome data and those that do not, we will adjust for those covariates in the models.¹¹⁷ If no systematic differences are found or if the missing data is intermittent, the missingness will be handled as part of the regression modeling. Using linear mixed models allows the use of all available data, including data from those who are missing one or more of the assessments. We will also perform sensitivity analyses to assess the impact of missing data.

Sample size calculations—We used the Repeated Measures ANOVA module in PASS 2008 to estimate sample sizes necessary to detect a 3-way interaction between study arm (positive intervention vs. neutral control), race (African American vs. White), and time (baseline vs. 6 months) in the pain subscale of the WOMAC. Because power calculation software is not able to accommodate 3-way interactions, we first redefined the interaction

between study arm and race as a single variable with 4 levels, with each level representing a different combination of the two variables. We then set up the estimation model to assess the interaction between the combined study arm/race variable and time. We requested the sample size needed to detect this interaction with 80% power, assuming a modest (.36) autocorrelation between multiple measurements for the same participant. We identified reasonable values to enter as baseline means and standard deviations for each racial group from a study that reported race differences in the WOMAC pain subscale in a similar patient population.⁷² Specifically, we entered a mean baseline pain score of 6.9 (5.3 sd) for African Americans and 5.0 (4.9 sd) for Whites. We used the same standard deviations for the 6-month time point, but calculated 6-month means based on changes that would be considered clinically meaningful. Although a 30% change in pain scores is widely accepted as a clinically meaningful improvement, changes on the WOMAC as small as 12% are also clinically meaningful.^{118,119} We therefore estimated the sample sizes needed to detect race differences in response to the positive intervention program, assuming 12%, 20%, and 30% changes in baseline scores for each racial group. Because African Americans were expected to have a higher baseline score than Whites,⁷² applying the same percent change to starting values of each group would accommodate our hypothesis that there would be a larger response to the positive intervention (in absolute terms). Calculations indicated that sample sizes of 804, 360 and patients 164 (split equally across study arm and race), would be needed to detect a 12%, 20%, and 30% change, respectively, in baseline WOMAC pain subscale scores with 80% power. We therefore selected a target sample size of 360.

Discussion

The SPA study is designed to test the effects of a positive psychological intervention program on racial disparities in pain and functioning in a sample of adults with knee OA. We hypothesize that a 6-week program consisting of evidence-based positive psychological activities will produce greater improvements in OA pain and functioning compared to a similarly structured control program consisting of affectively neutral activities. We further hypothesize that African American participants will experience greater improvements in response to the positive program compared to White participants.

The SPA study breaks new methodological ground in a variety of ways. It is the first randomized controlled trial of a positive psychological intervention that explicitly targets patients with chronic pain due to OA, and that is powered to detect effects in pain-related outcomes rather than focusing on psychological outcomes. Other than a pilot study conducted in preparation for the current study,⁸⁴ we are aware of no studies that have tested a positive psychological intervention among Veterans, an important and often underserved population. Perhaps most importantly, this will be one of a very small handful of studies evaluating a positive psychological intervention in comparison to an active control group. To date, studies of positive psychological interventions in clinical populations are few, and studies using a randomized design with an active control group are even less common. We took extreme care in developing a control program that was similar to the positive program in every way except for the nature of the specific activities included in each program. Whereas the positive intervention program contains activities drawn from and validated in the field of positive psychology, the control program contains structurally-similar activities

demonstrated as being affectively neutral in the same positive psychology literature. Although our construction of the control program may make it more difficult to detect a difference between the positive intervention and neutral control programs, the lack of significant differences would also raise major questions about the mechanisms underlying significant effects found in other studies of positive psychological interventions.

To our knowledge, our study is also the first to look at race as a moderator of responsiveness to positive psychological interventions in any population. While a small handful of studies have examined cultural factors that impact the effects of positive psychological interventions, these largely focus on comparisons between White Americans and Asians or Asian Americans, and none have explored difference between White and African American participants.^{120,121} African American participants are also underrepresented in pain research; a review of randomized controlled trials of non-pharmacological OA interventions found that only 3 of 25 studies included a substantial number of African American participants.²¹ Another review of OA interventions targeting disadvantaged populations (e.g., racial minority groups, low-literacy patients) found only 3 that focused on African American individuals with OA and only 1 included a White comparison group so that the effect of the intervention on disparities could be examined.¹²² In an effort to address this major gap in the OA literature, we designed our study specifically so that we could test racial differences in effects of the intervention. In addition to powering the study to detect the interaction between study arm, race, and time, we also designed our recruitment strategy to ensure our ability to recruit equal numbers of African American and White patients. Such practices are essential to overcoming the systematic underrepresentation of certain demographic groups in randomized controlled trials. We chose to follow patients for 6 months after the end of the intervention because of the paucity of existing data on either the long-term effects of pain treatments or the long term effects of positive psychological interventions. By measuring outcomes at multiple time points in this study, we will be able to determine the duration of effects in addition to the intervention's overall impact. Having data from multiple time points will also be useful in determining whether there is a need to add booster activities to prolong the effects after the program ends, and if so, when such activities should be introduced (e.g., after 1 month or 3 months).

A particularly groundbreaking feature of this study is the positive intervention being tested, which has been carefully designed so that it is acceptable to participants and scalable in the context where it is being tested. If the VA were to choose to implement our program amongst all Veterans with chronic pain, that would be possible with little or no modification, and at a very low cost. Many of the most rigorously-tested psychological interventions for pain require therapist administration, are complex and require intensive explanation to participants, and/or use technology that may be inaccessible to older participants.¹²³ All of these factors can inhibit real-world implementation, ultimately reducing the value of the research. In the SPA study, our positive intervention program will be administered by college graduates with no clinical training, with minimal contact time, and our materials are designed to be understandable by participants even without interaction with a study staff member. Therefore, if effective, implementation of our program would not be subject to any of the common barriers that prevent efficacious interventions from reaching the patients for whom it is intended.

Although the study has many strengths, it also has some key limitations. First, because so little data exists on race as a moderator of responsiveness to pain interventions and to positive psychological interventions, our moderator analyses are only exploratory. While we suspect our intervention will be especially effective for African American participants, this is a hypothesis that remains to be tested. Even if we find that the positive intervention program improves pain equally for African American and White participants, the program could still reduce disparities at the population level if uptake is greater among African American individuals due to its alignment with non-pharmacological and alternative OA treatment preferences. We will be able to assess whether future uptake of the SPA program is likely to be greater among African American patients by monitoring recruitment for racial differences in SPA study enrollment and testing for racial differences in program adherence and engagement among enrolled participants.

We also acknowledge that the writing component of our intervention might limit program adherence for participants with low literacy levels and hinder its potential for universal implementation. However, we do not anticipate that the written nature of the program will be problematic for most participants, as the activities were carefully crafted to require as little writing as possible, interventionists will be available to provide additional support by telephone, and low literacy levels did not prevent intervention engagement in a pilot study of the SPA program.⁸⁴ We will also assess health literacy of study participants so that we are able to adjust for its potential impact.

In comparing our intervention with an active control, we are not making other potentially interesting comparisons with existing standard care interventions, or even other psychological interventions for chronic pain such as Cognitive Behavioral Therapy or Mindfulness-Based Stress Reduction.¹²³ Comparative effectiveness studies or non-inferiority trials that directly compare positive psychological interventions for pain with other OA treatment approaches would be appropriate, should the current study establish clinical benefits of our positive intervention program relative to a strong control program.

Lastly, some may question our choice to delay the first post-treatment outcome to 1 month after treatment. Although we acknowledge that measuring outcomes immediately following treatment would likely reveal a stronger, undiluted treatment effect, our goal in this study is to improve upon prior studies of positive psychological interventions by focusing on longer-term benefits. As already noted, the broaden-and-build model of positive emotions upon which the intervention is based suggests that the short-term boost in positive emotional experiences during the 6-week intervention should launch a process that enables participants to continue experiencing benefits after the program ends. In addition, from our perspective, a behavioral intervention that does not demonstrate a detectable benefit 1 month later will not achieve its intended purpose, even if it shows an immediate impact. In the interest of placing priority on longer term effects and limiting response burden for participants, we therefore will not collect outcomes immediately following the treatment program.

Conclusion

Knee OA is a painful condition that causes substantial disability and disproportionately affects African Americans. Novel interventions that are consistent with the biopsychosocial model of pain and target psychosocial factors associated with OA outcomes and disparities in OA outcomes are needed. The positive psychological intervention that will be tested in the SPA study is uniquely positioned to address racial disparities in OA by improving multiple psychosocial factors that underlie racial differences in OA pain and functioning and because it is compatible with African American patient preferences for alternative, non-pharmacological, non-invasive treatments for OA. If effective in improving pain outcomes and reducing disparities in this study, our positive intervention program has far-reaching applications for the future. Designed for relatively easy and low-cost dissemination, the program tested in this study is poised for widespread implementation if it is shown to benefit the clinical population targeted in this study.

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Figure. Key Events and Compensation

Flow of patients from screening to 6-month follow up in the Staying Positive with Arthritis Study.

Table 1**Inclusion and Exclusion Criteria for the Staying Positive with Arthritis Study**

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> •Age 50 years or older •Receive primary care at a participating site •Self-report as non-Hispanic African American or non-Hispanic White •Have frequent pain characteristic of symptomatic knee osteoarthritis identified using questions from the Osteoarthritis Initiative (OAI)⁸⁰ •Pain level of 4 or higher on a 0–10 numeric rating scale •Have the ability to speak, read, and write in English 	<ul style="list-style-type: none"> •Self-reported serious problems with hearing, eyesight, or memory •Diagnosed with any type of arthritis other than OA or degenerative arthritis •Treated for cancer in the last three years •Had a steroid injection into one or both knees in the past 3 months •Had a knee replacement into one or both knees in the past 3 months •Plan to have a knee replacement in one or both knees in the next 6 months •Self-reported inability to complete the study procedures, which include telephone calls and program activities that involve reading and writing •Lack of a reliable telephone number •Answering 2 or more items incorrectly on a 6-item screener for cognitive impairment⁷⁹

Note: Eligibility will be determined based on self-reported responses to a screening survey. Most, but not all patients who will complete the screening will also have met the following criteria used to generate recruitment mailings based on administrative data: non-deceased; non-Hispanic African American or White race; 50 years or older; primary care appointment in the 12 months; diagnosis of OA (ICD-9-CM 715); and do not have diagnoses of inflammatory arthritis (rheumatoid arthritis [714.xx], lupus [695.4, 710.0], psoriatic arthritis [696.0], or ankylosing spondylitis [720.0]) or Alzheimer's disease/dementia (294.xx, 290.xx, 291.xx, 331.xx, 094.1).

Table 2

Activities included in the Positive Intervention and Neutral Control Programs in the Staying Positive with Arthritis Study

Week	Positive Intervention Program	Neutral Control Program
1	Three Good Things: Write down 3 good things that happened each day.	Events that Affect You: Write down 3 things that affected you each day.
2	Expressing Thanks: Write a letter to someone whose actions affected you but you never thanked. Deliver the letter in person, if possible.	Changing your Circumstances: Identify small ways you could change your life circumstances. Write down one change that you will try to make in the next week.
3	Making Good Moments Last: Spend 2–3 minutes each day focusing on a good moment and making it last. Write down what you focused on, how you made it last, and how it made you feel.	Early Memories: Each day, write down an early memory, how it made you feel, and who you were with.
4	Acts of Kindness: Do 5 acts of kindness in a single day. Write down what you did, how it made you feel, and how the recipient responded.	Getting Organized: Create a mental outline of everything you have done in the past 7 days and then make a written list.
5	Increasing Pleasant Activity: Identify activities you enjoy, give you a sense of achievement, or bring you closer to others. Try to do at least 4 each day. Write down the activities you do each day in the next week.	Planning the Future: Spend time each morning to plan what you are going to do that day. Write down your plans for each day.
6	Practice Your Favorite(s): Pick one of the first 5 activities that you really liked and do it again.	Practice Your Favorite(s): Pick one of the first 5 activities that you really liked and do it again.