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Protocols

Protocol for a Parallel Group Randomized Clinical Trial Comparing a Culturally Adapted Cognitive Behavioral Telerehabilitation Intervention to Usual Physical Therapy for Latino Patients With Chronic Spine Pain

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Abstract

Objective. Disparities exist in health care access, diagnosis, and treatment of chronic pain in Latino populations and other minority populations. Cognitive behavioral–based physical therapy (CBPT) interventions have been shown to be effective in predominantly non-Hispanic white populations with chronic spine pain. However, there is a need for culturally adapted CBPT interventions that focus on the conservative management of chronic spine pain. The primary purpose of the study described in this protocol is to test the efficacy of an adapted cognitive behavioral–based hybrid telerehabilitation intervention for Latino patients with chronic spine pain.

Methods. A single-blind, 2-arm parallel group, superiority randomized clinical trial is planned to compare an adapted CBPT intervention to Usual Care physical therapy. Goal Oriented Activity for Latinos with chronic Spine pain (GOALS/Metas) is an 8-week hybrid telerehabilitation intervention that integrates guideline-based physical therapy and pain management interventions using cognitive behavioral approaches and has been adapted for Latino patients with chronic spine pain. Usual Care physical therapy will be administered based on institutional standards at the referring health center. Outcome measures will be evaluated preintervention and at 1-week, 3-months, and 6-months postintervention. The primary outcome is pain-related disability 1-week postintervention using the Brief Pain Inventory Pain Interference subscale. Secondary outcome measures include behavioral measures of functional activity, social participation, physical activity, and sleep. Determinants of treatment effect, including pain-related psychological measures, posture and movement, self-efficacy, treatment expectancy, and therapeutic alliance, will be included in the secondary moderation and mediation analyses.

Impact. This clinical trial will provide information on the extent to which an adapted CBPT hybrid telerehabilitation intervention is effective in reducing pain-related disability for Latino patients with chronic spine pain. This information will be useful for clinicians to integrate in their practice, given the growing population of Latino patients who experience disparities in health care management of chronic pain.

Keywords: Adapted, Chronic, Cognitive Behavioral, Hispanic, Latino, Low Back, Neck, Pain, Physical Therapy, Spine

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Introduction

Chronic spine pain is a highly prevalent health condition, which has a profound impact on the lives of individuals affected and society. Up to 80% of the population experiences low back pain (LBP) at some point in their lives,[1] with an average of 62% reporting chronic LBP after an initial episode.[2] Neck pain affects 30% to 50% of the general population each year,[3] with 14% to 17% of people reporting chronic neck pain.[4,5] Further, LBP ranked highest and neck pain ranked fourth as most disabling among 291 diseases globally.[6,7] The impact of chronic spine pain on affected individuals and their families is substantial, including poor mood, persistent disability, reduced participation in leisure time and social activities, difficulty engaging in work activities, and inability to care for children.[8–11] The resulting socioeconomic impacts of chronic spine pain in the United States are profound; the estimated annual cost of LBP alone is approximately $100 billion due to reduced productivity and lost wages.[12]

Chronic spine pain is a problem for Hispanic and Latino-Americans in particular, with studies reporting chronic LBP in 24% to 55% of Hispanic and Latino adults.[13,14] This is likely an underestimate of prevalence, since Hispanic and Latino adults are less likely than non-Hispanic white adults to report chronic pain.[15] Further, compared to other racial and ethnic groups, Hispanic and Latino adults report higher pain-related anxiety,[16] which is a known risk factor for the development and persistence of spine pain.[17] Disparities in access to culturally competent care also have been reported for Hispanic and Latino adults with chronic pain.[15] Specifically, there are no existing culturally and linguistically adapted physical therapist interventions that focus on the conservative management of chronic spine pain in Hispanic and Latino adults.

Evidence-based physical therapist clinical practice guidelines have been established for chronic spine pain, with demonstrated effectiveness for reducing pain and improving function.[18,19] In addition, psychologically informed physical therapist interventions that incorporate cognitive behavioral approaches for pain management have been developed and tested to address the psychological risk factors associated with chronic spine pain.[17,20–26] Cognitive behavioral–based physical therapy (CBPT) interventions, in particular, have demonstrated efficacy for spine pain[27–32]; however, these interventions have yet to be culturally and linguistically adapted for Hispanic and Latino adults.

Difficulty with access to health care poses an additional barrier for Hispanic and Latino adults with chronic spine pain.[15] Telerehabilitation has been increasingly used to help improve access to medical care for populations that historically have had difficulty with access.[33] Further, the COVID-19 pandemic forced a shift to telerehabilitation in many physical therapy settings, including outpatient management of musculoskeletal conditions like chronic spine pain.[34] Preliminary evidence on telehealth for spine pain indicates that a hybrid approach is more effective for reducing disability.[35] Further, cognitive behavioral–based interventions can be readily delivered via telerehabilitation with outcomes that are comparable to traditional face-to-face delivery methods.[36]

An existing multimodal CBPT telerehabilitation intervention, with demonstrated efficacy for reducing pain and improving function in patients after spine surgery, was culturally and linguistically adapted for Latino adults with chronic spine pain.[28,37] The primary purpose of the study described in this protocol is to test the efficacy of the adapted cognitive behavioral–based hybrid telerehabilitation intervention for Latino adults with chronic spine pain, entitled Goal Oriented Activity for Latinos with chronic Spine pain (GOALS/Metas). We hypothesize that participants in the GOALS/Metas intervention will experience a greater improvement in pain-related disability than participants in a Usual Care group. A secondary purpose of this study is to examine the psychological and biological moderators and mediators of treatment response.

Methods

Overview of Study and Setting

The GOALS/Metas intervention will be compared to Usual Care physical therapy by conducting a single-blind, 2-arm parallel group, superiority randomized clinical trial (Fig. 1). This study is being conducted in partnership with a Federally Qualified Health Center (FQHC), serving uninsured, low-income, and medically underserved persons in San Diego County. Enrolled participants will be randomized into either the GOALS/Metas intervention arm or the Usual Care control arm. GOALS/Metas is an 8-week CBPT intervention for Latino adults with chronic spine pain, which is delivered in a hybrid format with 2 in-person sessions and 6 telerehabilitation sessions (Fig. 2). The Usual Care comparison intervention is 8 weeks of standard physical therapy at the FQHC. Outcome measures include questionnaires and objective measures of spine posture and movement, physical activity, and sleep behaviors. Study assessments will be conducted by the research staff 1 week before (baseline) and at 1 week (1-wk Post), 3 months (3-mo Post), and 6 months (6-mo Post) after completing the assigned intervention (Fig. 1). The primary outcome is pain-related disability as measured by the Brief Pain Inventory (BPI) Pain Interference subscale.[38]

Research staff conducting assessments and biostatisticians conducting analyses will be blinded to the treatment group. All research staff conducting recruitment and assessments and physical therapists implementing the GOALS/Metas intervention will be bilingual (English/Spanish) and have demonstrated fluency in oral and written communication in both languages. Study materials were professionally translated, and these are available in English and Spanish. All translated materials were pilot tested and adapted as appropriate during a 2-stage adaptation process. Assessments and GOALS/Metas intervention visits will be conducted in the participant's preferred language.

Participant Eligibility and Recruitment

One hundred thirty-eight Hispanic patients between the ages of 18 and 66, who are referred by their primary care physician to physical therapy for neck or LBP, will be enrolled. Consecutive patients from the FQHC's physical therapy referral database, who meet prescreening eligibility criteria for Hispanic ethnicity, age, and medical condition (neck pain or LBP), will be contacted by bilingual research staff to determine eligibility using a phone screening questionnaire. Additional symptom-related eligibility criteria assessed during the phone screening are included in Supplementary Appendix 1. Participants who are deemed eligible based on the phone screening will be enrolled in the study and will be scheduled for the first study assessment, where they will provide written informed consent prior to participation.

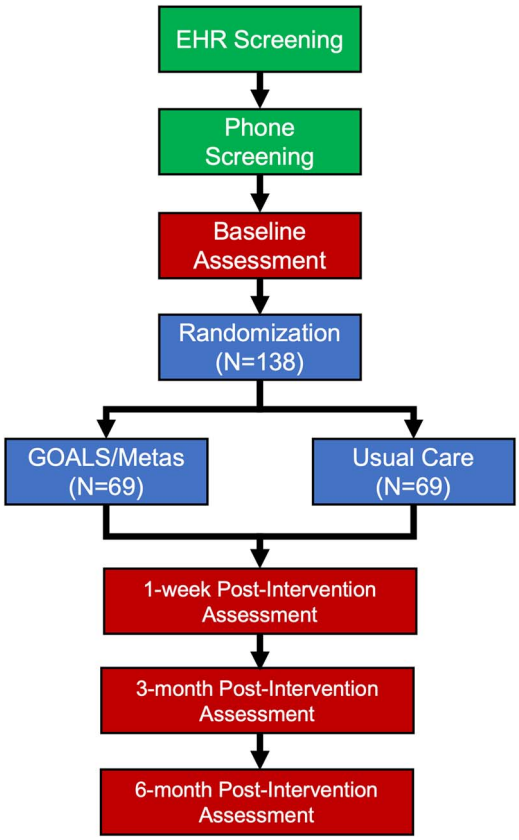

Figure 1. Study design for parallel group randomized clinical trial comparing the Goal Oriented Activity for Latinos with chronic Spine pain (GOALS/Metas) intervention to Usual Care physical therapy. EHR = Electronic Health Records.

Figure 2. GOALS/Metas hybrid telerehabilitation intervention, including content of face-to-face sessions and cognitive behavioral pain coping skills for each telephone session (*Note: Each telephone session also includes goal setting for graded aerobic activity, impairment-based therapeutic exercise, and graded functional activity).*

Randomization and Allocation of Interventions

Enrolled participants will be stratified based on the pain region (cervical and lumbar) and sex (female and male) and will be randomized into the GOALS/Metas or Usual Care intervention arm. The stratified randomization scheme was developed based on the prevalence of referrals for cervical (25%) and lumbar spine (75%) pain and for female (60%) and male (40%) patients extracted from the FQHC electronic health records. The randomization scheme will be generated in Statistical Analysis System (SAS) analytics software (Cary, NC, USA) and implemented using the custom randomization schedule function on the REDCap Cloud platform (Encinitas, CA, USA), with random assignments completed after eligible participants complete the baseline assessment. The allocation sequence and group assignment will be concealed from the blinded research staff conducting assessments by including this information in an event on REDCap Cloud, which is only accessible to unblinded research staff using permissions' restrictions. An unblinded recruitment coordinator will schedule participants with providers for their assigned group.

Interventions

GOALS/Metas Intervention

The GOALS/Metas intervention was systematically adapted for Latino patients with chronic spine pain from an existing evidence-based CBPT intervention.[28] GOALS/Metas combines clinical practice guideline-based physical therapy[18,19] with cognitive-behavioral skill training to address the physical, psychosocial, and behavioral factors known to influence the experience of chronic spine pain. Systematic adaptation of the intervention was conducted by a panel, including a team of physical therapists, a clinical psychologist, clinical scientists, and implementation scientists, and included input from Latino patients with chronic spine pain. The adaptation panel used Intervention Mapping[39] and considered the cultural and linguistic factors specifically relevant to Latino patients with chronic spine pain. Adaptation of the GOALS/Metas intervention has been presented in abstract form[40] and will be detailed in future reports.

Briefly, GOALS/Metas is an 8-week, hybrid telerehabilitation intervention implemented by a bilingual research physical therapist with formal training in the manualized intervention (see Supplemental Materials). The hybrid intervention begins with an initial face-to-face physical therapy evaluation, followed by 6 remote treatment sessions conducted once per week by telephone. A second face-to-face session is scheduled near the midpoint of the intervention to assess the progress and advance the participant's home exercise program (Fig. 2). Weekly remote treatment sessions are comprised of a graded activity program focused on goal setting in 4 treatment domains: pain coping skills, therapeutic exercise, aerobic activity, and functional activity. Pain coping

skills adapted from cognitive behavioral–based interventions described by Archer et al[28] and Thorn et al[41] include instruction in pain neuroscience,[42] under/overactive activity types and activity pacing,[43,44] deep breathing/relaxation,[45,46] soliciting helpful social support,[47] cognitive restructuring,[48,49] present mindedness,[46,48,50] and creating a plan for symptom self-management.[51] Therapeutic exercise, aerobic activity, and functional activities are individually tailored and progressed at the physical therapists' discretion based on impairments from the examination and to meet patient-identified goals using a bank of evidence-based exercises for neck pain and LBP[18,19] along with standard guidelines for progression of exercise time, intensity, and complexity.[52] To reduce fear of movement and promote increases in functional activity, the physical therapist also provides education on behavioral strategies to reduce pain-provoking spine postures and movements during daily activities.[53] Finally, principles of motivational interviewing are used throughout the intervention to facilitate adherence to patient-identified goals.[54] Participants receive an informational binder with worksheets to follow along with the therapist during treatment sessions. Each session includes an action plan and weekly assignments that are individually tailored to the participant's goals.

Usual Care Intervention

The Usual Care control intervention is delivered by physical therapists employed by the FQHC according to the institutional standards of care. Participants in the Usual Care group are scheduled for an initial physical therapy evaluation at 1 of 4 FQHC Rehabilitation clinics. The plan of care is then determined by the treating physical therapist. The number of physical therapy sessions and types of interventions provided during Usual Care will be characterized by extracting Current Procedural Terminology billing dates and codes from the participants' electronic health record over the 8-week study period. Physical therapists who provide the Usual Care intervention will be naive to the purpose of the study and details of the GOALS/Metas intervention. Participants in the Usual Care group will be instructed not to discuss their study participation with the treating physical therapist.

Intervention Fidelity, Adherence, and Adverse Event Monitoring

Delivery of the GOALS/Metas intervention will adhere to a manualized protocol. Physical therapists will self-monitor intervention fidelity for each session of GOALS/Metas by completing a checklist of required components and noting the reasons for any protocol deviations. Ten percent of audio-recorded treatment sessions will be reviewed by a principal investigator (K.S.M.) using the same fidelity checklist and discussed in biweekly meetings with GOALS/Metas physical therapists. Fidelity check meetings will occur throughout the duration of the trial to address protocol deviations and to review the cognitive behavioral and motivational interviewing skills as needed to minimize intervention drift.

Participants' adherence to the intervention will be monitored by assessing the percentage of scheduled physical therapy sessions attended by each participant. Adherence to behavioral goals for each GOALS/Metas treatment session will be monitored by the physical therapist using a Goal Attainment Scale.[55] Adverse events will be directly assessed and recorded by the research physical therapists. Adverse events will be reviewed weekly by the investigative team and biannually by a Data Safety and Monitoring Board and will be reported to the Institutional Review Board.

Outcome Assessments

Assessments will be conducted by blinded, bilingual research staff at baseline and at 1-week, 3-months, and 6-months postintervention (see Supplemental Materials). Assessments will include questionnaires administered electronically on REDCap Cloud, sensor measures of lumbar spine posture and movement (DorsaVi Inc, New York, NY, USA) and physical activity and sleep (Actigraph Inc, Pensacola, FL, USA). For questionnaires, assessors will read questions aloud in the participant's preferred language and will record the participant's responses in REDCap Cloud. To facilitate access and retention, participants will be offered the opportunity to complete assessments remotely via video or voice call if unable to attend in-person assessment visits. For remote assessments, participants will have a visual reference (paper copy) for all questionnaires, and sensors will be delivered directly to participants for remote monitoring. Assessment questionnaires that were available and validated in Mexican-American Spanish were used.[56–65] When validated Mexican-American translations were not available, 2-panel consensus translation was conducted to translate questionnaires.[66] All measures, constructs, time points at which they are collected, and references for validated English and Spanish measures are listed in Table 1.

Measures were selected to capture the demographic and clinical characteristics of the study sample as well as the *outcomes*, *behaviors*, *determinants*, and the *cultural and psychosocial contextual factors* hypothesized to influence treatment response in Latino patients with chronic spine pain. The primary outcome is the change in pain-related disability from baseline to 1-week postintervention based on the BPI Pain Interference subscale.[38,59,67–70] This primary outcome was selected because it reflects the extent to which spine pain interferes with various aspects of daily life, is a clinically meaningful outcome, and significant improvements in pain interference were observed in the previous CBPT intervention for postsurgical spine pain.[28] Secondary outcome measures include change in the following measures from baseline: BPI Pain Interference subscale at 3-month and 6-month time points; the BPI Pain Severity subscale[38,59,67–70]; the Pain, Enjoyment of Life, and General Activity Scale (PEG-3)[67,71]; and region-specific measures of pain-related disability, including the modified Oswestry Disability Index for LBP[57,58,72,73]; the Neck Disability Index for neck pain[57,62,74–78]; and the Patient-Specific Functional Scale[79,80] at all follow-up time points, and performance on functional tasks, including a self-paced and fast-paced 6-m walk (speed), overhead lift for neck pain (speed and repetitions), squat lift for LBP (speed and repetitions), and 30-s sit-to-stand for LBP (repetitions) at 1-week postintervention. More information on additional outcome measures and measures of *behaviors*, *determinants*, and the *cultural and psychosocial contextual factors* are described in Supplementary Appendix 2.

Data Analysis

Sample Size Calculation

Sample size calculations were derived based on the effect sizes for change in the BPI Pain Interference subscale between intervention and control groups 3-months postintervention

Table 1. GOALS/Metas timeline, measures and associated constructs for outcomes, behaviors, determinants, and cultural and psychosocial context[a]

Measure	Construct	Baseline	Postintervention		
			1-week	3-months	6-months
Primary Outcome					
Brief Pain Inventory (BPI) – Pain Interference Subscale[38,59,67,68,70]	Pain-Related Disability	X	X	X	X
Secondary Clinical and Behavioral Outcomes					
Brief Pain Inventory (BPI) – Pain Severity Subscale[38,59,67,68,70]	Pain Intensity	X	X	X	X
Pain, Enjoyment of Life, and General Activity Scale (PEG-3)[67,71]	Pain Intensity and Interference	X	X	X	X
Modified Oswestry Disability Index (ODI)[b,57,58,72,84]	Pain-Related Disability (Low Back)	X	X	X	X
Neck Disability Index (NDI)[57,62,74,76,78]	Pain-Related Disability (Neck)	X	X	X	X
Patient Specific Functional Scale (PSFS)[79,80]	Functional Activities (Behavior)	X	X	X	X
PROMIS Short-Form Questionnaires (Physical Function, Participation)[85]	Physical and Social Participation	X	X	X	NT
Physical Activity (Actigraph)[86,87]	Physical Activity (Behavior)	X	X	NT	NT
Rapid Assessment of Physical Activity (RAPA)[65,88]	Physical Activity (Behavior)	X	X	X	NT
Sleep (Actigraph)[89,90]	Sleep (Behavior)	X	X	NT	NT
PROMIS Short-Form Sleep Disturbance Questionnaire[85,91]	Sleep (Behavior)	X	X	X	NT
Global Impression of Change (GIC)[83]	Perceived Change	NT	X	X	X
Global Rating of Satisfaction (GRS)[83]	Satisfaction	NT	X	X	X
Determinants					
Demographic & Health History Questionnaire[83,92,93]	Sociodemographic & Clinical Characteristics	X	NT	NT	NT
Treatment Expectancy Measure (TEM)[41,94]	Treatment Expectations	X	NT	NT	NT
Fear Avoidance Beliefs Questionnaire (FABQ)[61,95,96]	Fear of Movement	X	X	X	NT
Pain Catastrophizing Scale (PCS)[b,97,98]	Pain Catastrophizing	X	X	X	NT
Pain Self-Efficacy Questionnaire (PSEQ)[b,99,100]	Pain Self-Efficacy	X	X	X	NT
New General Self-Efficacy Scale (GSES)[b,101]	General Self-Efficacy	X	X	X	NT
Self-Efficacy & Exercise Habits Survey (SEHS)[a,102]	Exercise Self-Efficacy	X	X	X	NT
Clinical & Functional Movement Testing (DorsaVi)[103–105]	Spine Posture and Movement	X	X	NT	NT
Kim Alliance Scale (KAS)[b,106–108]	Therapeutic Alliance	NT	X	NT	NT
Cultural & Psychosocial Context					
Bidimensional Acculturation Scale for Hispanics (BAS)[56,109–111]	Acculturation	X	NT	NT	NT
Connor-Davidson Resilience Scale[60,112–114]	Resilience	X	NT	NT	NT
Medical Outcomes Study – Social Support Measure (MOS-SS)[63,64,115]	Social Support	X	X	NT	NT
PROMIS Short-Form Questionnaires (Anxiety, Depression)[85]	Psychological, Anxiety and Depression	X	X	X	NT

[a]NT = not tested; PROMIS = Patient-Reported Outcomes Measurement Information System. [b]Translated into Spanish using the 2-panel consensus method.[66]

as reported in the CBPT study that provided the basis for the GOALS/Metas intervention.[28] A total sample size of 138 participants ($N = 69$ per group) is needed to detect a group difference in change in BPI Pain Interference of 1.5 (effect size = 0.57) with 80% power and an alpha of 0.0125 to govern the family-wise error rate to account for the secondary moderation and mediation analyses. This sample size assumes a within-subject correlation (rho) of 0.38 and actual drop-out rates (40%) observed during pilot testing of the adapted GOALS/Metas intervention. The high rate of attrition during pilot testing is consistent with the high nonadherence rates for physical therapy referrals at the FQHC based on a historical review of electronic health record data.

Primary Analysis of Treatment Effect

A modified intention-to-treat (mITT) approach will be used to test our primary hypothesis that participants in the GOALS/Metas intervention will experience a greater improvement in pain-related disability than participants in the Usual Care group. The analysis is considered a modified ITT approach because all participants who are randomized may not be included in the analysis due to the inclusion criterion that participants must complete at least 1 physical therapy session, which occurs after randomization. The mITT, which includes only participants who attend the first physical therapy session after randomization, was selected to account for the unusually high rates of nonadherence to physical therapy referral in the FQHC setting. Therefore, the primary mITT analysis will be conducted for all participants who complete the baseline assessment, are randomized, and complete at least 1 physical therapy session of either the GOALS/Metas or Usual Care intervention. Descriptive statistics and tests for data normality will be conducted, and missing data will be handled using a multiple imputation approach. A linear regression model will be used to test for the intervention group by time interaction effects for the primary outcome of BPI Pain Interference at 1-week postintervention. The model will be adjusted for the sociodemographic and clinical characteristics that may affect treatment response and are found to differ between groups.

Secondary Analyses

Secondary outcome measures will be analyzed as described above. Per protocol analyses also will be conducted using a similar approach for primary (1-wk Post) and secondary (3-mo Post and 6-mo Post) endpoints to assess the magnitude of treatment effects that can be expected for participants who complete at least 80% of scheduled physical therapy sessions in each treatment arm. Finally, planned secondary analyses will explore the physiological, psychological, and environmental moderators and mediators of treatment response. Multivariate logistic regression analyses will be conducted to explore candidate moderators (determinants) within each measurement domain. Potential mediators of treatment response will be explored with generalized structural equation modeling using maximum likelihood estimation methods. Treatment response will be characterized using a dichotomous variable distinguished by $\geq$30% reduction in BPI Pain Interference, which is considered a clinically meaningful improvement in people with chronic pain based on the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) guidelines.[81–83] All data analyses will be conducted using SAS, version 9.4, and Stata, Version 16.1 analytics software.

Role of the Funding Source

The funding source had no role in the study's design, conduct, and reporting.

Discussion

This is the first clinical trial to examine the efficacy of a culturally adapted cognitive behavioral–based telerehabilitation intervention for Latino patients with chronic pain. The intervention integrates guideline-based physical therapy and pain management interventions using cognitive behavioral approaches. This study protocol design includes several novel culturally informed components specifically designed for implementation in a population of Latino patients with chronic spine pain from an FQHC, including (1) a culturally and linguistically adapted intervention for Latino patients; (2) study materials available in English and Spanish, delivered in the participant's preferred language; (3) bilingual (English/Spanish) research staff and physical therapists implementing the GOALS/Metas intervention; and (4) a hybrid telerehabilitation approach to facilitate access to care and participation for Latino patients from an FQHC. One concern that has arisen with implementation of telehealth interventions in low-income and medically underserved populations is limitations in access to technology. A strength of the GOALS/Metas intervention is that it was specifically adapted as a hybrid intervention with telerehabilitation components delivered via telephone to avoid access barriers. If effective, this intervention could be integrated with the existing practice and implemented to provide the first culturally appropriate evidence-based physical therapist intervention for Latino patients with chronic spine pain.

There are several limitations of the proposed study protocol design. First, the GOALS/Metas intervention is complex and includes multiple components that require extensive training. However, this training is critical to implementing cognitive behavioral aspects of the program, given that prior studies have demonstrated the failed implementation of cognitive behavioral approaches which were attributed to lack of provider training.[24] Second, the complexity of a behavioral intervention, such as GOALS/Metas, limits the ability to isolate the effects of individual treatment elements. However, secondary responder, mediation, and moderation analyses will allow us to examine the influence of determinants of treatment response. Third, the comparison group is Usual Care physical therapy as determined by the physical therapist at the FQHC, which could result in variability in the intervention components for the comparison intervention. However, a Usual Care comparison group was selected because it is representative of physical therapy treatment that is currently available to the population of interest, and the intervention variability can be measured through precise chart-review. The current study was powered to test efficacy using the primary outcome at 1 postintervention endpoint (1-wk Post), but it is possible that it may not be adequately powered to test additional postassessment time points and/or secondary outcomes. However, this rich dataset will inform mechanistic modeling of treatment effects that can be used to refine future iterations of the intervention for clinical implementation. Last, the mITT analytic approach could introduce bias if engagement in the first physical therapy session is different between intervention groups. However, given the high rates of nonadherence to physical therapy referral at FHCSD, this

approach was selected instead of a traditional ITT approach to ensure adequate enrollment of participants who initiate treatment as recommended by their physician. Results from the mITT analysis will not reflect outcomes from those who are unwilling or unable to initiate physical therapy for the management of spine pain.

This clinical trial will provide clinicians with information on the extent to which an adapted CBPT intervention is effective in reducing pain interference for Latino patients with chronic spine pain. This information can be useful for clinicians to integrate in their practice, given the growing population of Latino patients who face disparities in the health care management of chronic pain.

Author Contributions

Concept/idea/research design: S.P. Gombatto, K.S. Monroe, K.R. Archer, S.T. Wegener, , S.-F. Lin
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Ethics Approval

This study was approved and is being monitored by the San Diego State University Institutional Review Board (HS-2021-0121).

Clinical Trial Registration

GOALS/Metas is registered on clinicaltrials.gov (protocol ID: 228489; NCT05005416). Trial enrollment began in August 2021, and data collection is ongoing.

Data Availability

The data that support the findings of this study will be openly available in Open Science once the trial is completed.

Disclosures

The authors completed the ICMJE Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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