#### **OBSERVATIONAL RESEARCH**





# Investigating the association between knee osteoarthritis symptoms with pain catastrophizing domains between Hispanics and non-Hispanic Whites

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#### **Abstract**

Knee osteoarthritis (KOA) is a chronic disease accompanied by debilitating symptoms including pain, stiffness, and limited physical functionality, which have been shown to be associated with pain catastrophizing. Previous studies have revealed racial discrepancies in pain catastrophizing, notably between Hispanics and non-Hispanics while pointing to potential health disparities. Using a conceptual model, this study aimed to investigate racial differences in associations between KOA symptoms with specific pain catastrophizing domains (rumination, magnification, and helplessness). Patients with KOA (n = 253; 147 Hispanics, 106 non-Hispanic Whites) completed a survey that included measures of knee symptoms, pain catastrophizing, and demographic variables. Structural equation modeling revealed that among Hispanics, each pain catastrophizing domain (rumination, magnification, and helplessness) was associated with at least two symptomatic experiences, including pain severity and difficulty in physical function. Specifically, pain severity was associated with (a) rumination:  $\beta = 0.48$ , p < 0.001, (b) magnification:  $\beta = 0.31$ , p = 0.003; and (c) helplessness:  $\beta = 0.39$ , p < 0.001). Additionally, a lower score in physical function was associated with higher magnification ( $\beta = 0.26$ , p = 0.01), and helplessness ( $\beta = 0.25$ , p = 0.01). Among non-Hispanic White patients, pain severity was further associated with two domains of pain catastrophizing, including rumination ( $\beta = 0.39$ , p < 0.001) and helplessness ( $\beta = 0.35$ , p = 0.01). In addition, association pathways for demographic variables revealed that older Hispanics experienced greater challenges with higher pain severity ( $\beta = 0.26$ , p = 0.01) and greater difficulty with physical function ( $\beta = 0.31$ , p < 0.001) while Hispanics females experienced higher pain ( $\beta = 0.19$ , p = 0.03). These findings highlight the importance of designing tailored interventions that consider key demographic factors such as age, and gender, to improve physical function that might alleviate pain catastrophizing among Hispanics with KOA.

**Keywords** Catastrophizing · Pain · Osteoarthritis · Disability · Ethnicity · Race · Knee

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# Introduction

Osteoarthritis (OA) is the most common joint disease in the United States and is recognized as the third most rapidly rising condition associated with disability, following diabetes and dementia [1], that affects over 32.5 million individuals [2]. Of all joints affected by this disease, knee osteoarthritis (KOA) is the leading cause of lower extremity disability due to functional limitations, such as decreased walking distance and inability to work [3]. There is a projected increase in both the prevalence and incidence of KOA [4] due to the aging population and the high prevalence of obesity, two primary risk factors for KOA.

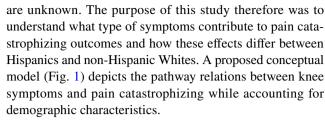
Conventional medicine characterizes KOA as a specific form of joint degeneration that primarily affects localized areas, as supported by radiographic evidence that causes



pain, stiffness, and physical dysfunction. However, there is a discordance between the radiographic findings and the severity of symptoms experienced by patients that fail to explain the magnitude of the present symptoms [5, 6]. This highlights additional determinants, such as psychosocial factors, that may play a significant role in the development of pain and disability outcomes associated with KOA. For instance, pain catastrophizing is a common psychological factor that is reported among patients, which contributes to magnified pain experiences. Pain catastrophizing can take forms of rumination, magnification, and helplessness [7–9]. Rumination is defined as excessive and ongoing repeated thoughts about the illness. Magnification is over-interpretation or exaggeration of the symptoms one experiences. Finally, helplessness is the belief that the individual is unable to change the progress or outcomes of their condition. Pain catastrophizing manifests from anxiety, depression, and fear rather than the actual symptom experiences [7, 10] that negatively impact patients' quality of life and deteriorate KOA-related outcomes [11–13].

Pain catastrophizing is most commonly reported among minorities including Black and Hispanic populations compared to their White counterparts [13–15] that contributes to health disparities among ethnic and racial groups. While several attempts have been made to investigate the determinants of pain catastrophizing experience among ethnic groups [16], there has been comparatively less focus on studying the Hispanic population with KOA, despite their high reports of elevated pain catastrophizing and debilitating symptoms [14, 17, 18]. Moreover, various studies have examined the influence of psychological factors including anxiety, and perceived discrimination on pain catastrophizing, however, there has been limited research identifying the specific symptoms of KOA that is associated with different domain of pain catastrophizing in patients. For instance, the symptoms that are frequently assessed in studies among people with KOA are pain, stiffness, and impaired physical function, which can be collectively measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scale. The total score of WOMAC has been shown to be correlated with the total score of pain catastrophizing [19–21]. However, there is no study that identifies which domain of WOMAC (function, stiffness, or pain) is best correlated with each domain of pain catastrophizing among Hispanics and non-Hispanic White patients

Investigations comparing ethnicities have consistently noted Hispanics who report higher pain with KOA symptoms demonstrate overall greater pain catastrophizing [14, 17, 18] compared to non-Hispanic Whites. However, details to further evaluate this important difference including the effect of other KOA symptoms such as stiffness and functional limitation on the magnitude of pain catastrophizing



Our primary objective was to develop a model that compared the relationship between each domain of the pain catastrophizing scale (helplessness, rumination, and magnification) and the three components of the WOMAC (pain, stiffness, and functional limitations) among Hispanics and non-Hispanic Whites with KOA. The secondary objective was to test the proposed model accounting for potential confounding variables including age, sex, BMI, and knee OA symptoms that might contribute to pain catastrophizing among Hispanics and non-Hispanic Whites.

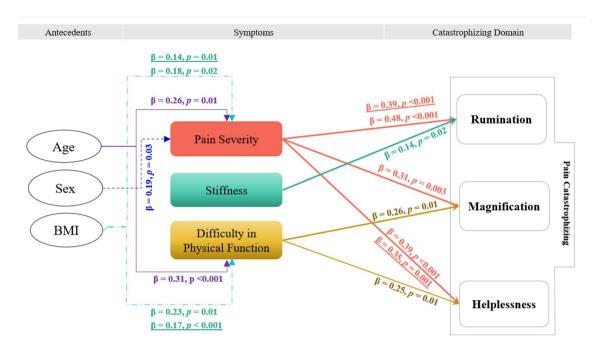
# **Methods**

All procedures for this cross-sectional study were approved by the University of Miami Institutional Review Board (#20,190,389) in 2019, and a data-sharing agreement was signed between University of Miami and Indiana University. Patients presenting to the practitioner's Sports Medicine Clinic (TMB) with a chief complaint of knee pain were considered for enrollment. To be eligible to participate in this study, patients were required to be age ranged 18-75 years old along with at least one of the following symptoms: knee stiffness, pain, or swelling lasting more than 3 months. From there the KL grading system (0-4) was applied to each subject using standard radiographs (AP standing, lateral, merchant). Participants were excluded if they had a previous fracture of the tibia/fibula or femur resulting in surgery, previous anterior cruciate ligament (ACL) reconstruction, previous microfracture or chondroplasty, known inflammatory arthritis (rheumatoid, psoriatic arthritis), intraarticular knee injection within 3 months of initial appointment and entry to study. Upon agreeing to participate using a written consent form, patients accessed an online survey via Research Electronic Data Capture (RedCap), a secure web application for building online surveys and databases. Participants completed the survey online at the clinic, where one of the investigators fluent in both Spanish and English (DQ) was present to address any questions.

#### Measures

The measures for the survey included the Osteoarthritis Index (WOMAC), pain catastrophizing scale (PCS), and demographic variables.





**Fig. 1** The conceptual model for determining pain catastrophizing among Hispanics and non-Hispanics Whites with Knee OA. The figure depicts pain catastrophizing outcomes (rumination, magnification, helplessness) predicted by WOMAC domains (pain severity, stiffness, difficulty in physical function). WOMAC domains are controlled by antecedents. β denotes standardized parameter estimates.

Non-significant pathways (p>0.05) have been omitted for clarity. Underlined equations represent non-Hispanic Whites, and non-underlined equations represent Hispanics. Different dashes are presented to distict the path from each anticidents into the WOMAC domains for more clarity

#### Osteoarthritis index

The WOMAC scale [22] was administered to characterize symptomology of KOA. The categories in this scale included pain severity (3 items), stiffness (2 items), and difficulty in daily functionality (17 items), which were rated on a Likert scale from non = 0 to extreme = 5 [23]. A total score for each sub-construct ranged from 0-15 for pain, 0-10 for stiffness, and 0-68 for difficulty in functioning during activity.

### Pain catastrophizing

The Pain Catastrophizing Scale (PCS) was employed to measure the three domains of pain catastrophizing that include rumination (4 items), magnification (3 item), helplessness (6 items) which were rated on a 4-point Likert scale (0 = not at all, to 4 = all the time) with total score ranged from 0–52. The PCS is a commonly used measure that has demonstrated strong reliability parameters [8, 9].

#### **Demographic variables**

The demographic section of the survey included questions regarding their age, sex, race and ethnicity, height, and weight.

Radiographic (Objective variables) OA grade was determined by treating physician (TMB) using the Kellgren-Lawrence (K-L) grading system, which is a common approach for categorizing the severity of osteoarthritis (OA) using five grades (0 no pathology on X-ray to 4 -severe findings on X-ray concerning for OA. The severity of findings on imaging was determined by (TMB) a fellowship-trained physician.

# Statistical analysis and model construction

Descriptive data of the patients and scores for each domain were computed using IBM SPSS Statistics for Windows, Version 28.0 [24]. Normality tests were conducted by computing the skewed and kurtosis values of the data. According to Field 2018 criteria [25], scores less than 1.96 indicate that the data pattern is within a normal range. Prior to hypothesis testing, demographic characteristics were compared by conducting ANOVAs (continuous variables) or Pearson's chi-square test (categorical variables). We then constructed a model that controlled for the aforementioned covariates including age, gender, and education. The model was constructed using structural equation modeling via Amos (Version 22.0) [Computer Program]. Chicago: IBM SPSS [26]. Full information maximum likelihood estimation was implemented to test the validity and predictive power of the



proposed conceptual model. The model (Fig. 1) was developed by setting pain catastrophizing outcomes (rumination, magnification, helplessness) predicted by WOMAC domains (pain severity, stiffness, difficulty in physical function). WOMAC domains, in turn, were controlled by antecedents. Missing data were handled using hierarchical regression imputation [27]. This modality was deemed appropriate as the MCAR test revealed that the data were missing at random (MCAR  $\chi 2 = 480.52$ , df = 479, p = 0.742). We used Wolf et al.'s criteria to identify the required sample size to test the model [28]. Power analysis was calculated by including three WOMAC factors, an average of four items per factor, and a factor loading greater than 0.65, which revealed a minimum of 200 patients would be required to test the proposed model. Recommended parameters [29] were observed for assessing model reliability which included Tucker-Lewis Index (TLI > 0.9), comparative fit index (CFI > 0.9), root mean square error of approximation (RMSEA < 0.08), and the standardized root mean square residual (SRMR < 0.08). The Chi square value reflects the congruency between the hypothesized/theoretical and model fit. The Chi square parameter itself is recognized for some limitations [30], though still recommended to report, hence computing TLI, CFI, RMSEA and SRMR provide greater precision on the model fitness [29, 30].

The Tucker Lewis Index (TLI) and Comparative Fit Index (CFI) compare the fit (similarity) between the hypothesized/theoretical model, and the constructed model. These

parameters consider the complexity of the model and degrees of freedom. In contrast, the Root Mean Square Error of Approximation (RMSEA) assesses the discrepancy between the hypothesized/theoretical model and constructed model, specifically the covariance matrix. This parameter estimates the discrepancy per freedom, and hence, lower values reflect lower discrepancy, or better fit. The Standardized Root Mean Square Residual (SRMR) has the same goal as RMSEA but assesses the discrepancy between the observed correlations and the predicted correlations in the model. Hence, lower SRMR values are favorable as they reflect better model fitness [29, 30]. A p-value < 0.05, or a 95% confidence interval that did not cross through zero was considered to be a significant finding.

#### Results

### **Study participants**

Two hundred fifty-three patients completed the study and were used in the analysis. Sample characteristics and descriptive data for main variables are presented in Table 1. The average age was 56.8 years (SD=10.8), 54.7% (n=139) were female, 58.3% were Hispanic (n=148), with an average BMI of 29.6 kg/m2 (SD=7.3). A total of 33.1% (n=82) and 43.7% (n=111) of patients were classified as overweight (BMI=25.0–29.9 kg/m2), and obese (BMI>30.0 kg/m2),

**Table 1** Participant characteristics and descriptive data for main variables

Variables	All patients 253 (100%)	Non-Hispanic 103 (40.7%)	Hispanic 150 (59.3%)	F/Chi square test; P-Value	
Sex, n (%)				$\chi 2 = 0.256$	
Male	112 (44.6)	44 (42.7)	68 (45.9)	p = 0.699	
Female	139 (55.4)	59 (57.3)	80 (54.1)		
Age					
>65, n (%)	63 (25.7)	28 (28.3)	35 (24.0)	p = 0.271	
Mean (SD)	56.8 (10.8)	57.6 (10.8)	56.2 (10.7)	F = 0.929 P = 0.336	
BMI (kg/m <sup>2</sup> ), n (%)					
Normal weight	55 (22.2)	27 (26.5)	28 (19.2)	p = 0.114	
≥Overweight	193 (77.8)	75 (73.5)	118 (80.8)		
Current Pain (VAS	5)				
Mean (SD)	3.90 (2.9)	3.55 (2.8)	4.1 (2.9)	F = 2.51 p = 0.114	
Total WOMAC					
Mean (SD)	25.39 (17.9)	23.92 (17.9)	26.4 (18.0)	F = 1.17 p = 0.280	
Pain Catastrophizii	ng				
Mean (SD)	7.5 (8.6)	6.0 (7.9)	8.5 (8.9)	F = 4.99 p = 0.026*	

Chi-square test was calculated for analyzing percentages, One-way ANOVA test was performed for comparing means. \*p < 0.05



respectively. Normality tests revealed the data to be normal (Skewed: 1.48, Kurtosis: 1.67). All demographic variables were non-significant between ethnicity groups. K-L grade was different between the Hispanics  $(1.7 \pm 1.1)$  and non-Hispanic Whites  $(1.9 \pm 1.2)$ . Pain catastrophizing was found to be significantly higher among Hispanic.

(M=8.5, SD=8.9) compared to non-Hispanic Whites (M=7.5, SD=8.6), F (1, 243)=4.99, p=0.026

#### **Conceptual model**

The measures yielded strong reliability parameters for the present study. The WOMAC scale demonstrated Cronbach's alpha scores of 0.78 for pain, 0.80 for stiffness, and 0.95 for difficulty during functioning in daily activities, with total  $\alpha$ =0.95 for all 24 items. The PCS scale showed internal consistency scores of  $\alpha$ =0.88 for rumination,  $\alpha$ =0.70 for magnification, and  $\alpha$ =0.85 for helplessness, with a total  $\alpha$ =0.93 for all 13 items. Model fit indices demonstrated good fit indices based on multiple criteria that have been depicted in Fig. 1 with values such as  $X^2$ =1103.65, df=574,p<0.001; CFI=0.91; TLI=0.90; RMSEA=0.060, (95% CI=0.055, 0.001); SRMR=0.051. Descriptive statistics and factor loading for the model's constructs have been shown in Table 2.

Supporting our hypothesis, the determinants of pain catastrophizing were different among Non-Hispanics White (**NH**) vs. Hispanics (**H**). For Hispanics, experiencing higher pain was associated with higher rumination (**H**:  $\beta$ =0.48, p<0.001), magnification (**H**:  $\beta$ =0.31, p=0.003), and helplessness (**H**:  $\beta$ =0.39, p<0.001). For non-Hispanic patients, these pathways were significant only for rumination (**NH**:  $\beta$ =0.39, p<0.001) and helplessness (**NH**:  $\beta$ =0.35, p=0.01). Experienced stiffness was associated with higher rumination among Hispanics (**H**:  $\beta$ =0.14, p=0.02). Also, greater difficulty in physical function were associated with magnification (**H**:  $\beta$ =0.26, p=0.01), and helplessness (**H**:  $\beta$ =0.25, p=0.01) only among Hispanics.

The association of antecedents such as age, sex, and BMI with WOMAC's domains also differed among the ethnicities in some of the variables. Among Hispanics, higher age was associated with higher pain severity (**H**:  $\beta$ =0.26, p=0.01) and greater difficulty with physical function (**H**:  $\beta$ =0.31, p<0.001). Sex was associated with higher pain severity only among Hispanics (**H**:  $\beta$ =0.19, p=0.03), with females experiencing higher pain severity. BMI was found to have a significant effect on difficulty in physical function for both Hispanics and non-Hispanics (**NH**:  $\beta$ =0.17, p<0.001, H:  $\beta$ =0.23, p=0.01) and pain (**NH**:  $\beta$ =0.14, p=0.01, H:  $\beta$ =0.17, p<0.001). No other antecedents have any significant effects on WOMAC domains among non-Hispanic Whites (p>0.05).

Table 2 Mean (M), Standard Deviations (SD), and Factor Loadings of Study Items

Indicator	Mean	SD	Factor loading
Rumination 1	0.69	1.02	0.68
Rumination 2	0.51	0.88	0.79
Rumination 3	0.49	0.90	0.87
Rumination 4	0.57	1.04	0.86
Magnification 1	0.75	0.98	0.74
Magnification 2	0.27	0.67	0.61
Magnification 3	0.57	0.93	0.64
Helplessness 1	0.92	1.10	0.61
Helplessness 2	0.43	0.84	0.74
Helplessness 3	0.50	0.86	0.78
Helplessness 4	0.62	0.90	0.72
Helplessness 5	0.39	0.79	0.74
Helplessness 6	0.38	0.81	0.69
Stiffness 1	1.06	1.08	0.64
Stiffness 2	1.1	1.08	1.06
Pain 1	1.06	1.04	0.71
Pain 2	1.8	1.15	0.59
Pain 3	1.07	1.14	0.57
Pain 4	0.72	0.92	0.52
Pain 5	0.95	1.00	0.69
Physical function 1	1.75	1.11	0.58
Physical function 2	1.75	1.14	0.59
Physical function 3	1.29	1.10	0.67
Physical function 4	0.92	1.06	0.59
Physical function 5	1.6	1.24	0.70
Physical function 6	0.94	1.03	0.66
Physical function 7	1.17	1.08	0.75
Physical function 8	0.72	0.98	0.75
Physical function 9	0.85	1.04	0.79
Physical function 10	0.91	1.09	0.81
Physical function 11	0.81	1.00	0.78
Physical function 12	0.78	1.09	0.69
Physical function 13	0.78	1.04	0.70
Physical function 14	0.67	0.95	0.63
Physical function 15	0.92	1.02	0.76
Physical function 16	1.04	1.07	0.80
Physical function 17	0.88	1.04	0.81

Antecedents were found to have an impact on knee OA symptoms with ethnic differences. Among Hispanics, age  $(\beta=0.26, p=0.01)$  and sex (females) predicted pain  $(\beta=0.23, p=0.01)$ . Age additionally predicted difficulty in physical function among Hispanics,  $(\beta=0.31, p<0.001)$ . BMI demonstrated predictive effects for Hispanics and non-Hispanic Whites for pain and difficulty in physical functioning. Figure 1 reports complete regression equations.



# **Discussion**

The aim of this study was to examine ethnic disparities, specifically between Hispanics and non-Hispanic Whites, concerning pain catastrophizing among patients diagnosed with KOA. This aim tested if the proposed pathways from KOA symptoms domain (pain, stiffness, and physical function) to pain catastrophizing domain (rumination, magnification and helplessness) were distinct between the two racial groups. The findings showed Hispanics reported higher on pain catastrophizing, despite not having different radiographic severity of OA (K-L grade) compared with their non-Hispanic White counterparts. Moreover, testing the proposed pathways revealed both common and unique patterns among the two racial groups. Specifically, it was found that pain intensity was associated with pain catastrophizing in both racial groups. However, the physical function score exhibited a significant association with pain catastrophizing exclusively among Hispanics. These findings highlight the significance of addressing physical dysfunction by healthcare providers as an important symptom among Hispanics. Addressing physical dysfunction is essential, as it may contribute to the reported disparity in pain catastrophizing [14].

Overall, the conceptual model supported the hypothesized effects and revealed patterns that could be informative for understanding patients and recognizing sources of pain catastrophizing. For both racial groups, rumination and helplessness components of pain catastrophizing were positively associated with pain level. This finding is supported and can be explained by the Transactional Model of Stress and Coping [31] to the extent that when individuals cannot effectively cope with an experienced pain, it could lead to a sense of helplessness or engaging in repetitive negative thoughts, or rumination [32]. However, it is worth noting that higher magnification was only associated with higher pain among Hispanics. This finding is important because strong magnification can represent perceived threats [31] that can impact patients' overall health and quality of life through increasing excessive caution in daily activities [33]. Consequently, this effect might result in kinesiophobia, which is defined as fear avoidance of physical activity related behavior [34], thus placing these individuals at higher risk of disability. Moreover, magnification is regarded to be one of the vital domains of pain catastrophizing because it is considered to be a contributing factor to health-related quality of life, physical health, and depression [31]. These findings are congruent with previous studies which documented specific symptomatology among different factors including race, ethnicity, age, gender, and BMI [14, 35].

The observed distinct pattern of association between physical function and pain catastrophizing among

Hispanic patients brings attention to the possible importance of developing interventions for improving physical function by healthcare providers as apart of standard clinical symptom management for individuals with KOA. Physical function is a core foundation of daily human activities, and its decline is recognized as a strong predictor of future disability [36]. While previous research has investigated pain catastrophizing as a mediator between race and level of pain [13, 14], our study takes a unique approach by placing KOA symptoms as a mediator between race and pain catastrophizing. This model configuration now highlights the role of KOA different type of symptoms in shaping pain catastrophizing and emphasizes the importance of addressing KOA symptoms such as physical dysfunction. For instance, future interventions could investigate if addressing physical dysfunction using exercise therapy, physical therapy, or exercise prescriptions could result in reduced pain catastrophizing. This could specifically be beneficial for Hispanics as their physical activity participation is lower compared to non-Hispanic white individuals [37], because physical activity is a determinant of physical functionality among people with KOA [38-42].

The model also revealed potential confounders in regards to pain catastrophizing and KOA symptoms between Hispanics and non-Hispanic White participants, highlighting similar BMI patterns but distinct variations in age and sex, which were linked to symptoms indicative of more severe KOA. Higher BMI poses a set of challenges for individuals with KOA, perhaps most importantly faster progression of the disease [43, 44]. This may explain why patients with higher BMI from both ethnicities experienced increased pain severity and difficulty in physical function. The importance of weight management as part of self-management behavior among patients with KOA is highlighted by several governing bodies and associations such as the American College of Rheumatology and the American Academy of Orthopedic Surgeons, 2021 [45, 46]. Antecedents that were significant among Hispanics in our study included age and gender, which indicate that those who were female and older experienced higher pain and greater difficulty in physical functionality compared to their non-Hispanic White counterparts. Our finding aligns with existing literature that indicates Hispanic women and older adults report higher levels of pain [14]. This disparity in pain among women and older adults Hispanics is attributed to various factors such as limited access to healthcare due to insurance constraints, greater family responsibilities, and a tendency to rely on homeopathic therapies, which could potentially impact disease progression and treatment outcomes [14].



# Strengths and limitations

The current study presents some valuable strengths, along with some limitations to guide future investigations. The study hypotheses were investigated using a cross-sectional design, which limits the interpretation of findings beyond associated effects. Future work should utilize a longitudinal design approach to confirm our initial findings. A notable strength of the current study is the sample size of KOA patients which allowed sufficient power to conduct comparative model analyses that include associations between antecedents and symptoms, and symptoms with pain catastrophizing. Relatedly, the methodological approach, which employed a conceptual model that was analyzed using structural equation modeling provides robustness in the results. The singular model that was able to simultaneously conduct comparative pathways is superior to models of regression which could inflate type 1 error. Additionally, model tests which comprise and determinants control for each other, provide more accurate effects [47]. The findings yielded from the model begin to chart a course for identifying which components of KOA symptoms need to be addressed to reduce pain catastrophizing based on ethnicity.

# **Clinical implications**

The findings from this study can be informative for clinicians when treating patients with KOA. Focusing on improving physical function as a complementary approach to pain medications might be instrumental in reducing pain catastrophizing among Hispanic patients. Healthcare providers should also consider referring patients to specialized sport medicine clinics and physical therapy facilities to target and increase physical activity levels. Enhancing physical function in turn can empower patients to engage in daily activities with greater ease and reduced discomfort, thus might influence their perception of pain and pain catastrophizing.

#### **Conclusion**

The conceptual model which placed KOA experience as the focal point permitted for the evaluation of possible associations with pain catastrophizing, and with antecedents. Our findings revealed that Hispanics and non-Hispanic White patients display both similar and distinct associations. The present results support further investigations in two directions. First, understanding the causes of pain catastrophizing is informative for physicians to understand psychological barriers experienced by their patients, which may be helpful for prescribing physical activity and increasing the

likelihood of sustained compliance. Second, future research utilizing a behavioral model to investigate how pain catastrophizing may limit physical activity participation would be informative for designing novel, culturally sensitive interventions for patients with KOA.

Data availability Data is available upon reasonable request.

#### **Declarations**

Ethical Approval The study received IRB approval from (Masked for review.

Human and animal rights Not applicable.

**Informed Consent** All participants completed an informed consent prior to participating.

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