Variables Describing Individuals With Improved Pain and Function With a Primary Complaint of Low Back Pain: A Secondary Analysis

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Abstract

Objectives: The purpose of this study was to identify descriptive factors in individuals with a primary complaint of low back pain (LBP) associated with improved pain and function after receiving physical therapy for LBP with or without manual therapy and exercise directed at the femoroacetabular joints.

Methods: Participants were enrolled in a randomized clinical trial investigating physical therapy interventions for their LBP, with or without interventions directed at the femoroacetabular joints (hips). A participant was deemed recovered if all of the following were met: Numeric Pain Rating Scale (NPRS) score of ≤2 points, ≤10% on the modified Oswestry Disability Index at discharge, and a global rating of change score of +4 at both 2 weeks and discharge. Logistic regression modelling determined descriptor variables that best predicted treatment recovery.

Results: Data from 90 participants were included in the analysis, with 44% (n = 40) achieving recovery by discharge from physical therapy (average 7.95 [±4.68]) visits. The variables of concurrent hip problems, lower body mass index ≤25.4, an irritable condition, and a baseline NPRS score of 4 points or less were retained in the final model (R^2 = .384). Having a concurrent hip problem had the highest odds of achieving recovery in the model (odds ratio: 5.34, 95 % confidence interval: 1.31-21.8).

Conclusions: The findings for the patients in this study suggest that those with a concurrent hip problem, a lower body mass index, irritable symptoms, and a baseline NPRS score of 4 points or less were associated with greater odds of achieving recovery with multimodal physical therapy interventions. Further research should continue to investigate the interplay between the lumbar spine and hip joints. (J Manipulative Physiol Ther 2018;41:467-474)

Key Indexing Terms: *Low Back Pain; Rehabilitation*

Introduction

Low back pain (LBP) is common among adults worldwide, with a global point prevalence of 9.4%.[1] Low back pain ranks highest for years lived with disability among all health conditions, and sixth for overall burden, according to the Global Burden of Disease study.[1] One possible contributor to LBP symptoms is the hip joint. In 1983, Offierski and MacNab coined the term "hip-spine syndrome" to describe the relationship between degenerative lumbar spinal stenosis and osteoarthritis of the femoroacetabular joints.[2] This association has been further supported by a study demonstrating a significant association between radiographic morphology of osteoarthritis of the femoroacetabular joints (hips) and degeneration of the lumbar spine.[3] Intervention studies have shown that

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patients who have a total hip arthroplasty for osteoarthritis experienced a significant reduction in LBP and disability[4] and that nonsurgical physical therapy interventions targeting 1 or both hips for individuals with LBP may improve outcomes for LBP.[5-7]

Bade et al randomized participants with a primary complaint of LBP to receive either a pragmatic LBP treatment approach only vs pragmatic LBP treatment plus a prescriptive set of manual therapy and exercise specifically targeting 1 or both hips.[7] The results of this trial demonstrated small to moderate effect sizes for LBP and disability favoring a multimodal physical therapy regimen that included intervention targeting the hips. The perceived global rate of improvement and patient satisfaction were higher in the group that received the hip intervention in addition to treatment targeting their LBP.

Given that there is emerging evidence indicating that intervention for the hips may be beneficial for some individuals with LBP, the authors aimed to investigate if there were any baseline characteristics that would assist with identifying which individuals with LBP may respond more favorably to physical therapy interventions targeting the hips. The purpose of this investigation, therefore, was to identify a set of potential descriptor baseline characteristics that assist in identifying individuals who are likely to achieve recovery after multimodal physical therapy interventions targeting their LBP with or without interventions targeting the hips.

Methods

Participants

The study sample was from a previous randomized clinical trial investigating the effects of 2 different treatment regimens: pragmatic physical therapy for LBP only compared to pragmatic physical therapy for LBP with the addition of prescriptive hip manual therapy and exercise (NCT01900925).[7] The present study utilized data from this previous trial that enrolled consecutive participants (n = 90) presenting to physical therapy clinics with a primary complaint of LBP from September 2013 to September 2015. All participants provided informed consent. The trial was approved by the Walsh University Institutional Review Board (protocol 13-41), while this secondary analysis was approved by the University of Newcastle's Human Research Ethics Committee (protocol H-201-0078).

The participants were recruited during routine clinical practice at multiple physical therapy sites, including hospital-based centers, outpatient private locations, and university locations. The locations of data collection included 5 within the United States and 1 at an international location in Santiago, Chile. Inclusion criteria were age ≥18 years, ≥20% on the modified Oswestry Disability Index (ODI), baseline score on the Numeric Pain Rating Scale (NPRS) ≥2 out of 10 points, and participants needed to demonstrate a within-session change (improvement) in pain or range of motion during the examination. Exclusion criteria were the presence of red flags (ie, metabolic disease, tumor, rheumatoid arthritis, osteoporosis, prolonged history of corticosteroid usage), signs of nerve root compression (straight leg raise ≤45°, myotome lower extremity muscle weakness, diminished sensation, and deep tendon reflexes), prior lumbar surgery, or current pregnancy.[7]

Study Design

Original Study. Background information on the original study is provided to give context to the current study. In the original study, eligible participants were randomized to receive pragmatic interventions targeting the LBP only or to receive a pragmatic LBP treatment plus a prescriptive set of manual therapy and therapeutic exercises targeting both hips.

Upon enrollment in the study, participants gave informed consent, completed baseline questionnaires and medical screening forms, and underwent a physical examination of their lumbar spine and hip regions. Participants completed a medical intake form and provided baseline measures for the modified ODI and NPRS. Figure 1 depicts a flow diagram of the original study.

Each participant received a standardized history and physical examination by the physical therapist. Each physical therapist involved in data collection received training on the examination procedures prior to beginning data collection. Further details regarding the examination procedures can be found elsewhere.[7] The primary outcome measures included the modified ODI and NPRS scales. These outcome measures were administered at each time point, including baseline, 2 weeks, and discharge. Secondary outcome measures, including global rating of change (GROC), were collected at 2 weeks and discharge (average 7.95 [±4.68]). Full descriptions of these outcome measures can be found elsewhere.[7]

Participants who were enrolled in the original study were randomized to receive pragmatic LBP only interventions that were at the discretion of the treating physical therapist. Participants that were randomized to the pragmatic LBP plus hip manual therapy and exercise group received a pragmatic approach to the interventions for the LBP plus a series of therapeutic exercises and nonthrust passive joint mobilizations directed at the hips. The nonthrust mobilizations for the hip included 3 30-second bouts of grade III-IV oscillatory movements, including long axis distraction, anterior to posterior and posterior to anterior accessory movements in a combined position of flexion, abduction, and external rotation.[8] The therapeutic exercises included side-lying resisted hip external rotation with hips and knees flexed ("clamshells"), quadruped unilateral hip extension, and hook-lying unilateral bridging.[7]

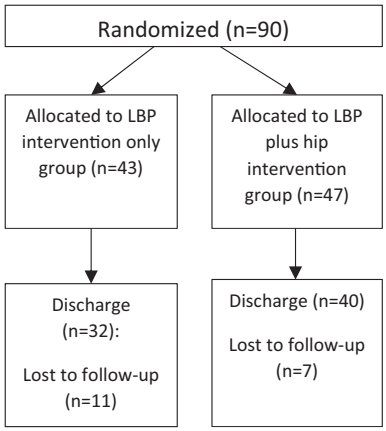

Fig 1. *Flow diagram for clinical trial.* LBP*, low back pain.*

Current Study. In the present study, the authors aimed to identify a set of descriptor variables in a sample of participants undergoing treatment for their LBP symptoms. Initially, the authors determined what would be a clinically meaningful outcome for individuals seeking physical therapy for their primary complaint of LBP. In accordance with the Outcome Measures in Rheumatology criteria, the authors want to have a terminal endpoint that represented a credible and meaningful outcome to both participants and physical therapists.[9]

Prior to data analysis, a multi-contextual model of recovery was developed, which was used to dichotomize participants as "recovered" or "not recovered" for the analyses of potential descriptor variables. The multi-contextual model of recovery included the 2 primary outcome measures from the original study, the modified ODI and NPRS, along with the GROC score. To be considered as recovered, a participant needed to score ≤10% on the modified ODI and ≤2 on the NPRS at discharge and record a GROC score ≥+4 at both 2 weeks and discharge (average of 7.95 [±4.68]). Participants had to achieve all 4 of these variables to be considered recovered.

For the present model of recovery, the authors selected a terminal outcome score, as opposed to a change score, for modified ODI and NPRS because the authors believe these represent a participant that has recovered from his or her symptoms and may no longer require physical therapy intervention. All participants had a baseline modified ODI of ≥20%; therefore, a terminal outcome of ≤10% represents at least a 50% improvement in perceived disability. The average baseline modified ODI score was 36.5%, so having a terminal score of ≤10% represents a substantial change from baseline. The inclusion criteria for NPRS was ≥2 points, with the average being 5.25 points. A 2-point change on the NPRS is considered clinically meaningful.[10] Despite recent controversy surrounding the GROC, particularly around the validity and stability of this measure, a stable GROC score of +4 or higher at 2 weeks and discharge was used to ensure there was stability of participant perceived recovery. For example, if a participant reported a +5 GROC at 2 weeks, but a +3 at discharge, this would be deemed "not recovered."

Data Analysis

In the original study, both of the treatment groups had improvements in the primary outcome measures. In the present analysis, both groups were included, consistent with multivariable recommendations.[11] Less than 10% of the original data was missing for the variables used in this investigation. Multiple imputation procedures were used to handle missing values after analysis of missing data using Little's missing completely at random test.[12] Participants were categorized into "recovered" or "not recovered," and descriptive statistics were calculated. A P value ≤ .05 was considered significant. Pearson's χ^2 was used to determine correlations between potential descriptor variables and outcome measures. Independent t tests examined differences between groups. During univariate analysis, a significance level of 0.15 was used to enter the model or if the variable had particular interest to the research question. After univariate analyses, a maximum of 10 variables were selected for the backward logistic regression to avoid overfitting the model. All variables entered into the model were screened for collinearity, and if a correlation coefficient of 0.40 was obtained, those variables were removed from the model. No variables that were selected after univariate analyses were over the 0.40 threshold.

Ultimately, 10 variables were entered into the model that demonstrated appropriate statistical value, have been previously cited in the literature, or were deemed clinically sensible. The variables of body mass index (BMI), irritability status, and previous similar injury were all included, as previous studies have shown a link with these factors and prognosis with physical therapy interventions.[13,14] The variables of group allocation and concurrent hip pain were included in the model based on the original study results.[7] The variables of age, sex, and duration of symptoms were included, mainly for clinical sensibility.[15,16] Group allocation was forced into the model because it was found to be significant in the original randomized clinical trial.[7] The 9 additional variables included age, sex, irritability status (defined as "yes" or "no" by the treating therapist), duration of symptoms (weeks), previous similar injury (yes or no), BMI, presence of a concurrent hip problem (defined as having pain in either hip or if any LBP symptoms were reproduced with hip examination), baseline modified ODI, and baseline NPRS less than 4 points. Table 1 outlines the univariate associations of each variable. The potential descriptor variables were entered into a stepwise logistic regression model to determine those that were associated with being recovered. After the final model was determined, receiver operating curves were used to

Table 1. *Univariate Associations for All Variables Entered in the Logistic Regression Model by Success on the Recovery Model*

Variable	Independent *t* Test	Pearson χ^2
Age (y)	0.83	–
Body mass index	<0.01	–
Duration of symptoms (wk)	0.43	–
Baseline Oswestry Disability Index	0.74	–
Group allocation	–	0.50
Sex	–	0.62
Irritability status	–	<0.01
Previous injury	–	0.51
Concurrent hip problem	–	0.06
Baseline Numeric Pain Rating Scale of 4 points or less	–	0.30

determine the cutoff point for continuous variables. Nagelkerke R^2 was used to determine the amount of variation explained by the descriptor variables. Odds ratios with 95% confidence intervals (CIs) were reported to indicate the odds of a successful response to either intervention group.

Data were analyzed using IBM SPSS Statistics version 23 (IBM Corp, Armonk, New York). All reporting methods followed the Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis guidelines.[17]

Results

Baseline demographic information for all participants in the original trial are located in Table 2. The sample was predominantly middle aged (mean age = 46 ± 16.1 years), with greater numbers of men (n = 53) than women (n = 37), and most had moderate levels of pain (mean = 5.25 ± 1.85) and perceived disability (mean modified ODI = 36.5% ± 12.2%) (Table 2). Forty-four percent (n = 40) of the sample achieved success according to this model of recovery after an average of 7.95 (±4.68) visits. Table 3 depicts descriptive statistics for individuals based on their recovery status.

Four variables were associated with recovery: the presence of a concurrent hip problem, BMI, irritability status, and a baseline NPRS score of 4 or less, with the final model explaining 38% of the variance in recovery (Table 4). The presence of a concurrent hip problem had the largest odds ratio (OR) of 5.34 ($P = .02$), indicating that having a concurrent hip problem made an individual 5.34 times more likely to be defined as recovered, regardless of group allocation. Body mass index had an OR of 0.840 ($P < .01$), indicating a lower BMI score was associated with improved odds of recovery. Using receiver operating curves, a BMI score of 25.4 or less was associated with improved odds of recovery. A baseline NPRS score of 4 points or less was also significantly associated with improved odds of achieving recovery, with an OR of 4.99 ($P = .01$). A clinical presentation that was deemed to be irritable by the treating physical therapist at baseline examination was also significantly associated with increased odds of recovery (OR = 3.63; $P = .03$). The variable of irritability status has also been found to be predictive of response to physical therapy

Table 2. *Descriptive Statistics for Whole Sample (Recovered and Nonrecovered)*

Total, N = 90	n (%)
Sex	
Male	53 (59)
Female	37 (41)
Concurrent hip problem	
Yes	15 (17)
No	75 (83)
Similar previous injury	
Yes	50 (56)
No	40 (44)
Symptoms considered irritable	
Yes	41 (46)
No	49 (54)
Baseline NPRS	
5 or higher	60 (67)
4 or less	30 (33)
	Mean (SD)
Age (y)	46 (16.1)
Body mass index	26.2 (6.84)
Baseline modified Oswestry Disability Index	36.5 (12.2)
Baseline Numeric Pain Rating Scale	5.25 (1.85)
Duration of symptoms (wk)	20.4 (46.1)
Number of visits to discharge	7.95 (4.68)

NPRS, numeric pain rating scale; *SD*, standard deviation.

Table 3. *Descriptive Statistics for Recovered and Nonrecovered Groups*

	Recovered (n = 40)	Nonrecovered (n = 50)
	X (SD)	% (SD)
Age (y)	46.0 (16.5)	46.7 (15.5)
Body mass index	26.6 (4.14)	28.4 (7.72)
Baseline modified Oswestry Disability Index (%)	36.1 (10.6)	36.9 (13.2)
Duration of symptoms (wk)	15.9 (47.7)	23.5 (44.1)
	Success (n = 40)	Nonsuccess (n = 50)
Irritable (yes)	61%	33%
Male sex	56%	61%
Similar previous injury (yes)	60%	53%
Concurrent hip problem (yes)	25%	10%
Baseline Numeric Pain Rating Scale of 4 points or less	17%	16%

SD, standard deviation.

Table 4. *Odds Ratios, Confidence Intervals, and* P *Values of Variables Retained in Final Model to Predict Recovered From Physical Therapy Intervention (R^2 = .384)*

Descriptor Variable	Odds Ratio (95% CI)	*P* Value
Presence of a concurrent hip problem	5.34 (1.31-21.8)	.02
Body mass index	0.84 (0.75-0.94)	<.01
Irritability status	3.63 (1.16-11.4)	.03
Baseline Numeric Pain Rating Scale of 4 points or less	4.99 (1.41-17.7)	.01
Group	0.50 (0.18-1.44)	.20

CI, confidence interval.

interventions in other studies.[13,14] Group allocation was not significant when using this model of recovery (P = .20).

Discussion

In individuals with a primary complaint of LBP, a set of descriptive variables was identified to assist with determining the chances of an individual recovering from their symptoms. The descriptive baseline factors included the presence of a concurrent hip problem, BMI ≤25.4, having a condition deemed to be irritable, and baseline pain of 4 points or less. All of these variables were associated with improved odds of achieving recovery at discharge from physical therapy for individuals with a primary complaint of LBP. Group allocation did not achieve significance in this study but was significant in the randomized clinical trial.

In the present study, the authors set a multicontextual model of recovery that included discharge modified ODI score of ≤10%, discharge NPRS ≤2 points, and a GROC score ≥+4 for both 2-week and discharge time points. The authors believe that this type of outcome would represent a successful outcome in clinical practice and may result in the patient discontinuing physical therapy. The entire sample had a baseline mean modified ODI score of 36.5% and a baseline mean NPRS of 5.25 points. The threshold for recovery was set for these outcome measures to represent a robust terminal outcome in both domains.

In the final model, the variable of BMI ≤25.4 was retained and is consistent with other literature. Using the BMI classification set by the World Health Organization, in which 25 to 29.9 is considered overweight and ≥30 is obese, the results indicate that individuals at the lower end of overweight or below tended to have improved odds of recovery.[18] Other research has concluded that overweight and obesity are risk factors for having LBP with or without leg symptoms, as well as having increased odds of being hospitalized and having surgery for a lumbar disc herniation.[19,20] In a cross-sectional study, Suri et al indicated that a BMI of ≥35.0 was associated with an increased lifetime prevalence of chronic LBP.[21]

The present findings indicate that a baseline NPRS rating of 4 points or less was associated with improved odds of achieving recovery with an OR of 4.99 (95% CI: 1.41-17.7). High baseline pain ratings have shown decreased odds of recovery after spinal surgery in children, and they tend to result in suboptimal outcomes in individuals with subacute LBP.[22,23] These results are similar to the findings in that individuals with higher levels of baseline pain may have reduced chances of achieving recovery. While pain intensity is an important clinical marker, the irritability status may also play a role in a person's recovery. Irritability status was originally defined by Maitland and has 3 main components.[8,24,25] First is how vigorous the activity is that provokes the person's symptoms, second is the severity of intensity of the person's symptoms, and finally the time required for the symptoms to return to baseline. The therapist dichotomizes their response regarding irritability status as either "present" or "not present." Barakatt et al found acceptable reliability in physical therapist assessment of patient irritability (K = 0.44).[25] The 2 variables of pain intensity and irritability status are closely related, and in the present study, participants with an irritable condition were 3.6 times more likely to achieve recovery at discharge (OR = 3.63, 95% CI = 1.16-11.4). This finding is contrary to the results

reported by Cook et al, who found that no irritability at baseline was more associated with a positive response to physical therapy.[13] These conflicting findings may be explainable by the concept of regional interdependence. When a patient is more irritable, a therapist may apply a concept of regional interdependence and choose to perform interventions at an adjacent region that may influence the primary complaint.[26,27] It is possible treating both the hip and lumbo-pelvic regions for individuals that were deemed irritable may contribute to this result. In addition, the pragmatic nature of the treatment to the lumbar spine may have allowed for the treating therapist to select interventions that were more in line with the expectations of the patient and, therefore, indirectly influenced the results. Donaldson et al found that patients with irritable LBP symptoms considered nonthrust mobilizations to the lumbar spine would be more effective for their condition.[14] It is unknown in the original clinical trial which interventions were performed with regards to participants' irritability status.

One of the most interesting findings of this trial was that having a concurrent hip problem had the largest OR of 5.34 (95% CI: 1.31-21.8). A concurrent hip problem was operationalized by an individual through either the provision of a musculoskeletal diagnosis of the hips or having hip pain reproduced during the physical examination of the hip. Individuals with a primary complaint of LBP and a concurrent hip problem tended to respond more favorably to a multimodal physical therapy intervention package targeting either the lumbar spine only or lumbar spine plus 1 or both hips. The role of a concurrent hip problem in individuals with LBP needs additional research to determine if they are more likely to respond to physical therapy interventions directed at the lumbar spine only or lumbar spine and hips. Caution needs to be taken with interpreting this result because of the wide CIs and because only 16.7% of the sample had a concurrent hip problem at baseline examination. Indeed, each variable in the model, with the exception of BMI, had wide CIs and should be interpreted cautiously. While the ORs are moderate, the wide CIs indicate that further study is required regarding the role of these variables in the clinical treatment of patients with LBP.

An additional area of concern that warrants cautious interpretation of the results is the use of the GROC as an outcome variable in the model of recovery.[28-30] In the definition of recovery used in this study, the authors utilized the GROC scores at both the 2-week and discharge time points to ensure stability of this measure over time. Given the concern that this measure may not be valid or stable, particularly over time, the authors aimed to ensure that a GROC was consistent across multiple time points. Schmitt and Abbott demonstrated modest correlations of GROC and functional status for individuals with knee pain and that there was a strong recall bias with the GROC toward discharge status.[30] The model used for this analysis uses a consistent score of a +4 or higher on the GROC and represents a stable and clinically meaningful component of a successful outcome for participants with LBP. In clinical practice, individuals may have a strong initial response to physical therapy intervention that then decreases over time, or they may start with a slower response but report high global ratings by discharge. The latter is the concern that has been raised by multiple authors regarding the use of the GROC because it only demonstrates perceived improvement at 1 time point, which may be situated near the end of care and may be inflated secondary to its positioning in the course of care.[30] By requiring the GROC score to be +4 or higher at both time points, the authors believe this will account for individuals who do not demonstrate stability in this rating and limit the bias that may be present with this measure.

Limitations

In the original clinical trial, a pragmatic approach was utilized for the treatment of the lumbar spine in both groups. The exercise program for the LBP plus hip group in the original trial may have had some potential crossover and impact the strength of the trunk musculature. The pragmatic nature of the interventions could have led to wide variation in treatments rendered. In addition, all of the treating therapists had advanced manual therapy training, thus may have provided a greater emphasis on the manual therapy techniques during the treatment sessions, which may not reflect typical clinical practice. This may limit the generalizability to the general physical therapy population. In addition, clinical or personal equipoise was not tracked in this study and may have influenced the outcomes unintentionally.[31] Furthermore, other interventions rendered during the treatment sessions may be variable between patient and therapist. For example, the educational component of the interventions was not controlled in the clinical trial, which may have a significant influence on outcomes.[32] Further research is required to determine whether interventions targeting these variables may result in improved outcomes for individuals with LBP.

There are some limitations to the data analysis in the current trial. It has been suggested that 10 to 15 participants per variable is an appropriate boundary to meet the statistical assumptions for regression analysis.[33,34] The authors have approximately 9 participants per variable, which may violate assumptions; however, Vittinghoff and McCulloch have suggested that the 10 events per variable may not be required in all cases.[35] In addition, just under 10% of the data was missing prior to the analysis, and using multiple imputation methods may have unduly altered the results. Moreover, the stepwise Backward-Wald method of logistic regression method of analysis is also a limitation. This method of analysis has questionable reliability and may result in an explanatory variable being incorrectly left out of the model.[36] This method of analysis was used, as it allows for initial variable selection and eliminates a variable in a stepwise fashion, as the variable does not contribute to model fit.

Concurrent hip problem, BMI, and irritability can all be targeted with interventions by physical therapists.

Conclusion

This study investigated factors that may influence recovery in individuals with a primary complaint of LBP. Lower BMI, having a concurrent hip problem, the presence of symptom irritability, and a lower baseline pain score improved the odds of achieving full recovery with multimodal physical therapy interventions for patients with a primary complaint of LBP.

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No funding sources or conflicts of interest were reported for this study.

Contributorship Information

Concept development (provided idea for the research): S.A.B., J.A.C., C.E.C., M.B., D.A.R., S.S.
Design (planned the methods to generate the results): S.A.B., J.A.C., C.E.C., S.S.
Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): S.A.B., J.A.C., C.E.C., M.B., D.A.R., S.S.
Data collection/processing (responsible for experiments, patient management, organization, or reporting data): S.A.B., M.B.
Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): S.A.B., J.A.C.
Literature search (performed the literature search): S.A.B.
Writing (responsible for writing a substantive part of the manuscript): S.A.B.
Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): J.A.C., C.E.C., D.A.R., S.S.

Practical Applications

- Having a concurrent hip problem in addition to the primary complaint of LBP had greatest odds of achieving recovery.
- Concurrent hip problem, irritable status, BMI <25.4, and NPRS ≤4 points were associated with improved odds of achieving recovery after physical therapy interventions.
- Identifying these variables in individuals with a primary complaint of LBP may assist a clinician in determining a clinical prognosis with physical therapy.

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