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Pain intensity, physical activity, quality of life, and disability in patients with mechanical low back pain: a cross-sectional study

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Abstract

Background Poorly managed mechanical low back pain (MLBP) and its sequelae, such as severe pain, physical inactivity, and disability, negatively impact patients' quality of life (QoL). The study aimed to determine the pain intensity (PI), physical activity (PA), QoL, and disability, the association between selected sociodemographic variables and PI, PA, QoL, and disability, and the relationship between PI, PA, QoL, and disability among Nigerians with chronic MLBP.

Methods This cross-sectional study employed a consecutive sampling technique. Outcome measures included the Numeric Pain Scale, International Physical Activity Questionnaire-Short Form, WHO Quality-of-Life Brief, and Oswestry Disability Index for PI, PA, QoL, and disability, respectively. Descriptive statistics were used to summarize participants' sociodemographic variables. Chi-square, Spearman's correlation, and structural equation modeling (SEM) were used for inferential analyses.

Results Two hundred and fifty chronic MLBP patients comprising 154 females and 96 males, completed the study. The mean PA, PI, QoL, and disability levels were $1118.03\text{MET} \pm 615.30$, 5.97 ± 2.69 , $73.45\% \pm 14.21$, and $21.7\% \pm 18.94$, respectively. There was a significant correlation between PA and QoL ($\rho = 0.36$, $p = 0.001$), PA and disability ($\rho = -0.42$, $p = 0.010$), QoL and disability ($\rho = -0.21$, $p = 0.008$), QoL and PI ($\rho = -6.72$, $p = 0.025$), PI and disability ($\rho = 0.90$, $p = 0.022$). Aside from age and PA ($\chi^2 = 8.52$, $p = 0.045$), there was no significant association between the sociodemographic variables and PI, PA, QoL, or disability. SEM showed a strong positive association between PI and disability ($\beta = 0.80$, $p < 0.001$).

Conclusion Individuals with chronic MLBP had a low PA, moderate QoL, and significant disability. Incorporating PA, QoL, and disability assessments may enhance the evaluation and management of MLBP.

Keywords Activities of daily living, Low back pain, Nigeria, Physiotherapy, Quality of life

Introduction

Pain is a physiological response to tissue damage. It causes significant neuromuscular, emotional, and psychosocial distress [1, 2]. Lower back pain (LBP) is a

common musculoskeletal disorder experienced by humans [3, 4]. Mechanical low back pain (MLBP) refers to back pain that arises intrinsically from the spinal column, intervertebral discs, or surrounding soft tissues. It includes pain from vertebral compression fractures, lumbosacral muscle strain, disc herniation, lumbar spondylosis, spondylolisthesis, spondylolysis, and acute or chronic traumatic injury [5, 6].

Low back pain was the leading cause of years lived with disability (YLDs) worldwide and is associated with a high disease burden [7]. There was a substantial increase

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in global prevalence from 1990 (386.0 million) to 2019 (568.4 million) [7]. In Nigeria, the 12-month prevalence of LBP was 44%, while the point prevalence was 39%, with the greatest burden accounted for by people living in rural areas [8, 9]. The prevalence of LBP increases with age, and many older Nigerians are rural dwellers [9]. Relative to urban settlements, rurality imposes a huge disadvantage in access to health care, leading to higher disease burdens such as MLBP, disability, and poor quality of life (QoL) [9, 10].

Mechanical low back pain is associated with physical, emotional, and psychosocial distress and has negative socioeconomic consequences for the patients and their community [11]. It reduces an individual's daily functioning capacity, and severe cases may lead to temporal or permanent disability, increasing the health care burden, absenteeism from work, and depletion of the community workforce [12]. Therefore, a comprehensive management plan for MLBP should involve an assessment of PI, PA, QoL, disability, psychological, sociocultural, and economic factors [13, 14]. These parameters have been incorporated into the MLBP management guidelines in some countries [15, 16]. There is a need to replicate such a study in sub-Saharan Africa to inform evidence for adopting these practices [10]. Africans have distinct sociocultural factors that impact their pain threshold, quality of life, and access to care [17]. With a population estimate of about 200 million people, Nigeria is the most populous country in sub-Saharan Africa and the most populous Black nation in the world [18]. Although few studies have assessed the correlation between some of these constructs, the present study further explored the direct and the PA- and QoL-mediated effects of chronic MLBP on disability using a multivariate structural equation model.

The overall aim of the study was to determine the levels and correlates of PI, physical activity (PA), QoL, and disability, among people with chronic MLBP in public-funded hospitals in Anambra State, Nigeria. The study hypotheses were that there would be no significant (i) correlation between PI, PA, QoL, and disability, (ii) association between PI, PA, QoL, and disability and the participants' sociodemographic characteristics, and (iii) direct effect of MLBP on disability while accounting for QoL and PA as mediator variables.

Methods

Study design

This study was a cross-sectional survey, a type of observational study that obtains and analyses data from a population at a specific point in time [19]. A consecutive non-probability sampling technique was used to recruit participants from public-funded hospitals in Anambra State, Nigeria, between May and July 2021.

The institutional Human Research Ethics Committees of the Faculty of Health Sciences and Technology, Nnamdi Azikiwe University, Anambra, Nigeria, approved the study protocol (reference number: NAU/FHST/2021/MRH60). The approved protocol, participants' privacy, and confidentiality of data were strictly adhered to. Participants were informed of their right to withdraw at any point in the study. Each eligible participant signed an individual informed consent form before participating in the study. All methods were carried out in accordance with the guidelines of the World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects [20]. The study was reported following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for reporting cross-sectional studies [21].

Participants and setting

Participants were recruited from persons with chronic MLBP attending physiotherapy clinics in public-funded hospitals in Anambra State, Nigeria. Following the submission of a copy of the approved study protocol, written permission was granted by the physiotherapist heading each clinic to assess the patients who met the inclusion criteria. In Nigerian hospitals, physiotherapy is accessed after initial diagnosis and referral from a primary physician or surgeon [1, 22–24]. Therefore, the participants enrolled in this study were diagnosed by consultant orthopedic doctors and referred to physiotherapy clinics for physical therapy.

Eligibility criteria

Participant inclusion criteria were being (i) diagnosed with MLBP of at least three months duration, (b) attending follow-up physiotherapy appointments in any of the public-funded hospitals in Anambra State, Nigeria, (c) fluent in the English language, and (d) willing to grant an informed consent and participate in the study procedures.

Participants were excluded if they were below 18 years of age, non-ambulant, diagnosed with non-MLBP, neurological or musculoskeletal disorders affecting their ambulation, or acute traumatic back injury. Patients with systemic diseases such as sickle cell disease, complex regional pain syndrome, cancer, chronic kidney disease, cardiovascular diseases, uncontrolled diabetes, patients on corticosteroids, or who had prior spinal surgery or epidural injection within one month before the study were also excluded.

Sample size estimation

The sample size ($n=226$) was calculated using a simple size formula for prevalence studies, $n=(Z^2P[1-P])/d^2$;

where n is the sample size, Z -score = 1.96 (95% level of confidence), d (precision/ effect size) = 0.05 and P (proportion) = 0.82 because the orthopedic-clinic-based prevalence of MLBP in the region was 82% [25]. In anticipation of a 10% incomplete survey response, we recruited 250 participants.

Research instruments and procedures for data collection

Participants' sociodemographic variables of age, gender, marital status, education level, employment, and location were obtained using a bio-data form. The Numeric Pain Scale (NPS) was used to obtain participants' PI on a scale of 0 (no pain) to 10 (worst imaginable pain). The NPS is a convenient, valid, reliable, and responsive measure of pain intensity among people with MLBP [26]. The interclass correlation reliability, $r = 0.99$ [26]. Afterwards, the participants were administered three questionnaires: International Physical Activity Questionnaire Short Form (IPAQ-SF), World Health Organization Quality of Life-Brief (WHOQoL-Brief), and Oswestry disability index (ODI), respectively.

The IPAQ-SF is a reliable, valid, and standardized self-completed questionnaire designed to measure the amount of energy spent on tasks (metabolic equivalent of task [MET]) or duration (minutes) and frequency (days) of physical activity in the last seven days based on the seven domains: job-related activity, active transportation, housework and maintenance, family care, recreation, sport, and leisure-time, and sitting time [27]. The IPAQ-SF was recommended for population prevalence studies, where time is limited because it is easier and more feasible to complete than the long form [27]. The IPAQ-SF was scored by rating PA level as multiples of metabolic equivalent (METs) expressed as MET-min per week, such that walking MET-minutes/week = 3.3 * walking minutes * walking days, moderate MET-minutes/week = 4.0 * moderate-intensity activity minutes * moderate days, and vigorous MET-minutes/week = 8.0 * vigorous-intensity activity minutes * vigorous days. Total PA MET-minutes/week = sum of walking + moderate + vigorous MET-minutes/week scores. Sub-scores can be calculated for walking, moderate-intensity, and vigorous-intensity activities. The total physical activity test-retest reliability of a Hausa (Nigerian) language version of IPAQ-SF was $(r) = 0.61$, and concurrent validity with the English version was $(r) = 0.92$ [28].

The WHOQoL-Brief was used to assess the participants' QoL. It is a standardized, reliable, and valid self-administered questionnaire comprising 26 questions on individuals' perceptions of their physical and physiological health, social relationships, and environmental well-being over the previous two weeks [29]. The responses are based on a 5-point Likert scale

(1 = "disagree" or "not at all" and 5 = "completely agree" or "extremely"). Domain scores were scaled positively such that higher aggregate scores signify a better QoL. Participants' aggregate scores were converted to percentages, expected range (26–130) = 20 to 100%. The test-retest reliability of WHOQoL-Brief was $(r) = 0.95$ [29].

The ODI, a self-completed standardized, valid, and reliable questionnaire, was used to assess disability among the participants. It is a 10-item questionnaire which gives a subjective percentage score of the level of function (disability) in activities of daily living in patients experiencing low back pain. The domains include pain intensity, personal care, lifting, walking, sitting, standing, sleeping, traveling, sex, and social life. Each of the 10 items is scored 0 to 5, giving a total score range of 0 to 50, converted to a percentage (0 to 100%) as described by Fairbank and Pynsent [30]. The ODI is an internally consistent ($\alpha = 0.85$) unidimensional scale with overall excellent construct validity and the ability to discriminate the severity of functional disability [31].

A staff physiotherapist trained as a research assistant in each of the selected hospitals assisted with questionnaire administration and data collection. The questionnaires were retrieved immediately from participants on completion and stored in a sealed brown envelope. At the end of the study, one of the authors retrieved all the completed questionnaires in person. Data were extracted with an encrypted electronic spreadsheet stored in a password-protected flash drive and locked in a drawer at the primary investigator's office till the time of data analysis. All the hard copies of the questionnaire were destroyed immediately.

Variables

The primary outcomes: PI, PA, disability, and QoL, were assessed with appropriate instruments and coded as continuous variables. The primary outcomes were categorized for PI (≤ 3 = mild, 4–6 = moderate, and ≥ 7 = severe pain) [32], PA (< 600 = low, 600–1500 = moderate, and > 1500 high MET) [27], disability ($\leq 20\%$ = mild, 21–40% = moderate, and ≥ 41 = severe disability) [33], and QoL (< 55 = poor, 55–85 = moderate, and > 85 = good QoL, using 70 ± 15 as the normative value [34]. The sociodemographic variable: age (years), was recorded as a continuous variable. Marital status (single = 1, married = 2, divorced/separated = 3, widowed = 4) was a nominal variable. Education level (informal = 1, primary = 2, secondary = 3, tertiary = 4) was considered an ordinal variable. Gender (female = 0, male = 1), employment (no = 0, yes = 1), and location (rural = 0, urban = 1) were dichotomous nominal variables.

Sampling and bias

The probability of sampling bias in the present study is low. The participants were consecutively drawn from eligible participants from all the selected hospitals synchronously. All persons who met the inclusion criteria had a chance to participate in the study. Consecutive sampling is a non-probability sampling technique in which every subject meeting the inclusion criteria is selected until the required sample size is achieved. It is better than convenience sampling in controlling sampling bias [35]. Moreover, the adequate sample size was carefully calculated and met.

Data analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS) version 26. Descriptive statistics such as frequency, percentage, mean, and standard deviation were used to summarize the participants' sociodemographic characteristics. We examined the association between sociodemographic variables and the primary outcomes using Chi-square (χ^2), and the correlation among the primary outcomes using Spearman's correlation coefficient (ρ); because PA data was skew. Finally, we completed a structural equation modeling (SEM) using IBM Analysis of Moment Structure (AMOS) software [36] to explore the direct effect and PA- and QoL-mediated effects of chronic MLBP intensity on disability. The paths' standardized regression coefficients, 95% CI, and *p* values were generated using the maximum likelihood estimation approach. The model's fitness indices threshold were the chi-square ($p > 0.05$), the root-mean-square error of approximation (RMSEA < 0.06), the goodness of fit index (GFI > 0.90), and the Tucker-Lewis index (TLI ≥ 0.90) [36]. The alpha level was set at 0.05.

Results

Participants' sociodemographic characteristics

A total of 250 individuals with MLBP completed the study and were included in the analysis. Table 1 shows the participants' sociodemographic characteristics. The majority of the participants 154 (61.6%) were women, and 127 (50.8%) were aged 50 years and above. Participants were mainly married 146 (58.3%), had secondary education 133 (83.2%), unemployed or retired 173 (69.2%), and resided in the urban area 164 (65.6%).

Univariate analyses: pain intensity, physical activity, disability, and quality of life

The average (mean \pm SD) participants' PI (5.97 \pm 2.69), PA (1118.03 MET \pm 615.30), disability (21.78% \pm 18.94),

Table 1 Participants' sociodemographic characteristics

Variable	Frequency	Percentage (%)
Gender		
Male	96	38.4
Female	154	61.6
Age group		
20–29	18	7.2
30–39	37	14.8
40–49	68	27.2
≥ 50	127	50.8
Marital status		
Single	52	20.8
Married	146	58.3
Divorced	10	4.2
Widowed	42	16.7
Educational level		
Informal	0	0.0
Primary	35	14.0
Secondary	133	53.2
Tertiary	82	32.8
Occupational status		
Employed	77	30.8
Retired/unemployed	173	69.2
Locality		
Urban	164	65.6
Rural	86	34.4

and QoL (73.45 \pm 14.21) were all moderate. Table 2 shows the frequency distribution of participants' PI, PA, QoL, and disability across the categorical levels. Remarkably, a greater number of the participants had low levels of PA.

Bivariate analyses

The chi-square test showed a significant association between PA and participant's age ($\chi^2 = 8.52$; $p = 0.045$) and between educational level and QoL ($\chi^2 = 0.75$; $p = 0.022$). There was no significant difference between other sociodemographic variables and the primary outcomes (Table 3). On the other hand, Spearman's correlation coefficient (Table 4) showed a significant negative correlation between PA and disability ($\rho = -0.45$; $p = 0.010$), but a significantly positive correlation with QoL ($\rho = 0.36$; $p = 0.001$). Similarly, PI had a strong inverse correlation with QoL ($\rho = -6.72$; $p = 0.025$) and a positive correlation with disability ($\rho = 0.90$; $p = 0.022$). Although there were negative correlations between PA and PI and between QoL and disability, these correlations were of low strength and not statistically significant (Table 4).

Table 2 Mean participants' level of physical activity, pain intensity, disability, and quality of life

Domain	Class	Frequency (%)	Mean	Standard deviation	Expected range
Physical activity (MET-min/week)	Low	116 (46.4)	1118.03	615.30	> 600
	Moderate	77 (30.8)			
	Vigorous	57 (22.8)			
Pain intensity	Mild	49 (19.6)	5.97	2.69	0–10
	Moderate	123 (49.2)			
	Severe	78 (31.2)			
Disability (%)	Mild	88 (35.2)	21.77	18.94	0–100
	Moderate	105 (42.0)			
	Severe	57 (22.8)			
Quality of life (%)	Poor	70 (28.0)	73.45	14.21	20–100
	Moderate	133 (53.2)			
	Good	47 (18.8)			

Table 3 Chi-square test for association between pain intensity, physical activity, disability, quality of life, and sociodemographic parameters ($n = 246$)

Variable	Statistics	Physical activity	Pain intensity	Quality of life	Disability
Age group	$\chi^2 =$	8.52	0.89	0.40	2.44
	$P =$	0.045*	0.823	0.654	0.062
Gender	$\chi^2 =$	0.97	0.48	0.88	1.43
	$P =$	0.728	0.632	0.619	0.367
Educational level	$\chi^2 =$	0.82	0.42	0.75	0.72
	$P =$	0.061	0.832	0.002*	0.065

* χ -statistic was significant at $p < 0.05$ (2-tailed test)

Table 4 Spearman's correlation matrix between physical activity, pain intensity, quality of life, and disability ($n = 246$)

Variables	Quality of life <i>rho</i> -statistic <i>p</i> value	Disability <i>rho</i> -statistic <i>p</i> value	Pain intensity <i>rho</i> -statistic <i>p</i> value
Physical activity	0.36 0.001*	-0.45 0.010*	-0.29 0.085
Quality of life	-	-0.21 0.008*	-0.67 0.025*
Disability	-	-	0.90 0.002*

* Spearman's correlation coefficient (*rho*) was significant at $p < 0.05$ (2-tailed test)

Multivariate analyses

Figure 1 shows the standardized regression coefficient for the direct effect of PI on disability and the mediation (indirect) effects of QoL and PA on the path. The SEM met the recommended threshold for fitness indices, $\chi^2(1) = 0.420, p = 0.517, RMSEA = 0.000, CFI = 1.000, TLI = 1.000, GFI = 0.994, \text{ and } AGFI = 0.941$ (Table 5). The direct effect of chronic MLBP intensity (PI) and disability was significant ($\beta = 0.80, p < 0.001$). However, the

direct effects of PI on PA ($\beta = -0.16, p = 0.327$), QoL ($\beta = -0.14, p = 0.396$), and PA ($\beta = -0.09, p = 0.310$) and QoL ($\beta = -0.19, p = 0.022$) on disability, were not significant. The total mediation (indirect) effect of PA and QoL ($\beta = 0.041, p = 0.322$) was insignificant. The SEM results aligned with Table 4, which showed that disability had the strongest correlation with PI.

Discussion

This study aimed to determine the association between sociodemographic factors, pain intensity, physical activity, quality of life, and disability among individuals with chronic MLBP. Although these parameters have been incorporated into the MLBP management guidelines in some countries [14, 15], more sub-Saharan African studies are needed to inform evidence for adopting these practices in the region [10]. The disease burden of MLBP is not limited to biophysical disorders and distress. Instead, psychosocial implications of MLBP can lead to increased sedentary behavior, disability, and poor QoL [13, 14]. Therefore, a comprehensive management plan for MLBP should involve an assessment of PI, PA, disability, QoL, and sociodemographic factors [9, 13]. The

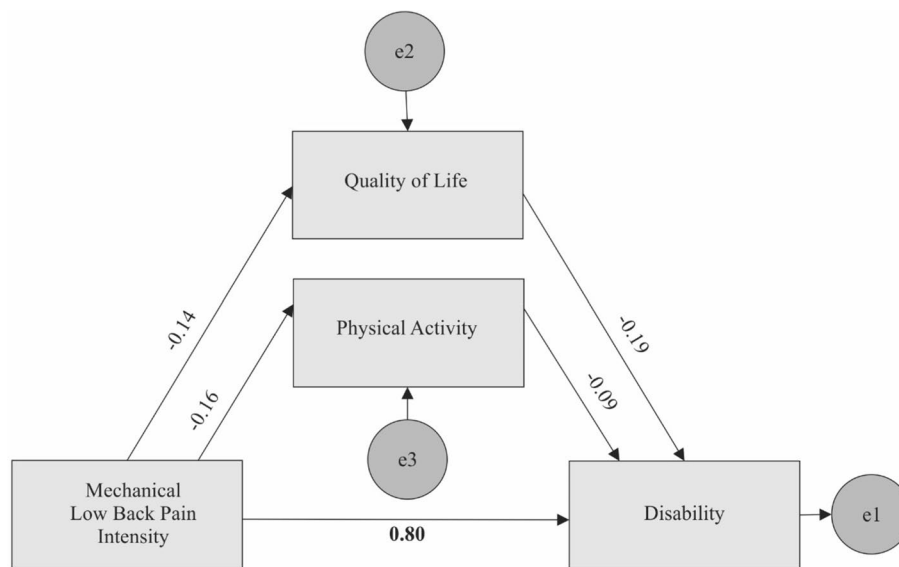


Fig. 1 Structural equation diagram for path analysis of associations between MLBP intensity, physical activity, QoL, and disability

Table 5 SEM fitness indices

Fit indices	RMSEA	CFI	TLI	GFI	AGFI
Present model	0.000	1.000	1.000	0.994	0.941
Acceptable value	< 0.06	≥ 0.900	≥ 0.900	> 0.900	> 0.800
Remarks	Met	Met	Met	Met	Met

RMSEA Root-mean-square error of approximation, CFI Comparative fit index, TLI Tucker-Lewis's index, GFI Goodness of fit index, AGFI Adjusted goodness of fit index

current study went beyond the simplistic analysis of these factors with bivariate models to construct a multivariate structural equation model for a holistic analysis of the constructs.

The goal of any healthcare system is to optimize care, including reduction of pain and disability and improvement of physical functioning and QoL. In the present study, a greater number of the participants recorded a low level of physical activity, moderate levels of pain intensity, disability, and QoL. This outcome was in line with Majedi et al. [37], who reported that most LBP patients with moderate pain intensity also had a moderate disability. The results also concurred with Johansson et al. [38], where most participants recorded moderate pain intensity and low physical functioning. However, the present study's participants had moderate QoL, while those in Johansson et al. [38] had good QoL. Although the average QoL in our study was 73.45%, we used more stringent criteria to categorize the levels of QoL based on the literature [34]. Unlike other instruments that have established cut-off points for their outcomes: NPS [32], IPAQ-SF [27], and ODI [32], there is a paucity of data on

the benchmark for WHOQoL-Brief among people with MLBP. Moreover, we used WHOQoL-Brief on the general population with MLBP, while Johansson et al. [38] used the Health-related Quality of Life Questionnaire on older adults. There is a need for future studies to establish categorical benchmarks for WHOQoL-Brief among people with MLBP. For instance, a WHOQoL score of 50% should be interpretable as fair, good, very good, or excellent QoL.

The bivariate analysis showed a significant positive correlation between physical activity and QoL. Research has shown that sedentary adults tend to report poorer QoL than their more physically active counterparts [39]. Moderate-to-severe low back pain can be debilitating, causing the patient to be less physically active, especially among older adults [3]. Similarly, Rétsági et al. [40] reported a positive relationship between physical activity level and QoL among adults. Physically active individuals are more capable of engaging in activities of daily living which lead to subjective satisfaction about one's life and wellbeing. Furthermore, there was a moderate inverse correlation between QoL, pain intensity, and disability. Kovacs et al. [41] opined that low back pain influences disability and QoL. Although disabling pain affected both the physical and psychological domains of QoL, the physical domain of quality of life is the most strongly related factor to disability levels compared to other domains [42].

The present study also found correlations between pain intensity, physical activity, and disability, such that an increase in pain intensity correlated with a decrease in physical activity. In contrast, a reduction in physical activity correlated with increased disability. It appears

that pain intensity has both a direct impact on disability and a mediating influence between physical inactivity and disability. These observations were confirmed by the multivariate SEM (Fig. 1), that increased pain intensity reduced physical activities and quality of life, in addition to the direct effect of pain leading to increased disability. Our study supported the finding of Houde et al. [43] that there was a significant positive correlation between pain intensity and disability in patients with low back pain. Chung et al. [44] also correlated low back pain intensity and physical disability among 55 patients with chronic low back pain and reported a linear correlation between the two variables. Another study found an association between pain intensity and disability in 195 hospital-attending patients with common low back pain [41]. On the other hand, Lin et al. [45] concluded from a systematic review of 18 studies that there was an association between physical activity and low back pain-related disability. Due to the observed negative correlation between physical activity, and disability among people with low back pain, Ryan et al. [46] suggested that physical activity can be used as an outcome measure of functional ability in people with chronic low back pain.

Clinical implications

The clinical implication of this study is that incorporating disability, physical activity, and quality of life assessment in the management and follow-up of people with MLBP may enhance the traditional biophysical approach mainly based on structural evaluation. Attention has been paid in the last decade to the biopsychosocial factors that may lead to the development and sustenance of LBP. Pain intensity, health-related QoL, and the degree of pain interference with an individual's daily activities (disability) belong to a set of primary-based outcomes in LBP [14]. However, research findings in this area are inconsistent because of the difficulty in standardizing the outcome measures and controlling for confounding factors [47]. Clinicians should expect psychosocial limitations such as poor QoL, activity restriction, and disability among clients with MLBP and be proactive in providing comprehensive care.

Limitations

The study has some limitations. Participants were sampled by a non-probability (consecutive) method—affecting the generalizability of our findings. However, the participants' demographic characteristics in the present study were similar to two previous studies conducted among people with LBP in the same region of the country [9, 25]. Self-reported instruments were used for data collection, which may lead to recall and social desirability

biases. For instance, participants may overestimate their pain intensity or physical activity levels.

Conclusion

There was a correlation between pain intensity, physical activity, and disability, such that an increased pain intensity reduced physical activities and quality of life, in addition to the direct effect of pain leading to increased disability. Therefore, incorporating physical activity, disability, and QoL assessment in the management and follow-up of people with chronic mechanical low back pain may enhance the traditional biophysical approach that has to do with structural evaluation.

Abbreviations

AGFI	Adjusted Goodness of Fit Index
CFI	Comparative Fit Index
GFI	Goodness of Fit Index
LBP	Lower back pain
MLBP	Mechanical lower back pain
PA	Physical activity
PI	Pain intensity
QoL	Quality of life
RMSEA	Root-mean-square error of approximation
SD	Standard deviation
SEM	Structural equation model
TLI	Tucker-Lewis's Index
YLD	Years lived with disability

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Authors' contributions

ECE and CVO contributed to the conception of this study. All authors made substantial contributions to the design and acquisition of data. OKO performed the statistical analysis. ECE and OKO were responsible for drafting the article and its critical revision. All authors approved the final manuscript for publication.

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Availability of data and materials

The dataset generated and analyzed during the current study will be made public by 2026 but is available from the corresponding author at a reasonable request. This is in adherence to our institution's 5-year data retention policy.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Human Research Ethics Committees of the Faculty of Health Sciences and Technology, Nnamdi Azikiwe University, Anambra, Nigeria (NAU/FHST/2021/MRH60). The study's objectives were clearly explained to each participant, who then signed an informed consent form. The approved protocol, participants' privacy, and confidentiality of data were strictly adhered to.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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