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Research Protocol

Physical Medicine and Rehabilitation Section

Psychometric Testing and Validation of Comprehensive Assessment Scale for Chronic Low Back Pain in Northern Indian Population: A Research Protocol

ADITI POPLI[1], MANU GOYAL[2]

ABSTRACT

Introduction: Low Back Pain (LBP) ranks as one of the most prevalent musculoskeletal conditions worldwide. The average lifetime prevalence of LBP in Northern India is reported to be 57%, with women (65%) exhibiting a significantly higher prevalence than men (47%).

Need of the study: The existing literature evaluating the combined effects of functional disability and psychological status in patients with chronic LBP in Northern India is quite limited. In countries like India, clinicians and researchers often rely on assessment scales developed in Western nations. However, no indigenous scales exist that simultaneously measure both functional limitations and psychological aspects in chronic LBP patients. When these internationally developed scales are used in Northern Indian clinical settings, they may fail to accurately capture patient progress during assessments and reassessments, as they are designed with different cultural and geographical considerations in mind.

Aim: The study aims to validate and test the psychometric properties of a Comprehensive Assessment Scale for patients with chronic LBP in Northern India.

Materials and Methods: The present cross-sectional study will be conducted at MM Super-Specialty Hospital, Mullana, Ambala, Haryana, India. The duration of the study will be from February 2025 to February 2026, and it will comprise three phases: 1) development phase, 2) validation phase, and 3) testing of psychometric properties. For the formation of domains and the framing of a pre-final draft for scale development, 7-8 patients with chronic LBP who have been experiencing symptoms for the past year will be interviewed over three rounds. This will be followed by literature searches and opinions from an expert panel. The draft will be validated in terms of content validity via the Delphi survey method. Construct validity will be examined through confirmatory factor analysis, and concurrent validity will be analysed by correlating the Comprehensive Assessment Scale (CAS) with other validated questionnaires such as the Oswestry Disability Index (ODI) and the Roland-Morris Disability Questionnaire (RMDQ-24). Data will be collected from patients to test the final draft of the CAS for its psychometric properties. Statistical analysis will be performed using IBM Statistical Package for the Social Sciences (SPSS) software (version 26). The data collected will be analysed for absolute and relative reliability, as well as other psychometric properties such as sensitivity, specificity, small worthwhile change, minimal detectable change, standard error of mean, and coefficient of variation.

Keywords: Delphi survey, Musculoskeletal diseases, Oswestry disability index, Validity

INTRODUCTION

Low Back Pain (LBP) is one of the most frequent musculoskeletal problems worldwide [1]. According to the World Health Organisation (WHO), LBP is ranked 6th and 1st globally in terms of overall health impact and disability, respectively, affecting approximately 619 million individuals worldwide in 2020 [2]. In Northern India, the average lifetime prevalence of LBP is reported to be 57%, with women (65%) exhibiting a significantly higher prevalence than men (47%) [3].

The majority of individuals suffering from chronic LBP eventually experience recurring episodes. Recurrence rates within one year are estimated to range from 24% to 80% [4]. Recovery from persistent chronic LBP is gradual and uncertain, often leading to functional limitations, psychological difficulties, and a poor quality of life. Given that LBP encompasses multi-dimensional clinical and psychological behaviours, systematic assessment and proper evaluation are necessary [5,6].

Several outcome measures are available to assess functional limitations associated with LBP, such as the RMDQ-24, ODI and Quebec Disability Scale (QDS) [7-9]. However, these measures do not provide a comprehensive assessment that captures functional disability, perceived stress, fear of avoidance, depression, sleep disturbances, anxiety, and somatisation in patients with chronic LBP. The purpose of this study is to develop a comprehensive assessment scale that quantitatively measures the impact of activity limitations and psychological behaviours in patients with chronic LBP in Northern India.

REVIEW OF LITERATURE

To evaluate the psycho-social well-being of chronic LBP patients, researchers often rely on scales developed in other countries. However, due to cross-cultural and geographical differences, assessing the quality of life of individuals with chronic LBP in developing nations remains inadequate. Currently, India lacks a dedicated assessment scale that measures both functional limitations and psychological behaviours in chronic LBP patients.

Numerous studies have examined the psychometric properties of existing scales. One such study evaluated the psychometric characteristics of the Tampa Scale of Kinesiophobia (TSK), a widely used tool known for its strong test-retest reliability and internal consistency (α=0.76-0.87). This 17-item scale assesses pain-related fear and avoidance behaviour but does not include functional assessments [10]. Conversely, the ODI is a highly regarded tool with excellent test-retest reliability (α=0.83-0.94). It consists of 10 items addressing various aspects of daily activities but does not assess

the psychological behaviours of individuals with disabilities. The ODI has been validated in multiple languages and has demonstrated strong correlations with other disability measures [7]. The RMDQ, a 24-item scale designed to evaluate physical disability in chronic LBP patients, exhibits strong internal consistency (α=0.84-0.93) and good treatment responsiveness [8].

A cross-sectional study conducted by Bansal D et al., at a tertiary care hospital in Chandigarh, India, investigated the prevalence of LBP in the Northern Indian population. Interviews were conducted across various community strata, assessing Quality of Life (QoL) and pain intensity using the Numeric Rating Scale (NRS-11). The study reported lifetime, point, and one-year prevalence rates with a 95% Confidence Interval (CI). Standardised lifetime prevalence rates were found to be 57%, 32%, 48%, and 59% for lifetime, point, and one-year prevalence, respectively. Additionally, LBP was shown to significantly impact sleep (24%), psychological well-being (24%), and social interactions (28%) [3].

In 2014, De Moraes Vieira ÉB et al., conducted a study examining the coexistence of fear avoidance beliefs and self-efficacy in chronic LBP patients. Data was collected from 215 individuals across three healthcare facilities and two businesses. The study found that high fear avoidance was significantly linked to factors such as male gender, depression, lower income, and greater impairment ($p<0.001$). Further analysis showed that increased impairment correlated with lower self-efficacy and higher fear avoidance [11].

Several questionnaires, including the ODI and the RMDQ-24, have been used to evaluate functional restrictions and quality of life in LBP patients. However, all these scales were developed outside India, based on the geographical and cultural needs of other populations experiencing LBP-related difficulties in daily activities. Similarly, psychological assessment tools such as the Depression, Anxiety and Stress Scales-21 (DASS-21) [12] and Patient Health Questionnaire (PHQ) [13] have been utilised, but no specific scale has been designed to assess psychological behaviour in LBP patients.

To address this gap, the present study aims to develop a valid and reliable assessment tool-the Comprehensive Functional and Psychological Assessment (CFPA) scale. This scale will provide an integrated evaluation of both functional limitations and psychological behaviour in chronic LBP patients in Northern India.

Primary objectives:

- To develop domains and items related to the CFPA scale.
- To determine the validity and reliability of the new scale.

Secondary objectives:

- To determine sensitivity, specificity, small worthwhile change, minimal detectable change, standard error of the mean, and coefficient of variation.

MATERIALS AND METHODS

The present cross-sectional study will be conducted at MM Super-Speciality Hospital, Mullana, Ambala, Haryana, India, from February 2025 to February 2026. The study has been approved at the preliminary stage by the Student Project Committee with reference number SPC-2025-01. Ethical clearance has been obtained from the Institutional Ethical Committee (IEC) with ethical number IEC-285-PE. The study will adhere to the Helsinki Declaration and the guidelines set forth by the Council for International Organisations of Medical Sciences (CIOMS), the International Ethical Guidelines for Health-Related Research Involving Humans (Revised 2017), as well as the National Ethical Guidelines for Biomedical and Health Research involving human participants issued by the Indian Council of Medical Research.

Zou G and Donner A suggested that 15-50 individuals should be included as a sample population, anticipating an Intraclass Correlation Coefficient (ICC) value of 0.8 [14]. Therefore, an estimated 51 individuals suffering from chronic mechanical LBP will be included in the study.

Inclusion criteria: Individuals with a duration of LBP of at least six months, both male and female, aged between 20-60 years, based on Body Mass Index (BMI) [15], and reporting pain greater than 5 on the Numerical Pain Rating Scale (NPRS) [16] will be included in the study.

Exclusion criteria: Patients with LBP of less than six months duration, a history of spinal surgery within the last year, definite neurodeficits, pregnant females, spinal injections, fractures, malignancies, spondylolisthesis, Prolapsed Intervertebral Discs (PIVD), those not willing to participate, inflammatory arthritis, or psychosomatic illnesses will be excluded.

Study Procedure

To develop an outcome measure, the "CFPA" scale for patients with chronic LBP, which will serve as a valid and reliable measure, several steps will be incorporated as follows:

Phase 1: Scale development [17-19]: For the formation of domains of the CFPA scale and the framing of a pre-final Draft (D1), three sub-phases will take place:

a) Literature search: Thorough searches will be conducted on various databases, including Scopus, Google Scholar, PubMed, and the Cochrane Library, focusing on literature related to LBP. Reviewing the literature will help identify current measures that can serve as models for the development of the scales.

b) Interviewing patients: In three rounds, 7-8 patients with chronic LBP lasting over the past year will be interviewed about the challenges and functional restrictions imposed by LBP in their daily lives and how it affects their psychological behaviour. This process is essential for gaining insights into patients' perspectives, which will aid in identifying and defining the domains and subdomains required for the development of the assessment tool. Once the final draft is completed following the validity phase, reliability testing will be performed with a sample of 51 patients. The methodology will involve two distinct steps: conducting interviews with 7-8 patients per round to refine the assessment framework, followed by testing the reliability of the finalised scale with the larger group of 51 patients.

c) Interviewing experts: An in-depth discussion will be held with one physiotherapist and one neurologist, both with over a decade of expertise, to develop appropriate domains and items related to chronic LBP. Any necessary changes, adjustments, or adaptations will be made from the perspective of these experts, providing further clarity and triangulating concepts that might otherwise be overlooked.

Phase 2: Validity testing:

a) Content validity: This aspect is crucial for creating measurement tools, ensuring that the items or tests accurately represent the behaviour under study and their applicability to the measured features [20]. To validate Draft D1 in terms of content validity, the Delphi survey method will be employed. A Google Form will be created and electronically distributed to a panel of 6-10 experts with over six years of experience in the field of LBP via email or WhatsApp [21]. Responses will be recorded, and a four-point rating system will be used to rate the items' relevance:
   - 4=extremely relevant
   - 3=relevant but needs minor adjustments
   - 2=relevant but requires substantial revisions
   - 1=not relevant

The evaluation documentation for the scale development will be based on experts' feedback, determined by careful questioning,

including: Are these items necessary and pertinent in the context of the given condition?

For the content validity of the newly developed CFPA scale, Item-level (I-CVI) and scale-level (S-CVI (Ave)) content validity will be calculated as follows [22]:

- I-CVI=number of experts who rated the item as relevant / total number of experts
- S-CVI (Ave)=subtotal of I-CVI scores / total number of items

b) Construct validity: Construct validity refers to the degree to which outcomes on an instrument align with theoretically established hypotheses about the concepts being measured. If 75% of these hypotheses are confirmed, construct validity is considered sufficient [23]. Confirmatory factor analysis will be performed to establish the construct validity of Draft D1 of the proposed CFPA scale [24].

c) Concurrent validity: This evaluation examines perceived physical exertion using a newly developed category scale by correlating a criterion variable with a concurrent response variable [25]. As there is no established "gold standard" for assessing functional limitations and psychological behaviours in LBP patients in Northern India, the new scale's concordance with existing measures will be analysed. The CFPA scale will be compared to the ODI and the RMDQ-24, with 51 patients completing both scales within a 15-minute interval. Results will be recorded, and any discrepancies in specific domains or the overall assessment will be investigated.

Phase 3: Reliability testing [26]: To assess test-retest reliability, patient consent will be obtained before administering the CFPA scale twice, with a time interval of 48 hours between assessments. The total scores from both instances will be correlated to evaluate the repeatability of the newly developed scale. Since test-retest reliability measures the consistency and reproducibility of results from the same individuals under identical conditions, patients will be asked to complete the form twice, with a 24-hour gap between administrations to ensure a reliable assessment.

STATISTICAL ANALYSIS

The data from participants will be analysed using SPSS software (version 26) to assess the normality of demographic characteristics, employing the Kolmogorov-Smirnov test for distribution analysis based on sample size. Content validity of the new CFPA scale will be measured using item (I-CVI) and scale (S-CVI (Ave)) metrics. Construct validity will be evaluated through factor analysis, and concurrent validity will be tested against ODI and RMDQ-24. For reliability testing, both relative and absolute reliability will be assessed in SPSS, including Cronbach's alpha for internal consistency, the Intra-rater ICC, and Bland-Altman plots for Level of Agreement (LoA). A Cronbach's alpha above 0.9 indicates excellent consistency. Additional psychometric properties, such as sensitivity, specificity, Smallest Worthwhile Change (SWC), and Coefficient of Variance (CV%), will also be analysed to compare the CFPA scale with established scales.

REFERENCES

[1] Shokri P, Zahmatyar M, Falah Tafti M, Fathy M, Rezaei Tolzali M, Ghaffari Jolfayi A, et al. Non-spinal low back pain: Global epidemiology, trends, and risk factors. Health Sci Rep. 2023;6(9):e1533.
[2] World Health Organization. WHO guidelines on chronic low back pain [Internet]. 2023 [cited 2025 Feb 11]. Available from: https://www.who.int/news/item/07-12-2023-who-releases-guidelines-on-chronic-low-back-pain.
[3] Bansal D, Asrar MM, Ghai B, Pushpendra D. Prevalence and impact of low back pain in a community-based population in northern India. Pain Physician. 2020;23(4):E389.
[4] Hoy D, Brooks P, Blyth F, Buchbinder R. The epidemiology of low back pain. Best Pract Res Clin Rheumatol. 2010;24(6):769-81.
[5] Elabd AM, Elabd OM. Effect of aerobic exercises on patients with chronic mechanical low back pain: A randomized controlled clinical trial. J Bodyw Mov Ther. 2024;37:379-85.
[6] Bener A, Verjee M, Dafeeah EE, Falah O, Al-Juhaishi T, Schlogl J, et al. Psychological factors: Anxiety, depression, and somatization symptoms in low back pain patients. J Pain Res. 2013;6:95-101.
[7] Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine (Phila Pa 1976). 2000;25(22):2940-52.
[8] Roland M, Fairbank J. The Roland–Morris disability questionnaire and the Oswestry disability questionnaire. Spine (Phila Pa 1976). 2000;25(24):3115-24.
[9] Kopec JA, Esdaile JM, Abrahamowicz M, Abenhaim L, Wood-Dauphinee S, Lamping DL, et al. The Quebec back pain disability scale: Conceptualization and development. J Clin Epidemiol. 1996;49(2):151-61.
[10] French DJ, France CR, Vigneau F, French JA, Evans RT. Fear of movement/(re) injury in chronic pain: A psychometric assessment of the original English version of the Tampa scale for kinesiophobia (TSK). Pain. 2007;127(1-2):42-51.
[11] De Moraes Vieira ÉB, de Góes Salvetti M, Damiani LP, de Mattos Pimenta CA. Self-efficacy and fear avoidance beliefs in chronic low back pain patients: Coexistence and associated factors. Pain Manag Nurs. 2014;15(3):593-602.
[12] Osman A, Wong JL, Bagge CL, Freedenthal S, Gutierrez PM, Lozano G. The Depression Anxiety Stress Scales-21 (DASS-21): Further examination of dimensions, scale reliability, and correlates. J Clin Psychol. 2012;68(12):1322-38.
[13] Kroenke K, Spitzer RL, Williams JB. The PHQ-9: Validity of a brief depression severity measure. J Gen Intern Med. 2001;16(9):606-13.
[14] Zou G, Donner A. Confidence interval estimation of the intraclass correlation coefficient for binary outcome data. Biometrics. 2004;60(3):807-11.
[15] Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults-The Evidence Report. National Institutes of Health. Obes res. 1998;6(Suppl 2):51S-209S.
[16] Farrar JT, Young JP Jr, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain. 2001;94(2):149-58.
[17] Ponsignon F, Smith JS, Smart A. Development and validation of a measurement scale for the experience capability construct. Journal of Service Management. 2021;32(3):315-45.
[18] Morgado FFR, Meireles JFF, Neves CM, Amaral ACS, Ferreira MEC. Scale development: Ten main limitations and recommendations to improve future research practices. Psicol Reflex Crít. 2017;30(1):3.
[19] Lamm KW, Lamm AJ, Edgar D. Scale development and validation: Methodology and recommendations. J Int Agric Ext Educ. 2020;27(2):24-35.
[20] Zamanzadeh V, Rassouli M, Abbaszadeh A, Majd HA, Nikanfar A, Ghahramanian A. Details of content validity and objectifying it in instrument development. Nurs Pract Today. 2014;1(3):163-71.
[21] Lynn MR. Determination and quantification of content validity. Nurs Res. 1986;35(6):382-85.
[22] Almanasreh E, Moles R, Chen TF. Evaluation of methods used for estimating content validity. Res Soc Adm Pharm. 2019;15(2):214-21.
[23] Barten JA, Pisters MF, Huisman PA, Takken T, Veenhof C. Measurement properties of patient-specific instruments measuring physical function. J Clin Epidemiol. 2012;65(6):590-601.
[24] Shrestha N. Factor analysis as a tool for survey analysis. Am J Appl Math Stat. 2021;9(1):04-11.
[25] Lin WL, Yao G. Concurrent validity. In Encyclopedia of quality of life and well-being research. Cham: Springer International Publishing, 2nd edition; 2023.1303-1304. Available from : https://doi. org/10.1007/978-3-031-17299-1_516.
[26] Bruton A, Conway JH, Holgate ST. Reliability: What is it, and how is it measured? Physiotherapy. 2000;86(2):94-99.

PARTICULARS OF CONTRIBUTORS:
1. PhD Scholar, Department of Physiotherapy, Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Mullana, Ambala, Haryana, India.
2. Professor, Department of Physiotherapy, Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Mullana, Ambala, Haryana, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Manu Goyal,
MMDU, Mullana, Ambala-133207, Haryana, India.
E-mail: manu.goyal@mmumullana.org

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