Research Protocol

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# Validity and Reliability of EuroQol 5-Dimension 5-Levels Questionnaire (EQ-5D-5L) in Assessing Health-related Quality of Life in Sacroiliac Joint Dysfunction: A Research Protocol for a Prospective Observational Study

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## ABSTRACT

**Introduction**: The EuroQol-5 Dimension-5 Level (EQ-5D-5L) is a commonly used, standardised tool for measuring Health-Related Quality of Life (HRQoL) across five areas: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Sacroiliac Joint (SIJ) dysfunction is a significant contributor to low back pain and adversely affects the functional ability and quality of life. Despite its widespread use, evidence regarding the reliability and validity of the EQ-5D-5L in this population remains limited.

**Need of the study**: There is a lack of validated instruments designed to evaluate HRQoL in individuals with SIJ dysfunction. Determining the reliability and validity of EQ-5D-5L in this population will support its clinical and research application. However, in the context of SIJ dysfunction, there is no universally accepted SIJ specific questionnaire that fully captures all relevant constructs, particularly those aligned with the domains assessed in our study.

**Aim**: To determine the reliability and validity of the EQ-5D-5L questionnaire in patients with SIJ dysfunction.

**Materials and Methods**: A prospective observational study will be conducted at the Maharishi Markandeshwar (Deemed to be University), Mullana, Haryana, from May 2025 to March 2026, in patients with SIJ dysfunction. A minimum of 50 participants will be included for reliability analysis, while approximately 100 participants will be included for concurrent validity assessment. Participants will be asked to complete the EQ-5D-5L at baseline, again within 30 minutes by two independent trained raters to assess inter-rater reliability, and after seven days to determine test-retest reliability. Concurrent validity will be assessed by having participants complete the Oswestry Disability Index (ODI) and the Roland-Morris Disability Questionnaire (RMDQ) at baseline and correlating their scores with those of the EQ-5D-5L. Descriptive statistics will summarise demographic data. Reliability will be assessed using the Intraclass Correlation Coefficient (ICC), and concurrent validity using Pearson or Spearman correlation coefficients. Floor and ceiling effects will also be evaluated. Statistical significance will be set at $p<0.05$.

**Keywords:** Anxiety, Depression, Low back pain, Self-care

## INTRODUCTION

The SIJ is the largest axial joint in the human body, classified as a diarthrodial joint that links the sacrum to the ilium in the posterior pelvis [1]. Throughout life, the SIJ undergoes notable structural changes. In early adulthood, its smooth joint surfaces facilitate multidirectional gliding movements [2]. However, age-related alterations commence during puberty and progress over time, potentially contributing to SIJ dysfunction [1].

The SIJ dysfunction can arise from several clinical conditions, including high-velocity trauma, degenerative arthritis, inflammatory arthropathy, infections, and moderate-impact exercise. Dysfunction may also develop during improper lifting, forward bending, or lordotic posturing [3]. Early identification and treatment can avoid any serious functional disability. However, effective clinical decision-making depends on the use of valid and reliable outcome measures. The measures help assess a patient's level of impairment and disability, which guide therapy choices and track progress over time. For an outcome measure to be meaningful in clinical settings, it should be easy to administer, score, and valid, reliable, and sensitive to changes [4]. However, a specific outcome measure to assess the quality of life in patients with SIJ dysfunction is currently lacking.

The Europe Quality of Life-5 Dimensions-5 Levels (EQ-5D-5L), on the other hand, is a self-reported questionnaire that is used to evaluate HRQoL in terms of valuing one's health [5] and is the preferred measure of quality of life for health technology assessment in many European countries [6]. It is widely used in Sweden in clinical practice, public health surveys, and health economic evaluations [7]. The instrument is generic and is constructed for self-assessment and has been used globally in research [5]. The EQ-5D was developed to apply to a wide range of client groups and interventions in research, health care, and public health [5]. The instrument is easy to administer, takes a short time to implement, and has been translated into many different languages [8,9]. The original version of it was introduced in 1990 and contained five dimensions: Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. The psychometric properties of the EQ-5D-5L have been validated in both general and different disease populations [10]. In recent years, with the availability of the EQ-5D-5L value sets, an increasing number of studies have been using it to

measure the HRQoL of patients with different diseases and perform economic evaluations to support health decision-making [11]. However, its applicability, validity, and responsiveness in individuals with SIJ dysfunction remain inadequately explored, highlighting a clear need for further research in this area.

## REVIEW OF LITERATURE

Several studies have investigated the psychometric performance of the EQ-5D-5L across different clinical populations. Existing evidence suggests that the instrument demonstrates acceptable validity, reliability, and responsiveness in a variety of musculoskeletal, psychological, and chronic health conditions. However, findings regarding its sensitivity and measurement performance have varied across populations, indicating the need for condition-specific evaluation [11-15]. Despite growing evidence in other disorders, limited literature is available regarding the applicability of the EQ-5D-5L in individuals with SIJ dysfunction, thereby justifying the need for the present study.

Bilbao A et al., reported good psychometric properties for the electronic EQ-5D-5L amongst patients with major depression, showing acceptable internal consistency (Cronbach's $\alpha$=0.77), strong convergent validity with the Patient Health Questionnaire-9, and moderate responsiveness to improvements in clinical status [11].

Lam et al. validated the electronic EQ-5D-5L in patients with chronic knee and back pain, with good test-retest reliability (ICC: 0.76-0.83), significant improvement in score among patients reporting better health over time, and it was a valid, reliable, sensitive, and responsive measure [12].

Similarly, Franklin M et al., confirmed good construct validity and responsiveness in individuals with anxiety and depression, although they noted that the instrument may be less comprehensive than disease-specific measures [13].

In the context of economic evaluation, Franklin M et al., compared the responsiveness and cost-effectiveness of the EQ-5D-5L, the recovering quality of life utility index for those affected by anxiety or depression. According to the authors, the EQ-5D-5L demonstrated greater sensitivity to changes in health status over time. It generated higher Quality-Adjusted Life Year (QALY) estimates than the recovering quality of life utility index in within-trial economic evaluations. Furthermore, it provided more stable utility estimates and showed greater responsiveness to improvements in clinical condition, supporting its use in economic evaluations and healthcare decision-making [16].

Despite these strengths, some studies have raised concerns regarding its sensitivity and methodological limitations. Dams J et al., demonstrated that the EQ-5D-5L showed good discriminative ability, construct validity, and test-retest reliability (ICC: 0.65-0.91) in adolescents and young adults with post-traumatic stress disorder following sexual and/or physical abuse. However, responsiveness indices, including effect sizes and ROC analyses, were comparatively weak, suggesting limited sensitivity in detecting clinical change over time, although the instrument was still considered suitable for assessing HRQoL in this population [14].

Furthermore, Hernández-Alava M et al., highlighted methodological concerns when comparing EQ-5D-3L and EQ-5D-5L, showing that factors such as instrument sequencing and mapping approaches can significantly influence measurement outcomes, thereby suggesting that the validity of results may vary depending on the analytical framework employed [15]. Such variability underscores the importance of evaluating its performance in specific patient populations, particularly in conditions such as SIJ dysfunction, where evidence remains limited. Thus, the study aims to evaluate the validity and reliability of the EQ-5D-5L in assessing the quality of life in patients with SIJ dysfunction.

**Primary objectives:** To determine the test-retest and inter-rater reliability of the EQ-5D-5L questionnaire in patients with SIJ dysfunction.

**Secondary objectives:** To assess the concurrent validity of the EQ-5D-5L through comparison with established disability measures, namely the ODI and the RMDQ.

**Null hypothesis ($H_0$):** The EQ-5D-5L will not demonstrate acceptable test-retest reliability, inter-rater reliability, and concurrent validity for assessing HRQoL in patients with SIJ dysfunction, as indicated by an ICC of <0.75 and a correlation coefficient of <0.50.

**Alternate hypothesis ($H_1$):** The EQ-5D-5L will demonstrate acceptable test-retest reliability, inter-rater reliability, and concurrent validity for assessing HRQoL in patients with SIJ dysfunction, as indicated by an ICC of ≥0.75 and a correlation coefficient of ≥0.50.

## MATERIALS AND METHODS

A prospective observational study will be conducted at the Maharishi Markandeshwar (Deemed to be University) from May 2025 to March 2026. Ethical approval was obtained from the Institutional Ethics Committee with the registration number MMDU/IEC-3097. The trial was registered under the number CTRI/2025/04/085056. Written informed consent will be obtained from all participants before their enrolment in the study.

**Inclusion criteria:** The inclusion criteria for the study will include male and female participants aged between 30 and 50 years who were clinically diagnosed with SIJ dysfunction. Several pain-provoking tests commonly used to identify SIJ dysfunction will be employed, including the FABER test, Gaenslen's test, compression test, distraction test, thigh thrust test, and sacral thrust test. A diagnosis of SIJD will be considered when at least three of these provocation tests are positive, in accordance with the diagnostic criteria described by Buchanan P et al., [17]. However, imaging findings will be reviewed when necessary to exclude other lumbar, hip, or pelvic pathologies. Therefore, diagnosis in the present study will primarily rely on clinically established SIJ pain provocation test clusters supported by detailed history taking and physical examination [17]. Only individuals who provide written informed consent and are willing to participate voluntarily will be included. Furthermore, the capacity to understand and answer the questionnaire's questions will be a prerequisite for participation.

**Exclusion criteria:** Participants with lower back discomfort due to any other orthopaedic or neurological disorder will be excluded from the study. Participants will be excluded if they have any health conditions that would affect the accuracy of the SIJ dysfunction evaluation. Furthermore, participants with any additional related musculoskeletal disorders or dysfunctions that could confound the study outcomes will be deemed ineligible.

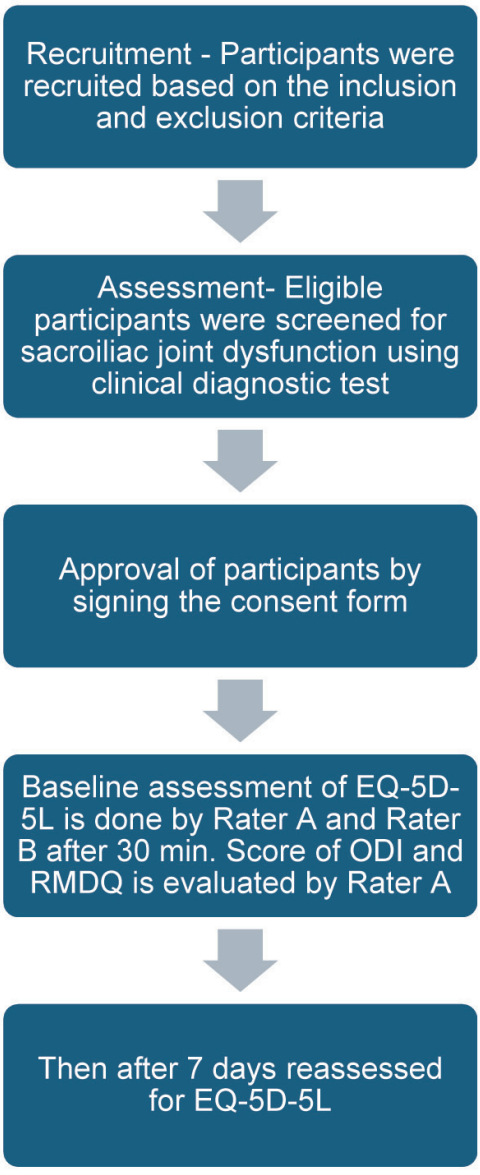
A minimum of 50 participants will be recruited to assess inter-rater and test-retest reliability. To assess inter-rater reliability, two independent raters, each having four years of clinical experience in musculoskeletal assessment, will administer the questionnaire to the patients. Methodological literature supports this sample size, indicating that 30 to 50 participants are sufficient to compute ICC with reasonable precision and statistical power [18].

The concurrent validity analysis will be conducted with a sample of 100 individuals. Correlations between scores from validated instruments, such as the RMDQ, the ODI and the target instrument EQ-5D-5L will be used to evaluate concurrent validity [4]. A purposive sampling method will be employed to recruit participants with predefined diagnostic criteria for SIJ dysfunction, ensuring inclusion of the target clinical population relevant to the psychometric properties of the EQ-5D-5L [19].

Participants meeting the predefined criteria will be recruited. The EQ-5D-5L scale will be administered by these eligible participants at baseline once informed consent has been obtained. Two trained raters (Rater A and Rater B), blinded to each other's coding and derived index values, will independently record, code, and

interpret the EQ-5D-5L health-state profiles obtained from the self-administered questionnaires of each participant within a period of 30 minutes on the same day, without access to previous scores, to evaluate inter-rater reliability.

To assess test–retest reliability, Rater A will administer the EQ-5D-5L to the same participants on two occasions separated by a 7-day interval under comparable clinical and environmental conditions. Participants will be reassessed only if no significant change in their clinical status has occurred during the intervening period. The 7-day interval was selected to minimise recall bias while maintaining relative clinical stability. Participants will be advised to maintain their usual level of activity and refrain from initiating or altering any therapeutic interventions during the 7-day interval. Any reported change in clinical condition during this period will lead to exclusion from the test–retest reliability analysis. To assess concurrent validity, each participant will be evaluated during the initial session using a validated region-specific functional or quality-of-life instrument for SIJ dysfunction, such as the ODI or the RMDQ. The study procedure is outlined in the flowchart presented in [Table/Fig-1].




**[Table/Fig-1]:** Study flowchart for study protocol.

### Primary Outcomes

**EQ-5D-5L:** HRQoL, assessed using the EQ-5D-5L, a standardised self-reported questionnaire. The questionnaire consists of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, each of which can be rated at five levels of severity: no problems, slight problems, moderate problems, severe problems, and extreme problems/unable to perform. The responses from these five dimensions can be converted into a single summary index value using a country-specific value set, which reflects the overall HRQoL. Additionally, the measure includes a Visual Analogue Scale (EQ-VAS) from 0 (worst health state imaginable) to 100 (best health state imaginable). Higher scores on both the EQ-VAS and index value indicate better perceived HRQoL [20].

The EQ-5D-5L will be administered at baseline, reassessed after 30 minutes by a second rater to evaluate inter-rater reliability, and readministered after seven days by the same rater to assess test-retest reliability.

### Secondary Outcomes

**1. Oswestry Disability Index (ODI):** The ODI is one of the most frequently used condition-specific outcome tools to assess disability associated with low back pain. It is composed of ten questions that describe how back pain limits one's ability to engage in daily activities such as personal hygiene, lifting, walking, sitting, standing, sleeping, sexual intercourse, socialising, and travelling. Each question is scored by the patient on a 6-point scale from 0 to 5, with higher scores indicating a greater level of disability. The overall score is calculated by adding the scores, then dividing by the maximum score possible, and finally multiplying by 100 to get a percentage. The score interpretation is as follows: 0-20% for minimal disability, 21-40% for moderate disability, 41-60% for severe disability, 61-80% for crippled, 81-100% for bed-bound or symptoms exaggerated [21].

The ODI will be administered at baseline to assess the concurrent validity of the EQ-5D-5L.

**2. Roland Morris Disability Questionnaire (RMDQ):** A self-reporting questionnaire used for measuring physical limitations resulting from low back pain. Individuals are requested to select the statements that best represent their present level of disability by referring to 24 items derived from the sickness impact profile. For each positive answer given, one point is awarded, and the total score can vary from 0 (no impairment) to 24 (maximum disability) [22]. The RMDQ will be administered at baseline to assess the concurrent validity of the EQ-5D-5L.

## STATISTICAL ANALYSIS

Data will be analysed using SPSS version 27. Descriptive statistics will summarise demographic and clinical characteristics. Normality will be assessed using the Shapiro-Wilk test. Test-retest and inter-rater reliability will be evaluated using the ICC, while internal consistency will be assessed using Cronbach's alpha. Measurement error will be quantified using the Standard Error of Measurement (SEM) and Minimal Detectable Change (MDC95). Concurrent validity will be examined using Spearman's correlation coefficient between the EQ-5D-5L and established measures, including the ODI and RMDQ. Floor and ceiling effects will be considered present if ≥15% of participants achieve the minimum or maximum possible score, respectively. Statistical significance will be set at $p < 0.05$, and all analyses will follow COSMIN guidelines for evaluating psychometric properties.

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