ClinicalTrials.gov Submission Document

Official Title: Anxiety level among patients with chronic low back pain: a cross-sectional study

NCT Number: NCT06404788

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Study Protocol

1. Background and Rationale

Chronic low back pain (CLBP) is one of the most common musculoskeletal conditions worldwide, associated with significant disability and socioeconomic burden. Psychological comorbidities, particularly anxiety disorders, frequently accompany CLBP and exacerbate pain, disability, and reduced quality of life. Previous international studies indicate that up to 60% of patients with CLBP experience anxiety symptoms. However, data from Polish populations remain scarce. This study aims to evaluate the prevalence and severity of generalized anxiety symptoms among Polish patients with CLBP and to identify sociodemographic and clinical correlates.

2. Objectives

Primary Objective: To assess the severity of generalized anxiety symptoms in adults with CLBP using the Generalized Anxiety Disorder 7-item scale (GAD-7).

Secondary Objectives: To analyze associations between anxiety severity and sociodemographic factors (age, gender, education, type of work), clinical characteristics (duration of CLBP), and presence of comorbidities.

3. Study Design

Type: Observational, cross-sectional.
Setting: NZOZ REHABMED-I Mirosław Smółka rehabilitation clinic, Katowice, Poland.
Duration: January 2024 – June 2024.

4. Participants

Inclusion criteria:
- ≥18 years old
- Diagnosed CLBP persisting >3 months
- Proficient in Polish language
- Provided informed consent

Exclusion criteria:
- Trauma or spinal surgery within past 12 months
- Severe psychiatric illness diagnosis
- Pregnancy within past 12 months

Sample size: 202 participants (calculated minimum = 196, achieved = 202).

5. Ethical Considerations

Approval: Bioethics Committee, Medical University of Silesia, Katowice (BWN/NWN/0052/KB/97/24).
Conducted in accordance with the Helsinki Declaration (1975).
Registered on ClinicalTrials.gov (NCT06404788).

6. Outcomes

Primary Outcome Measure: GAD-7 total score (0–21).
Secondary Outcome Measures: Distribution across anxiety severity categories; associations with age, gender, education, work type, pain duration, and comorbidities.

Statistical Analysis Plan

1. Descriptive statistics: Means (SD) for continuous variables, frequencies (%) for categorical variables.
2. Correlation analysis: Pearson's r to examine relationship between age and GAD-7 scores overall and within subgroups (<40, 40–60, >60 years).
3. Group comparisons:
   - Independent-samples t-test (with Welch's correction as needed) for binary comparisons (e.g., gender, comorbidity presence).
   - One-way ANOVA for comparisons across multiple groups (education, work type, pain duration).
4. Significance threshold: $p < 0.05$.
5. Software: R version 4.1.1 (R Core Team, 2021).

Informed Consent Form (Template)

Title of Study: Anxiety level among patients with chronic low back pain: a cross-sectional study

Principal Investigator: Tomasz Jurys, Medical University of Silesia in Katowice, Poland

Purpose

You are invited to participate in a research study about anxiety symptoms in patients with chronic low back pain. The purpose is to evaluate the severity of anxiety symptoms and identify factors associated with them.

Procedures

If you agree to participate, you will be asked to complete the Generalized Anxiety Disorder 7-item questionnaire (GAD-7) and provide basic sociodemographic and medical information.

Risks and Benefits

Risks: Minimal, related to answering questions about mental health and pain.
Benefits: No direct benefits, but your participation may help improve understanding and management of anxiety in CLBP patients.

Confidentiality

Your responses will remain confidential and will be stored securely. Data will be analyzed in aggregate without identifying you personally.

Voluntary Participation

Participation is voluntary. You may refuse to participate or withdraw at any time without consequences for your treatment.

Contact

If you have any questions, please contact: Tomasz Jurys, jurystomek3@gmail.com, tomasz.jurys@sum.edu.pl, +48 727 519 946

Consent Statement:
I have read the information provided above and agree to participate in this study.

Participant's Name: _____
Signature: _____
Date: _____