

Personalised vs standardised rehab for neck and lower back pain

Submission date 27/05/2026	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 27/05/2026	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 27/05/2026	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Background and study aims

This study compares two exercise-based rehabilitation approaches for individuals with neck or lower back conditions: a personalized program tailored to each participant and a standardized program. The objective is to determine which method more effectively improves spinal mobility, reduces pain, and enhances patient satisfaction.

Who can participate?

Eligible participants are adults aged 30 to 65 years with cervical (neck) or lumbar (lower back) pain syndromes, including subacute or chronic neck pain, low back pain, or lumbosciatica. Exclusion criteria include spinal surgery within the past six months and the presence of neurological or systemic conditions that limit active mobility. Participants must be able and willing to complete the entire rehabilitation program and associated assessments.

What does the study involve?

Participants are randomly allocated to one of two groups. Each participant receives ten supervised individual rehabilitation sessions over a two-week period. Sessions include active and passive mobilization, stretching, strengthening of spinal and paravertebral muscles, breathing exercises, and postural re-education using standard clinic equipment such as mats, resistance bands, stability balls, and electrostimulation if required. Outcome measures are collected before and after the intervention, including spinal range of motion (goniometer), pain intensity (Visual Analog Scale), and a brief patient satisfaction assessment.

What are the possible benefits and risks of participating?

Potential benefits include improved spinal mobility, reduced pain, and enhanced understanding of self-management through supervised exercise and education. Possible risks involve temporary increases in pain, muscle soreness, or discomfort resulting from exercises or manual techniques. Individuals with serious health conditions were excluded to minimize risk. All interventions are standard physiotherapy practices administered by qualified staff.

Where is the study run from?

The trial was conducted at the Fit Recovery 11 S.R.L. Medical Rehabilitation Center in Alba Iulia, Romania, with ethical approval granted by the Ethics Committee of the "George Emil Palade" University of Medicine, Pharmacy, Science and Technology, Târgu Mureş.

When is the study starting and how long is it expected to run for?

February 2026 to May 2026.

Who is funding the study?

"George Emil Palade" University of Medicine, Pharmacy, Science and Technology, Târgu Mureş.

Who is the main contact?

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Contact information

Type(s)

Principal investigator, Public, Scientific

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Additional identifiers

Study information

Scientific Title

Comparative effectiveness of personalised and standardised rehabilitation for cervical and lumbar spine disorders: a randomised clinical trial study

Study objectives

Primary objective:

Compare the effectiveness of a personalised rehabilitation program versus a standardised rehabilitation protocol in adults with cervical and/or lumbar spine disorders

Secondary objectives:

1. Compare pain reduction between personalised and standardised programs (measured by VAS)
2. Compare improvement in spinal joint mobility (flexion, extension, lateral flexion, rotation)

measured by goniometry)

3. Compare patient satisfaction with the rehabilitation process (5point scale)

4. Estimate effect sizes to inform sample size and design of future larger trials

Hypothesis:

Personalised rehabilitation will produce greater reductions in pain, larger gains in mobility, and higher patient satisfaction than the standardised protocol

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 05/02/2026, Ethics Committee of the G.E. Palade University of Medicine and Pharmacy in Târgu Mureş (Gheorghe Marinescu Str. No. 38, Târgu Mureş, 540139, Romania; +40 265 215.551; etica_cercetarii@umfst.ro), ref: nr. 4056 from 05.02.2026

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Health services research, Prevention, Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied

Cervical and lumbar spine disorders—specifically nonspecific neck pain and low back pain (including lumbosciatica); domain: spinal/musculoskeletal rehabilitation.

Interventions

Experimental arm — Personalised rehabilitation program

Format: 10 individual, supervised physiotherapy sessions over 2 weeks (5 sessions/week).

Content: tailored mix of active and passive mobilisations, adapted stretching, strengthening exercises targeting spinal and paravertebral muscles, breathing techniques, and postural re-education.

Personalisation: initial functional assessment (joint mobility, VAS pain, pain type, activity level) used to design and progressively adjust exercise selection, intensity, and progression according to patient response.

Devices/equipment: exercise mat, TheraBand elastic resistance, stability ball, electrostimulation if clinically indicated.

Delivery: one-to-one with a physiotherapist; progression and modifications recorded each session.

Control arm — Standardised rehabilitation program

Format: 10 individual, supervised physiotherapy sessions over 2 weeks (5 sessions/week).

Content: predefined protocol of active/passive mobilisation, stretching, strengthening, breathing and postural exercises based on common clinical protocols (no individual tailoring during the intervention).

Devices/equipment: same standard clinic equipment (mats, resistance bands, stability ball, electrostimulation when indicated).

Delivery: one-to-one with a physiotherapist following the fixed protocol.

Common features

Assessment schedule: baseline and post-intervention outcome assessments performed by the same trained examiner who did not deliver the interventions.

Adherence requirement: participants expected to attend all sessions; missing three or more sessions was an exclusion criterion.

Participants were randomly assigned in equal numbers to either the personalised or standardised rehabilitation group. An independent statistician, who was not involved in recruitment or outcome assessment, created the randomisation sequence using Minitab® v20.3. To keep group sizes balanced, permuted block randomisation with a block size of four was used. Assignments were placed in sequentially numbered, opaque, sealed envelopes by the independent statistician to ensure allocation concealment. Once baseline assessments were finished, the treating clinician opened the next envelope to determine group assignment. The outcome assessor did not know which group participants were in during data collection.

Intervention Type

Other

Primary outcome(s)

1. Spinal joint mobility (cervical and lumbar flexion, extension, lateral flexion, rotation) measured using Universal goniometer measured in degrees at Baseline (pre-intervention), post-intervention (immediately after completion of the 10-session 2-week program)
2. Pain intensity measured using Visual Analogue Scale (VAS) 0–10 at Baseline (pre-intervention), post-intervention (immediately after completion of the 10-session 2-week program)
3. Patient satisfaction measured using 5-point Likert scale at Post-intervention (immediately after completion of the 10-session 2-week program)
4. Pain severity category (mild, moderate, severe) measured using Categorisation based on Visual Analogue Scale (VAS) cutoffs at Baseline (pre-intervention), post-intervention (immediately after completion of the 10-session 2-week program)

Key secondary outcome(s)

Completion date

06/05/2026

Eligibility

Key inclusion criteria

1. Age 30–65 years
2. Diagnosis of cervical or lumbar spine pain syndrome (cervicalgia, low back pain, or lumbosciatica) in the subacute or chronic phase
3. No spinal surgery within the previous 6 months
4. Able and available to complete the full rehabilitation program (10 sessions over 2 weeks)
5. No neurological or systemic conditions affecting active mobility

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

30 Years

Upper age limit

65 Years

Sex

All

Total final enrolment

20

Key exclusion criteria

1. Active inflammatory rheumatic diseases
2. Recent spinal surgery (within last 6 months)
3. Severe neurological disorders affecting motor function
4. Decompensated cardiovascular conditions
5. Missing ≥ 3 rehabilitation sessions (absence from three or more sessions)
6. Inability to complete initial or final assessments

Date of first enrolment

06/02/2026

Date of final enrolment

26/02/2026

Locations

Countries of recruitment

Romania

Sponsor information

Organisation

Universitatea de Medicină, Farmacie, Științe și Tehnologie „George Emil Palade” din Târgu Mureș

ROR

<https://ror.org/03gwbzf29>

Funder(s)**Funder type****Funder Name**

Universitatea de Medicină, Farmacie, Științe și Tehnologie "George Emil Palade" din Târgu Mureș

Alternative Name(s)

"George Emil Palade" University of Medicine, Pharmacy, Sciences and Technology from Târgu Mureș, UMFST G.E. Palade Tg.Mureș, UMF, Tîrgu-Mureș

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Romania

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available