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Fascial manipulation and thoracolumbar pain

Submission date
28/03/2026

Recruitment status
Not yet recruiting

Registration date
31/03/2026

Overall study status
Ongoing

Last Edited
31/03/2026

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Low back and thoracolumbar pain are very common conditions that can limit daily activities and reduce quality of life. Increasing evidence suggests that fascia (connective tissue surrounding muscles) may play an important role in this type of pain. This study aims to evaluate whether Fascial Manipulation therapy, alone or combined with dry needling, can reduce pain and improve tissue properties and function in patients with acute and chronic myofascial pain.

Who can participate?
Adults aged 18–65 years with thoracolumbar or low back pain of myofascial origin can take part. Participants may have either recent (acute) pain or long-lasting (chronic) pain, depending on the study group.

What does the study involve?
Participants will be assigned to different treatment groups. They may receive Fascial Manipulation therapy, dry needling, a combination of both, or a control (placebo) treatment. The treatment will take place over 1 week (for acute pain) or 4 weeks (for chronic pain). Before and after treatment, participants will undergo assessments of pain, physical function, and tissue properties using non-invasive methods.

What are the possible benefits and risks of participating?
Possible benefits include reduction of pain, improved movement, and better physical function. Risks are minimal and similar to standard physiotherapy treatments. They may include temporary soreness, mild discomfort, or small bruising (especially after dry needling). Serious complications are very rare.

Where is the study run from?
The study is conducted in two clinical centers in Poland:
Centrum Medyczne Provita (Żory) and Centrum Fizjoterapii Baterie Zdrowia (Krzepice).

When is the study starting and how long is it expected to run for?
The study will start in April 2026 and is expected to finish in December 2026.

Who is funding the study?
The study is funded by the participating clinical centers and statutory funds of the Academy of Silesia in Katowice.

Who is the main contact?
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Study information

Scientific Title
The effect of fascial manipulation on pain and mechanical properties of the thoracolumbar fascia in patients with chronic nonspecific myofascial pain of the thoracolumbar spine

Acronym

FM

Study objectives
Study aims, assumptions, and research question

The primary aim of this study is to investigate the influence of hydration status and body position on the stiffness of the thoracolumbar fascia. The study is based on the assumption that the mechanical properties of fascial tissue are not static, but may vary depending on physiological factors such as body water content and biomechanical conditions related to posture or positioning during assessment.

The main research question is whether hydration status and body position significantly affect thoracolumbar fascia stiffness as measured by objective instrumental methods. In particular, the study seeks to determine whether reduced hydration is associated with increased fascial stiffness, and whether changes in body position alter the measured mechanical properties of the thoracolumbar fascia.

A secondary aim is to assess the reliability and repeatability of thoracolumbar fascia stiffness measurements under standardized testing conditions. This is important because body position and hydration may act as confounding factors in the interpretation of fascia-related biomechanical measurements.

The study is justified by the current lack of clear evidence regarding physiological and positional factors influencing thoracolumbar fascia stiffness. A better understanding of these relationships may improve the interpretation of elastographic and biomechanical measurements in both clinical practice and future interventional studies focusing on myofascial pain and fascial dysfunction.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/03/2026, Research Ethics Committee of Physiotherapists at the Polish Physiotherapy Association (Polish Physiotherapy Association Zygmunta Modzelewskiego Street 37, unit U8, Warsaw, 02-679, Poland; + 48 601 300 080; biuro@fizjoterapeuci.org.), ref: RESOLUTION No. 6/03/2026

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Diagnostic, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Prevention and treatment of thoracolumbar myofascial pain in adult patients with acute and chronic non-specific spinal pain.

Interventions
Methodology summary

The study is designed as a prospective, randomized controlled trial (RCT) with an additional within-subject comparative component evaluating the effects of hydration status and body position on the mechanical properties of the thoracolumbar fascia.

A total of 120 participants are enrolled, with approximately N = 30 participants per group. Participants are recruited from outpatient physiotherapy clinics. After eligibility assessment and baseline measurements, participants are randomly allocated to study groups using a computer-generated block randomization sequence with allocation concealment. Randomization is performed in a 1:1 or 1:1:1 ratio depending on the study component.

The study includes three interventional components.

In the chronic pain component (two-center study), participants are assigned to:
the FM group (Fascial Manipulation), receiving standardized fascial therapy, and
the EX group (exercise therapy), receiving movement-based physiotherapy including spinal stabilization exercises, functional exercises, and patient education.

In the combined therapy component, participants are assigned to:
the FM+DN group (Fascial Manipulation combined with dry needling),
the FM+sham DN group (Fascial Manipulation with sham dry needling), and
the DN+sham FM group (dry needling with sham Fascial Manipulation).

In the acute pain component, participants are assigned to:
the FM group (active therapy) and
the sham FM group (placebo manual intervention involving non-therapeutic contact).

Each group includes approximately 30 participants.

Interventions are delivered by licensed physiotherapists trained in the study protocol. Fascial Manipulation is performed using a standardized procedure including functional assessment, identification of fascial points, and application of deep fascial friction, sustained pressure, fascial stretching, and gliding techniques. Dry needling is applied to myofascial trigger points using sterile, single-use filiform needles with brief manual stimulation and a retention time of approximately 10–15 minutes. Exercise therapy consists of structured movement-based physiotherapy focused on spinal stabilization, functional movement training, and education. Sham interventions include superficial manual contact without therapeutic effect and simulated needling without skin penetration.

The intervention duration depends on the study component. In the acute pain protocol, participants receive three sessions over one week. In the chronic pain and combined therapy protocols, participants receive eight sessions over four weeks (two sessions per week). Each session lasts approximately 30–40 minutes.

In addition to the interventional component, the study includes a within-subject comparative design assessing the effects of hydration and body position. Hydration status is evaluated under dehydration and standardized rehydration conditions using bioelectrical impedance analysis (BIA) and urine specific gravity test strips. Measurements are performed in multiple body positions, including standing, sitting, trunk flexion, and lying (supine or prone), to assess the influence of posture and loading on fascia properties.

Outcome measures include both clinical and instrumental assessments. Primary outcomes are thoracolumbar fascia stiffness measured using shear wave elastography (SWE), pain intensity measured using VAS and NRS, pressure pain threshold measured using digital algometry, and functional disability measured using the Oswestry Disability Index. Secondary outcomes include fascia thickness assessed by B-mode ultrasonography, biomechanical tissue properties assessed using MyotonPRO, microcirculation assessed using laser Doppler flowmetry, spinal range of motion measured using inclinometer or goniometer, and hydration status assessed using BIA and urine test strips.

All assessments are performed by blinded assessors at baseline, immediately after completion of the intervention, and at follow-up. Measurement procedures are standardized to ensure reliability and reproducibility.
Timepoints:
T0 – baseline (before intervention)
T1 – immediately after completion of the intervention
T2 – follow-up (depending on study component, e.g. 2 or 4 weeks)
T3 – extended follow-up (e.g. 4–8 weeks, depending on protocol)

Intervention Type
Mixed

Primary outcome(s)
1. Thoracolumbar fascia stiffness measured using shear wave elastography (SWE) in kilopascals (kPa) at T0 (baseline), T1 (immediately after intervention), T2 (follow-up), and T3 (extended follow-up)

2. Pain intensity measured using the Visual Analog Scale (VAS) in millimeters (mm) and the Numeric Rating Scale (NRS, 0–10) at T0, T1, T2, and T3

3. Pressure pain threshold measured using digital pressure algometry in kilograms per square centimeter (kg/cm^2) at T0, T1, T2, and T3

4. Functional disability measured using the Oswestry Disability Index (ODI) expressed as a percentage (%) at T0, T1, T2, and T3

Key secondary outcome(s))
1. Thoracolumbar fascia thickness measured using B-mode ultrasonography in millimeters (mm) at T0, T1, T2, and T3

2. Biomechanical tissue properties measured using the MyotonPRO device (frequency in Hz, stiffness in N/m, elasticity as log decrement) at T0, T1, T2, and T3

3. Microcirculation measured using laser Doppler flowmetry in perfusion units (PU) at T0, T1, T2, and T3

4. Spinal range of motion measured using inclinometer or goniometer in degrees (°) at T0, T1, T2, and T3

5. Hydration status measured using bioelectrical impedance analysis (BIA) and urine specific gravity test strips at T0 (baseline), before and after hydration, and during positional assessments

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Adults aged 18–65 years.
2. Presence of myofascial pain in the thoracolumbar or lumbar spine region.
3. Duration of symptoms: ≥3 months (chronic pain) or ≤7 days (acute pain, depending on the study arm).
4. Pain intensity of at least 4/10 on the NRS within the last week.
5. Presence of myofascial symptoms (e.g., trigger points or soft tissue tenderness).
6. No signs of radiculopathy or serious spinal pathology.
7. Stable clinical condition with no changes in pain-related pharmacological treatment within the last 4 weeks.
8. Ability to participate in study procedures and understand instructions.
9. Signed informed consent to participate in the study.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
100

Key exclusion criteria

1. Signs of serious spinal pathology (e.g., malignancy, infection, fractures, inflammatory spinal diseases, cauda equina syndrome, progressive neurological deficits).
Symptoms of radiculopathy (e.g., radiating pain below the knee, dermatomal paresthesia, positive neurological tension tests).
2. History of spinal surgery within the last 12 months or presence of spinal implants.
3. Recent musculoskeletal injury of the spine, pelvis, or soft tissues (<6 months).
4. Neurological disorders affecting pain perception or motor control (e.g., Parkinson’s disease, multiple sclerosis, peripheral neuropathies).
5. Rheumatologic or systemic inflammatory diseases (e.g., rheumatoid arthritis, ankylosing spondylitis).
6. Severe uncontrolled systemic diseases (e.g., cardiovascular, respiratory, or uncontrolled hypertension).
7. Interventional spine pain treatments within the last 3 months (e.g., steroid injections, nerve blocks, radiofrequency procedures).
8. Participation in intensive physiotherapy for the spine within the last 4 weeks.
9. Contraindications to manual therapy (e.g., acute soft tissue inflammation, skin conditions, severe osteoporosis).
10. Pregnancy.
11. Participation in another clinical trial within the last 3 months.
12. Lack of consent or withdrawal of consent at any stage of the study.

Date of first enrolment
20/04/2026

Date of final enrolment
04/05/2026

Locations

Countries of recruitment
Poland

Sponsor information

Organisation
Provita Medical Centre

Funder(s)

Funder type

Funder Name
Baterie Zdrowia" Medical Center

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available