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Validation of clinical tests used in physiotherapy diagnostics

Submission date
20/05/2026

Recruitment status
No longer recruiting

Registration date
22/05/2026

Overall study status
Ongoing

Last Edited
21/05/2026

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Neck pain and shoulder pain are common problems in adults and may lead to pain, reduced movement, disability, and lower quality of life. In physiotherapy practice, diagnosis is often based on clinical examination, functional assessment, and the therapist's experience. However, single clinical tests may have limited diagnostic accuracy. This study aims to assess the value of clinical tests, structured diagnostic protocols, ultrasound examination, and targeted physiotherapy in patients with non-specific neck pain and suspected frozen shoulder.

Who can participate?
Adults aged 18–60 years with non-specific neck pain or symptoms suggesting frozen shoulder

What does the study involve?
The project includes three related clinical studies. One study compares targeted physiotherapy for myofascial neck pain with standard symptomatic physiotherapy. Another study assesses whether ultrasound examination improves diagnostic accuracy in patients with suspected frozen shoulder. The third study evaluates the diagnostic accuracy of clinical tests and combinations of tests, called diagnostic clusters, in patients with non-specific neck pain.
Participants will undergo clinical assessment, functional testing, pain assessment, and selected physical measurements. Some participants will receive physiotherapy sessions twice a week for 3 weeks. Patients with suspected frozen shoulder may also undergo ultrasound examination and, if needed, MRI as part of the diagnostic verification process.

What are the possible benefits and risks of participating?
Participants may benefit from a detailed clinical assessment, more precise diagnosis, and individually selected physiotherapy. Possible risks are low and similar to those associated with standard physiotherapy. Temporary soreness, increased pain, tissue tenderness, or muscle fatigue may occur after manual therapy or exercises. Ultrasound is non-invasive and is not expected to cause adverse effects. MRI may cause discomfort in some patients. All adverse events will be recorded, and procedures will be stopped if needed.

Where is the study run from?
1. Centrum Medyczne Provita, Żory (Poland)
2. Centrum Fizjoterapii Body Medica, Poznań (Poland)

When is the study starting and how long is it expected to run for?
May 2026 to January 2027

Who is funding the study?
The study is funded by internal resources of Centrum Medyczne Provita, Centrum Fizjoterapii Body Medica Poznań, and statutory funds of the University of Upper Silesia in Katowice (Poland)

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
Validation of clinical tests and diagnostic clusters in myofascial physiotherapy: a prospective clinical study

Study objectives
Primary Objective:
To evaluate the diagnostic accuracy and clinical utility of clinical tests and structured diagnostic protocols used in myofascial physiotherapy in patients with non-specific neck pain and shoulder dysfunction

Secondary Objectives
1. To evaluate the effectiveness of targeted myofascial physiotherapy compared with standard physiotherapy treatment
2. To assess whether diagnostic clusters improve diagnostic accuracy compared with individual clinical tests
3. To evaluate the impact of musculoskeletal ultrasound examination on physiotherapy diagnostic accuracy
4. To assess changes in pain intensity, functional disability, muscle activity, tissue biomechanics, and range of motion following intervention
5. To evaluate changes in muscle strength, tissue vascularity, and muscle architecture during therapy
6. To assess patient-reported improvement and treatment satisfaction
7. To evaluate the relationship between physiotherapist clinical experience and diagnostic accuracy

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/05/2026, Ethics Committee for Scientific Research of Physiotherapists at the Polish Physiotherapy Association (ul. Zygmunta Modzelewskiego 37 lok. U8, Warszawa, 02-679, Poland; +48 (0)601300080; biuro@fizjoterapeuci.org), ref: RESOLUTION No. 1/05/2026 dated 13 May 2026

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Diagnostic, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Non-specific neck pain, myofascial pain syndrome, shoulder pain and movement dysfunction, musculoskeletal disorders treated in physiotherapy

Interventions
The study is conducted as a prospective clinical research program including interventional and observational components in the field of myofascial physiotherapy. Adult participants with non-specific neck pain and shoulder dysfunction are recruited from physiotherapy clinics after eligibility assessment and informed consent.

In the interventional part of the study, participants are randomly allocated in a 1:1 ratio to either a targeted myofascial physiotherapy group or a standard physiotherapy group. Randomization is performed using a computer-generated block randomization procedure with allocation concealment. Outcome assessors and data analysts remain blinded to group allocation.

The experimental group receives targeted myofascial physiotherapy based on standardized clinical assessment and identification of dominant myofascial dysfunctions. Interventions include ischemic compression, myofascial release techniques, transverse friction massage, post-isometric relaxation, trigger point therapy, movement control exercises, deep cervical flexor activation, scapular stabilization exercises, stretching, and individualized home exercise programs.

The control group receives standard physiotherapy consisting of general massage techniques and non-specific exercise therapy. Treatment includes classical massage, active neck movements, isometric exercises, and general stretching exercises. The same exercise protocol is used for all participants in the control group.

Both groups participate in six treatment sessions performed twice weekly over a period of 3 weeks. Each session lasts approximately 45 minutes.

In the observational and diagnostic components of the study, participants undergo standardized physiotherapy examination including medical interview, pain assessment, range of motion testing, palpation examination, neurological screening, and selected clinical tests. Diagnostic clusters combining several clinical tests are evaluated to determine their diagnostic accuracy and clinical utility.

Selected participants additionally undergo musculoskeletal ultrasound examination and, when clinically indicated, magnetic resonance imaging (MRI). Diagnostic findings obtained by physiotherapists are compared with a reference diagnosis established by an expert panel.

Primary outcomes include pain intensity, diagnostic accuracy, functional disability, and pressure pain threshold. Secondary outcomes include range of motion, biomechanical tissue properties, patient satisfaction, and adverse events. All measurements are performed at predefined assessment time points before and after intervention.

Intervention Type

Mixed

Primary outcome(s)
1. Pain intensity measured using the Visual Analog Scale (VAS, 0–100 mm) and Numeric Rating Scale (NRS, 0–10) at baseline (T0), immediately after completion of the therapeutic cycle (T1), and 2 weeks after intervention completion (T3)

2. Pressure pain threshold measured using the FDX-25 Wagner Force Dial Algometer at standardized myofascial points in the neck and shoulder region at baseline (T0), immediately after completion of therapy (T1), and 2 weeks after intervention completion (T3)

3. Functional disability measured using the Neck Disability Index (NDI) for patients with neck pain and appropriate shoulder function assessment for patients with suspected frozen shoulder at baseline (T0), immediately after completion of therapy or diagnostic assessment (T1), and 2 weeks after intervention completion or final diagnostic verification (T3)

4. Diagnostic accuracy of clinical tests and clinical test clusters measured using comparison with the reference diagnosis established by an expert panel at T0, T1, and T3

5. Diagnostic accuracy of physiotherapists in patients with suspected frozen shoulder measured before and after ultrasound examination, measured using comparison with the reference diagnosis established by an expert panel using clinical data and imaging findings at T0, T1, and T3

Key secondary outcome(s)
1. Cervical range of motion measured using an electronic or mechanical inclinometer in flexion, extension, lateral flexion, and rotation at baseline (T0), immediately after completion of therapy (T1), and 2 weeks after intervention completion (T3)
2. Biomechanical properties of myofascial tissues, including muscle tone, stiffness, and elasticity, measured using MyotonPRO at standardized points in the neck region at baseline (T0), immediately after completion of therapy (T1), and 2 weeks after intervention completion (T3)
3. Skin microcirculation measured using laser Doppler flowmetry with the PeriFlux System 5000 at standardized points in the neck region at baseline (T0), immediately after completion of therapy (T1), and 2 weeks after intervention completion (T3)
4. Global perceived change measured using the Global Rating of Change Scale (GROC) immediately after completion of therapy (T1) and 2 weeks after intervention completion (T3)
5. Patient satisfaction measured using a Patient Satisfaction Scale immediately after completion of therapy (T1)
6. Shoulder soft tissue and rotator cuff assessment measured using ultrasound examination with the SonoScape P20 ultrasound system in patients with suspected frozen shoulder during diagnostic assessment
7. Adherence to the intervention measured by attendance rate, completion of at least 80% of planned sessions, and duration of therapeutic sessions throughout the intervention period
8. Safety and tolerability measured by the number, type, severity, and timing of adverse events recorded throughout the study period

Completion date
30/01/2027

Eligibility

Key inclusion criteria

1. Adults aged 18–60 years
2. Non-specific neck pain lasting from 1 month to 6 months
3. Presence of myofascial symptoms confirmed during physiotherapy examination
4. Pain intensity ≥4 on the Numeric Rating Scale (NRS)
5. Ability to participate in physiotherapy procedures and assessments
6. Signed informed consent

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Signs of serious spinal pathology (red flags)
2. Radiculopathy or neurological disorders
3. Previous spinal surgery within the last 12 months
4. Acute musculoskeletal injuries
5. Rheumatologic or systemic inflammatory diseases
6. Severe cardiovascular or systemic diseases
7. Recent interventional pain procedures
8. Pregnancy
9. Participation in another clinical trial within the last 3 months

Date of first enrolment
29/05/2026

Date of final enrolment
29/08/2026

Locations

Countries of recruitment
Poland

Sponsor information

Organisation
Centrum Fizjoterapii Body Medica

Funder(s)

Funder type

Funder Name
Centrum Fizjoterapii Body Medica

Funder Name
Centrum Medyczne Provita

Funder Name
University of Upper Silesia in Katowice

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			20/05/2026	No	No
Protocol file			20/05/2026	No	No