ISRCTN17648638 https://doi.org/10.1186/ISRCTN17648638

Interventional rehabilitation for jaw joint problems

Submission date
20/10/2025

Recruitment status
No longer recruiting

Registration date
24/10/2025

Overall study status
Completed

Last Edited
05/11/2026

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Temporomandibular disorders (TMD) affect about 5–12% of the population and represent the second most common source of musculoskeletal pain after low back pain. The myofascial form of TMD is associated with pain, limited mobility, and the presence of trigger points in the masticatory muscles. Standard treatment includes soft tissue techniques, joint mobilisation, targeted exercise and pharmacotherapy. Dry needling is a modern therapeutic approach focused on the deactivation of trigger points and modulation of pain.
The aim of this study is to evaluate the effectiveness of combining dry needling with standard rehabilitation compared to standard rehabilitation alone in patients with functional temporomandibular pain syndrome.
The combination of both methods may result in a greater reduction of pain and improvement of functional parameters compared to standard rehabilitation alone.

Who can participate?
Patients aged 18 years and over with functional temporomandibular disorder

What does the study involve?
Participants are randomly allocated to one of two groups:
Experimental group: standard outpatient rehabilitation program combined with dry needling applied to trigger points in the masseter and temporalis muscles during the first treatment session.
Control group: standard outpatient rehabilitation without dry needling.
Participants will undergo an evaluation of treatment effects using pain intensity scales, range of motion measurements, and quality of life assessments before and after therapy.

What are the possible benefits and risks of participating?
The main benefit is an objective evaluation of improvement in jaw function and pain reduction.
No significant risks are expected.

Where is the study run from?
Palacký University Olomouc (Czech Republic)

When is the study starting and how long is it expected to run for?
January 2024 to June 2026

Who is funding the study?
Palacký University Olomouc (Czech Republic)

Who is the main contact?
Petr Konečný, petr.konecny@upol.cz

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Reflex therapy of temporomandibular dysfunctions – randomized controlled pilot study

Study objectives
We hypothesise that combining dry needling with standard rehabilitation will result in greater improvement in pain reduction and functional outcomes compared to standard rehabilitation alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/01/2024, Ethics Committee of the Faculty of Health Sciences, Palacký University Olomouc (Hnevotinská 3, Olomouc, 77900, Czech Republic; +420 (0)585632860; lenka.stloukalova@upol.cz), ref: UPOL-3853/1030S-2025

Primary study design

Interventional

Study design
Single-centre interventional prospective parallel-group randomized controlled trial with concealed allocation, assessor blinding, and an active control

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Functional temporomandibular pain syndrome

Interventions
Single-centre interventional prospective parallel-group randomized (1:1) controlled trial with concealed allocation, assessor blinding, and an active control (standard rehabilitation alone) comparing dry needling + standard rehabilitation versus standard rehabilitation alone.

Experimental group: standard outpatient rehabilitation program combined with dry needling applied to trigger points in the masseter and temporalis muscles during the first treatment session.

Control group: standard outpatient rehabilitation without dry needling.

Each participant will undergo 10 outpatient sessions over 5 weeks (two per week).

Intervention Type
Procedure/Surgery

Primary outcome(s)
Subjective pain intensity in the TMJ region assessed using the Visual Analogue Scale (0–10) at baseline, 24 hours, and 1 month after the start of therapy

Key secondary outcome(s)
1. Quality of life is assessed using the WHOQOL questionnaire at baseline, 24 hours, and 1 month after the start of therapy
2. Range of motion is measured with a sliding millimetre ruler at baseline, 24 hours, and 1 month after the start of therapy

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Adult patients with functional temporomandibular pain syndrome

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Structural TMJ disorders
2. Neurological disorders
3. Acute infection
4. Botulinum toxin application within the last 6 months

Date of first enrolment
30/10/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Czech Republic

Study participating centre
Palacký University Olomouc
Department of Clinical Rehabilitation
Faculty of Healthy Sciences
Hněvotínská 3
Olomouc
Czech Republic
77900

Sponsor information

Organisation
Palacký University Olomouc

ROR
https://ror.org/04qxnmv42

Funder(s)

Funder type
University/education

Funder Name
Univerzita Palackého v Olomouci

Alternative Name(s)
Palacký University Olomouc, Palacký University, Olomouc, Palacký University, UP

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Czech Republic

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication. The datasets generated during and/or analysed during the current study will be available upon request from (petr Konecny, petr.konecny@upol.cz).
Data will be collected only from participants who provide written informed consent approved by the ethics committee.
Only anonymised summary data on treatment outcomes (pain, range of motion, quality of life) will be shared.
The data will be available after study completion for a period of five years, upon written request for scientific purposes.
Access will be granted only to qualified researchers after approval by the principal investigator.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Basic results	in Czech	10/08/2026	No	No
Basic results		10/08/2026	No	No
Protocol file		05/11/2026	No	No
Statistical Analysis Plan		05/11/2026	No	No