Protocol Summary

Study Identification

Unique Protocol ID (Organization)

IGA_FZV_2025_015

Brief Title

Dry Needling as an Adjunct to Rehabilitation of Temporomandibular Dysfunctions—Randomized Controlled Pilot Study

Acronym

Study Type

Interventional

Official Title

Evaluation of the Therapeutic Efficacy of Dry Needling Reflex Therapy in Patients with Functional Temporomandibular Pain Syndrome: A Prospective, Randomized, Controlled Pilot Study.

Secondary ID

Study Status

Record Verification Date

October 2025

Overall Recruitment Status

Recruiting

Study Start Date

November 2025

Actual

Primary Completion Date

December 1, 2026

Estimated

Study Completion Date

June 2026

Estimated

Sponsors and Collaborators

Responsible Party, by Official Title

Principal Investigator

Investigator Name [Username]

Petr Konečný [pkonecny]

Investigator Official Title

Associate Professor, Head of the Department of Clinical Rehabilitation, Palacký University Olomouc

Investigator Affiliation

Palacký University Olomouc

Sponsor Name

Palacký University Olomouc

Collaborators

Oversight

U.S. FDA-Regulated Product

U.S. FDA-Regulated Drug

No

U.S. FDA-Regulated Device

No

Investigational New Drug (IND)/Investigational Device Exemption (IDE) Information

U.S. FDA IND/IDE

No

Human Subjects Protection Review

Board Status

Approved

Approval Number

UPOL-3853/1030S-2025

Board Name

Ethics Committee of the Faculty of Health Sciences

Board Affiliation

Palacký University Olomouc, Czech Republic

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Data Monitoring Committee

None

Study Description

Brief Summary

This study aims to evaluate the effectiveness of dry needling in patients with functional temporomandibular pain syndrome by comparing standard rehabilitation therapy alone with rehabilitation combined with dry needling, with the objectives of reducing pain, improving jaw function, and enhancing quality of life.

Detailed Description

This prospective, randomized, controlled pilot study aims to evaluate the therapeutic effects of dry needling in patients with functional temporomandibular pain syndrome. A total of 40 participants will be randomly assigned to two groups: an experimental group receiving standard rehabilitation combined with dry needling, and a control group receiving standard rehabilitation alone. The intervention program will consist of ten outpatient rehabilitation sessions over five weeks. Outcome measures will include pain intensity (visual analogue scale, VAS), temporomandibular joint range of motion, the presence of joint sounds, and quality of life assessed using the World Health Organization Quality of Life–BREF questionnaire (WHOQOL-BREF). Measurements will be collected at baseline, immediately after the first therapy session, and after completion of the treatment course. Descriptive statistics will be used for data analysis. The Shapiro–Wilk test will assess data normality. Between-group differences will be analysed using parametric (t-test) or nonparametric (Mann–Whitney, Wilcoxon) tests, depending on data distribution. Correlation analyses will be performed using Pearson’s or Spearman’s correlation coefficient. Statistical

significance will be set at $p < 0.05$. All statistical analyses will be conducted using IBM SPSS Statistics for Windows, version 29.0 (Armonk, NY, USA).

Conditions

Conditions or Focus of Study

Temporomandibular Joint Dysfunction; Myofascial Pain Syndrome; Orofacial Pain; Musculoskeletal Disorders

Keywords

headache; temporomandibular disorders; dry needling; rehabilitation therapy; pain; quality of life

temporomandibular disorders; dry needling; rehabilitation therapy; pain; quality of life

Study Design

Primary Purpose

Treatment

Study Phase

Not Applicable

Interventional Study Model

Parallel Assignment

Model Description

Number of Arms

2

Masking

None (Open Label)

Masking Description

Allocation

Randomized

Enrollment

Estimated

40

Arms and Interventions

Arms	Interventions
Experimental: Dry Needling and Standard Rehabilitation Participants in this group will undergo standard outpatient rehabilitation therapy combined with one dry needling intervention targeting trigger points in the masseter and temporalis muscles during the first treatment session. The rehabilitation program will include mobilization, soft tissue techniques, and targeted therapeutic exercise. Each participant will attend ten outpatient rehabilitation sessions over five weeks (two sessions per week).	Procedure: Dry Needling One dry needling procedure targeting trigger points in the masseter and temporalis muscles during the first treatment session. Other name: trigger-point reflex injection therapy. Procedure: Standard Rehabilitation Therapy will include mobilization, soft tissue relaxation techniques, and specific exercises aimed at improving temporomandibular joint mobility and reducing muscle tension. Other name: standard physical rehabilitation program.
Active Comparator: Control Group — Standard Rehabilitation Participants in this group will receive the same standard outpatient rehabilitation program as the experimental group, excluding the dry needling procedure. Therapy will include mobilization, soft tissue relaxation techniques, and specific	Procedure: Standard Rehabilitation Therapy will include mobilization, soft tissue relaxation techniques, and specific exercises aimed at improving temporomandibular joint mobility and reducing muscle

exercises aimed at improving temporomandibular joint mobility and reducing muscle tension.	tension. Other name: standard physical rehabilitation program.

Outcome Measures

Primary Outcome Measures

1. Pain intensity measured using the Visual Analogue Scale (VAS)

Description: Assessment of subjective pain intensity in the temporomandibular region using the Visual Analogue Scale (VAS), a continuous scale ranging from 0 to 10, where 0 indicates no pain and 10 indicates the worst imaginable pain. Higher scores indicate greater pain intensity.

Measure Type: Continuous (0–10 scale).

[Time Frame: Baseline (before intervention)]

Immediately after the first therapy session

After completion of the treatment program (after 10 therapy sessions).

Secondary Outcome Measures

2. Temporomandibular joint (TMJ) range of motion, joint sounds, and quality of life (WHOQOL-BREF)

Description: Measurement of maximum mouth opening and mandibular range of motion using a caliper to assess functional improvement of the temporomandibular joint.

Measure Type: Continuous (millimetres).

and

Description: Clinical assessment of the presence or absence of joint sounds (clicking, popping, or crepitus) during mandibular movement as an indicator of functional stability of the temporomandibular joint.

Measure Type: Categorical (present/absent).

and

Description: Assessment of overall quality of life using the WHOQOL-BREF questionnaire, which evaluates physical, psychological, social, and environmental domains.

Measure Type: Continuous (score-based).

[Time Frame: Baseline (before intervention)]

Immediately after the first therapy session

After completion of the treatment program (after 10 therapy sessions)

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Eligibility

Accepts Healthy Volunteers

No

Sex

All

Gender-Based Eligibility

No

Age Limits

Minimum Age

18 years

Maximum Age

Not Applicable

Eligibility Criteria

Inclusion Criteria:

- Diagnosis of functional temporomandibular pain syndrome without structural damage to the temporomandibular joint.
- Age ≥18 years.
- Stable medical condition suitable for outpatient rehabilitation.
- Willingness to participate and ability to adhere to the treatment protocol.

Exclusion Criteria:

- Presence of degenerative, post-traumatic, or inflammatory changes in the temporomandibular joint.
- Cognitive or psychiatric disorders limiting cooperation.
- Lack of informed consent or failure to comply with the treatment regimen during therapy.

Contacts and Locations

Central Contact Person

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Study Officials

Locations

1 Location

Czech Republic

Faculty of Health Sciences, Palacký University Olomouc, Czech Republic

Recruiting

Olomouc,

, Czech Republic 77900

Principal Investigators: PETR Konečný, Dana Dvořáková

Individual Participant Data (IPD) Sharing Statement

IPD Sharing Plan

No

Plan Description

Individual participant data will not be shared due to patient privacy policies and institutional personal data protection policies.

References

Citations

3 citations

PubMed ID: 41064810

Citation report results: true

Quilghini C, Lefflot J, Buchholtz K

PubMed ID: 26294683

Citation report results: true

Armijo-Olivo S,Pitance L,Singh V,Neto F,Thie N,Michelotti A

PubMed ID:

Citation report results: true

Konečný P, Havlíčková J, Elfmark M, Tvrdý P, Hanáková D, Jureček M. Effects of rehabilitation in patients with temporomandibular joint disorders. Rehabil. Fyz. Lek. (2007) 14: 95–100. [Original publication in Czech.]

Links

0 links

Available IPD and Supporting Information

1 Available IPD and Supporting Information

Clinical Study Report

https://www.upol.cz/cs/research/clinical-rehabilitation

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Individual participant data are available upon reasonable request from the study sponsor (Palacký University Olomouc, Department of Clinical Rehabilitation).