

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of dry needling and sham dry needling effectiveness on pain, range of motion and pressure pain threshold in patients with temporomandibular joint dysfunction after dental procedure

Protocol summary

Study aim

Determining the effectiveness of dry needling on myofascial pain of temporomandibular joint as well as range of motion in patients with mobility impairment after dentistry

Design

The randomized control trial has a control group with a parallel double-blind randomized group, on 56 patients that will use the block balanced randomization method.

Settings and conduct

The study in the Nafis physiotherapy clinic, after randomization and collection of initial information, will be performed by dry needling in the intervention group and sham dry needling in the control group in two sessions with an interval of one week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women 20-50 years old. One week or a months interval from the onset of symptoms and limited range of motion following a visit to the dentist with or without medication. Not performing physiotherapy on the head and neck for the past 12 months. No scar tissue, infection, wound or inflammation on trigger point area. Do not use addictive substances and alcohol due to rising pain threshold. Restriction of mouth opening less than 30 mm or pain with Numeric Rating Scale above 3. Exclusion criteria: Both side pain. History of clenching while sleeping or night guard using. Temporomandibular joint (TMJ) degenerative disease. Inflammation in mouth, History of TMJ or dental surgery. History of systemic or metabolic disorders, such as metabolic syndrome Rheumatoid arthritis, atypical fascial pain, neuralgia and fibromyalgia. Instability in chewing structures. Orthodontic treatment. Anticoagulant therapy. Pregnancy

Intervention groups

The intervention group is treated with dry needling therapy by a second physiotherapist in the master,

temporalis, internal and external pterygoids muscles. People in the placebo group are also subjected to sham dry needling.

Main outcome variables

Range of motion, pain, pressure pain threshold

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200927048859N1**

Registration date: **2021-11-23, 1400/09/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-23, 1400/09/02**

Update count: **0**

Registration date

2021-11-23, 1400/09/02

Registrant information

Name

Nafiseh Zekri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3355 5455

Email address

nafiseh_zekri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of dry needling and sham dry needling effectiveness on pain, range of motion and pressure pain threshold in patients with temporomandibular joint dysfunction after dental procedure

Public title

Evaluation of dry needling effectiveness on temporomandibular joint pain and range of motion

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Men and women 20-50 years old. Pain and range of motion limitation on one side of the temporomandibular joint who visit the dentist in the past month or a week. One week interval from the onset of symptoms and limited range of motion following a visit to the dentist with or without medication. Not performing physiotherapy on the head and neck for the past 12 months. No scar tissue, infection, wound or inflammation on trigger point area. Do not use addictive substances and alcohol due to rising pain threshold. Restriction of mouth opening less than 30 mm or pain with Numeric Rating Scale above 3

Exclusion criteria:

Both side pain History of clenching while sleeping or night guard using Temporomandibular joint (TMJ) degenerative disease Inflammation in mouth History of TMJ or dental surgery History of systemic or metabolic disorders, such as metabolic syndrome Rheumatoid arthritis, atypical fascial pain, neuralgia and fibromyalgia Instability in chewing structures Orthodontic treatment Anticoagulant therapy Pregnancy

AgeFrom **20 years** old to **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **52****Randomization (investigator's opinion)**

Randomized

Randomization description

The randomization process will be done through closed envelopes and block balanced randomization method. First of all, the first physiotherapist considers all possible aabb arrangements and using a random number table, randomly selects 10 blocks and writes their components

one after the other. Each of these components will then be placed in a sealed envelope and numbers 1 to 52 will be recorded on the envelope. Since the therapist is not aware of how the groups are assigned until the intervention, the important feature of allocation concealment is observed in this study. On the day of the intervention, the first physiotherapist choose the envelopes one by one and based on that, places the patients in the intervention group and Placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

The first physiotherapist is blind to the grouping of patients and the second physiotherapist is blind to the data obtained from the assessments of each patient performed by the first physiotherapist. The patient is also blind to which group he or she belongs to. In the control group, a sharp needle-shaped plastic shield is used so that the patient can only feel the sharp object. It should be noted that the patient's eyes are covered in both groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Qom University of Medical Sciences

Street address

No.11, Shahid Akhlaghi St, Sepah Sq, Jomhuri St, Qom, Iran

City

Qom

Province

Ghoum

Postal code

3716699845

Approval date

2021-01-26, 1399/11/07

Ethics committee reference number

IR.MUQ.REC.1399.266

Health conditions studied**1****Description of health condition studied**

Pain and temporomandibular dysfunction after dental procedure

ICD-10 code

M26.6

ICD-10 code description

Temporomandibular joint disorders

Primary outcomes

1

Description

Pain with Numeric Rating Scale

Timepoint

At the beginning of the study, one week and two weeks after the start of the intervention

Method of measurement

Numeric Rating Scale; The 11-point numeric scale ranges from '0' representing one pain extreme (e.g. "no pain") to '10' representing the other pain extreme (e.g. "pain as bad as you can imagine" or "worst pain imaginable").

2

Description

Range of motion of temporomandibular joint

Timepoint

At the beginning of the study, one week and two weeks after the start of the intervention

Method of measurement

goniometer

3

Description

Evaluation of sensitivity of trigger points

Timepoint

At the beginning of the study, one week and two weeks after the start of the intervention

Method of measurement

Digital pressure algometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They are treated with dry needling on masseter, temporalis, internal and external pterygoid muscles. Initially, by touching and pressing the therapist's hand on each muscle, the most sensitive point to touch is found and targeted with a needle. In this way, the special needles enter this sensitive part of the muscle and remain in the muscle for 20 minutes with infrared heat. At first, the patient's eyes are covered with wet cotton so that the infrared light does not bother and the patient is also blind to the intervention.

Category

Treatment - Other

2

Description

Control group: This group is subjected to sham dry needling. Initially, by touching and pressing the therapist's hand in all four muscles of the masseter, temporal, internal and external pterygoid, the most sensitive point to touch is found and targeted by a sharp plastic needle guide to make the patient feel sharp. And infrared heat shines on the face for 20 minutes. Initially, the patient's eyes are covered with wet cotton so that the infrared light does not bother and the patient is also blind to the intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nafis Physiotherapy clinic

Full name of responsible person

Sepideh Paybast

Street address

No.11, Iran building, Akhlaghi St. Sepah Sq. Jomhouri St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Qom university of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Sepideh Paybast

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Nafiseh Zekri

Position

Physiotherapist

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Physiotherapist

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Measurement data and results obtained from each person can be shared.

When the data will become available and for how long

Upon completion of the study for 6 months

To whom data/document is available

Researchers on similar subjects

Under which criteria data/document could be used

To use the results of the study and citation for related studies

From where data/document is obtainable

Email researcher in charge. Dr Sepideh Paybast, sepideh.paybast@yahoo.com Physiotherapist Nafiseh

Zekri, nafiseh_zekri@yahoo.com

What processes are involved for a request to access data/document

Your email will be read and answered within a week.

Comments