

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The efficacy of self-care on ear symptoms in patients with temporomandibular joint disorders

Protocol summary

Study aim

Evaluating the effect of self-management in improving aural symptoms in patients with temporomandibular disorders

Design

Phase 2 clinical trial on 42 patients

Settings and conduct

Symptoms of Temporomandibular Disorders Patients who have ear symptoms and will refer to the Department of Oral and Maxillofacial Diseases Faculty of Dentistry of Tehran University of Medical Sciences will be examined and recorded by a trained examiner in the first visit. Pain intensity will be evaluated using a numerical analog scale. Then the necessary "self-care" training will be given. 2 weeks, 1 and 2 months later, again similar to the first session, the patient will be examined and the symptoms will be recorded.

Participants/Inclusion and exclusion criteria

Temporomandibular joint disorder, earache alone or accompanied by at least one ear symptom including tinnitus, ear fullness, having parafunctional habits, absence of inflammatory and infectious ear lesions, ear or head and neck neoplastic lesions, ear cystic lesions History of head and neck trauma, history of head and face surgery, pregnancy, neurological disorders

Intervention groups

Referees to the Department of Oral and Maxillofacial medicine, Faculty of Dentistry, Tehran University of Medical Sciences, with complaints of Temporomandibular joint disorders.

Main outcome variables

Temporomandibular Disorders

General information

Reason for update

Acronym

TMD

IRCT registration information

IRCT registration number: **IRCT20090118001559N12**

Registration date: **2022-11-23, 1401/09/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-23, 1401/09/02**

Update count: **0**

Registration date

2022-11-23, 1401/09/02

Registrant information

Name

Farzaneh Aghahoseini

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-21, 1401/08/30

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of self-care on ear symptoms in patients with temporomandibular joint disorders

Public title

The effect of self-care on ear problems in people with jaw problems

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Temporomandibular joint disorder Earache alone (with NRS=3) or accompanied by at least one of the ear symptoms including tinnitus, ear fullness having parafunctional habits (such as bruxism during sleep or waking up, biting nails or lips and resting the hand under the chin)

Exclusion criteria:

Inflammatory and infectious lesions of the ear Neoplastic lesions of the ear or head and neck Cystic ear lesions History of head and neck trauma History of head and face surgery pregnancy neurological disorders

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 42

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Dentistry, Tehran University of Medical Sciences

Street address

School of Dentistry, Tehran University of Medical Sciences, North Karegar St., Enghelab Sq., Tehran.

City

Tehran

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Tehran

Postal code

۱۴۳۹۹۵۵۹۹۱

Approval date

2022-11-02, 1401/08/11

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1401.104

Health conditions studied

1

Description of health condition studied

otalgia

ICD-10 code

ICD-10 code description

K07.6H92.0

2

Description of health condition studied

tinnitus

ICD-10 code

ICD-10 code description

H93.1

3

Description of health condition studied

Temporomandibular joint disorders

ICD-10 code

ICD-10 code description

K07.6

Primary outcomes

1

Description

Temporomandibular joint disorders

Timepoint

At the beginning of the study and 2 weeks later, the first month, the second month and the third month

Method of measurement

Numerical Analogue Scale

Secondary outcomes

1

Description

Changes in earache intensity

Timepoint

The beginning of the study, the first 2 weeks, the first month, the second month and the third month

Method of measurement

Numerical Analogue Scale

2

Description

changes in tinnitus

Timepoint

The beginning of the study, the first 2 weeks, the first month, the second month and the third month

Method of measurement

tinnitus handicap inventory

3

Description

changes in ear fullness

Timepoint

The beginning of the study, the first 2 weeks, the first month, the second month and the third month

Method of measurement

Numerical Analogue Scale

Intervention groups

1

Description

Intervention group: In patients who have jaw problems and also complain of ear pain, ear fullness or tinnitus, the symptoms of temporomandibular disorders will be examined by a trained examiner and the diagnosis of temporomandibular disorders will be confirmed with the criteria of the RDC-TMD questionnaire and the severity of dysfunction Helkimo's clinical criteria will be registered. Patients are then asked to rate the pain intensity on a scale of 0 to 10, where 0 represents no pain and 10 represents maximum pain. Tinnitus is evaluated by tinnitus handicap inventory and severity of earache and ear fullness by grading from 0 to 10. After recording symptoms, the necessary "self-care" training will be given in the form of a short seminar, along with skills training provided through demonstrations, exercises between sessions, and structured feedback during sessions and phone calls. Self-care includes: education (about the socio-biology model of TMD, chronic pain, multifaceted aspects of the cause of TMD, management methods, and the logic of self-management), bilateral chewing, limitation of mouth opening (opening the mouth within the range of the patient's pain threshold), diet control (avoid eating hard food), yawn control (opposite pressure on the back of both hands under the chin), thermal modalities (use of moist heat (twice a day for 20 minutes each time) and ice compresses (1 time and 10 minutes each time) alone or together), massage therapy (touching and caressing the muscles along them), controlling parafunctional behaviors (putting their tongue behind the front teeth of the upper jaw, such as when say "N" and then close your mouth and when the lower jaw was in a resting position, leave a few millimeters of space between the occlusion surfaces of the upper and lower teeth while the lips are slightly in contact with each other (free space) (Patients will be instructed to maintain this relaxed position at all times at rest, except when eating or talking and to avoid involuntary muscle contraction with teeth in central occlusion). Then two weeks, 1 month and 2 months later, the patient will be monitored to ensure that the training is done correctly, and again, similar to the first session, the examination will be done and the severity of the symptoms will be recorded.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

Parmiss omidsalar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Zahra Khorshidi

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Research Center of School of Dentistry, Tehran University of Medical Sciences, Enghelab Sq., Tehran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Parmiss Omidasalar

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr. Farzaneh Aghahosseini

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

After deidentifying the patient's demographic information, the results obtained after the treatment can be shared

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

For researchers working in academic and scientific institutions will be available

Under which criteria data/document could be used

After deidentifying the patient's demographic information, the results obtained after the treatment can be shared

From where data/document is obtainable

Faculty of Dentistry, Tehran University of Medical Sciences, Dr. Parmiss Omidasalar

What processes are involved for a request to access

data/document

The access period starts 12 months after receiving the

request

Comments