

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the effect of life-style factors on temporomandibular disorders

Protocol summary

Study aim

Evaluation of the effect of life-style factors on temporomandibular disorders

Design

A randomized clinical trial with 2 groups (intervention and control) of 50 patients.

Settings and conduct

Life-style of patients who are referred to the Oral and maxillofacial surgery department of Shahid Beheshti dental school and suffer from temporomandibular disorder, will be evaluated by questionnaire. Patients who get included in the trial will be randomly put in the intervention or control group. The control group will receive the routine pharmacotherapy regimen and the intervention group in addition to it, will follow a protocol to improve their life-style; Patients will be followed up every 3 months for 9 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with TMD signs and symptoms (clicking or crepitus accompanied by pain with or without limitation of mouth opening) who according to the questionnaire suffer from sleep disturbance and psychological distress. Exclusion criteria: Patients suffering from systemic diseases that affects TM joint; History of jaw fracture or trauma; History of orthognathic surgery or other joint surgeries

Intervention groups

Patients who are chosen after fillig out the questionnaire, are randomly put in the intervention and control group. Control group receive the routine pharmacotherapy regimen (Naproxen 250mg q8h AND Methocarbamol 500mg q8h for 2 weeks). Intervention group, in addition to pharmacotherapy, follow the following protocol: 1- listening to desired music at least 45 minutes daily 2- Walking or exercise of choice 30 minutes daily (At least 5 days a week) 3-Managing sleeping hours to a minimum of 7 hours daily (At least 5 days a week)

Main outcome variables

Joint pain; Clicking; Maximum mouth opening; Crepitus;

Stress; Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210209050304N1**

Registration date: **2021-07-29, 1400/05/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-29, 1400/05/07**

Update count: **0**

Registration date

2021-07-29, 1400/05/07

Registrant information

Name

Yasaman Shourmaej

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7705 0477

Email address

yasamanshourmaj@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of life-style factors on temporomandibular disorders

Public title
Effect of life-style on temporomandibular joint disorders

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with Temporomandibular disorder (TMD) signs and symptoms
 Patients suffering from sleep disturbance
 Patients suffering from psychological distress
Exclusion criteria:
 Patients suffering from systemic diseases that affects the temporomandibular joint
 History of jaw fracture or trauma
 History of orthognathic surgery or other joint surgeries
 Patients who have an acceptable life-style

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done by the simple method and with cards. Type of intervention is written on the cards which will be put in sealed opaque envelopes. Patients are included in the list of the participants in the order of the time of their first visit and the code of the questionnaire they have completed. After entering the trial, each patient chooses an envelope after folding the cards. Envelopes are prepared according to the predicted sample size and the number of patients; Therefore, each selected envelope will not be re-entered in the randomization sequence, so there would be the same number of patients in both groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Research institute for Dental Sciences - Shahid Beheshti University Of Medical S
Street address
 13th Fl, Block A, Ministry of Health, Treatment and Medical Education Headquarters, Between Zarafshan & South Falamak, Sima-Ye-Iran St, Qods Town
City
 Tehran
Province
 Tehran
Postal code
 1983963113
Approval date
 2020-11-23, 1399/09/03
Ethics committee reference number
 IR.SBMU.DRC.REC.1399.070

Health conditions studied

1

Description of health condition studied
Temporomandibular joint disorder

ICD-10 code
M26.6

ICD-10 code description
Temporomandibular joint disorders

Primary outcomes

1

Description
Joint pain

Timepoint
At the beginning of the trial and on the follow up sessions; 3, 6 and 9 months after starting the intervention

Method of measurement
Visual Analogue Scale

2

Description
Clicking

Timepoint
At the beginning of the trial and on the follow up sessions; 3, 6 and 9 months after starting the intervention

Method of measurement
Clinical examination

3

Description
Maximum Mouth Opening

Timepoint
At the beginning of the trial and on the follow up sessions; 3, 6 and 9 months after starting the

intervention
Method of measurement
Clinical Examination

4

Description

Crepitus

Timepoint

At the beginning of the trial and on the follow up sessions; 3, 6 and 9 months after starting the intervention

Method of measurement

Clinical Examination

5

Description

Stress Score according to Psychological General Well-Being Index

Timepoint

At the beginning of the trial and on the follow up sessions; 3, 6 and 9 months after starting the intervention

Method of measurement

Psychological General Well-Being Index

6

Description

Sleep quality according to The Pittsburgh Sleep Quality Index

Timepoint

At the beginning of the trial and on the follow up sessions; 3, 6 and 9 months after starting the intervention

Method of measurement

The Pittsburgh Sleep Quality Index Questinnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: They receive the routine pharmacotherapy regimen (Naproxen 250mg q8h AND Methocarbamol 500mg q8h for 2 weeks).

Category

Treatment - Drugs

2

Description

Intervention group: In addition to pharmacotherapy (Naproxen 250mg q8h AND Methocarbamol 500mg q8h for 2 weeks), they follow the following protocol: 1- listening to desired music at least 45 minutes daily 2- Walking or exercise of choice 30 minutes daily (At least 5 days a week) 3-Managing sleeping hours to a minimum

of 7 hours daily (At least 5 days a week)

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Dental School

Full name of responsible person

Reza Tabrizi

Street address

Shahid Beheshti Dental School, Daneshjou Blvd., Evin St., Shahid Chamran Hwy.

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info@sbmu.ac.ir

Web page address

<http://dentistry.sbmu.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

5th Floor, Building No. 2, Shahid E'rabi St., Yaman St., Shahid Chamran Hwy.

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1985717443

Phone

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Email

Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Tabrizi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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No. 2, Nabavi Ave., Shariati Street

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Yasaman Shourmaej

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Fax**Email**

yasamanshourmaj@sbmu.ac.ir

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

Age, sex and information on patients' life-style, without exposing their personal information and identity, and improvements on their temporomandibular disorder can be published.

When the data will become available and for how long

Starts after the trial is over.

To whom data/document is available

Researchers presenting a recommendation letter from a research center or an educational institute can access the data.

Under which criteria data/document could be used

Data can be accessed and used for further research by researchers providing a recommendation letter from a research center or an educational institute.

From where data/document is obtainable

Data can be obtained from the first author (Dr. Reza

Tabrizi) or the oral and maxillofacial surgery department of Shahid Beheshti dental school. Contact information has been presented in the previous sections.

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

After presenting a recommendation letter from a research center or an educational institute, the requested data will be presented to the researcher as soon as possible.

Comments