Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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.

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2217 5351

Email

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.

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9770

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
Street address
No. 2, Nabavi Ave., Shariati Street
City
Tehran
Province
Tehran
Postal code
1963815971
Phone
+98 21 2267 2126
Email
tabmed@gmail.com

Person responsible for scientific 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
Street address
No. 2, Nabavi Ave., Shariati Street
City
Tehran
Province
Tehran
Postal code
1963815971
Phone
+98 21 2267 2126
Email
tabmed@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Yasaman Shourmaej
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Farhangiyan Complex, Saheb Zaman St., 4th square,Tehranpars
City
Tehran
Province
Tehran
Postal code
1655696185
Phone
+98 21 7705 0477
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