Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effectiveness of Unified Protocol for Transdiagnostic Treatment on Emotional symptom, Emotion regulation, Kinesiophobia, Pain intensity, Quality of life in patients with temporomandibular disorders.

Protocol summary

Study aim
This Study Purpose is Determine the Effectiveness of Unified Protocol for Transdiagnostic Treatment on Emotional symptom, Emotion regulation, Kinesiophobia, Pain intensity, Quality of life in patients with temporomandibular disorders.

Design
Clinical Trial with Control Group, with Parallel Group, Single Blind, Randomized, on 58 Patients

Settings and conduct
Dental clinics affiliated with Kashan University of Medical Sciences, Patient who have the Inclusion Criteria are Selected And after Obtaining Informed Consent, they will be Randomly Placed in Experimental and Control Groups Also, before the Implementation of the Intervention, Questionnaires will be Provided to them. The Participants are not Given Information about which of the Groups is the Experimental and which of them is Control Group.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients with temporomandibular syndrome whose disease has been Diagnosed based on DC/TMD criteria. Non Inclusion Criteria: Age younger than 18 and older than 50, Degree less than middle School degree

Intervention groups
Experimental Group: The integrated Protocol for Transdiagnostic Treatment is implemented for them. Control Group: Training Sessions about Some Topics of Personality will be Provided that are not Related to the Main Intervention.

Main outcome variables
Emotion regulation ,Depression، Anxiety, stress

General information

Reason for update

Acronym
UP

IRCT registration information
IRCT registration number: **IRCT20221021056259N1**
Registration date: **2025-03-08, 1403/12/18**
Registration timing: **retrospective**

Last update: **2025-03-08, 1403/12/18**
Update count: **0**

Registration date
2025-03-08, 1403/12/18

Registrant information

Name
fatemeh molaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 4224 6474

Email address
fatemeh.molaei@ut.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-20, 1402/06/29

Expected recruitment end date
2024-07-21, 1403/04/31

Actual recruitment start date
2023-09-19, 1402/06/28

Actual recruitment end date
2024-07-20, 1403/04/30

Trial completion date
2024-07-20, 1403/04/30

Scientific title
Effectiveness of Unified Protocol for Transdiagnostic

Treatment on Emotional symptom, Emotion regulation, Kinesiophobia, Pain intensity, Quality of life in patients with temporomandibular disorders.

Public title
Effectiveness of Unified Protocol for Transdiagnostic Treatment in patients with temporomandibular disorders.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with temporomandibular syndrome whose disease has been Diagnosed based on DC/TMD criteria.
Exclusion criteria:
Age younger than 18 and older than 50 Degree less than middle School degree
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **58**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Purposive Sampling with Random Assignment: In this method, samples are selected based on specific characteristics that the researcher is interested in, and then participants are randomly assigned to control and intervention groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants are not Given Information about which Group is the Experimental Group and which is the Control Group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Qotb Ravandi Boulevard
City
Kashan
Province
Isfehan
Postal code
8715988141
Approval date
2022-09-10, 1401/06/19
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1401.115

Health conditions studied

1

Description of health condition studied
Temporomandibular Syndrome
ICD-10 code
M26.6
ICD-10 code description
Temporomandibular joint disorders

Primary outcomes

1

Description
Emotion Regulation score in DERS-16 questionnaire
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Difficulties in Emotion Regulation Scale (DERS-16)

2

Description
Anxiety score in DASS-21 questionnaire
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Depression- Anxiety- Stress Scale (DASS-21)

3

Description
Depression score in DASS-21 questionnaire
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Depression- Anxiety- Stress Scale (DASS-21)

4

Description
Stress score in DASS-21 questionnaire
Timepoint
Before the intervention and three months after the intervention
Method of measurement

Depression- Anxiety- Stress Scale (DASS-21)

Secondary outcomes

1

Description
Tampa Scale for Kinesiophobia-TSK
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Tampa Scale for Kinesiophobia questionnaire-TSK

2

Description
Intensity of pain
Timepoint
Before the intervention and three months after the intervention
Method of measurement
McGill pain questionnaire

3

Description
Oral Health Related Quality of Life score in OHIP-14 questionnaire
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Oral Health Impact Profile OHIP-14 questionnaire

Intervention groups

1

Description
"Participants will be asked to continue their medical treatment as before. Then, the transdiagnostic therapy will be administered to the experimental group in eight 50-minute sessions, conducted in groups of five.
Category
Behavior

2

Description
The control group will not receive any psychological treatment but will participate in the general psychology (personality) training sessions that have been arranged for them.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran University Of Medical Science School Of Dentistry
Full name of responsible person
Dr.Elahe Ghasemzadehosseini
Street address
Tehran University of Medical Sciences Faculty of Dentistry End of North Kargar Street, next to the Atomic Energy Organization Before the Hakim Highway East exit Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1439955991
Phone
+98 21 4279 4000
Fax
Email
Dr.el.ghasemzade@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Gholamali Hamidi
Street address
Ghotb ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
8715988141
Phone
+98 31 5558 9399
Email
hamidi_gh@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan University of Medical Sciences
Proportion provided by this source
50
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
Kashan University of Medical Sciences

Full name of responsible person
Fatemeh Molaei

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

Street address
No. 46, Shahid Abbas Ali Bideh Alley, Shahid Dastghib St, Yadgar Imam South highway, Tehran

City
Tehran

Province
Tehran

Postal code
1348834357

Phone
+98 21 6635 8962

Email
fatemeh.molaei@ut.ac.ir

Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Yes - There is 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
Details of the protocol used will be provided by session and source.

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
Academic researchers.

Under which criteria data/document could be used
Having permission from academic institutions. Provide a full explanation of the purpose and reason for using the data.

From where data/document is obtainable
Through the email of Ms. Fatemeh Molaei.

What processes are involved for a request to access data/document
Apply by email. Application review by all the executives. Making a request in the ethics committee.

Comments