# Efficacy of acupuncture in managing jaw joint and facial pain

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
19/06/2023	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
25/08/2023	Completed	Results
Last Edited	Condition category	Individual participant data
25/08/2023	Nervous System Diseases	<ul><li>Record updated in last year</li></ul>

#### Plain English summary of protocol

Background and study aims

The temporomandibular joint (TMJ) is like a hinge that connects your jaw to your skull. It helps you do things like chewing, talking, and swallowing. Sometimes, people have problems with this joint and the muscles around it. These problems are called temporomandibular disorders (TMD). They can cause a lot of pain in your face and jaw, and they can make it hard to do normal things and hang out with friends.

TMD is the most common long-lasting face and jaw pain condition. It can make life tough because it can stop you from doing your normal activities and being social. There are different types of TMD, and doctors use certain guidelines to figure out which type someone has. TMD can be short-term or last a long time. Sometimes it's simple, and sometimes it's more complicated, involving not just the jaw but also how we think and feel.

To treat TMD, doctors and experts from different fields like dentists, physical therapists, speech therapists, doctors, and psychologists work together. They use different methods to help with the pain. One of the methods is physical therapy, where they use exercises and treatments to make the pain better. Another method is acupuncture, which is a technique from Chinese medicine. It involves putting very thin needles into specific points on your body. This is thought to affect your body's nervous system and release chemicals that can help with pain and wellbeing.

Acupuncture has been found to be helpful for some people with TMD and muscle pain, but there's still not a lot of scientific proof for its effectiveness in this area. This research is important because it shows that acupuncture might be a good way to help people with TMD, based on careful studies done on patients during their treatments.

Who can participate?

Patients aged 18 years or above, with TMD.

What does the study involve?

They put thin needles in certain spots on the body to help with pain. People got these treatments four times, with a few days in between. Another group of people got a fake

acupuncture treatment with needles that didn't have strong electricity. They measured how much pain people felt and how well they could open their mouths before and after the treatments. This helped them see if the real acupuncture made a difference. They also asked people questions about their pain. This information was collected at different times over three months.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from?
Oral Medicine Department of the University of Damascus Dental School (Syria)

When is the study starting and how long is it expected to run for? January 2022 to August 2023

Who is funding the study? Damascus University (Syria)

Who is the main contact?
Dr Rida Younes
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## **Contact information**

#### Type(s)

Scientific

#### Contact name

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## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

4783/s.m

## Study information

#### Scientific Title

Evaluate the effectiveness of acupuncture in the management of tempo-mandibular disorders

#### **Study objectives**

- 1. Acupuncture is effective in managing temporomandibular joint pain and improving mouth opening
- 2. Acupuncture is well received by patients and improves quality of life in patients with TMJ

#### Ethics approval required

Ethics approval required

#### Ethics approval(s)

approved 10/01/2022, Faculty of Dentistry - Damascus University (Mazzeh highway, Damascus, -, Syria; +963 1133923192; info@damascusuniversity.edu.sy), ref: 00963992219044

#### Study design

Randomized controlled clinical study

#### Primary study design

Interventional

#### Study type(s)

Quality of life, Treatment

#### Health condition(s) or problem(s) studied

The sample was composed of patients with masticatory myofascial pain.

#### **Interventions**

A randomized controlled trails was undertaken at the Department of Oral Medicine, University of Damascus Dental School.

The patients were randomly distributed into the two study groups using the computer (Research Randomizer)

#### The Acupuncture intervention:

In this study, clinical overlap points were identified based on clinical studies of TMJ disorders and alternative Chinese medicine of meridian energy release and acupoint functions. Sixteen needle insertions were performed per subject per session, and all patients received the same treatment at all sessions in order to minimize variations across treatments. Before applying the needles, asepsis with 70% alcohol and cotton was performed.

Disposable stainless spiral cable needles were used. Needles were inserted in the following bilateral points on meridians that cross the area of pain or with analgesia and energy rebalancing function4, the periodic applications of needles within the specified points was carried out on 4 sessions, with a difference of 5 days between them. small intestine meridian point 18(Si 18), stomach meridian point 6(St 6), stomach meridian point 7(St 7)5. The depth of needle penetration followed the specifications of each point with respect to the physical characteristics of the patients, the acupuncturist performed manual stimulation with the index finger and thumb at a rate of three to five rotations per second, alternating clockwise and

counterclockwise rotations until obtaining of, this is according to instructions of traditional Chinese medicine TCM6.

The control group technique (placebo acupuncture):

Subjects underwent a simulated acupuncture technique (placebo acupuncture), as previously described. The placebo acupuncture procedure was performed similarly to the acupuncture group and used the same needle placements, but the differ in terms of electrical intensity 3 volts.

The needle was positioned at the same predicted points, and the needle insertion into the skin was simulated and that after skin asepsis was performed.

All patients were asked not to undergo other pharmacological or non-pharmacological treatments for pain during the study. If necessary, rescue medication for pain relief by analgesics or non-steroidal anti-inflammatory drugs was allowed as recommended by IMMPACT, to be recorded in the patients' research documents.

#### Follow up:

The outcome measures for patients treated with Acupuncture included levels of pain and discomfort. The questionnaire was given to patients before each intervention session and 48 hours after each session and at the following assessment times: 45 days, and 3 months after the last acupuncture intervention. All patients were instructed to mark their responses on a visual analog scale (VAS).

Mandibular function the amount of mouth opening was measured before the first interventional session and again after the last one, using a millimeter scale from the cutting edge of the upper left central incisor to the cutting edge of the lower left central incisor. The values are taken as follows: before the start of therapeutic intervention, after 3 weeks of treatment, 45 days, and 3 months after the last acupuncture intervention.

#### Intervention Type

Device

#### Phase

**Not Specified** 

#### Drug/device/biological/vaccine name(s)

Acupuncture

#### Primary outcome(s)

Pain measured using visual analog scale (VAS) before each intervention session and 48 hour after each session and at the following assessment times: 45 days, and 3 month after the last acupuncture intervention

#### Key secondary outcome(s))

Mandibular function: the amount of mouth opening was measured before the first interventional session and again after the last one, using a millimeter scale from the cutting edge of the upper left central incisor to the cutting edge of the lower left central incisor.

#### Completion date

30/08/2023

## **Eligibility**

#### Key inclusion criteria

- 1. Masticatory myofascial pain according to the diagnostic criteria for Temporomandibular Disorders (TMD);
- 2. Adult healthy patients from both sexes within over 18 years of age;
- 3. Pain intensity  $\geq$  4, as measured by the Visual Analog Scale (VAS) for at least 3 months

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

20 years

#### Upper age limit

45 years

#### Sex

All

#### Total final enrolment

30

#### Key exclusion criteria

- 1. History of facial trauma;
- 2. Needle phobia;
- 3. Continuous use of non-steroidal anti-inflammatory drugs, analgesics, antidepressants or central myorelaxant drugs;
- 4. Neurological disorders/other major causes of headache, other causes of orofacial pain (caries, periodontal disease and atypical toothache);
- 5. Arthralgia in the TMJ, diagnosis of fibromyalgia;
- 6. Use of total prosthesis;
- 7. Other current treatment for TMD or non-acceptance to voluntarily participate in the research.

#### Date of first enrolment

11/04/2022

#### Date of final enrolment

25/08/2023

### Locations

#### Countries of recruitment

Syria

## Study participating centre Damascus University

Oral Medicine Department of the University of Damascus Dental School Damascus Syria

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## Sponsor information

#### Organisation

**Damascus University** 

#### **ROR**

https://ror.org/03m098d13

## Funder(s)

#### Funder type

University/education

#### **Funder Name**

**Damascus University** 

#### Alternative Name(s)

University of Damascus, , DU

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

Universities (academic only)

#### Location

Ѕугіа

## **Results and Publications**

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. riday28@gmail.com

# **IPD sharing plan summary** Available on request