

# Comparative effectiveness of various treatment methods of masticatory myofascial pain

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| <b>Submission date</b><br>08/11/2023   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>10/11/2023 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>28/06/2024       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Myofascial pain syndrome (MPS) is a particular type of temporomandibular disorder, which presents as chronic fascial pain related to trigger points in the neck and facial muscles. Although MPS are not considered life-threatening, they negatively affect oral health-related quality of life (OHRQoL). Several therapies have been proposed for MPS, including psychosocial interventions, medications, occlusal adjustment, surgical and presurgical treatments, physiotherapy, splints, passive jaw movement devices, and ultrasound therapy. Various designs of splints are used to treat MPS, which are considered a familiar treatment option, such as soft bite guard, localized occlusal interference splint, anterior bite plane splint, anterior repositioning splint, and stabilization splint (SS). A passive jaw motion device has been used in degenerative joint injuries of muscular origin, such as limitation of the mouth opening and difficulty in moving the jaw. In addition, it is used in masseter muscle rehabilitation after temporomandibular joint reconstructive surgeries. TheraBite passive jaw motion device works by forcing the muscles to stretch or move to a certain degree to strengthen the masticatory muscles, increase the range of movement of the lower jaw, and relieve pain. Ultrasound therapy plays a crucial role in cases of myofascial pain, especially if the condition is accompanied by spasms and stiffness of the masticatory muscles, as well as articular disc displacement of muscular origin and degenerative injuries of the joint. Ultrasound therapy accelerates healing by increasing blood flow in the treated area, reduces pain by reducing swelling and edema, and relieves underlying stress within the muscles, ligaments, and tendons. Therapeutic jaw exercises are widely accepted among MPS patients because they are effective in reducing headache, and pain intensity. In addition, therapeutic jaw exercises are cost-effective when compared to other treatment approaches. However, research findings comparing the previous treatment approaches are scarce and controversial. Therefore, the aim of this study is to compare the effectiveness of ultrasound therapy, stabilization splint, TheraBite device, and masticatory muscle exercises in reducing pain intensity and improving mandibular mobility in patients with MPS.

### Who can participate?

Patient with myofascial pain for at least 6 months aged 18 years old and over

### What does the study involve?

In this study, the researchers used a randomization method to divide the patients into different

groups. They made sure that the groups had an equal number of patients, and each patient got a unique number between 1 and 40.

The study will be conducted in a way that keeps the patients, the doctors, and the people who were evaluating the results "blind" to which treatment each patient will be getting. This is done to make sure the results are as fair and accurate as possible.

The study tested four different treatments:

Ultrasound therapy: Patients receive ultrasound treatment on their facial muscles for four weeks, three times a week. This involves warm compresses, ultrasound waves, and muscle massages.

Stabilization splint: Patients wear a special mouthpiece at night for four weeks. It covered some of their upper teeth.

TheraBite device: Patients use a device that helps them exercise their jaw muscles for four weeks.

Masticatory muscle exercises: Patients do various exercises to strengthen their jaw muscles for four weeks.

All of this is done to see which treatment worked best for the patients, and the study is designed to ensure fairness and accuracy.

What are the possible benefits and risks of participating?

A possible benefit is reduced pain intensity and improved mandibular mobility in patients with myofascial pain syndrome. A possible risk is that some methods are questionable in their effectiveness.

Where is the study run from?

Damascus University (Syria)

When is the study starting and how long is it expected to run for?

April 2023 to October 2023

Who is funding the study?

Damascus University (Syria)

Who is the main contact?

Dr Mawia Karkoutly, Mawiamaherkarkoutly@hotmail.com (Syria)

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

Dr Mawia Karkoutly

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**Type(s)**

Public

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Dr Mawia Karkoutly

**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Funder No. 501100020595

## Study information

**Scientific Title**

Comparative effectiveness of ultrasound therapy, stabilization splint, and TheraBite device for the treatment of masticatory myofascial pain: A randomized controlled trial

**Study objectives**

The null hypothesis was that no statistically significant difference would be noted in the effectiveness of ultrasound therapy, stabilization splint, TheraBite device, and masticatory muscle exercises in reducing pain intensity and improving mandibular mobility in patients with myofascial pain syndrome.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 30/04/2023, Ethical and Scientific Committee of Damascus University (MazzeH Highway, Damascus, None available, Syria; +963 (11) 33923223; dean.dent@damascusuniversity.edu.sy), ref: N1771

## **Study design**

Tripleblind randomized parallelgroup active-controlled trial with four arms

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Dental clinic

## **Study type(s)**

Treatment

## **Participant information sheet**

No participant information sheet available

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

Myofascial pain syndrome

## **Interventions**

Randomization will be performed using a simple randomization method in a ratio of 1:1:1:1, by means of an online randomization software <https://www.randomizer.org/>. The number of sets generated is 4, with 10 patients per set. The number range is from 1 to 40, and each number in a set remains unique.

This is a triple-blind trial where subjects, researchers, as well as outcome assessors are masked to the treatment allocation.

### **Interventions**

#### **Ultrasound therapy**

The patient will undergo ultrasound therapy sessions for 4 weeks at a rate of 3 weekly sessions. Each treatment session includes:

1. Warm compress for 10 minutes.
2. Applying ultrasound waves to the facial muscle areas with contiguous spiral movements, with a frequency of 3 MHz and an intensity of 1 w/cm<sup>2</sup>, for 5-10 minutes.
3. Muscle massage for 10 minutes is performed by applying circular movements with light pressure on the area around the joint and sweeping movements from the middle of the forehead towards the earlobe and from the middle of the chin towards the earlobe.

#### **Stabilization splint**

A full-coverage maxillary stabilization splint is made of acrylic resin (Resilit-S, Erkodent, Baden-Württemberg, Germany) with a thickness of 1.5 mm. It covers approximately 1/3 of the buccal and palatal surfaces of the maxillary teeth. The patient is asked to wear the stabilization splint 8 hours at night daily for four weeks.

### **TheraBite device**

TheraBite passive motion device is used for 4 weeks in daily use. The bite pad is inserted into the mouth, and the device is opened by pushing the lever arm to the detected opening for 15 mm. The patient is instructed to bite down and hold for 10 seconds and rest for 30 seconds. Each session consists of 10 bites.

### **Masticatory muscle exercises**

Each exercise is performed in the morning and evening for one minute daily for four weeks. The masticatory muscle exercise program was as follows:

#### **Vertical movement**

The hand is placed under the chin, and the mouth is opened to half maximum. The movement is resisted for ten seconds, followed by a rest, then repeated five times.

#### **Lateral movement**

The hand is placed on the side of the chin, opposite to the side of the injury, and the jaw is moved towards the midline. The movement is resisted for ten seconds, followed by a rest, then repeated five times. The patient is asked to stand in front of a mirror, open the mouth to the maximum comfortable range, and then close it. Appropriate pressure is applied to open the jaw straight without deviation. The patient is asked to open the mouth slightly and to place the tongue on the buccal surface of the upper teeth, opposite to the side of the injury. The movement is resisted for ten seconds, followed by a rest, then repeated five times.

#### **Protrusive movement**

The tongue depressor is placed between the teeth of the upper and lower jaws at an angle of 45 degrees, then the lower jaw is slid over it to the maximum forward position, and the movement must occur straight. The movement is resisted for ten seconds, followed by a rest, then repeated five times.

### **Intervention Type**

Device

### **Pharmaceutical study type(s)**

Not Applicable

### **Phase**

Not Applicable

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

Ultrasound device, Stabilization splint, TheraBite device

### **Primary outcome measure**

The following primary outcome measures will be assessed at baseline (t0), at the 1st (t1), 2nd (t2), and 4th (t3) week of treatment, and at the 3rd (t4) and 6th (t5) month of follow-up:

1. Pain intensity measured using a visual analog scale (VAS). Each patient is asked to record their current level of pain by marking a point on the VAS line that represents their pain intensity.

Grading of pain according to the VAS score is as follows:

0-3 = Mild pain

3-8 = Moderate pain

8-10 = Severe pain

Active range of motion

2. Active range of motion (AROM) when the patient has their mouth open to the maximum comfortable range, measured using the distance from the incisal edge of the right maxillary central incisor to the incisal edge of the right mandibular central incisor in millimeters (mm)
3. Right lateral movement (RLM) when the patient moves their mandible to the right at the maximum comfortable extent, measured using the horizontal distance between the maxillary midline to the mandibular midline in mm
4. Left lateral movement (LLM) when the patient slides their mandible to the left to the maximum comfortable extent measured using the horizontal distance between the maxillary midline to the mandibular midline in mm

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

02/04/2023

### **Completion date**

07/11/2023

## **Eligibility**

### **Key inclusion criteria**

1. Patient with myofascial pain according to the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD).
2. Visual Analogue Scale (VAS) score  $\geq 4$ , with pain lasting for at least 6 months.
3. Patients aged 18 years old and over

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

45 Years

### **Sex**

Both

### **Target number of participants**

40

### **Total final enrolment**

80

### **Key exclusion criteria**

1. Fixed or removable prosthesis
2. Systemic diseases
3. Analgesics and/or muscle relaxants over the past 24 hours
4. Already undergone MPS treatment
5. Polyarthritis, osteoarthritis or arthralgia

**Date of first enrolment**

01/05/2023

**Date of final enrolment**

07/05/2023

## **Locations**

**Countries of recruitment**

Syria

**Study participating centre**

**Damascus University**

MazzeH Highway

Damascus

Syria

None available

## **Sponsor information**

**Organisation**

Damascus University

**Sponsor details**

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None available

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**Sponsor type**

University/education

**Website**

<https://www.damascusuniversity.edu.sy/>

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## 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

Syria

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

### Intention to publish date

31/01/2023

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Mawia Karkoutly, Mawiamaherkarkoutly@hotmail.com. The type of data that will be shared is currently not known. The timing for availability is upon a reasonable request. Informed consent was obtained.

Comments on data anonymization: N/A

Any ethical or legal restrictions: N/A

Any additional comments: N/A

### IPD sharing plan summary

Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------|---------|--------------|------------|----------------|-----------------|
|-------------|---------|--------------|------------|----------------|-----------------|



[Protocol file](#)  
[Results article](#)

|            |            |     |    |
|------------|------------|-----|----|
|            | 10/11/2023 | No  | No |
| 24/06/2024 | 28/06/2024 | Yes | No |