ISRCTN20833186 https://doi.org/10.1186/ISRCTN20833186

Comparative effectiveness of various treatment methods of masticatory myofascial pain

Submission date
08/11/2023

Recruitment status
No longer recruiting

Registration date
10/11/2023

Overall study status
Completed

Last Edited
28/06/2024

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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/cm2, 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

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ultrasound device, Stabilization splint, TheraBite device

Primary outcome(s)
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

Key secondary outcome(s))
There are no secondary outcome measures

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 ≥ 4, with pain lasting for at least 6 months.
3. Patients aged 18 years old and over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
All

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

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
Syria

Results and Publications

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?
Results article		24/06/2024	28/06/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			10/11/2023	No	No