Study Protocol

Background and aim

Temporomandibular joint disorders (TMDs) are among the most common conditions in dental clinics. TMDs is a term that covers a wide range of symptoms and signs, which is one of the most common disorders seen in the craniofacial region. In addition, it is the second cause of facial pain following odontogenic pain. The pathogenesis of TMDs is still not clearly defined, as it is considered a multi-etiological disorder. There are several predisposing factors, including genetic, hormonal, and anatomical, and causative factors such as, trauma, occlusal changes, and nonfunctional habits. In addition, various exacerbating factors prolong the duration of the disorders, including stress and parafunctional habits. TMD symptoms include facial pain, limited lower jaw movement, intracapsular sounds such as clicking or crepitus, tooth sensitivity of unknown cause, tooth or restorations fractures, and chronic headache. Approximately 20% of TMDs are symptomatic, and only 5% of patients request treatment. Myofascial pain syndrome (MPS) is a particular type of TMDs, which is presented as a chronic fascial pain related to trigger points in the neck and fascial muscles. Although MPS are not considered life-threatening, they negatively affect the 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). 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 TMJ 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 was 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.

Patients and methods

Study design and patient enrollment

This was a triple-blind, randomized, parallel-group, active-controlled trial with four arms. This study took place between April 2023 and October 2023 at the Department of Fixed Prosthodontics, Damascus University, and it was conducted by Declaration of Helsinki 2013 and the CONSORT statement. This trial was registered and approved by International Standard Randomised Controlled Trial Number registry (). Ethical approval was obtained from the Biomedical Research Ethics committee (N1771).

The inclusion criteria were as follows:

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. Patient older than 18 years.

The exclusion criteria were as follows:

1. Patient with fixed or removable prosthesis.
2. Patient with systemic diseases.
3. Patient taking analgesics and/or muscle relaxant over the past 24 hours.
4. Patient had already undergone MPS treatment.
5. Patient with polyarthritis, osteoarthritis or arthralgia.

The CONSORT flow diagram is presented in Figure 1. 63 patients were assessed for eligibility, and 40 were randomly assigned into four groups according to the approach used for MPS treatment:

Group 1: Ultrasound therapy (n=10).

Group 2: Stabilization splint (n=10).

Group 3: TheraBite device (TheraBite® Jaw Motion Rehabilitation System™, Atos Medical, Munich, Germany) (n=10).

Group 4: Masticatory muscle exercises (n=10).

Allocation

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

Blinding

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

Interventions

Ultrasound therapy

The patient has undergone 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 and 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 was 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 was asked to wear the stabilization splint 8 hours at night daily for four weeks.

TheraBite device

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

Procedure

The following primary outcome measures were considered at the baseline (t_0), at the 1st (t_1), 2nd (t_2), and 4th (t_3) week of treatment and at the 3rd (t_4) and 6th (t_5) month of follow-up:

Pain intensity

VAS was used to evaluate pain intensity. Each patient was 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 VAS score was as follow:

0-3 = Mild pain.

3-8 = Moderate pain.

8-10 = Severe pain.

Active range of motion

Each patient was instructed to open their mouth to the maximum comfortable range, and the active range of motion (AROM) was measured from the incisal edge of the right maxillary central incisor to the incisal edge of the right mandibular central incisor in millimeters (mm).

Right lateral movement

The patient was asked to move their mandible to the right at the maximum comfortable extent, and the right lateral movement (RLM) was measured as the horizontal distance between the maxillary midline to the mandibular midline in mm.

Left lateral movement

The patient was instructed to slide their mandible to the left at the maximum comfortable extent, and the left lateral movement (LLM) was measured as the horizontal distance between the maxillary midline to the mandibular midline in mm.

Sample size calculation and statistical analysis

Sample size calculation was performed using G*Power version 3.1.9.4 (Heinrich-Hein-Universität-Düsseldor, Germany). A sample size of 40 patients achieved a medium effect size f (0.55), 80% Power (1 - β err prob), and a significance level of 0.05. Statistical analysis was done using IBM SPSS software version26 (IBM Corp., Armonk, NY, USA). Data was presented as mean ± standard deviation (SD) since they were continuous variables. The Kruskal-Wallis test was run to compare between the study groups as the Kolmogorov–Smirnov test revealed that data was not normally distributed. Multiple comparisons were performed when the overall test showed significant differences across the samples.

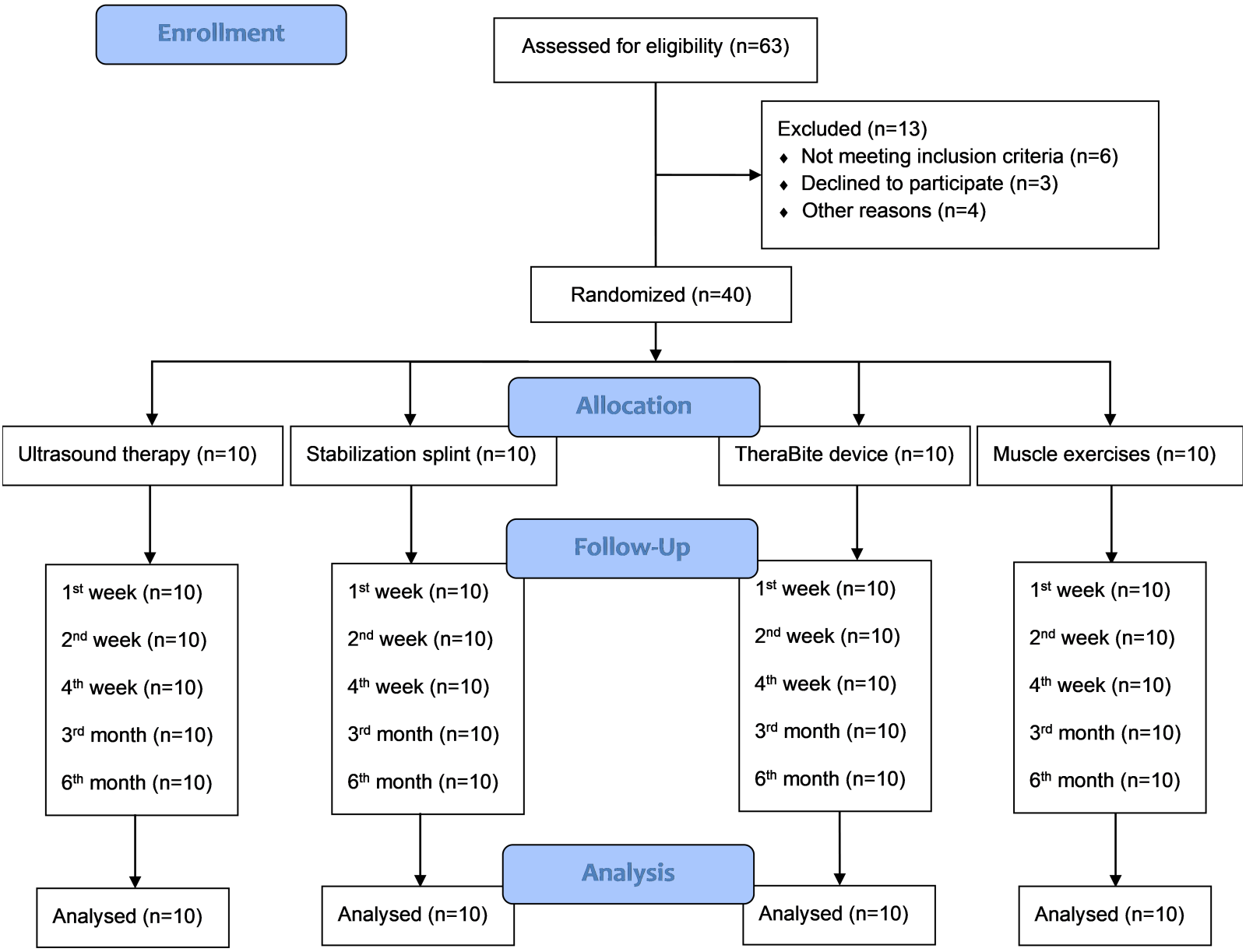

Figure 1. CONSORT flow diagram