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Efficacy of acupuncture in managing jaw joint and facial pain

Submission date
19/06/2023

Recruitment status
No longer recruiting

Registration date
25/08/2023

Overall study status
Completed

Last Edited
25/08/2023

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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 well-being.

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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Quality of life, Treatment

Participant information sheet

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Specified

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

Primary outcome measure

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

Secondary outcome measures
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.

Overall study start date
10/01/2022

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 ≥ 4, as measured by the Visual Analog Scale (VAS) for at least 3 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
45 Years

Sex
Both

Target number of participants
26

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
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-

Sponsor information

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University/education

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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
01/01/2024

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.
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IPD sharing plan summary
Available on request