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How ear symptoms affect recovery from jaw disorders using non-drug non-surgical treatment

Submission date	**Recruitment status**	[X] Prospectively registered
21/09/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/09/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
21/02/2025	Digestive System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Temporomandibular disorder (TMD) affects the jaw joint and can cause a variety of symptoms, including jaw pain, difficulty chewing, and limited movement of the jaw. Sometimes, TMD also causes ear-related symptoms like ear pain and ringing in the ears (tinnitus). This study aims to evaluate how ear symptoms can affect recovery from TMD when treated with physiotherapy and occlusal splints.

Who can participate?
Males and females of any age can participate if they have a temporomandibular disorder (TMD). In case of ear-related symptoms, a medical report will be needed from an ENT specialist to exclude that the ear is the origin of the symptoms.

What does the study involve?
After diagnosis, a treatment plan will be established which will include physiotherapy and an occlusal splint.
All participants receive the same type of treatment. The treatment will be individual according to the needs listed in the treatment plan.
The doctor will measure the pain and other symptoms before and after 3 months of the beginning of the treatment.

What are the possible benefits and risks of participating?
The benefits are the partial/complete healing of the symptoms. The treatment is very safe. Some people may experience mild discomfort or pain when starting physiotherapy exercises or wearing an occlusal splint. Also, the jaw muscles may feel sore as they adjust to new movements or the use of a splint. Finally, wearing a splint can sometimes cause a temporary change in how teeth fit together when biting.

Where is the study run from?
Al-Sham private university ASPU, faculty of Dentistry (Syria)

When is the study starting and how long is it expected to run for?
September 2024 to February 2025

Who is funding the study?
This study publication is financially supported by the doctor leading it. The patient will pay for the treatment.

Who is the main contact?
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Contact information

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Public, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
REC002

Study information

Scientific Title
Comparison between the prognosis of TMD with and without accompanying otologic symptoms after non-invasive non-pharmacological treatment

Acronym
TMD-POS

Study objectives
Null hypothesis: there is no significant relation between the prognosis of TMD and the accompanying otologic symptoms.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/09/2024, The Research Ethics Committee (RLC) at Al-Sham private university (Al-Baramkeh, Musab Bin Omair Street - next to Tishreen Stadium, Damascus, 0100, Syria; +963 11 215 3360; info@aspu.edu.sy), ref: REC002

Study design
Single-center interventional non-randomized clinical trial

Primary study design
Interventional

Secondary study design
Non randomised study

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

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Temporomandibular disorder (TMD)

Interventions
Both groups of patients will get the same type of intervention. Patients having TMD with accompanying otologic symptoms are allocated to one group, while patients having TMD without accompanying otologic symptoms are allocated to another group.

The intervention is non-invasive in the form of physiotherapy and occlusal splints.
1- Physiotherapy includes:
a- massage
b- hot compress
d- infrared radiation
c- stretching exercises for the joint capsule and ligament in cases of joint compression.
2-Occlusal splints:
They will be fabricated using a conventional technique based on initial diagnostic impressions of the maxillary and mandibular arches with alginate material and on a wax bite to record the desired jaw position for the splint.

The study itself will finish after three months but the intervention will last up to 6 months, depending on the improvement in the condition of the TMD of each patient individually. This means that some patients might finish earlier.

Intervention Type
Mixed

Primary outcome measure
1. The initial symptoms of a TMD and the accompanying otologic symptoms (if present) are recorded during the diagnosis
2. Improvement in symptoms of a TMD and in symptoms of the accompanying otologic symptoms are then recorded after a 3-month follow-up
3. In case one of the symptoms is pain, the Visual Analogue Scale (VAS) will be used to determine the amount of pain that a patient feels
4. The diagnosis, treatment, and follow-up phases will be done by the same experienced TMJ specialist Dr. Samer Al Akkad

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
09/09/2024

Completion date
01/02/2025

Eligibility

Key inclusion criteria
1. Having TMD only or having TMD with accompanying otologic symptoms.
2. If otologic symptoms are present, the patient should be referred by an ENT specialist who confirms a non-otologic origin of the symptoms.

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. Having TMD with otologic symptoms of otologic origins

Date of first enrolment
01/10/2024

Date of final enrolment
01/11/2024

Locations

Countries of recruitment
Syria

Study participating centre
Al-Sham private university ASPU, Faculty of Dentistry
Al Mazraa - next to Al Iman Mosque.
Damascus
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Sponsor information

Organisation
Al-Sham private university ASPU

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Sponsor type
University/education

Website
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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/04/2025

Individual participant data (IPD) sharing plan
The datasets genersated during and/or analysed during the current study will be available upon request from Dr. Samer Al Akkad. Email: Dr.samerakkad@gmail.com

IPD sharing plan summary
Available on request