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Improvement in quality of life of patients with myofascial pain treated with either conservative therapy only or conservative therapy with early self-physiotherapy

Submission date
28/02/2025

Recruitment status
No longer recruiting

Registration date
19/03/2025

Overall study status
Completed

Last Edited
19/03/2025

Condition category
Musculoskeletal 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
Myofascial pain is a common condition that affects the muscles around the jaw, leading to discomfort and difficulty in jaw movement. Temporomandibular disorders (TMD) can significantly impact a person's quality of life by causing pain and restricting normal jaw function. This study aims to compare two treatment methods: conservative therapy alone and conservative therapy with early self-physiotherapy. The objective is to evaluate effective way of improving the quality of life for patients with myofascial pain.

Who can participate?
Participants were men and women between the ages of 20 and 40 who had been diagnosed with myofascial pain of TMJ. Those with other medical conditions, previous jaw surgeries, or severe psychological disorders were excluded in the study.

What does the study involve?
The study involved 60 patients that were randomly divided into groups:
Group A: Patients received only conservative therapy, including soft diet instructions, avoiding teeth grinding, and heat therapy.
Group B: Patients received conservative therapy along with early self-physiotherapy, which included exercises to strengthen and stretch the jaw muscles.
The quality of life of each patient was assessed before treatment and after four weeks.

What are the possible benefits and risks of participating?
Participants benefited by getting structured treatment aimed at reducing jaw pain and improving their overall quality of life. Self-physiotherapy, in particular, may help strengthen muscles and prevent future problems.
The risks were minimal, but some patients may have experienced temporary discomfort while performing the exercises.

Where is the study run from?
The study was conducted at Fatima Memorial Hospital, College of Medicine & Dentistry, Lahore, in the Department of Oral and Maxillofacial Surgery.

When is the study starting and how long is it expected to run for?
January 2019 to August 2022

Who is funding the study?
The study did not have any external funding. It was carried out as part of academic research at Fatima Memorial Hospital.

Who is the main contact?
Dr Iqra Saleem, doctoriqrasaleem@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Iqra Saleem

ORCID ID
https://orcid.org/0009-0009-9755-5152

Contact details
Indus 46, Green Forts II Thokar Niaz Baig
lahore
Pakistan
-
+92 3218825239
doctoriqrasaleem@gmail.com

Additional identifiers

Study information

Scientific Title
A randomized controlled trial investigating the impact of conservative therapy alone versus conservative therapy with early self-physiotherapy on quality of life in patients with myofascial pain

Study objectives
Early self-physiotherapy is better than conservative therapy

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 10/11/2020, Istitutional Review Board FMH College of Medicine and Dentistry (Shadman, Lahore, 54000, Pakistan; +92 3218825239; Ali.mumtaz@fmhcmd.edu.pk), ref: FMH-06-2019-IRB-636-M

Primary study design
Interventional

Study design
Single centre interventional single blinded randomized controlled trial

Study type(s)
Quality of life, Efficacy

Health condition(s) or problem(s) studied
Improving quality of life of patients of temporomandibular joint disorder

Interventions
Sixty-two patients diagnosed with myofascial pain were randomly allocated to either of two treatment groups using Lottery method: Group A received conservative therapy alone, while Group B underwent conservative therapy combined with early self-physiotherapy. QOL assessment was conducted at baseline and after four weeks using a validated QOL index. Statistical analysis included paired sample t-tests for within-group comparisons and independent sample t-tests for between-group comparisons.

Intervention Type
Behavioural

Primary outcome(s)
Validated QOL index was used to assess quality of life before and after 4 weeks of therapy

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

Completion date
29/08/2022

Eligibility

Key inclusion criteria
1. Patients with myofascial pain (DC-TMD Axis 1 Group 1 only)
2. Both genders (male and female)
3. Age 20 - 40 years
4. Dentate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 Years

Upper age limit
40 Years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Patients with systemic health disorders including CVS, CNS, respiratory, endocrine, systemic musculoskeletal etc.
2. Known Psychiatric or psychological conditions
3. Those not willing to participate in research
4. Those already under treatment
5. Missing data for any variable
6. Deep bite
7. Neuropathic pain
8. A history of TMJ surgery
9. Condylar fractures

Date of first enrolment
01/08/2021

Date of final enrolment
01/08/2022

Locations

Countries of recruitment
Pakistan

Study participating centre
Fatima Memorial Hospital
Shadman Road
Lahore
Pakistan
54000

Sponsor information

Organisation
Fatima Memorial Hospital College of Medicine and Dentistry

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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
doctoriqrasaleem@gmail.com

IPD sharing plan summary
Available on request