

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/03/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 19/03/2025	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

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+92 3218825239

doctoriqrasaleem@gmail.com

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## 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, Institutional 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

## **Study design**

Single centre interventional single blinded randomized controlled trial

## **Primary study design**

Interventional

## **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