

# Comparison of three methods for treatment of temporomandibular disorders

<b>Submission date</b> 14/09/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/11/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/11/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Temporomandibular disorders (TMD) encompass a range of conditions affecting the temporomandibular joint (TMJ) and associated musculature, characterized by pain and dysfunction during jaw movement. TMD ranks among the most prevalent musculoskeletal disorders globally, following closely behind low back pain. Its impact extends beyond localized symptoms, often involving chronic pain and comorbidities such as depression and migraines, significantly compromising quality of life. The disorder predominantly affects individuals aged 20-40 years, with a higher prevalence among women. The economic burden associated with TMD is substantial, reflecting its complex symptomatology and prolonged treatment requirements. Etiologically, TMD is multifactorial, influenced by factors ranging from trauma and stress to genetic predispositions. Diagnostic approaches rely on clinical evaluation, with imaging techniques reserved for specific indications. Management strategies encompass conservative, minimally invasive, and invasive interventions, emphasizing evidence-based approaches tailored to individual patient needs. Despite various treatment modalities, achieving consensus on optimal management remains a challenge, underscoring the need for further research into effective therapeutic paradigms. The study aims to compare the effectiveness of different treatment regimens for pain-related TMD. The study will evaluate and compare the effectiveness of combined orthotic splint therapy and home care regimen versus each therapy individually. The goal is to determine if combined therapy is more effective than individual therapies in managing Pain-related TMD.

### Who can participate?

Patients aged between 18 and 80 years old diagnosed with TMD with pain present for at least 3 months

### What does the study involve?

Participants will be randomly assigned to one of three groups:

1. Combined regimen with Orthotic splint therapy and home care
2. Home care regimen only.
3. Orthotic splint therapy only.

Participants will undergo a thorough clinical examination based on DC/TMD criteria, and data will be collected over four visits. The study will measure pain intensity, muscle and joint pain levels, and range of motion.

What are the possible benefits and risks of participating?

Participants will benefit from a potential reduction in TMD-related pain, improvement in jaw function and increased understanding of effective treatment combinations for TMD.

Participants are at risk of feeling discomfort or pain during the clinical examination and treatment process, and the potential for ineffectiveness or adverse reactions to the treatment modalities.

Where is the study run from?

The Center for Temporomandibular Disorder and Orofacial Pain, Department of Diagnostic Sciences, Rutgers School of Dental Medicine, USA

When is the study starting and how long is it expected to run for?

May 2018 to December 2024

Who is funding the study?

Department of Diagnostic Sciences, Rutgers School of Dental Medicine, USA

Who is the main contact?

Gary M. Heir, DMD, (Department of Diagnostic Sciences, Rutgers School of Dental Medicine), heirgm@sdm.rutgers.edu

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Gary Heir

### ORCID ID

<https://orcid.org/0000-0001-9571-402X>

### Contact details

Department of Diagnostic Sciences

Rutgers School of Dental Medicine,

110 Bergen Street, Room D-805

P.O Box 1709

Newark

United States of America

07103

+1 973-972-6460

heirgm@sdm.rutgers.edu

### Type(s)

Public, Scientific

### Contact name

Dr Cibele Nasri-Heir

**ORCID ID**

<https://orcid.org/0000-0003-3651-1286>

**Contact details**

Department of Diagnostic Sciences  
Rutgers School of Dental Medicine,  
110 Bergen Street, Room D-805  
P.O Box 1709  
Newark, NJ 07103-1709  
Newark  
United States of America  
07103  
+1 (973) 972-318  
[nasrici@sdm.rutgers.edu](mailto:nasrici@sdm.rutgers.edu)

**Type(s)**

Scientific

**Contact name**

Dr Sowmya Ananthan

**ORCID ID**

<https://orcid.org/0000-0003-4261-9891>

**Contact details**

Department of Diagnostic Sciences  
Rutgers School of Dental Medicine,  
110 Bergen Street  
Newark  
United States of America  
07103  
+1 (973) 972-3418  
[ananths1@sdm.rutgers.edu](mailto:ananths1@sdm.rutgers.edu)

## **Additional identifiers**

**Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

Nil known

## **Study information**

**Scientific Title**

Comparison of three methods for treatment of temporomandibular disorders

**Study objectives**

TMD patients managed with combined treatment (orthotic splints AND home care regimen) demonstrate maximum improvement compared to individual therapy (orthotic splints vs home care)

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 26/09/2018, Rutgers Health Sciences IRB - Newark (65 Bergen St Suite 511, Newark, 07107, United States of America; +1 973-972-36608; IRBOffice@research.rutgers.edu), ref: Pro2018001261

### **Study design**

Single-center interventional randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment, Efficacy

### **Health condition(s) or problem(s) studied**

Treatment of temporomandibular disorders with non-invasive interventions

### **Interventions**

The patients will be randomized using a computer-generated random allocation sequence into 3 different groups:

Group 1: Combined regimen with Orthotic splint therapy AND home care instructions

Group 2: Home care regimen only

Group 3: Orthotic splint therapy only

### **Intervention Type**

Mixed

### **Primary outcome(s)**

1. Pain levels measured using a Visual Analogue Scale (VAS) at Baseline (V0) and all follow up visits at 2 weeks, 4 weeks, 6 weeks and 3 months (V1, V2, V3, V4)
2. Masticatory muscle pain measured using (Temporalis and Masseter) Diagnostic Criteria/ Temporomandibular Disorder (DC/TMD) Protocol at Baseline (V0) and all follow up visits at 2 weeks, 4 weeks, 6 weeks and 3 months (V1, V2, V3, V4)
3. Temporomandibular joint pain measured using Diagnostic Criteria/ Temporomandibular Disorder (DC/ TMD) Protocol at Baseline (V0) and all follow up visits at 2 weeks, 4 weeks, 6 weeks and 3 months (V1, V2, V3, V4)
4. Mandibular range of motion (pain-free mouth opening, active and passive range of motion) measured using Diagnostic Criteria/ Temporomandibular Disorder (DC/ TMD) Protocol at Baseline (V0) and all follow up visits at 2 weeks, 4 weeks, 6 weeks and 3 months (V1, V2, V3, V4)

### **Key secondary outcome(s)**

Rescue medication use measured using Rescue medication questionnaire at all follow up visits, 2 weeks, 4 weeks, 6 weeks and 3 months (V1, V2, V3, V4)

**Completion date**

23/12/2024

## Eligibility

**Key inclusion criteria**

1. Patients diagnosed with TMD based on DC/TMD criteria with symptoms consistent with myalgia, myofascial pain with/without a referral, arthralgia and/or a combination of the above
2. Pain present for at least 3 months
3. 18-80 years old
4. Male/Female
5. Patients should have functional occlusion with posterior teeth support.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

80 years

**Sex**

All

**Total final enrolment**

98

**Key exclusion criteria**

1. The presence of comorbid systemic disease which can alter pain perception such as generalized muscle/joint or chronic pain disorders such as fibromyalgia, rheumatoid arthritis, Lyme disease, Osteoarthritis, idiopathic condylar resorption.
2. Subjects using chronic pain medications.
3. Subjects with cognitive problems that can result in an inability to follow instructions. If the patient has any disorders such as Down's syndrome or Alzheimer disease will be excluded from the study.

**Date of first enrolment**

28/09/2018

**Date of final enrolment**

10/12/2024

## Locations

**Countries of recruitment**

United States of America

**Study participating centre**

**Rutgers School of Dental Medicine**

110 Bergen St

Newark

United States of America

07103

## Sponsor information

**Organisation**

Rutgers, The State University of New Jersey

**ROR**

<https://ror.org/05vt9qd57>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Rutgers, The State University of New Jersey

**Alternative Name(s)**

Rutgers University, Queen's College, Rutgers College, Rutgers, Universitas Rutgersensis Civitatis Novae Caesareae, RU

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United States of America

# Results and Publications

## **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (Rutgers School of Dental Medicine)

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request: Dr. Cibele Nasri-Heir (nasrici@sdm.rutgers.edu)

## **IPD sharing plan summary**

Stored in non-publicly available repository, Available on request