ISRCTN11741051 https://doi.org/10.1186/ISRCTN11741051

Comparison of three methods for treatment of temporomandibular disorders

Submission date 14/09/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 13/11/2024	**Overall study status** Completed	
Last Edited 06/11/2024	**Condition category** Oral Health	

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

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Additional identifiers

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

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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