

# Management of temporomandibular joint arthropathy: comparison of three non-invasive protocols

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<b>Registration date</b> 09/09/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/09/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Temporomandibular joint (TMJ) disc displacement with reduction and intermittent locking is a common issue where the jaw joint's disc moves out of place. This can lead to temporary limited jaw movement but usually resolves without treatment. This study will compare three different treatments to see which is most effective for managing this condition.

### Who can participate?

Participants aged 18 years and over with TMJ disc displacement with reduction and intermittent locking

### What does the study involve?

Participants are randomly allocated to a standard splint protocol (Group 1), a modified occlusal splint protocol (Group 2), or conventional physical therapy with exercises (Group 3). The first follow-up visit takes place after 1 month of therapy and after 1, 2, 3 and 4 years.

### What are the possible benefits and risks of participating?

Participants may benefit from reduced symptoms (pain and intermittent locking). The risks include worsening of symptoms.

### Where is the study run from?

Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico (Italy)

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

March 2018 to March 2024

### Who is funding the study?

This study was funded by the Italian Ministry of Health – Current Research IRCCS

### Who is the main contact?

Prof. Gianluca Martino Tartaglia, [gianluca.tartaglia@unimi.it](mailto:gianluca.tartaglia@unimi.it)

## Contact information

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Scientific

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Prot. No. 575-2018

## Study information

### Scientific Title

Comparison of modified occlusal splint and conventional physical therapy in the management of temporomandibular joint disc displacement with reduction and intermittent locking: a randomized controlled trial

**Acronym**

DDwRWIL management

**Study objectives**

The modified mandibular splint can be an effective alternative for the treatment of temporomandibular joint (TMJ) disc displacement with reduction and intermittent locking.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 17/07/2018, Ethics Committee of Area 2 Milano (Via Francesco Sforza, 28, Milano, 20122, Italy; +39 (0)255032982; federica.massacesi@policlinico.mi.it), ref: Prot. No. 575-2018

**Study design**

Single-blind randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Dental clinic

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

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

Temporomandibular joint disc displacement with reduction and intermittent locking

**Interventions**

The effectiveness of standard splint protocol (Group 1) modified occlusal splint protocol (Group 2), and conventional physical therapy with exercises (Group 3) will be compared. Patients shall be randomly assigned by computer-generated allocation sequence (1:1) to receive rehabilitation using conventional therapy approaches or modified occlusal splint protocol or disc re-modelling exercises. The first follow-up visit will take place after 1 month of therapy and after 1, 2, 3 and 4 years. Image analysis will involve the evaluation of morphology and function of intra-articular structures. The outcome will be defined as the disappearance of the pain and the intermittent locking.

**Intervention Type**

Other

### **Primary outcome measure**

Pain at rest and mastication assessed using a Visual Analogue Scale (VAS) from 0 to 10, the extremes of which were 'no pain' and 'pain as bad as the patient ever experienced' at baseline, 1 year (T1), 2 years (T2), 3 years (T3), 4 years (T4)

### **Secondary outcome measures**

1. Mastication competence assessed using a VAS from 0 to 10, the extremes of which were 'eating only semi-liquid food' and 'eating solid hard food', at baseline, 1 year (T1), 2 years (T2), 3 years (T3), 4 years (T4)
2. Functional limitation during usual jaw movements assessed using a Likert-type scale (0 - absent, 1 - slight, 2 - moderate, 3 - intense, 4 - severe) at baseline (T0) and the T1 after one year, 2 years (T2), 3 years (T3), and after 4 years (T4)

### **Overall study start date**

18/03/2018

### **Completion date**

18/03/2024

## **Eligibility**

### **Key inclusion criteria**

1. Joint sounds and impairment of jaw movements
2. A positive diagnosis of TMJ disc displacement with reduction and intermittent locking (DDwRWIL) based on clinical inspection
3. Patients of DDwR with intermittent locking confirmed by MRI examination
4. Adults ( $\geq 18$  years)
5. Able to give informed consent

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

99 Years

### **Sex**

Both

### **Target number of participants**

45

### **Key exclusion criteria**

1. Contraindication for MRI (such as patients with any metallic prosthesis or artificial pacemakers)
2. TMJ disc displacement without reduction (DDWoR)
3. Previous facial bone fracture
4. If they had already received any treatment before the MRI

**Date of first enrolment**

18/10/2018

**Date of final enrolment**

18/03/2020

## Locations

**Countries of recruitment**

Italy

**Study participating centre**

Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

via Francesco Sforza 35

Milan

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## Sponsor information

**Organisation**

Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.policlinico.mi.it/>

**ROR**

<https://ror.org/016zn0y21>

# Funder(s)

## Funder type

Government

## Funder Name

Ministero della Salute

## Alternative Name(s)

Italian Ministry of Health, Italy Ministry of Health, Ministry of Health of Italy, Ministry of Health - Italy, Ministry of Health, Italy

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

Italy

# Results and Publications

## Publication and dissemination plan

The researchers plan to publish the results possibly within 1 year of the study's conclusion

## Intention to publish date

18/03/2025

## Individual participant data (IPD) sharing plan

The datasets generated during this study will be available upon request from Gianluca Martino Tartaglia ([gianluca.tartaglia@unimi.it](mailto:gianluca.tartaglia@unimi.it)).

The type of data that will be shared: raw data Excel tables.

Dates of availability: upon publication.

The dataset of the patients has been stripped of any personally identifiable information such as names, addresses and phone numbers.

## IPD sharing plan summary

Available on request