

# Comparing the effectiveness of two different treatment methods in treating pain in facial muscles and joints of the jaw

<b>Submission date</b> 20/02/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/03/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/11/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Temporomandibular disorders are a series of several different pain symptoms in the face and jaw joints. A common treatment is to manufacture an oral splint to be used when sleeping. This method does not help every patient, so our aim in this trial was to study the effect of a coping method (applied relaxation) compared to the common splint treatment.

### Who can participate?

Any student of the age from 19 to 35 and studying in the Finnish Universities of Oulu or Lapland with symptoms of temporomandibular disorders could participate in this one-center trial at the Finnish Student Healthcare System in Oulu, Finland. Persons with a rheumatic disease, fibromyalgia, or suffering from severe mental conditions were excluded as those conditions could interfere with the results.

### What does the study involve?

The voluntary participants were divided to two treatment groups receiving either the oral splint treatment or the applied relaxation treatment. They could retire from the trial at any phase without conflict.

A questionnaire of general health and pain items was filled at baseline and at 12-month follow-up. A clinical examination including pain on palpation of the masticatory muscles, pain on moving the jaw, and noises when moving the jaw was performed at baseline, and 3-, 6, and 12-month follow-ups.

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

Neither of the treatments give any side effects, and the participants gained in receiving help to their pain symptoms.

### Where is the study run from?

The examinations, treatments and analysis of the data was and will be conducted during office hours at the Finnish Student Healthcare System and Universities of Oulu and Eastern Finland by dentist, physiotherapist, and researchers as part of their daily work.

When is the study starting and how long is it expected to run for?  
December 2011 to December 2013

Who is funding the study?  
Finnish Student Health Service

Who is the main contact?  
Outi Huhtela (outi.huhtela@uef.fi)

## 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**

186/2011

## **Study information**

**Scientific Title**

Effectiveness of applied relaxation method vs. splint in treatment of temporomandibular disorders in Finnish students

**Acronym**

TMD

**Study objectives**

Applied relaxation method is as effective as splint treatment in treating temporomandibular disorders of muscular origin

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 03/10/2011, Ethical Committee of the Hospital District of Northern Ostrobothnia, (P. O.Box 8000 FI-90014 University of Oulu, Finland; +358(0)294487001; Janne Kurtakko@oulu.fi), ref: 186/2011

**Study design**

Single-center longitudinal case-control study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

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

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

Signs and symptoms of temporomandibular disorders

## **Interventions**

Applied relaxation method and splint treatment. Patients were randomly assigned by computer-generated random number using SPSS software (version 18.0) into two treatment groups. Applied relaxation is administered by a physiotherapist in six group sessions according to a specified protocol. Splint treatment is applied and checked by a dentist at FSHS. Follow-ups were conducted by a research dentist at 3-, 6- and 12 months from baseline..

## **Intervention Type**

Mixed

## **Primary outcome measure**

Symptoms of TMD (pain on palpation; locking of jaws; joint noises) were measured according to the protocol of Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) Axis I at baseline, 3-, 6- and 12 month follow-ups.

## **Secondary outcome measures**

At baseline and at 12-month follow-up:

1. Experienced pain measured by visual analog scale (VAS)
2. Non-specific pain symptoms measured by RDC/TMD (Research Diagnostic Criteria for TMD) Axis II (Finnish version)
3. Depression symptoms measured by RDC/TMD Axis II (Finnish version)

## **Overall study start date**

08/06/2011

## **Completion date**

22/12/2014

# **Eligibility**

## **Key inclusion criteria**

1. Graduate student at University of Oulu or University of Lapland
2. Age 19 - 35 years
3. Attending Finnish Student Health Service's nurse/doctor/physiotherapist/dentist/dental hygienist appointment complaining of symptoms or signs that could have temporomandibular disorder (TMD) origin
4. No previous diagnosis of muscle or joint-related pain conditions, like fibromyalgia, rheumatic conditions or joint-related psoriasis, or mental disorder
5. Diagnosis of temporomandibular disorder (TMD)

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Sex**

Not Specified

## **Target number of participants**

123 participants at baseline. After randomization and possible exclusion two groups: applied relaxation group 55 participants and splint group 41 participants.

### **Total final enrolment**

96

### **Key exclusion criteria**

1. No diagnosis of TMD at baseline examination
2. Diagnosis of muscle or joint-related pain conditions, such as fibromyalgia, rheumatic conditions or joint-related psoriasis
3. Mental disorder

### **Date of first enrolment**

09/12/2011

### **Date of final enrolment**

01/12/2013

## **Locations**

### **Countries of recruitment**

Finland

### **Study participating centre**

**University of Oulu**

Aapistie 5

Oulu

Finland

90220

### **Study participating centre**

**Finnish Student Health Service**

Yliopistokatu 1 A

Oulu

Finland

90570

## **Sponsor information**

### **Organisation**

Finnish Student Health Service

### **Sponsor details**

Yliopistokatu 1 A  
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outi.huhtela@uef.fi

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.yths.fi/en>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Finnish Student Health Service

## Results and Publications

**Publication and dissemination plan**

Publication in a high-impact peer-reviewed journal

The trial is to be part of a doctoral thesis approximately in August 2020

**Intention to publish date**

19/06/2019

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

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository

Oulu university , Department of Odontology, <https://www.oulu.fi/university/research> for 10 years after which it is destroyed

**IPD sharing plan summary**

Stored in repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/02/2020	23/11/2020	Yes	No