

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

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

Type(s)
Scientific

Contact name
Mrs Outi Huhtela

ORCID ID
<https://orcid.org/0000-0003-1853-3182>

Contact details
Yliopistonranta 1 C
Kuopio
Finland
70210
+358407453688
outi.huhtela@uef.fi

Type(s)
Scientific

Contact name
Prof Kirsi Sipilä

ORCID ID
<https://orcid.org/0000-0001-9734-320X>

Contact details
Aapistie 5
Oulu
Finland
90220
+358504423654
kirsi.sipila@oulu.fi

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Finnish Student Health Service

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

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?
Results article	results	01/02/2020	23/11/2020	Yes	No