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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

Registration date
21/03/2019

Overall study status
Completed

Last Edited
23/11/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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Study participating centre
Finnish Student Health Service
Yliopistokatu 1 A
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Sponsor information

Organisation
Finnish Student Health Service

Sponsor details

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