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Myogenous temporomandibular disorders (TMD), I. physiotherapy compared with occlusal splint therapy, and II. occlusal adjustment compared with occlusal splint therapy combined with occlusal adjustment, using therapy-and-patient-specific treatment durations

Submission date
19/10/2016

Recruitment status
No longer recruiting

Registration date
11/11/2016

Overall study status
Completed

Last Edited
13/02/2017

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims

Temporomandibular Disorder (TMD) is a problem affecting the muscles used for chewing and the joints between the lower joint and the base of the skull. It is sometimes called myofascial pain disorder. The condition is not usually serious and the symptoms it causes (pain, jaw joint clicking/popping and difficulties eating) tend to only last a few months. However, they can also seriously affect a persons quality of life and specialist treatment may be needed if symptoms are severe. One third of patients have myogenous TMD, that is the condition that affects only the muscles and does not involve the joints. Alterations in central pain mechanisms may be involved anyhow. At least part of the problems may also arise from disturbances in the way antagonistic teeth fit together in the end phase of jaw closing during chewing and during clenching. These disturbances, called occlusal interferences, influence the activation of jaw muscles and central pain mechanisms. For patients without pronounced occlusal interferences, an occlusal appliance, or splint, is commonly used by dental practices to treat it. Alternatively, there is another treatment for such patients that involves a type of physiotherapy which includes massage of sore muscles and cognitive-behavioural therapy. When pronounced occlusal interferences occur along with myogenous TMD, occlusal adjustment (OA) of these interferences is usually carried out in combination with splint therapy. The question is whether OA alone would be similarly effective as the combination therapy to treat the myogenous TMD. The aim of this study is to compare two types of treatment for each of the patient categories, i.e. physiotherapy vs. splint therapy in patients without pronounced occlusal interferences, and OA vs. the combination of splint therapy and OA in patients with pronounced occlusal interferences. A scoring system called Treatment Duration Control is used to compare different therapies. The study looks at the

time and number of visits needed to decide whether a patient's treatment is either successful or unsuccessful and how effective each of the treatments are.

Who can participate?
Adults with myogenous TMD

What does the study involve?
Participants without pronounced occlusal interferences (group I) are randomly allocated to one of two subgroups I.1 and I.2. Those in subgroup I.1 receive the physiotherapy and cognitive behavioural therapy treatment. All participants in subgroup I.1 start with a 3-week program of 2-3 visits per week where they are counselled on how to correct habits that may contribute to their TMD, training on posture and jaw movements and techniques on the relaxation of jaw muscles and massage to help with pain management. After this initial 3-week program, all participants are given exercises tailored for them to do at home; the duration of the program offered and the number of visits each participant receives is also tailored individually. The treatment is given for between 10-21 weeks and the number of visits they receive varies between 10-16. Participants in subgroup I.2 receive splint therapy. They are given a splint to wear for at least 10-12 hours overnight for one or more 6-week periods. Once the symptoms begin to ease, the participant wears the splint for decreasing periods of time. The treatment is given for between 12-30 weeks and the number of visits they receive varies between 3-6. All participants in both subgroups are examined after the treatment period and then 4 weeks, 6 months and 12 months later.
Participants with pronounced occlusal interferences (group II) are randomly allocated to one of two subgroups II.1 and II.2. Those in subgroup II.1 receive solely occlusal adjustment (OA), which can be applied gradually, i.e. apart from the first visit with OA, OA can be completed at a second visit and/or a third visit, with intervals of 3 weeks between visits. Thus the entire period of 1-3 possible occasions of OA is 6 weeks at most. Including a period to assess whether the TMD symptoms have eased, OA therapy is given for between 6-12 weeks and the number of visits the participants receive varies between 3-4. Participants in subgroup II.2 start with splint therapy. They are given a splint to wear for at least 10-12 hours overnight for one or more 6-week periods. When the TMD symptoms begin to ease after 6 weeks of splint wearing, this therapy is then combined with OA. Otherwise splint therapy is combined with OA following 12 weeks of splint wearing. Like for subgroup II.1 receiving solely OA, there are 1-3 occasions for carrying out OA. Once the TMD symptoms begin to ease, the participant wears the splint for decreasing periods of time. The treatment is given for between 12-31 weeks and the number of visits they receive varies between 3-7. All participants in both subgroups are examined after the treatment period and then 4 weeks, 6 months and 12 months later.

What are the possible benefits and risks of participating?
Participants of both treatments in group I may benefit from an improvement of their pain levels and disability. If physiotherapy has at least a similar success rate and effectiveness as splint therapy, the patient may have additional benefits from this type of therapy because of its shorter duration and there being no need to wear an oral appliance in the long term.
Participants are not exposed to any known risks as the non-invasive treatments, which are commonly used, are safe.
Participants of both therapies in group II may also benefit from an improvement of their pain levels and disability. If solely OA has at least a similar success rate and effectiveness as the combination therapy, the patient may have additional benefits from solely OA therapy because of its shorter duration, fewer visits needed, and there being no need to wear an oral appliance in the long-term. Because OA would be invasive by grinding of healthy tooth tissue, three precautions are taken. First, only those patients are selected for the study whose pronounced occlusal interferences are mainly iatrogenic (i.e. related to restorative dental work [fillings and

/or crowns]). Second, dental casts of the patient's dentition are used to check that the goals of OA can be attained by grinding restorative dental work while healthy tooth tissue is less affected. Third, OA can by carried out gradually, by providing 1-3 possible occasions. Participants are not exposed to any known risks by the application of an occlusal splint.

Where is the study run from?
University Medical Centre Utrecht (UMCU) - Netherlands

When is the study starting and how long is it expected to run for?
April 1993 to March 2000

Who is funding the study?
Health Care Board, Department of Developmental Medicine (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Group I: Towards an optimal therapy strategy for myogenous temporomandibular disorders (TMD), physiotherapy compared with occlusal splint therapy in an RCT with therapy-and-patient-specific treatment durations

Group II: Towards an optimal therapy strategy for myogenous temporomandibular disorders (TMD),
occlusal adjustment compared to a combination of occlusal splint therapy and occlusal adjustment in an RCT with therapy-and-patient-specific treatment durations

Study objectives
For group I, the aim of this study is to compare the treatment outcome of physiotherapy for myogenous temporomandibular disorders (TMD) with that of splint therapy in three respects:
1. Number of visits/duration
2. Success rate
3. Effectiveness
Weighing of these outcomes will enable a decision on whether physiotherapy or splint therapy may be recommended as an initial treatment of myogenous TMD, following reassurance and counselling of the patients at the initial visit with diagnosis.

Added 07/12/2016:
For group II, the question is whether solely OA therapy will adequately diminish the signs and symptoms of myogenous TMD that occur concomitantly with pronounced occlusal interferences. Occlusal splint therapy is a traditional type of therapy for myogenous TMD with known effectiveness. If, as a null hypothesis, solely OA therapy were entirely unsuccessful to ease TMD, the effectiveness of solely OA will be much smaller than that of the combination of splint therapy with OA. The aim of this study is to compare the treatment outcome of OA for myogenous TMD with that of the combination therapy, in three respects:
1. Number of visits/duration
2. Success rate
3. Effectiveness
The null hypothesis is tested by comparing success rate and effectiveness between OA and splint therapy combined with OA. Weighing of all three outcomes will enable a decision on whether OA or the combination therapy may be recommended as an initial treatment of myogenous TMD, following reassurance and counselling of patients with pronounced occlusal interferences.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Ethics Committee and the Board of Developmental Medicine in the Netherlands, 21 /03/1993, ref: OG/93/002

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Chronic orofacial pain

Interventions
For group I as well as group II, treatment outcome of the first type of therapy (physiotherapy or OA respectively) is evaluated in comparison to that of the second type of therapy (solely splint therapy or splint therapy combined with OA respectively) using a type of randomized controlled trial with, comparable to clinical care, therapy-and-patient-specific treatment durations. Also comparable to clinical care, at the initial visit with diagnosis, all participants are informed in a standardized way by a dentist about myogenous TMD as being a non-life threatening disorder with a lack of an unambiguous cause of the pain and about possible contributing factors. Furthermore, the participants receive counselling on avoiding possibly stress-induced oral habits.

Participants of group I are then randomly allocated to one of two therapy subgroups I.1 and I.2.
I.1. first subgroup (active treatment): physiotherapy of the masticatory system:
Participants start with a 3 week program (2-3 visits/week) consisting of:
I.1.1. Counselling on and reversal of detrimental oral habits
I.1.2. Control and training on posture and jaw movements
I.1.3. Techniques for relaxation of jaw muscles and pain relief by means of self-massage.
Following the basic program, patient-specific exercises are continued at home for one or more periods of 6 weeks. The number of visits varies within a range of 10-16 and the treatment duration within a range of 10-21 weeks.
I.2. second subgroup (control treatment): occlusal splint therapy:
The occlusal appliance (Michigan type) is applied in the upper jaw, and the patient is instructed to wear the splint at least overnight for a minimum of 10 to 12 hours, for one or more periods of 6 weeks. As soon as the patient’s signs and symptoms decrease sufficiently, the splint is gradually withdrawn. The number of visits varies within a range of 3-6 and the treatment duration within a range of 12-30 weeks.

Added 07/12/2016:
Participants of group II are randomly allocated to one of two therapy subgroups II.1 and II.2.
II.1. first subgroup (active treatment): occlusal adjustment (OA):
Participants receive solely OA at a first treatment visit. If necessary, OA is completed at a second and/or third visit with inter-visit intervals of 3 weeks. Thus the entire period of 1-3 possible occasions of OA is maximally 6 weeks. Including a period to assess whether the TMD symptoms have eased, the treatment is given for between 6-12 weeks and the number of visits they receive varies between 3-4.
II.2. second subgroup (control treatment): occlusal splint therapy combined with OA:
Participants start with splint therapy. The occlusal appliance (Michigan type) is applied in the upper jaw, and the patient is instructed to wear the splint at least overnight for a minimum of 10 to 12 hours, for one or more periods of 6 weeks. When the TMD symptoms begin to ease after 6

weeks of splint wearing, this therapy is then combined with OA therapy. Otherwise it is combined with OA therapy following 12 weeks of splint wearing. Like for subgroup II.1 receiving solely OA, there are 1-3 occasions for carrying out OA. Once the symptoms begin to ease, the participant wears the splint for decreasing periods of time. The treatment is given for between 12-31 weeks and the number of visits they receive varies between 3-7.

For all four subgroups, each therapy has a specific program with a number of visits that varies depending on the rate of a patient's improvement. Hence, the duration of treatment will be therapy-and-patient-specific. The progress and ultimate effect of treatment are evaluated using Treatment Duration Control (TDC). By summarizing anamnestic and clinical data in TDC, the clinician (physiotherapist or dentist) controls treatment duration and the number of visits used (1st feature of treatment outcome) in a standardized way. A blinded assessor (a dentist) records anamnestic and clinical data which are used by an independent researcher to determine TDC-values following treatment. These post-treatment TDC-values yield success rate and effectiveness as the 2nd and 3rd features of treatment outcome, in the short-term and after a follow-up with a duration up to 1 year.

Intervention Type
Other

Primary outcome measure
1. Number of visits/duration of treatment used
2. Success rate based on post-treatment TDC
3. Effectiveness based on post-treatment TDC
While number of visits/duration of treatment are known at the end of treatment, success rate and effectiveness are determined following treatment, i.e. after 4 weeks, 6 months and 12 months.

Secondary outcome measures
1. Predominant pain intensity of the masticatory system, , scored on a 100 mm Visual Analogue Scale (VAS) at the initial visit with diagnosis (4 weeks before the start of treatment), at the start of treatment, and following treatment, i.e. after 4 weeks, 6 months and 12 months

Added 07/12/2016:
2. Mean actual pain intensity, scored on 100 mm VASs for 13 facial areas and 11 non-facial areas (neck and shoulder areas) which are depicted on illustrations of head, neck and shoulders from both sides of the body. These illustrations and VASs are included in the Pain Location Questionnaire
3. General Health-related Quality of Life, measured using utility values of Euroqol-5D (EQ-5D)
Both measured at the start of treatment, and following treatment, i.e. after 4 weeks, 6 months and 12 months

Overall study start date
22/04/1993

Completion date
31/03/2000

Eligibility

Key inclusion criteria

1. Age between 18 and 65 years
2. Female or male
3. Pain and tenderness of the masticatory muscles (in the absence of Temporomandibular Joint pathology, solely myogenous TMD), of 3 months duration or longer
4. A good understanding of Dutch

Added 07/12/2016:
5. Only for group II: Pronounced occlusal interferences, i.e. (i) a forward sliding of at least 2 mm and/or lateral sliding of at least 1 mm with respect to centric occlusion; and (ii) an interference on the non-active side that is not accompanied with contact on the active side
6. Only for group II: Feasibility of occlusal adjustment by grinding in a conservative way; assessment by mounting the patient's dental casts in a semi-adjustable articulator

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Clinical and/or radiographic evidence of organic changes in the temporomandibular Joints
2. Previous treatment with an occlusal stabilization appliance, occlusal adjustment, or physiotherapy of the masticatory system
3. Other treatments for pain (also nonfacial pain) more recent than a year
4. Predominant craniovertebral dysfunction (pain of neck and/or shoulders that predominates that of facial areas)
5. Metabolic, neurologic, vascular disease, or disorders (eg, diabetes, neuralgia, migraine)
6. Recent dramatic life event (divorce, bereavement, physical abuse by partner, incest, and victim of criminal assault) and/or psychotherapy and/or use of psycho-medication
7. Odd sleep/wake cycles due to work shift
8. Gross anomalies of the natural dentition: full/partial denture, loss of dorsal support, collapsed bite, extensive migrations, or morphological malocclusion (eg, cross bite)
9. Only for group I: Pronounced occlusal interferences, i.e. (i)) a forward sliding of at least 2 mm and/or lateral sliding of at least 1 mm with respect to centric occlusion; and (2) an interference on the non-active side that is not accompanied with contact on the active side

Date of first enrolment
01/09/1993

Date of final enrolment
01/03/1999

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Utrecht (UMCU)
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Organisation
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Government

Funder Name
Health Care Board, Department of Developmental Medicine (Ziekenfondsraad, Ontwikkelingsgeneeskunde)

Results and Publications

Publication and dissemination plan

The trial has completed recruitment and the results have been analyzed. Planning of publication of results of the trial in a peer-reviewed medical scientific journal.
Methodological aspects related to the tool used in the trial, TDC, and its validation have been published:
van Grootel RJ, der Bilt AV, van der Glas HW. Long-term reliable change of pain scores in individual myogenous TMD patients. Eur J Pain. 2007 11: 635-643.
van Grootel RJ, van der Glas HW. Statistically and clinically important change of pain scores in patients with myogenous temporomandibular disorders. Eur J Pain. 2009 13: 506-510.
van der Glas HW, van Grootel RJ. The index 'Treatment Duration Control' for enabling randomized controlled trials with variation in duration of treatment of chronic pain patients. BMC Med Res Methodology 2013 13: 123.
The Pain Location Questionnaire has been described in:
van Grootel RJ, van der Glas HW, Buchner R, de Leeuw JRJ, Passchier J. Patterns of pain variation related to myogenous temporomandibular disorders. Clin J Pain 2005 21:154–165.

Intention to publish date:
01/12/2016 (group I study) and 01/02/2017 (group II study)

Intention to publish date

01/02/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Hilbert van der Glas (h.vanderglas@dundee.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/02/2017		Yes	No