

# Etiology, diagnostics and management of bruxism

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(A) Determine the influence of anger and frustration on self-reported bruxism.(B) Validation of a new ambulant electromyographic (EMG) diagnostic device for bruxism (TeleBrux).(C) Determine the additional value of peripheral modulation with...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Muscle disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON38435

### Source

ToetsingOnline

### Brief title

Bruxism

### Condition

- Muscle disorders

### Synonym

Bruxism, tooth-clenching, tooth-grinding

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** Ministerie van OC&W,TMD Solutions BV

## Intervention

**Keyword:** Bruxism, Etiology, Muscle Stretching Exercises, Polysomnography

## Outcome measures

### Primary outcome

(A) Self-reported awake and sleepbruxism, anger and frustration.

(B, C) Established criteria for sleepbruxism (bruxism episodes per hour, bruxism bursts per episode/hour, episodes with sounds).

### Secondary outcome

(A) Use of alcohol, smoking, anxiety, stress, sleep quality.

(B) Subjective experiences with TeleBrux, sleep quality.

(C) Experiences with sleep quality, bruxism and stretching, range of motion of the jaw, pain threshold and pain tolerance, pain, bite force, mandibular function.

## Study description

### Background summary

Bruxism is a repetitive jaw muscle activity characterized by clenching and/or grinding of the teeth and has two distinct manifestations: it can occur during sleep (sleepbruxism, SB) or during wakefulness (awake bruxism). Bruxism can cause dental problems such as tooth wear and pain in the jaw muscles and joints. Psychosocial factors such as emotions are associated with bruxism. Studies on the emotions anger and frustration as etiological factors for SB are scarce and contradictory results. For the determination of SB is polysomnography (PSG) in a sleep laboratory, described as the gold standard. There is, however, both for clinical and research purposes, a strong need for ambulatory diagnostic devices which are user-friendly. In the treatment of SB is the standard care counseling and sleep hygiene. The question is whether bruxism can be modulated peripherally, for example, by stretching the jaw muscles.

## Study objective

- (A) Determine the influence of anger and frustration on self-reported bruxism.
- (B) Validation of a new ambulant electromyographic (EMG) diagnostic device for bruxism (TeleBrux).
- (C) Determine the additional value of peripheral modulation with stretching of the muscles of the jaw in the management of bruxism in comparison with standard care alone.

## Study design

- (A, B) Prospective cohort study.
- (C) Randomised controlled clinical trial.

## Intervention

- (A, B) No intervention.
- (C) Control group receives standard care (counseling and sleep hygiene), and intervention group receives standard care and stretching exercises.

## Study burden and risks

The studies do not bring any risks for the participants. The burden is minimal. In study A the burden is a minimal time investment for filling in the questionnaires. In studies B and C the burden also consists of discomfort by application and wearing the diagnostic devices. In study C the participants can experience discomfort by the stretching exercises.

## Contacts

### Public

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### Scientific

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

(A) Study on etiology

- Age: adults of >18 years

- Is aware of his/her clenching and/or grinding and/or his/her bed partner notice this;

(B) Study on diagnostics

- Age: 20-45 years

- Awareness of presence or absence of clenching and/or grinding;

(C) Study on management

- Age: 20-45 years

- Clear signs (partner/intraoral) and/or the subject is aware of his/her clenching and/or grinding

### **Exclusion criteria**

(A) Study on etiology

- Presence of neurological disorders, neoplasms, psychiatric diseases

- Removable intraoral device, such as a full prosthesis, frame prosthesis or plate prosthesis

- Treatment for TMD or bruxism

- Orthodontic treatment at the moment

- Use of medication which can influence the clenching and grinding

- Use of soft/harddrugs

- Toothache

- Dental treatment in the next 6 months, with plans for crowns, bridges, prosthesis of more than one filling;

(B) Study on diagnostics, and (C) Study on management

- Waking up with a pain complaint in the orofacial region

- Absence of natural teeth in the front, the presence of loose and/or painful elements

- Dislocated temporomandibular joint

- Limited mouth opening

- Excessive use of alcohol

- Use of soft/harddrugs
- Use of medication affecting sleep or motor behavior (psychotropic drugs, such as amphetamines, benzodiazepines, L-dopa, antipsychotics, tricyclic antidepressants, SSRI)
- Neurological and neuromuscular disorders with effects on motor skills (such as epilepsy, Parkinson's disease, SMA, Duchenne muscular dystrophy)
- Psychiatric disorders (such as schizophrenia)
- Severe systemic diseases (such as MS).

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	04-12-2013
Enrollment:	174
Type:	Actual

### Medical products/devices used

Generic name:	Stretching device
Registration:	No

## Ethics review

Approved WMO	
Date:	16-01-2014
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	01-09-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL46301.091.13