

# Brain activity during (neural correlates of) teeth clenching in bruxers with temporomandibular disorder (tmd) pain and non-bruxers without tmd pain: a pilot study

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|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Approved WMO               |
| <b>Status</b>                | Recruitment stopped        |
| <b>Health condition type</b> | Other condition            |
| <b>Study type</b>            | Observational non invasive |

## Summary

### ID

NL-OMON42866

### Source

ToetsingOnline

### Brief title

Brain activity during teeth clenching

### Condition

- Other condition
- Movement disorders (incl parkinsonism)

### Synonym

awake bruxism, teeth clenching

### Health condition

orale bewegingsstoornissen

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht

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

## Intervention

**Keyword:** awake bruxism, brain activity, teeth clenching, tmd pain

## Outcome measures

### Primary outcome

- a. the measure (qualitative/quantitative) of brain activity during teeth clenching
- b. the measure of brain activity during tmd pain

Endpoints will be if there is no brain activity at all or the measurements are too weak so that a follow up study will not be indicated anymore; if the measurements of brain activity are strong enough in case of teeth clenching but not in the case of tmd pain, the follow up study will be executed in a modified form.

### Secondary outcome

not applicable

## Study description

### Background summary

This pilot study will function as a baseline measurement of an intervention study, investigating changes in brain activity during awake state in the group

of awake bruxers with tmd pain by application of cognitive behaviour therapy and if/whether behaviour change correlates with the change in frequency of tooth contact and tmd pain.

Cognitive behaviour therapy (CBT) currently is an appropriate application in the management of bruxism. The intervention therapy, which is specific focused on awake bruxism, is based on the hypothesis that this behaviour (i.e. teeth clenching) shows neural correlates in human brains. To improve the objectivism of behavioural change, we want to deploy MRI. Before we can start with the intervention study, we want to investigate by this pilot study whether the neural correlates are strong enough to use in the intervention study. Apart from already in existing studies applied functional MRI, we also want applying \*resting-state\* MRI in this pilot study. Till now there are no studies publicised investigating behaviour change in bruxism by MRI and the neural correlates associated with it.

## **Study objective**

The objective of this pilot study is to provide further insights about the neural correlates of teeth clenching (during awake state) and tmd pain in bruxers and non-bruxers or more specific:

The primary objective of the study is to provide further insights about the neural correlates (i.e. the extent of brain activity) of teeth clenching (during awake state) in bruxers and non-bruxers.

The secondary objective of the study is to provide further insights about the neural correlates (i.e. the extent of brain activity) of tmd pain and to investigate the difference in brain activity between subjects (bruxers) with tmd pain and subjects (non-bruxers) without tmd pain.

## **Study design**

This is an exploring, observing and inventorying pilot study in which MRI measurements of brain activity in relevant brain structures are collected. All participants will undergo MRI measurements in which data are collected concerning relevant brain structures (motor cortex, somatosensory cortex), executive brain function, intrinsic organisation of brain function (functional connectivity) and white matter integrity.

## **Study burden and risks**

not applicable

## **Contacts**

### **Public**

Medisch Universitair Ziekenhuis Maastricht

P.Debyelaan 25  
Maastricht 6229 HX  
NL

**Scientific**

Medisch Universitair Ziekenhuis Maastricht

P.Debyelaan 25  
Maastricht 6229 HX  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

bruxers with tmd pain

non-bruxers without tmd pain

beside this criteria subjects needs to meet the following criteria: 18 years or older; mentally competent; in a good physical and mental health.

### Exclusion criteria

bruxers without tmd pain

non-bruxers with tmd pain

beside this criteria subjects who meets any of the following criteria will be excluded: persons with a full denture in upper and or lower jaw; persons with pain elsewhere in the body;

persons who meets one of the criteria below:

a history of head or brain operations,

in case of an implanted electronic device (i.g. pacemaker),

in case of an subcutaneous insulin pump,

in case of claustrophobia,  
in case of cardiac arrhythmia,  
in case of pregnancy,  
in case of, except tooth fillings and dental crowns, other metal particles embedded in the body such as: implants, blood vessel clips, metal particles in the eye, an IUD, metal wires, other kinds of metal objects.

## Study design

### Design

|                     |                                 |
|---------------------|---------------------------------|
| Study type:         | Observational non invasive      |
| Intervention model: | Other                           |
| Allocation:         | Non-randomized controlled trial |
| Masking:            | Open (masking not used)         |
| Control:            | Active                          |
| Primary purpose:    | Diagnostic                      |

### Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 19-04-2017          |
| Enrollment:               | 40                  |
| Type:                     | Actual              |

## Ethics review

|                    |                                                                                         |
|--------------------|-----------------------------------------------------------------------------------------|
| Approved WMO       |                                                                                         |
| Date:              | 05-10-2016                                                                              |
| Application type:  | First submission                                                                        |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

## 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**

| <b>Register</b> | <b>ID</b>      |
|-----------------|----------------|
| CCMO            | NL56974.068.16 |