

# Misophonia: an imaging study on the neurobiology and the efficacy of cognitive behavioural therapy

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Psychiatric disorders NEC
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON35548

### Source

ToetsingOnline

### Brief title

Misophonia: an imaging study on the neurobiology

### Condition

- Psychiatric disorders NEC

### Synonym

Hatred of sound

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

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

## Intervention

**Keyword:** Aggressiveness, Impulsivity, Misophonia, Sound

## Outcome measures

### Primary outcome

Main study parameters:

- Change in symptom severity as measured with the Amsterdam Misophonia Scale (AMISS) and Clinical Global Impression Scale (CGI)
- fMRI
- EEG
- Neuropsychological paradigms
- Genetic outcomes

### Secondary outcome

Psychiatric questionnaires (HARS, HDRS, IOA, AVL, SCL-90R)

## Study description

### Background summary

Rationale: Misophonia is a currently underrecognized and uninvestigated condition in which specific sounds, commonly produced by human beings, trigger impulsive aggressiveness in apparently normal people. The intensity of the anger initiates a profound feeling of loss of self-control which causes significant avoidant behaviour that result in limited social contacts and functioning.

Recently, diagnostic criteria have been formulated by Schröder and Denys to distinguish it as a separate psychiatric disorder. Subsequently, a pilot group therapy consisting of cognitive behavioural therapy (CBT) and psychomotor therapy (PMT), has been treated in the AMC, which resulted in significant symptom reduction in the majority of the patients.

### Study objective

The objective for this study is threefold. The first goal is to objectify differences in brain function between patients and normal controls. The second objective is to support preliminary findings that the combination of CBT/PMT is an effective treatment for misophonia. In addition, we will determine the effects of CBT/PMT on functional activation of the brain in misophonia patients. The final goal is to determine the genetic and epigenetic factors involved in misophonia and its treatment.

## **Study design**

Study design: an open-label case-control study.

## **Study burden and risks**

Patients:

- 10 weeks in a row, weekly CBT sessions. Daily homework assignments.
- before, after 5 weeks and after finishing therapy: psychiatric questionnaires
- bloodsamples will be taken before and after CBT treatment

Both patients and controls:

- Before and after treatment: two days of imaging (MRI and EEG)

## **Contacts**

### **Public**

Academisch Medisch Centrum

Meibergdreef 9  
1105 AZ Amsterdam  
NL

### **Scientific**

Academisch Medisch Centrum

Meibergdreef 9  
1105 AZ Amsterdam  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Symptoms of misophonia

18-65 yrs

### Exclusion criteria

Major Depression

Anxiety disorders

Bipolar disorder

Autism Spectrum Disorders

Psychotic disorders

Epilepsia/CNS disorders

## Study design

### Design

Study phase:	2
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-03-2012

Enrollment: 60  
Type: Actual

## Ethics review

Approved WMO  
Date: 16-01-2012  
Application type: First submission  
Review commission: METC Amsterdam UMC

## 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	NL37726.018.11