Innovative diagnostics and treatment of misophonia in children and adolescents: a new psychiatric disorder

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Ethical review	Approved WMO
Status	Completed
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON52247

Source
ToetsingOnline

Brief title
Diagnostics and treatment of misophonia in youth.

Condition

- Psychiatric disorders NEC

Synonym
hatred of sound, misophonia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Fonds Stichting Gezondheidszorg Spaarneland Zilveren Kruis (Fonds SGS)

Intervention

Keyword: Adolescent, Child, Cognitive behavioral therapy, Misophonia

Outcome measures

Primary outcome

(See also METC protocol)

The primary outcome of the study is the severity of misophonia symptoms, as measured by the AMISOS-Y.

Secondary outcome

(See also METC protocol)

Secundary outcomes are:

- Misophonia complaints (Misophonia Screening List - Child and Youth)
- Psychopathology in the child (attention and concentration problems, anxiety/depression, oppositional behavior, compulsions)
- Severity of psychopathology (change over time)
- School functioning
- Quality of life
- Attention problems
- Sensory processing
- Care related quality of life
- Cost of illness
- Social validity of treatment
- Family accommodation to misophonia

- Coercive disruptive behavior child

Study description

Background summary

Internationally, very little research has been conducted into complaints of misophonia. The disorder misophonia was first described worldwide by Prof. Denys of the Amsterdam UMC. This is special, because it is very rare that a new psychiatric disorder is discovered. Some research has already been carried out in adults, but very little is known about misophonia in children / adolescents. People suffering from misophonia are overcome by uncontrollable, extreme anger, disgust or hatred at hearing normal human sounds (such as chewing, smacking, nose sniffing, or breathing) especially in the home setting. This can also occur when seeing movements that arouse the feelings (e.g. grinding jaw). Epidemiological studies on misophonia in children have not yet been performed.Two studies among young students show that the prevalence of clinically significant misophonia symptoms varies from 6% -20%. Research at the psychiatry outpatient clinic of the Amsterdam UMC, location AMC, in nearly 600 adult patients with misophonia, has shown that the average age of onset is around 13 years, so the complaints develop at a young age. Children are regularly referred to the Bascule/Levvel from the age of 8, whilst they can have been suffering already for several years. Although many adults and children can experience these misophonia symptoms in a mild form, for some they mean tremendous suffering. The strong emotions and negative thoughts must always be suppressed, which is very tiring. Misophonia can have a serious disruptive impact on children's lives, at home, at school and within the family. For example, children can no longer eat, sleep, drive a car (e.g. while on vacation) or lead a normal family life with the family. There is a lot of avoidance and anticipation of fear of situations with the sounds. Thusfar, questionnaires for the screening and diagnostics of misophonia in children and adolescents have not been validated yet. Furthermore, there is no evidence-based treatment protocol.

Study objective

The two objectives of this study are:
1) validation of two questionnaires, the Misophonia Screening List - Child and Youth and the Amsterdam Misophonia Scale-Youth (AMISOS-Y) in order to screen adequately for misophonia
2) testing the effectiveness of an innovative group treatment protocol for misophonia in children and adolescents

Study design

(See also METC protocol)

Ad objective 1: validation of the questionnaires.
The two questionnaires will be validated using baseline (intake) data of children referred to the Amsterdam UMC/Levvel for diagnosis and treatment of misophonia. In addition, the scores on the questionnaires of 240 healthy control children will be used. The healthy control group will be recruited through collaboration of the research department of the Amsterdam UMC and Levvel, through elementary and secondary schools in Noord- and Zuid-Holland and Brabant. The gender ratios will be adjusted to the ratio in the research group.

Ad objective 2: effectiveness of the treatment protocol is investigated by the means of a randomized controlled trial (RCT).
The effectiveness of the treatment protocol will be investigated by using a single blinded randomized controlled trial (RCT) involving cognitive-behavioral therapeutic treatment and a waitinglist control group.

The moments of assessment will be:
T1 = baseline assessment at intake
T2 = after end group treatment intervention group or after 3 months of waiting
T3 = after end group treatment waitinglist control group or 3 months after T2

Intervention

(See also METC protocol)

The intervention group and the waitinglist control group will receive treatment according to the revised protocol "Group treatment for misophonia youth (12-20 years old)". This protocol is revised, in order to be suitable for children between the ages of 8 and 12 years old. This standardized cognitive behavioral protocol (CBT) consists of 7 weekly group sessions and 1 follow-up session after 1 month. After 3 months of waiting, the waitinglist control group will receive this intervention as well.

Study burden and risks

The risks associated with participation are negligible and the burden is minimal. The intervention that is being investigated is part of the care as usual.

Burden: the baseline measurement (T1) and direct post measurement after treatment (T2 for direct treatment group and T3 for waiting list contol group) are part of care as usual. During these measurements, the children/adolescents fill in questionnaires (total duration approx. 60 minutes). Most of the questionnaires that are administered during these measurements are also part of care as usual, including the diagnostic interview (duration approx. 90-120

minutes, only at T1). For this research, children will fill in extra questionnaires, that take a maximum of 25 minutes per measurement.

For parents, the questionnaires will take approx. 110 minutes, and the interview another 90-120 (only at T1). Again, most of these questionnaires and the diagnostic interview are part of care as ususal. For this research, the extra questionnaires will take a maximum of 65 minutes per measurement. Children and their parents do not have to travel to the Amsterdam UMC/Levvel for these measurement moments. These measurements can be completed at home (digitally). The researcher will contact the parents for one questionnaire through telephone on the three measurement moments.

The digital questionnaire for the teacher will take approx. 15 minutes and is part of care as usual.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)

Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Eligible for participation in the healthy control group for the validation study are: children between the ages of 8 and 18 years old, without psychopathological symptoms of misophonia, not having received treatment for misophonia in the past year. Children and their parents should have provided written informed consent.
Eligible for participation in the patient group of the validation study and the RCT study of treatment effectivity are: children between the ages of 8 and 18 years old, referred to the Amsterdam UMC / Levvel for diagnosis and treatment of misophonia, with treatment being indicated according to clinician, parents and / or child. Children and their parents should have provided written informed consent.

Exclusion criteria

Validation study (healthy control group): meeting the criteria for misophonia on a psychopathological level, needing treatment; having had the diagnosis of misophonia and / or treatment for misophonia in the past year; mental retardation (estimated IQ below 85 in children and / or parents); inability to read / write or understand Dutch.
Validation study (patient group) and RCT study of treatment effectivity: not meeting the inclusion criteria; does not have misophonia as primary problem domain; having psychiatric comorbid symptoms or diagnosis that hinder group functioning or require change of treatment protocol*; family problems that hinder participation or adherence to treatment protocol*; having had cognitive behavioral therapy for misophonia in the past year; self-injurious behavior (i.e. automutilation) at present or in the past year; mental retardation (estimated IQ below 85 in children and / or parents); inability to read / write or understand Dutch.
* as assessed during the screening, during the intake (by a psychiatrist and/or clinical psychologist), and by the questionnaires.

Study design

Design

Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	03-08-2021
Enrollment:	322
Type:	Actual

Ethics review

Approved WMO

Date:	09-06-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	09-03-2022
Application type:	Amendment
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

ID: 20775
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL76129.018.21

Study results

Date completed: 21-07-2023

Results posted: 16-07-2024

First publication
11-03-2023