Innovation of diagnostics and treatment of selective mutism: towards personalized care

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The objective of this study is to1) validate a specific Selective Mutism Questionnaire (SMQ) to screen adequately for selective mutism; 2) test the effectiveness of an innovative treatment protocol for selective mutism.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON49550

Source
ToetsingOnline

Brief title
Innovation of diagnostics and treatment of selective mutism

Condition

- Anxiety disorders and symptoms

Synonym
not daring to speak, selective mutism

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anxiety, Behavioral Therapy, Child, Selective mutism

Outcome measures

Primary outcome

(Please also see METC protocol)

The primary outcome of the study is the symptoms of selective mutism in the child. This is being measured by the use of the SMQ questionnaire and the selective mutism chapter of the ADIS-C clinical interview.

Secondary outcome

(Please also see METC protocol)

Secundary outcomes:

- Anxiety and mood problems
- Other psychopathology in the child
- Self image
- Quality of life
- Consumption of care

Study description

Background summary

Selective mutism is an anxiety disorder, characterized by consistent failure to speak in social situations in which this is expected of a child. Selective mutism usually occurs in young children and is often recognized as such in children between the ages of 3-5 years. The not speaking can not be explained

by another language or speech disorder or by inadequate knowledge of the language. Failure to speak impedes progress at school and social communication. Selective mutism is in many cases inadequately and not timely noticed by teachers and other professionals. Because the complaints usually do not occur at home, parents usually do not notice the symptoms. Since children with selective mutism do not speak in situations where this is expected of them (such as at school or at the nursery), this should be noticed by teachers and pedagogical staff. But not speaking is often perceived as non-disturbing by teachers. Teachers are often very busy and a lot of energy and attention goes out to pupils with eg behavioral problems or ADHD. Herein lies the danger that the problems of children with selective mutism are not recognized and acknowledged as such. This has short and long term adverse consequences for the development of the child.
If the problem is not identified in time, the development of children is at stake. Children then have a significantly higher risk of other anxiety and mood problems (eg social phobia, generalized anxiety disorder, depression). Children can unnecessarily duplicate at school. If children are struggling with this for longer, a chronic psychiatric disorder that is more complex, more demanding and long-term than therapy is aimed at remedying selective mutism. Chronic anxiety disorders and depression can occur, usually beginning with transition to high school. In the short and long term, selective mutism impedes social development and communication skills.

Study objective

The objective of this study is to
1) validate a specific Selective Mutism Questionnaire (SMQ) to screen adequately for selective mutism;
2) test the effectiveness of an innovative treatment protocol for selective mutism.

Study design

(Please also see METC protocol)
Ad objective 1: Validation study of the Selective Mutism Questionnaire (SMQ).
The SMQ will be validated using baseline (intake) data of children referred to the Bascule for diagnosis and treatment of selective mutism (SMut). In addition, analyses on data of 240 healthy control children will be used. The healthy control group is recruited in collaboration with the research department of the AMC. The control children are recruited through elementary and secondary schools and sports / recreation clubs in Amsterdam and suburbs. The gender ratios will be adjusted to the ratio in the research group.

Ad objective 2: Effectiveness of the treatment protocol is investigated by means of a randomized controlled trial (RCT).
The effectiveness of the treatment protocol will be investigated by using a

single blinded randomised controlled trial (RCT) involving behavioral therapeutic treatment and a waitinglist control group.

There will be moments of assessment as following:
T1 = baseline at intake
T2 = either after 12 weeks of waitinglist, before start of treatment or after 12 weeks of treatment
T3 = after completion of treatment

Intervention

(Please also see METC protocol)

Both groups will receive treatment according to the protocol 'Speaking in school, a matter of doing' (Wippo & Güldner, 2003). The waitinglist controlgroup will start treatment after a waiting period of 12 weeks.

During COVID-19 treatments were continued through video calls.

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: T1 and T3 are part of the care as usual. During these assessments parents will be asked to fill out extra questionnaires that will take approximately 45 minutes to fill out. T2 is an extra assessment outside of care as usual. This assessment will take parents approximately 60 minutes.
This assessment can be done from home by the parents, digitally, on the phone and partially by mail. Parents do not need to travel to De Bascule for this assessment. The digital questionnaire for parents takes approximately 15 minutes. For children who are participating in filling out questionnaires themselves, this will take approximately 30 minutes.

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 study of the treatment effectivity are: patients under 18 years, with selective mutism as a primary diagnosis and estimated intelligence above 85 in the patient and parents., Eligible for participation in the healthy control group for the validation study are children between the age of 3 and 18.

Exclusion criteria

Study of treatment effectivity: Mental retardation in patient and/or parents, inability to read or write Dutch, other primary diagnosis, having had cognitive behavioral therapy for selective mutism in the past year., Validation Study: diagnosis of selective mutism

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:	Recruitment stopped
Start date (anticipated):	18-09-2018
Enrollment:	320
Type:	Actual

Ethics review

Approved WMO Date:	17-09-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-06-2020
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

No registrations found.

In other registers

Register	ID
CCMO	NL66350.018.18