

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON26941

### Source

NTR

### Brief title

Diagnostics and treatment of selective mutism

### Health condition

Selective mutism, anxiety disorder, children, behavioral therapy

Selectief mutisme, angststoornis, kinderen, gedragstherapie

## Sponsors and support

**Primary sponsor:** Amsterdam UMC

**Source(s) of monetary or material Support:** Stichting Gezondheidszorg Spaarneland - Zilveren Kruis

## Intervention

## Outcome measures

### Primary outcome

Symptoms of selective mutism in the child

## **Secondary outcome**

Anxiety and mood problems

Other psychopathology in the child

Self image

Quality of life

Care consumption

## **Study description**

### **Background summary**

Selective mutism is an anxiety disorder that is characterized the consistent absence of speaking in situations where it is expected (e.g. in school), while the child can speak freely in other environments (e.g. at home). Selective mutism usually occurs in young children. As there is no evidence based treatment nor a validated diagnostical instrument, this study aims to investigate the effectiveness of an innovative treatment protocol for selective mutism and to validate the Dutch translation of the Selective Mutism Questionnaire.

### **Study objective**

Selective mutism is an anxiety disorder that occurs mostly in young children. Selective mutism is characterizes by consisted failure to speak in various specific social situations, in which the child is expected to speak (e.g. at school), whereas the child can speak in other situations (e.g. at home). Selective mutism is usually identified between the ages of 3-5 years and cannot be attributed to a language or speaking disorder. There is no evidence based treatment protocol nor psychometrically sound diagnostical tool for selective mutism available, the aim of this study is to investigate the effectiveness of an innovative treatment protocol and to validate the authorized Dutch translation of the Selective Mutism Questionnaire.

### **Study design**

The outcomes are assessed at baseline during intake, 12 weeks after baseline (either after the first 12 weeks of treatment or after the waiting list period of 12 weeks) and at the end of treatment.

Symptoms of selective mutism are assessed with the Selective Mutism Questionnaire and the Selective Mutism chapter of the ADIS-C clinical interview.

Anxiety and mood symptoms are assessed with the ADIS-C clinical interview.

Additional psychopathology in the child is assessed with the Child Behavior Checklist, the Teacher Report form and depending on age, the Youth Self Report.

The self-image is assessed depending on age with the Self-Perception Profile for Children/Adolescents.

The quality of life is assessed with the Child Health Questionnaire.

The previous care consumption is assessed during intake.

## **Intervention**

The intervention that is being investigated is behavioral therapy following the treatment protocol 'Speaking in school, a matter of doing' Wippo & Güldner, 2003). The intervention is investigated by the use of a randomized controlled trial. Participants will be randomized to either direct treatment or a waiting list control group.

## **Contacts**

**Public**

**Scientific**

## **Eligibility criteria**

### **Inclusion criteria**

Age between 4 and 18 years

Selective mutism as primary diagnosis

Estimated IQ of 85 and higher

## Exclusion criteria

Other primary diagnosis

Estimated IQ below 85

Child unable to understand Dutch

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2018
Enrollment:	320
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	05-10-2018
Application type:	First submission

## 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

NTR-new NL7318

NTR-old NTR7534

Other NL66350.018.18 (Medical Ethics Committee) : 2017284 (Funding Source)

## Study results