Emotion regulation in children with selective mutism: Project Omilía

Published: 25-09-2019
Last updated: 10-04-2024

Objective: Study 1: T0 case-control observational study1) Explore if the failure to speak in specific social situations is associated with social anxiety as expressed by autonomic emotional arousal.2) To assess if the failure to speak in specific...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON52684

Source
ToetsingOnline

Brief title
Project Omilía

Condition

- Anxiety disorders and symptoms

Synonym
Elective mutisme (ICD-10), Selective mutisme (DSM-5)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Stichting PDBO-Randstad (Postmasteropleiding Orthopedagoog-Generalist)

Intervention

Keyword: Anxiety, Cognitive control, Selective mutism, Social attention bias

Outcome measures

Primary outcome

Endpoints:

• (Social) Anxiety as expressed in heart-rate and skin conductance measures (% change in beats per minute (HR), heart rate variability (HRV), pre-ejection period (PEP), Respiratory sinus arrhythmia (RSA) and skin conductance level)

• Social information processing, as expressed in the duration and fixation towards social stimuli measured with eyetracking.

• Level of stress as expressed in HPA-axis responsivity (baseline cortisol level (saliva), cortisol reactivity levels (saliva), chronical cortisol levels (hair)

• Performance on (neuro)psychological test scores (accuracy, reaction times)

• Behavioural reports using questionnaires in Qualtrics (sumscores)

• Behaviour observations (video recorded) (sumscores)

Secondary outcome

Differences in the variables between groups (listed below) may either cause or mask differences on variables of interest and therefore need to be controlled for.

Child*s background information:

• Age

• Gender

• Immigrant status

• Multilingualism

• Confirming clinical diagnoses using a structured parental interview i.e.,

Subscale selective mutism of ADIS (dichotome score)

Parents background information:

• Level of anxiety and stress parents

• Socioeconomic status (SES)

Study description

Background summary

Selective mutism (SM) is a relatively rare, psychiatric condition typically occurring during childhood. It is characterized by a persistent absence of speech in specific public situations in which the child is expected to speak (e.g., school, social situations), whereas in other situations (e.g., at home), speech production is unaffected (American Psychiatric Association, 2013). The latest edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) conceptualizes SM as an anxiety disorder. However, aetiology of SM is still poorly understood, since controlled studies with sufficient power are scarce.
To date, SM is broadly understood as multifactorial, i.e., as caused by biological, psychological and or environmental factors. Many of the causal factors have also been implicated in the origins of other anxiety pathologies (e.g., Peter Muris, 2010), which strengthens the conceptualization of SM as an anxiety disorder but weakens our understanding of disorder-specific factors in this unique population. The most plausible mechanisms underlying the persistent failure to speak are avoidance of difficulties experienced as a consequence of (neuro)developmental problems e.g., social, communication difficulties, and/or avoidance of negative consequences of speaking e.g., feedback, social anxiety (P. Muris & Ollendick, 2015). We believe the way forward to improve etiological insights is to study SM from an emotion dysregulation- and neurodevelopmental

perspective. With this proposal we will address key gaps in the aetiology of SM regarding A) mechanisms underlying neurodevelopmental difficulties, using cognitive building blocks from the SOCIAL model by Beauchamp and Anderson (2010) and B) emotional arousal and distress (neurobiological functioning) underlying the failure to speak in children suffering from SM, using psychophysiological assessment methods. Finally, we follow-up on symptoms over time and explore if changes in symptoms are associated with / or can be predicted by cognitive and / or neurobiological functioning. Study results are expected to be of value in designing improved therapeutic interventions for children with SM. In addition, the insights obtained within this study will help to inform parents, teachers and clinicians.

Study objective

Objective:

Study 1: T0 case-control observational study
1) Explore if the failure to speak in specific social situations is associated with social anxiety as expressed by autonomic emotional arousal.
2) To assess if the failure to speak in specific social situations is correlated with cognitive control and receptive language skills in children suffering from selective mutism.
3) To explore if the failure to speak in specific social situations can be predicted by social information processing biases in children with selective mutism.

Study 2: T1 longitudinal study
7) To investigate whether reduction of symptoms over time is associated with a change in social anxiety as expressed by autonomic emotional arousal.
8) To assess if specific markers of autonomic arousal predict symptom outcomes at one year follow-up in children suffering from selective mutism.
9) To assess if reduction of symptoms over time can be predicted by cognitive control, and/or language and are associated with changes in social information processing in children with selective mutism.

Study design

This is a longitudinal study, including case-control observations.
Study 1: T0 case-control observational study
We aim to compare emotion regulation, as well as cognitive and affective mechanisms that are assumed to underlie the failure to speak in social situations in children with SM to and non-anxious (NON-ANX) controls.
Study 2: T1 longitudinal study
We aim to investigate if symptom reduction over time effects arousal or can be

predicted by cognitive and affective functioning in children with SM as compared to typical development in the non-anxious control group (pre-post-test design).

Study burden and risks

This is a outreaching study having the advantage of a minimal burden to participants (e.g., no traveling or babysitter required) and maximum study performance in familiar environment (e.g., less distress). Because we aim to identify how functioning, arousal, stressresponsivness, cognition and social information processing of children with SM differs from children with other anxiety disorders, it is necessary to to include a comparison group of children with an anxiety disorder other than selective mutism, matched on age. A typically developing, niet angstige group of children is needed in order to quantify to what degree children with SM differ from typically developing (non-anxious) children.

There are no risks involved. The burden includes time investment, with respectively 2 x 100 minutes105 minutes per assessment. Time investment for parents ranges between 85 to 135 minutes, and consists of a short interview and filling out questionnaires. Child assessments include behavior observations, neuropsychological tests, eye-tracking, and arousal measures (heart-rate, RSA and PEP), incl. HPA-axis responsivity (cortisol). All selected measures are developed for young children and administered by an experimenter trained in assessments with young children. The duration of the study is different for the different research groups. All two groups will participate in the first two assessments at T0, . A second assessment is scheduled for the SM group, in order to measure changes in functioning, arousal, stressresponsivness, cognition and social information processing over time within the SM group compared to typical development. Children do not directly benefit from participation but will receive a small present at the end of each assessment. All parents are offered a short report with individual results of their child. This report is based on the normed instruments that have been developed for clinical purposes.

In short, we are convinced that the investment that we ask from the children and their parents is well balanced. We believe that the time and effort we ask from children and parents outweight the potential insights that the research can yield. We expect that all children in the clinical groups will receive clinical treatment and this is no limitation to study participation.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:All children:
Both parents signed informed consent
Adequate command of the Dutch language
Age between 4,0 and 8,11 years Selective mutism group:
Diagnosis selective mutism
Confirmed diagnosis based on the Selective Mutism Questionnaire (SMQ; Bergman, Keller, Piacentini, & Bergman, 2008; Letamendi et al., 2008) and the Anxiety Disorders Interview Schedule (ADIS-IV; Silverman & Albano, 1996).

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:All children:
History of brain trauma or neurological illness
Hearing problemsSelective mutism group:

Mutism as a result of other pathology, for example, severe speech, language, or attachment disorder or trauma.Typically developing children:
Concern about psychopathology reported by parents on the Strengths and Difficulties Questionnaire (SDQ; Goodman, 1997).

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:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-09-2021
Enrollment:	88
Type:	Actual

Ethics review

Approved WMO Date:	25-09-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-06-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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	NL69902.058.19