Itch, Concentration, and Sensory Sensitivity in Children with Atopic Dermatitis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON53313

Source
ToetsingOnline

Brief title
Itch and concentration

Condition

- Epidermal and dermal conditions

Synonym
Atopic dermatitis, eczema

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atopic dermatitis, Attention, Itch, Sensory processing

Outcome measures

Primary outcome

The primary outcome is sustained attention measured with the Amsterdamse Neuropsychologische Taken (ANT) Sustained Attention Dots subtest.

Secondary outcome

Secondary outcomes are observations of task-oriented behavior and itch-related behavior (e.g. scratching), tests of interoceptive accuracy, interoceptive awareness, cutaneous sensibility, and thermal (cold and warm) and vibration detection thresholds, questionnaires on sensory processing modulation, emotional and behavioral problems, quality of life, and itch, and physician reported AD severity.

Study description

Background summary

Atopic dermatitis (AD) is a common inflammatory skin disorder that affects up to 20% of children in high-income countries. AD has many know psychological comorbidities including depression, anxiety, attention-deficit/hyperactivity disorder (ADHD), and autism spectrum disorders (ASD). Furthermore, children report that due to AD flares, their concentration at school is affected 7-10% of the time. The relation between AD and ADHD and ASD, in which concentration may play a role, is poorly understood
There is much debate whether ADHD and ASD can be regarded as distinct disorders since evidence accumulates that there is a shared etiology, biology, and phenotype for both conditions. Both conditions are characterized by interrelated problems with sensory processing, sleep, attention, and interoception. A similar pattern of problems emerges in children with AD, although literature is sparse. Investigation of the interrelation among attention, sensory processing, interoception and sensibility in children with

AD may shed light on the mechanisms behind the prevalence of ADHD and ASD in this group of children. Furthermore, we focus on the relation between AD severity and attention, as this hinders children in their school performance and may therefor impede future perspectives. A better understanding of sensory and interoceptive abilities could also directly benefit clinical practice, as adequate AD treatment is dependent on patient* own assessment of symptom severity which seems impaired in some patients.

Study objective

Our primary objective is to assess the relation between itch and sustained attention in 7-11 year old children with atopic dermatitis (AD). Secondary objectives are to assess the relation between itch and task-oriented behavior, to assess whether itch-related behavior (e.g. scratching) differs between task-oriented and task-free situations, and to explore levels of interoceptive accuracy, interoceptive awareness, cutaneous sensibility, thermal (cold and warm) and vibration detection thresholds, and sensory processing modulation and whether these are related to AD severity and emotional and behavioral problems in children with AD.

Study design

A cross-sectional, observational design. Children will have one visit to the outpatient clinic of the Erasmus MC.

Study burden and risks

The study consists of 1 visit to the outpatient dermatology clinic of Erasmus MC. Children will participate in 2 neuropsychological tests, 2 interoception tests, and 4 quantitative sensory test. During the neuropsychological tests children*s task-oriented and scratching behavior is video-recorded and whilst the child is in the waiting room a video-recording of scratching behavior is made. In addition, they will complete 3 numeric rating scales and 1 questionnaire. Children will participate in a standard dermatological assessment (5 minutes). Parents will complete 7 questionnaires, of which 4 have 10 questions or less. The neuropsychological and quantitative sensory testing are used in neuropsychological and neurological regular care. The interception tests are especially developed for young children. These tests take time, but usually children enjoy these test and the attention from the investigator. Without motivation from the child the test results are less reliable, therefore the test are made as pleasant as possible. Questionnaires for the children themselves and the dermatological assessment are limited in time as much as possible, to minimalize burden. Parents are asked to complete questionnaires about their child*s functioning, which costs time but the questionnaires do not contain confronting topics. There are no risks related to participating in this study.

Participating children and parents will not benefit directly from this study, although the results of the sustained attention test and dermatological assessment will be discussed with child and parents. In general, children with AD will eventually benefit from this study as results may shed light on the relation between itch and concentration, which could aid children in their school performance. Furthermore, it may also help to unravel why certain children with AD find it difficult to assess their eczema severity, which is necessary for adequate treatment. As a more distant outcome, results may help unravel the mechanism behind the high prevalence of ADHD and autism among children with AD.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Children aged 7 to 11 years, with atopic dermatitis (AD diagnosed according

to the UK working party criteria)
- Child and parent(s)/legal guardian(s) having sufficient comprehension of the Dutch language to understand study materials
- Children and parents/guardians able to participate in the study and willing to give
written informed consent

Exclusion criteria

- Children under the age of 7 or above the age of 11 years
- Children with large burn scars or other large scars
- Children with chicken-pox or other infections that cause skin itch or pain
- Children with itch without visible dermatological abnormalities (pruritus sine materia, e.g.renal failure (acute, chronic), hyperthyroidism, Hodgkin disease)
- Children with genetic syndromes known to affect cognitive performance
- Children with an IQ estimated <55 (moderate to severe intellectual disability)
- Prematurity <37 weeks of gestation
- Low birth weight (<2.5 SD for gestational age)
- Application of ointments including topical corticosteroids at the day of the assessments
- Children who have used sedating antihistamines within 5 times the half-life of the specific drug
- Children who use methylphenidate or other medication that could affect neuropsychological functioning within 5 times the half-life of the specific drug

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-03-2023

Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-04-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-02-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL83551.078.22