Social Cognition in Disruptive behavior and Aggression

Published: 28-01-2021 Last updated: 24-08-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON49770

Source ToetsingOnline

Brief title SCODA

Condition

- Other condition
- Cognitive and attention disorders and disturbances

Synonym

conduct disorder, oppositional defiant disorder

Health condition

disruptief gedrag en agressie

Research involving

Human

Sponsors and support

Primary sponsor: Accare Source(s) of monetary or material Support: Accare

Intervention

Keyword: aggression, disruptive behavior, EEG, social cognition

Outcome measures

Primary outcome

Behavioral: Empathy (score on EMQUE-CA questionnaire) Cognitive: Working memory (SWM accuracy) QEEG: resting state frontal alpha asymmetry ERPS: N170 during the emotion recognition task

Secondary outcome

Behavioral: Questionnaires on temperamental factors, emotional regulation, social reward, normative beliefs about aggression, environmental sensitivity, autism traits, sensory processing, strengths and difficulties Cognitive: Accuracy and reaction times on tasks measuring reaction time, visual matching, sustained attention, number of stages completed on the planning task, and accuracy and reaction times on the EEG tasks measuring emotion recognition, emotional interference, social approach/avoidance and theory of mind QEEG: resting state frontal theta activity and theta/beta ratio

ERPS: N170 and LPP during emotional interference, social approach-avoidance and theory of mind

Study description

Background summary

Antisocial, rule-breaking, and/or disruptive and aggressive behaviors are among the most frequent reasons for referral to child and adolescent mental health services and associated with poor long-term outcomes (such as antisocial personality disorder, criminality, employment or health problems). A major hurdle for finding effective approaches to diagnosis, prevention, and treatment is the heterogeneity of these behaviors. Social cognition is crucial to appropriate interpersonal functioning and may therefore provide valuable information about the processes involved in behavior problems as well as possible targets for intervention. However, currently, impairments in social cognition across the heterogeneous population of youth with clinically significant behavioral problems have not been fully elucidated, illustrating the need for studies incorporating multiple aspects of social cognition, on the behavioral, neuropsychological, and neurophysiological level, in a diverse population of youth with behavioral problems.

Study objective

The objective of this study is to elucidate unique and shared impairments across a broad range of social cognition tasks (at the behavioral, neuropsychological, and neurophysiological level by means of EEG recordings) related to subdimensions of behavior in youth with behavioral problems as compared to healthy controls, to improve the subtyping of these behaviors and possibly identify targets for intervention.

Study design

The current study will employ an observational case-control design. This allows for examining associations of neurophysiological and behavioral responses with behaviors of interest, as well as deviations from neurotypical functioning.

Study burden and risks

The burden of this study entails one research visit of about 5 hours with a total time investment about 6 hours for the participating adolescent and about 2 hours for one of the parents. During the visit, a clinical interview will be conducted with the adolescent and their parent(s) separately (each 1 hour). The participant will complete a neuropsychological test battery and IQ screening taking around 60 min. In addition, an EEG recording will be done (approximately 25 min preparation and 83 min of recording, and around 10-15 min for breaks in between the tasks), where we will record resting state activity and task-related activity during which the participant has to complete additional

neuropsychological tasks. The parent(s) will be able to complete all questionnaires (approximately 45 min) at home and/or during the research visit, whereas the participant is asked to fill out the questionnaires (approximately 45 min) at home, prior to the research visit. The risks of participating in this study are negligible and the possible physical and psychological discomfort mild. The inclusion of minors with behavioral problems is needed to elucidate underlying mechanisms of social impairment related to behavioral problems that may emerge or may be strongest during adolescence, a period with a marked importance of social interactions with the peer group, to identify possible treatment targets and develop strategies to prevent long-term negative outcomes.

Contacts

Public Accare

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years) Adolescents (16-17 years)

Inclusion criteria

- Aged 12-17 at inclusion
- Ability to comprehend and speak Dutch
- Deemed reliable and compliant with the study protocol
- Be right-handed

Those with behavioral problems must also meet the additional criteria:

• Presence of clinically significant behavioral problems as defined by T > 63 on the externalizing subscale of the Child Behavior Checklist (CBCL) or the Youth Self-Report (YSR). The externalizing dimension of the CBCL includes the rule-breaking behavior and aggressive behavior syndrome subscales (not ADHD). To ensure we also include youth with more severe behavioral (rule-breaking) problems, we aim to have at least 50% of participants with clinically significant behavioral problems scoring T > 70 on the rule-breaking subscale of the CBCL and/or YSR.

• At least 2 weeks of stable treatment /medication

Exclusion criteria

• Intellectual disability (IQ < 70) based on available IQ measure or the clinical opinion of the

investigator (taking into account relevant psychosocial information,

e.g. educational level)

- History of or current head injury
- History of neurological disorders
- A known lifetime history of epilepsy
- A known lifetime history of psychotic and bipolar disorder, or severe current mental state according to the impression of the researcher (such as depression)

Potential healthy control subjects who meet any of the following additional criteria will be excluded from participation in this study if they have:

- A parent or self-reported diagnosis of a psychiatric disorder
- T-scores in the borderline or clinical range on the externalizing (T \geq = 60), rule-breaking (T \geq = 65) or aggressive behavior (T \geq = 65) subscales of the CBCL or YSR.
- No stable use of psychotropic medication in the past four weeks

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

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-09-2021
Enrollment:	105
Туре:	Actual

Ethics review

Approved WMO	
Date:	28-01-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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

ССМО

ID NL74687.042.20