Neurobiology and Treatment of Adolescent Female Conduct Disorder: The Central Role of Emotion Processing.

Published: 25-08-2014
Last updated: 20-04-2024

The aim of the study is to investigate the neurobiology of Conduct Disorder (CD) in female and male children and adolescents, and examine for sex differences in the phenotype (clinical presentation) of CD, and the relationships between CD and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Observational invasive

Summary

ID

NL-OMON44782

Source
ToetsingOnline

Brief title
FemNAT-CD

Condition

- Personality disorders and disturbances in behaviour

Synonym
antisocial behaviour, behavioural problems

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: FP 7

Intervention

Keyword: Autonomic nervous system, Conduct Disorder, Female, Neurobiology

Outcome measures

Primary outcome

• Autonomic Nervous System activity: heart rate, heart rate variability, respiratory sinus arrhythmia, pre-ejection period, and skin conductance level in rest and during reactivity to emotionally arousing stimuli

• Neuroendocrinology: basal levels of cortisol, testosterone, dehydroepiandrosterone sulfate (DHEA-S), alpha-amylase, progesterone, estradiol, oxytocin, and Vasopressin (AVP). And reactivity to a social stressor of cortisol and testosterone.

Secondary outcome

• Psychiatric disorders

• Psychopathic traits

• Intelligence

• Reactive and proactive aggression

• Parenting behavior

• Emotion Regulation

• Empathy

• Pubertal development

• Callous-Unemotional traits

• Socio-demographic factors

• Medication and drug use

• Brain structure and functioning

Study description

Background summary

Antisocial behaviour is a major public health problem. Children and adolescents with persistent and severe antisocial behaviour, which in psychiatry is referred to as Conduct Disorder, have a poor prognosis with negative adult outcomes that frequently include criminality, alcohol and substance abuse, unemployment, and poor mental and physical health. The number of females exhibiting serious aggressive behaviours has increased over the last tow decades. The majority of studies examining the etiology and neurobiology of Conduct Disorder, have focused on male subject only. This means that we know far less about the development, risk factors and treatment of Conduct Disorder in females.

Study objective

The aim of the study is to investigate the neurobiology of Conduct Disorder (CD) in female and male children and adolescents, and examine for sex differences in the phenotype (clinical presentation) of CD, and the relationships between CD and changes in brain structure and function, stress and sex hormone concentrations, neuropsychological performance, psychophysiological activity, and molecular genetic and epigenetic markers. A broad age range is used to study these factors from pre- to postpuberty and study it's association with persistence and desistance.

Study design

This study comprises a cross sectional study, a longitudinal study and an RCT, executed in eight different European countries. We aim to study 1840 male and female adolescents in total.
Questionnaires, a semi-structured interview, neuropsychological tasks, psychophysiological and neuroendocrinological measurements, and a brain imaging protocol will be applied to study:
- The neurobiological correlates of female CD, instrumental/proactive aggression and reactive aggression
- Neurobiological measures as predictors of persistence versus remission from CD
- The effects of puberty on these measures in females and the impact of early versus on-time or late puberty on these measures in relation to CD, emotion processing, reactive- and proactive aggression.

Intervention

To date, treatment programs are not widely implemented and evaluated in middle childhood and adolescence, although adolescence is one of the key periods for intervening, most notably in CD girls due to their late onset. To date, there is an internationally recognized lack of randomised controlled trials (RCTs) demonstrating efficacy of new and promising interventions in female adolescents with CD. Thus, there is a strong need for RCTs investigating innovative intervention approaches for CD, especially in female adolescents.
The implementation of a dialectical-behavioural treatment program for female adolescents with conduct disorder (DBT-CD-A, publication name: START NOW) profoundly gives consideration to the repeatedly formulated necessity to develop integrative intervention approaches deriving from sound theoretical rationales, addressing core deficits of CD patients and applying gender specific strategies and materials (see State-of the Science Statements of the National Institutes of Health, NIH, 2004).
The planned RCT will for the first time systematically investigate the efficacy of a group-based DBT approach aiming at enhancing emotion regulation and emotion recognition in female CD patients. Within the Netherlands 30 CD-girls within the age range 13-18 years old, will participate in the RCT.

START NOW consists of 12 weekly group and individual sessions. Each session focuses on a specific topic and specific skills are taught during each session. START NOW is provided by two specifically trained social workers. Once every two weeks supervision is provided for these trainers. To improve their trainers skills and to ensure treatment adherence.

Study burden and risks

There are no risks associated with participation in this study. Several questionnaires and an interview might, in very few cases, cause discomfort. However, a researcher will always be present and will be focused on establishing a confidential and pleasant ambiance for the participant, and will take away any feelings of discomfort when present.
F.i.; during one of the tasks the participant will be exposed to a loud noise. The participant will be warned that she will hear the loud noise for 1 second. The noise might be unpleasant, but will absolutely do no harm to the participant or his/her hearing.
For another task the participant will watch two short film clips in which a sad situation is displayed. The movies are suitable for children from the age of 6 years old. After the film clips have been displayed the researcher will come up to the participant to ask how she feels and to chat a little to bring the participant into an emotional neutral state.

Several participants will be asked to perform a speech and a mental arrythmic task. These tasks might cause stress. After completing the tasks the researches

will provide positive feedback only, so the participant will feel comfortable and appreciated.

The MRI scannen for the brain imaging protocol might cause claustrophobic experiences to the participant. The participant is constantly monitored by the researchers and can contact the research anymoment. If the participant shows any sign of discomfort the brain imaging protocol will be stopped and the participant will be taken out of the scanner. Before we start the neuroimaging protocol we will check for claustrophobic experiences and each participant will do a test-session is a dummy-scanner.

Contacts

Public
Vrije Universiteit Medisch Centrum

Rijksstraatweg 145
Duivendrecht 1115 AP
NL
Scientific
Vrije Universiteit Medisch Centrum

Rijksstraatweg 145
Duivendrecht 1115 AP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Age: 9-18 years old
- normal or corrected to normal vision and hearing
- good level of Dutch reading and listening
- Diagnostic criteria for CASES:
current diagnosis of Conduct Disorder (CD) OR diagnosis of CD in the past, while currently 'only' two symptoms of Oppositional Defiant Disorder (ODD) are present in combination with one CD symptom.
OR:
- 9-12 year olds: Diagnosis of ODD + (at least) one symptom of CD
- 13-18 year olds: Diagnosis of ODD + (at least) two symptoms of CD;- Diagnostic criteria for controls: no current psychiatric disorder and no history of ADHD, ODD, CD

Exclusion criteria

- formal clinical diagnosis of an autism spectrum disorder or a neurodevelopmental syndrome
- IQ < 70
- Inability to speak or understand Dutch
- being pregnant or having recently given birth (within the last 6 months)
- severe head injury with prolonged loss of consciousness (> 1 hour) or confirmed traumatic brain injury
- severe epilepsy
- exclusion criterion for the control group: any Axis I disorder, or diagnosis of CD, ODD, ADHD in the past

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-08-2014
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	25-08-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-08-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-05-2018
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	NL47345.029.14