

Measuring Integrated Novel Dimensions in Neurodevelopmental and Stress-related Mental Disorders

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To gain a better understanding on common and diverse mechanisms of stress-related and developmental disorders at different genetic, cognitive, behavioral and neurobiological levels in an ultimate attempt to redefine psychiatric symptomatology by...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON50325

Source

ToetsingOnline

Brief title

MIND-Set

Condition

- Psychiatric disorders NEC

Synonym

Psychiatric diseases, Psychiatric disorders

Research involving

Human

Sponsors and support

Primary sponsor: Psychiatrie

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Behavior, Neurodevelopmental disorders, Neuroplasticity, Stress-related mental disorders

Outcome measures

Primary outcome

Socio-demographics

Descriptive psychopathology, somatic status and treatment history

Biological measures, such as cortisol levels

Neuropsychology

Genetics

Gut microbiome

Neuroimaging

Secondary outcome

na

Study description

Background summary

To integrate preclinical and clinical methodologies to assess and validate the relevance of common epigenetic mechanisms, stressregulators and their markers on neuroplasticity, neural functional connectivity and behavior in patients affected by stress-related and neurodevelopmental mental disorders.

Study objective

To gain a better understanding on common and diverse mechanisms of stress-related and developmental disorders at different genetic, cognitive, behavioral and neurobiological levels in an ultimate attempt to redefine psychiatric symptomatology by these means.

Study design

Observational cross-sectional study. We include four follow-up measure (online) during the Covid-19 crisis to assess resilience and symptom developmen.

Study burden and risks

In this observational study, we ask participants to fill out questionnaires, undergo neuropsychological tests, collect a faeces sample en undergo a functional MRI scan. These methods can be regarded as safe and are frequently used in scientific research.

The effects of the stress induction for the MRI scan are temporary.

Contacts

Public

Selecteer

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Scientific

Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients:

- Adult (age >17) in- and outpatients at the Department of Psychiatry of the Radboudumc
 - with a neurodevelopmental disorder: Autism Spectrum Disorder and/ or Attention-Deficit/ Hyperactivity Disorder
 - and/ or a stress-related disorder: mood disorder, addiction disorder, mood disorders with somatic comorbidity.
- Healthy controls:
- Adult (age >17) individuals
 - without a lifetime history of psychiatric disorders.

Exclusion criteria

Patients:

- Full scale IQ estimate < 70
- Diseases of the central nervous system resulting in (permanent) sensorimotor and/or (neuro)cognitive impairments
- Current psychosis
- Inadequate command of the Dutch language
- Mentally incompetent to sign informed consent

Additional criteria for control participants:

- Neurological disorders of the central nervous system
- Fifteen or more units of alcohol per week
- Recreational drug use of once or more per week
- Benzodiazepine use of once or more per week
- Malignancies
- Rare, chronic somatic disorders, for which matching will not be possible
- First degree relatives with severe psychiatric disorders

Exclusion criteria specifically for the MRI section of the MIND-Set study:

- Metal objects in the body (excluding dental fillings)
- Jewelry or piercings that cannot be removed
- Brain surgery
- Epilepsy
- Claustrophobia
- Pregnancy
- Ferromagnetic implants or pacemakers
- Inability to lie still for one hour

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-04-2016
Enrollment:	650
Type:	Actual

Ethics review

Approved WMO	
Date:	10-02-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	04-07-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	23-05-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	27-11-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date: 13-07-2020
Application type: Amendment
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL55618.091.15