Compass - Comorbidity of Major Depressive Disorder and Autism Spectrum Disorders

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The objective of this study is to assess common and variable processes related to executive functioning and affective processing bias on the behavioral, neurocognitive and neurobiological level between patients affected by autism and/or depression.

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

Summary

ID

NL-OMON43350

Source
ToetsingOnline

Brief title
Compass

Condition

- Developmental disorders NEC

Synonym
ASD, Autism

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Autism Spectrum Disorder, Comorbidity, Major Depressive Disorder

Outcome measures

Primary outcome

The main objective of this project is to increase knowledge about the specific and shared mechanisms of ASD and MDD on a behavioral, cognitive and neurobiological level.

Secondary outcome

The secondary objectives are divided for each domain that will be examined.

Neuropsychology

Our first aim is to study the nature of the alterations in executive functioning and emotional information processing across stress-related (MDD) and neurodevelopmental disorders (ASD) and in co-morbid ASD with MDD in order to better understand the underlying mechanisms of shared symptoms, like for example impaired emotion regulation, rigidity, rumination or alexithymia. A better recognition of these underlying mechanisms may help to tailor our future treatments to individual patients.

Our second aim is to understand the relationship between these cognitive mechanisms and prognosis of patients in sense of general functioning and level of participation.

A third aim is to examine neural markers as underlying mechanisms of

alterations in executive functioning, emotional information processing and shared symptoms.

Neuroimaging

We will examine brain activity using functional magnetic resonance imaging (fMRI). In the current protocol a reward- and punishment-based reversal learning task (Cools, Altamirano & D*Esposito, 2006) will be done. In this task the participants have to learn new rules using feed-back with changing contingencies (reward and punishment). As the rules change, the participants have to mentally switch between goals and change their response, therefore it is possible to examine cognitive flexibility. Furthermore, since participants have to learn new rules from both positive and negative feedback, it is possible to examine an affective processing bias.

On the behavioral level we can measure accuracy and reaction time. Furthermore, we will examine if activity differences correlate with other measures, such as the outcomes of the questionnaires or neuropsychological

Study description

Background summary

Co-morbidity of autism and depression has a high occurence, however, despite this high prevalence and the high impact of both disorders on the life of the patients, not much research into the co-morbidity of these disorders has been done. Patients with autism or depression show behavioral deficits in overlapping domains, such as executive functioning and affective processing. We therefore want to examine the differences and commonalities in underlying mechanisms of the different disorders. Characterizing these mechanisms will advance our understanding of these disorders and may open up new treatment

possibilities.

Study objective

The objective of this study is to assess common and variable processes related to executive functioning and affective processing bias on the behavioral, neurocognitive and neurobiological level between patients affected by autism and/or depression.

Study design

The study design is an observational cross-sectional study.

Study burden and risks

All patients that will be included in this study also participate in the MIND-Set study (CMO: NL 55618.091.015). Part of the measures from this study are used for clinical practice. No intervention is done. In comparison to the MIND-Set study, we will add a 45 minute neuroimaging task which will be incorporated in the neuroimaging assessment of the MIND-Set study. Since participants already go into the MRI scanner, the additional burden of this extra task for the Compass study is minimal. The control participants will undergo the same procedure as the patients. The burden will therefore be approximately the same for both the patient and the control groups.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria patients:
- ASD diagnosis based on the current Dutch guidelines
- MDD diagnosis based on DSM-IV criteria using the Structured Clinical Interview for DSM Disorders I (SCID-I).
- Age 18-65
- IQ>70;Inclusion criteria healthy controls:
- Age 18-65
- No history of psychiatric disorders

Exclusion criteria

Exclusion criteria patients:
- Sensorimotor handicaps
- Impaired vision or color blindness
- Inadequate command of the Dutch language
- Mentally incompetent to sign informed consent;Exclusion criteria all:
- Exclusion criteria specifically for the MRI section:
o Metal objects in the body (excluding dental fillings)
o Jewelry or piercings than cannot be removed
o Brain surgery
o Epilepsy
o Claustrophobia
o Pregnancy
o Ferromagnetic implants or pacemakers
o Inability to lie still for one hour

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-09-2016
Enrollment:	192
Type:	Actual

Ethics review

Approved WMO Date:	21-07-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-06-2017
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	NL57242.091.16