Anhedonia and reward processing deficits in schizophrenia and major depressive disorder

Published: 11-07-2019
Last updated: 09-04-2024

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

Summary

ID

NL-OMON48457

Source
ToetsingOnline

Brief title
Reward-processing deficits (RTOC)

Condition

- Psychiatric disorders NEC

Synonym
depression, psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Bedrijf: P1vital Products Ltd.,P1vital Products Ltd.

Intervention

Keyword: depression, negative symptoms, reward processing, schizophrenia

Outcome measures

Primary outcome

We will use one main outcome measure per task as a formal primary endpoint. As a primary study endpoint for the Grip Strength task we will compare the percentage of hard task choices at different reward levels in the Grip Strength Task, which will be compared at a group level between MDD vs. matched healthy controls, SZ vs. matched healthy controls, and MDD vs SZ. For the Reinforcement Learning/Working Memory task, we will compare the number of optimal choices per set size condition (2-5) between these groups, and for the Doors task, percentage of trials on which a participant choose the other door after experiencing a loss (*lose-shifting*). The test-retest reliability of these outcome measures will be investigated.

Secondary outcome

- We will compare group-level (control, MDD, SZ) means and distributions (standard deviations) of our primary endpoints with previously published work.
- Per task, we will compare event-related potential (ERPs, obtained from the EEG data) between the three groups
- Relationships between primary task endpoints, EEG endpoints and symptom severity (SHAPS sum scores) will be investigated using correlational analyses
- the intraclass correlation coefficient for all outcome measures mentioned under point 1 and 2 will be investigated.

Study description

Background summary

Rationale: Deficits or abnormalities in reward processing are present in a number of psychiatric disorders. Reward processing deficits in depression are thought to be linked to the presence of anhedonia (reduced ability to experience pleasure), while in schizophrenia to negative symptoms more generally. This study will investigate group differences in reward processing and learning between individuals with schizophrenia, depression, and healthy controls.

Study objective

The overarching objective of the study is to investigate whether individuals with schizophrenia, individuals with depression and healthy controls, on a group level, differ in performance on three previously-validated experimental computer tasks. All tasks measures aspects of reward learning and/or processing. We will also investigate how the severity of negative symptoms correlates with task performance. We will also investigate the test-retest reliability of our outcome measures.

Study design

Study design: MDD and SZ participants, as well as healthy control volunteers matched to the patient groups, will attend at least one study visit, comprising inclusion/exclusion screening, questionnaires and clinical assessment, and completion of three reward processing tasks, two of which are administered with simultaneous collection of EEG data. A subsample will complete the same study visit a second time, with the aim of assessing the test-retest reliability of the outcome measures.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: As a non-interventional study in which all participants complete a single study visit of maximum 5.5 hours, with non-invasive EEG measurements, risks are negligible and participant burden is minimal. A subsample of participants will undergo the same session a second time (for test-retest purposes). For some of the instruments the test-retest reliability has never been assessed. Recruitment of patient groups (MDD and SZ) is necessary for this study because we wish to specifically improve understanding of group differences between these two clinical 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

All groups:
- male/female
- age 20-55
- be able to read, write, and speak the language in which psychometric tests are provided

Schizophrenia group
- Primary diagnosis of schizophrenia (according to DSM-V)

Depression group
- Primary diagnosis of major depressive disorder (according to DSM-V)

Exclusion criteria

All groups:
- history of substance abuse (DSM-V)
- history of neurological disorder (Parkinson's, epilepsy, Alzheimer's)
- diagnosis of mental retardationTwo patient groups:
- Bipolar disorder (DSM-V)
- Obsessive-Compulsive disorder (DSM-V)
- Eating disorder (DSM-V)
- Attention-deficit hyperactivity disorder (DSM-V)
- Received treatment with clozapine in the last 6 months before screening.
- Experienced an acute exacerbation requiring hospitalization within the last 3 months.
- major changes to medication (~30% dose change) in the 4 weeks prior to participation

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:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2019
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	11-07-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-12-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-02-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL69565.068.19