Interactions of Aggression, Mentalizing, Metacognition and Empathy in a forensic population of persons with a psychotic disorder

Published: 10-09-2014
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P.11: This study seeks to contribute to our understanding of factors which contribute to violence in persons diagnosed with psychotic disorders, in order to improve clinical risk assessment and guide treatment choices.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41307

Source
ToetsingOnline

Brief title
I-AM-ME

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychosis, psychotic disorders

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen

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

Intervention

Keyword: Aggression, Empathy, Metacognition, Schizophrenia

Outcome measures

Primary outcome

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Metacognition / Mentalizing: Metacognition Assessment Scale - A

Theory of Mind: Faux Pas Test

Empathy: Empathic Accuracy Test, Interpersonal Reactivity Index

Aggression: Life History of Aggession (LHA), Impulsive / Premeditated Violence

Scale, Reactive-Proactive Questionnaire

Covariates: Affect Grid, HKT-30, Psychopathy Checklist - Revised, Positive and

Negative Symptom Scale, verkorte Temperament and Character Inventory, Trauma

Checklist, Threat-Control-Override Questionnaire

Neurocognition: Trailmaking Test A&B, Digit-Symbol Substitution

Secondary outcome

-

Study description

Background summary

PP6-10: Constructs such as 'Metacognition', 'Theory of Mind, 'Empathy' and 'Mentalizing' are often implicated as contributors to the risk of violence in persons diagnosed with a psychotisc disorder. Using several interviews, questionnaires, psychological tests and a computer task these domains will be measured in persons with a psychotic disorder that are currently in treatment at a forensic clinic. This data will be compared with the existing baseline

data of persons with a psychotic disorder (between-group) that have not been convicted of a felony, and correlations within the sample will be analysed (within-group). This way we hope to contribute to our understanding of these factors, construct a model of the most significant risk factors so as to contribute to future risk assessment, and to use these new insights to guide future treatment choices.

Study objective

P.11: This study seeks to contribute to our understanding of factors which contribute to violence in persons diagnosed with psychotic disorders, in order to improve clinical risk assessment and guide treatment choices.

Study design

Case-control study

Study burden and risks

Participants will be invited for an intake, during which the MINI-PLUS interview is conducted in order to verify their diagnosis. This is estimated to take 30 minutes.

A test battery will be delivered with an estimated time of 2 hours and 22 minutes. As the time such a battery requires is very dependent on the participant (neurocognitive deficit, reading speed, familiarity with computers) breaks can be scheduled upon request of the participant, or when deemed necessary by the research assistant based on their observations of the participant's well-being. Additionally, the test battery may be spread out over multiple sittings.

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

Primary diagnosis of schizophrenia or schizoaffective disorder (DSM-IV-TR)
Age >18
Ability to give informed consent
Currently in care at a forensic clinic
No change in medication in the past 30 days

Exclusion criteria

Co-morbid neurological disorder
Inability to read / write
IQ lower than 70

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	10-09-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-12-2015
Application type:	Amendment
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	ID
CCMO	NL47493.042.13