Stress reactivity in psychosis: the association between traumatic events, genetic vulnerability and psychotic reactivity to stress

Published: 14-09-2011
Last updated: 29-04-2024

The aim of this study is the investigate genetic and environmental factors which make a person vulnerable to develop a pychosis and (in patients) affect the progression of a psychosis. A second objective is to investigate the effects of genetic and...

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

Summary

ID

NL-OMON39714

Source
ToetsingOnline

Brief title
STRIP2

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychosis, schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

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

Intervention

Keyword: daily life, gene-environment, psychosis, stress

Outcome measures

Primary outcome

Psychotic experiences as measured in daily life (PsyMate)

Stress as measured in daily life (PsyMate)

Secondary outcome

Cortisol niveaus as measured in daily life (saliva samples)

The amount of experienced traumatic events as measured by questionnaires and

interviews

Genetic risk for psychosis (DNA)

Study description

Background summary

Daily life events can be experienced as stressful and subsequently induce subtle fluctuations in psychotic experiences, in both patients diagnosed with a psychotic disorder and healthy individuals. These psychotic experiences, induced by daily life stress, also have their effect on the human body; the production of stress-hormones such as cortisol increases during these psychotic experiences. Previous work has demonstrated that certain environmental factors as well as genetic vulnerability to develop a psychosis are associated with the amount of psychotic experienced induced by daily life stress. In this study, it will be investigated for the first time how one particular environmental factor which seems to be particularly involved in psychosis, namely the experience of traumatic events, in combination with a genetic vulnerability are associated with each other and affect the fluctuation of psychotic experiences induced by daily life stress. Furthermore, it will be investigated how this environmental factor, in combination with a genetic vulnerability, affect the production of cortisol throughout the day

Study objective

The aim of this study is the investigate genetic and environmental factors which make a person vulnerable to develop a pychosis and (in patients) affect the progression of a psychosis. A second objective is to investigate the effects of genetic and environmental factors on the human body, in the form of cortisol.
As psychotic experiences of both patients and non-patients fluctuate in the course of the day, the amount of psychotic experiences will be measured multiple times per day, as will cortisol.

Study design

This is an observational study, consisting of three meetings and a PsyMate week. During the first meeting, the participants will be extensively informed about the study. After the participant has had time to consider taking part in the study and has decided to take part in the study, a second meeting will be planned. During this second meeting, the participant will sign the informed consent form. Next, he/she will receive instructions to operate the PsyMate. Additionally, a number of questionnaires and short interviews will be completed. After the second meeting, a week of PsyMate measurements follows. During this week, the participants will carry the PsyMate, a small device, with them for 6 days. During these 6 days, on random moments will emit a signal. When the participants hears this signal, he/she will in fill a short questionnaire (approx. 3 minutes) en will produce a saliva sample (to assess cortisol). When the participants wakes up in the morning and before going to sleep in the evening, the participant will fill in an addtional very brief questionnaire (< 1 minute). After these 6 days a third meeting will be planned. In this meeting, the participant will be asked how he/she experienced last week. The PsyMate and saliva samples will be collected. Furthermore, remaining questionnaires and interviews will be completely. Lastly, the participants will give a saliva sample for DNA. At the end of this meeting the participants will receive a reimbursement for participating in the study

Study burden and risks

Participation in this study will take approximately 6 hours, for which participants will be reimbursed accordingly. As none of the questionnaires, interviewsa and PsyMate questionnaire create any risk, participation is virtually free of any risks. There was no risk in participating in previous daily life studies (identical to this study).

Contacts

Public
Universiteit Maastricht

Vijverdalseweg 1 Vijverdalseweg 1
Maastricht 6200MD
NL
Scientific
Universiteit Maastricht

Vijverdalseweg 1 Vijverdalseweg 1
Maastricht 6200MD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) aged between 18-60
2) sufficient command of the Dutch language
3) no intellectual impairment (IQ>80)
4) Additional inclusion criteria for the 22q11DS group:
A confirmed deletion at chromosome 22q11

Exclusion criteria

1) Current use of psychotropic medication (non-patients only)
2) Current cannabis dependence
3) Current alcohol dependence

5) Severe endocrine, cardiovascular or brain disease

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-10-2011
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	14-09-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	18-12-2014
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC 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	NL37272.068.11