Brave New Worlds: Virtual Reality Experiments Linking Psychosis and Social Environment

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

Summary

ID

NL-OMON39078

Source
ToetsingOnline

Brief title
Virtual Reality and psychosis

Condition

- Schizophrenia and other psychotic disorders

Synonym
Paranoia, Psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: environment, psychosis, social context, Virtual Reality

Outcome measures

Primary outcome

Degree of paranoia / physiological arousal / social anxiety in response to

virtual social environments.

Secondary outcome

n/a

Study description

Background summary

Epidemiological studies, my own included, have conclusively shown high rates of psychotic disorders in densely populated urban environments and among ethnic minorities, likely reflecting the causal influence of environmental exposures. The common denominator underlying these environmental risks may be repeated experience of social adversity, leading to sensitization in individuals with prior psychosis liability and culminating in progressively greater expression of psychotic responses to cumulative social adversity over time. To date, these hypotheses remain essentially untested, as it is difficult to accurately measure the social environment, and individuals* psychological and physiological responses to it. Recently, however, Virtual Reality (VR) techniques have been developed, that provide the opportunity for controlled experimental exposure to different social environments.

Study objective

In this project, I wish to take a novel step in understanding the influence of environmental exposures in the aetiology of psychotic disorders, by studying occurrence of (minor) psychotic symptoms and the (correlates of) physiological indicators of stress following controlled exposure to virtual social risk environments.

Key objectives are to investigate:

A. how exposure to the following virtual environments is associated with

development
of physiological stress, paranoid ideations and other (minor) psychotic symptoms:
1. High population density, 2. Low ethnic density, and 3. Social defeat
B. if the stress / psychotic response is greater in those with:
1. Higher degree of liability to psychosis, 2. Greater cumulative lifetime experience of
social adversity, 3. Cognitive biases
C. if the stress / psychotic response is associated with (expression of) gene variants that have previously been related to psychosis

Study design

Four groups of individuals (N=50 in each group), with different levels of liability to psychosis, will be exposed to virtual social risk environments that have been (hypothesized to be) associated with increased risk for psychotic disorders in earlier studies, i.e. high population density, low ethnic density and social defeat. In three experiments with a cross-over design, I will investigate how exposure to these environments is associated with development of (minor) psychotic symptoms and physiological stress, and whether these responses increase with higher level of prior psychosis liability, higher level of (sensitizing) cumulative lifetime social adversity, and (expression of) genes that have been related to psychosis in previous research.

Study burden and risks

The study concerns one visit to the research centre.

Burden:
- Completing questionnaires
- Three virtual experiments, total time 45 minutes
- Blood draw, twice, in total 40 ml

Risks:
- Emotional burden of completing questionnaires
- Nausea or dizziness as a result of virtual environment
- Potential complications blood draw

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

Four groups with different liability to psychosis will be exposed to VR environments:
1) high liability:
first episode psychosis patients [recruited from Parnassia Group, GGZ Delfland and GGZ Noord-Holland Noord], including DSM IV categories schizophrenia, schizophreniform disorder, schizoaffective disorder, mood disorder with psychotic features, brief psychotic disorder, delusional disorder and psychotic disorder nos.
2) intermediate liability:
individuals with either 2a. psychometrically defined risk [at risk mental state for psychosis, assessed at and recruited from Parnassia Group's Early Detection and Intervention Teams], or 2b. with familial risk: siblings from patients with psychotic disorder [Parnassia Group, GGZ Delfland and GGZ Noord-Holland Noord]
3) low liability:
healthy controls without family history of psychotic disorders [volunteers].

Exclusion criteria

1) IQ lower than 85

2) history of seizures / epilepsy
3) severe cognitive impairment

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2013
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	19-02-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	03-07-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL37356.058.12