

European Network of National Schizophrenia Networks Studying Gene-Environment Interactions (EU-GEI).

;Workpackage 2: Functional Enviromics

Published: 03-03-2010

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Objective: (1) to develop and apply methods for the detailed assessment of candidate environmental exposures, at both individual and area levels, by using an optimum, family-based, case-control design, in a diverse range of settings across Europe. (...)

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

Summary

ID

NL-OMON32490

Source

ToetsingOnline

Brief title

Functional Enviromics

Condition

- Schizophrenia and other psychotic disorders

Synonym

psychotic disorders, schizophrenia

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: environment, gene, interaction, schizophrenia

Outcome measures

Primary outcome

Detailed assessment of candidate environmental exposures, at both individual and area levels, by using a case-control design, in a diverse range of settings across Europe

Secondary outcome

n.a.

Study description

Background summary

Interactions will be investigated between environmental risk factors based on recent literature with genetic risk, to more clearly elucidate the pathogenic processes underpinning the observed high rates of schizophrenia spectrum disorders in urban areas (Krabbendam & van Os, 2005) and migrant and ethnic minority groups (Fearon & Morgan, 2007; Cantor-Graae & Selten, 2005). In doing so, we will collect information on potential mediating psychological and emotional processes (i.e. core negative beliefs, anxiety, and depression).

Study objective

Objective:

- (1) to develop and apply methods for the detailed assessment of candidate environmental exposures, at both individual and area levels, by using an optimum, family-based, case-control design, in a diverse range of settings across Europe.
- (2) To investigate the impact of hypothesised environmental exposures, measured at individual and area levels on: a) risk of schizophrenia spectrum disorders; and b) high rates of disorder in urban centres and in migrant and ethnic minority groups.
- (3) To examine evidence for a) hypothesized gene x environment interactions

(GXE); and b) hypothesized environment x environment interactions (ExE) across the life course.

(4) To develop a translational risk assessment chart indexing environmental load.

Study design

A European incidence and case-control study of schizophrenia spectrum disorders.

Study burden and risks

Patients will be assessed with an approximately three-hours lasting (neuro-) psychological testbattery. In addition, 12 ml blood will be drawn for DNA purposes. Neither risks nor direct benefits are attached to this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Cases:

1. age 16-64
2. Resident within a clearly defined catchment (study) area for a period of at least 6 months
3. First in life contact with physician for suspected psychotic disorder (ICD-10: F20-29; F30-33 [psychosis codings]) during the study period(1th may 2010 to 30st April 2013);Siblings:

1. Age 16 or over
2. Full or half-sibling;Controls:

1. Age 16-64
2. Resident within a clearly defined catchment (study) area for a period of at least 6 months
3. No evidence of current or past treatment with antipsychotic medication

Exclusion criteria

Cases:

1. Age under 16 or over 64
2. Resident within a clearly defined catchment (study) area for a period of less than 6 months
3. Treatment with anti-psychotic medication for an episode of psychosis outside of the study period
4. Evidence of psychotic symptoms precipitated by an organic cause
5. Transient psychotic symptoms resulting from acute intoxication as defined by ICD-10
6. Illegal migrant (i.e., no legal right to remain in country)
7. Incompetence. If incompetence is caused by psychosis we will approach the patient for informed consent as soon as the treatment for psychosis has made him competent (according to the responsible physician);Siblings:

1. Age under 16
2. Current or past psychotic disorder (including diagnosis within the time frame of the study)
3. Current or past treatment with antipsychotic medication;Controls:
1. Age under 16 or over 64
2. Resident within a clearly defined catchment (study) area for a period of less than 6 months
3. Current or past psychotic disorder (or treatment within antipsychotic) (including diagnosis or treatment within time frame of the study)
4. Illegal migrant (i.e., no legal right to remain in country)

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-05-2010

Enrollment: 625

Type: Anticipated

Ethics review

Approved WMO

Application type: First submission

Review commission: METC Amsterdam UMC

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

CCMO

ID

NL30078.018.09