

Mapping individual routes of risk and resilience

Published: 30-07-2015

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The aim of this project is to determine the value of a dynamic network approach to predict illness course and outcome of early psychotic symptoms.

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

Summary

ID

NL-OMON47218

Source

ToetsingOnline

Brief title

MIRORR study: Mapping individual routes of risk and resilience

Condition

- Schizophrenia and other psychotic disorders

Synonym

Psychosis proneness

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: NWO;veni beurs nr: 016.156.019

Intervention

Keyword: clinical staging, psychopathology, psychosis, symptom networks

Outcome measures

Primary outcome

Network parameters of individuals in different clinical stages will be compared. These network parameters include the strength and directionality of symptom connections and centrality indices. Also, within-individual changes in these network parameters (from baseline to follow-up) will be linked to progression through clinical stages.

Secondary outcome

Please, see "primary study parameters" for the most important primary and secondary study parameters.

Study description

Background summary

Psychotic disorders are among the most severe mental disorders in terms of individual and societal impact. Our current ability to predict the course and outcome of early psychotic symptoms is limited; this hampers timely intervention and treatment. Research in this area to date relies heavily on diagnostic categories, group-level comparisons and assessment of static symptom levels. However, symptoms may wax, wane or change individually and regularly cross diagnostic borders. To improve our understanding of the development of psychosis, we propose to re-conceptualize psychopathology as a dynamic system of fluctuating symptoms that impact on each other, over time and across diagnostic boundaries, forming symptom networks. These networks can then be used to predict progression through subsequent stages of clinical severity. We hypothesize that 1) distinct symptom network characteristics will be differentially associated with need for care and illness course, and that 2) dynamic networks based on multiple symptom domains will predict psychopathological development better than commonly used predictors that are based on cross-sectional levels of early psychotic expressions.

Study objective

The aim of this project is to determine the value of a dynamic network approach to predict illness course and outcome of early psychotic symptoms.

Study design

At baseline and optionally at 1-year follow-up, participants will report their day-to-day symptoms, affective states and (stressful) experiences for three consecutive months. Symptomatology, functioning and need for care will be assessed every year by means of questionnaires and interviews.

Study burden and risks

There are no risks involved in participating in the study. The burden associated with participation consists of: an interview before (2 hours) and after (1 hour) the ambulatory assessment period, filling in a diary using a mobile application every evening for three months at baseline (5-15 minutes per day), and three follow up assessments (1 hour per assessment). Participants are given the option to repeat the ambulatory assessments in year 2, which has a similar burden to the first. Benefits are an increased insight in one's own daily mood states and symptoms, and person-specific factors that may promote the reduction of these symptoms.

Contacts

Public

Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Scientific

Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

All participants:

- Are aged between 18 and 35 years
- Read and speak Dutch fluently
- Should be capable of following the research procedures
- Provide Informed Consent;Participants subsample 1:
 - Are currently (i.e. at moment of screening) not in clinical care for mental health (e.g. GGZ, POH-GGZ, Psychologist);Participants subsample 2:
- Are currently in clinical care for mental health
- Have mild, non-psychotic psychopathology, as evidenced by a score below 6 on the Prodromal Questionnaire (PQ) ;Participants subsample 3:
- Are currently in clinical care for mental health
- Have mild psychopathology including subclinical psychotic symptoms, as evidenced by a score of or above 6 on the PQ, but are not at UHR for psychosis, as indexed by the Comprehensive Assessment of At Risk Mental State (CAARMS) ;Participants subsample 4:
- Are currently in clinical care for mental health
- Are at clinical high risk for psychosis, as indexed by the CAARMS

Exclusion criteria

- History of or current psychotic episode, according to the DSM-IV criteria
- Pregnancy
- Significant hearing or visual problems impairments
- No internet connection at home or on mobile phone or tablet

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-12-2015

Enrollment: 175

Type: Actual

Ethics review

Approved WMO

Date: 30-07-2015

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 23-03-2016

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 23-09-2016

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 16-05-2018

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 07-08-2019

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

ID: 25975
Source: NTR
Title:

In other registers

| Register | ID |
|----------|----------------|
| CCMO | NL52974.042.15 |
| OMON | NL-OMON25975 |