Mapping individual routes of risk and resilience

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25975

Source
NTR

Brief title
MIRORR

Health condition

Psychosis, Psychotic development, Psychopathology
Psychose, Psychose ontwikkeling, Psychopathologie

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: NWO, VENI nr: 016.156.019

Intervention

Outcome measures

Primary outcome

Network parameters will be compared (1) for individuals in different clinical stages, (2) for individuals with different progression through clinical stages (i.e. who worsen or improve) and (3) within each individual when both diary assessments are completed. These parameters include the strength and directionality of symptom connections (see Figure 3) and centrality

indices (information about the position of a symptom in the network). The symptoms that make up these networks are monitored from day to day by means of an electronic diary. They cover a broad range of feelings and experiences that are characteristic for (subclinical) psychotic experiences, depression, anxiety, mania, obsessive compulsive behaviour and anger. These disorders are known for the co-occurrence of psychotic symptoms and comorbidity.

Secondary outcome

Important outcomes that are linked to the above described network characteristics are (progression through) clinical stages, functioning and need for care. Progression through clinical stages will be assessed with the PQ16, the CAPE and the CAARMS, the Symptom Check List-90 and the mini-SCAN. Social functioning will be assessed using the Groningse Vragenlijst voor Sociaal Gedrag (GVSG-45) and the Flourishing Scale. Need for care will be assessed using self-reported information on care use. Additionally, need for care will be assessed by linking data from the psychiatric case registry to our sample when approved by the participant (as stated on the informed consent form). Specifically, the frequency and type of care use throughout the study period will be obtained.

Study description

Background summary

Rationale: 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, change individually or 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.

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 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.

Study population: The total sample comprises of 175 individuals between 18-35 years of age. After screening and a first selection, 100 participants enter the main study. These individuals are divided over four subgroups (4x n=25), representing successive stages of clinical progression (i.e. with increasing psychopathological severity). Individuals in subgroup 1 will be recruited from the general population. First, 100 participants will be recruited, whereof the quartile with the highest levels of subclinical psychotic experiences will be included in the main study (n=25). Individuals in subgroups 2-4 will be recruited from various mental health care institutions in the North of the Netherlands in the context of an ongoing Early Detection of Psychosis program and will directly be included in the main study (3x n=25).

Main study parameters/endpoints: 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.

Study objective

1) Distinct symptom network characteristics will be differentially associated with need for care and illness course.

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 design

Idiographic (within-person) and nomothetic (between-person) observational study designs will be combined. The nomothetic aspect of the study is captured by questionnaire and interview data; the idiographic aspect is captured by diary assessment.

During baseline (at start and finish of the diary period), as well as during three follow-up assessments (at one, two and three years after baseline), we will assess symptomatology, functioning and need for care by means of questionnaires. Data on coping, social support,

bonding, objectively measured physical activity (protective factors), trauma, social cognition and stressful life events (risk factors) will also be collected at these assessments to investigate the role of stress-related risk and resilience factors in symptom networks.

At baseline, participants will have an intensive 3-month period of daily ambulatory assessment of symptoms, functioning and stress (T=90). These diary data are used to map symptom networks. Participants will record data using an “app” on their smartphone/tablet at fixed times in their natural environment. Items will be presented in a semi-random order. At 1-year follow-up, participants are invited to participate in a second 3-month period of ambulatory assessments, similar to the assessments at baseline. Participants can also opt to keep continuing the questionnaire follow-ups, also if they do not wish to have a second diary period.

Intervention

Not applicable

Contacts

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Eligibility criteria

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

Subsample 1:

- Are currently (i.e. at moment of screening) not in clinical care for mental health (e.g. GGZ, POH-GGZ, Psychologist)

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)

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 Ultra high risk (UHR) for psychosis, as indexed by the Comprehensive Assessment of At Risk Mental State (CAARMS)

Subsample 4:

- Are currently in clinical care for mental health

- Are at UHR for psychosis, as indexed by the CAARMS

Exclusion criteria

All participants:

- History of or current psychotic episode, according to the DSM-IV criteria

- Significant hearing or visual problems impairments

- Pregnancy, as stated on a general health questionnaire

- No internet connection at home or on mobile phone or tablet

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2015
Enrollment:	175
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	27-10-2016

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47218
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6058
NTR-old	NTR6205
CCMO	NL52974.042.15
OMON	NL-OMON47218

Study results

Summary results
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