# Translating neuroimaging findings from research into clinical practice (PSYSCAN): Clinical High Risk

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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-OMON47887

**Source**
ToetsingOnline

**Brief title**
PSYSCAN - UHR

### Condition

- Schizophrenia and other psychotic disorders

**Synonym**
high risk of psychosis, schizophrenia

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Institute of Psychiatry, King's College, London
**Source(s) of monetary or material Support:** Europese Commissie

## Intervention

**Keyword:** high risk of psychosis, illness course, outcome, prediction

## Outcome measures

### Primary outcome

Psychopathology will repeatedly be examined using semi-structured interviews and questionnaires including the Comprehensive Assessment of At-Risk Mental States (CAARMS), Hamilton Depression Rating Scale (HAM-D), Young Mania Rating Scale (YMRS). Psychosocial function is assessed with the Global Assessment of Functioning scale (GAF). The PANSS will also be used to assess illness severity and symptomatic remission. Brain structure and function are measured in two Magnetic Resonance Imaging (MRI) sessions, consisting of structural MRI, resting state functional MRI and Diffusion Tensor Imaging (DTI). Cognition will be assessed using a computerised battery of neuropsychological tests that capture key deficits associated with psychosis, such as attention, memory, emotion recognition and executive function. Blood samples will be drawn to assess levels of genetic, proteomic, metabolomic and immune parameters. One hair sample will be taken for keratinocyte biomarker analyses. EEG measurements will be done, but this is optional for the participant.

### Secondary outcome

Other study parameters include sociodemographics, medical history, physical health, current medication use, recent psychiatric history, psychiatric disorders in first-degree relatives, hospitalisations, and use of drugs of abuse. Handedness (Edinburgh Handedness Inventory), childhood maltreatment (Childhood Trauma Questionnaire) and resilience (Resilience Scale for Adults)

will be assessed with self-report questionnaires. Premorbid function is determined using the Premorbid Adjustment Scale (PAS), health and social needs are assessed with the Camberwell Assessment of Need Short Appraisal Schedule (CANSAS-P) and IQ is assessed using the Wechsler's Adult Intelligence Scale (WAIS).

Current and past episodes of psychopathology will be determined using the Structured Clinical Interview for DSM Disorders (SCID).

# Study description

### Background summary

Psychotic disorders are relatively common and severely disabling, although illness onset, course and outcome vary greatly among patients. Not all people with a high risk of developing psychosis will develop the disease. In addition, following a first episode of acute psychosis, some patients make a good recovery, whereas others have series of relapses and remissions, or have an unremitting course of the illness. To date, however, we are not able to reliably predict onset, course and outcome of psychosis at an individual level. As such, there is a pressing need to assist clinical decision-making by developing objective methods to predict psychotic episodes and outcomes in order to tailor psychiatric care to the needs of each patient * i.e. to provide personalised care. Through the current study, we aim to predict illness course and outcome in patients with a very high risk of developing psychosis on the basis of measures of psychopathology, brain structure and function, cognition, and biological markers in blood. These data will be used to develop and validate a quantitative and objective tool that will enable healthcare professionals to tailor psychiatric care to the particular needs of each patient.

### Study objective

Primary objective of the current study is to develop and validate a prediction tool focusing on illness onset, course and outcome at an individual level in individuals at high risk for developing psychosis. This will be achieved by combining the predictive values of measures of psychopathology, clinical characteristics, brain structure and function, cognition, psychosocial

functioning and biological markers in blood.

### Study design

An international, multicentre, naturalistic follow-up study.

### Study burden and risks

This study includes seven visits (see for details Table 1 of the protocol). Visit 1 consists of collection of demographic and medical information, assessment of IQ, handedness, childhood trauma, resilience and premorbid function, and administration of a diagnostic interview. In addition, baseline examination of psychopathology, psychosocial functioning, health and social needs, drug use, and cognition is performed, and subjects will undergo a baseline MRI session of at maximum sixty minutes. A blood sample is drawn to assess genetic, proteomic, metabolomic and immune parameters. An EEG will be made, but this is optional for the participant. Both MRI and blood sampling are safe procedures, and standard procedures will be followed to minimise any risks. Participants will be asked to come back after 3 months (visit 2), 6 months (visit 3), 12 months (visit 4), 18 months (visit 5) and 24 months (visit 6). The visits at 6 and 12 months (visit 3 and 4) will involve the same assessments, EEG sampling, MRI scanning, and blood sample as visit 1, but without some of the initial questions about things like age and medical history and hair sampling. Assessments at 3,18 and 24 months (visit 2, 5 and 6) will involve only questionnaires about recent experiences and things like medication. The assessments of each visit can be completed in multiple days.

Individuals younger than eighteen years of age (*16) can be included in this study, as the risk of developing psychosis typically emerges in adolescence or young adulthood. Potential individual benefits are those associated with the close monitoring and extensive examination of participants. Since the current study entails a naturalistic design, and assessments (with the exception of drawing blood) are essentially non-invasive, associated risks are deemed negligible. Although there are a substantial number of assessments, it is allowed to complete assessments of each visit in multiple days and participants will be offered frequent breaks. Hence, the burden associated with participation is deemed minimal.

## 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

* 16-40 years old
* Written informed consent of subjects aged 18 to 40 years
* Written informed consent of parents and/or legal guardians for subjects aged 16 or 17, in
addition to assent from the minor subject, following local laws and regulations
Participants at high risk of psychosis will be evaluated using a quantitative clinical tool that
assesses:
* Inclusion into one of three groups as assessed by the Comprehensive Assessment of At-Risk Mental States (CAARMS version 2006):
i) vulnerability group,
ii) attenuated psychosis group,
iii) brief intermittent psychosis symptoms group.

## Exclusion criteria

* Any previous neurosurgery or neurological disorder, including epilepsy
* History of head injury resulting in unconsciousness lasting at least 1 hour
* Pregnancy
* Any contraindications for MRI
* Refusing to have blood drawn and/or MRI performed
* Subject is unable to fully comprehend the purpose of the study or make a rational
decision whether or not to participate
* Estimate of IQ < 70
* Antipsychotic medication for > 30 days (cumulative number of days) in the 3 months
before the baseline assessments (including self-ratings and screening assessments), at
doses that would be adequate for treating a first episode of psychosis (i.e. excludes very
low doses)
* Any past episode of frank psychosis lasting > 7 days

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-02-2017 |
| Enrollment: | 74 |
| Type: | Actual |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 16-03-2016 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 16-09-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 31-05-2017 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 10-08-2017 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 08-11-2017 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 01-02-2018 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 22-08-2018 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 12-12-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |

# 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 | NL55065.041.15 |