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# The prevention of psychosis in at risk mental state

| Submission date | Recruitment status |
|---|---|
| 04/04/2008 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 11/07/2008 | Completed |
| **Last Edited** | **Condition category** |
| 21/03/2016 | Mental and Behavioural Disorders |

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
ZonMW 120510001; NTR1085

## Study information

**Scientific Title**
Prevention of psychosis with a cognitive behavioural intervention in help-seeking young people with an at risk mental state for developing psychosis

**Acronym**

EDIE.NL (Early Detection Intervention Evaluation Netherlands)

## Study objectives
A cognitive behavioural therapy (CBT) intervention will reduce the transition rate into psychosis.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Centrale Commissie Mensgebonden Onderzoek (CCMO) Central Committee for Research Involving Human Subjects, 29/08/2007, CCMO nr NL17123.097.07

## Primary study design
Interventional

## Study design
Randomised controlled trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Psychosis

## Interventions
In both arms treatment as usual will be provided for the complaints that made the person seek help. In the experimental arm there will be a 25-session (over six months) add-on with a CBT therapist aimed at normalising psychotic-like experiences, becoming aware of and changing risky thinking styles such as jumping to conclusions, confirmatory bias, selective attention, covariation bias, emotional reasoning, etc.

Treatment duration is six months, patients will be followed-up for 18 months.

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome(s)
Rate of transitions into psychosis, diagnoses will be made using Schedules for Clinical Assessment in Neuropsychiatry (SCAN) 2.1 interview.

Measurement moments for primary and secondary measures are at 0, 6, 12, and 18 months. A check on the increase or decrease of psychotic-like experiences are additionally assessed in a short session at months 2, 4, 9, and 15.

## Key secondary outcome(s)
1. Depression (Beck Depression Inventory [BDI])
2. Social anxiety (Social Interaction Anxiety Scale [SIAS])
3. European quality of life (EQ5D) health questionnaire

Measurement moments for primary and secondary measures are at 0, 6, 12, and 18 months.

### Completion date
01/12/2011

## Eligibility

### Key inclusion criteria
1. Aged 14 to 35 years, either sex
2. Fullfilling At Risk Mental State criteria of the Comprehensive Assessment of At Risk Mental State, criteria of July 2007

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Current or previous receipt of antipsychotic medication
2. Moderate to severe learning disability
3. Organic impairment
4. Non-Dutch speaking

### Date of first enrolment
01/12/2007

### Date of final enrolment
01/12/2011

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**Oude Haagweg 357**
Den Haag
Netherlands
2552 ES

# Sponsor information

### Organisation
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

### ROR
https://ror.org/01yaj9a77

# Funder(s)

### Funder type
Research organisation

### Funder Name
ZonMw (ref: ZonMW 120510001)

### Alternative Name(s)
Netherlands Organisation for Health Research and Development

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Other non-profit organizations

### Location
Netherlands

# Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/11/2012 | | Yes | No |
| Results article | results | 01/09/2016 | | Yes | No |
| Protocol article | protocol | 22/03/2010 | | Yes | No |