

The prevention of psychosis in at risk mental state

Submission date 04/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/07/2008	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 21/03/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Study design

Randomised controlled trial

Primary study design

Interventional

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

