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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/12/2007

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

Age group
Adult

Sex
Both

Target number of participants
240

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)

Sponsor details
Laan van Nieuw Oost Indië 334
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Sponsor type
Research organisation

Website
http://www.zonmw.nl

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	22/03/2010		Yes	No
Results article	results	01/11/2012		Yes	No
Results article	results	01/09/2016		Yes	No