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# Prodromal symptoms and early intervention to prevent a relapse

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 27/01/2006 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 27/01/2006 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 18/08/2009 | Mental and Behavioural Disorders | [ ] Record updated in last year |

**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**
N/A

# Study information

## Scientific Title

## Study objectives
Could early treatment of prodromal symptoms prevent or postpone a psychotic relapse in schizophrenia?

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Received from local medical ethics committee

## Study design
Multicentre randomised single blind active controlled parallel group trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied
Schizophrenia, Schizophreniform disorder

## Interventions
The Symptom Management Module (SMM), one of the independent living skills modules developed by the Los Angeles rehabilitation research group, is a psychosocial intervention to improve the capability of patients with schizophrenia to detect early warning signs (EWS) of a psychosis and to teach the patients to manage them.
Two treatment conditions (symptom management module [N = 46] versus self monitoring [N = 52]) and a comparison group (treatment as usual [N = 49]) in patients with schizophrenia or related psychotic disorders.

## Intervention Type
Other

## Phase
Not Specified

### Primary outcome measure
Occurrence of a psychotic relapse: a worsening of at least two points on the CGI as assessed by psychiatrist and verified by researcher by a PANSS-interview within a week.

### Secondary outcome measures
1. Hospitalisation
2. Psychopathology

### Overall study start date
01/01/1997

### Completion date
01/01/2002

## Eligibility

### Key inclusion criteria
1. ICD-10 diagnosis of schizophrenia (F20) or schizoaffective disorder (F25)
2. A remitted state established by no more than one score of 4 on the positive scale of the PANSS
3. Necessary skills in Dutch language to undergo a training in Dutch

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
147

### Key exclusion criteria
Substance abuse

### Date of first enrolment
01/01/1997

### Date of final enrolment
01/01/2002

## Locations

### Countries of recruitment
Netherlands

### Study participating centre

**Department of Psychotic Disorders**
Assen
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9400 RA

# Sponsor information

**Organisation**
Mental Health Care Services Drenthe (Netherlands)

**Sponsor details**
Department of Psychotic Disorders
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**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/0107rkg57

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
Netherlands Organisation for Health Research and Development (ZonMw)

**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

### Funder Name
Support Foundation (Stichting tot Steun) (Netherlands)

### Funder Name
Netherlands Care Cooperative (Zorgcoöperatie Nederland [formerly: De Open Ankh]) (Netherlands)

### Funder Name
The Per V. Petersen Foundation (Netherlands)

### Funder Name
National Foundation of Mental Health Care (Nationaal Fonds Geestelijke Volksgezondheid [NFGV]) (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