# Prodromal symptoms and early intervention to prevent a relapse

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

#### Contact name

Dr J. Arends

#### Contact details

Department of Psychotic Disorders Mental Health Care Services Drenthe P.O. Box 30.007 Assen Netherlands 9400 RA +31 (0)592 334883 Johan.Arends@GGZDrenthe.nl

# 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 Netherlands 9400 RA

# Sponsor information

## Organisation

Mental Health Care Services Drenthe (Netherlands)

#### Sponsor details

Department of Psychotic Disorders P.O. Box 30.007 Assen Netherlands 9400 RA

#### 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