

Prodromal symptoms and early intervention to prevent a relapse

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/08/2009	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

1. Hospitalisation
2. Psychopathology

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration