

# Prodromal symptoms and early intervention to prevent a relapse.

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

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestopt       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON20905

### Bron

NTR

### Verkorte titel

N/A

### Ondersteuning

**Primaire sponsor:** Department of Psychotic Disorders

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### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

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.

## Toelichting onderzoek

### Achtergrond van het onderzoek

This study tested the effectiveness of an intervention that trained patients with schizophrenia with the Symptom Management Module (SMM) in terms of improvement in relapse risk and psychopathology during 18 months of follow-up compared with a self-monitoring of Early Warning Signs (EWS) intervention and treatment as usual.

Both the training group as well as the self-monitoring group showed a significant less total number of relapses during the follow up period of 18 months in comparison with the treatment as usual group.

The patients in the training condition had fewer relapses, compared with the patients in the monitoring condition. The difference was nearly significant.

The results were neither influenced by age, gender, diagnosis, age of illness, number of previous relapses, number of previous hospitalisations, medication and employment status.

No difference in duration of rehospitalisation was observed between the training and the self-monitoring condition during the follow up period.

Conclusion: The study provides evidence that training with SMM and self-monitoring of EWS are effective interventions compared to standard care.

Training with SMM showed an additional relapse preventive effect compared with another rigorous intervention.

### Doel van het onderzoek

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

### Onderzoeksopzet

N/A

### Onderzoeksproduct en/of interventie

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 EWS of a psychosis and to learn the patients to manage them.

Two treatment conditions (symptom management module (N=46) vs self monitoring (N=52)) and a comparison group (treatment as usual N=49) in patients with schizophrenia or related psychotic disorders.

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 (28);
3. Necessary skills in Dutch language to undergo a training in Dutch.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Substance abuse.

## Onderzoeksopzet

### Opzet

|                  |                       |
|------------------|-----------------------|
| Type:            | Interventie onderzoek |
| Onderzoeksmodel: | Parallel              |
| Toewijzing:      | Gerandomiseerd        |
| Blindering:      | Enkelblind            |
| Controle:        | Geneesmiddel          |

### Deelname

|                         |                       |
|-------------------------|-----------------------|
| Nederland               |                       |
| Status:                 | Werving gestopt       |
| (Verwachte) startdatum: | 01-01-1997            |
| Aantal proefpersonen:   | 147                   |
| Type:                   | Werkelijke startdatum |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 13-09-2005       |
| Soort:          | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register       | ID             |
|----------------|----------------|
| NTR-new        | NL403          |
| NTR-old        | NTR443         |
| Ander register | : N/A          |
| ISRCTN         | ISRCTN17350364 |

## Resultaten

### Samenvatting resultaten

Relapse Prevention in Schizophrenia: a randomised controlled trial between self-Monitoring and Training with the symptom management module, and a comparison with Treatment As Usual (submitted).