# Treatment adherence therapy in nonadherent patients with psychotic disorders; a randomised trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

# **Summary**

### ID

NL-OMON26923

**Source** Nationaal Trial Register

Brief title

#### **Health condition**

1. Schizophrenia;

2. psychosis;

(NLD: schizofrenie, psychose).

### **Sponsors and support**

**Primary sponsor:** Erasmus MC University, Rotterdam, THE NETHERLANDS **Source(s) of monetary or material Support:** ZonMw; the Netherlands organisation for health research and development

### Intervention

### **Outcome measures**

#### **Primary outcome**

Treatment adherence, as defined by no-show contacts, the degree of collaboration in managing the illness, help seeking behaviour in crisis situations, and medication compliance.

#### Secondary outcome

- 1. Symptoms;
- 2. quality of life;
- 3. insight into illness;
- 4. relapse;
- 5. and readmission.

# **Study description**

#### **Background summary**

Non-adherence to treatment of patients with psychotic disorders is related to higher rates of relapse, hospitalization, and suicide. Attempts to improve adherence have shown that psychoeducation alone is not fully effective, and that motivational interviewing, behavioral strategies, and linking a patientâ€<sup>™</sup>s personal goals to treatment may increase adherence. Based on the empirical data reviewed, we formed three clusters of possible causes of non-adherence, each of which can be targeted by a specific module of our developed Treatment Adherence Therapy (TAT). These three modules are: motivational interviewing, medication dosage trials, and behavioral training.

### Study objective

Treatment Adherence Therapy + Treatment as Usual (TAT+TAU), as compared to TAU-only, has a beneficial effect on treatment adherence, as defined by no-show contacts, the degree of collaboration in managing the illness, help seeking behaviour in crisis situations, and medication compliance.

### Study design

T0 at baseline, T1 directly after completion of the intervention, T2 at six month follow-up. Each of the outcome measures mentioned above are assessed at all three timepoints.

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#### Intervention

The Treatment Adherence Therapy (TAT) protocol is an intervention consisting of about ten sessions in which one or a combination of the three available modules get applied during about six months. Each module targets a specific cause for non-adherence in patients with schizophrenia. In the two arms of the study, TAT + Treatment as Usual (TAU) gets compared with TAU-only.

# Contacts

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# **Eligibility criteria**

### **Inclusion criteria**

- 1. A diagnosis of schizophrenia or related psychotic disorder;
- 2. non-adherence to treatment as defined by no-show contacts;
- 3. the degree of collaboration in managing the illness;
- 4. help seeking behaviour in crisis situations;
- 5. and medication compliance.

# **Exclusion criteria**

- 1. Not speaking the Dutch language;
- 2. being admitted in a hospital;
- 3. court-ordered involuntary treatment.

# Study design

# Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-05-2005
Enrollment:	120
Туре:	Anticipated

# **Ethics review**

Positive opinion	
Date:	07-12-2007
Application type:	First submission

# **Study registrations**

## Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL1124
NTR-old	NTR1159
Other	projectnumber of the financer: ZonMw : 100-002
ISRCTN	ISRCTN wordt niet meer aangevraagd

# **Study results**

#### Summary results

Staring ABP, Mulder CL, van der Gaag M, Selten JP, Loonen AJM & Hengeveld MW (2006). Understanding and improving treatment adherence in patients with psychotic disorders; a review and a proposed intervention. Current Psychiatry Reviews, 2(4), p487-494.