Improving medication adherence with Treatment Adherence Therapy.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25257

Source
NTR

Brief title
none

Health condition

Patients with schizophrenia and poor medication adherence

Sponsors and support

Primary sponsor: Arkin Amsterdam
Source(s) of monetary or material Support: Arkin, Stichting Agis

Intervention

Outcome measures

Primary outcome

The proportion of non-adherent patients based on the Brief Adherence Rating Scale (BARS).

Secondary outcome

1. (Re-)hospitalization;

2. Quality of life (MANSA);

3. Functioning (GAF);

4. Therapeutical alliance (HAQ);

5. Psychopathology (BPRS-E);

6. Insight (SAI);

7. Treatment Satisfaction Questionnaire for Medication (TSQM).

Study description

Background summary

Background:

It is well established that approximately 50% of patients with schizophrenia have poor medication adherence. In general this results in increased risk of relapse and hospitalisation, and poorer outcomes. Up to date there is no adherence intervention with sufficient evidence base for its efficacy. Adherence interventions usually target one of a variety of reasons for non-adherence. With TAT it is possible to tailor the adherence intervention to the reasons of non-adherence. A first study of the effectiveness of TAT has shown that medication adherence significantly improved (Starring et al 2010; NTR1159).

Research Question:

In this randomised controlled trial we want to examine the effectiveness of TAT on clinical outcomes in patients with schizophrenia.

Methode/design:

This is a randomised controlled trial. In total 745 outpatients with schizophrenia will be screened for medication adherence. Patients with poor medication adherence, and who give informed consent will be included. Included patients will be allocated to the control condition or the experimental condition. In the control condition, patients receive care as usual according to the principles of FACT. In the experimental condition, patients receive care as

usual and in addition will be offered TAT performed by a trained psychologist who is not the regular key worker of the patient. Measurements will be performed at baseline, and after 12 (T1), and 24 months (T2).

Sample size calculation/data analysis:

At baseline all patients will be non-adherent. A large scale study amongst 34.128 patients with schizophrenia showed that 30% of NA patients will be adherent the following year (35). This corresponds with a study based on 2% of the Dutch population which showed that 23% of NA patients (using antipsychotics) were only temporarily NA (36). In this study we expect 70% of NA patients to remain non-adherent in the control condition after 12 months. We expect this to be 50% in the experimental condition. This is considered a clinically meaningful effect of MI. To detect this difference in a 1-sided test (alpha=0.05; 1-beta=0.80) we need 150 participants in total. Analyses are according intention to treat principles.

Study objective

Compared to treatment as usual adding a tailored adherence interventions Treatment Adherence Therapy (TAT) for outpatient will schizophrenia will improve medication adherence.

Study design

Baseline measurements will be conducted after randomization and follow-up measurements will be conducted at 12, and 24 months after the baseline measurement.

Intervention

Treatment as usual:

Treatment as usual consists of regular outpatient care according to the principles of FACT.

TAT:

Treatment Adherence Therapy (TAT) has recently been developed by Prof Dr Niels Mulder en Dr Tonnie Staring (Erasmus Universiteit, Rotterdam). TAT consists of three main therapeutical modules, based on an empirical theoretical model developed by Staring (2006). Modules will be deployed based on an extensive assessment of the underlying cause of non adherence. TAT is therefore tailored to needs and situation of the patient. TAT consists of 10 individual weekly sessions and 3 monthly individual booster sessions.

Contacts

Public
Arkin Academy
Klaprozenweg 111
M.J. Kikkert
Amsterdam 1033 NN
The Netherlands
+31 (0)20 5904422
Scientific
Arkin Academy
Klaprozenweg 111
M.J. Kikkert
Amsterdam 1033 NN
The Netherlands
+31 (0)20 5904422

Eligibility criteria

Inclusion criteria

1. Diagnosis schizophrenia according to DSM-IV criteria;

2. Current prescription of an antipsychotic medication;

3. Outpatient and autonomous in collecting and using his ofr her antipsychotic medication;

4. Poor medication adherence.

Exclusion criteria

1. Unable to follow TAT treatment due to inadequate mastery of the Dutch language, or severe cognitive impairment;

2. Severe substance abuse.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2012
Enrollment:	150
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL3035
NTR-old	NTR3183

Register	ID
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A