Improving medication adherence with Treatment Adherence Therapy in patients with Schizophrenia.

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The primary objective of this study is to evaluate in a randomized controlled clinical trial the clinical effectiveness of TAT on the proportion of medication non-adherent patients over 24 months, in schizophrenia outpatients who have poor...

Ethical review	Approved WMO
Status	Pending
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON37335

Source
ToetsingOnline

Brief title
Medication adherence in patients with Schizophrenia

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychotic disorder; Schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Stichting Agis

Intervention

Keyword: antipsychotic, medication adherence, Schizophrenia, TAT, Treatment Adherence Therapy

Outcome measures

Primary outcome

Assessment of main and secondary study parameters will be conducted at baseline, 12 and 24 months after randomization. The time patients spent each assessment is approximately 55 minutes.

The primary outcome measure is the proportion of non-adherent patients based on the Brief Adherence Rating Scale (BARS). The BARS is a brief clinician-administered adherence assessment (Byerly et al, 2008). The BARS evaluates episodes of missed medication taking in the past month. The score on the BARS represents the proportion of the taken doses to the prescribed doses. Based on a cut-off score of 80% of prescribed medication, patients will be labelled adherent or non-adherent. This is the most frequent used cut-off criterion in adherence studies for patients with schizophrenia (Valenstein et al., 2002).

Secondary outcome

The following secondary outcome measures will be used to examine secondary clinical effects of TAT, moderators of effect, and costs of health care and work absence;

The following secondary outcome measures will be used to examine secondary

clinical effects of TAT, moderators of effect;

1. Re-hospitalization and drop out, based on case files

2. Quality of life, as measured with the *Manchester Short Assessment of quality of life* (MANSA),

3. Functioning, as measured with the *Global Assessment of Functioning* (GAF), and the Personal and Social Performance Scale (PSP)

4. Therapeutical alliance, as measured with the *Helping Assessment Questionnaire* (HAQ),

5. Psychopathology, as measured with the 'Brief Psychiatric Rating Scale' (BPRS-E),

6. Insight as measured with the *Birchwood Scale*,

7. Clients satisfaction with treatment and with medication as measured with the *Treatment Perceptions Questionnaire* (TPQ), the *Client Satisfaction Questionnaire* (CSQ), and the *Treatment Satisfaction Questionnaire for Medication* (TSQM),

8. Clients readiness to change as measured with the *Readiness to Change Questionnaire* (RTCQ),

9. Attitudes towards medication as measured with the *Drug Attitude Inventory* (DAI).

Study description

Background summary

It has been estimated that non-adherence rates for prescribed antipsychotic medications are about 50% (Cramer & Rosenheck, 1998; Lacro et al., 2002; Nose

et al., 2003; Valenstein et al., 2002). Relapse rates have been shown to be five times higher in people with schizophrenia who are non-adherent to medication compared with adherent people, resulting in a significant social and economic burden (Robinson et al., 1999).
To date, several interventions have been developed to enhance adherence. Each of these interventions typically target a different aspect of medication non-adherence. Some focus more on behavioural or practical aspects of medication intake, others on social, affective or cognitive areas.
Unfortunately, there is no single approach underpinned by convincing evidence that it is effective (Byerly et al., 2007; van Dulmen et al., 2007). As a result, professionals remain deprived of proper interventions, guidelines or recommendations. The Dutch Multidisciplinary Guideline for the treatment of schizophrenia (2005) notes that cognitive behavioural therapy and family interventions may be effective in improving medication adherence. However, it does not provide specific recommendations about how to cope with non-adherence.
Obviously, many patients have no problems adhering to their medication regimens, and adherence interventions are unlikely to have any effect in these cases. It would therefore be advisable to make an individual assessment of the need to take action with respect to medication adherence. Furthermore, if intervention is indicated, a careful assessment may identify the underlying cause of non-adherence. Some patients may find side effects intolerable, others lack insight, or forget to take the medication. As a result, the effectiveness of any intervention will depend on how well it fits in with patients' needs, ideas and expectations. Some strategies may not be effective for all patients, but only for a small subsample. Daily SMS reminders will for instance only be effective in patients who want to use their medication but find it difficult to do so regularly. Given this differentiation, it is unlikely that any single intervention will be effective for the vast majority of patients (Marland & Cash, 2005). A good example is a study by Hudson et al. (2008), which showed that patient-tailored strategies to address individual medication adherence barriers were more effective in improving adherence than a basic implementation strategy. This also supports the conclusion of several reviewers who found that complex combinations of strategies are most effective in improving adherence (Dolder et al., 2003; Haynes et al., 2008; McDonald et al., 2002; Roter et al., 1998).
Recently Prof. Dr. Mulder and Dr. T. Staring of the Erasmus University have developed the Treatment Adherence Therapy (TAT). TAT consists of three main therapeutical modules, based on an empirical theoretical model developed by Staring (2006). Each of these modules focus on one of three main reasons for non-adherence; a. cognitive deterioration or poor daily structure resulting in forgetting of medication mistakes, b. poor subjective medication efficacy and or adverse side effects, c. deliberate non-adherence due to denial of sickness, poor medication attitude, not aware of consequences of non-adherence (Staring et al., 2006). Modules will be deployed based on an extensive assessment of the underlying cause of non-adherence. TAT is therefore tailored to the needs and the situation of the patient. If the patient is adherent TAT will not be deployed. TAT consists of 12 individual weekly sessions and 3 monthly

individual booster sessions. A first randomized controlled trial in 109 outpatients with psychotic disorders, demonstrated that TAT added to TAU significantly improved service engagement and compliance (Staring et al., 2010). Given the huge impact of non-adherence, it is important that evidence based adherence interventions become available. The positive results with TAT are most promising. Therefore, in this study proposal, we would like to further examine the effectiveness of TAT added to treatment as usual in patients with schizophrenia.

Study objective

The primary objective of this study is to evaluate in a randomized controlled clinical trial the clinical effectiveness of TAT on the proportion of medication non-adherent patients over 24 months, in schizophrenia outpatients who have poor medication adherence, compared with treatment as usual.

Patients will be allocated at random to either TAU or TAU with added TAT. TAU consists of the regular care that patients receive at our FACT teams for severe mental illness patients. This care is provided by an experienced multidisciplinary team and typically consists of regular outpatient visits and medical treatment. The experimental TAT intervention will last 10 weekly sessions in the first three months, and 3 monthly booster sessions in the following three months. Assessment of outcome variables will be performed at baseline prior the start of the intervention, and 12 and 24 months later.

Secondary objectives of this study are:
1. The effect of added TAT on (re-)hospitalization, quality of life, functioning, therapeutical alliance, psychopathology, insight, and medication treatment satisfaction.
2. Cost effectiveness of added TAT compared with TAU.

Study design

A randomized controlled clinical trial comparing the effectiveness of added Treatment Adherence Therapy (TAT) to Treatment As Usual (TAU), versus TAU alone.

Time-schedule; recruitment: months 1-3, intervention: months 2-7, follow-up assessments: months 2-26, data-analysis/reporting: months 26-30.

Intervention

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 followed by 3 monthly individual booster sessions.

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

Study burden and risks

Benefits:
All subjects receive unrestricted TAU.
Subjects allocated to the experimental trial arm will be offered an additional intervention for which there is evidence to suggest that this will improve their medication adherence and consequently reduces risk for relapse and hospitalization.

Risks:
We see no risks associated with participating in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1). diagnosis 'schizophrenia' according DSM-IV criteria
2). current presciption for antipsychotic medication
3). expected to stay on antipsychotic medication for the next 12 months.
4). outpatient and autonomous in collecting and using antipsychotic medication
5). poor medication adherence, defined as using <80% of prescribed antipsychotic medication

Exclusion criteria

1). Unable to follow TAT 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:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2012
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO Date:	09-10-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL39974.029.12