Money for Medication: A randomized controlled study on the effectiveness of financial incentives to improve medication adherence in patients with a psychotic disorder and comorbid substance abuse.

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The primary goal of this study is to assess how M4M affects acceptance of antipsychotic depot medication, during the intervention and after terminating the intervention.

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

Summary

ID

NL-OMON34809

Source
ToetsingOnline

Brief title
Money for Medication (M4M) in patients with a dual diagnosis

Condition

- Schizophrenia and other psychotic disorders

Synonym
1. Disorder in the perception of reality, 2. Disorder with periods of hallucinations, delusions or disorganization

Research involving

Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)
Source(s) of monetary or material Support: Palier den Haag

Intervention

Keyword: Adherence, Medication, Money, Psychosis

Outcome measures

Primary outcome

The primary outcome measure of the current study is the number (percentage) of accepted depot injections. This number is defined as the *Medication Possession Ratio* (MPR) first reported by Sclar, Chin and Skaer (1991). The MPR is the number of accepted depots antipsychotic medication divided by the number of prescribed depots antipsychotic medication (the number of supplies needed for continuous use of antipsychotic medication).

Secondary outcome

Our secondary outcome measures include the longest period of uninterrupted depot acceptance, the time expired before the depot is taken, the number of admissions in psychiatric hospitals, the effort initiated by the clinicians to provide the depot, patients symptomatology, social and psychological functioning, substance abuse, subjective quality of life and subjective wellbeing under neuroleptics. We will also assess cost-effectiveness of M4M from a societal perspective. Furthermore, we will explore how medication acceptance is related to impulsivity, patients attitudes towards medication and we will explore patients and clinicians attitudes towards M4M.

Study description

Background summary

Money for Medication (M4M) is a randomized controlled study on the effectiveness of contingency management in improving adherence with antipsychotic depot medication in patients with psychotic disorders and co-morbid substance abuse. Non-adherence with antipsychotic medication is a frequently occurring problem, particularly among patients with psychotic disorders and co-morbid substance abuse (often called *dually diagnosed patients*). Non-adherence reduces the effectiveness of the treatment of a chronic psychotic disorder and interferes with therapeutic efforts. Failure to take the prescribed medication is strongly associated with a wide array of adverse consequences for both the individual and the community. As non-adherence to antipsychotic medication is one of the most preventable causes of relapse and admission, interventions that effectively improve adherence are needed.

Prior research has shown encouraging results for interventions based on *Contingency Management* (CM), where desirable behavior is encouraged by providing rewards contingent upon the behavior. However, little research has been done on the effectiveness of CM on medication adherence in patients with psychotic disorders and co-morbid substance abuse. An earlier pilot-study by our group showed promising results in reducing admission days and increasing adherence. The current study is a randomized controlled trial to assess the effectiveness of M4M in improving adherence with antipsychotic medications in dually diagnosed patients.

Patients will be randomly assigned to the experimental group (M4M, n = 84) receiving M4M plus treatment as usual (TAU), or to the control group (n = 84) receiving TAU only. The duration of the intervention is twelve months, after which a six months follow-up will take place in which the effects of discontinuing M4M on medication acceptance will be monitored.

Our primary outcome measure will be the percentage of accepted depots during and after stopping the intervention. Our secondary outcome measures include the longest period of uninterrupted depot acceptance, the time expired before the depot is taken, the number of admissions in psychiatric hospitals, patients* substance abuse, symptoms and social and psychological functioning and subjective wellbeing. We will also assess cost-effectiveness. In addition, we will explore patient*s experiences with M4M through assessing their perceived control over their health and treatment, their attitudes towards medication and M4M and their treatment. Finally we will assess the clinicians* attitude towards M4M.

Study objective

The primary goal of this study is to assess how M4M affects acceptance of antipsychotic depot medication, during the intervention and after terminating the intervention.

Study design

The current study is a randomized controlled trial. Patients will be randomly assigned to the experimental condition (M4M) or the treatment as usual (TAU) control condition. Patients assigned to the experimental condition (M4M) will receive a financial incentive for each time they accept their prescribed depot, in addition to treatment as usual.

Intervention

The proposed intervention is money for medication. Money for medication is based on Contingency Management (CM) principles. The essence of CM-based interventions is that a pre-set desirable behaviour is reinforced. In M4M, patients who accept their prescribed antipsychotic depot medication will receive a financial incentive directly upon acceptance.

Patients assigned to the intervention group (M4M) will receive treatment as usual, plus a financial incentive for each time they accept their prescribed depot of antipsychotic medication. All patients in the intervention group (M4M) will receive an average maximum of 30 euro per month. The amount of money they will receive is dependent upon the frequency of the depot. For example, a patient who receives a two-weekly depot will receive 15 euro per accepted depot. A patient who receives a three-weekly depot will receive 22.50 euro for each accepted depot etcetera. The money will be given by the clinician directly upon administration of the depot injection. Patients will sign a proof of receipt.

The intervention will take 12 months. After the intervention period, there will be a follow-up period of 6 months in which the patients receive no financial incentives for accepting their prescribed antipsychotic depot medication.

All patients will receive treatment as usual. Patients assigned to the control group will receive treatment as usual only (including the regular encouragement to take their prescribed depot medication). Treatment as usual includes case management, sometimes receiving psychosocial interventions, use of crises services, admission to hospitals and prescribing medication.

The type and dosage of the depot antipsychotic medication and other medications patients receive will be determined by the patients* clinician. The type, frequency and dosage will not be affected by participation in the study.

Administration of the depots will be done by the patients* clinicians at the regular times and locations.

Study burden and risks

Patients will receive three assessements at month 0 (baseline), 12 (end of intervention) and 18 months (follow-up). The assessments will take a maximum of 90 minutes. During the assessments, patients will also be asked to provide a urine-sample. All participants will receive 20 euro per assessment (including urine-sample).

We expect no serious harmful effects of the current intervention. However, if M4M successfully increases medication adherence, patients could experience more side effects of the prescribed medication. This will be monitored by patients clinician and by asking patients about their subjective wellbeing under neuroleptics (SWN, de Haan et al., 2002). Another potential adverse event would be that patients could spent their money on drugs and/or alcohol. We deliberately kept the amount of money restricted in considering this risk. Furthermore, we will monitor patients drug use through urine analysis and assessments (ASI, Hendriks et al., 1989). When this protocol is considered by the METiGG, we would like to attend the meeting to consider issues more in depth and to consult the members of the METiGG about how to handle these considerations best.

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. Age between 18 - 65 years
2. Psychotic disorder (including schizophrenia, schizoaffective disorder or other psychotic disorders)
3. Substance use disorder (alcohol and/or drugs)
4. An indication for antipsychotic depot medication
5. Outpatient treatment (either starting outpatient treatment or being in outpatient treatment for at least four months and having missed at least 50% (cf. Priebe, 2009) of prescribed depot medications).
6. Have given informed consent

Exclusion criteria

1. Not meeting all inclusion criteria
2. Inability to participate in this study due to cognitive impairments
3. Inability to understand the Dutch language sufficiently to participate in this study

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-07-2010
Enrollment:	168
Type:	Actual

Ethics review

Approved WMO Date:	21-05-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28385
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL31406.097.10
OMON	NL-OMON28385