Mentalization-Based Treatment for Psychosis: a randomized controlled trial for outpatients with a nonaffective psychotic disorder.

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

Summary

ID

NL-OMON44966

Source
ToetsingOnline

Brief title
MBT-P

Condition

- Schizophrenia and other psychotic disorders

Synonym
Non-affective psychotic disorders

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Rivierduinen

Intervention

Keyword: Mentalization-Based Treatment, Psychosis, Randomized Controlled Trial, Schizophrenia

Outcome measures

Primary outcome

Social functioning, the primary outcome measure, is measured with the Social Functioning Scale

Secondary outcome

-Social Cogntition (Mediator Variable): The TAT (Thematic Apperception Test), scored with the SCOR System (Social Cognition and Object Relations System), is used to assess the patients* mentalizing capacity. It assesses a patient*s emotional differentiation, the affect tone of his/her relationships, reflective functioning, capacity for reality testing, emotional investment in relationships and understanding of social causality. The hinting task is used to asses the quality of patients' Theory of Mind.

- Social stress reactivity: Using an Experience Sampling Monitoring (ESM) device called the PsyMate, we will measure changes in mood during stressful social interaction. There will be four consecutive assessments: one assessment before treatment, one assessment during treatment, one assessment directly after treatment and one assessment six months after treatment. Each assessment will last for five days. During these assessments, patients record daily social interactions and the degree of social tension in those situations. Questions pertaining to social stress include: *I would rather be alone'and 'I like the

present company'. Mood is measured with items such as: 'I feel gloomy' (negative affect) and 'I feel enthousiastic' (positive affect).

- Quality of Life: Using the MANSA, the Manchester Short Assessment of quality of life changes in overall life quality of patients are measured

- Positive, Negative, Anxious and Depressive Symptoms: anxious and depressive symptoms are assessed by independent bachelor psychology graduates that are blind to treatment allocation and measured with several items of the PANSS (Item G2 and G4; Positive and Negative Syndrome Scale7). The PANSS, is a 30-item, 7-point Likert scale rating instrument developed for the assessment of phenomena associated with schizophrenia. Symptoms over the past week are rated. A Dutch version is used.

- Substance abuse: Patients are asked to report the instances of substance (ab)use on the PsyMate during the PsyMate ESM measurement sessions.

- Awareness of having a mental disorder: measured using item G12 from the PANSS.

- Personality organization (Moderator variable): Assessment of structural personality pathology is done using the theory driven profile approach to the DSFM (Dutch short Form of the MMPI).Three levels of Personality Organization (PO) are distinguished: Neurotic PO (identity integration), Borderline PO (identity diffusion) and Psychotic PO (identity diffusion combined with impaired reality testing).

- Childhood Trauma (Moderator variable): The Childhood Experience of Care and Abuse (CECA) interview is used to measure childhood and adolescent neglect and abuse. The CECA is a semi-structured interview that aims to assess details and

the time-sequence of traumatic childhood experiences. It assesses lack of care

(neglect, antipathy), physical abuse, sexual abuse and psychological abuse,

known risk factors for psychosis.

- Somatization: somatization is measured using items pertaining to somatization

in the DSFM (Dutch short Form of the MMPI).

- Adherence to treatment is rated with the Medical Adherence Scale.

Study description

Background summary

Mentalization-Based Treatment (MBT) was initially developed by Peter Fonagy to treat borderline personality disorders (BPD). In a set of studies, Peter Fonagy and Anthony Bateman have shown that the effectiveness of MBT surpasses that of standard psychiatric care regarding the treatment of Borderline Personality Disorder. Although MBT was initially developed for the treatment of BPD , it has since branched out as a treatment for a multitude of psychological disorders. Most of these disorders, like BPD, are rooted in problematic personalities, past attachment difficulties and current *mentalization* impediments.
Mentalization - or social cognition - is the capacity to infer and understand one*s own and others* mental states. It is believed that this capacity is underdeveloped in patients with nonaffective psychotic disorders (NAPD). We therefore hold that MBT might be especially effective regarding these patients. Mentalization Based Treatment for Psychosis (MBT-P) is developed to target this impediment in social cognitive capacity. It is a psychodynamic treatment rooted in attachment and cognitive theory developed for the treatment of NAPD. MBT-P aims to strengthen patients* social cognitive capacity in order to reduce emotional reactivity in stressful social situations and improve social functioning. It is expected that this can lead to a higher quality of life and disease awareness and a reduction in substance abuse and depressive and anxious symptoms.

Study objective

The primary aim of this study is to examine whether TAU plus MBT-P has a more positive effect on social functioning than TAU only.
Secondly it will be examined whether this potential therapeutic effect is driven by an increase in social cognitive capacity and a decrease in social

stress reactivity. Secondary outcome measures are: quality of life, disease awareness, substance abuse and depressive and anxious symptoms.

Study design

The study is a partly open, partly single blind randomized controlled trial, in which TAU plus MBT-P is compared to control condition (TAU only). Patients, the clinicians and the local researcher (Jonas Weijers) know in which treatment condition the patients are. However, the researchers (the research assistent and psychology students) that perform the measurements after randomization do not know to which condition the patients are allocated.

Intervention

Mentalization Based Treatment for Psychotic Disorders (MBT-P):
MBT-P is a type of MBT that has been specifically designed for patients with non-affective psychotic disorders (NAPD), such as schizophrenia, schizophreniform or schizoaffective disorder (295.x), delusional disorder (297.1), brief psychotic disorder (298.8) or psychotic disorder not otherwise specified (298.9). MBT-P is a long-term, psychological treatment consisting of both group and individual sessions. It aims to increase the capacity of social cognition, i.e. the capacity to understand mental states of both oneself and others, in order to help individuals adapt to complex social interactions and regulate distressing affect. It helps patients develop a more coherent and reflective life narrative and interpersonal attunement. An adapted version of the treatment protocol, as developed by Bateman and Fonagy for patients with personality disorders (MBT-PD), is used for the treatment of NAPD. MBT-P is limited to the first tree steps in the MBT-PD protocol: 1) learning to become (self)conscious, 2) being reflective and 3) focusing on social interaction. MBT-P is less intensive than MBT-PD in order to regulate arousal level. Adjustments were made by adapting the treatment to the patients: this was done by changing the dosage and by offering both group and individual sessions in order to maximize compliance. Treatment goals were set realistically. Instead of curing NAPD, the treatment focuses on improving quality of life a reduction of social tension.

Study burden and risks

There are no known health risks to participation in this study. Although group therapy can have adverse effects on patients, for example caused by exlusion. Filling out questionnaires and participating in interviews does require a certain level of energy and concentration. The study requires a substantial time investment. Participating in the study itself will take a total of 22 hours in 2 years. Treatment in both conditions will last for 18 months. Some activities will have to be interrupted in order to respond to the PsyMate. Sometimes this will warrant an explanation to others nearby. Most people

however get used to this relatively quickly. Most of the measurements (about 16 hours in a total of 22 hours) will be measurements in daily life, which we assess to be an acceptable burden. Participation is voluntary and everyone can stop participation at any given moment without providing a reason. The MBT condition contains 60 hours of grouptherapy sessions (60 sessions of 60 minutes) and 15 hours of individual therapy sessions (30 sessions of 30 minutes) spread over 18 months.

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

* At least six months of prior treatment, which should include relevant psycho-education regarding nonaffective psychotic disorders (schizophrenia, schizophreniform or schizoaffective disorder (295.x), delusional disorder (297.1), brief psychotic disorder (298.8)

or psychotic disorder not otherwise specified (298.9))
* Less than ten years of prior treatment for a nonaffective psychotic disorder.
* Age 18-55
* Informed consent

Exclusion criteria

* Intellectual disabilities and/or illiteracy (having attended Dutch MLK or ZMLK education).
* A lack of mastery of the Dutch language.
* Severe addiction to such an extent that inpatient detoxification is necessary. After detoxification the patient is still eligible for participation in the study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-08-2014
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	25-06-2014
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-12-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-07-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL47236.068.13

Study results

Date completed:	01-10-2018
Actual enrolment:	90