

Mentalization Based Treatment for Psychosis

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21688

Source

NTR

Brief title

MBT-P

Health condition

Nonaffective psychotic disorders:
schizophrenia, schizophreniform or schizoaffective disorder (295.x)
delusional disorder (297.1)
brief psychotic disorder (298.8)
psychotic disorder not otherwise specified (298.9).

Sponsors and support

Primary sponsor: Maastricht University, the Netherlands

Source(s) of monetary or material Support: Rivierduinen Institute for Mental Health Care

Intervention

Outcome measures

Primary outcome

Social Functioning (Social Functioning Scale: average score), Timepoints: 0 months, 18

months, 24 months.

Secondary outcome

- Quality of Life (MANSA), Timepoints: 0 months, 18 months, 24 months.
- Psychotic Symptom Severity (PANSS / Psymate), Timepoints: 0 months, 9 months (Psymate only), 18 months, 24 months.
- Negative Affect (Psymate), Timepoints: 0 months, 9 months, 18 months, 24 months.
- Positive Affect (Psymate), Timepoints: 0 months, 9 months, 18 months, 24 months.
- Social Stress (Psymate), Timepoints: 0 months, 9 months, 18 months, 24 months.
- Social Cognition (Thematic Apperception Test), Timepoints: 0 months, 18 months, 24 months.
- Theory of Mind (Hinting Task), Timepoints: 0 months, 18 months, 24 months.
- Disease Awareness (Item G12 of the PANSS), Timepoints: 0 months, 18 months, 24 months.
- Substance abuse (Psymate), Timepoints: 0 months, 9 months, 18 months, 24 months.
- Negative symptoms (Subscale N of the PANSS), Timepoints: 0 months, 18 months, 24 months.
- Anxious symptoms (Item G2 of the PANSS), Timepoints: 0 months, 18 months, 24 months.
- Depressive symptoms (Item G4 of the PANSS), Timepoints: 0 months, 18 months, 24 months.

Study description

Background summary

Many patients with nonaffective psychotic disorders (NAPD) suffer impairments in social cognition and an emotional hyperreactivity to social stress, which often lead to decreased social functioning.

Mentalization Based Treatment for Psychosis (MBT-P) is developed to target impaired social cognition. It is a psychodynamic treatment rooted in attachment and cognitive theory developed for the treatment of NAPD. It is expected to improve social cognition and decrease social stress reactivity which in turn are expected to improve social functioning. MBT-P is

further expected to increase quality of life and disease awareness, and to reduce substance abuse, positive, anxious and depressive symptoms.

Study objective

Patients who receive treatment as usual (TAU) plus mentalization-based treatment for psychosis (MBT-P) will show a greater improvement in social functioning than patients who receive TAU only.

This effect is mediated by an increase of social cognition and a decrease of social stress reactivity.

Study design

0 months: baseline measurement

9 months: halfway treatment measurement

18 months: end of treatment measurement

24 months: follow-up measurement

Intervention

-Mentalization Based Treatment for Psychosis

-Treatment as usual for NAPD: psychiatric consults, supportive therapy, welfare aid, case management.

Contacts

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Eligibility criteria

Inclusion criteria

- Age 18-55
- Informed consent
- Diagnosis of a nonaffective psychotic disorder
- In treatment for at least a year, but no longer than 10 years

Exclusion criteria

- Intellectual disabilities and/or illiteracy.
- 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:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-08-2014
Enrollment:	90
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	19-08-2014
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	NL4588
NTR-old	NTR4747
Other	MEC AZM / MU : 13-3-066.5/ab

Study results

Summary results

none yet