

Reflex.

No registrations found.

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

Summary

ID

NL-OMON24576

Source

NTR

Brief title

N/A

Health condition

psychic disorders; schizophrenia and other psychotic disorders

Sponsors and support

Primary sponsor: University Medical Centre Groningen

Source(s) of monetary or material Support: NWO, European Science Foundation

Intervention

Outcome measures

Primary outcome

Insight is the primary outcome measure.

The following instruments will be used:

1. Beck Cognitive Insight Scale;
2. SAI-E.

Secondary outcome

Social functioning, depression, internalized stigmata, quality of life and symptoms.

1. Social Functioning Scale;
2. BDI-II;
3. Panss;
4. ISMIS;
5. SERS-SF 20.

Study description

Background summary

Many people with schizophrenia demonstrate impaired insight. It is often assumed that poor insight plays an important role in the negative prognosis of schizophrenia. Indeed, impaired insight has been linked to unfavourable outcome of the disease and poorer medication compliance. Impaired insight is therefore considered as one of the most prominent clinical symptoms of schizophrenia. There are a number of interventions to improve insight, but results of these interventions are mixed. We expect that insight in schizophrenia will increase by stimulating self-reflection. Based on a new model of insight in schizophrenia, a new intervention is developed and will be evaluated in a RCT. The primary objective is to enhance insight in individuals with psychosis. Secondary objectives are to enhance patients' quality of life and community functioning.

Design: A multi-centre randomised controlled trial, the intervention will be compared to treatment as usual.

Study population: 80 patients with psychosis and poor insight will be included and randomised over two conditions.

In the first part of the intervention stigmatizing beliefs are disputed and self-reflection is stimulated. Concurrently, SMS-messages will be sent to patients on a daily basis to stimulate self-reflection and self-monitoring. The control condition consists of care as usual and additional befriending sessions with a therapist.

The primary outcome are the changes in two insight assessment instruments. Secondary outcome are changes in structured assessment of community functioning, depression, self-esteem, quality of life, internalised stigma and symptoms.

Study objective

Can poor insight with schizophrenia be improved with a treatment aimed at selfreflection and the decrease of internalized stigma.

Study design

Start: 01-09-2009.

Intervention

Patients will have 16 group therapy sessions with a psychologist. In these sessions, stigmatizing beliefs are disputed and self-reflection is stimulated. On a daily basis SMS-messages will be sent to stimulate self-reflection. After a prompt patients are required to fill out a short form with short questions about their cognitions and emotions. Weekly group sessions will be based on the patients' responses.

Contacts

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Eligibility criteria

Inclusion criteria

1. A diagnosis of schizophrenia according to DSM-IV-TR criteria;
2. Impaired insight (based on structured assessment);

3. Willing to give written informed consent.

Exclusion criteria

1. Florid psychosis;
2. Patients falling under the BOPZ law, or who are unable to give informed consent according to the 'Wet op Geneeskundige Behandelovereenkomsten';
3. Co-morbid neurological disorder;
4. IQ below 75.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	80
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	NL691
NTR-old	NTR1799
Other	ABR : 27146
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A