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Reflex

Submission date	Recruitment status	[X] Prospectively registered
04/05/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/06/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/06/2020	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ABR 27146

Study information

Scientific Title
Reflex

Study objectives
Current information as of 10/12/09:
The preconditions of poor insight in schizophrenia, self-reflection, idiosyncratic self-certainty and stigma sensitivity, can be improved by a treatment aiming to stimulate perspective taking and to decrease of internalized stigma.

Initial information at time of registration:
Can poor insight with schizophrenia be improved with a treatment aimed at self-reflection and the decrease of internalized stigmata?

Please note that as f 10/12/09 this record has been extensively updated. All updates can be found under the relevant field with the above update date. In addition, please note that the target number of participants has been changed from 80 to 145. The anticipated start and end dates for this trial have been updated from 01/09/2009 and 01/09/2011 to 01/05/2010 and 01/10 /2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 10/12/09:
Approved by the Medical Ethical Testing Committee (METc) UMCG on 13th of October 2009

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Psychic disorders; schizophrenia and other psychotic disorders

Interventions
Current information as of 10/12/09:
Patients will have 12 one-hour group therapy sessions with a psychologist. The training consists of three modules, each module consists of four group sessions. During these sessions patients are stimulated to reflect upon their own thoughts, behavior and feelings and integrate changes that have occurred during their illness in the self-image. They are constantly encouraged to distinguishing factual information from opinions and to take the perspective of others. The active control condition consists of group wise drill and practice cognitive remediation training. The total duration of the intervention will be 12 hours.

Initial information at time of registration:
Patients will have 16 group therapy sessions with a psychologist. In these sessions, stigmatising 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.

Control condition: care as usual and additional befriending sessions with a therapist.

The total duration of interventions will be 16 hours. Follow-up assessments will take 3 x 90 minutes.

Added 03/01/2011:
Added to the trial is a fMRI/MRS evaluation for 40 of the 145 patients in the study (20 patients and 20 controls). For the 20 patients the fMRI/MRS will be added before and after the psychosocial intervention/training. Duration: 2x 1 hour.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current information as of 10/12/09:
Self-reflection, idiosyncratic self-certainty and stigma sensitivity:
1. Beck Cognitive Insight Scale (BCIS)
2. Selfreflection and Insight Scale (ZRIS)
3. Internalised Stigma: Internalized Stigma of Mental Illness Scale (ISMIS)

Initial information at time of registration
Insight, assessed by the following:
1. Beck Cognitive Insight Scale (BCIS)
2. Schedule for the Assessment of Insight - Expanded Version (SAI-E)

Key secondary outcome(s))
Current information as of 10/12/09:
Depression, symptoms, self-esteem and quality of life:
1. Insight (SAI-E)
2. Depression: Beck Depression Inventory (BDI-II)
3. Symptoms: Positive and Negative Syndrome Scale (PANSS)
4. Self-esteem
5. Quality of life: Manchester Short Assessment of Quality of Life (MANSA)

Initial information at time of registration:
Social functioning, depression, internalised stigma, quality of life and symptoms will be assessed by the following:
1. Community Functioning: Social Functioning Scale
2. Depression: Beck Depression Inventory (BDI-II)
3. Symptoms: Positive and Negative Syndrome Scale (PANSS)
4. Internalised Stigma: Internalized Stigma of Mental Illness Scale (ISMIS)

5. Self-esteem: Self-Esteem Rating Scale (SERS) SF-20 (Dutch version)
6. Quality of life: Manchester Short Assessment of Quality of Life (MANSA)

Completion date
01/10/2011

Eligibility

Key inclusion criteria
1. Both males and females, age: 18 years or older
2. A diagnosis of schizophrenia according to Diagnostic And Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) criteria
3. Impaired insight (based on structured assessment) (PI< 9)
4. Internalized stigma (ISMIS items 6+13+17+18 <6)
5. Able to give informed consent

Initial information at time of registration:
1. Both males and females, age between: 18-65
2. A diagnosis of schizophrenia according to Diagnostic And Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) criteria
3. Impaired insight (based on structured assessment)
4. Willing to give written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
121

Key exclusion criteria
Current information as of 10/12/09:
1. Florid psychosis
2. Co-morbid neurological disorder

Initial information at time of registration:
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

Date of first enrolment
01/05/2010

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Neurosciences
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Sponsor information

Organisation
University Medical Center Groningen (UMCG) (Netherlands)

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Research organisation

Funder Name
European Science Foundation/ The Netherlands Organization for Scientific Research (NWO) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2019	18/06/2020	Yes	No
Protocol article	study protocol	05/10/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes