Meta Cognitive Training in patients recovering from recent onset psychosis

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To establish the effect of an adapted form of MCT (MCT-a) on paranoid ideation and cognitive insight in patients with recent onset psychotic symptoms.

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

Summary

ID

NL-OMON39554

Source
ToetsingOnline

Brief title
Meta Cognitive Training in patients recovering from recent onset psychosis

Condition

- Schizophrenia and other psychotic disorders

Synonym
schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Metacognition, Psychosis, Randomised Controlled Trial, Training

Outcome measures

Primary outcome

The main outcome measures are

1) paranoid ideation as measured with the Green Achterdochtige Gedachten Schaal (GAGS), a validated Dutch version of the Green Paranoid Thought Scales (GPTS) (Green et al., 2008);

2) cognitive insight as measured with the Beck Cognitive Insight Scale (BCIS).

3) psychotic symptoms and general symptoms, as measured with the Positive and Negative Syndrome Scale (PANSS) (Kay, Lewis & Fiszbein, 1987) and with experience sampling (Palmier-Claus et al., 2011)

4) Client satisfaction, as measured with the Client Satisfaction Questionnaire-8 (CSQ-8) (de Brey, 1983).

5) Feasibility of the training as measured with the Client Evaluation Questionnaire (CEQ).

Secondary outcome

1) "Jumping to conclusions (JTC)" as measured with the Beadstest (Huq, Garety, & Hemsley, 1988).

2) "Attribution bias" as measured with the Internal, Personal, and Situational Attributions Questionnaire (IPSAQ, Kinderman and Bentall 1996)

3) Psychotic symptoms and dthe distress caused by them as measured with the Community Assessment of Psychic Experiences (CAPE)

4) "Theory of mind" - a social cognition task- as measured with the Hinting Task (Corcoran et al. 2005).

5) "Theory of mind" as measured with the Degraded Facial Affect Recognition

(van't Wout et al., 2004, 2007).

6) Metacognition, as measured with the Metacognitions Questionnaire (Wells &

Cartwright-Hatton, 2004).

Study description

Background summary

Meta-analyses suggest that cognitive interventions are effective in ameliorating symptoms of psychosis. Cognitive biases, such as jumping to conclusions, are likely to be involved in the pathogenesis of paranoid ideation and psychosis. A recently developed group program, called meta cognitive training (MCT), aims to target these biases.

Study objective

To establish the effect of an adapted form of MCT (MCT-a) on paranoid ideation and cognitive insight in patients with recent onset psychotic symptoms.

Study design

Randomised controlled study with occupational therapy as an active control condition.

Intervention

MCT is a hybrid of psycho education, cognitive remediation and cognitive-behavioural therapy. The training consists of 8 sessions of 45 minutes, and will be given once a week. We adapted a group-based protocol for patients with recent onset psychosis by introducing specific homework assignments based on MCT +, an individualized MCT program, in order to target cognitive biases and to enhance generalisation of treatment effect. The control group receives 45 minutes of occupational therapy; a group-based therapy in which effective functioning and skills in relation to daily life and work are addressed.

Study burden and risks

Expected risk of participation in the study is negligible; the intervention

will be part of the treatment program of patients admitted to a recent psychosis ward; No physical examinations of discomfort are expected related to study participation.

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

In order to be eligible to participate in this study, a subject must meet the following criteria: recently developed schizophrenia or related disorder and an age between 18 and 35.

Exclusion criteria

Patients scoring 6-7 on the PANSS positive subscales (patients suffering from serious positive symptoms that interfere with their daily functioning) are excluded as this is considered detrimental for group training.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2013
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	30-09-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL42590.018.12