Metacognitive training: A randomized controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25876

Source
Nationaal Trial Register

Health condition

psychosis
paranoid schizophrenia

Sponsors and support

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Source(s) of monetary or material Support: ZON MW

Intervention

Outcome measures

Primary outcome

Primary outcome: Paranoid ideas and ideas of social reference. The GPTS was chosen as

primary outcome. The GPTS is a questionnaire that measures paranoid ideas and ideas of social reference with 32 items on a 5-point Likert-scale. The internal consistency is good, with a Crohnbach alpha > 0.70 and the test is consider valid.

Secondary outcome

Parameters:

1. Quality of life;

2. Subjective experience of cognitive biases;

3. Cognitive insight;

4. Delusional thinking;

5. Metacognitions;

6. Jumping-to-conclusionsbias;

7. Theory of mind;

8. Depression;

9. Memory bias.

The EQ-5D is a standardized measure of health status developed by the EuroQoL Group in order to provide a simple, generic measure of health for clinical and economic appraisal. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status that can be used in the clinical and economic evaluation of health care as well as in population health surveys.

The Davos Assessment of Cognitive Bias Scale (DACOBS) is a questionnaire thath measures the subjective experience of cognitive bias using 42 items on a 7-point Likert-scale. The following cognitive biases are measured: the jumping-to-conclusions bias, dogmatism bias, selective attention bias and the self-as-target bias. In addition, there are questions regarding cognitive limitations and safety behaviors. The psychometric qualities of this questionnaire are currently being investigated.

The Beck Cognitive Insight Scale (BCIS) is a 15-item self-report scale measuring 2 constructs: the ability to acknowledge fallibility, labeled self-reflectiveness and certainty about belief and

judgments, labeled self-certainty. A composite score reflecting cognitive insight is calculated by subtracting the self-certainty scale from the self-reflectiveness scale. The BCIS has demonstrated good convergent, discriminant, and construct validity with inpatients.

The PSYRATS DRS is a semi-structured interview whichs measures qualitative and quantitative aspects of delusions.

The Metacognitions Questionnaire 30 (MCQ30) is a questionnaire that measures metacognitions via 30 items on a 4-point Likert-scale. The manual distinguishes between cognitive self-confidence, positive views, cognitive self-awareness, uncontrollability and danger and need-for-control.

The Beads Task is used to measure the tendency to jump to conclusions. In the beads task, participants are shown two jars of coloured beads, informed of the relative proportions of beads in each, then told that they will be shown a series of beads drawn from one of the jars. They are then asked, on the basis of the observed sequence, to judge which jar is the source of the beads, and to be ‘as certain as possible’, but it is never possible to be completely certain as to which jar the beads have been drawn from.

The Hinting Task measures wether the participants have an understanding of the real meaning behind indirect language use. The task consists of ten short stories about interactions between two people. If the participant makes an error, a hint is given. If another error is made, another hint is given.

The Beck Depression Inventory (BDI) is a series of questions developed to measure the intensity, severity and depth of depression in patients with psychiatric diagnoses. Its long form is composed of 21 questions, each designed to assess a specific symptom common among people with depression.

In the Memory Task participants get time to look at a picture and are then asked to recall as many details about it as possible. They are also asked to estimate the degree of certainty they have about the recalls.

Study description

Background summary

State-of-the-art treatment of psychoses and delusions consists of antipsychotic medication prescribed by a psychiatrist, with or without therapist-administered cognitive-behavioral therapy (CBT). In CBT, delusions are examined and challenged in order to bring about a reduction of symptoms and to improve interpersonal relationships. Behavioral experiments are also directed toward testing concepts and towards the adaptation of beliefs based on the outcome of behavioral experimentation. This is the case for all DSM Axis I dis-orders. However, a delusion is not simply an incorrect interpretation such as occurs with anxiety and mood disorders. Recent findings in fundamental research however suggest that several cognitive biases in schizophrenic patients play an important role in the etiology and maintenance of positive symptoms (hallucinations and delusions). In an effort to translate findings about cognitive biases into clinical practice a groupwise training called Metacognitive Training (MCT) was developed by Moritz an Woodward. The intention of these authors was to fill a gap in order to create a more effective treatment for this population. The purpose of MCT is two-fold: 1) to educate the patient about these cognitive biases and 2) to highlight the negative consequences of these cognitive tendencies. Since the training focuses mostly on the form in which thoughts arise more than on the content of these thoughts it is expected to be a less intrusive and more playful way of gaining effects. This form-based training (versus content-based) might be cost-effective because it is also more suitable for groupwise training because of the fact that patients will not discuss the content of their hallucinations and delusions. Metacognitive training consists of 8 group sessions in which two therapists explain and train patients to overcome the most common cognitive bias (such as memory bias, jumping-to-conclusions bias, attentional bias) with attractive visual aids. In the period following the session patients are encouraged to complete their homework assignments to make generalization possible. It is hypothesized that Metacognitive therapy is more effective than the standard treatment (TAU) for changing paranoid thinking and ideas of social reference.

Method: The first two pilot studies show stimulating results on subjective and objective outcome measures. In a Dutch multi-centre randomized controlled trial (RCT) sixty-four subjects receiving the training additional to the treatment as usual will be compared with sixty-four subjects receiving only treatment as usual (TAU) in terms of paranoid thinking and ideas of social reference (primary outcome), quality of life, effect on several cognitive biases and effect on metacognitions before and after the intervention and with a 4-month follow-up. Patients between the ages of 18-65 with overt psychosis and suffering from an axis-I disorder in the schizophrenia spectrum (295-codes) will be included.

Results: Results will be stated in terms of efficacy and cost-effectiveness (a CEA will be conducted by a HTA-specialist).

It is expected that there are no risks for the patients involved. Patient will make 12 visits to their local mental health institution. Four of the visits consist of screening and measurements and will take about 90 minutes. The other 8 visits consist of the MCT-sessions en will take a maximum of 90 minutes.

Study objective

Metacognitive training is more effective than the standard treatment (TAU) for changing paranoid thinking in patients with
psychotic disorders.

Study design

In a Dutch multi-centre randomized controlled trial (RCT) sixty-four subjects receiving the training additional to the treatment as usual will be compared with sixty-four subjects receiving only treatment as usual (TAU) in terms of paranoid thinking and ideas of social reference (primary outcome), quality of life, effect on several cognitive biases and effect on metacognitions before and after the intervention and with a 4-month follow-up. To summarize, there's three timepoints for all measurements:

1. t(0) = Before the intervention;

2. t(1) = Right after the intervention;

3. t(2) = 4 month follow-up.

Intervention

Metacognitive Training (MCT): MCT is a group intervention intended for 3-10 patients. Sessions are typically conducted either by a clinical psychologist, psychiatrist, occupational therapist or psychiatric nurse. Each of the eight sessions lasts 45-60 minutes and deals with specific cognitive aberration. In each module, patients are first familiarized with the target domain (e.g., attributional style, jumping to conclusions, theory of mind) by means of a number of everyday examples and illustrations. To emphasize the relevance of the modules for psychosis and to ensure a lasting impact on patients, the linkage of these biases with psychosis formation/maintenance is repeated at the end of each session an eventually elucidated with anecdotal accounts of psychosis. Excercises form the core of the modules.

Patients practice to counteract cognitive biases such as jumping to conclusions. Leaflets with homework and discussions about symptoms of the participants personalize and generalize the practiced skills into the daily life of the patients.

Treatment as usual (TAU): Concerns standard treatment for psychotic patients, which consist of medication prescribed by a psychiatrist and outpatient treatment by a social-psychiatrist

nurse and/or psychologist.

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Eligibility criteria

Inclusion criteria

1. Patients with schizophrenia and/or another psychotic disorder (established with SCAN);

2. With delusional symptoms (PANSS P1>3 & PSYRATS DRS 5>1 & PSYRATS DRS 6>1);

3. Aged between 18-65.

Exclusion criteria

1. Primary addiction;

2. Insufficient understanding of the Dutch language;

3. IQ<70.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-04-2010
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	NL2183

Register	ID
NTR-old	NTR2307
Other	ZONMW : 171001010
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A