Metacognitive training: a randomized controlled trial to evaluate efficacy and cost-effectiveness of a training that aims to change cognitive biases that perpetuate psychosis in people with paranoid schizophrenia

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The following hypotheses are tested in the current study: 1) Metacognitive training is more effective than the standard treatment (TAU) for changing paranoid thinking in patients with psychotic disorders. Subhypothesis: 1a) Metacognitive training is...

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

Summary

ID

NL-OMON35242

Source
ToetsingOnline

Brief title
Metacognitive training: a randomized controlled trial.

Condition

- Schizophrenia and other psychotic disorders

Synonym
delusions, psychosis

Research involving

Human

Sponsors and support

Primary sponsor: Reinier van Arkelgroep (Den Bosch)
Source(s) of monetary or material Support: subsidie ZONMW

Intervention

Keyword: cognitive bias, delusion, psychotic disorders, schizophrenia

Outcome measures

Primary outcome

Primary outcomes: 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

Secondary outcomes: 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 [25]. The Davos Assessment of Cognitive Bias Scale (DACOBS) [26] 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, slective 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) [18] 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 [23] is a semi-structured interview whichs measures qualitative and quantitative aspects of delusions. The Metacognitions Questionnaire 30 (MCQ30) [27] 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 [28] 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 [29] 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) [30] 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 [31] 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

In the Netherlands, the yearly incidence of schizophrenia and schizophrenic psychoses is approximately 1 per 10,000 inhabitants. The prevalence has been estimated to be 60 per 10,000 inhabitants. In many cases, the course of schizophrenia is unfavourable and relapse is a common problem. In particular, hallucinations and delusions are more common than has previously been thought. The current study focuses on patients with clinically relevant delusions.
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). The multidisciplinary guidelines for the treatment of schizophrenia states that, *cognitive behavioural therapy is indicated for patients with persistent positive symptoms*.Such therapy should also be considered for patients with limited insight into their condition, or with a lack of faith in medication.* CBT is known to have a small to medium effect-size and it does not influence the chance of relapse.
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 disorders. However, a delusion is not simply an incorrect interpretation such as occurs with anxiety and mood disorders. Psychosis also involves cognitive deficits. These deficits are associated with negative symptoms and limitations in the ability to fulfill social roles such as student, parent, or employee. On the other hand, cognitive biases are associated with positive symptoms such as delusions and hallucinations and play a role in the development and persistence of delusions and hallucinations. Recent theories related to the development and persistence of psychoses refer

to both the content of delusional thoughts and the cognitive biases as fundamental to psychopathology. Experimental studies have shown that patients who suffer from schizophrenia, in particular those with positive symptoms, have several cognitive biases. Examples include the tendency to jump-to-conclusions, source monitoring, a tendency to place too much faith in false memories, problems with mentalization and the *bias against disconfirmatory information*. The associations between cognitive biases and psychotic symptoms have been demonstrated in experimental research. Recently, Moritz and Woodward developed the Metacognitive training (MCT) that will be tested in this study. 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 biases. So this study translates theoretical findings into clinical practice. Only one feasability study has been published about this training. That study demonstrated that patients enjoy the training and that there were no drop-outs. A pilot study has been completed by us in eight mental health institutions in the Netherlands. This pilot with 34 patients in an open trial confirmed the low drop-out and enjoyment of the training. The results were modest and showed only tendencies because of the low power. The module 'changing opinions*, significantly improved flexibility of thinking immediately after the training-module. The study in this proposal will investigate the efficacy and cost-effectiveness of MCT. The training is culture-free. Both men and woman in the age range of 18-65 will be included in this study.

Study objective

The following hypotheses are tested in the current study: 1) Metacognitive training is more effective than the standard treatment (TAU) for changing paranoid thinking in patients with psychotic disorders.

Subhypothesis: 1a) Metacognitive training is more effective than the standard treatment (TAU) for changing attributional style in patients with psychotic disorders. 1b) Metacognitive training is more effective than the standard treatment (TAU) for changing the jumping-to-conclusion-bias in patients with psychotic disorders. 1c) Metacognitive training is more effective than the standard treatment (TAU) for changing memory-bias in patients with psychotic disorders. 1d) Metacognitive training is more effective than the standard treatment (TAU) for changing point of view in patients with psychotic disorders. 1e) Metacognitive training is more effective than the standard treatment (TAU) for changing quality of life in patients with psychotic disorders. 1f) Metacognitive training is more effective than the standard treatment (TAU) for changing ideas of social inference in patients with psychotic disorders. 1g) Metacognitive training is more effective than the standard treatment (TAU) for changing subjective cognitive functioning in patients with psychotic disorders. 1h) Metacognitive training is more effective than the standard treatment (TAU) for changing cognitive insight in patients with psychotic disorders. 1i) Metacognitive training is more effective than the standard treatment (TAU) for changing metacognitions in patients with psychotic

disorders. 1j) Metacognitive training is more effective than the standard treatment (TAU) for changing depressive symptoms in patients with psychotic disorders.

In addition, the impact of the presence and severity of the symptom hearing voices will be investigated. Furthermore, predictors for treatment success will be sought and an analysis of cost-effectiveness will be made.

Study design

Design: The proposed study will employ a multi-center randomized controlled trial. We expect the MCT+TAU group to do better than the TAU only group (control group). Data collection for the pre-test will take place prior to the intervention (t0), the post-test data will be collected immediately following the intervention (t1) and follow-up data will be collected at 4 months after the intervention (t2). All data collection will be blinded.

Interventions:
Metacognitive Training (MCT): MT 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 bias. 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. Patients will participate in two sessions per week. After four weeks six different kinds of cognitive bias have been discussed and trained: attribution, jumping to conclusions (2x), memory, to empathize (2x), changing beliefs and self-esteem and mood.
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.

Intervention

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Study burden and risks

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.

Ethical issues are also considered:
-first of all we agreed that treatment as usual should be continued during the length of the study. Also medical treatment will be continued.
-We also conducted a pilot study testing the feasibility and patients agreed that the training was fun and it was not too heavy.
-patients are informed about the fact that they can withdraw from the study at any given point without any further explanation.
-Decent time-management should garantuee that patients won't have to visit the institution too often.
-because of negative symptoms the training will take place in the second part of the day.

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

-patients with schizophrenia and/or another psychotic disorder (established with SCAN)
-With delusional symptoms (established with PANNS, PSYRATS and GPTS)
-age between 18-65

Exclusion criteria

-primairy addiction
-insufficient understanding of the dutch language
-IQ<70

Study design

Design

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

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-04-2010
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	06-04-2010
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)
Approved WMO Date:	11-01-2011
Application type:	Amendment
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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	NL28883.097.09