Metacognitive therapy for Generalized Anxiety Disorder in patients with a schizophrenia-spectrum disorder

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This study examines whether MCT is effective in patients with schizophrenia-spectrum disorder and comorbid GAD. It is expected that:a) MCT leads to a significant decrease in worryingb) MCT leads to significant reduction of psychotic symptomsc) The...

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

Summary

ID

NL-OMON49487

Source
ToetsingOnline

Brief title
MCT for GAD with schizophrenia-spectrum disorder

Condition

- Schizophrenia and other psychotic disorders

Synonym
generalised anxiety disorder, psychosis, schizophrenia-spectrum disorder, worrying

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)
Source(s) of monetary or material Support: Parnassia groep

Intervention

Keyword: GAD, MCT, schizophrenia-spectrum disorder

Outcome measures

Primary outcome

The primary outcome measure is the Penn State Worry Questionnaire (PSWQ), a reliable and valid self-report questionnaire to chart persistent, excessive and uncontrollable worry. The list consists of 16 items that are scored on a five-point Likert scale. The total score can vary from 16 to 80. This questionnaire is administered at all measuring moments.

At group level, it is verified by means of paired t-tests whether worrying is stable during the baseline period (measurement 1 and measurement 3). Effects of MCT on worry, delusions and metacognitions are also examined by means of paired t-tests (measurement 3 and measurement 4). In order to check whether the effects found are maintained afterwards, paired t-tests are also performed (measurement 4 and measurement 5). The size of the effects (effect sizes) is calculated using Cohen's d (M1 - M2 / pooled SD, Cohen, 1992). All statistical analyzes will be performed using SPSS, version 23.

At the individual level, two widely used methods are used in case series research, the evaluation of the graphical representation of changes in symptoms over time (Parsonson & Baer, **1992), and the more conservative method of mapping the clinical significance. for the primary outcome measure, the PSWQ, using the procedures described by Jacobson and Truax (1991). According to this

method, patients are considered recovered if a) their score on a particular questionnaire after the end of the treatment falls within the normal range of scores (ie below a set cut-off point), and b) the difference between the starting and final score on that questionnaire reflects a statistically reliable improvement (ie a difference score greater than a set Reliable Change Index [RCI]). Based on the normative data of the Dutch version of the PSWQ, the RCI was set at 7 and the cut-off point at 53 (Van der Heiden et al., 2012).

Secondary outcome

In addition to the primary outcome measures, the following questionnaires are taken:

The PSYRATS is a semi-structured interview consisting of eleven items that measure aspects of hallucinations and six items that map characteristics of delusions. The items are scored on a 5-point Likert scale running from 0-4 and cover the past week. Items related to preoccupation, duration, conviction and disruption form the factor 'cognitive interpretation', items that deal with the frequency and intensity of experienced distress constitute the second factor, 'emotional impact'.

The remission tool-PANNS is a semi-structured interview in which 7 areas, corresponding to the characteristics of the schizophrenia-spectrum disorder, are questioned. It concerns the areas Delusions and unusual thought content; Conceptual disorganization; Hallucinations; Passive / apathetic withdrawal; Lack of spontaneity; Feeling dulled; Mannerism and poses. This questionnaire is

part of the standard ROM and is not an extra list.

The MCQ-30 is a self-report questionnaire that maps out individual differences in positive opinions about worrying, negative views about worrying, opinions about the need to keep control over one's own thoughts, cognitive self-awareness, and cognitive self-confidence. The list consists of 30 questions scored on a 4-point Likert scale, ranging from 'disagree' (1) to 'very strongly agree' (4). For this study only the subscales positive and negative views on worrying will be used. The psychometric qualities of the MCQ-30 are good (Hermans, Crombez, Van Rijsoort & Laeremans, 2002).

A final outcome measure is the already described GAD-7 (Spitzer et al., 2006), which is taken before participation (for inclusion), at the start of the treatment and then at the end of the treatment and at the follow-up measurement.

Study description

Background summary

Worrying is an important comorbid problem in patients with schizophrenia-spectrum disorder. Worrying is, in addition to insomnia, the strongest predictor of a later psychosis, and is associated with the maintenance of delusions. 68% of patients with delusions worries to an extent comparable to patients with generalized anxiety disorder (GAD), a disorder of which persistent uncontrollable worrying about various issues is the central feature. In almost 11% of cases psychotic patients even meet the criteria of a (comorbid) GAD. Although several studies have shown that treatment of worrying with cognitive behavioral therapy leads to a decrease in both worrying and delusions in patients with perspiration delusions, no research has yet been

done into the treatment of comorbid GAD in this target group.

In this study it will be investigated whether metacognitive therapy (MCT) for GAD is effective in patients with schizophrenia-spectrum disorder. MCT is an effective treatment for GAD and is one of the psychological treatments of first preference for GAD (NHS, 2012). The interventions in this treatment are not focused on the worrying itself, but on the views that someone has about his / her worry, the so-called metacognitions. Positive opinions about worrying, such as 'I'm well prepared for possible problems', are seen as a factor that contributes to the maintenance of worrying. Negative views about worrying, such as 'worrying is uncontrollable' and 'worrying makes me go crazy', are seen as crucial for the development of GAD. They lead to 'worrying about worrying' and an increase in feelings of fear, and counterproductive attempts to prevent or control the worrying once it has started.
Interesting in this context is that such metacognitive views are associated with psychotic experiences, the perceived stress as a result of these experiences and with negative affect. It is possible that even transitions can be prevented with MCT for GAD. Morrison, French and Wells (2007) found indications that negative metacognitions make patients susceptible to anxiety, but positive metacognitions (MCs) for psychoses. However, this can not be determined within the current study.
No previous studies have been conducted on the treatment of GAD in this target group.

Study objective

This study examines whether MCT is effective in patients with schizophrenia-spectrum disorder and comorbid GAD. It is expected that:
a) MCT leads to a significant decrease in worrying
b) MCT leads to significant reduction of psychotic symptoms
c) The decrease in complaints is retained at follow-up after 3 months

Study design

The study was set up as a case-based time series design with baseline measurement (a so-called ABA design). This design is ideally suited to verify in clinical practice whether a proven effective treatment for a particular disorder (ie GAD) is also suitable for patients with a different primary disorder (ie, a schizophrenia-spectrum disorder with comorbid GAD), without requiring large numbers of participants, control conditions and / or randomisation procedures.

Intervention

After informed consent, patients are offered fourteen weekly MCT sessions for GAD, cf. Van der Heiden's protocol (2017). This treatment takes place alongside

the regular treatment for psychotic complaints. The treatments are performed by three registered cognitive-behavioral therapists from Parnassia The Hague, who were trained and supervised by the principal investigator (CH) in the application of the MCT protocol to GAD in some patients from their own caseload who met the inclusion criteria. Each therapist treats three patients with MCT within the study.

Study burden and risks

It is estimated that completing the questionnaires takes a maximum of 30 (measurements 1 and 2) to 90 minutes (measurement 3-5) per session. The patient is asked to complete questionnaires at 5 moments, namely 2 and 1 week before start of treatment, at start of treatment, at the end of treatment and 3 months after completion of treatment (follow up).

The burden of research is relatively small, while, as far as we know, there are no risks associated with participation in the research.
The treatment method to be investigated (metacognitive therapy) is part of the cognitive behavioral therapy and is considered to be the treatment of first preference in generalized anxiety disorder.

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

1. Age between 18-65;
2. primary diagnosis of schizophrenia-spectrum disorder according to DSM-5
3. A score of 10 or higher on the GAD-7, a diagnostic screening list for GAD
4. A clinically significant degree of worrying, shown by a high score (* 49) on the Penn State Worry Questionnaire
5. In case of intended radical changes in the field of pharmacotherapy, patients can only enter the study if the dose is stable for at least one month.

Exclusion criteria

Patients are excluded when:
1. they are unable or seem unable to give informed consent;
2. they don't sufficiently master the dutch language to undergo treatment without an interpreter
3. there is alcohol or drug abuse that interferes with treatment
4. they have an IQ of 70 or below
5. they have an organic disorder

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-03-2020
Enrollment:	9
Type:	Anticipated

Ethics review

Approved WMO Date:	20-10-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL67665.058.18