

# Less rumination, less paranoid thinking? The effects of reducing rumination/worry in patients with persecutory delusions: a pilot study

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

## Summary

### ID

NL-OMON41032

### Source

ToetsingOnline

### Brief title

Less rumination, less paranoid thinking?

### Condition

- Schizophrenia and other psychotic disorders

### Synonym

Paranoia, Persecutory delusions

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Parnassia (Den Haag)

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Competitive memory training (COMET), Paranoia, Rumination, Worry

## Outcome measures

### Primary outcome

Primary measurements will be the scales taken from the Green Paranoid Thought Scale (GPTS) that assesses delusion, and the Psychotic Symptoms Rating Scale - Delusions (PSYRATS-DRS), rumination, assessed with the Ruminative Response Scale (RRS) and worry, assessed with the Penn State Worry Questionnaire (PSWQ).

### Secondary outcome

Secondary measurements will be anxiety, assessed with the Beck Anxiety Inventory (BAI) and depression, assessed with the Beck Inventory of Depression - II (BDI2). In addition feasibility will be evaluated by interviewing patients on their opinion about the treatment and its effects. Also the participating therapists will be interviewed on their opinion about the feasibility and effectiveness of the treatment and on their collaboration. If a patient drops out of treatment, the reason for drop-out will be assessed by contacting the patient and the therapist.

## Study description

### Background summary

Previous research found that worry is a factor that plays an important role in generating persecutory delusions. The tendency to worry is found to be a predictor of the prevalence of paranoid thinking, the severity of worry predicts persistence of persecutory delusions and worry makes delusional ideas

more distressing. Foster and colleagues (2010) randomly assigned patients with persecutory delusions to a four session worry reduction intervention or treatment as usual. They found that reducing levels of worry leads to the decrease of persecutory delusions. This research also suggests that rumination may be a significant feature of the cognitive style of patients with paranoia. One research that explored the association between paranoia and rumination is a study done by Martinelli, Cavanagh and Dudley in 2013. They found that rumination was associated with maintained levels of paranoia and suggested that rumination could be considered as a potential pathway to the persistence of delusional distress and paranoid beliefs. Based on these findings and the notion that little research had explored the role of rumination in paranoid beliefs, we intend to study the effect of a new treatment which targets both worry and rumination, the competitive memory training for worry and rumination or COMET-wr

## **Study objective**

In the last ten years there has been a lot of research to understand persecutory delusions, but these findings had not yet been translated into treatment until Freeman and colleagues (2011). They targeted worry, but showed that rumination has to be targeted too. It had been proposed that patients with paranoia ruminate on their negative interpersonal experiences. This leads to increased feelings of vulnerability. Because of this, patients will develop a certain attention bias toward negative experiences, which leads to greater awareness of negative information. This enhances the sense of being victimized and increases feelings of anxiety. These increased feelings of anxiety leads in turn to reinforced paranoid beliefs. This vicious cycle can be disengaged by using adaptive coping strategies and that is what the COMET-wr targets. COMET-wr was originally developed by Ekkers, Korrelboom & van der Gaag to reduce rumination in depressed patients. The aim of this study is to examine in a small pilot study whether the COMET-wr intervention has potential to be effective at reducing levels of worry and rumination and therefore reducing delusional distress in patients with paranoid delusions.

## **Study design**

This research is a pilot study with an ABA-design as used in Hepworth et al. (2011). Patients will be assessed three times during the research: before the intervention, after the intervention and after one month follow-up. The COMET-wr will be an add-on, patients receive their treatment as usual and an extra intervention. There will be no control group and thus no randomisation.

## **Intervention**

COMET is a cognitive treatment for rumination in depressed patients, developed by Ekkers and colleagues (2011). The COMET protocol encompasses six steps or

stages: (1) Motivation enhancing, (2) treatment rationale, (3) awareness of their paranoia, (4) identify earlier successes in letting go, (5) strengthening successes by imagining and (6) apply in real life. The ability to let go, during step two, can be done following two strategies: a) acceptance or b) being indifferent. One or both strategies can be learned and will be practiced. A COMET session takes 7 sessions of 45 minutes, homework assignments not included.

### **Study burden and risks**

This study does not acknowledge any risks.

The burden for each patient is estimated to be 550 minutes. This includes the weekly sessions and three assessments but it does not include the homework assignments. We expect patients will be engaged with these homework assignments for approximately 15 minutes a day.

## **Contacts**

### **Public**

Parnassia (Den Haag)

Leggelostraat 85  
Den Haag 2541 HR  
NL

### **Scientific**

Parnassia (Den Haag)

Leggelostraat 85  
Den Haag 2541 HR  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)  
Elderly (65 years and older)

## Inclusion criteria

Age above 18, primary diagnosis of schizophrenia, schizoaffective disorder, or delusional disorder, all with current experience of persecutory delusions or paranoid thinking based on the criteria from the Diagnostic and Statistical Manual of Mental Disorders IV. Text Revision (DSM-IV-TR) and verified with the Mini International Neuropsychiatric Interview Plus (MINI-plus), a score above 50 on the persecutory item from the Green Paranoid Thought Scales (GPTS) and one question from the Positive and Negative Syndrome Scale (PANSS) regarding delusion which has to have a score between four and eight.

## Exclusion criteria

Insufficient knowledge of the Dutch language, cognitive impairment with a cut-off score of < 24 on the Mini Mental State Examination (MMSE) (only assessed in patients 55 years and older), acute suicidal behavior, current involvement in any other cognitive behavior therapy and comorbid diagnosis of severe drug or alcohol dependence that requires primary treatment.

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 20-06-2014

Enrollment: 12

Type: Anticipated

## Ethics review

Approved WMO

Date: 22-09-2014

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

## 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	NL49626.058.14