

# Metacognitive Reflection and Insight Therapy

Published: 04-12-2013

Last updated: 24-04-2024

Primary objective of this study is to investigate if the Metacognitive Reflection and Insight Therapy (MERIT) improves metacognitive abilities in people with schizophrenia. Secondary objective is to examine whether improvement in metacognitive...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Schizophrenia and other psychotic disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON39038

### Source

ToetsingOnline

### Brief title

MERIT

### Condition

- Schizophrenia and other psychotic disorders

### Synonym

psychosis, schizophrenia

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Rijksuniversiteit Groningen

**Source(s) of monetary or material Support:** Ministerie van OC&W, fonds NutsOhra zorgsubsidie. Zij hebben geen betrokkenheid bij de inhoud van het onderzoek.

## Intervention

**Keyword:** metacognition, psychosis, psychotherapy, treatment

## Outcome measures

### Primary outcome

The main study parameter is metacognitive functioning, which will be assessed using the Metacognitive Assessment Scale (MAS-NL).

### Secondary outcome

Depression Beck Depression Inventory-II (Beck et al., 1996)

Internalized Stigma ISMI (Ritscher et al., 2003)

Quality of Life MANSA (Priebe et al., 1999)

Social Functioning Time Use

Symptoms Positive and Negative Symptom Scale

Neurocognitive function Trailmaking test A&B

Neurocognitive function Digit Symbol Test (WAIS I)

Premorbid IQ Nederlandse Leestest voor Volwassenen (NLV)

Theory of Mind Faux Pas Task

Empathy Interpersonal Reactivity Index (IRI)

Empathy Empathic Accuracy Test

Cost effectiveness SF-12

Cost effectiveness Zorg consumptie vragenlijst

## Study description

### Background summary

One percent of the total Dutch population has schizophrenia. Research has shown deficits in Metacognitive abilities in more than half of people with schizophrenia and association between deficits and poor course of illness. Metacognition is the ability to think about thoughts and feelings of oneself and others. It is a broad concept and involves several aspects:

- the ability to think about ones own thoughts and emotions;
- the ability to think about the thoughts and emotions of others;
- decentration; the ability to understand that you are not the center of the world and peoples lives continue when your not around;
- the ability to use the three aspects above to adapt your behavior to the circumstances.

Research has shown that improvement in Metacognitive abilities leads to improvement in social functioning and less symptoms. It also seems to improve the therapeutic relationship, insight and the experienced quality of life.

Dr. P. Lysaker has developed the Metacognitive Reflection and Insight Therapy (MERIT) that aims to improve metacognitive functioning. Pilot studies show promising results. We now want to investigate this therapy in a Randomized Controlled Trial.

## **Study objective**

Primary objective of this study is to investigate if the Metacognitive Reflection and Insight Therapy (MERIT) improves metacognitive abilities in people with schizophrenia. Secondary objective is to examine whether improvement in metacognitive abilities leads to enhanced quality of life, experience of symptoms, insight, social functioning, depression and work readiness in people with psychotic disorders. We also want to investigate the cost-effectiveness of the Metacognitive Reflection and Insight Therapy.

## **Study design**

Multicenter randomized controlled trial.

## **Intervention**

The treatment condition will receive the Metacognitive Reflection and Insight Therapy (MERIT). This psychotherapy seeks to enhance the metacognitive abilities of people with schizophrenia and is developed by dr. P. Lysaker. The therapy is standardized with a treatment protocol. The therapy will consist of a one hour individual therapy session per week, for ten months.

## **Study burden and risks**

Assessments will take place before, after and six months after the therapy.

Assessment of each patient will take 2x 1,5 hours. The proposed intervention consists of weekly individual therapy sessions of one hour. Our expectation is that improved metacognitive skills will play an important role in the recovery process of schizophrenia and will help patients to gain more control of their lives.

## Contacts

### **Public**

Rijksuniversiteit Groningen

Grote Kruisstraat 2/1

Groningen 9712 TS

NL

### **Scientific**

Rijksuniversiteit Groningen

Grote Kruisstraat 2/1

Groningen 9712 TS

NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

A diagnosis of schizophrenia or schizoaffective disorder, according to DSM-IV-TR criteria;  
Impaired metacognitive skills, measured with 4 questions for the therapist and the MAS-A;  
Being able to give informed consent;  
18 years or older;

No change in medication in the past thirty days.

## Exclusion criteria

Florid psychosis (positive symptoms  $<4$  measured by PANSS);  
co-morbid neurological disorder;  
substance dependence (not substance abuse);  
IQ  $<70$ .

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	120
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	04-12-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	02-07-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

## 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	NL41317.042.13