

# Reflex.

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Can poor insight with schizophrenia be improved with a treatment aimed at selfreflection and the decrease of internalized stigma.

<b>Ethische beoordeling</b>	Niet van toepassing
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON24576

### Bron

NTR

### Verkorte titel

N/A

### Aandoening

psychic disorders; schizophrenia and other psychotic disorders

## Ondersteuning

**Primaire sponsor:** University Medical Centre Groningen

**Overige ondersteuning:** NWO, European Science Foundation

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Insight is the primary outcome measure.

The following instruments will be used:<br>

1. Beck Cognitive Insight Scale;<br>
2. SAI-E.

# Toelichting onderzoek

## Achtergrond van het onderzoek

Many people with schizophrenia demonstrate impaired insight. It is often assumed that poor insight plays an important role in the negative prognosis of schizophrenia. Indeed, impaired insight has been linked to unfavourable outcome of the disease and poorer medication compliance. Impaired insight is therefore considered as one of the most prominent clinical symptoms of schizophrenia. There are a number of interventions to improve insight, but results of these interventions are mixed. We expect that insight in schizophrenia will increase by stimulating self-reflection. Based on a new model of insight in schizophrenia, a new intervention is developed and will be evaluated in a RCT. The primary objective is to enhance insight in individuals with psychosis. Secondary objectives are to enhance patients' quality of life and community functioning.

Design: A multi-centre randomised controlled trial, the intervention will be compared to treatment as usual.

Study population: 80 patients with psychosis and poor insight will be included and randomised over two conditions.

In the first part of the intervention stigmatizing beliefs are disputed and self-reflection is stimulated. Concurrently, SMS-messages will be sent to patients on a daily basis to stimulate self-reflection and self-monitoring. The control condition consists of care as usual and additional befriending sessions with a therapist.

The primary outcome are the changes in two insight assessment instruments. Secondary outcome are changes in structured assessment of community functioning, depression, self-esteem, quality of life, internalised stigma and symptoms.

## Doel van het onderzoek

Can poor insight with schizophrenia be improved with a treatment aimed at selfreflection and the decrease of internalized stigma.

## Onderzoeksopzet

Start: 01-09-2009.

## Onderzoeksproduct en/of interventie

Patients will have 16 group therapy sessions with a psychologist. In these sessions, stigmatizing beliefs are disputed and self-reflection is stimulated. On a daily basis SMS-messages will be sent to stimulate self-reflection. After a prompt patients are required to fill out a short form with short questions about their cognitions and emotions. Weekly group sessions will be based on the patients' responses.

# Contactpersonen

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. A diagnosis of schizophrenia according to DSM-IV-TR criteria;
2. Impaired insight (based on structured assessment);
3. Willing to give written informed consent.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Florid psychosis;
2. Patients falling under the BOPZ law, or who are unable to give informed consent according to the 'Wet op Geneeskundige Behandelovereenkomsten';
3. Co-morbid neurological disorder;
4. IQ below 75.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

### Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2009
Aantal proefpersonen:	80
Type:	Verwachte startdatum

## Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

<b>Register</b>	<b>ID</b>
NTR-new	NL691
NTR-old	NTR1799
Ander register	ABR : 27146
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Resultaten

### Samenvatting resultaten

N/A