# Cognitive Behavioural Therapy - Social Functioning In Adolescence with recent onset schizophrenia

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To evaluate the applicability and (cost-) effectiveness of a shortened, partly group based, Cognitive Behavioural Therapy (CBTsa) focussing on social activation in patients with recent

onset schizophrenia.

**Ethical review** Approved WMO

**Status** Recruitment stopped

Health condition type Schizophrenia and other psychotic disorders

**Study type** Interventional

## **Summary**

#### ID

NL-OMON41291

#### Source

ToetsingOnline

**Brief title** 

**SOFIA** 

#### **Condition**

Schizophrenia and other psychotic disorders

#### **Synonym**

psychosis, schizophrenia

#### Research involving

Human

### **Sponsors and support**

**Primary sponsor:** Psychiatrie, afdeling Vroege Psychose

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

#### Intervention

**Keyword:** CBT, Negative symptoms, Recent onset schizophrenia, Social withdrawal

#### **Outcome measures**

#### **Primary outcome**

Negative symptoms, social withdrawal behavior / inactivity

#### **Secondary outcome**

Social functioning, Quality of life, cost, Positive and General symptoms, Need

for Care

# **Study description**

#### **Background summary**

Cognitive Behavioural Therapy (CBT) is one of the most commonly provided forms of therapy in the Netherlands. It is a short-term, structured therapy that is sometimes offered groupwise and sometimes individually. In CBT it is assumed that not the events themselves, but rather thoughts, interpretations and expectations about these events evoke negative feelings. CBT focuses on changing both thinking patterns (cognitions) and behaviors. The effectiveness of cognitive behavioral therapy has often been studied in people with a psychotic disorder, but research to date has focused mainly on reducing symptoms such as hallucinations or delusions.

Aaron T. Beck, founder of Cognitive Behavioural Therapy (CBT), and colleagues have developed and investigated a new CBT approach, in which they target inactivity in a chronic schizophrenia population with severe negative symptoms. The therapy is based on accumulating evidence that dysfunctional beliefs in conjunction with neurocognitive impairments can impede functioning. These results suggest that CBT can be highly successful in establishing clinically meaningful improvements. However, the therapy has not yet been investigated in a recent-onset population.

In this study, we particularly focus on maintaining social activities and reducing symptoms such as a lack of initiative or diminished interest. We expect that CBT focused on social withdrawal behavior will be effective in reducing negative symptoms, improving the performance, cost and quality of life

of patients with recent-onset schizophrenia.

#### **Study objective**

To evaluate the applicability and (cost-) effectiveness of a shortened, partly group based, Cognitive Behavioural Therapy (CBTsa) focussing on social activation in patients with recent onset schizophrenia.

#### Study design

Single blind randomized controlled trial with 6 month-follow up.

#### Intervention

Individual and group-based CBT intervention targeting social withdrawal.

#### Study burden and risks

Patients will undergo a 2-hour during testbattery and will carry along a mobile device with which participants are prompted by a beep at random intervals throughout the day (for a 6-day period) to report about their current experiences and withdrawal behaviour. These assessments will be repeated post-treatment and at 6-month follow-up. No risks are attached to this study.

## **Contacts**

#### **Public**

Selecteer

Meibergdreef 5 Amsterdam 1105AZ NL

#### **Scientific**

Selecteer

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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) recent onset schizophrenia (start antipsychotic medication <2 yr);
- (2) Social withdrawal (> 3 moderate severity on the PANSS N4; Passive/apathic social withdrawal);
- (3) Aged 18-35 years;
- (4) Fluent in Dutch
- (5) IQ > 70;
- (6) Able and willing to give informed consent

#### **Exclusion criteria**

- Neurological disease or damage that would compromise cognitive functioning
- Negative symptoms as a consequence of positive symptoms, or as a consequence of a physical handicap

# Study design

## **Design**

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Single blinded (masking used)

Control: Active

Primary purpose: Treatment

#### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 06-05-2014

Enrollment: 112

Type: Actual

## **Ethics review**

Approved WMO

Date: 03-04-2014

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 01-07-2015

Application type: Amendment

Review commission: METC Amsterdam UMC

# **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 NL46776.018.13