

# The effectiveness of behavioral activation for persons with a psychotic disorder and negative symptoms: a multicentre randomized controlled trial

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Other
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON23158

### Source

Nationaal Trial Register

### Brief title

BANS

### Health condition

Schizophrenia, psychosis, behavioral activation, negative symptoms

Schizofrenie, psychose, behavioral activation, negatieve symptomen

## Sponsors and support

**Primary sponsor:** GGZ Friesland

RijksUniversiteit Groningen

**Source(s) of monetary or material Support:** Self funding

RijksUniversiteit Groningen

## Intervention

## Outcome measures

### Primary outcome

Degree of negative symptoms

### Secondary outcome

- Frontal brain activity, measured with a Near Infrared spectroscopy
- Social functioning
- Depression
- Quality of life

## Study description

### Background summary

Negative symptoms are highly prevalent in psychotic disorders and have been associated with poor prognosis, lower social functioning and reduced quality of life. Despite the attention these symptoms receive, so far no evident treatment strategies are available. Major depression shares several features with negative symptoms: loss of goal directed behavior and amotivation. Moreover, anticipatory pleasure, or the ability to experience pleasure related to future activities, is diminished in both. Behavioral activation (BA) is a well-researched and effective treatment strategy for depression. BA focuses on stimulating behavior, in which therapist and patient cooperatively analyse potential rewarding activities and plan these activities subsequently. Recent pilot data showed that behavioral activation might be effective in patients with negative symptoms in schizophrenia.

Primary objective of the study is to investigate whether Behavioral Activation for Negative Symptoms (BANS) improves negative symptoms. Secondary objective is to investigate whether effects of BANS on negative symptoms is mediated or moderated by the ability to experience anticipatory pleasure. We also want to examine whether improvement in negative symptoms is associated with frontal hypo-activity. Finally, we want to examine whether Behavioral Activation for Negative Symptoms leads to better social functioning, improved quality of life and objective increase in activities.

### Study design

T0: baseline assessment

T1: post treatment assessment (15 weeks)

T2: follow-up assessment (6 months)

### Intervention

Participants in the treatment condition will receive the Behavioral Activation for Negative Symptoms (BANS). This behavioral therapy focuses on regaining activities. Increased pleasurable activities and associated reward, is expected to diminish apathy. The therapy will consist of 15 hours of individual therapy, carried out by a nurse. In this therapy, the activity level of the patient increases gradually, with activities that are in accordance with patients personal life values.

Participants in the control group will receive 15 weekly individual sessions of befriending, carried out by a nurse.

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

- Primary diagnosis of schizophrenia or schizoaffective disorder (DSM-IV-TR)
- Mild to severe negative symptoms negative symptoms, measured by Positive And Negative Syndrome Scale (PANSS, > 15 on Negative Syndrome Scale)
- 18-65 years old
- Ability to give informed consent

### **Exclusion criteria**

- Co-morbid neurological disorder
- Substance dependence (not substance abuse)

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Other
Start date (anticipated):	01-12-2014
Enrollment:	148
Type:	Unknown

## Ethics review

Positive opinion	
Date:	04-12-2014
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 40340  
Bron: ToetsingOnline  
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL4871
NTR-old	NTR4989
CCMO	NL47108.042.13
OMON	NL-OMON40340

## Study results