

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

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|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Anders                |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON23158

### Bron

NTR

### Verkorte titel

BANS

### Aandoening

Schizophrenia, psychosis, behavioral activation, negative symptoms

Schizofrenie, psychose, behavioral activation, negatieve symptomen

## Ondersteuning

**Primaire sponsor:** GGZ Friesland

RijksUniversiteit Groningen

**Overige ondersteuning:** Self funding

RijksUniversiteit Groningen

## Onderzoeksproduct en/of interventie

# Uitkomstmaten

## Primaire uitkomstmaten

Degree of negative symptoms

## Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Onderzoeksopzet

T0: baseline assessment

T1: post treatment assessment (15 weeks)

T2: follow-up assessment (6 months)

### Onderzoeksproduct en/of interventie

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.

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

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

- 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

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

- Co-morbid neurological disorder

- Substance dependence (not substance abuse)

## Onderzoeksopzet

### Opzet

|                  |                       |
|------------------|-----------------------|
| Type:            | Interventie onderzoek |
| Onderzoeksmodel: | Parallel              |
| Toewijzing:      | Gerandomiseerd        |
| Blinding:        | Enkelblind            |
| Controle:        | Geneesmiddel          |

### Deelname

|                         |            |
|-------------------------|------------|
| Nederland               |            |
| Status:                 | Anders     |
| (Verwachte) startdatum: | 01-12-2014 |
| Aantal proefpersonen:   | 148        |
| Type:                   | Onbekend   |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 04-12-2014       |
| Soort:          | Eerste indiening |

## Registraties

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

ID: 40340  
Bron: ToetsingOnline  
Titel:

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

Geen registraties gevonden.

## In overige registers

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

## Resultaten