A RCT on the effectiveness of Behavioral Activation for Negative Symptoms (BANS) for negative symptoms in schizophrenia

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON40340

Source
ToetsingOnline

Brief title
Behavioral Activation for Negative Symptoms (BANS) for schizophrenia

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychosis, psychotic disorders

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen

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

Intervention

Keyword: Behavioral activation, Negative symptoms, Psychosis, Schizophrenia

Outcome measures

Primary outcome

The main study parameter is the degree of negative symptoms.

Secondary outcome

Secondary parameter outcomes are frontal brain activity, anticipatory pleasure,

social functioning, quality of life, and motor activity.

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.

Study objective

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

The study is a Randomized Controlled Trial (RCT). The intervention (BANS) will be compared with a group receiving befriending.

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. The therapy is standardized with a treatment protocol (see Appendix C). The therapists receive a two-day training. All sessions will be audio-taped and scored by a blind assessor to monitor therapists* adherence to the treatment protocol. Therapists will receive weekly supervision.
Participants in the control group will receive 15 sessions of befriending. They have the option to receive the therapy when the trial is completed

Study burden and risks

Before treatment two assessments will take place; first diagnosis will be verified as well as inclusion criterion (approximately 1 hour), followed by baseline assessment of approximately 2,5 hours, which can be subdivided in two assessments of 1,5 (questionnaires and interviews) and 1 hour (NIRS).
Post-treatment assessment (1,5 and 1 hour) and follow-up assessment (1.5 hours) will take place directly after the intervention and six months later. Thirty participants (15 per condition) will participate on voluntary basis in a sub-study Experience Sampling and use a PsyMate during a total period of three weeks (six days prior (ES1), six days after intervention (ES2), and at follow up (ES2)) They are required to fill out a simple digital questionnaire at ten random moments a day (total of 3*6*10= 180 measurements of 2 minutes (total: 360 minutes). Patients are asked to wear in the same period of experience three times for a period of one week, an validated actimeter (ActiCal) for the continuous recording of motor activity.The proposed intervention consists of 15 hours of individual behavioral activation for negative symptoms therapy, the control condition receives an equal amount of befriending sessions.
The risks involved are minimal. No risks are expected deriving from participating with the BANS intervention. With regard to NIRS, extensive safety experiments have shown no (cumulative) physical or genetic harmful effects.

Contacts

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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-5 criteria, verified by MiniScan
- Mild to severe negative symptoms negative symptoms, measured by Positive And Negative Syndrome Scale (PANSS, > 15 on Negative Syndrome Scale) (Kay, Fishbein, & Opler, 1982)
- 18 - 65 years old and being able to give informed consent

Exclusion criteria

- Co-morbid neurological disorder
- Substance dependence (not substance abuse) of alcohol, marijuana, opiates, stimulants and cocaine, verified by MiniScan

- Forensic care

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):	20-02-2015
Enrollment:	148
Type:	Actual

Ethics review

Approved WMO

Date:	01-08-2014
Application type:	First submission
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

ID: 23158
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL47108.042.13
OMON	NL-OMON23158