Een RCT naar het effect van Behavioral Activation voor Negatieve Symptomen (BANS) voor negatieve symptomen van schizofrenie

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Primary objective of the study is to investigate whether Behavioral Activation for Negative Symptoms (BANS) improves negative symptoms in schizophrenia. Secondary objective is to examine whether improvement in negative symptoms is associated with...

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Schizofrenie en andere psychotische stoornissen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON40340

Bron
ToetsingOnline

Verkorte titel
Behavioral Activation voor Negatieve Symptomen (BANS) bij schizofrenie

Aandoening

- Schizofrenie en andere psychotische stoornissen

Synoniemen aandoening
psychose, Psychotische stoornissen

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Rijksuniversiteit Groningen
Overige ondersteuning: Ministerie van OC&W,GGz Friesland

Onderzoeksproduct en/of interventie

Trefwoord: Behavioral activatie, Negatieve symptomen, Psychose, Schizofrenie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is the degree of negative symptoms.

Secundaire uitkomstmaten

Secondary parameter outcomes are frontal brain activity, anticipatory pleasure,

social functioning, quality of life, and motor activity.

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

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. 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

Inschatting van belasting en risico

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Locaties

Landen waar het onderzoek wordt uitgevoerd

Netherlands

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Diagnose van schizofrenie of schizo-affectieve stoornis, vastgesteld met de MiniScan
- Milde tot ernstige negatieve symptomen, gemeten met Positive And Negative Syndrome Scale (PANSS, > 15 on Negative Syndrome Scale) (Kay, Fishbein, & Opler, 1982)
- 18 - 65 jaar oud en wilsbekwaam om informed consent te geven.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Comorbide neurologische stoornis

- Middelenafhankelijkheid (niet middelenmisbruik) van alcohol, marijuana, opiaten, stimulanten en cocaïne, geverifieerd met de MiniScan
- In zorg op basis van forensische titel

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-02-2015
Aantal proefpersonen:	148
Type:	Werkelijke startdatum

Ethische beoordeling

Goedgekeurd WMO

Datum:	01-08-2014
Soort:	Eerste indiening
Toetsingscommissie:	METC Universitair Medisch Centrum Groningen (Groningen)

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

ID: 23158
Bron: NTR
Titel:

In overige registers

Register	ID
CCMO	NL47108.042.13
OMON	NL-OMON23158