Does cognitive remediation training improve daily functioning and well-being in bipolar disorder?

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Cognitive remediation focused on executive functioning for patients with bipolar disorder improves executive functioning on (1) personal goals in daily life, and (2) general well-being. Exploratory hypotheses: - Cognitive remediation focused on...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27541

Bron
NTR

Verkorte titel
TBA

Aandoening

Bipolar disorder, type I and type II

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: Funding by GGZ Delfland, study budget

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Goal Attainment Scale (GAS): A 5-point scale for individual assessment of outcome, originally introduced by T.J. Kiresuk and R.E. Sherman in 1968. In rehabilitation this is an important measure of outcome; strong evidence has been found for the reliability, validity and sensitivity of goal attainment scaling (Hurn et al., 2006). SMART goals (Specific, Measurable, Achievable, Relevant, Time-bound) will be formulated. The scale runs from -2 to +2: 0 is the SMART formulated goal; -2 and -1 is scored when outcome is below the goal; +1 and +2 is scored when outcome is above the goal. Participants will fill in the scale weekly on a smartphone app, which will take about 2 minutes.
This scale is used to investigate whether participants improve in personal goals with regard to their functioning in daily life by means of the cognitive remediation intervention.

Happiness single item scale: This scale is used to assess general wellbeing. The question is asked: “Do you feel happy in general?” The participant answers on a 11-point score (0-10). This single item scale by A.M. Abdel-Khalek (2006) shows good concurrent, convergent and divergent validity. Participants will fill in the scale weekly on a smartphone app, which will take about 1 minute.
This scale is used to investigate whether the general wellbeing of participants improves by means of the cognitive remediation intervention.

To account for the covariate sleep in the weekly measures of goals and general wellbeing, participants also will be asked to give an indication of hours slept the previous night on the smartphone app.

Toelichting onderzoek

Achtergrond van het onderzoek

Mood symptoms in bipolar disorder (BD) generally tend to lessen within a foreseeable time, but functional recovery often takes a lot longer and ±50% maintain having problems in daily functioning (APA, 2013; Sanchez-Moreno et al., 2009). Literature indicates that in almost 50% of the cases of BD (BDI as well as BDII) is accompanied by neurocognitive impairments that persist after recovery from mood symptoms and cannot be explained by medication. The impairments resemble neurocognitive problems seen in schizophrenia (Tsitsipa et al., 2015), and relate to the reduced psychosocial functioning in BD (s.a. Gitlin & Miklowitz, 2017). So, it can be argued that an approach aimed at improving the neurocognitive problems (known as cognitive remediation) in BD can lead to improvements in daily functioning and well-being. With schizophrenia this approach has already claimed positive results (s.a. Best & Bowie, 2017), with BD this is still in its infancy. Goal of this study is to find out if cognitive remediation focused on executive functioning for patients with bipolar disorder improves (1) functioning on personal goals in everyday life, and (2) improves general wellbeing. Expectations are that the intervention will lead to a positive outcome on these different aspects.

Doel van het onderzoek

Cognitive remediation focused on executive functioning for patients with bipolar disorder improves executive functioning on (1) personal goals in daily life, and (2) general well-being.

Exploratory hypotheses:
- Cognitive remediation focused on executive functioning for patients with bipolar disorder improves subjective cognitive functioning in daily life.
- Cognitive remediation focused on executive functioning for patients with bipolar disorder improves psychosocial functioning and self-sustainability.
- Cognitive remediation focused on executive functioning for patients with bipolar disorder improves quality of life.
- Cognitive remediation focused on executive functioning for patients with bipolar disorder improves symptomatology.

Onderzoeksopzet

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Onderzoeksproduct en/of interventie

The experimental treatment will consist of a 12-week cognitive remediation program focussed on enhancing executive functioning. There will be weekly sessions of 2 hours and the treatment will take place in a group consisting of 10 participants. The treatment will be given by two experienced neuropsychologists.
The cognitive remediation will be based on both a treatment protocol for patients with acquired brain injury and problems in executive functioning (Boelen et al., 2012) and a treatment protocol for patients with ADHD (Scholtissen-In de Braek et al., 2012). Both protocols rely heavily on Goal Management Training (GMT, Levine et al., 2000). The treatment protocol for acquired brain injury also relies on Problem Solving Training (PST, von Cramon & Matthes von Cramon 1994). Both protocols encompass compensatory remediation, whereby participants learn new skills to better manage cognitive impairment. Themes in the protocol will be (1) Information and Awareness, (2) Goal Setting and Planning, and (3) Initiation, Execution, and Regulation. The protocol will be revised for the bipolar group and submitted for expert review by two experienced neuropsychologists.
There will be weekly homework assignments, that will be discussed in the following group session.
Treatment as usual consisting of pharmacotherapy and supportive care will continue during the cognitive remediation treatment.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
Participants need to be of adult age (18-65 years old), diagnosed with a bipolar I of bipolar II disorder, and need to be stable for 3 months. At the moment of inclusion stability of symptomatology is assessed by a score of <5 on the Altman Self-Rating Mania Rating Scale (Altman et al., 1997) and a score of <16 on the Quick Inventory of Depressive Symptoms (Rush et al., 2003); these are criteria also used in the study by Zyto et al (2016). The clinical DSM diagnosis will be confirmed with the MINI-plus 5.0.0. The Cognitive Failure Questionnaire (CFQ; Broadbent et al., 1982; Merckelbach et al., 1996; Ponds, van Boxtel & Jolles, 2006) will be used to assess perceived cognitive dysfunction in daily life. To participate the CFQ score must be >43 (1 SD above mean).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
An IQ < 80 as assessed by the Dutch Adult Reading Test (DART; Schmand and Van Harskamp, 1992), neurological problems, acquired brain injury, electric convulsive therapy in the past 12 months, substance abuse in the past 3 months, psychotic disorder, autism spectrum disorder, attention deficit disorder, rapid cycling, and neurocognitive disturbances due to severe posttraumatic stress disorder.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8654
Ander register	METC Erasmus MC : No ID yet, it is still to be issued

Resultaten