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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27541

Source
NTR

Brief title
TBA

Health condition

Bipolar disorder, type I and type II

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Funding by GGZ Delfland, study budget

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Quick Inventory of Depressive Symptomatology (QIDS-SR: Rush et al., 2003): A questionnaire that consist of 16 questions by which to assess the severity of the nine diagnostic symptom criteria of depression used in the DSM. Internal consistency was high and total scores were highly correlated with IDS-SR30 (.96) total scores (Rush et al., 2003). It takes about 5 minutes to complete this questionnaire. This scale will be used as a descriptive measure. It will also be used as a covariate and an exploratory measure, to examine if the cognitive remediation improves symptomatology.

Altman Self-Rating Mania Scale (ASRM-NL; Altman et al., 1997): A 5-item self-rating questionnaire, used to measure the presence and/or severity of manic symptoms. The questionnaire has a significant correlation with the Young Mania Rating Scale (YMRS). Specificity is 85.5, sensitivity is 87.3. Questions are scored on a Likert scale from 0-4 (Altman et al., 1997; Renes, J.W. and Kupka, R.W., 2009). It takes about 3 minutes to complete this questionnaire. This scale will be used as a descriptive measure. It will also be used as a covariate and an exploratory measure, to examine if the cognitive remediation improves symptomatology.

Cognitive Failure Questionnaire (CFQ; Broadbent et al., 1982; Merckelbach et al., 1996; Ponds, van Boxtel & Jolles, 2006): A commonly used questionnaire that is used to assess the level of subjective cognitive complaints. The scale consists of 25 items measuring the occurrence of cognitive problems in everyday life; items are scored on a 5-point scale. Higher scores indicate more frequent cognitive failures. The scale is validated in Dutch, internal consistency is acceptable to good, and test-retest reliability is high. A cut-off score of >43 is used to indicate problems in everyday life, which is 1 SD above mean. Time to administer is about 5-10 minutes.

The CFQ is used as an exploratory measure to examine if cognitive functioning in daily life improves by means of the experimental intervention. This scale is also used to select participants.

Functioning Assessment Short Test (FAST; Rosa et al., 2007): A short (3-6 minutes) interview-administered instrument to measure functioning in daily life. The FAST is developed by Rosa et al. (2007) as a measure of disability of psychosocial functioning in bipolar disorder. The 24 items of the scale are divided among 6 specific areas of functioning: autonomy, occupational functioning, cognitive functioning, financial issues, interpersonal relationships and leisure time. Higher scores indicate more problems and lower functioning on the indicated domains. The FAST showed strong psychometrics properties in the study by Rosa et al. (2007). Renes & Kupka (2010) made a Dutch translation (the FAST-NL-P), which was also used by Zyto et al. (2016). This translation is not yet formally validated.
The FAST is used as an exploratory measure to investigate possible amelioration in psychosocial functioning by means of the experimental intervention.

EuroQol (EQ-5D-3L): A questionnaire to assess quality of life, the general wellbeing of a person on various aspects of life. The questionnaire comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The respondent is asked to judge his/ her health state on these dimensions by choosing between three levels: no problems, some problems, extreme problems. Also, respondents are asked to judge their health state on a visual analogue scale (VAS-scale). Different studies have shown the EQ-5D-3L to be a reliable and valid instrument (Dyer et al., 2010; Prieto et al., 2003; Luo et al., 2003). Time to administer is about 5-10 minutes.
This questionnaire is used as an exploratory measure to investigate if the experimental intervention leads to an improvement in quality of life.

Session Rating Scale (SRS; Miller et al., 2000): An adaptation of the SRS will be used to explore treatment satisfaction with regard of the experimental intervention. Participants will be asked to judge the intervention on 4 dimensions (relationship, goals and topics, approach or method, overall) on VAS-scales. It will take about 5 minutes to complete this scale.

Study description

Background summary

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.

Study objective

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.

Study design

31

Intervention

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.

Contacts

Public
GGZ Delfland
Meike Smit

0612658680
Scientific
GGZ Delfland
Meike Smit

0612658680

Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results