Cognitive rehabilitation treatment (CRT) in patients with bipolar disorder and cognitive problems.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Manic and bipolar mood disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON49678

Source
ToetsingOnline

Brief title
CRT with bipolar disorder and cognitive problems.

Condition

- Manic and bipolar mood disorders and disturbances

Synonym
bipolar disorder and manic-depression

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Breburg Groep (Rijen)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bipolar disorder, cognitive problems, Cognitive rehabilitation treatment

Outcome measures

Primary outcome

The primary outcome of "subjective complaints" is measured with the Cognitive Failure Questionnaire (CFQ) (Broadbent, Cooper, FitzGerald & Parkes, 1982). The CFQ (appendix 1) is a self-report questionnaire in which patients indicate the number of mistakes made regarding their cognitive impairment (e.g., forgetting names). The questionnaire contains 25 items measured with a 5-point scale (0 = *never* to 4 = *always*), with a range from 0 to 100. The CFQ has good psychometric qualities, including test-retest reliability (Ponds, van Boxtel & Jolles, 2006) and reliability (Bridger, Johnsen & Brasher, 2013). A higher score on the CFQ indicates more subjective cognitive symptoms than a lower score on the CFQ. Significant differences between thee CFQ score at T1 and T0 will be examined.

Secondary outcome

The objective cognitive symptoms are measured by a short neuropsychological examination (NPO), in which attention and concentration, verbal learning and memory, and executive functioning are measured. The scores on this neuropsychological assessment are subsequently classified as *no neurocognitive problems* (greater than or equal to the 20th percentile), "deficit" (between the 2.4th-20th percentile) or "impairment" (less than the 2.4th percentile) (Lezak, Howiesan, & Loring, 2012).

At T0, the Digit Series subtest and the Symbol Substitution subtest of the

Wechsler Adult Intelligence Scale (WAIS-IV-NL; Wechsler, 2012) are administered and measure working memory and processing speed, respectively. The Tower Test of the D-KEFS is used to measure executive functioning (Delis et al, 2001). The 15-word test is used to measure verbal memory and learning ability (15WT; Kalverboer & Deelman, 1986). The d2 is used to measure sustained attention (Brickenkamp, 2002). The psychometric qualities of these tests are sufficient to good and can be found in the test manuals (Brickenkamp, 2002; "Delis et al., 2001; Kalverboer & Deelman, 1986; Wechsler, 2012).

This neuropsychological assessment is repeated after completion of CRT at T1.

Study description

Background summary

A bipolar disorder is a chronic and recurring mental disorder, that is characterized by one or multiple hypomanic or manic episodes, usually altered with depressive episodes (Kupka & Hilligers, 2012). Bipolar disorder affects approximately 2% of the Dutch population in life, while the prevalence for the wider bipolar spectrum [hypomanic without depressive phase, hypomanic less severe or shorter in duration than specified in the Diagnostic and Statistical Manual of Mental Disorders (DSM) and the International Statistical Classification of Disease and Related Health Problems (ICD)] is estimated at 5% (van der Werf-Eldering, Schouws, Arts & Jabben, 2012). Bipolar disorder is associated with enhanced disability compared to other prominent chronic disorders, such as asthma or diabetes (Sajatovic, 2005). Patients with bipolar disorder experience difficulties in work functioning, a decrease in social engagement, weaker family relationships, and difficulties in long-term relationships (Michalak, Yatham, Maxwell, Hale, & Lam, 2007; Bauwens, Tracy, Pardoen, Elst, & Mendlewicz, 1991; Shapira et al., 1999; Mitchell, Slade, & Andrews, 2004; Thomas, Nisha, & Varghese, 2016). Cognitive dysfunction in bipolar disorder is associated with a reduced functional outcome in general (Depp et al., 2012).
The last two decades, studies exploring cognitive dysfunction in patients with bipolar disorder increased in number. These studies did not result in a consistent neuropsychological profile, but consensus was reached; primarily difficulties regarding executive functioning and memory were

reported. In addition, cognitive dysfunction has also been reported in the processing speed and concentration domains (Sagar, Sahu, Pattanayak, & Chatterjee, 2018, Tsitipa & Fountoulakis, 2015). According to Sagar and colleagues (2018), there are indications that cognitive dysfunction in patients with bipolar disorder can be regarded as a trait as well as a state. Other studies suggest that neurodevelopmental factors play a role in cognitive dysfunction in patients with bipolar disorder (Bora & Özerdem, 2017; Kloiber et al., 2020).
Studies estimated the prevalence of cognitive dysfunction in patients with bipolar disorder around 40 to 60 percent, which remain also in the euthymic phase (Martino, 2008; Martinez-Aran et al., 2009). Cognitive dysfunction in the euthymic phase of the bipolar disorder is considered an important predictor for limitations in psychosocial functioning (Depp et al., 2012; Zarate, Jr., Tohen, Land, & Cavanagh, 2000). One intervention that offers a treatment option for cognitive dysfunction is neuropsychological treatment.

Neuropsychological treatment focuses on: *The treatment of patients with cognitive, emotional, social and / or behavioural consequences of brain injury and / or treatment of the system of these patients, aimed at learning how to deal with these consequences as well as possible.* (Van Heugten, Bertens, & Spikman, 2017). This kind of treatment includes training of mental processes and tasks (Anaya et al., 2012; MacQueen & Memedovich, 2016). Some studies show positive effects of neuropsychological treatment on cognitive dysfunction in patients with acquired brain injury (Vaessen & van Balen, 2014; Anaya et al., 2012). However, studies that focus on these kinds of treatment are limited since they mostly focus on patients with acquired brain injury. Nevertheless, cognitive dysfunctions in people with mental disorders are comparable to both the cognitive and the emotional, social and / or behavioural consequences in people with brain damage (Konrad et al., 2010).
Neuropsychological tests are valuable to gain insight into the strengths and weaknesses profile surrounding cognitive dysfunction, but do not identify problems in daily life due to the cognitive symptoms (Wilson, 2003).
The best of our knowledge, studies exploring the effect of neuropsychological treatment in patients with bipolar disorder lack. However, a recent case-study exploring the effect of cognitive rehabilitation therapy (CRT) showed positive results regarding executive functioning in a patient with bipolar disorder (De Vroege et al., under review).
These first results suggest that CRT offers an option of treatment that improves cognitive symptoms in patients with bipolar disorder. CRT improves cognitive functioning by training previously acquired skills and learning alternative strategies (Tsaousides & Gordon, 2009) CRT was primarily developed for patients with cognitive impairment after stroke or traumatic brain damage (van Heugten, Caldenhove, Crutsen, & Winkens, 2019) but may also be beneficial for patients with bipolar disorder.
GGz Breburg has opted to offer CRT to patients with bipolar disorder in order to improve their cognitive functioning. Because cognitive dysfunction is seen as an important predictor for limitations in psychosocial functioning.

Psychosocial functioning may improve as a result of improved cognitive functioning (Depp et al., 2012; Zarate et al., 2000). Therefore, the present study investigates whether patients receiving CRT improve with regard to subjective cognitive symptoms. We expect such an improvement after CRT and hypothesize that this improvement can also be measured using a neuropsychological assessment.

Study objective

The primary objective of the study is to investigate whether CRT reduces subjective cognitive symptoms.
It is hypothesized that there is a significant improvement in subjective cognitive symptoms as measured by the Cognitive Failure Questionnaire (CFQ; Ponds et al., 1998) on the post-test (T1, after CRT) compared to the pre-test (T0, before CRT).
The secondary objective is to investigate whether this improvement can be measured using a neuropsychological assessment.
It is hypothesized that cognitive improvement is apparent i.e., higher scores on neuropsychological assessment are expected after CRT (T1) compared to before CRT (T0). Whether these kinds of improvements can be measured using a neuropsychological assessment is debated (Harvey,2012; Wilson, 2003) but we expect to find significant differences between the two neuropsychological assessments.

Study design

This study is a naturalistic pre-test-post-test design. Patients follow the regular treatment procedure designed for patients with bipolar disorder who experience cognitive difficulties. The research will last three years and will take place within GGz Breburg, with team bipolar West and team bipolar East. A pre-test-post-test design is chosen because it allows to determine whether there are indications that CRT may have a positive effect on cognitive complaints in patients with bipolar disorder. The advantage of such a design is that burden for patients is considered minimal (i.e., CRT is regular care, the first, short, neuropsychological assessment serves as an indicator for the direction/aim of CRT). The disadvantage of this design is that it does not allow any statements regarding the causality.

Intervention

CRT is made freely available (Boom, 2010) (https://www.boompsychologie.nl/productgroep/101-15_Neuropsychologie#downloads).

The CRT is offered individually to a patient. It is applied to a specific cognitive problem that must be objectified prior to the CRT (conformed in the protocol, see

https://www.boompsychologie.nl/media/13/protocol_dysexecutief_syndroom.pdf). This allows a practitioner to tailor treatment to a patient's perceived cognitive symptom. At the start of the CRT, the problems in daily are examined together with the patient which he or encounters as a result of the cognitive symptoms. Treatment consists of three phases; 1) psychoeducation, 2) goal setting and planning, and 3) implementation. CRT can be aimed at improving executive functioning, memory problems or problems with time constraints. Treatment is adapted to the patient's problems. Because of this there is a variation in the duration of treatment. During CRT, various information leaflets are used, worksheets and exercises are provided by the treatment protocol. There is a minimum of 12 sessions and a maximum of 19 sessions. The intensity and degree of recurrence can be adapted to the patient.

Study burden and risks

The baseline measurement (pre-test T0) and the intervention are part of the standard care. The supplement to the study is a post-measurement (post-test) of no more than one hour. Patients may participate voluntarily and can stop the study at any time, without giving any reason. The reason for withdrawal from the CRT is asked, but it is explicitly stated that patients are not required to provide the reason.
Participation will take place with a signed informed consent for the pseudo-anonymised use of the collected data. The practitioners are trained in CRT. With this study, we hope to gain more insight whether CRT may have a positive effect on the cognitive symptoms of patients with a bipolar disorder. To the best of our knowledge, this is the first study that explores such a treatment in this patient group.

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

- primair classification is bipolar disorder
- presence of cogntive problems in the neuropsychological profile
- patiënt are in the euthymic phase
- treatment with medication is stable.

Exclusion criteria

- a depressive, hypomanic or manic phase
- no objective cognitive problems

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	01-01-2020
Enrollment:	34
Type:	Actual

Ethics review

Approved WMO Date:	16-12-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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
CCMO	NL75016.028.20