A combined group and individual functional remediation blended care program for patients with unipolar recurrent depression or bipolar-I disorder; A pilot study.

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Primary objective: To investigate the feasibility of a program for functional remediation for patients with BD-I or recurrent MDD, through • Evaluation of user experiences with the program. • Evaluation of drop-out and reasons for drop-out. •…

Ethical review	Approved WMO
Status	Completed
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON52514

Source
ToetsingOnline

Brief title
FRMD

Condition

- Cognitive and attention disorders and disturbances

Synonym
cognitive impairment in mood disorders, impairment of memory and attention in depression and mania

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: GGZ NHN

Intervention

Keyword: cognitive impairment, functional remediation, mood disorders, psycho-social functioning

Outcome measures

Primary outcome

The main study parameter will be the feasibility of the program as defined by

the evaluations of the participants on closed and open ended questions and the

non-compliance and drop-out rate and reasons for dropout and non-compliance.

The two variants, fully offered online and blended, will be compared to each

other on these variabels. In addition the experiences with the online

application " Niet rennen maar plannen" will be evaluated through ratings on

closed questions.

Secondary outcome

The secondary study parameters will be the indication of change in subjective

cognitive complaints, functional improvement and change expressed in QALYs.

Study description

Background summary

This study is a pilot to evaluate the feasibility of a functional rehabilitation program in a mixed group of patients with bipolar or unipolar recurrent depression and cognitive complaints.
Although there is evidence that the cognitive deficits in the euthymic phase of mood disorders are important predictors of enduring limitations in psychosocial functioning (Depp et al.,2012; Baune et al., 2010, Baune & Malhi, 2015, Lam et

al., 2012, Wingo et al.,2009) there have been few studies addressing functional remediation in this group of patients.

Study objective

Primary objective:
To investigate the feasibility of a program for functional remediation for patients with BD-I or recurrent MDD, through

• Evaluation of user experiences with the program.
• Evaluation of drop-out and reasons for drop-out.
• Evaluation of user experiences with working with an E-health module.
• Evaluation of user experiences per diagnostic subgroup.
• Evaluation of user experiences with a complete online program versus blended

Secondary objective:
Exploration of functional improvement and subjective complaints through:

• Exploring change of psychosocial functioning, immediately after the treatment, and at 3 months.
• Exploring change of subjective cognitive complaints, immediately after the treatment, and at 3 months.
• Exploring change expressed in Quality-Adjusted Life Years (QALYs).

Study design

Uncontrolled clinical pilot study to investigate the feasibility of a functional remediation program added to TAU, excluding group-treatment, in patients with BD-I or recurrent MDD.

Intervention

The intervention consists of a functional remediation program, based on strategies for the treatment of patients with acquired brain injury (Sohlberg en Mateer, 2001, Wilson, 2003, Haskins, 2012). The strategies are aimed at the neuropsychological problems associated with mood disorders as reported in the literature: memory, speed of information processing and executive functioning. The 12-session program consists of 6 group sessions followed by 6 individual computer based online sessions. The program has 2 variants of which the first, *Niet rennen maar plannen -online*, is fully offered online, by GGZ inGeest.The group sessions will be held through a secure Google Meet application. The second variant, *Niet rennen maar plannen*, is a blended program, with live group sessions that will be held at GGZ NHN.The individual sessions will be given through the same computer based application as the first, online variant. The program will be preceded by an individual pre-treatment session in which the results of the neuropsychological assessment will be communicated to the

patient by the researcher. Between sessions, homework assignments will be made online.
The group based intervention consists of 6 weekly sessions of two blocks of 45 min, with a 15 min break between the blocks. During the *rst session, neurocognitive problems associated with mood disorders, and their implications for daily life, will be discussed in an interactive way.
The subsequent group sessions consist of specific information, homework and practices, based on theory about the functioning of attention, processing speed, and executive functioning. During the first computer based individual session patients set goals. In the subsequent online sessions the patients work weekly towards their goals using the online protocols and strategies presented in worksheets. After each online session the patients receive feedback of the filled out worksheets from one of the psychologists involved in the program.

Study burden and risks

The objective of the current study is to test the feasibility of a functional remediation program, as an adjunctive intervention to treatment as usual (TAU). The treatment may lead to an improvement in psycho-social functioning and quality of life.
The treatment protocols have previously been used in treatment for a wide range of patients including patients with brain injuries, bipolar disorder and schizophrenia.Participants may benefit directly from the intervention. A possible risk associated with participation may consist of confrontation with own disability and that of others.
The extra burden of all participants is undergoing a structured diagnostic interview, undergoing a neuropsychological assessment and filling out rating scales.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

o Age: 18-60
o Bipolar I Disorder or recurrent Major Depression according to DSM 5 as diagnosed by a psychiatrist and verified by MINI-Plus
o Subjective cognitive complaints
o At least moderate levels of functional impairments, Functioning Assessment Short Test (FAST) interview > 18
o NLV (Dutch National Adult Reading Test) IQ > 85
o Informed consent signed by patient before participation
o Availability of a computer with internet and sufficient computer skills
o Being able to read and write in Dutch
o Mentally competent as documented in the formal treatment plan.

Exclusion criteria

oCurrent mania or severe depression (defined by scores > 5 on the Altman Self-Rating Mania Rating Scale and >15 on the Quick Inventory of Depressive Symptoms)
o Substance or alcohol abuse within the last 3 months (de*ned as more than 2 units/day for men, and more than 1 unit/day for women).
o A history of neurological disease or traumatic brain injury
o Electroconvulsive treatment (ECT) within the last 12 months
o Currently participating in a group-treatment, or planning to participate within 3 months after the intervention.
oPrior participation in the study *A pilot study of a combined group and individual functional remediation program for patients with bipolar I disorder*.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	28-02-2020
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	12-11-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-04-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL66487.029.18