BrainFit, the effect of online cognitive training on cognition in patients with late life moodsymptoms.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54929

Source
ToetsingOnline

Brief title
BrainFit

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
subjective cognitive complaints in patients with a depressive or bipolar disorder / self-experienced cognitive complaints in patients with mood disorders

Health condition

cognitieve klachten

Research involving

Human

Sponsors and support

Primary sponsor: GGZ inGeest (Amsterdam)
Source(s) of monetary or material Support: Stichting tot Steun VCVGZ

Intervention

Keyword: cognitive training, late life bipolar disorder, late life depression, online intervention

Outcome measures

Primary outcome

Primary outcome is the effect on cognitive executive functioning (Stroop

Task).

Secondary outcome

Secondary outcome measures includes objective cognitive functioning, and also

the effect on mood symptoms, social functioning, quality of life and sense of

Mastery. Also the feasability of the training will be studies.

Study description

Background summary

Relevance
An effective therapeutic intervention for cognitive impairment is an important unmet medical need in patients with late onset mood disorders (LLMD). Cognitive impairment is a core feature of the illness and responsible for poor outcome. By treating cognitive impairment we expect to improve cognition and depressive symptoms in LLMD. Additionally, as cognition is related to social functioning, an effect of cognitive training on improvement of social functioning is to be expected. In current treatments, cognitive complaints are highly underestimated, with a less positive prognoses for these patients. Cognitive training has showed its benefits in other diseases. Our primary goal is to investigate the effect on (subjective) cognitive symptoms. A secondary goal is to explore the effect on objective cognitive functioning, moodsymptoms,

social functioning and the feasability of an online cognitive training for depressed patients.

Study objective

Our primary goal is to develop an easy access cognitive training for older patients with mood disorders suffering from (subjective) cognitive complaints. We want to study the effect on both objective and subjective functioning. Secondary, we aim to study the effect on mood symptoms, social functioning and the feeling of Mastery and quality of life. Furthermore we aim to study whether the effects will last during 3 months after quitting the training. Also we want to enlight the feasability of the online cognitive training for our study population.

Study design

In this current dubbelblind, randomized controlled study patients will be randomly assigned to the online cognitive training (BrainGymmer > executive functioning, attention) versus the active control cognitive training (no specific trainingseffect expected). We will stratify for polarity (unipolar and bipolar depression). This active control condition is different from Care as usual as control-condition, by profiding this active control training we hope to rule out a-specific effects.
Patients will train 3 x/week 45 minutes for 8 weeks. We will do pre-post- and follow-up measures three months after the last training.

Intervention

Intervention
The training games are specifically designed to enhance attention, information processing speed, working memory and executive functioning, cognitive domains that are commonly affected in LLMD, by dynamically adjusting to the individual*s performance. As a comparator we use an active control condition where patients play games that do not make great demands on executive processes (solitaire) or rely on general knowledge (hangman, trivia questions). The training can be performed at the patient*s convenience at their preferred place and time on a computer or tablet. Both conditions will last approximately 45 minutes, three times a week during eight weeks.

Study burden and risks

Risks
During the study, the participant will be asked to come over to GGZ inGeest for four times. First for intake and neuropsychological assessment. If no inclusion > questionnaires (1.5 - 2 hours). second for explanation of the training, third and fourth for post-training measurements. On voluntary basis participants are

asked to joing mirror sessions or feedback sessions to evaluate the training in a group ow fewllow participants.
If possible the visits will be combined with appointments that where already planned for regular care. If traveling is too much of a burden for the participants, the screening, neuropsychological assessment and questionnaires can take place at home. During the intervention, participants need to train for 45 minutes, three times a week during 8 weeks. This can either be the online cognitive trainingprogram or a 'control' training. We think the risk negligible. Based on a previous study we do even expect beneifts for the partcipants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

- Subjective cognitive complaints measured with the Subjective Cognitive

Failure Questionnaire, with a cut-off of * 44.
- early or partial remission of depressive episode with a diagnosis of unipolar recurrent depression (current episode is at least the third episode and shorter than 2 years) or bipolar disorder according to DSM 5 criteria.
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Exclusion criteria

- Possible Dementia syndrome, measured by the Montreal Cognitive Assessment score < 22, or when described in the medical file.
- Drugs- of alcohol abuse, measured by CAGE-AID = 1.
- Inability to do a neuropsychological assesment or to do the computerized intervention (fatigue, eye complaints or language barrier).
- Current psychotic symptoms as described in their medical file.
- Serious suicidal thoughts
- Serious personality disorder as main diagnosis.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2019
Enrollment:	38
Type:	Actual

Ethics review

Approved WMO Date:	12-09-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-11-2021
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	NL69568.029.19