Changing treatment of patients with a recurrent depressive disordered from cognitive behavioral therapy to acceptance and commitment therapy after early non-response to treatment

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21689

Source
NTR

Brief title
CBTACTMDD

Health condition

Recurrent major depressive disorder

Sponsors and support

Primary sponsor: HSK-groep
Source(s) of monetary or material Support: HSK-groep

Intervention

Outcome measures

Primary outcome

Total outcome scores on the QIDS-SR (depressive symptoms questionnaire), compared between groups

Secondary outcome

Total outcome scores on the MHC-SF (positive mental health questionnaire), compared between groups

Study description

Background summary

For more than a third of patients with major depressive disorder (MDD) cognitive behavioral therapy (CBT) does not lead to remission. Therefore, methods to help improve treatment outcome would be desirable. Possibly, this improvement can be achieved by offering these patients recently developed new treatment options though a stepped care system. Since early reduction of symptoms are a good predictor to final treatment outcome, changing CBT to a different kind of treatment might help more patients reach remission. In this study we will compare CBT with acceptance and commitment therapy (ACT) for early non-responders to CBT. All patients will first receive 5 sessions of CBT. If there is insufficient decline of depressive symptoms, then those patients will receive either 15 more sessions of CBT or 15 sessions of ACT. During the treatment we will score their depressive symptoms and positive mental health with questionnaires every 5 sessions. The aim of this non-randomized clinical trial is to compare the effectiveness of this stepped care program and to generate recommendations for further research.

Study objective

1) Early non-responders with MDD who after 5 sessions of CBT change from CBT to ACT will have fewer depressive symptoms by the end of therapy in comparison to early non-responders with MMD that continue CBT.
2) Early non-responders with MDD who after 5 sessions of CBT change from CBT to ACT will score higher on positive mental health by the end of therapy in comparison to early non-responders with MDD that continue CBT.

Study design

This study will follow patients over 20 weekly sessions. The first 5 sessions consist of CBT in both conditions. The last 15 sessions will consist of either CBT or ACT, depending on the allocated condition. Measurements with the QIDS-SR and the MHC-SF will be done at session 5, 10, 15 and 20. There is a measurement with the QIDS-SR before session 1, solely with the intention of being able to see if patients lack response to treatment at session 5. There is lack of response to treatment when the total score of the QIDS-SR dropped less than 25% by session 5. After session 20 the study will end (although treatment may continue), there is no

follow up.

Intervention

All participants will receive five sessions of CBT in treatment phase 1 based on a manual by Bockting, Van Rijsbergen & Huibers (2017). In treatment phase 2, the CBT-group will continue with CBT from this manual for 15 more therapy sessions. In the ACT-group patients will switch to an ACT manual (A-Tjak, 2020) for 15 more therapy sessions as soon as they enter treatment phase 2. All sessions will consist of face to face, 45-minute sessions, at HSK-groep locations.

Contacts

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Eligibility criteria

Inclusion criteria

Participants will be selected from patients, aged between 18 and 70 years, referred by their general practitioner to mental health care organization HSK-groep. During the first diagnostic assessment we will screen patients for criteria of a recurrent depressive disorder. Only patients who have a total score of 11 or higher on the Quick inventory of Depressive Symptomatology – Self Report (QIDS-SR), indicating at least a moderate level of depressive symptoms, are admitted to this study. Use of anti-depressive medication is allowed as long as patients do not change medication or dose.

Exclusion criteria

Exclusion criteria for the study are a high risk of psychosis or suicide, organic brain syndrome, severe substance-abuse, borderline or antisocial personality disorder, inability for

patients to focus sufficiently on their treatment, inability for patients to fill out questionnaires or having other problems taking precedence over their depression.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-02-2021
Enrollment:	36
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Participants will receive a randomized patient code. This code can only be traced to their name through an secure electronic patient file system at HSK. Patients data will analyzed without their names and only their patient code. Data is collected by participating therapists and shared on a protected electronic system with the study leader, who will start with data-analysis. Analysis is done through SPSS with an ANOVA repeated measures (within-between interaction) comparison. The study will share its results through a published article. Only group scores and comparisons will be shared, no individual data.

Ethics review

Positive opinion

Date:	22-12-2020
Application type:	First submission

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	NL9137
Other	Commissie Mensgebonden Onderzoek regio Arnhem-Nijmegen : 2020-7153

Study results

Summary results
No publications have been done yet. However, out aim is to publish the results of this study in a scientific journal.