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

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21689

Bron
NTR

Verkorte titel
CBTACTMDD

Aandoening

Recurrent major depressive disorder

Ondersteuning

Primaire sponsor: HSK-groep
Overige ondersteuning: HSK-groep

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	11-02-2021
Aantal proefpersonen:	36
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
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.

Ethische beoordeling

Positief advies

Datum:	22-12-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9137
Ander register	Commissie Mensgebonden Onderzoek regio Arnhem-Nijmegen : 2020-7153

Resultaten

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