Effectiveness of core elements in CBT for depressed youth

No registrations found.

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

Summary

ID

NL-OMON26169

Source
NTR

Brief title
STARr_individual

Health condition

Depressive disorder

Sponsors and support

Primary sponsor: Trimbos Instituut
Source(s) of monetary or material Support: Zonmw

Intervention

Outcome measures

Primary outcome

The primary study parameters are the change in depressive symptomatology.

Secondary outcome

The secondary parameters are: cognitions, behaviour and emotions as measured with the

daily assessment, treatment adherence, demographic information (gender, age, ethnicity, education level, family income and/or experience to the self-report questionnaires), depression symptoms, presence of a depression diagnosis, depression severity, comorbidity, quality of life, the top three problems, negative automatic thoughts, behavioral activation, treatment satisfaction, treatment integrity and suicide risk.

Study description

Background summary

SUMMARY
Rationale: Depression is one of the most prevalent mental disorders in adolescence, and a major health concern. Thus far, Cognitive Behavioural Therapy (CBT) programs are most applied and found most effective. However, little is known about the differential and sequential
effects of the different CBT components. Objective: Based on previous research, the proposed study will investigate the differential and sequential effects of the two most effective
components of CBT, Cognitive Restructuring (CR) and Behavioural Activation (BA). More specifically, we will investigate to what extent each module reduced depressive symptoms, and which order of modules leads to a larger symptom reduction. We will further investigate how adolescents and their therapists evaluate this sequential treatment. Study design: We will use a Single Case Experimental Design (SCED) with two conditions/groups. Study population: Participants (N=12) will be adolescents aged 12-18, diagnosed with a clinical depression using the Kiddie Schedule for Affective Disorders and Schizophrenia, present and lifetime version. Intervention: All participants take part in the following 12-week trajectory: first
diagnostic measurement (T0, clinical interview and online questionnaires); 3-week baseline period (daily monitoring); second diagnostic measurement (T1: online questionnaires), first 3-week intervention phase (BA or CR and daily monitoring), third diagnostic measurement (T2: online questionnaires); second 3-week intervention phase (CR or BA and daily monitoring); fourth diagnostic measurement (T3: online questionnaires); 3-week post-treatment phase (daily monitoring); fifth and last diagnostic measurement (clinical interview and online questionnaires). Half of the participants (N=6) will be randomly assigned to the BA first, CR second condition, and the other participants (N=6) to a CR first, BA second condition. Main study parameters/endpoints: The primary study parameters are the change in depressive symptomatology as measured with the CDI-2 at the diagnostic measurements, and changes in core depression symptomatology, cognitions, behaviour and emotions as measured with the
daily questionnaire. Changes in these parameters across the different phases will be investigated using SCED-specific analyses, comparing phases within individuals and individuals between conditions. As such we aim to provide insights into the differential and sequential effects of the CR and BA CBT-elements.

Study objective

The beneficial effect will be bigger than average for those adolescents who receive BA before CR, and smaller than average for those
adolescents who receive CR before BA.

The primary objective is to establish the differential and sequential effectiveness of cognitive restructuring (CR) and behavioral activation (BA) (and the optimal sequence of these elements) on depressive symptoms (PHQ-2 at post treatment) in referred adolescents diagnosed with a depressive disorder.

The secondary objective is to investigate the feasibility and effectiveness of the CBT elements as judged by the clinicians and adolescents.

Study design

Assesments and CBT-elements for each condition per session.
Week 1 2 3 4 5 6 7 8 9 10 11 12
Condition A baseline CR CR CR BA BA BA Follow Up
Condition B baseline BA BA BA CR CR CR Follow Up
Daily ass. X. X X X X X X X X X X
Diagnostics T0 T1 T2 T3 T4
Note: CR = cognitive restructuring; BA = behavioral activation

Intervention

The two most effective components of CBT, Behavioural Activation (BA) and Cognitive Restructuring (CR) will be researched. Each component consists of three weekly sessions of 45 minutes.
The BA module aims to educate adolescents on the relationship between activity and behavior, and how to influence their emotional wellbeing through behavioral activation.
The CR module aims to train adolescents to: identify their own cognitions; understand the relation between events and their cognitions, feelings, and behaviors; challenge unhealthy
cognitions; create new, healthier cognitions. Each of the three sessions, adolescents take a step further in this learning process,

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• age between 12-18 years old;
• sufficient knowledge of the Dutch language;
• diagnosed with a major depressive disorder with the K-SADS

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• absence of adolescents' or parental permission (for subjects aged younger than 16)
• acute and severe suicidal thoughts and/or intentions
• if the adolescent receives medication for depression and the medication is not yet stable at the start of the study, or is changed during the course of the study
• when the adolescent does not own a mobile phone to complete the daily questionnaires on

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2019
Enrollment:	12
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-12-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49844
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8201
CCMO	NL66762.041.18
OMON	NL-OMON49844

Study results