

Effectiveness of core elements in CBT for depressed youth

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

Samenvatting

ID

NL-OMON26169

Bron

NTR

Verkorte titel

STARr_individual

Aandoening

Depressive disorder

Ondersteuning

Primaire sponsor: Trimbos Instituut

Overige ondersteuning: Zonmw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary study parameters are the change in depressive symptomatology.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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,

Contactpersonen

Publiek

University Utrecht
Yvonne Stikkelbroek

0644057782

Wetenschappelijk

University Utrecht
Yvonne Stikkelbroek

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2019
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	02-12-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49844
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten