Core elements of Cognitive Behavioural Therapy in treatment of depression in youth: does the type and sequence of elements matter

Published: 20-02-2019
Last updated: 15-05-2024

Primary Objective: 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...

Ethical review	Approved WMO
Status	Pending
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON49844

Source
ToetsingOnline

Brief title
Effectiveness of core elements in CBT for depressed youth

Condition

- Mood disorders and disturbances NEC

Synonym
Major Depressive Disorder / Depression

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Oost Brabant (Rosmalen)

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

Intervention

Keyword: Cognitive Behavioural Therapy, Depression, Effectiveness, Single Case Experimental Design

Outcome measures

Primary outcome

i. Primary study parameters

Parameters concerning the adolescents. These parameters will be addressed via the daily questionnaires.

* The core symptoms of depression will be assessed using the Patient Health Questionnaire-2 (PHQ-2: Löwe, Kroenke, & Gräfe, 2004).

The PHQ contains two items, namely *feeling down, depressed or hopeless*, and *little interest or pleasure in doing things*. Both items assess symptomatology on a 4-point scale ranging from *not at all* to *nearly every day*. The PHQ-2 has sufficient to great sensitivity and specificity (Kroenke, Spitzer & Williams, 2003). The PHQ-2 can be used in children of aged 12 and older.

Assessment at daily questionnaires

* Other EMA items of potential influence on the primary study parameter (PHQ-2). We want to know whether important life events occurred during the course, by asking (*). Furthermore we measured EMA items that have proven useful in previous EMA studies: *I found the activity I was doing

pleasurable* (translated from *De activiteit waar ik mee bezig was vond ik plezierig om te doen*), *the activity I was doing cost me a lot of energy* (translated from *De activiteit waar ik mee bezig was kostte energie*), *today was stressful so far* (translated from *Vandaag was tot nu toe stressvol*).

Assessment at daily questionnaires

* Treatment adherence by monitoring how many times the exercises from the CBT were performed, by asking *how many times did you perform the instructions or exercises from the CBT course today?* (translated from *Hoe vaak heb je vandaag de instructies of oefeningen uit de cursus toegepast?*).

Assessment at daily questionnaires

Secondary outcome

ii. Secondary study parameters/endpoints

Parameters concerning the adolescents that will be addressed via digital questionnaires (T0-T4). Also included is the parameter Treatment integrity.

* Demographic information of the adolescent will be gathered by adding questions about gender, age, ethnicity, education level, family income and/or experience to the self-report questionnaires.

Assessment at T0

* Presence of a depression diagnosis will be measured by a semi-structured diagnostic interview using the Kiddie-Schedule for Affective Disorders and

Schizophrenia, present and lifetime version (K-SADS-PL; Kaufman et al., 1997; Reichart, Wals, & Hillegers, 2000).
In this schedule, the view of the adolescent, the parent and the independent clinician can be taken into account. The schedule can be used to assess 33 different disorders, including anxiety disorders, psychotic disorders, and affective disorders. Previous research supports the concurrent and convergent validity of the K-SADS, and provides excellent interrater agreement (range: 93% to 100%) and test-retest reliability (.77 to 1.00) (Kaufman et al., 1997; Lauth et al., 2010). The K-SADS-PL can be used for children age 6-18.
Assessment at T0, T4

* Depression severity will be rated by an independent researcher on the K-SADS-PL.
Assessment at T0 and T4

* Comorbidity will be assessed with the Brief Problem Monitor (BPM; Achenbach, McConaughy, Ivanova, & Rescorla, 2011).
The BPM is an abbreviated version of the Child Behavior Checklist, and comprises three scales: internalizing, externalizing and attention. In total the BPM contains 19 items, which are rated on a 3-point scale ranging from *not true* to *very true*. Psychometric properties are qualified as good, with a high overall internal consistency (Chronbach*s alpha=0.91), sufficient internal consistency for the subscales (Chronbachs alpha between 0.78 and 0.87), and high sensitivity (Achenbach, McConaughy, Ivanova, & Rescorla, 2011; Piper,

Gray, Raber, & Birkett, 2014). The BPM applies to children aged 6-18.

Assessment at T0, T1, T2, T3, T4

* Depression symptoms in adolescents will be measured with the Children*s Depression Inventory-2 Self Report (CDI-2 SR: Kovachs, 2011).
The CDI-2 SR consists of 28 items, such as *I feel sad*. All items offer three options: 0 indicating the absence of symptoms, 1 indicating mild symptoms, and 2 indicating definite symptoms. Items are grouped within two subscales: emotional problems and functional problems. The Dutch CDI-2 SR has good internal consistency, test-retest reliability and convergent validity (Bodden, Braet & Stikkelbroek, 2016). The CDI-2 has been evaluated for children age 7-18.

Assessment at T0, T1, T2, T3, T4

* Quality of life will be assessed using the Dutch version of the EuroQol Questionaire (EQ-5D adolescent version; EuroQol Group, 1990), and expressed in quality adjusted life years (QALYs).

The EQ-5D comprises five items representing different dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension is rated on a three-point scale, from no problems to moderate to large problems on that dimension. An extra dimensional visual analogue scale from 0 to 100 is used to assess one*s general health status. The reliability and validity of both the adolescent and parent version of the Dutch EQ-5D have

been established (Brooks & EuroQol group, 1996; Stolk, Busschbach, & Vogels, 2000). The EQ-5D can be used for children of age 12 and older.

Assessment at T0, T1, T2, T3, T4

* The top three problems of adolescents will be measured with the Top Problems (TP) measure (Weisz et al., 2011).

TP provides a strategy to identify three problems of greatest concern at pre-treatment and assess these problems throughout their treatment. The TP measure appears to be a psychometrically sound, client-guided approach that complements empirically derived standardized assessment; the approach can generate evidence on trajectories of change in the problems during treatment (Weisz et al., 2011). The TP measure has been evaluated in children aged 7-13.

Assessment

Study description

Background summary

Depression is one of the most prevalent mental disorders among adolescents, and a major public health concern (Merikangas et al., 2010). Besides a high prevalence, adolescents* depression is associated with comorbid psychiatric diagnoses (Cooper & Goodyer, 1993), high treatment costs (Meijer et al., 2006), social impairments (Verboom, Sijtsema, Verhulst, & Penninx, 2014), poor academic performance (Fletcher, 2008), and suicide (Portzky & Van Heeringen, 2009).
Treatment programs based on the principles of Cognitive Behavioural Therapy (CBT) appear most effective and most applied for depression among adolescents (e.g., Cuijpers, Muñoz, Clarke, & Lewinsohn, 2009). Most common CBT-elements for depression in adolescents are cognitive restructuring, behavioral activation, relaxation, and training of problem-solving skills (Weersing, Rozenman & Gonzales, 2009). Although empirical evidence for the effectiveness of these specific elements is scarce (Horowitz, & Garber, 2006),

a recent meta analysis identified two CBT elements, behavioral activation and cognitive restructuring, as contributing most to the effectiveness of CBT (Oud et al., in preparation). Both modules were reported as greatly effective in reducing depressive symptoms (Ng, Eckshtain & Weisz, 2015). Moreover, adolescents who received CBT treatment reported the feasibility of cognitive restructuring and behavioral activation as high (Ng, Eckshtain & Weisz, 2015).
Behavioral activation is a structured approach of increasing social, physical or successful activities that can elicit positive experiences and counteract the typical patterns of withdrawal and inactivity that characterize depression. The activity level is gradually increased and obstacles in avoiding difficult activities are addressed (e.g., Dimidjian, Barrera, Martell, Muñoz, & Lewinsohn, 2011). As such, this approach may have a beneficial effect on depression by reducing the inactivity (resulting, e.g., in school refusal) which can occur due to depressive symptoms (Scharree, 2007).
Cognitive restructuring is focused on learning to identify negative aspects of thoughts, to systematically evaluate the accuracy and helpfulness of thoughts, and to modify it into a more balanced appraisal of their problems (Wenzel, Dobson, & Hays, 2016). As such, this cognition-focused approach may improve depressive symptomatology, for example, by targeting the negative bias present during information processing common amongst adolescents with depressive disorder (Axelson & Birmaher, 2001). However, although cognitions play an important role in the theoretical explanation of mood disorders and may therefore provide a welcome target for reducing depression (e.g., Beck, 1979), cognitive ability to reflect on their own core beliefs has not yet fully developed in adolescents (e.g., Longmore & Worrell, 2007).
Empirical evidence on the specific effects of these core modules of CBT is scarce, and there is no to little empirical support for how exactly these elements should be offered*i.e., what their optimal sequencing is. Hence, there is a need for clarification regarding the specific differential effects of the two seemingly most effective CBT-modules, behavioural activation and cognitive restructuring, in adolescents with depression. Moreover, no research has specifically evaluated the sequential effect of the cognitive restructuring and behavioural activation modules in depressed adolescents, despite the need for treatment optimalization. Therefore, the proposed STARr study aims to investigate and provide insights into the differential and sequential effectiveness these two most commonly used CBT-elements: behavioural activation and cognitive restructuring. This knowledge can be used for recommendations to optimize CBT-programs for treatment of depression in adolescents.

Study objective

Primary Objective:
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.

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

Study design

We will investigate the differential and sequential effects of the two core elements of CBT, behavioral activation (BA) and cognitive restructuring (CR), using a Single-Case Experimental Design (SCED; Smith, 2012). Such a design uses repeated measurements to systematically investigate within-subject differences to assess treatment outcomes. More specifically, this study will use a replicated cross-over single case design (Vlaeyen et al., 2001).
This replicated cross-over single case design will last 12 weeks, including a 3-week baseline period, a 6-week intervention period of the CBT elements Cognitive Restructuring (CR) and Behavioral Activation (BA), and a 3-week follow-up period. All (N = 12) participants will be randomly assigned, using computerized random assignment, to CR followed by BA (n = 6), or to BA followed by CR (n = 6). CR and BA will both consist of three sessions, one per week. By administering the two modular elements in a specific order, this study design allows to establish the independent contribution of the CR and BA elements

Measurements will be the same for all participants, i.e., in both condition A (CR followed by BA) and B (BA followed by CR). There are three types of assessments.
Diagnostic assessments will take place at the start of the 3-week baseline period (T0); after the 3-week baseline period, right before the intervention (T1); after the 3-week period of the first CBT-element (T2); post-intervention assessment after the 3-week period of the second CBT-element (T3); after a 3-week period for follow up (T4). Both adolescent and their parent will participate in these diagnostic measurements: digital questionnaires at all assessment points (T0, T1, T2, T3 and T4), and a clinical interview at assessment point T0 and T4 are conducted to investigate the presence of a clinical depression disorder, symptom severity, measures of cognitions and behavioral activation, and quality of life. These assessments consist partially of measurements that are regularly distributed with CBT.
Daily assessments will take place throughout the entire 12-week study period, in which only the adolescents will participate. Ten questions will be asked once a day, at the end of the day, about the participant*s two core depressive symptoms, most important personal problems, emotions, cognitions, and behavior. These daily assessments will be completed on the adolescent*s mobile phone, and take less than 5 minutes per day. The proposed daily assessments will lead to 21 measurements per phase, which has been shown to be sufficient for analysis (Vlaeyen et al., 2001).
By combining periodic diagnostic assessments with daily measurements, SCED will allow for evaluation of the differential and sequential treatment effects of BA and CR in two complementary ways. Treatment outcomes can be

assessed by descriptively comparing the diagnostic measurements at T0, T1, T2, T3 and T4 within participants across time and across participants between conditions. Similarly, patterns of daily depressive symptomatology, behavioral activation, cognitions, emotions, top problems, and the passive behavioral measurements can be descriptively and statistically compared across phases*the baseline phase, first intervention phase, second intervention phase, and post-intervention phase*both within individuals and between conditions.

Intervention

The Cognitive Restructuring (CR) and Behavioral Activation (BA) modules come from the STARr Training. STARr is developed and researched by researchers of the Trimbos Instituut, Utrecht University and GGZ Oost Brabant in close collaboration with certified CBT therapists and experts in the field. STARr is developed based on current Dutch CBT-protocols (e.g., Doepressie and Op Volle Kracht) and on MATCH-ADTC (Modular Approach to Therapy for Children with Anxiety, Depression, Trauma, or Conduct Problems; Weisz et al., 2012). For this Single Case study the modules have been adapted to an individualized format, suitable for (severely) depressed adolescents. Each module consists of three sessions, one per week, each one lasting 45 minutes.

The Cognitive Restructuring (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, according to the following content:
Session 1: psycho-education on (identifying) events, cognitions, feelings and behavior
The first session consists of psycho-education and exercises regarding: cognitions; basic emotions such as joy and anger, and more complicated emotions; one*s behavior; how events, cognitions, feelings and behavior are linked. Then automatic thought processes and the distinction between healthy (helpful) and unhealthy (unhelpful) thoughts are introduced. Finally, adolescents receive exercises to identify their own top three of helpful thoughts/cognitions and assess their own event-thought-feeling-act patterns.
Session 2: challenging unhelpful cognitions.
In the second session, adolescents focus on understanding and identifying unhealthy (unhelpful) thoughts/cognitions, such as catastrophic thoughts, mind-reading thoughts, self-blame, and a negative self-bias. Thereafter adolescents are explained how to challenge their unhelpful thoughts/cognitions, by means of a 7-step approach: identify a set of a situation, unhelpful thought, feeling and behavior; evaluate credibility of the unhelpful thought; come up with arguments for and against their thought/cognition; focus on the strongest argument against the unhelpful thought; come up with a (counteractive) helpful thought; evaluate the credibility of this thought; re-evaluate the credibility of the unhelpful thought. As a homework exercise they will have to practice with this 7-step approach to challenge their

negative or unhelpful cognitions.
Session 3: learning how to challenge unhelpful cognitions in difficult situations.
In this third and last session adolescents reflect on what they have learned so far, and on how well they have been able to identify and challenge unhelpful thoughts. In this session they have to explore events, thoughts, feelings and behavior with regards to more ambiguous or complicated events, to further practice the skills they have learned.

The Behavioral Activation (BA) module aims to educate adolescents on the relationship between activity and behavior, and how to influence their emotional wellbeing through behavioral activation.
Session 1: learning about the relation between acting and feeling.
The first session covers psychoeducation and exercises about the influence of activities on one*s emotions. Adolescents will rate their emotions, link activities to emotional experiences, and explore positive and negative spirals of emotions and behavior influencing one another. Adolescents are explained how to monitor their activities and their emotions, to become more aware of the effects of their behavior on how they feel. This will be their homework exercise.
Session 2: goal setting for behavioral activation.
After evaluation the feeling- and activity monitoring exercise, adolescents reflect on their own positive and negative spirals. Thereafter, they explore the possible causes of negative spirals, think of ways to enhance their positive spirals, and set goals to improve their mood.
Session 3: evaluation of behavioral activation and goals.
Adolescents evaluate their monitoring results of the past two weeks, to see if things have changed, if they have achieved their goals, and if they want to set new goals. They receive tips for fun things to do and evaluate the exercises.

Study burden and risks

Risks are expected to be the same as in regular Cognitive Behavioural Therapy. Regular CBT provides 12 to 15 sessions that involve cognitive restructuring (CR), behavioral activation (BA), relaxation, and training of problem-solving skills. In the current study we will administer three sessions of CR and three sessions of BA. Participants will either receive the three sessions of CR first followed by the three sessions of BA, or vice versa. After participating in the study, participants have the opportunity to follow the other CBT modules (relaxation, and training of problem-solving skills). The extra burden on clients for participating in this study is: filling out five times a digital questionnaire (40-65 minutes each), two times a structured interview (K-SADS, 45-90 minutes each), and 84 daily questionnaires (5 minutes each). In total, this requires approximately, on average, 13,5 hours extra from clients who participate in the study. See Table 2 in the protocol for an overview of the extra burden of questionnaires on the participants. A major benefit for the participant is that all questionnaires provide additional information/input for

the CBT treatment. Therefore, participating in the study provides an advantage for the participants as well as the provided CBT. As suicide risk and depression are tightly monitored we expect the study design to reduce participants* chances of committing suicide. Because the additional information provides substantial benefits for monitoring and distributing the CBT modules, the burden on participants is not expected to be higher.can contribute to plan further treatment.*

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion 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

* absence of adolescents* or parental permission (for subjects aged younger than 16)
* acute and severe suicidal thoughts and/or intentions
* recently introduced medication that has not yet stabilized / changes in antidepressant medication during the period of the study

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	12
Type:	Anticipated

Ethics review

Approved WMO Date:	20-02-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	09-07-2020

Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26169
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL66762.041.18
OMON	NL-OMON26169