

Core elements of Cognitive Behavioral Therapy in preventing depression in youth:

Does the type and sequence of elements matter?

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

Summary

ID

NL-OMON45491

Source

ToetsingOnline

Brief title

STARr-project: Preventing depression in youth

Condition

- Mood disorders and disturbances NEC

Synonym

depression, depressive symptoms

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Utrecht

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: adolescents, CBT-elements, depression, differential effectiveness

Outcome measures

Primary outcome

Self-reported depressive symptoms

Secondary outcome

Depressive symptoms according to the parent

Depression diagnosis

Top three problems

Suicide risk

Quality of life

Care costs

Other study parameters are:

Possible moderator variables: Depression severity, comorbidity and demographic variables.

Possible mediator variables: Negative automatic thoughts, behavioral activation, relaxation and problem solving skills.

Treatment characteristics: Expectancy of treatment, previous treatments, therapeutic alliance, groups cohesion, cooperation with treatment, satisfaction with treatment and treatment integrity.

Study description

Background summary

Depression during adolescence is a major public health concern, because of its high prevalence, association with suicide, co-morbid psychiatric diagnoses and high treatment costs. Even sub-clinical levels of depressive symptoms put adolescents at risk for several negative outcomes. Therefore, it is important that depression is detected at an early stage and is treated preventively. Prevention programs based on the principles of Cognitive Behavioral Therapy (CBT) have proven to be the most effective and most applied in preventing depression among adolescents. Thus far, research has mainly focused on effectiveness of *prevention packages* consisting of multiple CBT-elements. Most common CBT-elements in existing programs are cognitive restructuring, behavioral activation, relaxation and problem solving skills. It is unclear which of these elements contribute to the positive prevention outcomes and how these elements should be offered (i.e., what their optimal sequencing is). This study proposes to evaluate the differential (cost-)effectiveness of different types and sequences of CBT-elements in the prevention of depression among adolescents.

Study objective

The primary objective is to investigate whether (and if so, which) type of CBT-element (cognitive restructuring (CR), behavioral activation (BA), relaxation (RE) and problem solving skills(PS)) is relevant for the positive effect of CBT-programs on the level of depressive symptoms in adolescents. The secondary objective is to investigate whether (and if so, which) sequence of CBT-elements is relevant for the positive effect of CBT-programs on the level of depressive symptoms in adolescents. In addition, it will be explored for whom (i.e., moderation) and how (i.e., mediation) a given element, or set of elements, is most effective. Besides, the cost-effectiveness of the prevention of depression will be investigated.

Study design

A Randomized Controlled Trial with four conditions (all prevention programs).

Intervention

The prevention program will be developed by the researchers themselves in close collaboration with experts and CBT-therapists. The program will be designed as a Cognitive Behavioral Therapy, a therapy which has proven to be effective. It will consist of twelve weekly sessions, each 45-60 minutes long. Prior to the training an introductory meeting will take place, which lasts 30 minutes. For

each of the four CBT-elements a module of three sessions will be developed. Each condition starts with a different module and contains a different sequence of modules (condition 1: CR, BA, RE, PS; condition 2: BA, CR, RE, PS; condition 3: PS, BA, CR, RE; condition 4: RE, PS, BA, CR).

The prevention program will be given in same-sex groups consisting of six to eight participants. It will be provided by certified alumni pedagogy and psychology, who will be trained and supervised by certified CB-therapists.

Study burden and risks

The potential value of the study is that we gain insight in the differential effectiveness of the four most commonly used CBT-elements in the prevention of depression among adolescents, and in their most optimal sequence. This knowledge can be used for recommendations to optimize CBT-programs in the prevention of adolescents with depressive symptoms. Possible direct benefits of participating in this study, is that we offer adolescents with elevated levels of depressive symptoms an effective program to prevent them from becoming severely depressed. As an indirect positive effect, suicide can possibly be prevented. A direct burden for the participating adolescents is that they have to fill out questionnaires, will be interviewed and have to attend treatment sessions. However, in our opinion this burden outweighs the possible benefits of less depressed adolescents and a lower suicide risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Inclusion criteria are:

- age between 12-18 years old
- sufficient knowledge of the Dutch language
- (sub)clinical levels of depressive symptoms

Exclusion criteria

Exclusion criteria are:

- absence of adolescents* or parental permission (for subjects aged younger than 16)
- currently receiving treatment for psychological problems
- acute and severe suicidal thoughts and/or intentions

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	24-04-2017
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO	
Date:	17-02-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	29-11-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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: 25759
Source: NTR
Title:

In other registers

Register	ID
Other	6176
CCMO	NL59152.041.16

Study results

Date completed:	29-01-2020
Results posted:	19-10-2021
Actual enrolment:	289

First publication
01-01-1900