

STARr-project: Preventing depression in youth

No registrations found.

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

Summary

ID

NL-OMON25759

Source

NTR

Brief title

STARr: Solve, Think, Act, Relax and repeat

Health condition

Depression, depressive symptoms

Depressie, depressieve klachten

Sponsors and support

Primary sponsor: Trimbos Instituut in samenwerking met de Universiteit Utrecht

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The primary outcome is the level of self-reported depressive symptoms which will be measured with the CDI-2 (Bodden et al., 2016).

Secondary outcome

Secondary study parameters are depressive symptoms according to the parent, depression diagnosis, top three problems, suicide risk, quality of life and care costs. Other study parameters are depression severity, comorbidity and demographic variables (possible moderator variables); negative automatic thoughts, behavioral activation, relaxation and problem solving skills (possible mediator variables); and expectancy of treatment, current and previous treatments, satisfaction with treatment and treatment integrity (treatment characteristics).

Study description

Background summary

Background: Depression during adolescence is a major public health concern, because of its high prevalence, association with suicide, comorbid psychiatric diagnoses and high treatment costs. Even subclinical 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. 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.

Objectives: 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).

Study population: Adolescents between 12 and 18 years old with elevated levels of depressive symptoms. They will be recruited via secondary schools (from vocational training up to pre-university level) and ROC's around the Netherlands. Adolescents who meet the inclusion criteria will be randomly assigned to one of the four conditions.

Adolescents who are identified with acute and severe suicidal thoughts and/or intentions will be excluded from the study and redirected to mental health care.

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. 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 CBT- therapists.

Study objective

n/a

Study design

In all conditions assessments will take place at baseline (T0), during the intervention phase after session 3 (T1), during the intervention phase after session 6 (T2), during the intervention phase after session 9 (T3), at post-intervention (T4) and at 6-months follow-up (T5).

Intervention

The prevention program will be developed by the researchers themselves, in close collaboration with therapists and experts in the field. The program will be designed as a Cognitive Behavioral Therapy, a therapy which has proven to be most effective and most applied in the prevention of depression among adolescents (e.g., Cuijpers et al., 2009). It will consist of twelve sessions, each 45-60 minutes long. For each of the four most commonly used CBT-elements a module of three sessions will be developed; one module with three sessions cognitive restructuring, one module with three sessions behavioral activation, one module with three sessions relaxation and one module with three sessions problem solving

skills. The modules will be 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; Chorpita & Weisz, 2009). In each step of this developing process, a group of certified CBT-therapists and experts in the field will be consulted.

To investigate whether the type of element is relevant for the positive effect of CBT-programs on the level of depressive symptoms in adolescents, we distinguish four conditions, all of which start with a different module; condition A starts with the module cognitive restructuring, condition B starts with the module behavioral activation, condition C starts with the module problem solving and condition D starts with the module relaxation. To investigate whether the sequence of elements is relevant for the positive effect of CBT-programs on the level of depressive symptoms in adolescents, the sequence of the four modules will differ per condition (see Table 1). As it is impossible to test all combinations, because of limited time and budget, three theoretically most logical variants (condition A, B and C) and one theoretically least logical variant (condition D) are chosen in close consultation with mental health professionals.

Table 1: Sequence of CBT-modules per condition.

Condition A CR BA RE PS

Condition B BA CR RE PS

Condition C PS BA CR RE

Condition D RE PS BA CR

Note. CR = cognitive restructuring; BA = behavioral activation; PS = problem solving; RE = relaxation.

The prevention program will be given in same-sex groups consisting of six to eight participants. It will take place at the participating schools directly after school. Group sessions take place one to two times a week, depending on holidays. The prevention program will be provided by certified alumni pedagogy/psychology, who will be trained and supervised by certified CBT therapists.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- absence of adolescents' or parental permission (for subjects aged younger than 18)
- 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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2017
Enrollment:	240
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	13-10-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45491
 Bron: ToetsingOnline
 Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5584
NTR-old	NTR6176
CCMO	NL59152.041.16
OMON	NL-OMON45491

Study results