Strong teens and resilient minds: School-based prevention of depression and suicide

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

Summary

ID

NL-OMON43664

Source
ToetsingOnline

Brief title
STORM-project

Condition

- Mood disorders and disturbances NEC

Synonym
depression

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Oost Brabant (Rosmalen)
Source(s) of monetary or material Support: Gemeente Oss

Intervention

Keyword: adolescents, depression, prevention, suicide

Outcome measures

Primary outcome

Depression

Secondary outcome

School related factors such as academic grades, drop-outs, truancy and

non-attendance

Suicide risk

Cost-effectiveness

Anxiety

Somatic complains

Independant and personal life-events

Coping style

Perfectionism

Study description

Background summary

Depression is a major concern of public health. The prevalence of depression in Dutch adolescents is approximately 3.8%. This rate does not even include those 21,4% with elevated but sub-clinical levels of depressive symptoms. Depression and suicide are strongly related as depression is the most frequently reported risk factor associated with adolescent suicide. Since 2010 suicide is the most important case of death in the age category 15 to 29 years, in the Netherlands. Given the prevalence, the recurrence and the negative outcomes of adolescent depression, it is crucial to implement prevention programs for high-risk adolescents. This study proposes to screen children, offer them a prevention program to prevent the onset or maintenance of depression and evaluate the

(cost-)effectiveness of this prevention program.

Study objective

The primary goal is to evaluate the effectiveness of a screening and prevention program for adolescents who experience depressive symptoms. The secondary goal is to find factors which possibly relate to the effectiveness of the prevention program. In addition we investigate the effect of the screening, the effect of the intervention on suicide risk and the cost-effectiveness.

Study design

Randomised controlled trial with two conditions (intervention versus control). Additionally, adolescents with elevated suicide risk will be monitored by filling in the same set of questionnaires as the adolescents in the intervention and control group.

Intervention

The intervention that is evaluated is called 'Op Volle Kracht'. It consists of 8 lessons of each 60 minutes. The intervention is based on the principles of cognitive behavioral therapy (CBT). In the first lesson, the participants learn about emotions en depressive feelings. The adolescents learn which emotions they experience and how they can recognize them. During this program, they will use a schedule to find out that activating events, beliefs, emotional consequences and behavioral consequences are related. In the second lesson, the adolescent learn about the relationship between activating events, beliefs and emotional consequences. Beliefs can be optimistic or pessimistic and play a major role in the emotional consequences. The adolescents learn how they can recognize pessimistic beliefs. In the third lesson, adolescents learn how they can recognize the pattern of their beliefs and cognitive errors. In the fourth lesson, adolescents learn to investigate their thoughts and to find evidence for and against their thoughts. In the fifth lesson, adolescents continue to find evidence for and against their thoughts and start to test if their thoughts are actually true. In the sixth lesson, participants investigate theirs thoughts by asking the question *what*s next?*. They learn to questioning their thoughts by fantasizing the worst case scenario*s of their thoughts. In addition, they learn to make up an action plan to prevent that the worst case scenario will actually happen. In the seventh lesson, adolescents learn how they can replace thoughts and how they can prove the alternative belief is true. The eight and last lesson is meant to finish the intervention on a fun way. Adolescents can share their experiences about the intervention and participate in a quiz about all the things they learned. An application is designed to support the OVK program. In this app, adolescents can manage their homework and monitor their mood.

The participants in the control condition will receive a psycho-educational brochure and two emails with useful tips to boost their mood.

Study burden and risks

The potential value of the study is that we can offer children a prevention program that is proven to be effective. In order to achieve this goal we need to evaluate the effectiveness of this prevention program. We are of opinion, however, that the risks associated with participation can be considered negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- adolescents are aged between 11-15 years old
- sufficient knowledge of the Dutch language
- elevated depressive symptoms

Exclusion criteria

absence of parental permission
adolescent already receiving treatment for mood problems

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2016
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	25-02-2016
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-10-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-07-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
Other	is aangemeld bij NTR (5725)
CCMO	NL55328.091.15

Study results

Summary results
Trial ended prematurely