

Strong teens and resilient minds: Depression and Suicide Prevention in Secondary Education

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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-OMON45835

Source

ToetsingOnline

Brief title

STORM-Project South

Condition

- Mood disorders and disturbances NEC

Synonym

depression; mood disorder

Research involving

Human

Sponsors and support

Primary sponsor: GGZ Oost Brabant (Rosmalen)

Source(s) of monetary or material Support: Gemeentes

Intervention

Keyword: adolescents, depression, prevention, suicide

Outcome measures

Primary outcome

Suicidal behavior

Secondary outcome

Depression

Stigma

Mastery

Social identity

Worry

Life Events

Perfectionism

Schoolrelated factors such as academic grades, drop-outs, truancy and non-attendance

Study description

Background summary

Since 2010 suicide is the leading cause of death among 15-29 year olds.

Depression is the most important risk factor associated with suicide.

Therefore, prevention of suicide ought to be in conjunction with reducing the risk of depression. Depressive symptoms and suicidal behaviour could lead to self-injurious behaviour, substance abuse, learning disabilities, social problems and obesity. These, in turn, lead to declining school results and school dropout. Moreover, the costs associated with depression and suicidality are quite high.

Often depressive symptoms and suicidal behaviour are not recognized in adolescents and remain untreated for an extended period. This is not a problem

exclusive to health care or so-called gatekeepers (schoolteachers), but is also very common among youth themselves. Help-seeking behaviour in youth is lower than any other age group. Part of this problem is due to stigma and feelings of self-reliance among adolescents. Therefore it is imperative to prevent these feelings among youth and increase help-seeking intentions and behaviour while increasing knowledge about when they should seek help. Despite all these known facts the prevention of suicide and depression is still underappreciated. Apart from increasing knowledge and reducing stigma it is important to know which adolescents already experience depressive symptoms and are on the road to develop a clinical depression. This helps us to give these students the right tools to reduce the risk of the development of a clinical depression and in turn suicidal behaviour. Given the prevalence, negative outcomes associated with depression and health care costs of depression it is crucial to implement a multimodal prevention program that reduces the risk of depression and suicidal behaviour.

Study objective

The primary objective of the current study is to evaluate the efficacy of a multimodal prevention program for adolescents. The secondary objective of the study is to investigate which child factors might mediate the efficacy of the program and predict outcome.

Study design

The current study is a cluster randomized controlled trial (RCT) containing two conditions to evaluate the efficacy of a multimodal prevention program. Furthermore, adolescents with acute suicide risk shall be monitored using questionnaires.

Intervention

The multimodal prevention program consists of four modules in total. Both the intervention and control condition will be screened for suicide risk and in case of acute suicide risk the student will be referred to mental health care. Furthermore, all mentors of participating school will be trained as gatekeepers in order to recognize suicidal behaviour. These modules will not be evaluated as they are equal in both conditions.

The intervention that will be evaluated consists of two modules, namely a universal and an indicated module. Both modules will only be offered to schools in the intervention condition.

The universal module that will be evaluated is called **Moving Stories**. It is a serious game that students will play using their smartphones for five consecutive days, approximately 10 minutes a day, and two mentor classes of approximately one hour each. During the first mentor class the mentor explains to the students how to download and play the app. They are also told that even

though the entire class will play this game at the same time, it is an individual game and no one is able to see their actions in the game. Then, it is explained that the students will virtually spend five days with their cousin, Sanne, and she will not come out of bed. Students are expected to help Sanne feel better and maybe even get out of bed. Then, they will receive background information about Sanne, her family and the students' relationship with Sanne. After the mentor class the game can begin. Once the students have gained access to the game, they will find themselves in a virtual house (on their phones*) where they can walk around, can execute several actions and talk to Sanne. Every morning the student has approximately 10 minutes to talk to Sanne and execute actions. They are allowed to execute only 10 actions. During the afternoon virtual Sanne will send them text messages containing feedback about the actions they executed that morning. The ultimate goal of the app is that students learn that Sanne is in fact depressed and that the only action that will help Sanne with her depression is to call upon an adult. After the five days of app playtime a second mentor class shall be organized. During this class an experienced expert (who has suffered from depression in the past) will explain that Sanne was depressed and what it means to be depressed, how it is different from being sad and what adolescents should do if they experience these complaints or recognize these complaints in someone else. Also, there will be plenty of time for the students to talk about their experiences in the app and how they felt while playing the app.

The indicated module 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). During the first lesson, the participants learn about emotions and 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. During the second lesson, the adolescents learn about the relationship between activating events, beliefs and emotional consequences. Beliefs can be either optimistic or pessimistic and play a major role in the emotional consequences. The adolescents learn how they can recognize pessimistic beliefs. Throughout the third lesson, adolescents learn how they can recognize the pattern of their beliefs and cognitive errors. During the fourth lesson, adolescents learn to investigate their thoughts and to find evidence in favor of and against their thoughts. Throughout the fifth lesson, adolescents continue to find evidence in favor of and against their thoughts and start to test whether their thoughts are actually true. During the sixth lesson, participants investigate their thoughts by asking the question 'what's next?*' They learn to question their thoughts by fantasizing about the worst case scenarios of their thoughts. In addition, they learn to create an action plan to prevent that the worst case scenario will actually occur. During the seventh lesson, adolescents learn how they can replace non-helping thoughts and how they can prove the alternative belief is true. The eighth and last lesson is meant to finish the intervention on a fun note. Adolescents can share their experiences about the intervention and participate in a quiz about everything they learned. An application is designed to support the OVK program.

In this app, adolescents can manage their homework and monitor their mood.

Study burden and risks

The potential value of the study is that adolescents with suicide risk will be identified sooner and in turn can be referred to mental health care. Also help-seeking behaviour will be stimulated by the universal module and adolescents with increased depressive symptoms will be identified and offered an indicated prevention module that is effective. To evaluate the effectiveness of this program within this specific population, adolescents between 11-15 years old, the study should use a study population that meets these criteria. The risks associated with participation can be considered negligible. The burden of the study lies within completing questionnaires and playing an app on their smartphones. Both prevention modules will furthermore be completed during school hours. To determine whether this prevention program is effective and contributes to wellbeing of adolescents, we need to evaluate the program among adolescents. The risks associated with participation may provide for a more effective prevention program.

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

Exclusion criteria

absence of permission

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2017
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO

Date: 02-08-2017
Application type: First submission
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO
Date: 09-11-2017
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
CCMO	NL61559.091.17

Study results

Date completed: 01-07-2021
Actual enrolment: 1941