Strong Teens and Resilient Minds: Depression and suicide prevention in secondary vocational 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-OMON46146

Source
ToetsingOnline

Brief title
STORM MBO

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, mood disorder

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos-instituut
Source(s) of monetary or material Support: ZonMw en gemeente Bernheze

Intervention

Keyword: adolescents, depression, prevention, suïcide

Outcome measures

Primary outcome

Severity of suicidality

Secondary outcome

Self-esteem

Self-efficacy

Quality adjusted life year (QALY) health gains

Student motivation and classroom satisfaction

School related factors (academic grades, drop-outs, truancy and non-attendance)

Demographic characteristics

Study description

Background summary

In the Netherlands since 2010 a national increase in the amount of suicides has been observed (CBS, 2016). Nowadays, suicide is the most important cause of death in the age category 10 to 25 years (CBS, 2016). It has been shown that among the adolescents that successfully committed suicide 60-90% was suffering a depressive disorder (Orbach et al., 2009), indicating an association between suicide and depression. Within the age range of 15-21 years old the amount of clinical depressions increases steeply with higher age (Hankin, 2002). Yearly, 4% of the adolescents suffers from a depressive disorder (Meijer et al., 2006). 20% of the adolescents until the age of 20 experienced depressive thoughts (Bertha & Balazs, 2013). Depressive thoughts are a risk factor for the development of a depression (Johnson et al., 2009). Furthermore, depressive thoughts can on themselves lead to dysfunction (Balazs et al., 2013). This shows that depression and suicide among adolescents are important problems to tackle. Currently no interventions are deployed in the Netherlands that are well organized intervention and/or have been proven effective to prevent depression and suicide (RIVM, 2014). This indicates that preventive strategies

concerning suicide and depression in adolescents are necessary.

Study objective

One of the primary goals is to establish whether students in the first grade of secondary vocational education receiving the multimodal school-based stepped approach towards preventing suicidal behaviours and depression show a clinically significant reduction of suicidal behaviours and depressive symptom severity levels when compared to the students receiving care as usual.

Study design

In order to achieve the primary and secondary aims of this research a clustered randomized controlled trial (RCT) will be conducted in two parallel groups comparing an experimental condition with a control condition. Randomization will be conducted at the level of school location to avoid contamination. Both the control and experimental conditions receive two interventions: (1) a gatekeeper training for the mentors of the students in the first grade of secondary vocational education for early recognition of suicidality and referral where required, and (21) screening for depression and suicidality (with prompt referral to professional health care when indicated). These two interventions will ensure the safety of suicidal students in both trial conditions. It should also be noted that all students will have unrestricted access to care as usual as offered by the general practitioners and mental health care services that are available in the Netherlands. This means that the control condition consists of care as usual plus the two interventions that act as a safety net. The control condition will therefore be described as enhanced usual care. The experimental condition receives two additional interventions: (3) a universal preventive intervention directed at raising awareness about depression and reducing (self-) stigma with regard to depressive symptoms, and (4) an indicated preventive intervention offered to those with elevated levels of depressive symptoms. The multimodal integrated stepped nature of the program requires integral testing of the interventions rather than testing the effects of the single components of the prevention program. Outcomes will be assessed primarily through adolescent self-reports at baseline, mid-intervention, post-intervention, and at 6, 12 and 18 months after program ending.

Intervention

The multimodal prevention program consists of four modules. Both the experimental and the control condition will receive 2 modules, including the gatekeeper training for mentors of the students in the first grade of secondary vocational education and a screening for the students. These modules will ensure the safety of possibly suicidal students. The experimental condition will, in addition to the gatekeeper training and screening, receive two extra interventions, including universal prevention (*Moving Stories*) and indicated

prevention (*Op Volle Kracht MBO*). Details concerning the interventions are described below.

Gatekeeper training
All mentors of the students in the first grade of secondary vocational education will receive a gatekeeper training. In this training the mentors will learn to (1) recognise suicidality, (2) make contact with the student and to frankly discuss suicidality, and (3) refer the students with high severity of suicidality to professional health care (either the student*s GP or specialised mental health care).

Screening
All students in the first grade of secondary vocational education will be screened for suicidality by filling in the 10-item VOZZ-Screen (Kerkhof et al., 2015) and the CDI-2 (Kovacs, 2011). The screening will be conducted by the community health services (in Dutch: GGD). The screening doubles as the baseline assessment of the study. Based on the VOZZ-Screen score and item 8 of the CDI-2 (suicide question) we will determine the individual students in the high suicide risk group. Screen-positive students (10-item VOZZ-Screen > 23 or CDI-2 item 8 >1) will be seen within 48 hours by GGD staff for a 1-hour semi-structured interview. The interview includes assessment of suicide risk through open but systematic discussion of issues that are relevant to the individual student. Immediately following these interviews and when the screen-positive result is confirmed in the suicide risk assessment, the parents or guardians will be contacted and informed about the findings and concerns regarding the safety of that student. At this time a safety plan will be agreed upon, including (potential) referral to primary care (general practitioner) or the specialized mental health services (GGZ Oost Brabant).

Universal prevention (*Moving Stories*)
All students in the first grade of secondary vocational education whose school location is randomized in the experimental condition will first receive the universal prevention *Moving Stories*, consisting of depression awareness training, targeting (self-) stigma related to depression and aiming to induce better help-seeking behaviours when confronted with depression. *Moving Stories* starts with an introductory session taking place during a mentoring class, which includes an explanation of how to download and play the serious game. Furthermore, it will be explained that everybody plays the serious game 5 consecutive mornings and that, during the afternoon, feedback will be provided about the students* performed actions in the game that morning. After the serious game has been played for 5 consecutive mornings another mentor lesson will be used to offer insight in what (living with) depression entails via a discussion with an experiential expert. Furthermore, students* experiences with *Moving Stories* will be discussed and the question *how to act when you yourself experience depressive symptoms and/or recognize these symptoms in peers* will be answered in an interactive fashion. The discussion will be led by a well-trained and supervised psychiatric nurse (from GGZ Oost Brabant).

Indicated prevention (*Op Volle Kracht MBO*)
All students in the first grade of secondary vocational education randomized in the experimental condition and showing elevated severity of depressive symptoms (CDI-2 > 14) upon screening will be asked to participate in the indicated prevention *Op Volle Kracht MBO* (OVK MBO). OVK MBO is modified from of the original *Op Volle Kracht* program, which is based on the principles of cognitive behavioral therapy (CBT). OVK MBO also includes an e-mental health mobile application called *Boost My Mood* which entails a stepped depression prevention approach consisting of evidence-based CBT modules, exercises and techniques. Via the e-mental-health mobile application (*Boost My Mood*) students* will be able to enhance their knowledge concerning CBT techniques, to practice CBT techniques and to monitor their depressive symptoms (part of CBT). All students that provided active informed consent will follow 6 face-to-face group sessions, each of 45 minutes and provided twice a week or weekly. These face-to-face CBT sessions will be delivered by professionals that received an extensive 3-day training program in the necessary skills such as CBT and its theoretical background, a training manual, and the intervention protocol. Via the e-mental-health mobile application (*Boost My Mood*) students will be able to enhance their knowledge concerning CBT techniques, to practice CBT techniques and to monitor their depressive symptoms in their own time whenever suits them.

Study burden and risks

Risk
Previous research concerning the various aspects of our study has shown no risk for participants * rather on the contrary. Suicidal participants feel less distressed after completing a survey about suicidal behaviours (screening) (Gould et al., 2005). According to an extensive review of the research literature, no adverse effects have been observed in participants concerning suicidality in any research * meaning that suicidal thoughts and behaviours did not increase when people engage in research (Kerkhof & Huisman, 2017). It is even recommended by Kerkhof & Huisman (2017) to include a screening, followed by referral, and gatekeeper trainings in the research design of a study, because it is appreciated by the study*s participants and lowers risk of suicide. A similar universal prevention program to the one in this study did not show any adverse effect among students (Asiltine et al., 2007). In another youth awareness program (Wasserman*s et al. school-based suicide prevention (SEYLE) study among more than 11,000 students, which was published in The Lancet in 2015) indicated that severe suicidal ideation was reduced to a half (OR=0.45) in the recipients of this program. Lastly, for the intervention on which the indicated intervention in this study is based, no adverse effects have been described (Wijnhoven et al., 2013). Moreover, every component of this study is in compliance with the recommended guidelines on how to communicate about suicide in order to minimalize the effect of imitation (Wasserman & Narboni, 2001; De Jaegere, & Portzky) and to ensure the safety of our participants (Kerkhof & Huisman, 2017). Therefore, we are of opinion that the

risks associated with participation can be considered negligible and that participating in our study and the interventions embedded therein is mitigating the risk of suicide rather than increasing this risk.

Burden
Suicidality and depressive symptoms during adolescence are a prominent individual and societal problem. In order to determine whether the prevention program is effective in reducing severity of suicidal behaviours among adolescents in the first grade of secondary vocational education, it is necessary that these adolescents participate in the interventions and fill in the questionnaires in order to monitor the effect of the interventions. Within the prevention program it is expected that (self-)stigma concerning depressive symptoms will be reduced via the universal prevention, and that in addition help-seeking and health-promoting behaviours will be encouraged. Furthermore, adolescents with high severity levels of suicidality will be referred to professional health care. We believe that due to the societal impact and the gain of students with depressive and suicidal thoughts (reduction of these thoughts due to the interventions and referral) justifies the burden (participating in screening, filling in 6 questionnaires and participating in 2 interventions) of the subjects. Lastly, receiving interventions and filling in questionnaires will happen at the location of the school of the student and mostly during mentoring lessons (of the regular school curriculum) to ensure that the time investment after school hours is kept to an absolute minimum and would essentially consist of engaging in both e-health interventions (Moving Stories and Boost My Mood), both of which have been designed specifically for this target group with avoiding the participant*s burden in mind (which is why Moving Stories has been developed as a serious game).

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

In order to participate in the study participant must meet all of the following criteria:
* Participation in the first grade of secondary vocational education
* Providing informed consent
* Informed parental consent when the student is younger than 16 years old
* Sufficient command of the Dutch language;In order to be eligible to participate in the indicated intervention (*OVK MBO*) a participant must meet all of the following criteria:
* Participation in the first grade of secondary vocational education
* Providing informed consent
* Informed parental consent when the student is younger than 16 years old
* Sufficient command of the Dutch language
* Presenting with elevated severity of depressive symptoms (CDI-2 >14)

Exclusion criteria

In order to participate in the study participant must meet not meet the following criteria:
:
* None;In order to be eligible to participate in the indicated intervention (*OVK MBO*) a participant must not meet all of the following criteria:
* Present depression treatment

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):	13-05-2019
Enrollment:	1710
Type:	Actual

Medical products/devices used

Generic name:	Boost My Mood
Registration:	No

Ethics review

Approved WMO

Date:	02-01-2019
Application type:	First submission
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

ID: 25713

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65756.091.18
OMON	NL-OMON25713