Strong teens and resilient minds: Depression and Suicide Prevention in Higher Vocational Education

No registrations found.

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

Summary

ID

NL-OMON25713

Source Nationaal Trial Register

Brief title STORM MBO

Health condition

suicide, suicidal behaviour, depressive symptoms, depression

Sponsors and support

Primary sponsor: Municipality of Bernheze, the Netherlands **Source(s) of monetary or material Support:** ZonMw, Municipality of Bernheze

Intervention

Outcome measures

Primary outcome

VOZZ

Secondary outcome

1 - Strong teens and resilient minds: Depression and Suicide Prevention in Higher Vo ... 25-05-2025

VOZZ-Screen suicidal behaviour risk (screening) CDI2 depressive symptoms (screening) Rosenberg's self-esteem scale DSS personal depression stigma DSS perceived depression stigma PSWQ worry PMS mastery EQ-5D-5Y quality adjusted life year (QALY) health gains Social connectedness

Study description

Background summary

The current study examines the effectiveness of the multimodal prevention program for suicidality and depressive symptoms using a cluster randomized trial. This includes a combination of preventive interventions, such as (1) early detection and identification with subsequent clinical referral, (2) a safety net consisting of gatekeepers at school, (3) universal prevention focusing on stigma reduction, (4) screening to identify students that have elevated signs of the most important risk factor for suicidal behaviour, i.e. depression and subsequent indicated prevention for screen-positive students. The primary outcome will be suicidal behaviours, i.e. suicidal thoughts and plans, deliberate self-harm and suicide attempts as measured with the VOZZ. Secondary study outcomes are depressive feelings, self-esteem, self-efficacy, children's quality adjusted life year (QALY) health gains, worry, mastery, stigma, school-related factors. Measurements of primary and secondary outcomes will be conducted in intervention and control condition at baseline and at 6-, 12- and 18-months after baseline.

Study objective

It is expected that students receiving the multimodal school-based stepped approach towards preventing suicidality and depression, show a clinically significant reduction in severity of suicidality when compared to students receiving enhanced usual care.

Study design

Screening T0; baseline T1; 6-month follow-up T2; 12 month follow-up T3; 18-month follow-up

Intervention

2 - Strong teens and resilient minds: Depression and Suicide Prevention in Higher Vo ... 25-05-2025

Screening

Gatekeepers training for school mentors

Universal preventive intervention focused on depression stigma in the form of a serious game indicated preventive intervention focused on depressive symptoms in the form of a cbt-based skills training and an e-mental health mobile application.

Contacts

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Eligibility criteria

Inclusion criteria

Participation in the first grade of secondary vocational education

Providing informed consent, including parental consent when the student is younger than 16 years

Sufficient command of the Dutch language

In order to be eligible to participate in the indicated intervention ('OVK MBO'):

Providing informed consent, including parental consent when the student is younger than 16 years

Sufficient command of the Dutch language

Presenting with elevated severity of depressive symptoms (CDI-2 >14)

Willing and able to download and use the 'Boost My Mood' application (mobile phone with operating system Android version 6+ or IOS 9+)

Exclusion criteria

For the study:

None

For the indicated intervention ('OVK MBO'): Engaged in present depression treatment

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2017
Enrollment:	1710
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date: Application type:

07-05-2019 First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46146 Bron: ToetsingOnline Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7719
ССМО	NL65756.091.18
OMON	NL-OMON46146

Study results