Strong Teens and Resilient Minds: School-based depression and suicide prevention in adolescents attending special schools

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

Summary

ID

NL-OMON53295

Source
ToetsingOnline

Brief title
Depression and Suicide prevention in Adolescents attending Special Schools

Condition

- Mood disorders and disturbances NEC

Synonym
depression; mood problems

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Oost Brabant (Rosmalen)

Source(s) of monetary or material Support: de gemeenten: Bernheeze;Boekel;Boxmeer;Cuijk;Grave;Landerd;Maashorst;Meierijstad;Mill en Sint Hubert;Oss;Sint Anthonis;en Uden

Intervention

Keyword: Adolescence, Depression, Prevention, Special education

Outcome measures

Primary outcome

The main study parameter is depressive symptomatology.

Secondary outcome

Secondary study parameters are suicidality, anxiety and somatic complaints,

depression and axiety according to parents.

Other study parameters are possible baseline differences between the two groups

in demographic variables. Besides: Educational history, reason for attending

special schools, diagnosis and full scale IQ.

Study description

Background summary

Depression is a major public health concern. In Dutch adolescents, the prevalence of major depressive disorder is estimated at 3.8% (Meijer, Smit, Schoemaker & Cuijpers, 2006) and 23.4% report depressive symptoms (van den Heuvel et al, 2021). Depression is a risk factor in adolescent suicide (Fried, Williams, Cabral, Hacker, 2013). Prevention programs, for example the STORM approach, are effective in decreasing depressive symptoms among adolescents with elevated depressive symptoms at screening (De Jonge-Heesen, et al., 2020). Besides, the prorgram helps detecting sui*cidal adolescents, and guides them to mental healthcare. However, not all adolescents attend general education. In the Netherlands, 7% of all adolescents enters special education (voortgezet speciaal onderwijs and prakijkonderwijs; Rijksoverheid, 2022). These adolescents form a vulnerable subgroup concerning developing depressive symptoms and suicidality, but are usually left out in the (initial) development of programs. To adapt programs for these students, and to implement prevention

in special schools, is a crucial next step. This study aims to screen adolescents, offer them a prevention program to prevent the onset or continuation of depression and evaluate the effectiveness of this program.

Study objective

The aim of the study is to establish depression and suicide prevention reaching students who attend special education.

The primary goal is to evaluate the effectiveness on depressive symptoms 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.

Study design

Clusterend randomised controlled trial with two conditions (intervention versus waitlist). Randomization is clustered by school-type and will take place before the study starts.

Intervention

Participants in the experimental condition will be offered the CBT-based preventive group training Op Volle Kracht. This consists of eight lessons and seven check-in moments, thaught by two experienced mental health professionals. The lessons takes place during school hours and the group consists of three to five participants. The control condition will consist of monitoring and is offered the training after data collection of the study has ended and when the intervention has shown to be effective. All participants will fill in longitudinal measurements. At all times, adolescents will be guided to mental health care if necessary.

Furthermore, teachers in all participating schools will attend a training on how to detect and address depressive and suicidal symptoms among adolescents.

Study burden and risks

The potential value of the study is that we can offer adolescents in the special educational sector a prevention program that is proven to be effective. Besides, we can detect and refer adolscents presenting with suïcidality in an early stage. In order to achieve this goal we need to evaluate the effectiveness of this prevention program in this target group.
We are of opinion, that the risks associated with participation can be considered negligible. Participation consists of filling in questionnaires (adolescents and their parents) to determine the effectiveness of the intervention. Participation might lead to more efficient prevention. The new

aspect of this prevention program is that it is specifically aimed at depressive symptoms, within a vulnerable and young subgroup.

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 attend second or third grade of secondary special education OR (only if a special school does not operate in grades) adolescents will reach the age of 14 or 15 during this academic year
Attending special school (voortgezet speciaal onderwijs or praktijkonderwijs)
Score above the cut-off on an depression symptomlist (>= 14 on the CDI-2)

Exclusion criteria

Adolescents who score 2 on item 8 of the CDI-2 or >= 23 on the VOZZ-screen (suicidality)
Clinical depression based on the clinical interview held at baseline (ADIS-C)
Absence of parental permission
Adolescent already receiving treatment for depressive symptomatology
Insufficient knowledge of the Dutch language

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:	Recruiting
Start date (anticipated):	13-12-2023
Enrollment:	236
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	07-12-2023
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-08-2024
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
ClinicalTrials.gov	NCT06203899
CCMO	NL83816.091.23