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

No registrations found.

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

Summary

ID

NL-OMON27977

Source
Nationaal Trial Register

Health condition

Depression, Suicide, Prevention, Adolescents, School-based

Sponsors and support

Primary sponsor: GGZ Oost Brabant
Source(s) of monetary or material Support: ZON-MW

Intervention

Outcome measures

Primary outcome

Depressive symptoms: Child Depression Inventory 2 (CDI 2) and Anxiety Disorder Interview Schedule for Children (ADIS-C; section of affective disorders)

Secondary outcome

1. Suicidal ideation: item 8 of CDI 2

2. Anxiety: State Trait Anxiety Inventory (STAI)

3. Suicide risk: VOZZ-Screen

4. Healthcare costs: cost diary (Bodden et al., 2008; Stikkelbroek et al., 2013)

5. Health Status: EQ-5D-5L

6. Somatic complaints: Children's Somatization Inventory (CSI)

7. Cognitive errors: The Children's Negative Cognitive Errors questionnaire-Revised (CNCEQ-R)

8. Independant and personal negative life-events: The Adolescent Live Event Questionnaire-Revised (ALEQ-R)

9. Academic functioning: School grades, drop-outs, non-attendance, and truancy (obtained in collaboration with schools)

10. Depression symptoms according to the parents: Child Depression Inventory 2 for parents (CDI 2-P)

Study description

Background summary

In this randomized controlled trial (RCT with 2 conditions, intervention and control group) the effectiveness of an indicated prevention program aimed at depression will be tested. Adolescents in their second year of secondary school (11-15 years) will be screened for depression by the mental health service of school (GGD). Adolescents with presence of suicidal ideation or severe depressive symptoms will be seen and eventually redirected to mental health care. Adolescents with clinical level of depressive symptoms will be randomly assigned to the experimental and control condition. Participants in the experimental condition will receive the prevention program 'Op Volle Kracht' consisting of 8 sessions of 60 minutes that will be implemented at school. Participants in the control condition will receive psycho-educational information. Measurements of primary and secondary outcomes will be conducted in the intervention and control group at baseline, post-intervention, at 6-, 12-, 24-, 36-, and 48 months follow-up.

Study objective

The effectiveness of a school-based indicated depression prevention program ('Op Volle Kracht') will be tested in a Dutch sample of adolescents with elevated depressive symptoms (aged 12-14 years). It is expected that the adolescents who receive the intervention will show

lower levels of depressive symptoms during follow-up, compared to the control group. Moreover, it is expected that the intervention will be cost-effective and screening and intervening will reduce suicide risk.

Study design

1. Baseline

2. Post-intervention (after session 8)

3. Follow-up 1 (6 months)

4. Follow-up 2 (12 months)

5. Follow-up 3 (24 months)

6. Follow-up 4 (36 months)

7. Follow-up 5 (48 months)

Intervention

The adolescents with symptoms of depression will be randomly assigned to the intervention or control condition. Participants in the intervention condition receive the program, consisting of 8 sessions of 60 minutes that will be implemented at school. Participants in the intervention and participants in the control condition will fill in questionnaires at seven moments during the study. After the study, the participants in the control condition will also get the chance to follow the lessons.

Contacts

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Eligibility criteria

Inclusion criteria

1. Adolescents in their second year of secondary school (11-15 years)

2. Informed consent from children and parents

3. Sufficient knowledge of the Dutch language

4. CDI 2-score > 14.

Exclusion criteria

1. Absence of parental permission

2. Adolescent already receiving treatment for mood problems

2. Children with suicidal ideation (score 2 on item 8 CDI 2) or servere depression (measured with clinical interview) will be excluded from the intervention

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2016
Enrollment:	160

Type:	Anticipated

Ethics review

Positive opinion

Date:	11-03-2016
Application type:	First submission

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
NTR-new	NL5618
NTR-old	NTR5725
Other	NL55328.091.15 : 2016-02 CMO Arnhem-Nijmegen

Study results

Summary results
N/A