A randomized controlled trial comparing school-based (Op Volle Kracht) and computerized (SPARX) depression prevention programs with adolescent girls.

No registrations found.

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

Summary

ID

NL-OMON20445

Source
NTR

Health condition

Depression, Prevention, Adolescents, Depressie, Preventie, Adolescenten.

Sponsors and support

Primary sponsor: Radboud University
Source(s) of monetary or material Support: Radboud University

Intervention

Outcome measures

Primary outcome

Depressive symptoms: Reynolds Adolescent Depression Scale Second Edition (RADS-2).

Secondary outcome

1. Daily stressors. Daily stressors will be measured by asking adolescents if they experienced a negative event last week. Questions include what kind of event it was, who was involved in the event, what emotion(s) were most prominent during the event, what the intensity was of the emotion and if the stress from the event has been resolved or not;

2.. Motivation. Adapted version of the Autonomous and Controlled Motivations for Treatment Questionnaire (ACMTQ);

3. Cognitive coping. Cognitive Emotion Regulation Questionnaire (CERQ);

4. Cognitive errors. Revised Children's Negative Cognitive Errors Questionnaire (CNCEQ-R);

5. Active coping. Brief-COPE;

6. Self-efficacy. Self Efficacy Questionnaire for Children (SEQ-C);

7. Hopefulness. General Positive Expectancies (GPE);

8. Theory of emotion. Implicit Theory of Emotion scale (ITE);

9. Depression Anxiety Stress Scale (DASS 21).

Study description

Background summary

In this randomized controlled trial (RCT with 4 conditions, 3 intervention conditions and control group), the effectiveness of school-based ('Op Volle Kracht') and computerized ('SPARX') depression prevention programs will be tested in a Dutch sample of adolescent girls with elevated depressive symptoms. Girls with elevated depressive symptoms are randomly assigned to one of four conditions. The first condition will consist of 8 lessons of 50 minutes at school during or after school time. The second condition consists of seven 30 minute levels of a video game which girls play at home. The third condition consists of both the 8 school-based lessons and the seven levels of the video game. Measurements of primary and secondary outcomes will be conducted in all groups at baseline, immediately after each lesson, three, six and twelve months after the last lesson.

Study objective

The effectiveness of school-based ('Op Volle Kracht') and computerized ('SPARX') depression prevention programs will be tested in a Dutch sample of adolescent girls with elevated depressive symptoms. The programs will be tested separately and combined. It is expected

that the adolescent girls who receive one or both of the interventions will show lower levels of depressive symptoms during posttreatment and follow-up, compared to the control group.

Study design

1. Screening (all primary and secondary outcomes);

2. Pretreatment (all primary and secondary outcomes);

3. Immediately after each lesson (Depressive symptoms (RADS-2); Suicidal ideation; Daily stressors);

4. Midtreatment (all primary and secondary outcomes);

5. Posttreatment (all primary and secondary outcomes);

6. Three months after the last lesson (follow-up; all primary and secondary outcomes);

7. Six months after last lesson (all primary and secondary outcomes);

8. Twelve months after last lesson(all primary and secondary outcomes).

Intervention

Girls with elevated depressive symptoms are randomly assigned to one of four conditions.

1. The first condition, 'Op Volle Kracht', will consist of the first 8 lessons of 50 minutes of the 'Op Volle Kracht' program (including homework assignments), which the girls will receive at their school during or after school time under supervision of a psychologist.

2. In the second condition, ‘SPARX’, girls play one 30 minute level of the ‘SPARX’ video game at home each week, until they have completed all seven levels.

3. The third condition, ‘Op Volle Kracht and SPARX’, consists of both the first 8 lessons of ‘Op Volle Kracht’ (as received by the girls in the first condition) and the seven levels of ‘SPARX’ (as received by the girls in the second condition).

4. Finally, the control condition, will receive an intervention after the completion of the study (either OVK or SPARX), but no intervention during the study. Participating girls in all conditions fill out weekly questionnaires during the programs.

Contacts

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Eligibility criteria

Inclusion criteria

1. Adolescent girls in 7th and 8th grade, middle school (ages 12-14);

2. Informed consent from children and parents;

3. Elevated depressive symptoms. In line with other indicated prevention studies (see for a meta-analytic review Horowitz & Garber, 2009) and earlier studies with the SPARX (Fleming et al., 2012; Merry et al., 2012; Lucassen et al., in preparation) girls with a RADS-2 score of above the 70th percentile will be included.

Exclusion criteria

1. No informed consent from children and parents;

2. Children with severe depressive score and suicidal ideation (score 3 on item 9 of the CDI);

3. Children currently receiving mental health care.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2012
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-12-2012
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	NL3579

Register	ID
NTR-old	NTR3737
Other	ECG : 2012-2711-069
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A