A Randomized Controlled Trial Testing the Effectiveness of an Indicated Depression Prevention Program ('Op Volle Kracht') Among Adolescent Girls with Elevated Depressive Symptoms.

No registrations found.

Ethical review Not applicable **Status** Recruiting

Health condition type -

Study type Interventional

Summary

ID

NL-OMON26120

Source

NTR

Health condition

Adolescent girls, Depression, Prevention, Implicit Self-Esteem

Sponsors and support

Primary sponsor: GGZ Oost-Brabant

> GGZ Oost Brabant

> Burgemeester de Kuyperlaan 5

> 5461 AA Veghel > The Netherlands

> Telefoon: 0413 - 84 68 00

Source(s) of monetary or material Support: Stichting Olim

Intervention

Outcome measures

Primary outcome

- 1. Implicit Self-esteem: Implicit Association Task (IAT);
- 2. Depressive symptoms: Child Depression Inventory (CDI).

Secondary outcome

- 1. Implicit Self-esteem: Name Letter Task (NLT);
- 2. Depressive symptoms: Center for Epidemiologic Studies Depression Scale (CES-D scale);
- 3. Self-esteem: Rosenberg Self-Esteem Scale (RSES);
- 4. Self-esteem: State Self-Esteem Scale (SSES);
- 5. Anxiety: State Trait Anxiety Inventory (STAI);
- 6. Positive & Negative affect: Positive and Negative Affect Schedule (PANAS);
- 7. Relationship best friend;
- 8. Loneliness: UCLA loneliness scale (UCLA);
- 9. Emotional Eating Behaviour: Nederlandse Vragenlijst voor Eetgedrag (NVE);
- 10. Psychopathology Parents.

Study description

Background summary

In this randomized controlled trial (RCT with 2 conditions, intervention and control group) the effectiveness of an indicated depression prevention program for adolescent girls with elevated depressive symptoms (12-14 years of age) will be tested. Adolescents in the intervention condition receive the program consisting of the first 8 lessons of 50 minutes that will be implemented after schooltime. Measurements of primary and secondary outcomes will be conducted in the intervention and control group at baseline, immediately after each lesson and one month after the last lesson.

Study objective

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The effectiveness of a school-based indicated depression prevention program ('Op Volle Kracht') will be tested in a Dutch sample of adolescent girls with elevated depressive symptoms (aged 12-14 years). It is expected that the adolescent girls who receive the intervention will show lower levels of depressive symptoms during follow-up, compared to the control group. Moreover, we will examine whether implicit self-esteem predicts or mediates treatment outcome.

Study design

- 1. 0 (start);
- 2. Immediately after each lesson;
- 3. One month after last lesson (follow-up);
- 4. Six months after last lesson.

Intervention

The girls with elevated depressive symptoms of the participating schools are at random assigned to the intervention or control condition. The participating girls in the intervention condition receive the program, consisting of the first 8 lessons of 50 minutes that will be implemented after schooltime. They will also fill in questionnaires after each lesson. The participating girls in the control condition will only fill in the questionnaires at the same time points. After the study, they will also get the chance to follow the lessons.

Contacts

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Eligibility criteria

Inclusion criteria

- 1. Adolescents in 8th grade, middle school (ages 12-14);
- 2. Middle school grade 8 (VMBO-t, HAVO, VWO, Gymnasium);
- 3. Informed consent from children and parents;
- 4. CDI-score > 16.

Exclusion criteria

- 1. Parents (on behalf of their child) do not allow their child to participate in the study;
- 2. Children with CDI-score > 19 and suicidal ideation (score 2 on item 9).

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): 01-09-2011

Enrollment: 100

Type: Anticipated

Ethics review

Not applicable

Application type: Not applicable

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 NL2978 NTR-old NTR3126

Other Stichting Olim: 2011-01

ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A