Prevention of Depression and Anxiety in Adolescents with a High Familial Risk.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20973

Source
Nationaal Trial Register

Health condition

Prevention, depression, anxiety, adolescents, parental psychopathology

Sponsors and support

Primary sponsor: GGZ Oost Brabant
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

1. Depression;

Secondary outcome

- Anxiety
- Suicidal ideation
- Response style

- Cognitive errors
- Relational support
- Parental psychopathology
- Parenting stress
- Child depression according to parents
- Child anxiety according to parents

Study description

Background summary

In this randomized controlled trial (RCT with 2 conditions, intervention and control group) the effectiveness of an indicated and selective prevention program aimed at depression and anxiety for adolescents (aged 11-15) with high familial risk will be tested. Adolescents in the intervention condition receive the program consisting of the 6 sessions of 90 minutes that will be implemented at school. Measurements of primary and secondary outcomes will be conducted in the intervention and control group at baseline, immediately after each session 2, 4 and 6 (post-intervention), at 6 months and 12 months follow-up.

Study objective

The effectiveness of an indicated indicated depression and anxiety prevention program ('Een Sprong Vooruit') will be tested in a Dutch sample of adolescents (aged 11-15) with high familial risk. It is expected that the adolescents who receive the intervention will show lower levels of depressive and anxiety symptoms during follow-up, compared to the control group.

Study design

1. Baseline;

2. Intervention phase 1 (after session 2);

3. Intervention phase 2 (after session 4);

4. Post-intervention (after session 6);

5. Follow-up 1 (6 months);

6. Follow-up 2 (12 months).

Intervention

The children with symptoms of depression and/or anxiety and with parents with elevated levels of depression and/or anxiety randomly assigned to the intervention or control

condition. Participants in the intervention condition receive the program, consisting of 6 sessions of 90 minutes that will be implemented at school. Participants in the intervention and participants in the control condition will fill in questionnaires at six moments during the study. After the study, adolescents in the control condition will also get the chance to follow the lessons.

Contacts

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Eligibility criteria

Inclusion criteria

- adolescent is aged between 11-15 years old;

- shows increased levels of depression and or anxiety;

- at least one of the parents shows symptoms of a depression or anxiety disorder;

- both adolescent and parents have sufficient knowledge of the Dutch language

Exclusion criteria

- absence of parental permission;

- adolescent already receives treatment for mental health problems

- presence of prominent suicide ideation (score of 2 CDI 2 suicide item)

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:	Recruitment stopped
Start date (anticipated):	01-01-2013
Enrollment:	160
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-11-2012
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	NL3563
NTR-old	NTR3720
Other	- : -
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A