Test of the effectiveness and underlying mechanisms of a group-based cognitive behavioural therapy-based indicative prevention program for children with elevated anxiety levels.

No registrations found.

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

Summary

ID

NL-OMON26873

Source
Nationaal Trial Register

Health condition

Anxiety, Effective elements, CBT, Children, Mediator, Coping, Cognitions, Prevention, Group intervention.

Sponsors and support

Primary sponsor: ZONMW 159010001
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

Child and parent report:

1. Anxiety symptoms: Spence Children's Anxiety Scale (SCAS) & Multidimensional Anxiety Scale for Children (MASC-10).

Secondary outcome

Child reports:

1. Active coping: Coping Strategieën Lijst voor Kinderen (CSLK);

2. Positive cognitive restructuring: Coping; Strategieën Lijst voor Kinderen (CSLK);

3. Cognitions about coping: Coping Questionnaire Child (CQ-C);

4. Self-efficacy: Self-Efficacy Questionnaire for Children (SEQ-C).

Trainers reports:

5. Therapeutic Alliance: Therapeutic Alliance Scale (TASC).

Study description

Background summary

In this randomized controlled trial (RCT with 2 conditions, intervention and control group) the effectiveness of a CBT program (Coping Cat) in the form of an indicative group-based prevention will be evaluated. The second aim is to gain insight into the mechanisms underlying its effectiveness.
Primary school children (grades 5 till 8) in the intervention condition receive the program consisting of 12 lessons of 1 hour that will be implemented after school time. Measurements of primary and secondary outcomes will be conducted in the intervention and control group at baseline, directly before each lesson and at 3 months follow up.

Study objective

The main aim of this project is to conduct a Randomized Controlled Trial (RCT) to evaluate the effectiveness of an adapted and translated version of Coping Cat in the form of an indicative group-based prevention program.

The main aim of this project is to conduct a Randomized Controlled Trial (RCT) to evaluate the effectiveness of a CBT group treatment program (“Coping Cat”) in the form of an

indicative anxiety prevention program. The second aim it to gain insight into the mechanisms underlying its effectiveness. Coping Cat will be tested in Dutch primary school children (grades 5-8) with elevated levels of anxiety. It is hypothesized that children in the intervention condition will experience reduced levels of anxiety in comparison with the control group. Three potential mediators will be examined, namely active coping, cognitions about coping and positive cognitive restructuring.

Study design

1. Screening;

2. Baseline (just before start intervention);

2. Directly before each lesson (child reports only);

3. Three month after last lesson (follow-up).

Intervention

Children randomly assigned to the intervention condition will receive a 12-session, 1-h group therapy. Therapy will take place at the schools, after regular school hours. Children will fill in questionnaires before each lesson.

Participating children in the control condition will only fill in questionnaires at the same time points. After the 3-month follow-up assessment, they will also get the chance to follow the program.

Contacts

Public
PO Box 9104
Manon L.A. Starrenburg, van
Nijmegen 6500 HE
The Netherlands
+31 (0)24 3612123
Scientific
PO Box 9104
Manon L.A. Starrenburg, van
Nijmegen 6500 HE
The Netherlands
+31 (0)24 3612123

Eligibility criteria

Inclusion criteria

1. Primary school children in grades 5 till 8 (ages 7 till 12);

2. Screening participation: passive consent from parents;

3. SCAS-C score > 1 SD;

4. After screening: Active consent from parents.

Exclusion criteria

1. Parents (on behalf of their child) do not allow their child to participate;

2. Children with SCAS-P score > 1SD and high score on suicidal item CDI (score 3 on item 9);

3. Children who score above the cut off score on the obsessive compulsive disorder scale only;

4. Child who received CBT in the last year, or are currently in therapy with a CBT basis.

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):	28-01-2013
Enrollment:	130
Type:	Anticipated

Ethics review

Positive opinion Date:	28-01-2013
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	NL3630
NTR-old	NTR3818
Other	RU : ECG2012-0910-053
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A