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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26873

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: ZONMW 159010001
Overige ondersteuning: initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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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.

Onderzoeksopzet

1. Screening;

2. Baseline (just before start intervention);

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

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	28-01-2013
Aantal proefpersonen:	130
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-01-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3630
NTR-old	NTR3818
Ander register	RU : ECG2012-0910-053
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A