Treating anxiety using blended treatment

No registrations found.

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

Summary

ID

NL-OMON26513

Source
NTR

Brief title
KAT (Karakter Angst Training)

Health condition

Anxiety, angst

Sponsors and support

Primary sponsor: Karakter, kinder- en jeugdpsychiatrie
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

ADIS-C

The main study parameter is the prevalence of a diagnosis of anxiety disorders as measured with the ADIS-C. The ADIS-C is a semi structured diagnostic interview of childhood anxiety disorders as well as mood and externalizing disorders (Silverman& Albano, 1996). Separate

diagnostic profiles are derived from a parent and a child interview, which are combined to form a consensus diagnosis (Silverman & Albano, 1996). The ADIS-C has good interviewer–observer reliability (kappa = .75) and test–retest reliability (.75) (Silverman, Saavedra, & Pina, 2001).

Following each diagnostic interview, ADIS-IV-C/P interviewers complete a separate measure that required them to assign severity ratings for 13 DSM-IV disorders, whether or not criteria are met for those disorders. Ratings are based on clinicians' assessments of the degree to which the dimension of each disorder is present in the child. Ratings are completed separately for parent and child interviews. These scores range from 0 to 8, with higher scores representing increased clinical severity. Thus, a child with severe panic disorder might get a rating of 7 or 8 for that disorder, whereas a child with mild apprehension about shortness of breath might receive a rating of 2 or 3.

RCADS

Anxiety symptoms are assessed by the Dutch translation of the RCADS (Chorpita et al., 2000). The RCADS is a self-report questionnaire, consisting of 47-items measuring five anxiety subtypes and depression symptoms (Chorpita et al., 2000). Chorpita et al. (2000) showed good reliability and internal consistency (GAD= 0.79, a = 0.77; OCD= 0.65, a = 0.73; PD = 0.76, a = 0.79; SA = 0.75, a=0.76; SP = 0.80, a = 0.82; MDD= 0.77, a = 0.76) as well as convergent and discriminant validity in a sample of n = 246 children and adolescents aged 8–18 years (Chorpita et al., 2000). In this study the total score will be used for analyses.

Secondary outcome

Tic-P Questionnaire

Direct and indirect costs as a consequence of the child's psychiatric disorder, i.e. the medical costs and productivity losses in parents are measured using the 'Trimbos and iMTA questionnaire on Costs associated with Psychiatric illness' (Tic-P questionnaire) (Bouwmans, Schawo, Hakkaart- van Roijen, 2012). Validity and reliability have been established (Bouwmans et al., 2012). For every patient, the duration and type of each contact as well as the type of health care worker with whom the contact was will be registered and used to calculate the cost-effectiveness of both trajectories. Productivity losses of parents associated with their child's health problem or its treatment will be registered as well.

EQ 5D

The EQ-5D is primarily designed for self-completion by respondents. It measures five different dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.

Each dimension has three levels of perceived problems: no problems, some problems, and severe problems. The respondent is asked to indicate his/her health state by placing a cross in the box against the most appropriate statement in each of the 5 dimensions.

Subsequently, the respondent is asked to self-rate the state of health on a visual analogue scale (VAS). The VAS ranges from 0 to 100, where 100 is rated as ‘Best imaginable health state’ and 0 as ‘Worst imaginable health state’. This information can be used as a quantitative measure of health outcome as judged by the individual respondents. Instructions to respondents are included in the questionnaire.

Semi-structured interview

At the end of the study a semi-structured interview will be completed by telephone with a random sample of 10 patients and therapists in the intervention condition for a qualitative view on their experiences on blended treatment.

Topics will include:

* What are their positive and negative experiences with the blended intervention?

* How did they feel about the support of the therapist?

* Are their suggestions for improvement of the treatment?

* If applicable reason for drop-out.

Study description

Background summary

Rationale: Anxiety is a normal and useful feature of development, but becomes a problem when fears are extreme or prolonged. Anxiety disorders are common amongst children and adolescents and often co-occur with psychiatric disorders like ADHD, Autism Spectrum Disorders (ASD) and with intellectual disabilities. Cognitive behaviour therapy has shown to be an effective treatment in anxiety disorders in a face-to-face setting, but so far there are no evidence based internet interventions for children with psychiatric or intellectual disabilities and comorbid anxiety disorders. The aim of this study is to investigate the efficacy of the blended version of the Coping Cat Program in a naturalistic sample of children diagnosed

with an anxiety disorder and possible ADHD, ASD, or mild intellectual disability/borderline intellectual functioning (50 85).

Objective: The main objective of the study is to evaluate the efficacy of the ‘Blended Coping Cat’ program in reducing anxiety levels in children diagnosed with anxiety disorders and possible ASD, ADHD, mild intellectual disability or borderline intellectual functioning.

The secondary objectives are to evaluate the cost-effectiveness of the ‘Blended Coping Cat’ program in children diagnosed with anxiety disorders and possible ADHD, ASD, mild intellectual disability or borderline intellectual functioning and to evaluate the experience of patients and therapists using the ‘Blended Coping Cat’ program. Study design: This is an explorative study.

Study population: 20 children and adolescents with an anxiety disorder and possible ADHD or ASD or mild intellectual disability/borderline intellectual functioning (age 8;0 – 13;11, 50< IQ< 85)

Intervention: Children will be treated with the blended Coping Cat Program and pre and post intervention scores will be compared. Main study parameters/endpoints: The main study parameter is the measured difference in reported anxiety diagnosis and anxiety level (ADIS-C and RCADS).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Risks are considered minimal. Two additional questionnaires and if applicable an intelligence test will be completed by the child/adolescent and three additional questionnaires by the parent/legal representative. These are the only burden for the participants.

Study objective

The main objective of the study is to evaluate the efficacy of the ‘Blended Coping Cat’ program in reducing anxiety levels in children diagnosed with anxiety disorders and possible ASD, ADHD, mild intellectual disability or borderline intellectual functioning.

Secondary Objectives:

- To evaluate the cost-effectiveness of the ‘Blended Coping Cat’ program in children diagnosed with anxiety disorders and possible ADHD, ASD, mild intellectual disability or borderline intellectual functioning.

- To evaluate the experience of patients and therapists using the ‘Blended Coping Cat’ program.

Study design

0 weeks, 12 weeks.

Intervention

All children will receive treatment using the Dutch version of Blended Coping Cat. Treatment will be given by or under supervision of a registered Cognitive Behaviour Therapist. This version of the treatment was developed by Jouw omgeving (NJI, 2014; Nauta, Vet, Kok & Vos, 2014). The original Coping Cat Program (CCP) is an evidence-based cognitive behavioral treatment for anxiety disorders in children. The program consists of 12 sessions in which exposure is the main strategy. Different skills are taught during the CCP. Children learn to recognize and understand emotional and physical reactions to anxiety, clarify thoughts and feelings in anxious situations, develop new strategies to cope with anxiety (for example by using relaxation techniques and constructive thoughts), and to evaluate their coping efforts and use self-reinforcement techniques (Kendall, Kane, Howard & Siqueland, 1990). All elements of the paper and pencil version of the CCP are maintained in the blended version. The first and last sessions are face to face with a therapist. The other parts can be either online or face-to-face. With the blended version of the CCP the children can work more independently and at their own pace. All the information, including therapist feedback, can be reviewed again by the child (Jouw Omgeving, 2014). The blended version consists of a secure portal for the child and a secure portal for the parent. The parent can read information about anxiety disorders and can support the child with the program. The blended program consists of 12-16 sessions, depending on the amount of support the child receives at home and the progress of the child. The blended program is more individually tailored. The child can choose which part of the program is most helpful to him or her (Jouw Omgeving, 2014).

Contacts

Public
Utrechtseweg 320

A Heinemann
Oosterbeek 6862 BC
The Netherlands
026-4002100
Scientific
Utrechtseweg 320

A Heinemann
Oosterbeek 6862 BC
The Netherlands
026-4002100

Eligibility criteria

Inclusion criteria

To be included in this study, a subject must meet the following criteria:

1. Children (boys and girls) aged between 8;0 years and 13;11 years

2. Diagnosed with an anxiety disorder, classified by the Diagnostic and Statistical Manual of Mental Disorders, DSM-IV (APA, 2000) by a child- and adolescent psychiatrist of Karakter.

3. Anxiety treatment is indicated by a child- and adolescent psychiatrist of Karakter.

4. Optionally diagnosed with one of the below comorbid disorders

a) ADHD

b) ASD

c) Mild intellectual disability or borderline intellectual functioning (50
5. Access to a PC with internet connection

Exclusion criteria

Patients that meet any of the following criteria will be excluded from this study:

1. Children receiving other treatment focused on the anxiety disorder

2. Acute psychoses

3. Children with current suicidal problems

4. Children with severe motor or visual impairment

5. Children who can’t independently deal with verbally presented information on a computer

6. Participation in another clinical trial simultaneously

7. Insufficient motivation to follow the treatment

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:	Pending
Start date (anticipated):	01-05-2015
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-04-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42739
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5073
NTR-old	NTR5204
CCMO	NL52685.091.15
OMON	NL-OMON42739

Study results

Summary results
N/A