A randomized waiting-list controlled study on the efficacy and cost effectiveness of blended treatment to reduce anxiety in children with Anxiety disorders and possible comorbid ADHD, ASD or mental disability.

Published: 15-10-2015
Last updated: 19-03-2025

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 ADHD, ASD, mild intellectual disability or borderline intellectual...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON42739

Source
ToetsingOnline

Brief title
Treating anxiety using blended treatment

Condition

- Anxiety disorders and symptoms

Synonym
anxiety disorder

Research involving

Human

Sponsors and support

Primary sponsor: Karakter, Kinder en Jeugdpsychiatirie
Source(s) of monetary or material Support: Eigen instelling Karakter;Kinder- en Jeugdpsychiatrie

Intervention

Keyword: Anxiety, Blended treatment, Child Psychiatry, Randomized Controlled Trials

Outcome measures

Primary outcome

The main study parameter is the measured difference in reported anxiety level

and anxiety diagnosis (ADIS-C, RCADS).

Secondary outcome

The health care consumption of the child and the parents (TIC-P), excluding the

research intervention is the second study parameter. The EQ-5d will be used to

look at health outcome as judged by the individual respondents and finally a

qualitative interview is conducted to look at the experiences of clients

(parents en children) and therapists with the blended intervention.

Study description

Background summary

Anxiety is a normal and useful part of development, but becomes a problem when fears are extreme or prolonged. Anxiety disorders are common amongst children and adolescents and can lead to problems in development. Many children with psychiatric disorders like ADHD or ASD or mild intellectual disability/borderline intellectual functioning experience high anxiety levels. Cognitive behaviour therapy has been shown to be an effective treatment in a face to face setting, but there are no evidence based internet interventions for children with anxiety disorders and possible comorbid psychiatric or

intellectual disabilities. The aim of this study is to investigate the effectiveness of the blended version of the Coping Cat Program in comparison with a wait list control group in children and adolescents who are diagnosed with ADHD, ASD, or mild intellectual disability/borderline intellectual functioning and a comorbid anxiety disorder.

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 ADHD, ASD, mild intellectual disability or borderline intellectual functioning (50The second objective is 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 a stratified randomized wait-list controlled trial.

Intervention

Children in the intervention condition will be treated with the blended Coping Cat Program and are compared to a wait-list control group.

Study burden and risks

Risks are considered minimal. Two additional questionnaire and if applicable an intelligence test will be completed by the child/adolescent and one additional questionnaire by the parent/legal representative before the intervention/waiting list condition; and two questionnaires will be completed by the child and three addiotional ones by the parent/legal representative after the intervention/waiting list condition. These are the only burden for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

1. Children (boys and girls) aged between 8;0 years and 17;11 years
2. Diagnosed with an anxiety disorder, classified by the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, 2000) by a child- and adolescent psychiatrist within Karakter.
3. Optionally diagnosed with one of the below comorbid disorders
a) ADHD
b) ASD
c) Mild intellectual disability or borderline intellectual functioning (504. Access to a PC with internet connection

Exclusion criteria

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. Participation in another clinical trial simultaneously
6. Insufficient motivation to follow the treatment

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-07-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	15-10-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-01-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26513
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL52685.091.15
OMON	NL-OMON26513