ADHD Treatment at Home through E health? A Non-inferiority pilot trial and Examination of costs and consumer satisfaction of blended versus face to face parent training for children with ADHD and behavioral problems

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON42788

Source
ToetsingOnline

Brief title
ATHENE

Condition

- Psychiatric and behavioural symptoms NEC

Synonym
ADHD, attention-deficit/hyperactivity disorder

Research involving

Human

Sponsors and support

Primary sponsor: Kinder- en jeugdpsychiatrie Accare
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ADHD, behavioral problems, parent training, treatment effect

Outcome measures

Primary outcome

Our primary outcome will be the severity of parent reported behavior problems,

as measured with the Externalizing scale of the Child Behavior Checklist

(CBCL).

Secondary outcome

Secondary outcome measures include parental satisfaction with the training,

parenting competence and stress, the amount of therapist time, and children*s

comorbid problems.

Study description

Background summary

Children with attention-deficit/hyperactivity disorder (ADHD) often show behavior problems (e.g., temper tantrums, disobedience, aggressive behaviors) that can severely influence their daily life and development. Parent training is a well-established intervention for children with ADHD and behavior problems; its effectiveness has been shown particularly with respect to the reduction of behavioral problems. Due to the growing need to enhance the cost-effectiveness of treatments in mental health care, a blended parent training program has been developed, providing parent training partially online and partially face-to-face. The blended program aims to reduce costs by diminishing therapist time and to enhance the availability, accessibility, and user-friendliness of the intervention, without reducing its effectiveness.

Study objective

The current pilot study will explore 1) whether the effect of blended parent training is noninferior to the effect of face to face parent training, 2) whether therapist time can be reduced by offering the intervention partially online, 3) whether parents are satisfied with the blended parent training program, and 4) the opinion of parents regarding the feasibility of the blended program.

Study design

We will conduct a randomized controlled trial, with two conditions: 1) individual face to face parent training (n=10), and 2) individual blended parent training (n=10). Assessments will take place before randomization and directly after completion of the parent training program.

Intervention

Face to face parent training consists of 10-17 manualized face to face contacts with homework to practice learned skills. In the blended parent training, parents participate in a training with the same content, but delivered largely online, with an additional minimum of four face to face contacts. The duration of both treatments is approximately twenty weeks. In both conditions participants are allowed to receive other treatments (e.g., psychosocial and/or pharmacological), with the exception of behavior therapeutic interventions through parents directed at the behavior of their child.

Study burden and risks

Parents have to complete rating scales before randomization and immediately after treatment. None of the measures or the interventions form a risk for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) 1) The child has a diagnosis of ADHD according to DSM IV-TR or DSM-5 criteria.
2) The child is 4 through 12 years old.
3) The child has an IQ higher than 70.
4) At least one parent experiences behavioral problems at home and is able to select at least three problem behaviors on the List of Target Behaviors (LTB).
5) Both parents (if present) are willing to participate in the BPTG program.
6) The child is not taking any psychotropic medication or, when taking psychotropic medication, is on a stable dose for at least 6 weeks prior to the inclusion.
7) The referring clinician does not expect any changes in drug treatment policy during the BPTG.
8) Parent(s) have given their informed consent for participation.
9) Parent(s) have a laptop or PC at their disposal.

Exclusion criteria

1) Parents participated in a behavioral parent training in the year prior to the current study.
2) There are problems with the child and/or the family that require immediate intervention (e.g. crisis in the family).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-11-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	19-11-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL54104.042.15