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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22850

Source
NTR

Brief title
ATHENE

Health condition

ADHD; behavioral problems; children; parent training;
e-health; blended treatment; online; gedragsproblemen; kinderen; ouders; training; oudertraining; blended

Sponsors and support

Primary sponsor: Accare Child and Adolescent Psychiatry
Source(s) of monetary or material Support: University Medical Center Groningen (Healthy Ageing Pilots)

Intervention

Outcome measures

Primary outcome

The severity of parent reported child behavior problems, as measured with the Externalizing scale of the Child Behavior Checklist (CBCL).

Secondary outcome

• Frequency and severity of disruptive behaviors (ECBI)

• Behavioral non-compliance in everyday settings (HSQ)

• The occurrence and severity of specified problem behaviors (List of Target Behaviors)

• Emotional problems, behavioral problems, hyperactivity / attention problems and social problems (SDQ)

• Parenting stress (PSI-SF)

• Parenting style (PS)

• Parenting sense of competence (PSOC)

• Parental satisfaction with the content and effect of parent training

• Belief of parents concerning the effectiveness of the training (one question).

• Use of skills learned during BPTG (one question)

• Use of mental health care

• Parental attribution (two questions)

• Parental computer experience (two questions)

• Number of face to face sessions

• Therapist time

Study description

Background summary

Parent training is a well-established intervention for children with ADHD and behavior 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. 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 in children with ADHD and behavioral problems, (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. 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).

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 measures include parental satisfaction with the training, parenting competence and stress, the amount of therapist time, and children's comorbid problems.

Study objective

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.

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

There are two time-points: assessments will take place before randomization and

immediately after the BPTG.

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.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet the following criteria:

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

A potential subject who meets any of the following criteria will be excluded from participation in this study:

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2015
Enrollment:	20
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-11-2016
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	NL6092
NTR-old	NTR6239
Other	Medical Ethical Committee (METc) of the University Medical Center Groningen (UMCG) : METc 2015.289

Study results