Home-based behavioral treatment for ADHD.

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

Samenvatting

ID

NL-OMON27585

Bron
NTR

Aandoening

attention-deficit/hyperactivity disorder, ADHD

Ondersteuning

Primaire sponsor: Accare, Division University Medical Center for Child and Adolescent Psychiatry, Groningen, the Netherlands.
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Parent reported disruptive behavior problems with Eyberg Child Behavior Inventory.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Most referred, school-aged children with attention-deficit/hyperactivity disorder (ADHD) profit well from treatment with medication, i.e. behavioral parent training or a combination of both treatments. However, a considerable proportion of children do not respond sufficiently to these first line treatments. In Dutch clinical practice a next treatment step is to offer home-based treatment to address remaining disruptive behavior problems. Our clinical impression is that this treatment is often successful. However, there is a lack of empirical evidence for the effectiveness of home-based treatment directed at behavior problems in children with ADHD.

Objective:

To investigate the short-term effectiveness of a 4 month manualized home-based behavioral treatment for referred children with ADHD, aged 6 to 12 years, who have responded insufficiently to first line treatment with medication or behavioral parent training or a combination of both treatments. Our primary objective is to examine the improvement of disruptive behavior problems as reported by parents. Secondary objectives are to investigate long-term effectiveness, the effectiveness on secondary study parameters, and the effect of various psychosocial, cognitive, and biological moderators and mediators of treatment success.

Study design:

The study involves a randomized controlled trial (N=120), including three study conditions: (1) manualized treatment (n=40), (2) treatment with home based care as usual (CAU) treatment (n=40), and (3) a waiting list (n=40).

Study population:

Children with ADHD, aged 6 to 12 years, referred to our outpatient mental health clinic (University Center for Child- and Adolescent Psychiatry, Accare) who have not responded sufficiently to pharmacotherapy and/or behavioral parent training. Families who discontinued previous behavioral treatment or did not consent medication treatment will also be included.

Intervention:

The families in the condition with the manualized treatment will receive 14-16 weekly home-visits spread over four months and additional telephone sessions with their therapist twice a week. This treatment involves a fully manualized behavioral treatment. The families in the CAU-condition will receive home based treatment which is variable in content, length, and frequency of home-visits. The waiting-list-condition will have a duration of four months, in line with the regular waiting list, after which families will be allocated to home-based treatment. Other ongoing treatments will be allowed across all study arms.

Main study parameters:

Parent reported disruptive behavior problems. Main secondary study parameters are children’s internalizing problems, parent reported impairment of the child, and parenting skills.

Doel van het onderzoek

Most referred, school-aged children with attention-deficit/hyperactivity disorder (ADHD) profit well from treatment with medication, i.e behavioral parent training or a combination of both treatments. However, a considerable proportion of children do not respond sufficiently to these first line treatments. In Dutch clinical practice a next treatment step is to offer home-based treatment to address remaining disruptive behavior problems. Our clinical impression is that this treatment is successful. However, there is a lack of empirical evidence for the effectiveness of home-based treatment directed at behavior problems in children with ADHD.

Purpose of the study is to investigate the short-term effectiveness of a 4 month manualized home-based behavioral treatment for referred children with ADHD, aged 6 to 12 years, who have responded insufficiently to first line treatment with medication or behavioral parent training or a combination of both treatments. Our primary objective is to examine the improvement of disruptive behavior problems as reported by parents. Secondary objectives are to investigate long-term effectiveness, the effectiveness on secondary study parameters, and the effect of various psychosocial, cognitive, and biological moderators and mediators of treatment success.

Onderzoeksopzet

1. Baseline;

2. Intermediate measurements (Manualized treatment: after each treatment module; CAU treatment: after 4 months of treatment);

3. Directly post-treatment;

4. Follow up (6, 12 and 24 months after treatment).

Onderzoeksproduct en/of interventie

1. Manualized intervention, a 14-16 weekly home-visits spread over four months and additional telephone sessions with their therapist twice a week, fully manualized behavioral treatment.

2. The control group is:

A. A home based care as usual (CAU) treatment with a variable content, length, and frequency of home-visits, or;

B. A waiting list condition, four months duration in line with regular waiting list.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. The child is 6 to 12 years old;

2. The child meets DSM-IV-TR (American Psychiatric Association, 1994) criteria for ADHD, any subtype, as determined through a semi-structured interview (such as the Parent's Inventory of Children's Symptoms [Schachar et al., 1994] and the Teacher Telephone Interview [Tannock et al., 1995] at time of referral;

3. The parents and/or the child have received psycho-education and have either started or considered pharmacological treatments directed at ADHD symptoms, and have at least made a start with outpatient behavioral parent training;

4. The child has a DSM-IV-TR Global Assessment of Functioningscore < 55, as determined by the last involved clinician;

5. The child has an intensity scale score > 130 and problem scale score > 2 (irrespective of item 36, i.e. referring to enuresis nocturna) on the Eyberg Child Behaviour Inventory completed by the primary care-taker;

6. The child has a total verbal, and performance IQ > 70 as assessed with a standardized intelligence test;

7. The legal parent(s) caretaker(s) have provided written consent for participating in the study, in accordance with the rules laid down in the Dutch "Wet medisch-wetenschappelijk onderzoek met mensen".

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. The child has a medical ailment, which prohibits participation in the study;

2. One of the parents/caretakers is unable to understand or imitate instructions;

3. The child is more than three days a week absent from the home of the parent(s) who participate in the treatment;

4.The family lives or is planning to move to a location more than one hour travel time from the Groningen Accare outpatient clinic;

5.The family has followed a form of home-based therapy through our center during the previous year.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2010
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-08-2011
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	NL2876
NTR-old	NTR3021
Ander register	ZonMw / METC : 15700.3010 / 2010.289;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A