Parent Child Interaction Therapy versus methylphenidate in preschool ADHD.

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

Summary

ID

NL-OMON29136

Source
NTR

Brief title
Study of Treatment of ADHD and behavior problems in Preschool ADHD (STAP)

Health condition

ADHD and behavior problems in preschool children. ADHD en gedragsproblemen bij peuters en kleuters.

Sponsors and support

Primary sponsor: Accare, Division University Medical center for Child and Adolescent Psychiatry, Groningen, The Netherlands.
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The primary outcome measure will be the primary caretaker's ECBI. This is a widely used parent rating scale designed to measure conduct problem behavior in children between the ages of 2 and 16 years.

Secondary outcome

All of the secondary outcome measures will be completed by both caretakers separately, where applicable.
1. Conduct problem behaviors - second caretaker report on the ECBI;
2. Parent reported internalizing problems: the Internalizing scale of the Child Behavior Checklist;
3. Parent reported ADHD symptoms: the Conners Parent Rating Scale-Revised: Short Form;
4. Parenting practices: Parenting Scale; parenting stress: Parenting Stress Index – Short Form; and parenting sense of competence: Parenting Sense of Competence scale;
5. Teacher report of conduct problem behaviors and internalizing symptoms: the C-TRF/1½-5;
6. Functional impairment – parent, teacher, and clinician report: the Impairment Rating Scale;
7. Side effects of medication: Side Effect Rating Scale.

Predictor and moderator variables will be completed by both caretakers separately, where applicable.
Parental factors:
1. Household income, highest level of parent's education, parental age;
2. Quality of marital relationship: Maudsley Marital Questionnaire;
3. Parent cognitions about themselves, their parenting, and their child: Rosenberg Self-Esteem Scale, Interactions Questionnaire;
4. Psychopathology in parents: Beck Depression Inventory, Adult ADHD Rating Scale, SubTypes of Antisocial Behavior questionnaire, parental substance and alcohol use by direct interview;
5. Parental genetic factors (polymorphisms of the norepinephrine and dopamine transporters [NET, DAT], of dopamine receptors [DRD2, DRD3, DRD4], and Dopamine Beta Hydroxylase, Monoamine A, and serotonergic polymorphisms): DNA of both parents will be collected non-invasively from buccal swabs or saliva.

Child factors:
1. Age and intelligence;
2. Range of comorbidities at the time of referral;
3. Child's genetic factors (CYP2D6 polymorphisms, polymorphisms of the norepinephrine and dopamine transporters [NET, DAT], of dopamine receptors [DRD2, DRD3, DRD4], and Dopamine Beta Hydroxylase, Monoamine A, and serotonergic polymorphisms): DNA of the child will be collected non-invasively from buccal swabs or saliva;
4. Ethnicity and gender.

Study description

Background summary

Rationale:
Disruptive behavior problems, i.e., attention-deficit/hyperactivity disorder (ADHD), oppositional defiant disorder (ODD), and conduct disorder (CD), form a major burden for parents, are associated with a wide range of functional impairments, and are risk factors for child maltreatment. Although parent management training (PMT) is an effective treatment for behavior problems in preschool children, a subgroup of children does not respond sufficiently to this treatment.

Objective:
The primary aim of our study will be to compare the effectiveness of parent child interaction therapy (PCIT) with methylphenidate in decreasing conduct behavior problems in children with ADHD and disruptive behaviors. The study will be conducted in a population of referred children, aged 2;6 till 6 years, who have not responded sufficiently to previously offered PMT. As secondary objectives we aim to identify predictors and moderators of treatment response, which include both parental and children's characteristics, and to examine a range of secondary outcome measures, including internalizing symptoms, ADHD symptoms, functional impairment, and parental functioning.

Study design:
The research project involves a randomized controlled trial. Eligible children will be randomly assigned to either PCIT or to the most optimal dose of methylphenidate, as determined through placebo-controlled cross-over trials with low, medium, and high doses.

Study population:
Participating patients will be referred preschool children with ADHD and disruptive behavior problems who have improved insufficiently through PMT.

Intervention:
In PCIT, parents are taught a combination of behavioral therapy and play therapy techniques to enhance their effective discipline, to improve the parent-child relationship, to increase their child's prosocial behavior, and to decrease negative behavior. Treatment with methylphenidate is aimed at reducing hyperactivity and impulsive behaviors.

Main study parameter/endpoint:
The primary outcome measure will be the primary caretaker's Eyberg Child Behavior Inventory (ECBI). This is a widely used parent rating scale designed to measure conduct problem behavior in children between the ages of 2 and 16 years.

Study objective

Preschool disruptive behavior problems, i.e., attention-deficit/hyperactivity disorder (ADHD), oppositional defiant disorder (ODD), and conduct disorder (CD), form a major burden for parents, are associated with a wide range of functional impairments, and are risk factors for child maltreatment. Although parent management training (PMT) is an effective treatment for

behavior problems in preschool children, a subgroup of children does not respond sufficiently to this treatment. There is consensus in the field that behavioral interventions should be the first focus of treatment in preschool children with disruptive behavior problems, most appropriately in the form of PMT. In PMT, parents are taught behavioral strategies to modify their children's behavior and re-establish positive relationships within the family. There have been a number of trials indicating that PMT is an effective treatment for preschool children with disruptive behavior problems. Still, a subgroup of these children remains significant behavior problems upon completion of PMT. Little is known about the best treatment strategy for this subgroup. Two options seem to be the best candidate second-line treatments for children not having responded favorably to PMT, Parent-Child Interaction Therapy (PCIT) and pharmacological treatment with methylphenidate. Compared to PMT, PCIT is a more intensive and individualized form of parent training, thus justifying it as second-line treatment within a stepped care approach. Methylphenidate, the second option, has been shown to be an effective treatment for preschool children with ADHD (Greenhill et al., 2006), although the magnitude of effect has been somewhat smaller compared with school age children.
PCIT and methylphenidate have never been studied or compared to each other in the group of non-responders to PMT. Our hypothesis is that preschool children respond more favorably to PCIT than to methylphenidate, given that the effect sizes of treatment with methylphenidate as found in the preschool ADHD treatment study (PATS; Greenhill et al., 2006) appeared to be lower than those achieved through treatment with PCIT (Thomas & Zimmer-Gembeck, 2007).

Study design

Outcome measurements will be collected at baseline, after completion of the treatment and after 3, 6, 12, 18, and 24 months.
Predictor/moderator variables will only be collected at baseline. The primary and secondary outcome measures will be collected at baseline, after completion of treatment and 24 months after treatment. Only the primary outcome measure will also be collected 3, 6, 12 and 18 months after completion of treatment.

Intervention

1. PCIT is an empirically-supported manualized treatment for conduct-disordered young children that places emphasis on improving the quality of the parent-child relationship and changing parent-child interaction patterns. In PCIT, parents are taught specific skills to establish a nurturing and secure relationship with their child while increasing their child's prosocial behavior and decreasing negative behavior. This treatment focuses on two basic interactions: Child Directed Interaction is closely related to play therapy in that parents engage their child in a play situation with the goal of strengthening the parent-child relationship; Parent Directed Interaction resembles clinical behavior therapy in that parents learn to use specific behavior management techniques as they interact with their child. The length of PCIT treatment is variable and consists of 1–2 hour weekly sessions (the number of sessions depends on parental progress; the length of sessions depends on the number of participating parents);
2. Treatment with methylphenidate will start with a one week open label tolerance phase,

followed by a four week double blind crossover titration in which the best dose will be determined. Thereafter, the blind will be broken and the child will be given the individually determined optimal methylphenidate dose for the next six weeks; doses can be titrated up or down following consensus involving two experienced clinicians in these six weeks. In case the best response is to placebo, the child will be given no medication.

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Eligibility criteria

Inclusion criteria

1. Children of both sexes, of any ethnic and cultural background, ages 2;6 to 6 years;
2. At time of referral a diagnostic and statistical manual fourth edition (DSM-IV; American Psychiatric Association, 1994) consensus diagnosis of ADHD any subtype, including ADHD-Not Otherwise Specified;
3. At time of referral presence of oppositional behavior as evidenced through either a DSM-IV (American Psychiatric Association, 1994) consensus diagnosis of ODD, or CD, or Disruptive Behavior Disorder Not Otherwise Specified; or a baseline primary caretakers ECBI score > 131 and identification of minimally three target problem behaviors;
4. Previous treatment through PMT has resulted in less than 30% reduction on the primary caretaker Eyberg Child Behavior Inventory (ECBI) score, or on the Externalizing scale of the Caregiver-Teacher Report Form for ages 1½-5 (C-TRF 1½-5); or has resulted in a rating of less than improved on the Clinical Global Impression Scale of improvement by the clinician;
5. Full Scale IQ equivalent of >70;
6. The same primary caretaker for at least six months before inclusion;
7. Parents have provided informed consent to participate in the study, in accordance with Dutch ethical regulations;

8. Systolic and diastolic blood pressure below 95th percentile for age and gender.

Exclusion criteria

1. Previous PCIT; other forms of previous treatments are acceptable, including the use of previous psychotropic medication;
2. The child has a major medical condition that would interfere with involvement in a long-term study or could be affected negatively by methylphenidate, including the presence of schizophrenia, hyperthyroidism, cardiac arrhythmias, angina pectoris, and glaucoma;
3. Ongoing psychosocial treatment or ongoing treatment with psychotropic medication;
4. Inability of the parent to understand or follow study instructions;
5. Patients whose families anticipate a move outside the geographic range of the investigative site;
6. Use of any other psychotropic medication or has taken an investigational drug in the past 30 days.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-04-2011
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-11-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36319
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3053
NTR-old	NTR3201
CCMO	NL31116.042.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36319

Study results

Summary results
N/A