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Does the treatment of maternal Attention Deficit Hyperactivity Disorder enhance the effectiveness of parent management training for children's attention deficit hyperactivity disorder?

Submission date
20/10/2006

Recruitment status
No longer recruiting

Registration date
29/03/2007

Overall study status
Completed

Last Edited
17/12/2018

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Andreas Warnke

Contact details
Department of Child and Adolescent Psychiatry and Psychotherapy
Wuerzburg University Hospital
Fuechsleinstr. 15
Wuerzburg
Germany
D-97080
+49 (0)931 780 10
warnke@kjp.uni-weurzburg.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BMBF-ADHD-C2

Study information

Scientific Title
Does the treatment of maternal Attention Deficit Hyperactivity Disorder enhance the effectiveness of parent management training for children's attention deficit hyperactivity disorder?

Acronym
AIMAC: (ADHD In Mothers And Children)

Study objectives
Attention Deficit Hyperactivity Disorder (ADHD) is a serious mental disorder with a persistent pattern of severely impaired attention and concentration, hyperactive and impulsive behaviour, emotional instability, restlessness and disorganised behaviour. The prevalence in childhood is estimated to be about 5% and in adulthood the prevalence is indicated to 2% and 4%.

ADHD is highly familial. About one quarter of children presenting with ADHD will have an ADHD parent, and more than half of all parents with ADHD will have a child with ADHD. Bringing up a child with ADHD can prove to be very stressful. Calm and consistent parenting in structured settings is especially important.

However, parents with ADHD are less likely to be able to provide such care. Parent's ADHD can be expected to have negative impact on parenting, family functioning, and the child. Parental ADHD may also have negative influence on the treatment outcome of childhood ADHD. This may especially be the case for the efficacy of parent management training, because parents with ADHD are expected to present difficulties in following instructions and in complying with the treatment regime.

Furthermore they tend to impulsively switch to alternative treatment plans promising quick cures, to act disorganised and argumentative or to have problems with the implementation of token economies and consistent rewards. Therefore, the control of ADHD symptoms in parents is supposed to be a prerequisite for the success of parenting programs for ADHD children.

The proposed study will be the first controlled multi-centre clinical trial investigating the effect of the treatment of maternal ADHD on the efficacy of parent management training for childhood ADHD.

The principal research question is: Does the treatment of maternal ADHD enhance the effectiveness of parent management training for children's ADHD?

Other questions to be addressed are:
1. To what extent does treatment effects generalise across problem areas (ADHD core-symptoms, externalising symptoms at home, family functioning, global symptom severity), settings (school and home environment) and rater-perspectives respectively (child, mother, teacher)?

2. Is there a greater acceptance of parent management training in mothers treated for ADHD?
3. Are the effects of treatment stable over time?
4. Does the sole treatment of maternal ADHD already have influences on the childs symptoms?
5. Is there an association between the child's co-morbidity and treatment outcome?

The main hypothesis is: parent management training for children's ADHD is more effective in children whose mothers received treatment for adult ADHD as in children whose mothers did not.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the faculty of medicine, Wuerzburg University, ref: 120/06

Study design
Randomised controlled trial, open study design, observer blinded

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Attention Deficit Hyperactivity Disorder (ADHD) in children and their mothers

Interventions
Two-armed design:
Experimental Group (EG): treatment of mother's ADHD with methylphenidate and a specific group psychotherapy program (12 weekly sessions, followed by monthly sessions, duration: 52 weeks)

Control Group (CG): clinical management for mother's ADHD without any specific pharmacological or psychotherapeutic interventions (12 weekly sessions, followed by monthly sessions, duration: 52 weeks)

In both groups - after week 13 - children and their mothers will receive parent management training to treat the child's ADHD (12 weekly sessions and two booster sessions).

Manualised cognitive-behavioural programs are used for group psychotherapy (ADHD mother) and parent management training (ADHD child). Trained therapists are treating mothers and children. Treatment integrity is ascertained by independent supervision.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Methylphenidate

Primary outcome measure
Primary endpoint is the extent of externalising symptoms in the children:
1. ADHD-ODD-Scale (ODD: Oppositional Defiant Disorder): number of symptoms of ADHD and ODD present during the last two weeks before assessment (ADHD-section and ODD-section of the Kiddie Schedule for Affective Disorders and Schizophrenia [KIDDIE-SADS], blind investigator-rating)

Secondary outcome measures
Children:
1. ADHD-section and ODD-section of the KIDDIE-SADS (diagnosis +/-, responders-nonresponders: 30 percent reduction of the ADHD-ODD-Scale, blind investigator-rating)
2. Externalising and internalising symptoms: Strength and Difficulties Questionnaire (SDQ) (mother and teacher report)
3. Family functioning: Home-Situations-Questionnaire (HSQ, mother-report)
4. Impact of the child's symptoms on the family: Family Impact Questionnaire (FIQ, mother-report)
5. Process-quality, related to parent training (Fragebogen zur Beurteilung der Behandlung, FBB, mother- and therapist-report)

Mothers:
1. Symptom-Checklist (SCL-90-R, self-rating mother)
2. Conners Adult ADHD Rating Scale (CAARS-S:L, self-rating mother; CAARS-O:L, blind investigator rating)

Overall study start date
01/01/2007

Completion date
31/12/2009

Eligibility

Key inclusion criteria
All patients:
1. Voluntary and written informed consent of the mother, the child and other persons having the care and custody of the child

Children:
1. Aged six to 12 years

2. Diagnosis of ADHD according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria
3. No medication or on stable medication for at least four weeks before baseline assessment

Mothers:
1. Diagnosis of ADHD according to DSM-IV criteria
2. A score of 30 or more on the short version of the Wender-Utah-Rating-Scale
3. Aged 18 to 60 years, inclusive
4. Chronic course of ADHD symptoms from childhood to adulthood, onset of ADHD symptoms before the age of seven
5. No abnormality detected on physical examination, routine blood testing (blood count, renal, hepatic and thyroid function), Electrocardiogram (ECG) and Electroencephalogram (EEG)

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
To be randomised: 144 mother-child pairs

Key exclusion criteria
All patients:
1. Participation in another clinical trial
2. Specific interventions for the treatment of ADHD within the last six months before screening
3. Need for inpatient treatment

Children:
1. Intelligence Quotient (IQ) less than 80
2. Pervasive developmental disorder, psychosis, schizophrenia, bipolar disorder, severe depressive episode

Mothers:
1. IQ less than 80
2. Schizophrenia, bipolar disorder, borderline personality disorder, antisocial personality disorder, suicidal or self-injurious behaviour, autism, motor tics, Tourette's syndrome
3. Substance abuse/dependence within six months prior to screening. Episodic abuse is not an exclusion criterion
4. Neurological diseases, seizures, glaucoma, uncontrolled hypertension
5. Current eating disorder/low weight (Body Mass Index [BMI] less than 20)
6. Pregnancy or breast-feeding

Date of first enrolment
01/04/2007

Date of final enrolment
01/05/2010

Locations

Countries of recruitment
Germany

Study participating centre
Wuerzburg University Hospital
Wuerzburg
Germany
D-97080

Sponsor information

Organisation
Wuerzburg University Hospital (Germany)

Sponsor details
Josef-Schneider-Strasse 2
Wuerzburg
Germany
D-97080

Sponsor type
Hospital/treatment centre

Website
http://www-i.klinik.uni-wuerzburg.de/deutsch/Home/content.html

ROR
https://ror.org/03pvr2g57

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2013		Yes	No
Results article	results	01/12/2015		Yes	No
Results article	results	13/12/2018		Yes	No