

Evaluation of a parent training for families with children suffering from Attention-Deficit Hyperactivity Disorder (ADHD)

Submission date 11/07/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 25/07/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/05/2008	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

Primary goal:

The study will examine whether a parent training run by a trainer (pooled individual and group training) leads to a significant and strong long-term decline in problem behaviour among children with Attention-Deficit Hyperactivity Disorder (ADHD) compared with a waiting controls group.

Secondary and further goals:

1. The study will examine whether individual training compared with group training leads to an above random and marked decline in problem behaviour in children with ADHD
2. It will examine whether the above-mentioned between-group comparisons can also be found directly after training
3. It will examine whether these effects are also reflected in a decline in family stress levels
4. It will examine whether these effects are also reflected in a change of educational behaviour
5. It will perform a cost-benefit analysis to determine which intensity of intervention is needed to attain strong and stable training effects
6. It will analyse which families fail to complete training, do not implement recommended measures adequately, or do not cooperate in the training
7. Finally, it will analyse whether certain forms of training prove to be particularly effective in certain families (e.g., as a function of socioeconomic status, child's age, family status, etc.)

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study will commence only after being granted a positive evaluation by the Ethics Committee of the University of Cologne. At each further study centre, it will also commence only after being granted a positive evaluation by the appropriate Ethics Committee.

The present study protocol and any potential changes to it are, and will continue to be, formulated in line with the October 1996 version of the Helsinki Declaration (48th General Assembly of the World Medical Association, Somerset West, Republic of South Africa).

The study received a positive evaluation by the Ethics Committee of the University of Cologne on the 20th September 2007 (ref: 06-213).

Study design

Open, multicentre, randomised, control-group study in Germany

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Attention-Deficit Hyperactivity Disorder (ADHD)

Interventions

Competence training for parents with socially disruptive children diagnosed with ADHD. The parent training will be carried out according to the manual in both intervention conditions. It will take a total of seven weekly sessions:

1. Weeks 1 - 6: six weekly three-hour sessions (regular training)
2. Weeks 7 - 10: four-week pause with no sessions
3. Week 11: single three-hour refresher session

Six months after is the follow up measurement.

Duration of the study for individual clients: 7 x three hours over a period of 11 weeks. Total duration of the whole trial for each participant is approximately 9 months.

Each training unit pursues one single goal. As a result, each unit addresses one clear topic. All training units follow the same standardised routine:

1. Announcement of the agenda, so that each participant knows what is coming next. This is posted on a notice board
2. Evaluation of the task of the week (therapy homework) agreed upon at the previous session
3. Content-specific units and exercises on the focus of the specific training unit
4. Finding one's own strengths to encourage a solution-oriented and confident attitude in the participants allowing them to go back home feeling stronger
5. Presentation and discussion of the task of the week to be carried out before the next week's session

The treatment branches are:

1. Treatment Branch A: individual training - a trainer works through the seven three-hour training units according to the manual with the main caregiver in the family home
2. Treatment Branch B: group training - a trainer works through the seven three-hour training units according to the manual with a group of 6 - 8 parents at a study centre. Only the main caregiver participates in training
3. Treatment Branch C: waiting controls group - the control group will initially receive the usual treatment. Data on the control group will be gathered at the same times as that on other groups. After the final data collection at the follow up, main caregivers in the control group will be offered the intervention that has proved to be most effective up to then

Contents of Training Sessions:

1. Training unit 1 goal: What needs to change? What can stay the same?
Pinpointing - parents should grasp their current problems as behaviour difficulties, name concrete interaction problems with the child, and formulate their own training goals
2. Training unit 2 goal: Confirming the emotional core - positive play

Strengthening the positive relationship with the child - parents should spend "precious time" with their child every working day. They should find about 30 minutes a day for uninterrupted play

3. Training unit 3 goal: Being aware of one's own feelings and thoughts

ABC scheme for emotional regulation and de-escalation - parents should analyse difficult everyday situations in terms of the thinking patterns associated with them and distinguish between beneficial and dysfunctional patterns

4. Training unit 4 goal: Breaking fixed routines

Changing dysfunctional everyday routines, modifying situational contingencies - parents learn to restructure recurring everyday situations (e.g., going to bed, mealtimes, homework) in a more positive way

5. Training unit 5 goal: Showing how actions have consequences

Strengthening prosocial behaviour, avoiding reinforcement traps - parents learn to provide effective and behaviour-related consequences (reinforcement, punishment)

6. Training unit 6 goal: Making effective demands

Setting clear rules and making demands correctly - parents practice formulating and communicating demands

7. Refresher session goal: Looking Back on the Way Forward

Problem-solving behaviour in the family, structuring in the family - parents review what has been achieved so far and specify unresolved problems. Discussions address how to further reduce family stress and how parents can support each other

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Intention-to-treat analysis of the reduction in child behaviour problems on the Home Situations Questionnaire (HSQ) by comparing the differences in mean scores on the 16 items (Likert scales from few [1] to very strong [10]) from pretest to follow up across the three conditions.

Comparisons between three randomised matched groups receiving one of the following forms of intervention: individual training, group training, and a waiting controls group.

All endpoints will be assessed at three measurement times:

T1: First measurement at Week 0 (pre)

T2: Second measurement at Week 6 (post)

T3: Third measurement 6 months after Week 11 (follow-up)

Secondary outcome measures

1. Intention-to-treat analysis of the reduction in child behaviour problems on the Child Behaviour Checklist (CBCL) by comparing differences in means from pretest to follow up across the three conditions

2. Sensitivity-analysis of the reduction in child behaviour problems on the Home Situations Questionnaire by comparing the differences in means from pretest to follow up across the three conditions

3. Analyses of the reduction in degree of family stress on the Parenting Stress Index by comparing differences in means from pretest to follow up across the three conditions

4. Analyses of improvement in educational behaviour on the Being A Parent scales (BAP) by

comparing differences in means from pretest to follow up across the three conditions
5. Furthermore, a cost-benefit analysis will be conducted to compare the two forms of intervention

All endpoints will be assessed at three measurement times:

T1: First measurement at Week 0 (pre)

T2: Second measurement at Week 6 (post)

T3: Third measurement 6 months after Week 11 (follow-up)

Overall study start date

13/08/2007

Completion date

13/08/2010

Eligibility

Key inclusion criteria

1. Parents' age greater than or equal to 18 years
2. Responsibility and legal capacity in parents
3. Diagnosis of ADHD in child (Diagnostic System for Psychiatric Disorders in Childhood and Adolescence [DISYPS])
4. Age of child between 6 and 11 years
5. Informed consent of the parents and the children available

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

11 Years

Sex

Not Specified

Target number of participants

To be assessed for eligibility: n = 366 (max. 30% ineligible), to be allocated to trial: n = 258, to be analysed: n = 192 (per protocol)

Key exclusion criteria

1. Earlier or current participation in other intervention trials that might interfere with the current study
2. The main caregiver is currently receiving psychotherapeutic treatment
3. Developmental disorders in the child
4. Manifest critical life events as listed in Diagnostic and Statistic Manual of Mental Disorders -

fourth edition (DSM-IV-TR)

5. Insufficient parental resources to implement the intervention

Date of first enrolment

13/08/2007

Date of final enrolment

13/08/2010

Locations

Countries of recruitment

Germany

Study participating centre

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Funder(s)

Funder type

Research council

Funder Name

German Research Council (Deutsche Forschungsgemeinschaft) (DFG) (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