

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

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<b>Registration date</b> 25/07/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/05/2008	<b>Condition category</b> 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

**Contact name**  
Prof Gerhard Lauth

**Contact details**  
Faculty of Human Sciences  
University of Cologne  
Klosterstr. 79b  
Cologne  
Germany  
50931  
+49 221 470 5514  
gerhard.lauth@uni-koeln.de

## Additional identifiers

**Protocol serial number**  
uni-koeln-707 v2-06

## 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

## **Study type(s)**

Treatment

## **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(s)**

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)

### **Key secondary outcome(s)**

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)

### **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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 years

**Upper age limit**

11 years

**Sex**

Not Specified

**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**

Faculty of Human Sciences

Cologne

Germany  
50931

## Sponsor information

### Organisation

University of Cologne (Germany)

### ROR

<https://ror.org/00rcxh774>

## Funder(s)

### Funder type

Research council

### Funder Name

German Research Council (Deutsche Forschungsgemeinschaft) (DFG) (Germany)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration