

# Prevention program for Externalising Problem behaviour

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
21/07/2009	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
26/01/2010	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
29/12/2020	Mental and Behavioural Disorders	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

Efficacy or indicated prevention in children with deviant externalising behaviour aged 3 to 6: a cluster-randomised indicated prevention trial

### Acronym

## **Study objectives**

1. Reduction of externalising symptoms assessed by parents and kindergarten teachers
2. Improvement of parents' and teachers' educational behaviour
3. Reduction of parental stress
4. Long-term stability of these effects

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics Committee of the German Research Foundation approved on the 7th November 2000

## **Study design**

Cluster-randomised indicated prevention trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Externalising behaviour (symptoms of attention deficit hyperactivity disorder [ADHD], oppositional defiant disorder [ODD], aggression)

## **Interventions**

PEP consists of 10 sessions (90 to 120 minutes each) and a constituting session. Minimum time between two sessions was 1 week. Therefore after the pre-test period (4 months, including home visits at each family) the training period took 3 to 4 months depending on holidays and external reasons for each groups' schedule. Appointments for post test in both arms were planned just after the last session of PEP within the intervention group. Follow ups were carried out via questionnaires only and via mail 1 year after pre-test. Therefore the interval between the timepoints was about six months for each family. The trial was carried out in 2 waves.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

ADHD and ODD Symptom Checklist (Diagnostic and Statistical Manual of Mental Disorders, fourth edition [DSM IV]) rated by parents and teachers, measured at pre- and post-test.

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

Dimensions of educational behaviour, burden and stress, measured at pre- and post-test.

## **Completion date**

14/09/2009

# Eligibility

## Key inclusion criteria

1. Children enrolled in public kindergarten
2. Aged 3 to 6 years, either sex
3. At risk for developing externalising behaviour problems
4. Increased scores in a screening questionnaire rated by parents and teachers

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## Total final enrolment

155

## Key exclusion criteria

Does not meet inclusion criteria

## Date of first enrolment

15/07/2001

## Date of final enrolment

14/09/2009

# Locations

## Countries of recruitment

Germany

## Study participating centre

Robert Koch Str. 10

Cologne

Germany

50931

# Sponsor information

## Organisation

University Hospital of Cologne (Uniklinik Köln) (Germany)

## ROR

<https://ror.org/05mxhda18>

## 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	23/12/2013	29/12/2020	Yes	No
<a href="#">Other publications</a>	participation rate analysis	28/05/2010	29/12/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes