

# Prevention program for Externalising Problem behaviour

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

**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**  
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**

PEP

**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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**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 measure**

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.

**Secondary outcome measures**

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

**Overall study start date**

15/07/2001

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

2500 for screening, 150 indicated individuals for randomisation

**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)

## Sponsor details

c/o Prof Dr Manfred Doepfner

Klinik und Poliklinik für Psychiatrie und Psychotherapie des Kindes- und Jugendalters

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## Sponsor type

Hospital/treatment centre

## Website

<http://www.medizin.uni-koeln.de/index.e.shtml>

## ROR

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

# Funder(s)

## Funder type

Research council

## Funder Name

## 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?
<a href="#">Other publications</a>	participation rate analysis	28/05/2010	29/12/2020	Yes	No
<a href="#">Results article</a>	results	23/12/2013	29/12/2020	Yes	No