

Prevention program for Externalising Problem behaviour

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

Contact name
Prof Manfred Doepfner

Contact details
Robert Koch Str. 10
Cologne
Germany
50931
+49 (0)221 4786105
Manfred.Doepfner@t-online.de

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

Robert-Koch-Str. 10

Köln

Germany

D-50931

+49 (0)221 478 6105

manfred.doepfner@uk-koeln.de

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?
Other publications	participation rate analysis	28/05/2010	29/12/2020	Yes	No
Results article	results	23/12/2013	29/12/2020	Yes	No