

# Preventing Anxiety in Children through Education in Schools

<b>Submission date</b> 13/09/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 06/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/11/2016	<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

**Contact name**  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
NIHR/PHR/09/3000/03

## Study information

**Scientific Title**

A randomised controlled cluster trial comparing the effectiveness and cost effectiveness of a school based cognitive behaviour therapy programme (FRIENDS) in the reduction of anxiety and improvement in mood in children aged 9/10 years

**Acronym**

PACES

**Study objectives**

Group based cognitive behaviour therapy (FRIENDS) delivered by trained school and health staff is effective and cost effective in preventing anxiety and improving mood compared to usual school lessons (Personal, Social and Health Education [PSHE]).

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The University of Bath, School Research Ethics Approval Panel, 28/07/2010, ref: PACES/SREAP

**Study design**

Randomised controlled cluster trial

**Primary study design**

Interventional

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

School

**Study type(s)**

Prevention

**Participant information sheet**

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

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

Anxiety

**Interventions**

Schools will be randomised to one of three treatment groups:

1. Health-led FRIENDS: The intervention will be delivered by trained and supervised health professionals (e.g. school nurses, psychology assistants) external to the school.
2. School-led FRIENDS: The intervention will be delivered by trained and supervised members of the school teaching group.

FRIENDS involves ten, 60-minute weekly sessions of cognitive behaviour therapy. Intervention teaches children practical skills to identify their feelings; to learn to relax; to identify unhelpful thoughts and to replace them with more helpful thoughts; and how to face and overcome their problems and challenges.

3. Treatment as Usual: Children will participate in the usual personal social and health education (PSHE) lessons provided by the school. These lessons will be planned and led by the class teacher. A standardised record sheet will be used to summarise the content of each session so that any potential overlap with the active intervention can be determined.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

1. Children: Children's Anxiety Scale

2. Parents and teachers: Strength and Difficulties Questionnaire

Used to assess changes in anxiety and symptoms of low mood at baseline, 6 and 12 months.

### **Secondary outcome measures**

1. Children: Children's Anxiety Scale, used to assess changes in self esteem and bullying

2. Parents and teachers: Strength and Difficulties Questionnaire

All assessments will be undertaken at baseline, 6 and 12 months.

### **Overall study start date**

01/01/2011

### **Completion date**

31/12/2013

## **Eligibility**

### **Key inclusion criteria**

All children aged 9 - 10 years (years 4 and 5) attending study schools (n = 54) and participating in PSHE lessons

### **Participant type(s)**

Patient

### **Age group**

Child

### **Lower age limit**

9 Years

### **Upper age limit**

10 Years

### **Sex**

Both

### **Target number of participants**

1080 children attending 54 schools

### **Key exclusion criteria**

None. There will be some occasions when children do not participate in PSHE for religious or other reasons. These will be respected but it is expected that these will be limited.

**Date of first enrolment**

01/01/2011

**Date of final enrolment**

31/12/2013

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**University of Bath**

Bath

United Kingdom

BA2 7AY

## **Sponsor information**

**Organisation**

Avon and Wiltshire Mental Health Partnership NHS Trust (UK)

**Sponsor details**

Jenner House

Langley Park Estate

Wiltshire

Chippenham

England

United Kingdom

SN15 1GG

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.awp.nhs.uk/>

**ROR**

<https://ror.org/0379k6g72>

# Funder(s)

## Funder type

Government

## Funder Name

Public Health Research Programme (ref: 09/3000/03)

## Alternative Name(s)

NIHR Public Health Research Programme, PHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# 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="#">Protocol article</a>	protocol	27/11/2012		Yes	No
<a href="#">Protocol article</a>	24-month follow-up protocol	13/03/2014		Yes	No
<a href="#">Results article</a>	results	01/08/2014		Yes	No
<a href="#">Results article</a>	results	01/11/2015		Yes	No
<a href="#">Results article</a>	results	01/11/2016		Yes	No