

# 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

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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Prevention

**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(s)**

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.

**Key secondary outcome(s))**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

9 years

**Upper age limit**

10 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**  
**University of Bath**  
Bath  
United Kingdom  
BA2 7AY

## Sponsor information

**Organisation**  
Avon and Wiltshire Mental Health Partnership NHS Trust (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, The Public Health Research (PHR), PHR

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<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
<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="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes