# Preventing Anxiety in Children through Education in Schools

Submission date Recruitment status [X] Prospectively registered 13/09/2010 No longer recruiting [X] Protocol [ ] Statistical analysis plan Registration date Overall study status 06/10/2010 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 03/11/2016 Mental and Behavioural Disorders

## Plain English summary of protocol

Not provided at time of registration

## **Contact information**

## Type(s)

Scientific

#### Contact name

Prof Paul Stallard

#### Contact details

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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?
Results article	results	01/08/2014	Yes	No
Results article	results	01/11/2015	Yes	No
Results article	results	01/11/2016	Yes	No
Protocol article	protocol	27/11/2012	Yes	No
Protocol article	24-month follow-up protocol	13/03/2014	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes