

Preventing Anxiety in Children through Education in Schools

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

Contact details
Department for Health
22-23 Eastwood
University of Bath
Bath
United Kingdom
BA2 7AY

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