

# A single-blind randomised controlled trial to determine the effectiveness of group Cognitive Behaviour Therapy (CBT) in the prevention of depression in high risk adolescents

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<b>Registration date</b> 01/10/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/05/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

We aim of this study is to test whether a school-based depression prevention programme developed in Australia, the Resourceful Adolescent Programme (RAP), is effective at reducing depressive symptoms in high-risk children in the UK.

### Who can participate?

Children aged 13-16 from 9-12 mixed comprehensive schools in Bath, Bristol, Nottingham and Swindon

### What does the study involve?

Participants complete a questionnaire. Their scores are used to categorise them as either low or high risk of depression or probably depressed. We want to find out what happens to the high risk group (about 20% of each class). Whole classes of children are randomly assigned to receive either the RAP, a placebo (dummy) intervention, or treatment as usual (Personal Health and Social Education - PHSE). For RAP and the placebo intervention each student has a workbook and sessions are led by trained and supervised mental health professionals. We assess children's mood, negative thoughts and self-image before we start and again at 6 and 12 months. This allows us to see whether RAP is effective and if these gains last. We also want to find out whether RAP is good value and so we work out how much it costs and what it saves.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

Royal United Hospital (UK)

### When is the study starting and how long is it expected to run for?

September 2008 to December 2011

Who is funding the study?  
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?  
Prof. Paul Stallard  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Paul Stallard

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
HTA 06/37/04

## Study information

**Scientific Title**  
A single-blind randomised controlled trial to determine the effectiveness of group Cognitive Behaviour Therapy (CBT) in the prevention of depression in high risk adolescents

**Study objectives**  
Group based CBT delivered in schools is effective and cost effective in preventing depression in adolescents at high risk of depression.

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/063704>  
Protocol can be found at: [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0006/51378/PRO-06-37-04.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0006/51378/PRO-06-37-04.pdf)

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

University of Bath Ethical Committee: School for Health: School Research Ethics Approval Panel (SREAP), 18/12/2007

**Study design**

Cluster randomised controlled 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 participant information sheet

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

Depression

**Interventions**

Interventions will be provided during the usual Personal, Social and Health Education (PSHE) sessions (1 hour per session, total of 11 sessions over one school term).

Arm A: Group CBT. CBT recognises the importance of negative thoughts and low self-worth /image in the onset and maintenance of depression. These are therefore actively targeted during CBT with core treatment components including psycho education, identifying and challenging negative/dysfunctional thoughts, identifying personal strengths (thereby enhancing self-esteem/image), managing social problems, and learning to problem solve.

Arm B: Attention placebo. The attention placebo intervention will involve similar time and contact with an external group leader but will not include the active components of the CBT intervention. The content will be based upon the PSHE provided in schools but will be provided by leaders from outside of the school. This will therefore control for the non-specific effects of interventions that are considered important in studies of depression.

Arm C: Usual PSHE

**Intervention Type**

Other

**Phase**

Not Specified

### **Primary outcome measure**

Changes in depression symptoms as assessed by the short form Mood and Feelings Questionnaire at 12 months follow-up.

### **Secondary outcome measures**

1. Changes in self-image and negative thoughts. These will be assessed at 12 months by the following questionnaires:

1.1. Self Image Profiles (SIP-A). An easily completed 25-item scale for adolescents assesses how they perceive themselves and how they would like to be. Twelve items assess positive attributes (e.g. confident, fun to be with), twelve assess negative attributes (e.g. annoying, moody) and one is neutral (i.e. feel different from others).

1.2. Children's Automatic Thoughts Scale (CATS). This self-completed scale assesses a range of negative self statements in children and young people aged 7-16. For each item the child is asked to rate whether they have had a similar thought over the past week. Each item is rated as "not at all" (scores 0), "sometimes" (scores 1), "fairly often" (scores 2), "often" (scores 3) or "all the time" (scores 4). The 10-item personal failure sub-scale will be used.

2. Cost effectiveness at 12 months

### **Overall study start date**

01/09/2008

### **Completion date**

31/12/2011

## **Eligibility**

### **Key inclusion criteria**

All children aged 13-16 attending participating schools (n = 8-12)

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

Patient

### **Age group**

Child

### **Lower age limit**

13 Years

### **Upper age limit**

16 Years

### **Sex**

Both

### **Target number of participants**

5,000 children of whom 1,000 will be at "high risk" of depression.

### **Total final enrolment**

5030

**Key exclusion criteria**

No exclusion criteria

**Date of first enrolment**

01/09/2008

**Date of final enrolment**

31/12/2011

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Royal United Hospital

Bath

United Kingdom

BA1 3NG

## Sponsor information

**Organisation**

University of Bath (UK)

**Sponsor details**

School for Health

Bath

England

United Kingdom

BA2 7AY

**Sponsor type**

University/education

**Website**

<http://www.bath.ac.uk/health/>

**ROR**

<https://ror.org/002h8g185>

# Funder(s)

## Funder type

Government

## Funder Name

Health Technology Assessment Programme

## Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

## 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	29/11/2010		Yes	No
<a href="#">Results article</a>	results	01/10/2013		Yes	No
<a href="#">Results article</a>	cost-effectiveness results	01/12/2014		Yes	No
<a href="#">Results article</a>	results	05/10/2012	08/05/2019	Yes	No