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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

Submission date
28/09/2007

Registration date
01/10/2007

Last Edited
08/05/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Scientific

Contact name
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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

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 competed 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?
Protocol article	protocol	29/11/2010		Yes	No
Results article	results	01/10/2013		Yes	No
Results article	cost-effectiveness results	01/12/2014		Yes	No
Results article	results	05/10/2012	08/05/2019	Yes	No