

# A pilot trial of computerised cognitive behaviour therapy for depression in adolescents

<b>Submission date</b> 29/09/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/02/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Each year around 2% of young people are affected by low mood or depression. Some worry about giving teenagers drug treatments in these situations as they question whether or not they work and they worry about their possible side effects. This study aims to find out whether a treatment called 'cognitive behaviour therapy' helps young people with a low mood when it is delivered on a computer (and not by a person).

### Who can participate?

Both male and female adolescents aged between 12 and 18 and suffering from low mood/depression will be asked if they would like to take part.

### What does the study involve?

Participants will be randomly allocated to one of two groups. In one group participants will be asked to complete a computer package, 'Stressbusters', in the other they will be asked to look at websites about low mood. Both groups will involve eight 45 minute sessions on a computer. Both before and after the computer sessions, participants will be asked to complete questionnaires about how they are feeling. Some will also be invited to take part in an interview.

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

It is hoped that by taking part in the trial adolescents with low mood or depression will notice an improvement in their symptoms. In addition all adolescents will receive a £10 gift voucher at 4 months following the trial to thank them for taking part.

### Where is the study run from?

The study is being run at Lime Trees Child, Adolescent and Family Unit in York and within a local school. It is hoped that this will expand to more schools and GP practices as the trial continues.

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

The study officially started in June 2011 and will last 3 years. We will be recruiting for 2 years, up until the end of July 2013.

Who is funding the study?

The research has been organised by Lime Trees Child, Adolescent and Family Unit at York which is part of the NHS. It has been funded by a special research grant.

Who is the main contact?

Lucy Tindall

lucy.tindall@nyypct.nhs.uk

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

9518

## Study information

### Scientific Title

A feasibility study and pilot trial of computerised cognitive behaviour therapy for depression in adolescents

### Study objectives

This study is a pilot and feasibility trial to establish the acceptability of cCBT treatment for adolescent depression.

### Ethics approval required

Old ethics approval format

Ethics approval(s)

Leeds (West) Research Ethics committee, 08/02/2011, ref: 10/H1307/137

## **Study design**

Randomised; Interventional; Design type: Treatment

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

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

Depression

## **Interventions**

Stressbusters, computerised CBT programme aimed at adolescents with low mood/depression. The intervention comprises 8, 45 minute weekly sessions; Follow Up Length: 0 month(s); Study Entry : Single Randomisation only

Young people between the ages of 12 and 18 with low mood (as determined by a score of 20 or above on the MFQ) will be randomised to either a cCBT programme 'Stressbusters' or an attention control - spending the equivalent time viewing current internet self help websites. At baseline all consenting participants will be asked to complete the Spence Anxiety Scale, the Beck Depression Inventory, a Risk Factor Schedule and a life story epidemiology proforma. At both four and twelve months follow up each participant will complete the Spence, Beck and MFQ again. Qualitative information about recruitment, acceptability and satisfaction with the cCBT programme will also be collected through interviews with participants.

Given the affinity young people have with information technology this trial questions whether young people could be treated effectively and more widely using computer administered CBT. Thus this study will produce important research evidence which will inform the care of young people in the UK NHS.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

Mood and Feelings Questionnaire; Timepoint(s): 4 months & 12 months follow up

**Secondary outcome measures**

1. The Beck Depression Inventory; Timepoint(s): 4 months & 12 months follow up
2. The Spence Anxiety Scale; Timepoint(s): 4 months & 12 months follow up

**Overall study start date**

01/09/2011

**Completion date**

31/08/2014

## Eligibility

**Key inclusion criteria**

1. Children and young people aged 12-18 years with low mood as measured by a MFQ score of 20 or above.
2. We will also include participants with either co-morbid physical illness or co-morbid non-psychotic functional disorders, such as anxiety
3. Target Gender: Male & Female

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

12 Years

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 96; UK Sample Size: 96

**Key exclusion criteria**

1. We will exclude participants who are seeking to end their life
2. Suffering psychotic symptoms or depressed in the post-natal period
3. Cases of psychotic depression
4. Participants with previous depression or previous treatment with anti-depressants or experience of cognitive therapy will not be excluded.

**Date of first enrolment**

01/09/2011

**Date of final enrolment**

31/07/2013

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

NHS North Yorkshire and York

York

United Kingdom

YO30 5RE

# Sponsor information

## Organisation

York Hospital NHS Trust (UK)

## Sponsor details

Learning and Research Centre

Wigginton Road

York

England

United Kingdom

YO31 8HE

+44 (0)1904 631 313

enquiries@york.nhs.uk

## Sponsor type

Hospital/treatment centre

## Website

<http://www.york.nhs.uk/>

## ROR

<https://ror.org/027e4g787>

# Funder(s)

## Funder type

Government

**Funder Name**

NIHR - Research for Patient Benefit (RfPB), ref: PB-PG-0609-19295

## 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	31/10/2014		Yes	No
<a href="#">Results article</a>	results	27/01/2017		Yes	No