ISRCTN31219579 https://doi.org/10.1186/ISRCTN31219579

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

Submission date
29/09/2011

Recruitment status
No longer recruiting

Registration date
29/09/2011

Overall study status
Completed

Last Edited
01/02/2017

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Miss Lucy Tindall

Contact details
NHS North Yorkshire and York
31 Shipton Road
York
United Kingdom
YO30 5RE
+44 (0)1904 721 219
Lucy.Tindall@nyypct.nhs.uk

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?
Protocol article	protocol	31/10/2014		Yes	No
Results article	results	27/01/2017		Yes	No