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The effectiveness of a new computerised treatment, "Stressbusters", for young people (aged 11 to 16 years) with symptoms of depression

Submission date
07/10/2011

Recruitment status
No longer recruiting

Registration date
21/12/2011

Overall study status
Completed

Last Edited
16/03/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
There are many pressures on young people today, and life can be very stressful at times. When stress mounts up, it can affect how young people feel. Stress might make young people feel moody or really low. It might mean that they stop enjoying things as much as they used to. It can affect young peoples sleep, appetite, and concentration. It can even stop them getting on with friends and family. To help fight stress, we have developed a computer program called Stressbusters for young people. Many young people suffering from stress have already used the program, and they found it helpful.
The aim of the current project is to test how helpful Stressbusters is at treating the symptoms of depression. The project is in two parts and is being conducted in two main-stream secondary schools in South London.

Who can participate?
The research is in two stages. In the first stage, we are inviting all pupils to take part (unless they have trouble reading English). In the second stage, we are inviting pupils whose scores on a questionnaire show that they are suffering from stress and low mood to take part (unless they are already receiving help for stress from someone else). If the childs scores on the questionnaire show that they are suffering from symptoms of depression, they will be invited to take part in stage 2. If their scores show that they are not suffering from symptoms of depression, they will not be invited to take part in stage 2.

What does the study involve?
In stage 1, your child will be asked to fill in a questionnaire. The questionnaire takes a few minutes to fill out. It is not a test and there are no right or wrong answers. Your child will complete the questionnaire in their classroom in class time. The questionnaire is private. It will be handed back to us. It will not be seen by any other pupils or by teachers.
In stage 2, if your child is eligible, he or she will be invited to use Stressbusters. The program contains 8 weekly computer sessions, each lasting about 30 to 40 minutes. Sessions were

designed with the help of young people - each one is interactive, and has videos, animations, graphics, and fact sheets to print out. Sessions will be done at school. They will be done in private, but there will always be someone there to help if needed.
To see how well Stressbusters works, half of young people will use it immediately while half will use it after a delay of 10 to 12 weeks. Whether your child is invited to use Stressbusters immediately or after a delay is decided by chance, like flipping a coin. Your child will have a 50:50 chance of using it immediately. Before and after using Stressbusters, we will ask your child to fill in three more questionnaires about how they are feeling. This will take them about 15-20 minutes. We will ask them to fill in the same questionnaires 3 months and 6 months after finishing Stressbusters. We will also ask teachers to fill in questionnaires about young people, and their attendance and achievements at school. After finishing Stressbusters, we will ask your child what they thought about the program, to help us improve it further. This interview will take about 20-30 minutes, and we will ask your childs permission to record it. We will ask you to fill in three questionnaires about your child. They will take about 15-20 minutes to fill out. These will be posted to you at home, and we will ask you to return them to us in a prepaid envelope.

What are the possible benefits and risks of participating?
It is unlikely that there are any risks. Sometimes, combating low mood and stress is hard work and it can be upsetting, but there will always be someone there to help if the young person needs it. All the information the young person tells us is private and confidential. But if we are told something that suggests that they are at risk of harm (for example if someone is threatening them, or if they want to hurt themselves), then we would need to break confidentiality, and we would contact the parents. If we need to do this, we will always tell the young person first. We will offer the young person immediate specialist help if they are in this situation.
The main benefit is that the evidence so far shows that young people are likely to be helped by using Stressbusters. We hope that they will benefit by learning to cope better with stress and low moods.

When is the study starting and how long is it expected to run for?
The study started in one school in March 2011. We aim to start in the second school in November 2011 and the study is expected to run until September 2013.

Who is funding the study?
Guys and St Thomas Charity (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
N/A

Study information

Scientific Title
Randomised controlled trial (RCT) comparing a computerised Cognitive Behavioural Therapy (CBT) program, called Stressbusters, to a wait-list control condition, in young people aged 11-16 years

Study objectives
To evaluate the effectiveness of a recently developed computerised Cognitive Behavioural Therapy (C-CBT) program (called Stressbusters) for the school- based treatment of depressive symptoms in young people.

Principal research question:
For young people aged 11-16 years who have mild-moderate symptoms of depression (as identified in Part 1 of the project), is weekly use of the Stressbusters C-CBT program in school for 8-weeks associated with significant reductions in symptoms of depression, relative to a waiting list control condition (Part 2)?

Primary hypothesis:
At post treatment follow-up, young people who were randomly allocated to the Stressbusters group will have significantly fewer symptoms of depression, ascertained by scores on a standardised self report measure of depressive symptoms (the Mood and Feelings Questionnaire, MFQ, see below), compared to young people who were randomly allocated to the Wait List group, after controlling for initial symptom severity. This will be tested using Analysis of Covariance (ANCOVA).

Secondary hypotheses:
1. At post treatment follow-up, young people who were randomly allocated to the Stressbusters group will have significantly fewer symptoms of anxiety, ascertained by scores on a standardised self report measure of anxiety symptoms (Screen for Anxiety and Related Disorders, SCARED, see below), compared to young people who were randomly allocated to the Wait List group, after controlling for initial symptom severity. This will be tested using Analysis of Covariance (ANCOVA)
2. At post treatment follow-up, young people who were randomly allocated to the Stressbusters

group will have significantly fewer symptoms of depression, anxiety, and emotional and behavioural problems as reported by parents and teachers using standardised report measures (MFQ-Parent report, SCARED-Parent report, Strengths and Difficulties Questionnaire for parents and teachers, see below), compared to young people who were randomly allocated to the Wait List group, after controlling for initial symptom severity. This will be tested using Multivariate Analysis of Covariance (MANCOVA)
3. Effects of treatment will be mediated by changes in young peoples thinking styles (measured using the Ruminative Response Styles Questionnaire, see below). This will be tested using a series of regression equations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nursing & Midwifery Research Ethics Committee, Kings College London, 27/07/2010, ref: PNM/09/10-123

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
Randomised controlled trial comparing Stressbusters to wait-list control, conducted out of two secondary schools. Individual randomisation, stratified according to age, gender, and symptom severity.

Computerised CBT treatment called Stressbusters compared with waitlist control group. Stressbusters consists of eight weekly sessions delivered over nine to 11 weeks (one school term). Each session lasts 30 to 40 minutes. Follow up assessment to take place immediately post treatment and at three and six months post treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Severity of depression symptoms, as measured by the self-report Mood and Feelings Questionnaire (MFQ; Costello and Angold, 1988). The MFQ is to be administered pre- and post-intervention and again at three and six months follow up.

Secondary outcome measures
1. Severity of self-reported anxiety symptoms, as measured by the Screen for Child Anxiety Related Disorders (SCARED; Birmaher et al., 2002). The SCARED is to be administered pre- and post-treatment and again at three and six months follow up.
2. Severity of depression, anxiety, and emotional and behavioural problems as reported by parents and teachers using standardised report measures (MFQ-Parent report; SCARED-Parent report, Strengths and Difficulties Questionnaire for teachers). These measures are to be administered pre- and post-treatment and again at three and six months follow up.
3. Changes in young peoples thinking styles, as measured by the Childrens Response Style Questionnaire (CRSQ; Abela, Brozina, & Haigh, 2002).

Overall study start date
11/03/2011

Completion date
30/09/2013

Eligibility

Key inclusion criteria
Part 1 (screening stage):
All consenting young people (male and female), in Years 7 to 12 (aged 11-16 years) attending mainstream secondary school.

Part 2 (Stressbusters RCT):
1. Young people (male and female), aged 11-16 years old currently experiencing significant symptoms of depression, as identified in Part 1.
2. A score of 20 or greater on a brief standardised self report measure of depression for young people, the Mood & Feelings Questionnaire (MFQ, Angold, Costello, et al 1987). This well-established threshold has 70% sensitivity and 81% specificity for detecting any mood disorder, including Major Depression and Dysthymia (Daviss et al 2006).

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit

16 Years

Sex
Both

Target number of participants
Part 1: 900 participants to be screened (part 1) over both sites. Part 2: 146 to be recruited into RCT (part 2) in total (73 in each group)

Key exclusion criteria
Part 1 (screening stage):
Young people who are unable to read English.

Part 2 (Stressbusters RCT):
1. Young people who are receiving treatment for a mood disorder from their GP or local CAMHS clinic
2. Those reporting significant current risk of suicide

Date of first enrolment
11/03/2011

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Psychiatry
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
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Sponsor type
University/education

Website
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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Guy's and St Thomas' Charity (UK)

Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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?
Results article	result	01/10/2015		Yes	No