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TARGET: Targeted depression prevention program for at-risk adolescents

Submission date	Recruitment status	[X] Prospectively registered
28/06/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/06/2013	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/08/2020	Mental and Behavioural Disorders	[ ] Record updated in last year

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 increases, it can affect how young people feel. Stress might make young people feel moody or really low. Depression is now common among young people. Those whose parents suffer from depression are at greater risk of developing depression themselves, compared to young people whose parents don't suffer from depression. Against this background, this study has two main aims. The first aim is to find out how many young people whose parents suffer from depression have some mild symptoms of stress and depression themselves. The symptoms young people might have are things like feeling irritable or sad, not enjoying things, and having trouble sleeping, concentrating, or eating. Second, for young people who report such symptoms, the aim is to find out if a new course, called 'Coping with Stress', can help prevent symptoms of stress and depression from getting worse. Many young people in America have benefited from this course, but it has never been used in England before.

Who can participate?

The research is in two stages. In the first stage, parents who have suffered from depression in the past or currently, and have a son or daughter aged between 10 and 17 years old, are inivited to take part. If they choose to take part, then their son or daughter is invited to also take part in Stage 1 (unless they have trouble reading English). In the second stage, young people are invited whose scores on a questionnaire show that they are suffering from mild symptoms of stress and low mood.

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. It can be completed online, or by filling in a paper copy. The questionnaire is private. Only the research team will see the answers. After young people have completed the questionnaire, we will ask some parents and young people to talk to one of our research team for about 30-45 minutes. The purpose of this interview is to ask for your views about the project and about filling in this sort of questionnaire. We would like to record this discussion, and would ask your permission to do so. You don't have to talk to the researcher if you don't want to.

In stage 2, if your child is eligible, he or she will be invited to come to the Coping with Stress

course. The course is for groups of 8-10 young people. There will be 8 meetings once a week, for about 90 minutes for young people. Afterwards, there will be 6 more meetings once a month, also for about 90 minutes. There will also be three groups for parents. The groups will be led by a clinical psychologist. This would be an opportunity for you to meet other parents in a similar situation as you, and to hear about ways to help young people.
To see how well the Coping with Stress course works, half of the young people who agree to take part will use it immediately while half will use it after a delay of 8 months. Whether young people are invited to come to the Coping with Stress course immediately or after a delay is decided by chance, like flipping a coin. Young people will have a 50:50 chance to do the course immediately.
Before the course, after the 8-week course has finished, and 6 months later, we will ask you and your son or daughter to complete a few questionnaires. This will take about 30 minutes. Additionally, we would like to interview you about your son or daughter's symptoms, and about your relationship, which will take about 90 minutes. We would also like to interview your son or daughter about their symptoms, and about your relationship, which will take about 90 minutes. After the course, we would like to talk to you, and your son or daughter, to find out what you thought of it. This is to see if we can improve the course for the future. These interviews would take about 20-30 minutes each. We would like to record the interviews, and would ask your permission to do so.

What are the possible benefits and risks of participating?
The main benefit is that the evidence so far shows that young people are likely to be helped by coming to the Coping with Stress course. We hope that young people will benefit by learning to cope better with stress and low moods. It is unlikely that there are any risks. Sometimes, combating stress and low mood is hard work and it can be upsetting for young people and families, but there will always be someone there to help if you or your son or daughter needs it. All the information you tell us is private and confidential. If your son or daughter tells us something that means 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 let you know. We will offer immediate specialist help if this situation arises.

Where is the study run from?
The study has been set up by King's College London in collaboration with South London and Maudsley NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in September 2013, and continue until October 2014. The study is expected to run until November 2015.

Who is funding the study?
National Institute for Health Research (NIHR), Research for Patient Benefit (RfPB) Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13173

Study information

Scientific Title
Prevention of major depression in at-risk adolescents: a pilot randomised controlled trial of a screen-and-intervene program

Acronym
TARGET

Study objectives
The objective of the research is to conduct a pilot trial to assess the acceptability, feasibility, and preliminary clinical effectiveness of a targeted screen-and-intervene CBT program to prevent depression in at-risk young people.

Principal research question:
At Stage 1: Is screening of offspring of parents with a history of depression acceptable to young people and their parents; and is screening feasible to carry out? (This part of the research is exploratory and there are no hypotheses to be tested.)

At Stage 2: Is a group Cognitive Behavioural Therapy (CBT) prevention program acceptable to young people, feasible to implement, and clinically effective?

Hypotheses:
1. Participants randomly allocated to CBT will show a lower incidence of depression diagnosis at post-intervention and at 6-month follow-up, compared to those allocated to Usual Care.
2. Participants randomly allocated to CBT will show less severe symptoms of depression on

continuous measures of depression at post-intervention and 6-month follow-up, compared to those allocated to Usual Care.
3. Response to intervention will be moderated by parental depression severity, family atmosphere and communication, and participant cognitive style.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South East Coast - Kent, 24/12/2012, ref: 12/LO/1475

Study design
Single-centre interventional randomised single-blind controlled trial

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
Randomised controlled trial comparing Coping with Stress group to Usual Care control. Randomisation stratifying for age, gender, initial symptom severity and parental depression severity.

Group CBT depression prevention program, called Coping with Stress, will be compared with "usual care" control group. The Coping with Stress group consists of weekly group sessions delivered over 8 weeks, followed by monthly sessions once per month for 6 months. Each session will last 90 minutes.

The control group will receive usual care during the study period, and will be invited to take part in the Coping with Stress group after a delay of 8 months.

Follow-up assessment to take place immediately after the 8-week group and at 6-month follow-up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
LIFE Interview; Timepoint(s): Post CBT group and at 6-month follow-up

Secondary outcome measures
1. Children's Depression Rating Scale (CDRS); Timepoint(s): The CDRS is to be administered pre and post group, and at 6-month follow-up
2. Moods and Feelings Questionnaire (MFQ); Timepoint(s): The MFQ is to be administered pre and post group, and at 6-month follow-up
3. Screen for Anxiety and Related Disorders in Childhood (SCARED-C); Timepoint(s): The scared will be administered pre and post group, and at 6-month follow-up
4. Strengths and Difficulties Questionnaire (SDQ); Timepoint(s): The SDQ will be administered pre and post group, and at 6-month follow-up

Overall study start date
12/08/2013

Completion date
30/11/2015

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Stage 1:
Adults:
1. Current or past diagnosis of an affective disorder (i.e. a major depressive episode in the last 3 years OR >= 3 major depressive episodes or >= 3 cumulative years in a major depressive or dysthymic episode in the young person's lifetime)
2. Have a son or daughter between 10-17 years old
Young people:
1. Aged between 10-17 years old
2. Able to read English

Stage 2:
1. Young people: aged between 10-17 years old
2. Able to read English
3. MFQ score 20-29 or previous diagnosis of Major Depressive Disorder

Participant type(s)
Patient

Age group
Mixed

Sex

Both

Target number of participants
Planned Sample Size: 250; UK Sample Size: 250; Description: Stage 1 190 parent offspring pairs. Stage 2 RCT 60 high risk young people

Key exclusion criteria
Stage 1:
Adults: past or current diagnosis of bipolar affective disorder or schizoaffective disorder

Stage 2:
Young people: Current diagnosis of major depressive disorder (determined by clinical interview KSADS); another primary disorder in need of treatment

Date of first enrolment
01/09/2013

Date of final enrolment
01/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Psychiatry
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Sponsor information

Organisation
King's College London (UK)

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Sponsor type
University/education

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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme; Grant Codes: PB-PG-021124152

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

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?
HRA research summary			28/06/2023	No	No