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The Feasibility and Acceptability of Behavioural Activation treatment for young people with depression in Child and Adolescent Mental Health Services

Submission date
01/12/2014

Recruitment status
No longer recruiting

Registration date
12/12/2014

Overall study status
Completed

Last Edited
05/08/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression is a mental health condition where a person feels persistently sad and low in mood for two weeks or more. It affects people in different ways. Sufferers can feel hopeless, anxious and lose interest in doing things they used to enjoy. It can also lead to problems with sleeping, feeling constantly tired, a loss of appetite and a low sex drive. In the most extreme cases, it can result in a person harming themselves or attempting to take their own life (suicide). Depression in young people is common and can result in poor academic achievement and feeling suicidal. Behavioural activation (BA) therapy is a treatment for depression. When people are depressed they tend to avoid others and isolate themselves which often serves to make them feel worse. BA works by encouraging people to do activities that are known to improve mood. Recent research has suggested that BA therapy may be useful as a treatment for depression in young people but, to date, there have been no published studies showing this in the UK. Here, we want to test if it is possible to use BA therapy to treat young people attending UK Child and Adolescent Mental Health Services (CAMHS). We also want to know if such a treatment would be acceptable to this age group.

Who can participate?
Young people, aged 12 to 17 years, with a diagnosis of major depressive disorder and attending UK CAMHS.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 receive 8 weeks of BA therapy. Those in group 2 receive their usual treatment for depression. A series of questionnaires that explore each participants mood and feelings are filled in by them at the beginning of the study and then 3 months later. Those participants in the BA therapy group, and the clinicians giving the treatment, are also offered an interview to discuss their feelings and experiences of the therapy. Participants are asked to fill in another series of questionnaires over the phone six months after they started the study.

What are the possible benefits and risks of participating?
There may be risks and burdens to taking part; the treatment may not be as good as the usual treatment, harm may be caused to the participants and the participants will be asked to attend interviews that they would not normally be asked to attend. These risks are countered by the opportunity for young people to access a previously unavailable treatment, to receive an more in-depth assessment and longer follow-up than normal. In addition, Child and Adolescent Mental Health Service capacity may be improved by the use of a treatment that is suitable for less experienced staff to deliver.

Where is the study run from?
This study is being run by Durham University (UK) and takes place in CAMH sites in the UK.

When is the study starting and how long is it expected to run for?
March 2015 to September 2016

Who is funding the study?
Tees, Esk and Wear Valleys NHS Foundation Trust (UK)

Who is the main contact?
Dr Charlotte Kitchen

Contact information

Type(s)
Public

Contact name
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Contact details
University of York
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial

Acronym
The BUDDY Study

Study objectives
To assess the feasibility and acceptability of behavioural activation treatment for depression for young people in a Child and Adolescent Mental Health Service setting. This information will be used to inform the methods and procedures for a definitive randomised controlled trial in the future.

Ethics approval required
Old ethics approval format

Ethics approval(s)
School of Medicine, Pharmacy and Health Ethics Sub-Committee at Durham University, 01/12/2014, ref. ESC2/2014/14

Study design
A single-centre, parallel group randomised controlled trial with a nested qualitative component

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Major Depressive Disorder

Interventions
Participants are randomly allocated to one of two groups. Behavioural activation therapy is the active arm and treatment as usual is the control arm. Individual randomisation was used via remote telephone randomisation. The randomisation list is created by a statistician who used blocked randomisation (with stratification according to Tier of care and depression severity). The assessor was not involved in the randomisation process.

In the behavioural activation (BA) arm participants receive eight sessions of a brief BA treatment following a structured treatment manual. In addition, participants receive any other non-psychological treatment deemed necessary by their clinician.

In the treatment as usual (TAU) arm participants receiveany treatment deemed necessary by their clinician. Details of the treatment provided were obtained from the Trust's patient electronic records system.

The total duration of treatment is recorded but not restricted (so varied between participants).

Participants are followed up at three and six months (and a selection of those attend a qualitative interview which may have occurred during their three month follow-up or at a later date if their treatment had not been completed by that stage).

Intervention Type
Behavioural

Primary outcome measure
The feasibility and acceptability of the study will be assessed by quantifying the flow of patients (in terms of eligibility, recruitment, adherence and attrition rates).

Secondary outcome measures
Current outcome measures as of 20/10/2017:
1. Assessor-rated depression status (DSM major depressive disorder or not) using the K-SADS-PL (structured diagnostic interview in person with participant and parent/carer [in some cases]) at baseline and three month follow-up
2. Young person self-report depression severity using the MFQ-C (validated questionnaire) at baseline, three and six month follow-up (baseline and three month follow-up were in person and six month over the telephone)
3. Parental report of their young person's depression severity using the MFQ-P (validated questionnaire for parents/carers of some participants) at baseline, three and six month follow-up (baseline and three month follow-up were in person and six month over the telephone)
4. Self-reported self-esteem using the RSE (validated questionnaire) at baseline, three and six month follow-up (baseline and three month follow-up in person and six month over the telephone).
Assessor-rated level of functioning using the CGAS (part of the K-SADS) as above at baseline and three-month follow-up
5. Self-reported activation using the BADS (questionnaire not validated in young people) used for descriptive purposes at baseline, three and six month follow-up (baseline and three month follow-up were in person and six month over the telephone).
6. Self-reported satisfaction with study and intervention using the end of study survey (designed specifically for this study for young people and parents/carers [in some cases]) at three month follow-up.

Previous outcome measures:
1. The feasibility and acceptability of the Behavioural Activation intervention will be evaluated via survey and qualitative interview data gathered from participants and clinicians on receiving and implementing the intervention.
2. The feasibility and acceptability of the study design and procedures will be evaluated via survey data from participants and parents/carers (in both arms of the study).
3. To obtain stable estimates of the variance in the outcome measures; score on Mood and Feelings questionnaire, the Behavioral Activation for Depression Scale Short Form and Rosenberg Self-esteem measure will be used.
4. To describe whether participants still meet the Kiddie-SADS-Present and Lifetime version DSM-IV diagnosis of depression (or are in remission) and also to comment upon the use of

Routine Outcome Measures in treatment sessions. This information will be used to explore the differences between groups.

Overall study start date
09/05/2014

Completion date
01/09/2016

Eligibility

Key inclusion criteria
1. Aged between 12 and 17 years old
2. Young person (if under 16) to give valid informed assent AND parent/carer valid informed consent OR young person [if aged 16 or over] to give valid informed consent
3. If on antidepressants, a stable dose must have been established for 6 weeks
4. Primary diagnosis of major depressive disorder according to the Kiddie-SADS-Present and Lifetime version

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
40

Total final enrolment
22

Key exclusion criteria
1. Presence of significant active substance abuse/dependence
2. Currently receiving a psychological therapy
3. Reading age <10 years for written English

Date of first enrolment
01/03/2015

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
United Kingdom

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
United Kingdom
-

Sponsor information

Organisation
Durham University

Sponsor details
Wolfson Building
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veronica.crooks@durham.ac.uk

Sponsor type
University/education

ROR
https://ror.org/01v29qb04

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Tees, Esk and Wear Valleys NHS Foundation Trust

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 05/08/2020:
A lay summary was sent to participants and their families, as well as the staff who took part in the trial. Powerpoint presentations were made to the participating CAMHS teams to discuss the implications for clinical practice. One paper detailing the results of the trial has now been published (see below). A second paper will shortly be submitted to a peer-reviewed academic journal, which will focus on the qualitative components of the trial. This work has also been presented at various academic conferences.

Intention to publish date

20/10/2018

Individual participant data (IPD) sharing plan

The thesis where the results of this trial have been detailed has been deposited in Durham University's e-thesis depository (http://etheses.dur.ac.uk/secure/cgi/users/home). The thesis has been embargoed until 20th February 2023 to allow sufficient time for the results to be published in peer-reviewed journals, after which time it will be open access (http://etheses.dur.ac.uk/12564/). Qualitative data is included in the thesis in the form of direct quotes but the original transcripts have not been included due to the inability to adequately anonymise the data set. Copyright of the thesis is held by Dr Charlotte Kitchen.

Previous publication and dissemination plan:
It is intended that two papers will be submitted to peer-reviewed academic journals from this trial. A short report detailing the recruitment and participant flow within the trial and a longer more in-depth qualitative paper focusing on the intervention. I intend to publish by 20/10/2018. I also hope to present my work at a relevant academic conference in 2018.

A lay summary will be sent to participants and their families in both arms of the trial. A similar summary will also be sent to staff who participated in the trial and a PowerPoint presentation will be offered to all participating CAMHS teams to discuss the implications for clinical practice.

IPD sharing statement:
The thesis (including the quantitative data set as an appendix) has been deposited in Durham University's e-thesis depositary (https://etheses.dur.ac.uk/secure/cgi/users/home). The thesis has been embargoed for a two year period (until 26/04/2020) to allow sufficient time for the results to be published in a peer-reviewed journal, after which time it will be open access (http://etheses.dur.ac.uk/12564/). Qualitative data is also included in the thesis in the form of direct quotes but the original transcripts have not been included due to the inability to adequately anonymise the data set. Copyright of the thesis is held by Miss Charlotte Kitchen.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2020	31/07/2020	Yes	No
Basic results		21/07/2020	05/08/2020	No	No