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Community-based behavioural activation training for depression in adolescents

Submission date
18/11/2021

Recruitment status
No longer recruiting

Registration date
22/11/2021

Overall study status
Completed

Last Edited
07/07/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression is a major cause of poor health and social disability, affecting children of all ages but peaking in adolescence. Common symptoms include persistent sadness or irritability, loss of interest in activities and people, and fatigue. Child and Adolescent Mental Health Services (CAMHS) offer interventions for depression; however due to increased demand and limited resources, waiting lists are long and entry thresholds are high. This creates gaps between treatment provision and need, with resources often prioritised for severe and complex presentations. Young people with mild-to-moderate depression often do not meet threshold criteria for CAMHS entry. Staff trained to provide mental health support in schools and charities are limited in numbers and many of the non-specific, supportive interventions available are not evidence-based and may contain but not treat depression.

Behavioural Activation (BA), a brief psychological intervention, is recommended for adults with depression. BA's premise is that engaging in meaningful, purposeful and rewarding activities can lift people's mood, energise them and restore their interest and pleasure in day-to-day life. BA with adults has been successfully delivered by non-specialists in the community and requires fewer sessions and shorter training than other types of psychological therapies, such as cognitive therapy. BA has shown promising results for young people in small research projects when delivered in specialist clinics. Large-scale research in the community is needed to establish the acceptability, effectiveness and cost-effectiveness of BA for young people with mild to moderate depression.

This feasibility study aims to evaluate BA with a small group of 12–18-year-olds and explore what usual care for depression is in community settings and whether BA is part of usual care. Through an embedded qualitative study, we will ask young people, parents/guardians and professionals about their experiences of receiving, supporting or delivering BA. In parallel, we will gather information about current treatment provision for young people with mild to moderate depression via an online survey with professionals. The results of this feasibility study will inform a subsequent large-scale randomised controlled trial (RCT), which will compare standardised BA with usual care in schools and community settings.

Who can participate?
Young people aged 12 to 18 years who experience mild to moderate depression. This means that they struggle with low mood or persistent irritability and have lost interest and pleasure in day-to-day life. Other symptoms include: not being able to concentrate, to pay attention, or to make decisions; they may feel guilty or hopeless and think of death or self-harm; they may have problems with their sleep or appetite; they may feel either sluggish and slowed down, or agitated and on edge; they may have no energy and feel tired all the time.

Parents/guardians who support young people with mild to moderate depression will also be invited to offer their views and experiences as part of this study.

Organisations and professionals in the UK who work with young people, some of whom may struggle with depression, can also join this study. Services and organisations who do not currently offer clinical interventions to young people with depression, but who wish to upskill their staff and enable them to provide BA to improve young people's mental health and functioning, are also invited to join this study.

What does the study involve?
Adolescents who agree to participate in the study will be offered up to 8 weekly sessions of BA lasting 30-40 minutes with a professional who may be based in a school, a young people's charity or in CAMHS. Before the participants start BA they will complete the following questionnaires: demographic details, Revised Children's Anxiety and Depression Scale (RCADS) – Brief Version (25 items), Children's Depression Rating Scale-Revised (CDRS-R), Behavioural Activation for Depression Scale (BADS), Child Health Utility-9 Dimensions (CHU-9D), Behavioural Activation Literacy and Insights (BALI) Questionnaire and Resource Utilisation Questionnaire for Adolescents (RUQ-A). All questionnaires will be repeated 8-weeks post-baseline.

On completion of the BA sessions, all young people will be invited to attend a face-to-face interview with the researcher about their views and experiences of BA. Focus groups (and interviews where more appropriate) will also be conducted with a sample of parents and professionals to obtain their views about BA.

A brief online survey will be circulated to services involved in supporting young people. Survey questions will explore the types of services, care pathways and interventions offered to young people with depression – including BA, the professionals responsible for delivering interventions to young people, any thresholds in place for service acceptance, how young people reach services (i.e. self-referral, GP referral) and whether services signpost young people with mild to moderate depression elsewhere.

What are the possible benefits and risks of participating?
This study wishes to build on the experience and skills of professionals who work with young people in various capacities. We will offer training and supervision to professionals in the participating sites so that they can deliver BA with the view of making a meaningful change in the young people's depression. Our ambition is to maximise the skills of professionals and enable them to effectively support young people with depression. BA can potentially be embedded into the portfolio of options within schools and community organisations that strive to support young people's mental health.

This small study cannot tell us whether the BA intervention is likely to be an effective treatment for all young people; however, some young people taking part in the research may find it beneficial for reducing their symptoms of depression and improving their knowledge of therapy techniques that they can use in the future. Through participating in this research, young people

will have an opportunity to tell us what they think about BA and how we can make it better so that it can be used in a larger study to benefit other young people. and make the most of opportunities at school and work and in their relationships and life.

Taking part in this research will require young person participants to attend treatment sessions over a period of up to 8 weeks, complete a series of outcome measures at baseline and follow-up and attend an interview about their experiences. This will be demanding on young people's time and energy, but they always have the option to discontinue taking part if it is too much for them and to speak to their support professional about ways to make things easier (for example, by changing the frequency of sessions).

Taking part in this research may bring up issues or risks that the young people or their parents were unaware of until then. The young people participating in this study will be monitored for any worsening of their symptoms or risk, so that they can be directed to additional care if necessary. We will always ask permission from the parent/guardian and the young person to liaise with the relevant support services if these are needed (e.g. social care or mental health services); if the level of risk warrants it, we may directly contact the relevant services.

Where is the study run from?
Researchers based at the University of York and at Tees, Esk and Wear Valleys NHS Foundation Trust (TEWV) (UK) are running the study in partnership. Participating young people, parents /guardians and professionals may access the study from NHS services, schools and community organisations largely in the North of England.

When is the study starting and how long is it expected to run for?
July 2021 to May 2022

Who is funding the study?
National Institute for Health Research (NIHR) Programme Grants for Applied Research (PGfAR) (UK) (Award ID: NIHR201174 https://fundingawards.nihr.ac.uk/award/NIHR201174)

Who is the main contact?
Lucy Tindall, Research Programme Manager, lucy.tindall@york.ac.uk or combat-project@york.ac.uk

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
302389

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 302389, CPMS 50816

Study information

Scientific Title
Community-based Behavioural Activation Training (ComBAT) for Depression in Adolescents: A single-group pre-post feasibility study with an embedded qualitative study and a parallel professional survey

Acronym
ComBAT

Study objectives

1. Behavioural Activation (BA) for adolescents aged 12 to 18 years with mild to moderate depression is a feasible and acceptable intervention for the young service users, their parents and the professionals who support them.
2. Provision of BA in the NHS and community settings is limited and inconsistent.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/11/2021, North East - Newcastle & North Tyneside 1 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)203 443 6294; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 21/NE/0182

Study design
A single-group pre-post feasibility study with an embedded qualitative study and a parallel professional survey

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild to moderate depression

Interventions
All participants will be offered Behavioural Activation (BA) in the form of 8 weekly sessions lasting up to 40 minutes each with a professional from schools, third sector organisations or child and adolescent mental health services (CAMHS). BA encourages young people to engage with meaningful, purposeful and rewarding activities that can lift their mood, energise them and re-instate their interest and pleasure in life. The first step is to identify activities that are aligned with areas of their lives that are important to them and then schedule day-to-day activities that fulfil different purposes: some are done for pleasure, others are routine tasks and others are building blocks towards a bigger project or aspiration. As part of BA, young people also learn problem solving techniques, methods to reduce avoidance and to prevent relapse.

Intervention Type
Behavioural

Primary outcome(s)
Anxiety and depression measured using Revised Children's Anxiety and Depression Scale (RCADS) - Brief Version (25 items) - completed at baseline and 8 weeks post-baseline

Key secondary outcome(s))
1. Children’s Depression Rating Scale-Revised (CDRS-R) - completed at baseline and 8 weeks post-baseline
2. Behavioural Activation for Depression Scale (BADS)- completed at baseline and 8 weeks post-baseline
3. Child Health Utility-9 Dimensions (CHU-9D) - completed at baseline and 8 weeks post-baseline

4. Behavioural Activation Literacy and Insights (BALI) Questionnaire - completed at baseline and 8 weeks post-baseline
5. Resource Utilisation Questionnaire for Adolescents (RUQ-A) - completed at baseline and 8 weeks post-baseline

Completion date
31/05/2022

Eligibility

Key inclusion criteria
Young people
1. Are aged 12-18 years at the date of consent.
2. Score ≥65 on the depression subscale (10 items) of the Brief Revised Children's Anxiety and Depression Scale (RCADS) (this is the standardised cut-off by which elevated symptoms of depression warrant further assessment and potential intervention)
3. Provide consent (if they are 16-18 years old), or assent (if they are 12-15 years old) along with their parent's consent, to participate in the study.

Parent/Guardians
1. Parent/guardians will be eligible to take part if they are a parent/guardian of a young person aged 12 to 18 years and participating in the feasibility study

Professionals
1. Professionals will be eligible to take part if they have experience of working with young people with mild to moderate depression.

Participant type(s)
Patient, Health professional, Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 years

Sex
All

Total final enrolment
38

Key exclusion criteria
1. Young people eligible for secondary care (tier 3/high intensity therapy) in CAMHS based on local service entry criteria, which usually are: risk of suicide, inability to function because of the

severity of the depressive symptoms, complex circumstances such as learning disability.
2. Cannot speak English, because translations of the BA materials, outcome measures, interview topic guides and online survey are not possible for this small study.

Date of first enrolment
10/01/2022

Date of final enrolment
31/05/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Tees Esk and Wear Valleys NHS Foundation Trust
Flatts Lane Centre
Flatts Lane
Normanby
Middlesborough
United Kingdom
TS6 0SZ

Study participating centre
University of York
Heslington
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
Tees, Esk and Wear Valleys NHS Foundation Trust

ROR
https://ror.org/04s03zf45

Funder(s)

Funder type
Government

Funder Name
Programme Grants for Applied Research

Alternative Name(s)
NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 07/07/2022:
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

Previous individual participant data (IPD) sharing statement:
Data sharing plans for this study will be made available at a later date as part of the larger programme of research.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/07/2025	07/07/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.3	08/04/2022	06/10/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes