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Community-Based Behavioural Activation Training (ComBAT) for Depression: Randomised Controlled Trial

Submission date
21/07/2022

Recruitment status
No longer recruiting

Registration date
25/07/2022

Overall study status
Ongoing

Last Edited
18/11/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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. Providing therapy at the earliest opportunity is essential. 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 the threshold criteria for CAMHS entry. Staff trained to provide mental health support in schools and charities are limited in numbers and many non-specific, supportive interventions are available but may not be evidence-based or may be used to contain depression rather than treat it.

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 psychological therapies, such as cognitive therapy. BA has shown promising results for young people in small research projects when delivered in specialist clinics.

The current study is a large randomised controlled trial (RCT) comparing BA to usual care for treating mild-to-moderate depression in young people (aged 12 to 18 years) within the NHS, schools, and third sector organisations such as charities. The RCT, along with embedded phenomenological and ethnographic studies, will examine the clinical and cost-effectiveness of BA and assess its acceptability from the perspectives of those who receive it and those who deliver it.

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, pay attention, or 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.

Professionals who support the participating young people will be invited for an interview about their experiences.

What does the study involve?
Eligible young people who agree to participate in the study will sign a consent/assent form (alongside consent from a parent/guardian if applicable) and then be invited to complete questionnaires about their demographics, anxiety and depression symptoms, and their use of health resources and services.

Young people will be randomly offered either BA or usual care, which is what they would be usually offered for mild-to-moderate depression if BA were not available. They will have an equal chance of being in either group (like tossing a coin). Participants and researchers will not have a choice in the treatment given.

Professionals based within schools and young people's charities will support the participating young people. Some sessions will be recorded or observed by a member of the research team to enable them to see how treatments are delivered in different participating sites.

After 6 and 12 months, participants will be invited to complete the same questionnaires as at the start of the study, with the exception of the demographics and with the addition of the a questionnaire on their experience of staff interactions. At the 6-month follow-up session, 20% of participants will be invited to an interview with a member of the research team about their experiences.

All professionals who supported the young participants will also be invited to an interview about their experiences.

What are the possible benefits and risks of participating?
Professionals in the participating sites will receive training in BA with the view of making a meaningful change in the young people's low mood/depression. Our ambition is to maximise the skills of professionals who work with young people and enable them to effectively support those who struggle with low mood/depression. BA can potentially be embedded into care pathways within schools and community organisations that strive to support young people's mental health.

Through participating in this study, young people will be offered an assessment and follow-up support (either BA or usual care) that is expected to help with their low mood/depression. We cannot tell before we complete the study whether BA or usual care are effective and for whom, but all participants will have a better understanding of depression and its treatments through their involvement with the study. Young people will be followed up over the course of 12 months during which there will be opportunities to signpost them to available sources of help beyond this research if needed. Through their participation in this study, young people will make a contribution to the wider body of knowledge about depression and its treatments, and to the community of practice that supports their peers who struggle with low mood/depression.

Completing questionnaires and an interview as part of this study and attending sessions as part of BA or usual care will demand young people's time and energy. The researchers and professionals who support young people will be flexible in the delivery to suit a young person's circumstances, for example, by changing the frequency of sessions or breaking up the questionnaires and interviews into smaller chunks. Young people will always have the option to withdraw from the study if they no longer wish to participate without giving any reason.

Taking part in this research may bring up issues or risks that the young people 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 help if necessary. We will always ask permission from the parent/guardian (where applicable) 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?
The University of York (UK) and Tees, Esk and Wear Valleys NHS Foundation Trust (TEWV) (UK) are running the study in partnership. Participating young people and professionals can access the study from participating NHS services, schools, and community organisations across England.

When is the study starting and how long is it expected to run for?
From July 2021 to October 2026

Who is funding the study?
National Institute for Health Research (NIHR) Programme Grants for Applied Research (PGfAR) (UK)

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

Contact information

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Public

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
310085

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 310085, CPMS 53142, Award ID: NIHR201174

Study information

Scientific Title
Community-Based Behavioural Activation Training (ComBAT) for Depression in Adolescents: Randomised Controlled Trial (RCT) with Economic and Process Evaluations

Acronym
ComBAT RCT

Study objectives
1. Behavioural Activation for adolescents with mild-to-moderate depression is more effective and more cost-effective than usual care
2. Behavioural Activation is received well by adolescents with mild-to-moderate depression and is delivered with fidelity by professionals who support those adolescents

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/07/2022, 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:22/NE/0100

Study design
Randomized controlled trial (RCT) with economic and process evaluations

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild-to-moderate depression/low mood

Interventions
Arm 1 - Intervention (Behavioural Activation):
All participants randomised to the intervention arm will be offered Behavioural Activation (BA). This will comprise 5 modules, delivered in up to 8 weekly sessions lasting up to 40 minutes. Sessions will be delivered by professionals 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.

Arm 2 - Comparator (Usual Care):
Those randomised to the comparator arm will receive the usual care offered for those with mild-to-moderate low mood in the service from which they have been recruited. This may include no intervention, signposting to alternative sources of support, general discussion, supportive counselling, relaxation, recreation groups, guided self-help or psychological therapies including CBT and IPT. The usual care delivered in the comparator arm cannot be an intervention based upon Behavioural Activation. Usual care will be provided by professionals based within the services responsible for recruitment (i.e. schools, third sector organisations, child and adolescent mental health services (CAMHS)). We will record and monitor what usual care means for each young person recruited into the study.

Randomisation:
We will use simple randomisation with participants randomised on a 1:1 ratio to either BA or usual care. Randomisation will be implemented using a web-based system designed and developed by the data management team at York Trials Unit (YTU). The allocation sequence will be generated by a YTU statistician and embedded into the randomisation system.

Assessments:
Young people:
Baseline: Demographics, 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-Short Form (BADS-SF), Child Health Utility-9 Dimensions (CHU-9D), and Resource Utilisation Questionnaire for Adolescents (RUQ-A).
6 months: 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-Short Form (BADS-SF), Child Health Utility-9 Dimensions (CHU-9D), Resource Utilisation Questionnaire for Adolescents (RUQ-A), and Aspects of Care Questionnaire (ASQ). 20% of participants (across both arms) will be invited to take part in a qualitative interview about their experiences.
12 months: 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-Short Form (BADS-SF), Child Health Utility-9 Dimensions (CHU-9D), Resource Utilisation Questionnaire for Adolescents (RUQ-A), and Aspects of Care Questionnaire (ASQ).

Professionals:
Qualitative interview 6 months after recruitment has ended or sooner if a site stops recruiting earlier than the trial's recruitment end date.

Intervention Type
Behavioural

Primary outcome(s)
Anxiety and depression symptoms measured using the Revised Children's Anxiety and Depression Scale (RCADS) - Brief Version (25 items) at 6 months follow-up

Key secondary outcome(s))
1. Depression symptoms measured using the Children's Depression Rating Scale-Revised (CDRS-R) at baseline, 6, and 12 months
2. Changes in avoidance and activation measured using the Behavioural Activation for Depression Scale- Short Form (BADS-SF) at baseline, 6, and 12 months
3. Health-related quality of life measured using the Child Health Utility-9 Dimensions (CHU-9D) at baseline, 6, and 12 months
4. Health service use measured using the Resource Utilisation Questionnaire for Adolescents (RUQ-A) at baseline, 6, and 12 months
5. Patient experience of staff interactions measured using the Aspects of Care Questionnaire (ASQ) at 6, and 12 months
6. Intervention fidelity measured using the BA Fidelity Assessment completed throughout the trial
7. Contamination within the control condition measured using the Usual Care Contamination Checklist completed throughout the trial
8. Acceptability of the support received during ComBAT by the young people receiving it and the professionals delivering it measured using qualitative interviews at 6 months

Completion date
31/08/2026

Eligibility

Key inclusion criteria
Young people:
1. Aged ≥12 and ≤18 years at the date of consent

2. Scores ≥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. Scores <15 on the PHQ-9A and does not answer 'more than half of the days' or 'nearly every day' to question 9 of the PHQ-9A or answers "yes" to either SQ3 or SQ4 of the PHQ-9A
4. Provide consent, or assent along with their parent's consent (if applicable), to participate in the study

Professionals:
All professionals who have provided support to young people with depression during the research (BA or usual care)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 years

Upper age limit
18 years

Sex
All

Key exclusion criteria
Young people:
1. Have severe depression or an increased risk of suicide, assessed with an interview by a clinical member of the ComBAT team. The assessment interview will only be carried out if the young person scores ≥15 on the PHQ-9A, or answers 'more than half of the days' or 'nearly every day' to question 9 of the PHQ-9A, or answers "yes" to either SQ3 or SQ4 of the PHQ-9A.
2. Meet criteria for secondary care (tier 3/high intensity therapy), other than the risk of suicide or severity of the depressive symptoms, such as a learning disability or complex comorbid conditions, confirmed through a discussion with the referrer and the local secondary care team
3. Cannot speak English and do not have a carer or other designated adult to translate the intervention and research materials, and to translate conversations during sessions with a professional

Date of first enrolment
08/08/2022

Date of final enrolment
30/11/2024

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
The University of York
Heslington
York
United Kingdom
YO10 5DD

Study participating centre
Northorpe Hall Child & Family Trust
53 Northorpe Lane
Mirfield
United Kingdom
WF14 0QL

Study participating centre
Westbourne Academy
Marlow Rd
Ipswich
United Kingdom
IP1 5JN

Study participating centre
The Oldham Academy North
Broadway
Oldham
United Kingdom
OL2 5BF

Study participating centre
Integrated Specialist Public Health Nursing Service (ISPHNS)
Humber Teaching NHS Foundation Trust
Trust Headquarters
Willerby Hill
Hull
United Kingdom
HU10 6ED

Study participating centre
St Margaret's School
Merry Hill Road
Bushey
United Kingdom
WD23 1DT

Study participating centre
Bridgnorth Endowed School
Northgate
Bridgnorth
United Kingdom
WV16 4ER

Study participating centre
Lancashire Youth Challenge
Cornerstone Building
Sulyard Street
Lancaster
United Kingdom
LA1 1PX

Study participating centre
West Walsall E-ACT Academy
Primley Avenue
Walsall
United Kingdom
WS2 9UA

Study participating centre

More Music
13-17 Devonshire Rd
West End
Morecambe
United Kingdom
LA3 1QT

Study participating centre
Willenhall E-Act Academy
Furzebank Way
Willenhall
United Kingdom
WV12 4BD

Study participating centre
East Norfolk Sixth Form College
Church Lane
Gorleston-on-Sea
Great Yarmouth
United Kingdom
NR31 7BQ

Study participating centre
York School Wellbeing Service
West Offices
York
United Kingdom
Y01 6GA

Study participating centre
South West Yorkshire Partnership NHS Foundation Trust
Trust Headquarters
Fieldhead Hospital
Ouchthorpe Lane
Wakefield
United Kingdom
WF1 3SP

Study participating centre
Invictus Wellbeing
E Mill

Dean Clough Mills
Halifax
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HX3 5AX

Study participating centre
Locala
Beckside Court
286 Bradford Road
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WF17 5PW

Study participating centre
Rotherham Doncaster and South Humber NHS Foundation Trust
Woodfield House
Tickhill Road
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Study participating centre
Bradford District Care Trust
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Study participating centre
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West Offices
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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

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data sharing plans for this study are currently unknown and will be made available at a later date.

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?
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 1.1	21/06/2022	22/07/2022	No	No
Protocol file	version 4	25/09/2023	03/11/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes