ISRCTN12315118 https://doi.org/10.1186/ISRCTN12315118

Behavioural activation for young people

Submission date
24/07/2023

Recruitment status
Recruiting

Registration date
29/08/2023

Overall study status
Ongoing

Last Edited
19/09/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
In 2017, nearly 1 in 4 teenage girls and 1 in 10 boys in the UK reported high levels of depressive symptoms. Since then, emotional problems have been increasing in young people (YP) and now the COVID-19 pandemic has seriously affected their lives. Even before COVID-19, three quarters of YP with the highest levels of mental health problems could not get help from specialist Child and Adolescent Mental Health Services (CAMHS). Even when they do, many YP with high levels of depression wait months for specialist therapy. These therapies are expensive and need highly trained staff but there are not enough therapists. Depressed YP struggle to do everyday things. Behavioural Activation (BA) is a treatment which may help, through planning and doing more things that matter to the YP (activities they value), like hobbies and keeping in touch with people. BA works well for adults and less experienced therapists can offer it. There is not enough proof that BA works well for YP, but small studies suggest it may be helpful. The study team developed a behavioural activation with YP and carers and tested it in 2 small studies in CAMHS. YP liked the therapy and almost half did not need further treatment; YP also told us that they think this is an important question. Whether BA really works now needs to be tested in a large study where there is a 50:50 chance of receiving it. Training in BA is easier and quicker than other therapies, and staff who don't have therapy training, like newly qualified nurses and assistant psychologists, can provide BA. YP could be offered BA while they are waiting for more specialist therapy rather than just getting 'routine care' (e.g. check-ins). Because of COVID-19, services are working with YP in a mixed way, seeing them in clinics, and over the phone or video. YP like to choose how they talk to their therapist when possible. Our study showed that BA could work with a therapist over the phone or video and use BeActive on our website. The study aims to ask If adding BA to routine care works better than 'usual routine care plus information about depression', while YP wait for specialist therapy; what YP, carers and clinicians think about BA; and, does BA provide value for money. Other questions will be answered like if YP still need more therapy after BA. A test period will be included to make sure enough people want to take part. The website will be refined with YP before the study starts, as YP told us that they liked seeing our workbook on the website but it could be made better.

Who can participate?
YP aged between 11 and 17.5 years old with depression in 4 areas of England

What does the study involve?
The YP will be divided by chance into 2 groups. One group will get BA and routine care; the

other, routine care plus information on depression. a few YP may be left out, like those needing urgent care. Less experienced clinicians will be trained to give the intervention with a few more sessions being given face to face. This helps develop a good relationship between a therapist and YP and helps the therapist monitor risks. The other sessions will be planned together, including options for video or phone calls. YP will be offered 8 sessions of 50 minutes, and include carers as needed.

Analysis and Outputs: Researchers will collect a range of information from YP, carers and clinicians. YP and carers will help us plan the study and inform people about the findings, through social media, publications, events and conferences.

What are the possible benefits and risks of participating?
Behavioural activation might be useful in helping young people with their low mood, and the study offers an opportunity to try a therapy that they might not be able to access in CAMHS. There are no known risks of BA.

Where is the study run from?
University of York (UK)

When is the study starting and how long is it expected to run for?
June 2022 to February 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Emma Standley, bay-project@york.ac.uk

Study website
https://bayresearchstudy.co.uk/

Contact information

Type(s)
Principal Investigator

Contact name
Prof Bernadka Dubicka

Contact details
Chief Investigator
Department of Health Sciences
Faculty of Science
University of York
Heslington
York
United Kingdom
YO10 5DD
-
bay-project@york.ac.uk

Type(s)
Public

Contact name
Miss Emma Standley

Contact details
Department of Health Sciences
Faculty of Science
University of York
Heslington
York
United Kingdom
YO10 5DD
-
bay-project@york.ac.uk

Type(s)
Scientific

Contact name
Miss Rachel Ellison

Contact details
Trial Manager
Department of Health Sciences
Faculty of Science
University of York
Heslington
York
United Kingdom
YO10 5DD
-
bay-project@york.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
319136

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55671, IRAS 319136

Study information

Scientific Title
Behavioural activation for young people with depression in specialist child and adolescent mental health services

Acronym
BAY

Study objectives
To examine the clinical effectiveness, cost-effectiveness and acceptability of BA (BAY programme) using blended delivery, when compared to treatment as usual + psychoeducation in depressed young people referred to specialist CAMHS at 12 weeks, 6 months (primary outcome) and 1-year follow-up post-randomisation (naturalistic sub-group).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/06/2023, East of England - Cambridge South Research Ethics Committee (Equinox House, City Link , Nottingham, NG2 4LA , United Kingdom; +44 (0)207 104 8084, +44 (0)207 104 8194; cambridgesouth.rec@hra.nhs.uk), ref: 23/EE/0073

Study design
Randomized interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

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

Interventions
This is a full-scale randomised controlled trial with an internal pilot to assess the clinical, cost-effectiveness and acceptability of a novel blended behavioural activation (BA) intervention, the BAY programme. Behavioural activation is a therapy for people with depression that encourages clients to schedule and take part in manageable activities that they enjoy, or from which they gain a sense of acheivement, or increased closeness to others.

In the trial, participants will be randomly allocated to receive BA + psychoeducation (PE) + treatment as usual (TAU) or PE + TAU. Outcome measures will be collected at baseline, 12 weeks, 6 months, and 12 months (for those recruited in the first year), to determine clinical and cost-effectiveness. Qualitative interviews will be conducted with young people, carers, therapists and supervisors to determine acceptability. This study follows a feasibility trial in which the workbooks for the BAY programme were co-designed with young people, and preliminary effectiveness was demonstrated.

Identification and recruitment:
The recruitment target is 528 and the internal pilot intends to recruit 176 of 528 to warrant progression to the full trial.

Participants will be identified via three pathways: a) a research assistant (RA) or Clinical Research Network (CRN) delivery staff will attend CAMHS multi-disciplinary meetings which determine if the young person has been accepted into CAMHS, b) a research assistant or CRN delivery staff will screen CAMHS records of recently accepted referrals, c) a clinician will identify and screen potentially eligible young people.

Inclusion criteria are: between the ages of 11 and 17 years old (up to 17th birthday), scores >27 on the Moods and Feelings Questionnaire (MFQ), recently referred (<4 weeks) to CAMHS for depression.

Exclusion criteria are: a severe mental illness that is not primarily depressive (e.g. schizophrenia, non-depressive psychosis, current mania, anorexia), high risk of imminent suicide or presenting with a high frequency of severe self-harm and therefore need a different pathway of care and support (clinical decision), cannot speak English to a sufficient level to understand the intervention and research materials, an intellectual disability of a level which prevents adequate understanding of the study or intervention materials, has received 8 sessions of therapist-led CBT (which includes BA alone) in the previous 6 months.

The time required to screen eligible participants will be minimal. The research assistant will attend CAMHS MDT meetings and screen records in some sites to identify potentially eligible participants who have recently been accepted into CAMHS. The CAMHs clinician/team member will then contact the carer and YP to discuss the project and ask the YP to complete the Moods and Feelings Questionnaire. In some cases, the research assistant will ask a clinician at CAMHS to confirm with the carer and YP via phone call, email or letter that they are happy to be contacted by the research assistant to discuss the research and therefore if they are happy for their contact details to be passed on.

This will be in line with each Trust’s local policy. If they agree, the research assistant will contact them to discuss the project further and ask the YP to complete the Moods and Feelings Questionnaire. Alternatively, the clinicians will be provided with information sheets to give to the potential participants, a screening form, and the Moods and Feelings Questionnaire for the YP to complete. These information sheets will have the research team's contact details so that the young person and their parents can contact the research team for further information if required. If the participant is potentially eligible based on the clinician’s screening assessment, the clinician will ask the carer and YP if they are happy to be contacted by the research assistant and if they are happy for their details to be passed on. If they agree, the research assistant will contact them to discuss the project and confirm screening. Information packs can be distributed via email or post. The research assistant in all cases will attempt to leave a message no more than four times.

There will be three separate information sheets, one for carers, one for young people aged 16-17 and one for young people aged 11-15. Sufficient time will be given (at least 24 hours) to read through the information sheets. Once contacted, if the young person is eligible and decides to take part, and their carer is also happy for them to take part if they are under 16, they will be asked to book the baseline appointment.

Consent:
Participation in the study will be entirely voluntary and informed consent/assent will be obtained on paper or via an online data capture link. This will be sent to participants in advance of the baseline appointment and they will have the option to complete it before the appointment following a phone call with the researcher, or at the baseline appointment prior to data collection. A research assistant will send the information sheet and consent/assent form via email or post, and allow the young person at least 24 hours after receiving the information to decide if they would like to take part, before booking the baseline appointment.

Before beginning participation, informed consent/assent will be collected from the young person and their carer (if under 16). If completed already prior to the appointment, the researcher will check that the YP and carer are still happy to go ahead and check that the consent form has been completed correctly. For participants aged 11-15, informed consent will be collected from a carer as well as the child themselves (assent). The research assistant, with guidance if necessary from the clinician or PI at the local CAMHS site, will determine the participant's capacity to provide informed consent/assent (the YP can understand the information given to them about the study, retain the information, be able to relay the information back to the research assistant and can make a decision about participation). Training will be provided to RAs regarding assessing competence/capacity.

Baseline Data Collection:
Following informed consent/assent the young person will be assigned a participant number and will be asked to complete a series of standardised measures with a trained researcher captured electronically using REDCap (Research Electronic Data Capture).

The young person will repeat the MFQ at baseline with the researcher. Those with a score ≥27 MFQ will go on to complete the full baseline assessment. Those who do not meet the threshold will not be recruited to the study and will continue to receive treatment as usual (this will be explained to the participant prior to giving consent).

The baseline appointment will be led by the research assistant. YP and carers will each have their own set of questionnaires to complete. For YP aged 16-17, their carer may not be involved in the study and therefore may not complete the carer outcome measures. The research assistant and carer can support the YP during outcome measure completion as needed. We expect the questionnaire completion to take 60-90 minutes.

This will include: Demographic information, Moods and Feelings Questionnaire, Revised Children' s Anxiety and Depression Scale (RCADS; Chorpita 2003), Bespoke self-harm and suicidality questions, Behavioural Activation for Depression Scale, CHU-9D, EQ-5D-Y (EuroQol Group, 2009), Adapted Child and Adolescent Service Use Schedule,

Goal-based outcome measure:
Parents will be asked to complete: MFQ, EQ-5D-5L on behalf of their child's mental health, and Patient Health Questionnaire (PHQ-9) and Generalised Anxiety Disorder (GAD-7) for their own mental health.

The baseline will also include a diagnostic interview, the Development and Well Being Assessment (DAWBA) and the Strengths and Difficulties Questionnaire (SDQ; Goodman et al., 1998), which can take up to 90 minutes, depending on complexity. This includes both the YP and carer. They will be given the option to complete this after the questionnaires, or book an additional appointment to complete this.

The participant will then be randomised to receive BA+PE+TAU or PE+TAU. The control arm will therefore receive PE and will remain under the care of CAMHS. Randomisation will be conducted on a data management system and managed by the Trial Managers at York Trials Unit. Research assistants will be blinded to allocations.

Intervention Delivery:
The intervention will be delivered by a trained Band 4 or 5 specialist CAMHS staff in roles such as Children's Wellbeing Practitioner, Assistant Psychologist, and newly qualified nurse. The rationale for this is to train less qualified and experienced staff to alleviate the workload from senior staff in CAMHS and therefore allow this therapy to be more accessible, as well as increase the skills of less experienced staff. The intervention will be facilitated by the therapist using our BA website, with the first session being in person at CAMHS and the following sessions having the flexibility to be done online or in person, according to the preference of the young person, or clinical need. The intervention is eight sessions over a maximum of 12 weeks, and each session is approximately 40 minutes long. Young people that do not have access to technology will be provided with print-out versions of the web material, so that receive the same content and format as others, and will not be disadvantaged. They will also be able to access the website with the therapist during in-person sessions.

The intervention aims to improve people's mood by encouraging them to take part in activities they may have stopped doing that they previously enjoyed. The sessions help young people to identify activities that are meaningful and enjoyable and they are encouraged to take part in these activities, with the support of carers; young people aged 16 and over may sometimes prefer to nominate another adult for support. Young people will be shown how to set goals, use problem-solving, learn methods to deal with stress and avoidance and will be taught what to do if they think they may have a relapse (i.e. are feeling better and then see symptoms return). All BA sessions have been developed from previous BA therapies and through discussions with professionals, carers and young people.

Data collection during the intervention:
YP will be asked to complete the Working Alliance Inventory halfway through the eight-session intervention to monitor how their working relationship with their therapist is going. YP will be reassured that their therapist will not have access to this data. BAY therapists will be asked to complete an online session log each time they complete an intervention session. Therapists will ask if YP are happy for their sessions to be audio recorded (also highlighted in the consent form) and if so, they will record their sessions and send them via secure transfer to the research team. The research team will conduct a fidelity assessment on a sample of the recordings to ensure that BA has been delivered with all the required elements.

Post-intervention data collection:
After the final session, YP will be asked to complete the End of Treatment Questionnaire, addressing the acceptability of the intervention and barriers to treatment.

12-week follow-up:
All participants will be asked to complete a 12-week follow-up. These participants will be contacted via their preferred method of contact by a research assistant and arrange to complete

the outcome measures again. These can be completed via videocall or in person depending on the participant's preferences. This includes all of the same questionnaires as the baseline except the demographics questionnaire and the DAWBA. We expect this to take 45-60 minutes. In addition, this will include the Aspects of Care Questionnaire which addresses specific elements of behavioural activation. This will be used to identify whether any control participants have received any elements of behavioural activation.

6-month follow-up:
All participants will be asked to complete a 6-month follow-up. These participants will be contacted via their preferred method of contact by a research assistant and arrange to complete the outcome measures again. These can be completed via videocall or in person depending on the participant's preference. This assessment will include the primary outcome (Moods and Feelings Questionnaire at 6 months). This includes all of the same questionnaires as the 12-week follow-up. We expect this to take 45-60 minutes.

12-month follow-up:
The recruitment period ends 6 months prior to the end of the follow-up stage, to allow all primary outcome data (6 months) to be collected. Participants who are recruited with 1 year prior to the end of the follow-up period will be asked to complete a 12-month follow-up assessment. Participants recruited any closer to the end of the follow-up stage will be required to complete the 6-month follow-up only. This will provide an indication of the clinical and cost-effectiveness of the intervention at 12 months in a subset of participants.

Qualitative Interviews:
Young people, carers, therapists and their supervisors will be invited to take part in a semi-structured interview after their 6-month follow-up. If they have indicated on their consent form that they are happy to be approached for an interview, the qualitative researcher will be alerted to this information via the online data management program. The qualitative researcher will contact them to invite them to an interview.

Participants who would like to take part in an interview will be given a participant information sheet and will be asked to complete another consent form specifically designed for the qualitative interviews. The interviews aim to collect qualitative information regarding the acceptability and views of the intervention. We will gather detailed information on what aspects they believe helped them and the effects of the intervention on their mental and general health. CAMHS clinicians will also be invited to participate in interviews to gather their experiences of running the intervention and of the research trial.

There will be three separate information sheets provided, one for the carers, one for young people aged 16-17 and one for young people aged 11-15. They will be given sufficient time to read through the information sheet (at least 24 hours) and ask any questions of the research team. We will collect informed consent before completing the interview.

For an interview with a young person aged 16-17, participants can provide informed consent for themselves. For an interview with a young person aged 11-15, both the parent and young person must provide informed consent/assent retrospectively. Informed consent will be obtained via an online data capture link, which will be sent by the qualitative researcher along with the information sheet. This will be sent via post or email 1 week in advance allowing the participant time to read over the documents. The participant can then complete the consent form independently or with the research assistant at the interview. The interview will take place online due to the recruiting sites being located across the country.

Clinical records data collection:
Upon the participant's completion of the trial, the research assistant will screen their CAMHS clinical records and complete the 'treatment as usual' questionnaire. The RA will use the records to identify what other treatments and interventions the young person has received over the course of their involvement in the trial. This will be used to describe what 'treatment as usual' is in specialist CAMHS services.

Intervention Type
Behavioural

Primary outcome measure
Depression in young people is measured using the self-reported Moods and Feelings Questionnaire at baseline, 12 weeks, 6 months and 12 months

Secondary outcome measures
1. Depression in young people is measured using the self-reported Strengths and Difficulties Questionnaire (SDQ) at baseline, 12 weeks, 6 months and 12 months
2. Depression and anxiety in young people are measured using the self-reported Revised Children's Anxiety and Depression Scale (RACDS) Brief Version at baseline, 12 weeks, 6 months and 12 months
3. Descriptive accounts of young person's mental health are measured through the Development and Wellbeing Assessment (DAWBA) at baseline
4. Current engagement in activities in young people is measured using the self-reported Behavioural Activation for Depression at baseline, 12 weeks, 6 months and 12 months
5. Self-harm and suicide behaviours in young people are measured using the self-reported self-harm and suicidality questionnaire at baseline, 12 weeks, 6 months and 12 months
6. Goal achievement in young people is measured using the self-reported goal-based outcome measure at baseline, 12 weeks, 6 months and 12 months
7. Quality of life in young people is measured using the self-reported Child Health Utility at baseline, 12 weeks, 6 months and 12 months
8. Quality of life in young people is measured using the self-reported EQ-5D-Y at baseline and 6 months
9. Service use in young people is measured using the self-reported Healthcare Service Use schedule at baseline, 12 weeks, 6 months and 12 months
10. Elements of behavioural activation in therapy for young people are measured using the self-reported Aspects of Care Checklist at 12 weeks, 6 months and 12 months
11. Relationship with a therapist and young people is measured using the self-reported Working Alliance Inventory halfway through therapy delivery
12. Experiences of BA treatment for young people are measured using a self-reported end-of-treatment questionnaire after the final session of BA therapy
13. Depression in young people is measured using parent completed Strengths and Difficulties Questionnaire at baseline, 12 weeks, 6 months, and 12 months
14. Descriptive accounts of a young person's mental health are measured through the parent-completed Development and Wellbeing Assessment (DAWBA) at baseline
15. Depression in young people is measured using parent completed Moods and Feelings Questionnaire at baseline, 12 weeks, 6 months and 12 months
16. Quality of Life in carers is measured through EQ-5D-5L at baseline and 6 months
17. Depression and anxiety in carers are measured through Generalised Anxiety Disorder (GAD-7) questionnaire at baseline and 6 months
18. General health in carers is measured through Patient Health Questionnaire (PHQ-9) at baseline and 6 months

19. Whether the young person has been discharged from CAMHS services will be measured by a discharge form throughout the study
20. Serious adverse events in young people will be monitored through standardised and spontaneous methods

Overall study start date
01/06/2022

Completion date
28/02/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/09/2024:
1. Young people aged 11-17 years. Participants will be accepted up to 17 years and 6 months but not beyond
2. Young people must have been recently accepted into specialist CAMH (≤6 weeks)
3. Young people must score ≥27 on the Moods and Feelings Questionnaire (this is the standardised cut-off by which elevated symptoms of depression warrant further assessment and potential intervention)
4. Young people must provide consent, or assent along with their carer's consent (if applicable), to participate in the study

Previous inclusion criteria:
1. Young people aged 11-17 years. Participants will be accepted up to their 17th birthday and on the birthday itself, but not beyond
2. Young people must have been recently accepted into specialist CAMH (≤4 weeks)
3. Young people must score ≥27 on the Moods and Feelings Questionnaire (this is the standardised cut-off by which elevated symptoms of depression warrant further assessment and potential intervention)
4. Young people must provide consent, or assent along with their carer's consent (if applicable), to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
11 Years

Upper age limit
17.5 Years

Sex
Both

Target number of participants

Planned Sample Size: 528; UK Sample Size: 528

Key exclusion criteria
1. Young people with severe mental illness which is not primarily depressive and requires a different treatment pathway (schizophrenia/non-depressive psychosis, current mania, anorexia, drug and alcohol addiction)
2. Young people who cannot speak English to a sufficient level to understand the intervention and research materials
3. Young people who have an intellectual disability of a level which prevents adequate understanding of the study or intervention materials (clinical judgement)
4. Young people at a high risk of imminent suicide and therefore need a different pathway of care and support (clinical judgement)
5. Young people who present with a high frequency of severe self-harm and therefore need a different pathway of care and support (clinical judgement)
6. Young people who have received 8 sessions of cognitive behavioural therapy (or BA) in the past 6 months
7. If there is more than one eligible child in the family, only one child will be consented into the study and randomised and the same randomised treatment will be offered to the sibling*

*This is applicable to a young person who has a sibling already consented into the study (regardless of whether the sibling is being actively followed up), and if two or more siblings are assessed and accepted into CAMHS at the same time

Date of first enrolment
01/03/2023

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Bolton Hospital
GMMH: Bolton CAMHS
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre

Carol Kendrick Centre
MFT: South Manchester CAMHS (Carol Kendrick Centre), Salford CAMHS
Stratus House
Southmoor Industrial Estate
Southmoor Road
Manchester
United Kingdom
M23 9XD

Study participating centre
The Royal Oldham Hospital
Pennine: Tameside CAMHS, Oldham CAMHS
Reflections Building
Oldham
United Kingdom
OL1 2JH

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
Hopewood CAMHS
Hopewood
Foster Drive
Nottingham
United Kingdom
NG5 3FL

Study participating centre
Brookside Family Consultation Clinic
18a Trumpington Road
Cambridge
United Kingdom
CB2 8AH

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

Sponsor details
Prestwich Hospital
Bury New Road

Prestwich
Manchester
England
United Kingdom
M25 3BL
+44 (0)161 271 0076
researchoffice@gmmh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.gmmh.nhs.uk//

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR132808

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
28/02/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. Consent will be obtained from participants to store the data in a publicly available repository. All data will be collected under pseudonyms and therefore anonymised.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Carer version 3.0		02/08/2023	No	Yes
Participant information sheet	Young Person (11-15) version 2.0		02/08/2023	No	Yes
Protocol file	version 2	03/04/2023	02/08/2023	No	No