Trials

https://doi.org/10.1186/s13063-026-09695-3

Article in Press

A study protocol for a randomised controlled trial investigating the clinical effectiveness, cost effectiveness and acceptability of Behavioural Activation for Young people (BAY) in CAMHS settings

Received: 19 Nov 2025

Accepted: 29 Mar 2026

Published online: 13 May 2026

Cite this article as: Standley, E., Ellison, R., Bee, P. *et al.* A study protocol for a randomised controlled trial investigating the clinical effectiveness, cost effectiveness and acceptability of Behavioural Activation for Young people (BAY) in CAMHS settings. *Trials* (2026). https://doi.org/10.1186/s13063-026-09695-3

Emma Standley, Rachel Ellison, Penny Bee, Anupam Bhardwaj, Jane Blackwell, Lesley-Anne Carter, Gokce Yilmaz, Abbie Cowling, Rachel Elvins, Catherine Hewitt, Paula Hull, Susanne Marwedel, Amy McCulloch, Alex Mitchell, Camila Piccolo-Lawrance, Kapil Sayal, Hannah Strange, Melissa Street, Emma Wakefield, Toni Wakefield, Paul Wallis,

***Trials* structured Study Protocol template**

Title

A study protocol for a randomised controlled trial investigating the clinical effectiveness, cost effectiveness and acceptability of Behavioural Activation for Young people (BAY) in CAMHS settings

Names protocol contributors

Emma Standley, Rachel Ellison, Penny Bee, Anupam Bhardwaj, Jane Blackwell, Lesley-Anne Carter, Gokce Cokamay Yilmaz, Abbie Cowling, Rachel Elvins, Catherine Hewitt, Paula Hull, Susanne Marwedel, Amy McCulloch, Alex Mitchell, Camila Piccolo-Lawrance, Kapil Sayal, Hannah Strange, Melissa Street, Emma Wakefield, Toni Wakefield, Paul Wallis, Han-I Wang, Pauline Whelan, Clare White, Sam Young, Bernadka Dubicka

Corresponding author: Emma Standley, emma.standley@york.ac.uk

Abstract (350 words)

Background: Emotional disorders in young people have been increasing, leading to a high demand for support and long waiting times for UK child and adolescent mental health services (CAMHS). Consequently, access to evidence-based psychological therapy is limited; in addition, many young people do not respond to existing treatments. Blended delivery of therapy, which combines face-to-face and digital interventions, offers a promising solution to improve the reach and effectiveness of mental health support. However, the efficacy of blended behavioural activation (BA) for young people with depression is not yet established.

Methods: This randomised controlled trial will investigate the clinical and cost effectiveness of blended behavioural activation intervention for adolescents aged 11-17 years with moderate to severe depression. We will recruit 446 participants from CAMHS across 6 sites in the UK. Participants will be randomised to receive either BA with psychoeducation (PE) and treatment as usual (TAU) or PE and TAU. The primary outcome measure will be depressive symptoms, assessed using the child-completed Mood and Feelings Questionnaire (MFQ-C) at 6 months. A range of secondary outcome measures will be collected to estimate the clinical and cost effectiveness and acceptability of the intervention. A nested qualitative investigation exploring provider and young people/carer perspectives will be included.

Discussion: The findings from this trial will provide crucial evidence on the effectiveness of blended BA for young people with moderate to severe depression. If effective, this intervention could offer a scalable and accessible treatment option, potentially transforming the delivery of mental health services for adolescents. The large sample size and pragmatic approach will enhance the generalisability of the results, informing future clinical practice and policy.

Trial registration: ISCRTN12315118

Keywords

BA. RCT. Mental health. Child and adolescent. Digital. Blended delivery. Depression

Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

Title (1)	Behavioural Activation for Young people (BAY): a study protocol for a randomised controlled trial investigating the clinical effectiveness, cost effectiveness and acceptability of behavioural activation for young people in Child and Adolescent Mental Health Services settings
Trial registration {2a}	ISRCTN12315118 (29.08.2023)
Trial registration: data set {2b}	The datasets generated during and/or analysed during the current study will be stored in a publicly available repository after study completion.
Protocol version {3}	V6 25.06.2025
Funding {4}	NIHR Health Technology Assessment
Author details {5a}	Emma Standley: York Trials Unit, Health Sciences, University of York Rachel Ellison: York Trials Unit, Health Sciences, University of York Penny Bee: Faculty of Biology, Medicine and Health, Division of Nursing, Midwifery and Social Work, University of Manchester Anupam Bhardwaj: 1) Cambridgeshire and Peterborough NHS Foundation Trust, 2) University of Cambridge, 3) University of Nottingham Jane Blackwell: York Trials Unit, Health Sciences, University of York Lesley-Anne Carter: Division of Population Health, Health Services Research & Primary Care, University of Manchester Gokce Cokamay Yilmaz: Faculty of Biology, Medicine and Health, Division of Nursing, Midwifery and Social Work, University of Manchester Abbie Cowling: York Trials Unit, Health Sciences, University of York Rachel Elvins: Manchester University Hospitals NHS Foundation Trust Catherine Hewitt: York Trials Unit, Health Sciences, University of York Paula Hull: Pennine Care NHS Foundation Trust Susanne Marwedel: Lancashire & South Cumbria NHS Foundation Trust

	Amy McCulloch: University of Manchester, Manchester University Hospitals NHS Foundation Trust Alex Mitchell: York Trials Unit, Health Sciences, University of York Camila Piccolo-Lawrance: York Trials Unit, Health Sciences, University of York Kapil Sayal: 1) Unit of Mental Health & Clinical Neurosciences, School of Medicine, University of Nottingham 2) Institute of Mental Health, Nottinghamshire Healthcare NHS Foundation Trust, Hannah Strange: Nottinghamshire Healthcare NHS Foundation Trust Melissa Street: Greater Manchester Mental Health NHS Foundation Trust Emma Wakefield: PPI Co-chair, Young person representative, Expert by Experience Toni Wakefield: PPI Co-chair, Parent/Carer representative, Expert by Experience Paul Wallis: Manchester University Hospitals NHS Foundation Trust Han-I Wang: York Trials Unit, Health Sciences, University of York Pauline Whelan: University of Manchester Clare White: Cambridgeshire and Peterborough NHS Foundation Trust Sam Young: Patient and Public Involvement Lead, Real Participation Ltd (Independent Consultant) Bernadka Dubicka: Hull York Medical School, University of York, Greater Manchester Mental Health NHS Foundation Trust; University of Manchester
Name and contact information for the trial sponsor {5b}	Natalie Garratt Greater Manchester Mental Health Foundation Trust Rawnsley Building, Hathersage Road, Manchester, M13 9WL
Role of sponsor {5c}	The proposed study is sponsored by the Greater Manchester Mental Health NHS Foundation Trust. The Greater Manchester Mental Health NHS Foundation Trust, as the employer of the Chief Investigator will be liable for negligent harm caused by the design of the study. The sponsor is responsible for funding, oversight of Serious Adverse Events, data collection as a recruiting site, and conducting audits of the data as required. The following responsibilities are delegated to York Trials Unit: study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication.

Introduction

Background and rationale {6a}

The COVID-19 pandemic disproportionately affected the mental health of young people (YP) (Newlove-Delgado et al. 2021) and rates of emotional disorders for YP in the UK have been increasing, with approximately 1 in 5 YP aged 8 to 25 years having a probable mental disorder (1). Consequently, the demand for Child and Adolescent Mental Health Services (CAMHS) has continued to rise: urgent referrals to Crisis Care teams for under 18s rose to 3,758 referrals in January 2024, a 183% increase from 2,051 referrals in January 2023 (2). Furthermore, those who do access services often have long waits for specialist therapy after assessment: the number of YP waiting for over a year has increased significantly, from 51,866 in 2022/23 to 78,577 in 2023/24 (3) which significantly exceeds the UK government's goal of four weeks to deliver support (4). Due to the combination of long waiting lists and high thresholds to receive care, resource continue to be stretched, and YP may face an escalation in their mental health difficulties to the point of crisis before receiving support (5). The shortage of skilled staff (6, 7), and an insufficient therapy skillset is also met with rise in demand for services that has outpaced the mental health workforce (8).

Behavioural activation (BA) is a relatively simple therapy that can be delivered by junior mental health workers with similar outcomes to a more complex therapy (cognitive behaviour therapy) delivered by specialist clinicians for adult depression (9). A systematic review of BA for depression in children and adolescents (10) incorporated 24 studies and, in a meta-analysis of four RCTs (n=156), showed that BA had a small effect of 0.24 (Hedge's adjusted g) in reducing depressive symptoms compared to a waiting-list control, usual care and other therapies. Two UK studies were included that took place in specialist CAMHS: a feasibility study (11) and a small RCT (n=11) (12), which indicated some promising findings. A US trial (n=60) recruited YP with more severe depression and compared BA with an active comparator; outcomes were promising with 21/27 YP completing BA no longer meeting criteria for depression (13). The review concluded that BA shows sufficient promise to warrant further RCTs, contingent on five conditions being met: adequate power, fit-for-purpose materials, follow-ups longer than six months, child-reported outcomes, and the reporting of intervention costs and adverse events.

In response to Covid-19, delivery modes for therapy have changed with more remote working and blended therapy (14, 15). A scoping review has identified the potential benefits of using technology (e.g. online platforms and educational technologies) in promoting adolescent mental health, however, emphasises the need to continue research to optimise the design, implementation, and evaluation of these interventions (16). Yet, there has been limited research evaluating the use of technology assisted therapy delivery in CAMHS. A feasibility trial conducted at a specialist outpatient clinic in Sweden to evaluate internet-delivered Behavioural Activation (I-BA) for adolescents (13-17) with mild-to-moderate major depression (17). The study, which included both therapist-guided and self-guided I-BA, found both versions of the intervention were acceptable to adolescents and showed large, statistically significant within-group changes in depressive symptoms. A full-scale randomised controlled trial (RCT) is currently underway for this study (18).

To our knowledge, currently there is no trial of BA being undertaken in specialist CAMHS recruiting YP with higher levels of depression severity and risk, and also offering clinician guided, web-based delivery. We have developed a standardised BA package for use by clinicians without specialist therapy training, which can be delivered online or in-person within specialist CAMHS for YP experiencing more severe depression and risk. Our feasibility study (19) recruited 36 YP aged 11-17, scoring 27 or above on the Mood and Feelings Questionnaire - Children (MFQ-C) (20) within a CAMHS clinic and demonstrated preliminary evidence for effectiveness, utility and satisfaction with the intervention. Staff without specialist therapy training were able to deliver the BA package, and of the 33 YP who participated in BA therapy, 12 (36%) recovered and were able to be discharged, demonstrating the potential to reduce waiting times for more specialist therapy and optimising the use of more experienced clinicians.

There remains a lack of fully powered RCTs and economic evaluations of the use of BA interventions for depression within specialist CAMHS. The current trial aims to train mental health practitioners with no specialist therapy skills (UK NHS Band 4 and Band 5 clinicians) within NHS specialist CAMHS, to deliver a flexible web-based BA intervention, which can be offered online or in-person ('blended delivery'), according to YP's personal preference. A fully powered RCT will evaluate its effectiveness, cost-effectiveness and acceptability compared to psychoeducation (PE) within the context of treatment as usual (TAU).

Objectives {7}

Primary aim

To examine the clinical effectiveness, cost-effectiveness and acceptability of BA using blended delivery + PE + TAU when compared to TAU + PE in CYP with depression referred to specialist CAMHS at 12 weeks, 6 months (primary outcome) and 1 year follow up post randomisation (naturalistic sub-group).

Objectives

Conduct an internal pilot to assess recruitment and acceptability in all sites, with clear progression criteria to the full trial. The pilot will include a detailed qualitative component to understand reasons why YP refused to participate, why they may have dropped out early, and also understand potential barriers from the perspective of staff.
Examine immediate and longer-term acceptability, including blended delivery, potential barriers to uptake and engagement from multiple stakeholder perspectives.

Trial design {8}

This trial is a multi-site, pragmatic, superiority RCT using a 1:1 allocation ratio comparing BA, PE and TAU with a control group receiving PE and TAU. PE is an online resource with information about depression and signposting. TAU is defined as the existing support routinely provided for a young person with depression in specialist CAMHS. The trial includes an 8-month internal pilot, a process evaluation (including qualitative interviews and an examination of treatment fidelity) and an economic evaluation.

Methods: Participants, interventions and outcomes

Study setting {9}

Participants will be recruited once they have been formally accepted and assessed in specialist CAMHS and have agreed to receive treatment from CAMHS. Three identification pathways will be utilised by the Research Assistant (RA) and/or a CAMHS clinician. Intervention delivery will take place at CAMHS sites or via videoconferencing with a BA trained CAMHS clinician. Recruitment at each site is planned to take place over 24 months, with an additional 9 months to the recruitment phase granted by the funder. A full list of study sites involved can be found at https://www.isrctn.com/ISRCTNISRCTN12315118.

Eligibility criteria {10}

YP will be screened for eligibility by the site researcher and included if they are 11-17 years old at the date of consent (up to 17 years 6 months), score ≥27 on the Moods and Feelings Questionnaire, recently accepted into specialist CAMHS (≤6 weeks) and have provided consent, or assent along with their carer's consent (if applicable), to participate in the study.

YP will be excluded if they have a severe mental illness that is not primarily depressive (e.g. schizophrenia, non-depressive psychosis, current mania, anorexia), are at a 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, cannot speak English to a sufficient level to understand the intervention and research materials, have an intellectual disability of a level which prevents adequate understanding of the study or intervention

materials, have received at least 8 sessions of therapist-led BA/cognitive behavioural therapy in the previous 6 months. 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 their non-study sibling).

There will be at least two trained BAY therapists within each NHS Trust. The PI and psychology lead (qualified clinical psychologist) at the site will identify suitable Band 4 or 5 clinical professionals for BA training within CAMHSe. These professionals may include assistant psychologists, family support workers, wellbeing practitioners or newly qualified nurses.

Who will take informed consent? {26a}

Age-appropriate information sheets will be given to the child and their carer at their clinical assessment. There will be three separate information sheets, one for parents, one for YP aged 16+ and one for YP aged 11-15. Participants aged 16 will provide informed consent for themselves. For participants aged 11-15, informed consent will be collected from a parent/carer as well as the child themselves (assent) if they are competent to do so (they can understand the information given to them about the study, retain the information, be able to relay the information back to the RA and can make a decision about participation).

The RA will determine the participant's capacity to provide informed consent/assent, with guidance and advice from the clinician involved in the screening process. Full informed consent/assent will be taken on paper or via ticking all clauses that apply and provide an electronic signature on a secure online data capture tool. Participants will be sent a link and given the option to complete before the first appointment, or during the appointment with the researcher. Consent for the qualitative study will be taken independently of that of the trial.

Participants aged 16 and over will be encouraged to involve their carers. Whilst carer consent will not be required for this age group, YP will be reminded that involving carers in the completion of BA may provide a useful form of additional support during their participation (e.g. completing activities outside of therapy sessions).

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Not applicable - no additional consent processes required and no biological specimens collected.

Interventions

Explanation for the choice of comparators {6b}

Participants allocated to the control arm of the trial will receive a website link to a PE leaflet providing standardised signposting and information about depression (Royal College of Psychiatrists) and the care that they would usually receive from CAMHS and/or third sector providers. The PE leaflet was chosen because we expect that those allocated to TAU will be on a waiting list for a significant amount of time.

Participants are not restricted with regards to seeking and/or accessing additional support outside of CAMHS.

Intervention description {11a}

The intervention will be delivered by Band 4 or 5 mental health professionals, using a blended approach of online and in-person BA sessions. If Band 5 clinicians are promoted to Band 6 during the course of the study, for pragmatic reasons they will still be able to deliver the intervention on the basis they were

employed at Band 5 during training and initial delivery. However, if clinicians start training for specialist therapy skills, such as for cognitive behavioural therapy, they will no longer deliver the BA intervention.

Our workbooks (8 sessions) have been developed to allow for blended delivery (face-to-face using the website, or therapist-led online delivery) within the context of routine CAMHS care. The BA program is designed to be structured, yet flexible in delivery, for example, therapists may choose the order of later sessions. Each BA workbook consists of an overview of the session, agenda, symptom and risk check, homework review, session content, session summary (feedback and goals review) and carer information (see Table 1).

A website for blended delivery will be developed to improve the experience of remote therapy, and will include animations co-designed with young people. In the first phase of the study, we will co-design an enhanced platform with YP, focussing on making the site more engaging, usable, safe and accessible. The platform will comply with NHS Digital-recommendations and will not be a Medical Device. We will use Agile methodology and track analytics to understand how the platform supports intended outcomes (Yardley et al, 2016). Development will include 4 co-design workshops with YP (n=4) and members of the research and software teams. In month 7, we will beta-test with 5 healthy volunteer YP, 5 professionals, & assess user acceptance in month 8. The updated website will be live prior to the recruitment of the first participant.

The BA training programme has 3 components: a clinician's manual which includes guidance on providing remote delivery, cultural adaptation, and links to demonstration videos; training to use workbooks including understanding of fidelity ratings, cultural issues, and remote delivery (initial 2 days training plus 2 further half days led by local therapy leads which includes practice case discussion); and required reading of existing material on behavioural activation and depression. Training day sessions are recorded and available for future training, and regular community of practice sessions for therapists and supervisors, enable sharing of best practice. After familiarising themselves with the training material, therapists are required to engage in a role play working through the 8 sessions on the training BA website, followed by treating 2 depressed YP currently in CAMHS, one to 8 sessions, and the other to a minimum of 5 sessions. This is overseen by a band 7 or above therapy supervisor with CBT expertise within weekly 1:1 or group supervision sessions; reviewing audio-recordings is encouraged within supervision (with the consent of the YP for recording). Once training is completed, the local BAY therapy lead will undertake an online check of BA skills using BA scenarios. On occasions, it may be agreed that the therapist will undertake a skills check after completing BA with one YP, and then deliver BA to a BAY participant, but continue with weekly supervision, and a further skills check on completing this case. Once therapists have completed 2 courses of BA with YP and passed the skills assessment, they will attend fortnightly group supervision. The BAY therapy lead will meet regularly with all site psychology leads to ensure consistent BA delivery at all sites.

Table 1: A summary of the eight BA modules in BA

Module	Topics covered
Module 1: Goal setting, Psychoeducation and Recording	Engagement, personalisation, getting to know the YPand establishing a therapeutic rapport Setting out rationale and contents of the programme Finding person-centred ways to plan and record activities
Module 2: Introduction to Valued Living	Understanding the value of the effort that the young person makes outside of therapy sessions Introduction of 'ACEs': Measures of Achievement, Closeness and Enjoyment
Module 3: Values Clarification	Fun (leisure), Work (school), Relationships (family and/or friends), Self-care (sleep, eating, exercise) How to personalise values and link them to key tasks Clarifying that values are "owned" by the young person Encouraging and expecting the recording of activities and address any barriers to doing this if identified
Module 4: Activity Planning and Addressing Barriers	Young person should be in a routine of recording activities linked to values and ratings of mood, alongside ratings of achievement, closeness and enjoyment Break down more challenging tasks into small steps Explore options for support to engage in planned activities Developing a personalised activity log
Module 5: Rewards and Getting Support	Reviewing theory of BA and getting support via rewards Conversation about types of rewards (social, material and self-rewards) Planning rewards for successful activity planning and achievement Being positive and looking for evidence of progress (using SMART goals)
Module 6: Avoidance Patterns – TRAP(s)	Triggers, Responses and Avoidance Patterns (TRAPs) Seeking and exploring young person's unhelpful but typical patterns and habits of avoidance
Module 7: Problem Solving – TRAC	Triggers, Responses and Alternative Coping (TRAC) Exploring personalised and real-life examples of problems to teach problem-solving skills and develop alternative coping behaviours Collaborative work Encouragement for young person to identify their own solutions

Module 8: Staying Well and Review	Developing a relapse prevention plan between therapist and young person Revisit rationale for BA, document advice about potential low mood triggers and warning signs of relapse, and review and summarise what has been helpful for the young person during the programme. Signposting to additional sources of support and accessible resources

Criteria for discontinuing or modifying allocated interventions {11b}

In line with usual clinical care, cessation or alteration of trial treatment at any time will be at the discretion of treating clinicians or the participant themselves who may choose to withdraw from the study intervention at any time.

A clinician may decide that a participant should be withdrawn from the research if there is reason to believe that they have, after screening and consent, become unsuitable to take part as the study could become harmful or interfere with other necessary treatments. Reasons for withdrawal could include: very high prolonged risk such as active suicidal behaviours/plans and imminent intent; indication that the intervention is leading to a clear worsening of mental health; further or emergent physical or mental health problems that may exclude the possibility of engagement in the intervention; loss of capacity to consent; significant issues with addiction to alcohol or drugs. If any of these situations for withdrawal occur, the clinician identifying the issue will follow their usual practice within their Trust and notify the PI at the recruiting site.

Participants may receive an additional one to two sessions if required, at the discretion of the clinician, if there are circumstances which may impact on the young person's ability to process the information within 8 sessions, for example, if there is a neurodevelopmental condition present .

Strategies to improve adherence to interventions {11c}

All BA therapy sessions will be recorded with the consent of the participant by the therapist via a Trust-approved platform. Recordings will be used in supervision sessions to improve the quality of therapy delivery. Supervision will take place fortnightly either 1:1 or in groups, as previous feedback suggested that this was helpful for sharing best practice. Community of practice sessions, oversight by local senior psychology leads and regular meetings between the senior psychologists and the BAY therapy lead will also be in place to maintain adherence. Additional top up training events will also take place regularly.

The digital tool allows the therapist to deliver the program online and also provide paper and online options for both the therapy sessions and completion of homework, dependent on the needs and preferences of the young person. They can choose if they want to meet with the therapist in the CAMHS clinic or online. These options facilitate engagement allowing participants choice with regards to the delivery of the intervention.

Relevant concomitant care permitted or prohibited during the trial {11d}

CAMHS sites are asked to refrain from delivering BA to participants in the control arm or from sharing the study BA materials with other CAMHS clinicians during the trial to minimise contamination effects. Any other support (including but not limited to Cognitive Behavioural Therapy, Dialectical Behaviour Therapy, family therapy) that CAMHS or associated services usually deliver and is deemed appropriate can be delivered to the young person, other than another simultaneous individual therapy to a YP receiving BA in

the trial, as this would not be usual clinical good practice. Participants who have received BA will be reviewed by the clinical team at the end of the intervention and assessed with regards to a need for any further CAMHS interventions, including any further individual therapy. Antidepressant medication is permitted in both arms and is recorded in the Treatment as Usual questionnaire.

Provisions for post-trial care {30}

Participants will remain under the care of CAMHS if deemed necessary for their mental health or be discharged from the service if their mental health has improved. Participants receive signposting throughout the course of the trial and are made aware of services to support them if necessary.

The study is sponsored by the Greater Manchester Mental Health NHS Foundation Trust. The NHS has a duty of care to patients treated, whether the patient is taking part in a research study, and the NHS remains liable for clinical negligence and other negligent harm to patients under this duty of care. The Greater Manchester Mental Health NHS Foundation Trust, as the employer of the Chief Investigator will be liable for negligent harm caused by the design of the study.

Outcomes {12}

The researcher will administer a series of questionnaires with the young person and parent/carer (if applicable). Follow-up assessments will be made at 12 weeks, 6 months and 12 months post-randomisation.

Primary outcome

The primary outcome is the MFQ-C (20) score at 6 months post-randomisation, which will estimate the clinical effectiveness of BA + PE + TAU on depressive symptoms compared to PE + TAU. Peer-reviewed studies have found the Mood and Feelings Questionnaire to be a reliable and valid measure of depression in children in both clinical and non-clinical samples (20-22).

Secondary outcomes

Validated self-reported questionnaires include: Strengths and Difficulties Questionnaire (SDQ) (23), Revised Children's Anxiety and Depression Scale (RCADS) (24), Behavioural Activation for Depression Scale (25), CHU-9D, EQ-5D-Y (26) and MFQ-C at other timepoints. Non-validated self-reported measures include: demographics questionnaire, bespoke self-harm and suicidality questions, Adapted Child and Adolescent Service Use Schedule, Aspects of Care and a goal-based outcome measure. Participants in the intervention arm will be asked to complete the WAI (27) and end of treatment questionnaire.

Parent/carer involvement is optional. Those who have consented to provide their own data will be asked to complete the MFQ, EQ-5D-5L on behalf of their child's mental health, and the Patient Health Questionnaire (28) and Generalised Anxiety Disorder (29) for their own mental health.

A list of the self-reported measures and assessments can be found in the Participant Timeline (Table 2).

The Development and Well-Being Assessment (DAWBA) will be administered to YP and their parent/carer at baseline using a computerised semi-structured interview measure. The DAWBA covers the common emotional, behavioural and hyperactivity disorders, as well as disordered eating, autism and trauma-related difficulties. Information from the different informants (YP and parents) is drawn together by a computer program that summarises a prediction of likely diagnoses.

Qualitative Interviews

An embedded qualitative study will capture and compare the experiences of YP, carers and professionals participating in the RCT as a means of assessing BA's acceptability, but also as a way of understanding the contextual, implementation and mechanistic factors that may influence intervention use and outcomes. Across the internal pilot and main trial phases, we will complete one-to-one semi-structured qualitative interviews with 25-30 YP and 25-30 carers per arm (~120 interviews) to explore intervention acceptability. During the internal pilot, at the end of training, we will seek to interview all consenting professionals (therapists and supervisors who have been trained in BA) to discuss their experiences and views of intervention training processes, perceived barriers/enablers to treatment delivery and service readiness. During the main trial, we will invite all participating therapists and supervisors/service managers (approximately 12 per group) to have an interview. These interviews will explore post-treatment views on intervention preparation, delivery and implementation. The final sample size of professionals for the embedded qualitative study will be determined by convenience in the absence of reaching saturation.

Interview schedules for parents and YP will be codeveloped with the PPI panel members and informed by the Theoretical Framework for Intervention Acceptability (TFA) (30). Professional interviews will be informed by the TFA and the Consolidated Framework for Implementation Research (CFIR) (31).

Interviews will be digitally recorded with consent and transcribed. We will use Framework Analysis combining inductive and deductive coding by the constant-comparison method. Deductive codes will be informed by the Theoretical Framework for Intervention Acceptability (TFA) (30) and Consolidated Framework for Implementation Research (CFIR) (31).

Participant timeline {13}

Table 2: Participant timeline: Schedule of enrollment, interventions, and assessments (32)

	Enrollment		**Post-randomization**			**Close-out**
TIMEPOINT[b]	**-t_i to 0**	**0**	**t_1**	**t_2**	**t_3**	**t_x**
ENROLLMENT:						
Screening	X					
Moods and Feelings Questionnaire	X	X	X	X	X	
Contact Details	X					
Demographics		X				
Eligibility Check	X					
Informed consent	X					
Randomization		X				
INTERVENTION/ COMPARATOR:						
Behavioural Activation		X →	→	→	→	

***Treatment as usual*[d]**		X →				
ASSESSMENTS (YOUNG PERSON):						
Strengths and Difficulties (SDQ)		X	X	X	X	
Development and Wellbeing Assessment (DAWBA)		X				
Revised Children's Anxiety and Depression Scale (RCADS) – Brief Version		X	X	X	X	
Behavioural Activation for Depression (BADS)		X	X	X	X	
Self harm & suicide questions		X	X	X	X	
Goal based outcomes		X	X	X	X	
Child Health Utility – 9 Dimensions (CHU-9)		X	X	X	X	
EQ-5D-Y		X		X		
Healthcare Service Use schedule		X	X	X	X	
Aspects of Care Contamination Checklist			X	X	X	
Working Alliance Inventory			Collected halfway through intervention delivery			
End of BA treatment questionnaire			Collected after final session of BA therapy			
Optional Qualitative Interview				X		
ASSESSMENTS (CARER)						
Strengths and Difficulties Questionnaire (SDQ) Parent Version		X	X	X	X	
Development and Wellbeing Assessment (DAWBA)		X				
Moods and Feelings Questionnaire (MFQ) Parent Version		X	X	X	X	

Carer EQ-5D-5L		X		X		
Generalised Anxiety Disorder (GAD-7)		X		X		
Patient Health Questionnaire (PHQ 9)		X		X		
Optional Qualitative Interview				X		
ASSESSMENTS (OTHER)						
Treatment as Usual Questionnaire				X	X	
Safety Reporting			Collected throughout			
BA Completion (Discharge Information)			Collected throughout			
Trial Withdrawals			Collected throughout			

Sample size {14}

For 90% power to detect an effect size of 0.3125 we require 8 groups of 28 (where groups are defined by the treating therapist) in the intervention arm and 224 individuals in the control arm, giving a total of 448 participants. This effect size corresponds to a minimally important difference of 5 points on the MFQ-C (REF) with a standard deviation of 15. This calculation was performed in Stata using the 'clsampsi' command and includes a baseline-follow up correlation of 0.41 and an ICC of 0.01 in the intervention arm. Parameter estimates were informed by our feasibility study and previous IMPACT trial (33). In terms of attrition, 7% attrition was observed at 6 months in the HTA ADAPT trial (34) and 16% in IMPACT, however this was at 18 months. We conservatively inflated the current sample size by 15%, with the aim of recruiting a total sample size of 528.

On 28th April 2025, the funder approved a request from the study team for a costed extension with the sample size recalculated with 80% power. This level of power still gives a substantial chance of detecting a difference between groups assuming a minimally important difference of 5 points in the primary outcome. Other parameters were also updated baseline-follow-up correlation 0.45 (based on available data), 13 groups of 12 participants in the intervention arm, 30% attrition (based on available data), an effect size of 0.30 with all other parameters held constant giving a new sample size of 446 participants. The level of attrition assumed was updated based on follow-up rates observed during the conduct of the trial before the extension request was made to the funder.

Recruitment {15}

We will recruit participants through NHS CAMHS sites within 6 NHS Trusts. NHS Trusts will be invited to both promote the RCT and assist with identifying YP who may be suitable and interested in participating. There will be 3 methods of recruitment through the CAMHS service: 1) Identification by clinician, 2) Multidisciplinary Team Meetings (MDT), and 3) Screening records

Identification by clinician

CAMHS clinicians conducting post-referral assessments will be provided with an information leaflet about the trial and the inclusion criteria, as well as multiple study information packs prepared by the research team to distribute to potential participants. They will be asked to consider potential participants for the trial when conducting post-referral assessments.

If considered by the clinician to potentially be eligible for the trial, the clinician will briefly discuss the trial with the participant. If they are interested and with their permission, the clinician will use the eligibility screening criteria pro-forma to determine whether they are potentially eligible. The Moods and Feelings Questionnaire (MFQ) may have been conducted via routine clinical assessment and this score will be used by the clinician to help determine potential eligibility. If the young person seems potentially eligible as a result of clinician screening, they will be provided with a study information pack by the clinician. This will include participant information sheets (ones for YP and ones for parents/guardians as appropriate). Having read the study information, if a young person is interested in taking part in the research, the clinician will email (via secure NHS email) their contact details and name (with the participants verbal consent) to the researcher. The researcher will telephone potentially eligible participants to discuss the study with them and answer any questions.

MDT Meetings attended by the RA & Screening records

After CAMHS have conducted an initial assessment with the young person, an MDT meeting is held to confirm the young person's acceptance into specialist CAMHS. RAs will attend this meeting on a regular basis to identify potentially eligible participants for the study. Alternatively, as the RA will be employed by the relevant NHS Trust, they will be provided with access to the patient records of the CAMHS service involved in the study. On a regular basis, the RA will screen the records to identify newly accepted YP with low mood who are potentially eligible young people. Search terms for screening patient records will be standardised across CAMHS sites.

Once identified by the RA, an invitation letter from the CAMHS clinician and study information pack will be sent to the family including a copy of the Participant Information Sheet by a CAMHS clinician/team member. The participant is asked to call or email the RA if they are interested in the study or have any questions. If the RA does not hear back within 7 days of sending out the study information, they contact the family via telephone and/or email to see if they are interested in the study and follow the eligibility screening process specified below.

Eligibility screening process

Once a young person has been identified as being potentially eligible from clinician screening, a MDT or records, and the family have received the study information pack as highlighted above, the RA will contact the young person if 16 or over, or the carer if under 16, introduce the study, and, with their written agreement, determine whether a young person is eligible for participation by asking the young person to complete the screening MFQ and completing a screening checklist. Anyone attaining a score of ≥27 on the MFQ will be eligible for study entry (if they also satisfy the other inclusion criteria).

The researcher will then arrange a suitable time to meet to complete the consent form and conduct the MFQ at baseline. All baseline visits will be arranged ensuring that participants (and parent/guardians) have had at least 24 hours to decide whether to take part in the research after receiving study information. 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 on to the study and will continue to receive TAU. If an eligible young person declines to participate, they will be asked verbally their reason for this and the RA will complete a pro-forma based on their response. Baseline assessments will be offered face-to-face at CAMHS, NHS or affiliated University sites, in the family home, via video conferencing or another suitable location at a mutually agreed time and date with the young person and parent/guardian.

Qualitative Study Recruitment

At the baseline visit, young people and carers will indicate in their consent/assent form whether they would be happy to be contacted about taking part in an interview with a member of the research team, 0-4 weeks after their 6-month follow-up date. Consent to contact will be recorded on the YTU trial database. The research team will purposively select a sample across trial arms, sites and intervention engagement level (0, <4, 4+ sessions) and representing different ages, genders, socio-economic backgrounds and levels of depression to approach to participate. Interviews will be conducted within 4-6 weeks post primary outcome point in both internal pilot and main trial phase.

In the internal pilot phase, all professionals (BAY therapists and their supervisors from each site) who have been trained in BA will be invited to qualitative interviews to discuss the training that they received.

In the main trial, all professionals (therapists and supervisors/service managers) as part of the RCT will be invited to attend an individual interview with a member of the research team to discuss their experiences and/or thoughts of treatment delivery. We will also invite any participating professionals who left the study early to attend an interview within 9 months of their last participation in the BAY Trial.

Assignment of interventions: allocation

Sequence generation {16a}

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. Randomisation will be stratified by site using randomly-varying blocks of randomly-varying size.

Concealment mechanism {16b}

Randomisation will be conducted on a data management system and managed by the Trial Managers at YTU. RAs will be blinded to allocations, therefore only the site PI, psychology leads and therapists will be notified of the allocation. To minimise instances of unblinding, RAs will not be informed of, or involved in group allocation, organising therapy sessions, collecting end of treatment questionnaires, completing SAE forms, or access allocation information in the study's database. These duties will be the responsibility of the Trial Managers, who do not need to be blind to treatment allocation. The RAs will remind each participant at the beginning of their follow-up meetings not to tell the RA about their treatment or who they saw as part of their involvement in the BAY project. Clinical teams will also be trained on the importance of minimising blinding.

Implementation {16c}

Researchers based in the recruiting NHS Trusts will recruit participants and complete a Google randomisation form which sends the randomisation result directly to YTU. YTU will then contact the service and family with the randomisation outcome. The secure Google form is used for the purpose of randomisation, which sits outside of REDCap, and REDCap is used as the primary data management system for storage of data.

Assignment of interventions: Blinding

Who will be blinded {17a}

All RAs collecting follow up data will be blind to participant group allocation. It is not possible to blind participants or clinical staff due to the nature of a psychological intervention. The statistician will not be blinded during analysis.

Procedure for unblinding if needed {17b}

If unblinding occurs all blind breaks including accidental unblinding will be recorded by YTU and reviewed by the Chief Investigator for patterns in unblinding and be reported to the Trial Steering Committee (TSC) and Data Monitoring Ethics Committee (DMEC). If unblinding occurs a researcher from another site will collect follow up data from the young person and carer (if applicable).

Data collection and management

Plans for assessment and collection of outcomes {18a}

Participants will be requested to complete a questionnaire at baseline, 12 weeks and 6- and 12-months (naturalistic sample) post randomisation. Participants will be required to complete their questionnaires in-person or online with support from a researcher who is blind to the treatment allocation.

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 left prior to the end of the follow-up period will be asked to complete a 12-month follow-up assessment (n= approx. 300/participants). 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.

Mood and Feelings Questionnaire (MFQ)

The MFQ-Children (20) is a screening tool for depression in children and YP aged 6 to 19. The MFQ consists of a series of 33 descriptive phrases regarding how the subject has been feeling or acting recently. Respondents are asked whether descriptions in the questionnaire are 'true', 'sometimes true' or 'not true' for them over the past two weeks. The MFQ is scored by summing together the point values of responses for each item and higher scores on the MFQ suggest more severe depressive symptoms (scoring 27 or higher on the long version may indicate the presence of depression in the respondent). Peer-reviewed studies have found the MFQ to be a reliable and valid measure of depression in children in both clinical and non-clinical samples (20-22).

The MFQ Parent Report is a 34-item measure (35). Parents are asked to report how their child has been feeling or acting in the past two weeks. Respondents are asked whether descriptions in the questionnaire are 'true', 'sometimes true' or 'not true' for their child over the past two weeks.

Demographics questionnaires

On entry to the study, participating YP will be asked to complete a short demographic questionnaire to obtain information about their age, gender, ethnicity, religion, family circumstances (who they live with), school meals, and education or work. YP will also be asked about their digital use, accessibility to digital devices and internet, privacy around use, and preference for online or in-person therapy. On entry to the study, participating parents will also be asked to complete a short demographic questionnaire to obtain information about their age, gender, ethnicity, religion, and socioeconomic status.

All professionals involved in the delivery of BA treatment for the trial will be asked to complete a short demographic questionnaire when they are assigned a young person to work with as part of the trial. This will capture information about their professional role, grade, organisation, years in service, age range, sex and previous experience of BA (if any).

Development and Well-Being Assessment (DAWBA)

The DAWBA is a package of interviews, questionnaires and rating techniques designed to generate ICD-10 and DSM-IV or DSM-5 psychiatric diagnoses on 2-65 year olds (36). The DAWBA covers the common emotional, behavioural and hyperactivity disorders, without neglecting less but sometimes more severe disorders.

In BAY, information is collected from two sources at baseline: 1) An interview with 11-17 year olds themselves. 2) An interview with the parents of 11-17 year olds. The DAWBA involves a mixture of open and closed questions and the parent interview takes around 50 minutes to administer and the youth interview takes around 30 minutes to administer. Information from the different informants (YP and parents) is drawn together by a computer program that also predicts the likely diagnosis or diagnoses, generating six probability bands, ranging from a probability of less than 0.1% of having the relevant diagnosis to a probability of over 70% of having the relevant diagnosis. The initial validation study of the DAWBA suggested it had considerable potential as an epidemiological measure and promise as a clinic assessment (36). The DAWBA has been successfully used and completed in other CAMHS-based RCTs of emotional disorders, such as STADIA (37).

Strengths & Difficulties Questionnaire (SDQ)

The SDQ measures emotions and behaviours of YP and the SDQ (25 items) + impact scale will be used here (23). The SDQ is comprised of 5 subscales: 1) Emotional symptoms; 2) Conduct problems; 3) Hyperactivity/inattention; 4) Peer relationships problems; 5) Prosocial behaviour. All items are rated using the options 'Not true', 'Somewhat true', or 'Certainly true'.

A parent version of the SDQ (25 items) + impact scale will be given to parents/carers and this will be completed from their perspective on behalf of the child. The above principles of the questionnaire remain the same.

Revised Children's Anxiety and Depression Scale (RCADS) – Brief Version - 25 items

The RCADS brief version is a 25-item questionnaire that assesses children's depression and anxiety; it is a condensed version of the original 47-item (24) and has been validated as a self-completed outcome measure for 8-to-18-year-olds. Both versions of the RCADS have sub-scales that capture symptoms in 6 domains: one domain relates to depression and five to anxiety problems (generalised anxiety disorder, panic disorder, obsessive compulsive disorder, separation anxiety disorder and social anxiety). All items are rated on a 4-point Likert-scale from 0 to 3, where 0 = Never, 1 = Sometimes, 2 = Often, and 3 = Always. Raw scores are transformed into t-scores by matching the raw score to its corresponding age and gender normed t-scores. Higher t-scores denote greater clinical need. Clinical cut-offs for the t-scores are: 0-64 non-clinical range, 65-69 borderline clinical range, and ≥70 clinical range.

Self-harm and suicidality measures

A brief bespoke measure of self-harm and suicidality will be used to collect information directly from YP in the trial at baseline, 12 weeks, 6 months and 12 month follow up post randomisation. The measure has been designed with expert input from depression specialists and our young people and carer advisory panels. Questions will ask about suicide attempts, self-harm and thoughts about suicide. This will be asked firstly in relation to the past 6 months at baseline. The subsequent follow-ups will ask about self-harm and suicide attempts since the previous timepoint.

Behavioural Activation for Depression (BADS)

The BADS-SF is a 25-item BADS (25) that measures levels of activity on 4 sub scales: Activation, Avoidance/Rumination, Work/School Impairment, and Social Impairment. The questions are rated on a seven point scale ranging from 0 (not at all) to 6 (completely); higher scores represent increased behavioural activation. Although the scale has not been validated with an adolescent population, there are no alternative similar tools to help us explore behavioural activation as a mediator for changes in depression symptoms.

Child Health Utility-9 Dimensions (CHU-9D)

We will use the CHU-9D (38) to derive health utility and calculate quality-adjusted life years (QALYs). The questionnaire consists of 9 domains, each with 5 statements (scored 1–5) that will assess the young person's functioning across domains of worry, sadness, pain, tiredness, annoyance, school, sleep, daily routine and activities on that specific day. For example: 1= I don't feel sad today, 2=I feel a little bit sad today, 3=I feel a bit sad today, 4=I feel quite sad today, 5=I feel very sad today. The responses under the 9 domains can be taken together as a description of the young person's "health state" using a descriptive system that combines all responses across all items (e.g. 11232152). Different utility weights were assigned to each level of each domain. Different combinations of responses across the 9 dimensions therefore result in different health states that have a utility value on a 0–1 scale, where 1 is perfect health and 0 is equivalent to being dead. The UK YP valuation set will be used to derive the utility values (39). Utility values from each time point in the trial will be used to calculate quality-adjusted life years (QALYs) which will be the measure of health benefit in the economic evaluation.

EQ-5D-Y

This will be completed by participants. The EQ-5D-Y comprises five dimensions of health: mobility, looking after myself, doing usual activities, having pain or discomfort and feeling worried, sad or unhappy. Each dimension has 3 levels: no problems, some problems and a lot of problems (26). As with the CHU-9D, each profile of responses can be converted into a utility value. We will use the valuation method recommended by the National Institute of Health and Care Excellence (NICE) at the time the analysis is conducted.

EQ-5D-5L

This will be completed by carers, in relation to their own health. The EQ-5D-5L consists of 5 dimensions of health: mobility, self-care, usual activities, pain, anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems (26). Each profile of responses will be converted into its respective utility value according to the method recommended by NICE at the time the analysis is conducted.

Adapted Child and Adolescent Service Use Schedule

We have adapted the Child and Adolescent Service Use Schedule for completion by participants, with assistance from their parent/carer. Its purpose is to collect information about the use of health and social care by each young person during the study period. The bespoke resource use questionnaire will include hospital-based health services (e.g., outpatient visits), community-based health services (e.g., GP visits), school-based health services (e.g., educational psychologist appointments), and parental productivity costs. The collected data will be used to estimate costs for the economic evaluation.

Goal Based Outcome measure

YP will be asked to work with the RA to set a goal for themselves to work towards, which will be measured on a Likert scale of 0 to 10, 0 goal met 'none of the time' and 10 being goal met 'all of the time' (40). This will evaluate clinical progress throughout either BA or TAU. YP will set a primary goal for the purpose of the trial (related to their mental health) during the baseline appointment with the RA and will be asked to

review the goal using the Likert scale at each follow-up. The measure allows the YP to personalise their care.

Aspects of Care Questionnaire

We developed the Aspects of Care Questionnaire that has 4 items to help assess contamination, i.e. where an individual randomised to TAU has inadvertently or intentionally received elements of BA. The items are 4 statements that correspond to BA-specific activities: 1. “I talked to my therapist about the things and people that I value in my life.” 2. “I made plans for activities I enjoy and necessary tasks/routines in a weekly activity diary.” 3. I wrote down things I did for pleasure and necessary tasks/routines in a weekly activity diary.” 4. “I gave an ACE score (Achievement, Closeness, Enjoyment) to activities I completed in a weekly activity diary.” Responses to each item are: ‘yes, ‘no’ or ‘I don’t know’. Participants in the intervention group would be expected to answer ‘yes’ whereas participants randomised to TAU would be expected to answer “no” or ‘I don’t know’.

Working Alliance Inventory (WAI-S)

The WAI-S (27) aims to capture how the YP feels about their relationship with their BA therapist and to ensure there is a collaborative consensus between them. It measures 3 domains: a) agreement on the goals of the treatment; b) agreement about the tasks to achieve these goals; c) quality of the bond between therapist and YP (41). YP will be asked to rate a series of statements on a 5-point Likert scale, ranging from 1 (rarely or never) to 5 (always). The Goal, Task and Bond domains each have scores ranging from 5-20 and higher scores indicate better therapeutic alliance. (42).

End of treatment questionnaire

After their final session, YP will complete end of treatment questionnaires which will measure engagement with the intervention via self-report, website acceptability, preference for mode of delivery and any barriers to treatment. These will be distributed by an unblinded member of the research team. YP who withdraw from the intervention before their 8th session will be asked to complete this measure at the point they stop their BA sessions.

BA therapists will complete bespoke questionnaires when they have completed delivering all therapy sessions. End of treatment questionnaires will address acceptability of the intervention, acceptability of using a digital platform, preferences for mode of delivery, and any barriers faced during treatment.

End of treatment questionnaires will generate a combination of quantitative and qualitative data, which will contribute to overall acceptability measures of the intervention.

BA Completion Form (Discharge Information)

The therapist will also be asked to complete information about discharge and any further treatment offered to the young person following completion of behavioural activation The form will capture information about how many sessions were delivered, and the reasons for delivering more or less than the planned 8 if applicable.

Patient Health Questionnaire (PHQ-9)

The PHQ-9 is a self-administered patient questionnaire used to monitor the severity of depression, which scores each of the nine DSM-IV criteria for depression as "0" (not at all) to "3" (nearly every day) (28). This will be completed by the parent/carer to report their own mental health.

Generalised Anxiety Disorder (GAD-7)

The GAD-7 is a seven item instrument that is used as a severity measure for generalised anxiety disorder (GAD) (29). Each item asks the individual to rate the severity of his or her symptoms over the past two weeks as 'not at all', 'several days', 'more than half the days', and 'nearly every day', respectively. This will be completed by the parent/carer to report their own mental health.

Session log for BA

BA therapists will be asked to complete a session log after each BA session they have delivered. Session logs will identify whether the session was recorded, whether the session was in-person or remote, who was present in the room and any problems encountered during the session. Session logs will be used to monitor intervention delivery by the Trial Managers and support the statistical analysis.

Fidelity to BA rating scale

Where consent has been provided from the participant, BA therapy sessions will be audio recorded for the purpose of assessing fidelity to the BAY treatment manual. A fidelity assessment tool was developed and piloted in our feasibility study, based on a tool used by (43) to assess fidelity to a BA intervention for people with learning disabilities. The fidelity assessment tool covers key BA principles and the broader skills required for therapeutic interventions. It has been made available to all therapists and supervisors involved in the trial and is used as part of their training and supervision 10% of BA session recordings will be randomly selected (ensuring a range of sites, therapists and sessions) and assessed by three trained clinicians external to the delivery of BA in the BAY trial.

Plans to promote participant retention and complete follow-up {18b}

To thank participants for their time and to help promote retention, participants will receive vouchers worth £30 for the baseline, £15 for the 12 week follow-up, £20 for the 6 month follow-up (primary outcome) and £15 for the 12 month follow-up. For any participants that withdraw during the trial period, data collected up to the point of withdrawal will be analysed as explained to the participant in the information sheet and during consent. **We will follow-up participants who have withdrawn from treatment but agreed to remain in the study.**

Data management {19}

Each study participant is assigned a unique trial identification number at the start of assessments and written on all clinical assessment forms/datasheets and databases used to record data on study participants. A record sheet linking patient identity, contact details and trial identification number for all participants will be kept at each site, stored in a secure electronic file that only members of the BAY team can access.

All data will be held securely on the cloud-hosted REDCap server or on Qualtrics. Access to the study interface will be restricted to named authorised individuals granted user rights by a REDCap administrator at YTU. Authorised users will be required to set passwords in line with Health Sciences Department's policy. Those with access to the Qualtrics data must have a University of York login and have to be granted access to the documents by the YTU trial team. For accessibility reasons some participants may choose to complete their consent and questionnaires on paper. The data will then be entered into REDCap within 1 week of data collection and the paper booklet will be stored in a locked cabinet in the NHS Trust separate from any written consent forms. Only data required to fulfil the study outcomes will be collected.

Computerised data cleaning and validation checks will be used in addition to manual review to check for discrepancies and to ensure consistency of the data and data will be checked according to procedures detailed in a trial specific Data Management Plan held at YTU. An electronic audit trail system will be

maintained within the data management system to track all data changes in the database once the data has been saved initially into the system or electronically loaded.

All qualitative interviews will be held online using a video conferencing platform approved by the study sponsor or via telephone and recorded via inbuilt recording software within the videoconferencing platform used or using an encrypted Dictaphone. The recordings will be downloaded and saved in a folder on the secure network on the GMMH server with access restricted to the study team.

Data from the digital tool will be stored in secure ISO27001 cloud-hosted servers managed by the University of Manchester. Website data will be securely exported and transferred to the University of York for analysis.

Confidentiality {27}

Participants will be assured that their data will remain confidential to the research team and stored securely, apart from in situations where imminent risk is identified, in which case the research team at site will contact relevant clinical contacts or emergency services (with the participant's prior knowledge/consent).

All personal data will be destroyed following completion of the trial with study data (e.g. transcripts, questionnaires) archived for ten years as per the requirements of the National Institute for Health Research (NIHR).

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable, no biological specimens collected.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Analyses will be conducted in Stata version 17 (or later) following intention-to-treat principles and will follow a detailed pre-specified statistical analysis plan. Statistical significance will be assessed at the 5% level unless otherwise stated, and 95% confidence intervals will be provided as appropriate. Analyses and results will be reported according to CONSORT guidelines. The flow of individuals through the trial will be reported in a CONSORT diagram, including the number screened (and reasons for ineligibility) and approached for consent (and reasons for non-consent), the number randomised, adherence to allocated treatment, follow-up data completeness and the number of participants included in the primary analysis. Descriptive summaries of continuous data will be given in terms of the mean and standard deviation (or median and inter quartile range as appropriate) and of categorical data in terms of frequencies and proportions. No formal statistical testing will be conducted at baseline. Information on intervention delivery including number and duration of sessions will be summarised descriptively.

The primary outcome (total MFQ-C score) will be summarised descriptively at each time point and analysed using a mixed-effects linear regression model, including all available time points. The model will include trial arm, time, arm-by-time interaction, baseline MFQ score and other important baseline variables as fixed effects. Random effects will be included to account for the repeated measures within patients and for possible clustering by the therapist (nested within the treatment arm). The primary analysis model will include data from assessments at 12-weeks and 6-months post-randomisation. The estimated treatment group difference at 6-months post-randomisation will be reported alongside a 95% confidence interval and associated p-value. A secondary analysis will include an estimate of the treatment group difference at 6-

weeks post-randomisation. A separate model additionally including data at 12-months post-randomisation will derive treatment group differences at that timepoint. Different covariance patterns for the repeated measurements will be explored and the most appropriate pattern will be used for the final model. Data will be assumed missing at random. Secondary outcomes will be analysed using similar models as described above (with binary outcomes being analysed using a mixed-effects logistic regression model), adjusting for the same fixed and random effects.

Interim analyses {21b}

There will be no interim analyses carried out during the study.

Methods for additional analyses (e.g. subgroup analyses) {20b}

Any planned subgroup analyses will be pre-specified in the statistical analysis plan. Subgroup analyses will be carried out by repeating the primary analysis model with the inclusion of an interaction term between the subgroup variable and treatment allocation. Statistical significance of the subgroup effect will be assessed using the likelihood ratio test.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Sensitivity analyses assessing the robustness of results to deviations from the missing at random assumption will be carried out.

The efficacy of the intervention in participants who complied with the intervention will be assessed using Complier-Average-Causal-Effect (CACE) analysis. The CACE analysis will be implemented using an instrumental variable regression model treatment allocation as the instrument and received treatment as the exogenous variable. Separate CACE analyses will be carried out using minimal and full compliance definitions.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

The full protocol is available at https://fundingawards.nihr.ac.uk/award/NIHR132808. Participant-level data and statistical code will be made available upon reasonable request, after consultation with the TMG and CI.

Economic Evaluation

An economic evaluation, following intention-to-treat principles and guided by a pre-specified health economics analysis plan (HEAP), will be conducted to evaluate the cost effectiveness of BA + TAU + PE compared to TAU + PE. The primary economic analysis will be a trial-based cost-utility analysis conducted over the trial follow-up period (6 months) from the UK NHS and personal and social services perspective.

Costs will include both the delivery of the BA intervention and the use of health and social services related to YP, with resource use data collected via a self-reported bespoke questionnaire and multiplied by unit costs to calculate total costs for each trial arm. Unit costs will be obtained from national data sources such as the Unit Costs of Health and Social Care report (44) and National Cost Collection (45). In addition, the health benefit will be measured in YP's Quality-Adjusted Life Years (QALYs), based on individual utility scores from Child Health Utility 9D (CHU-9D), a widely used health-related quality of life (HRQoL) instrument originally designed for YP aged 7–11 (38) with applicability extended to 17 (39). To complement CHU-9D, the EQ-5D-Y, another commonly used HRQoL instrument developed by the EuroQoL group for YP aged 8-15 (46) will also be used. Additionally, carers' HRQoL will be assessed using EQ-5D-5L, an instrument also developed by the EuroQoL group and recommended by NICE for adults aged 16 and older(47, 48). The self-report versions of these instruments will be administered at baseline and follow-up timepoints, with

QALYs calculated using an area under the curve approach. Since the study time horizon is less than 12 months, no discounting will be applied.

The difference in costs and QALYs between trial arms will be calculated using regression models that control for baseline differences in utility (49) and costs. Uncertainty in the cost and QALY differences will be captured using a non-parametric bootstrap method. The incremental cost-effectiveness ratio (ICER) will be calculated and assessed against the UK's willingness-to-pay (WTP) threshold of £20,000-£30,000 per QALY gained to determine cost-effectiveness. Bootstrapped results will be presented as a cost-effectiveness acceptability curve (CEAC), which shows the probability of the intervention (BA) being cost-effective at different WTP thresholds.

To ensure the robustness of the primary analysis, the following sensitivity analyses will be performed: (1) a cost–utility analysis using the EQ-5D-Y outcomes instead of CHU-9D, (2) a cost–utility analysis from a societal perspective, and (3) a cost–utility analysis over a 12-month period.

Study Within a Trial (SWAT)

Recruitment SWAT

The recruitment SWAT for the BAY Trial will embed a QR code vs website link into the PIS that takes potential participants directly to the recruitment animation video. Clinics within the NHS Trusts will be cluster randomised to distribute information packs including a PIS with either the QR code or website link. The aim is to see whether the QR code & watching the animation facilitates recruitment into the trial. A protocol for this SWAT has been developed and provided to each study site.

Retention SWAT

The YTU has been successful in securing funding for 'Implement SWATs', a project which provides additional funding to host trials to test the effectiveness of various monetary incentives (funded by UK NIHR, award reference: NIHR302256). The BAY Trial will collaborate with Implement SWATs to deliver a retention SWAT, with additional funding to provide unconditional reward (voucher prior to follow-up completion) vs conditional incentive (voucher after completion) at the 6-month follow-up. A protocol for this SWAT has been developed and provided to each study site.

Patient and Public Involvement (PPI)

PPI will be embedded throughout the project to add impact and value to the research. The aims of involvement from YP and carers are to: shape the research so that it focuses on issues that are most important to them; build capacity so that those involved gain knowledge and skills; provide support and training; collaborate and participate in dissemination.

All approaches to PPI and levels of engagement will be encouraged, to ensure that all members are confident in their role and enjoy their experience. Panel members will be reimbursed according to Involve guidance. Members will be recruited through our local organisations and established contacts.

In the initial stages of the project, the PPI members will be asked to review study documentation before submission to ethics to ensure that the language and accessibility is appropriate for the target audiences. PPI members will also be asked to review the trial processes to ensure they are acceptable and feasible, for example how to minimise burden to participants. This panel will actively contribute to aspects of the intervention development e.g. website co-design, reviewing the content of BA training and animations and participating in training events. Throughout the trial there will be additional opportunities to get involved, for example creating and reviewing content for our social media pages, participant information, co-

producing trial updates for participants e.g. newsletter, social media and video blogs. There will be a range of opportunities for participating in project dissemination activities including co-facilitating and presenting at the dissemination meeting, video-blogs, publication authorship as peer researcher and presenting at conferences.

Besides the PPI panel members, we plan to recruit a YP PPI co-researcher for the Qualitative Study. They will contribute to the qualitative analysis for YP data which will be led by a qualitative researcher.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

YTU provides the day to day running of the trial and will carry out data management responsibilities and statistical analysis. The trial team will be made up of two trial managers, trial support officers and statisticians. Trial monitoring processes will follow trial monitoring and site monitoring procedures in accordance with the standard operating procedures of both the YTU and the study sponsor (GMMH). The trial team will meet weekly to address day-to-day operations of the trial, and monthly with the Chief Investigator for oversight. The conduct of the trial will be governed by the TSC that has an independent chair, three independent senior academics, and two representatives of YP and carers. The TSC will meet at a minimum of twice a year to monitor progress and protocol adherence and to advise the study team.

Composition of the data monitoring committee, its role and reporting structure {21a}

The trial will be monitored by a DMEC which has an independent chair and two senior academics. The DMEC will meet a minimum of twice a year to monitor the data and ethical processes.

Adverse event reporting and harms {22}

Due to the population that will be recruited into the trial, some events including mood fluctuations and self-harm not requiring medical intervention will be common and expected and therefore we will not be monitoring this as an adverse event. Due to the difficulties of defining these types of events for the purposes of the study, we will focus on serious adverse events. As participants will be under the care of CAMHS throughout the trial (unless discharged due to improvements), emotional and behavioural events will be monitored and the young person will receive appropriate care through CAMHS following their usual procedures. The research team will therefore monitor only serious adverse events as outlined below:

- Requires hospitalisation for mental health reasons (or prolongation of existing hospitalisation), including any A&E attendance.
- Results in a clinical decision being made that a participant's mental state has seriously deteriorated.
- Results in persistent or significant disability or incapacity.
- Results in death.
- Is otherwise considered medically significant (including a mental act assessment).

Items relating to hospitalisation on the CA-SUS as well as concerning responses on the self-harm and suicidality questions will be flagged up via REDCap at all follow-up timepoints in both arms and the Trial Manager (TM) will be made aware as soon as possible and liaise with the clinical team from that participants site. A designated person from the research team will schedule a phone call with the participant and/or their carer and discuss the adverse event. The TM or designated person from the research team will record it using a serious adverse events form. Copies of any serious adverse forms will be sent to the site and clinical teams will be informed.

If a serious adverse event is disclosed to a RA or BAY therapist, or the site team becomes aware of such an event in the TAU arm, it will be reported to the Trial Manager as soon as possible and processed at the

Trials Unit. The Chief Investigator will review any serious adverse events if they arise. Any serious adverse events will be reported to the study sponsor within 3 working days of being notified.

Safety issues will be reported to the Research Ethics Committee (REC) in the annual progress report. A summary of all events will also be reported to the TSC and Sponsor. Expedited reporting of events to the REC and the Sponsor will be subject to current NRES guidance, the YTU Standard Operating Procedures (SOPs) and Sponsor requirements.

Frequency and plans for auditing trial conduct {23}

We will follow trial monitoring and site monitoring procedures in accordance with the standard operating procedures of both the YTU and the study sponsor (GMMH).

The conduct of the trial will be governed by the Trial Steering Committee (TSC) that has an independent chair, three independent senior academics, and two representatives of young people and carers. The TSC will meet at a minimum of twice a year to monitor progress and protocol adherence and to advise the study team. The trial will be monitored by a Data Monitoring and Ethics Committee (DMEC) which has an independent chair and two senior academics. The DMEC will meet a minimum of twice a year to monitor the data and ethical processes.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Any protocol amendments will be discussed with oversight committees as necessary, submitted to the funder and sponsor for review, and then submitted to the REC for ethics approval. The current approved protocol will always be circulated to sites for information and action. Amendments relevant to trial participants will be communicated via email from the YTU.

Dissemination plans {31a}

Approaches to dissemination will include:

1) Dissemination Events: Clinicians, service manager, commissioners, academics, policymakers, PPI panel members and research participants will be invited to attend local interactive dissemination events to discuss the findings and generate recommendations to inform services and commissioners implement best practice.

2) Focused NHS dissemination: we will use our professional networks to meet with NHS clinicians, service providers, commissioners and other stakeholders (e.g. NHSE, Health Education England HEE, Centre for Mental Health), regionally and nationally, to outline findings and implications for policy and practice.

3) Professional Training: we will aim to reach a wide group of CAMHS professionals regarding the learning from the study. BD and SM have already co-produced an RCPsych CPD learning module based on our behavioural activation, which will be freely available during our training; BD/TW/EW have contributed to the RCPsych MindED website (freely available resource on mental health for families and professionals), so we will aim to add e-learning to this platform to support training for new CAMHS staff, CPD for clinicians, as well as information for families.

4) Media: press releases will be sent to print, radio and TV media. BD has extensive experience in dealing with the media through RCPsych, and also through NIHR. The Universities of Manchester, Nottingham and York and GMMH sponsor press offices have a wide range of networks to disseminate findings.

5) Conferences: findings will be presented to a range of audiences including the NHS Confederation Mental Health Network (attended by researchers, commissioners, clinicians, service users, carers), local ARCs, clinician conferences professional bodies involved with YP's mental health (e.g. RCPsych, Royal College of

Nursing RCN, British Psychological Society BPS, Association for Child and Adolescent Mental Health ACAMH), NHSE, and regional and national PPI events (e.g. YoungMinds).

6) Publications: a series of high impact publications in international peer reviewed journals, including open access publications will be published. A detailed project report for the NIHR library will be made available.

7) Website and Newsletters: we will set up a project webpage to promote the research throughout the duration of the project, with regular newsletters. We will produce a plain language summary and headline findings for the ARC and HIM website and newsletters. We are closely involved with local ARCs, as well as HIM, which enables access to a network of communities including commissioners and clinicians.

8) Social & other media. Networks include RCPsych, ACAMH, RCN, BPS, HEE

Discussion

This mixed methods RCT will add much needed knowledge about BA as a first-line treatment for YP with moderate-severe depression and risk in specialist CAMHS as delivered by clinicians without specialist training. Our trial will also assess the acceptability of blended delivery, which has become routine since the COVID-19 pandemic (Wessex Academic Health Science Network, 2020; Bhardwaj et al., 2021), and where we have little research to inform practice. We aim to assess the service provision implications of training clinicians with minimal therapy skills, which may have a significant impact on service delivery and optimise use of specialist therapists.

If BA is effective and cost-effective, this could increase access to a treatment that can be delivered at scale as a first-line intervention in CAMHS. BA could free up more experienced staff and reduce waiting times for more specialist interventions, at an unprecedented time in terms of rising prevalence and demand.

Trial status

Ongoing, recruitment began in July 2024, 4 months later than planned. The NIHR granted a 9-month extension, so recruitment will be completed at the end of November 2025. During the extension, the sample size was reduced from 528 to 446. Outcome data will be available 6 months post- randomisation of the last participant.

Protocol version number and date: V6 25.06.2025

Date when recruitment began: 14.07.2023

Approximate date for recruitment completion: 30.11.2025

Abbreviations

BAY
YP
CAMHS
YP
PE
TAU
RCT
BA
MFQ
MFQ-C
DAWBA

SDQ
RCADS
BADS
CHU-9D
EQ-5D-Y
EQ-5D-5L
CA-SUS
WAI-S
PHQ-9
GAD-7
SWAT
PPI
YTU
TM
REC
TSC
DMEC
SOPs
NRES

Declarations

Acknowledgements

We would like to thank the independent members of our Trial Steering and Data Monitoring and Ethics Committees and the Sponsor team at Greater Manchester Mental Health Trust for their advice and support in the set up and conduct of the study. Sarah- Bailey, Dan Pearson and the Data Management team from York Trials Unit are also thanked for the set up and maintenance of the study database.

The authors would like to thank the site research staff, without whom this research would not be possible, in particular the researchers and clinical studies officers who were integral in the screening and recruitment of participants. For this we extend our thanks to Alex Bailey-Smith, Rhianne Bostock, Paula Brown, Lucy Carr, Elinor Hopkin, Katie Large, Laura-May Land, Jessica McGiffen, Stephanie Noble Hernandez, Faizan Patel, Matthew Walsh, Elsie Williams and Alexandrea Wusu.

The authors would also like to acknowledge our patient and public involvement representatives on both the young person and parent/carer panel for their input in the trial design, development and review of trial documentation. Your insights and experience have helped shape this research, which we are extremely grateful for.

Authors' contributions {31b}

BD is the Chief Investigator and conceived the study, led the proposal, study setup and oversight and protocol development. ES and RE are the lead trial managers and contributed to the development of the protocol and study setup. CH is the Director of the York Trials Unit and senior statistician. AM and AC are statisticians at the York Trials Unit. JB and CPL are part of the trial team. HW is the health economist. PB has oversight of the qualitative research component and GCY is conducting qualitative interviews and analysis. LC was the trial statistician prior to a change in trials unit and remains on the trial management group. BD,

AB, RE, PH, SM and KS are Principal Investigators at the NHS Trust sites. PH is the primary intervention lead. BD and SM developed the intervention. HS, MS, PW and CW are psychology leads for the NHS Trust sites. TW and EW are experts by lived experience and chair the PPI panels, supported by SY. AM is leading on the fidelity work. PW led the development team who created the digital intervention tool. All authors read and approved the final manuscript.

Funding {4}

The trial and costed extension has been funded by the National Institute of Health and Care Research Health Technology Assessment Programme (Reference: NIHR132808). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. The recruitment SWAT has been funded by IMPLEMENT SWATs (NIHR302256).

Availability of data and materials {29}

York Trials Unit at the University of York and Greater Manchester Mental Health NHS Foundation Trust are joint data controllers. Statisticians at the York Trials Unit will analyse the final dataset. The final dataset will be published and data will be available from the corresponding author on reasonable request.

Ethics approval and consent to participate {24}

Ethical approval for this study was sought and received from East of England - Cambridge South Research Ethics Committee (REC reference: 23/EE/0073)

Written informed consent will be obtained from all participants in the trial.

Consent for publication {32}

Not applicable. No identifying information or other personal or clinical details of participants are presented here or will be presented in reports of the trial results. The participant information materials and informed consent form are available from the authors on request.

Competing interests {28}
PW is Chief Operating Officer of CareLoop Health Ltd, a University of Manchester spin-out company in digital mental health.

References

1. Mental Health of Children and Young People in England, 2023 - wave 4 follow up to the 2017 survey [Available from: https://digital.nhs.uk/data-and-information/publications/statistical/mental-health-of-children-and-young-people-in-england/2023-wave-4-follow-up.
2. The Good Childhood Report 2024 [Available from: https://www.childrenssociety.org.uk/information/professionals/resources/good-childhood-report-2024.
3. 52% increase in young people waiting over a year for mental health support [Available from: https://www.youngminds.org.uk/about-us/media-centre/press-releases/increase-in-young-people-waiting-over-a-year-for-mental-health-support/.
4. Crenna-Jennings W, Hutchinson J. Access to child and adolescent mental health services in 2019. Education policy institute. 2020;10:1–32.
5. The government's response to the Health and Social Care Committee report: children and young people's mental health [Available from: https://www.gov.uk/government/publications/children-and-young-peoples-mental-health-government-response/the-governments-response-to-the-health-and-social-care-committee-report-children-and-young-peoples-mental-health.

6. Securing money to improve mental health care... but no staff to spend it on 2019 [Available from: https://www.kingsfund.org.uk/insight-and-analysis/blogs/improve-mental-health-care-no-staff.
7. Mental health 360: workforce 2024 [Available from: https://www.kingsfund.org.uk/insight-and-analysis/long-reads/mental-health-360-workforce.
8. Progress in improving NHS mental health services 2023 [Available from: https://publications.parliament.uk/pa/cm5803/cmselect/cmpubacc/1000/report.html#heading-0.
9. Richards DA, Ekers D, McMillan D, Taylor RS, Byford S, Warren FC, et al. Cost and Outcome of Behavioural Activation versus Cognitive Behavioural Therapy for Depression (COBRA): a randomised, controlled, non-inferiority trial. The Lancet. 2016;388(10047):871–80.
10. Tindall L, Kerrigan P, Li J, Hayward E, Gega L. Is behavioural activation an effective treatment for depression in children and adolescents? An updated systematic review and meta-analysis. European Child & Adolescent Psychiatry. 2024;33(12):4133–56.
11. Pass L, Lejuez CW, Reynolds S. Brief behavioural activation (Brief BA) for adolescent depression: A pilot study. Behavioural and cognitive psychotherapy. 2018;46(2):182–94.
12. Kitchen CE, Tiffin PA, Lewis S, Gega L, Ekers D. Innovations in Practice: A randomised controlled feasibility trial of Behavioural Activation as a treatment for young people with depression. Child and Adolescent Mental Health. 2021;26(3):290–5.
13. McCauley E, Gudmundsen G, Schloredt K, Martell C, Rhew I, Hubley S, et al. The adolescent behavioral activation program: Adapting behavioral activation as a treatment for depression in adolescence. Journal of Clinical Child & Adolescent Psychology. 2016;45(3):291–304.
14. Chandler J, Darnton P, Sibley A. Very rapid insight generation to support UK health and care systems: An AHSN approach. Frontiers in sociology. 2023;8:993342.
15. Bhardwaj A, Moore A, Cardinal RN, Bradley C, Cross L, Ford TJ. Survey of CAMHS clinicians about their experience of remote consultation: brief report. BJPsych Open. 2021;7(1):e34.
16. Ferreira A, Moreira MT, Rodrigues S, Lima A, Ferreira S, Fernandes CS. Use of technologies in promoting adolescent mental health: A scoping review. Creative Nursing. 2025;31(2):111–8.
17. Andersson R, Ahlen J, Mataix-Cols D, Lenhard F, Henje E, Månsson C, et al. Therapist-guided and self-guided internet-delivered behavioural activation for adolescents with depression: a randomised feasibility trial. BMJ open. 2022;12(12):e066357.
18. Andersson R, Vigerland S, Lenhard F, Ahlen J, Bottai M, Mataix-Cols D, et al. Single-blinded, randomised, parallel-group, controlled trial comparing the efficacy and cost-effectiveness of therapist-and self-guided internet-delivered behavioural activation versus treatment as usual for adolescents with mild to moderate depression: study protocol. BMJ open. 2024;14(10):e083507.
19. Dubicka B, Marwedel S, Banares S, McCulloch A, Tahoun T, Hearn J, et al. Feasibility study of a new behavioural activation programme for young people with depressed mood. Child and Adolescent Mental Health. 2022;27(2):131–7.
20. Wood A, Kroll L, Moore A, Harrington R. Properties of the mood and feelings questionnaire in adolescent psychiatric outpatients: a research note. Journal of child psychology and psychiatry. 1995;36(2):327–34.
21. Burleson Daviss W, Birmaher B, Melhem NA, Axelson DA, Michaels SM, Brent DA. Criterion validity of the Mood and Feelings Questionnaire for depressive episodes in clinic and non-clinic subjects. Journal of child psychology and psychiatry. 2006;47(9):927–34.
22. Sund AM, Larsson B, Wichstrøm L. Depressive symptoms among young Norwegian adolescents as measured by the Mood and Feelings Questionnaire (MFQ). European child & adolescent psychiatry. 2001;10(4):222–9.
23. Goodman R. The Strengths and Difficulties Questionnaire: a research note. Journal of child psychology and psychiatry. 1997;38(5):581–6.
24. Chorpita BF, Moffitt CE, Gray J. Psychometric properties of the Revised Child Anxiety and Depression Scale in a clinical sample. Behaviour research and therapy. 2005;43(3):309–22.

25. Kanter JW, Mulick PS, Busch AM, Berlin KS, Martell CR. The Behavioral Activation for Depression Scale (BADS): psychometric properties and factor structure. Journal of Psychopathology and Behavioral Assessment. 2007;29(3):191–202.
26. Group TE. EuroQol-a new facility for the measurement of health-related quality of life. Health policy. 1990;16(3):199–208.
27. Horvath AO, Greenberg LS. Development and validation of the Working Alliance Inventory. Journal of counseling psychology. 1989;36(2):223.
28. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. Journal of general internal medicine. 2001;16(9):606–13.
29. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Archives of internal medicine. 2006;166(10):1092–7.
30. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. BMC health services research. 2017;17(1):88.
31. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implementation science. 2009;4(1):50.
32. Chan A-W, Boutron I, Hopewell S, Moher D, Schulz KF, Collins GS, et al. SPIRIT 2025 statement: updated guideline for protocols of randomised trials. The Lancet. 2025;405(10491):e19–e27.
33. Goodyer IM, Reynolds S, Barrett B, Byford S, Dubicka B, Hill J, et al. Cognitive behavioural therapy and short-term psychoanalytical psychotherapy versus a brief psychosocial intervention in adolescents with unipolar major depressive disorder (IMPACT): a multicentre, pragmatic, observer-blind, randomised controlled superiority trial. The Lancet Psychiatry. 2017;4(2):109–19.
34. Goodyer I, Dubicka B, Wilkinson P, Kelvin R, Roberts C, Byford S, et al. A randomised controlled trial of cognitive behaviour therapy in adolescents with major depression treated by selective serotonin reuptake inhibitors. The ADAPT trial. Health Technology Assessment (Winchester, England). 2008;12(14):iii–iv, ix.
35. Angold A, Costello EJ, Pickles A, Winder F, Silver D. Mood and feelings questionnaire. Unpublished document Duke University Developmental Program. 1987.
36. Goodman R, Ford T, Richards H, Gatward R, Meltzer H. The development and well-being assessment: Description and initial validation of an integrated assessment of child and adolescent psychopathology. Journal of child psychology and psychiatry. 2000;41(5):645–55.
37. Sayal K, Wyatt L, Partlett C, Ewart C, Bhardwaj A, Dubicka B, et al. The clinical and cost effectiveness of a STAndardised DIagnostic Assessment for children and adolescents with emotional difficulties: the STADIA multi-centre randomised controlled trial. Journal of Child Psychology and Psychiatry. 2025;66(6):805–20.
38. Stevens K. Developing a descriptive system for a new preference-based measure of health-related quality of life for children. Quality of Life Research. 2009;18(8):1105–13.
39. Stevens K, Ratcliffe J. Measuring and valuing health benefits for economic evaluation in adolescence: an assessment of the practicality and validity of the child health utility 9D in the Australian adolescent population. Value in health. 2012;15(8):1092–9.
40. Law D, Jacob J. Goals and goal based outcomes (GBOs). Guide to using outcomes and feedback tools with children, young people and families. 2013.
41. Hatcher RL, Gillaspy JA. Development and validation of a revised short version of the Working Alliance Inventory. Psychotherapy research. 2006;16(1):12–25.
42. Paap D, Dijkstra PU. Working alliance inventory-short form revised. Journal of Physiotherapy. 2017;63(2):118.
43. Jahoda A, Hastings R, Hatton C, Cooper S-A, Dagnan D, Zhang R, et al. Comparison of behavioural activation with guided self-help for treatment of depression in adults with intellectual disabilities: a randomised controlled trial. The Lancet Psychiatry. 2017;4(12):909–19.
44. Unit Costs of Health and Social Care [Available from: https://www.pssru.ac.uk/project-pages/unit-costs/.

45. National Cost Collection for the NHS 2025 [Available from: https://www.england.nhs.uk/costing-in-the-nhs/national-cost-collection/.
46. Wille N, Badia X, Bonsel G, Burström K, Cavrini G, Devlin N, et al. Development of the EQ-5D-Y: a child-friendly version of the EQ-5D. Quality of life research. 2010;19(6):875–86.
47. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Quality of life research. 2011;20(10):1727–36.
48. NICE. Guide to the methods of technology appraisal 2013 2013 [Available from: https://www.nice.org.uk/process/pmg9/chapter/foreword.
49. Manca A, Hawkins N, Sculpher MJ. Estimating mean QALYs in trial-based cost-effectiveness analysis: the importance of controlling for baseline utility. Health economics. 2005;14(5):487–96.