FULL/LONG TITLE OF THE STUDY: Behavioural Activation for Young people with depression in specialist child and adolescent mental health services

SHORT STUDY TITLE / ACRONYM:

Behavioural Activation for Young (BAY) people with depression: Randomised Controlled Trial

Chief Investigator: Professor Bernadka Dubicka

Sponsor: Greater Manchester Mental Health NHS Foundation Trust

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Amendment history:

List details of all protocol amendments here whenever a new version is produced

Version Number	Date	Amendment Details
2	03.04.2023	
3	19.01.2024	
4	20.06.2024	
5	28.02.2025	

Health Research Authority (HRA) guidance has been considered when writing this protocol

BAY Protocol Signature Page

The undersigned confirm that the BAY protocol (version 6, dated 25/06/2025) has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the trial publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

Signature: Date:

.....

......./...../.....

Name (please print):

.....

Position:

.....

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Signature: Date:

..../...../.....

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TABLE OF CONTENTS

- **RESEARCH REFERENCE NUMBERS**

Governing body or organisation	Reference
Integrated Research Application System (IRAS)	319136
ISRCTN	
Funder's reference	NIHR132808
Research Ethics Committee (REC)	

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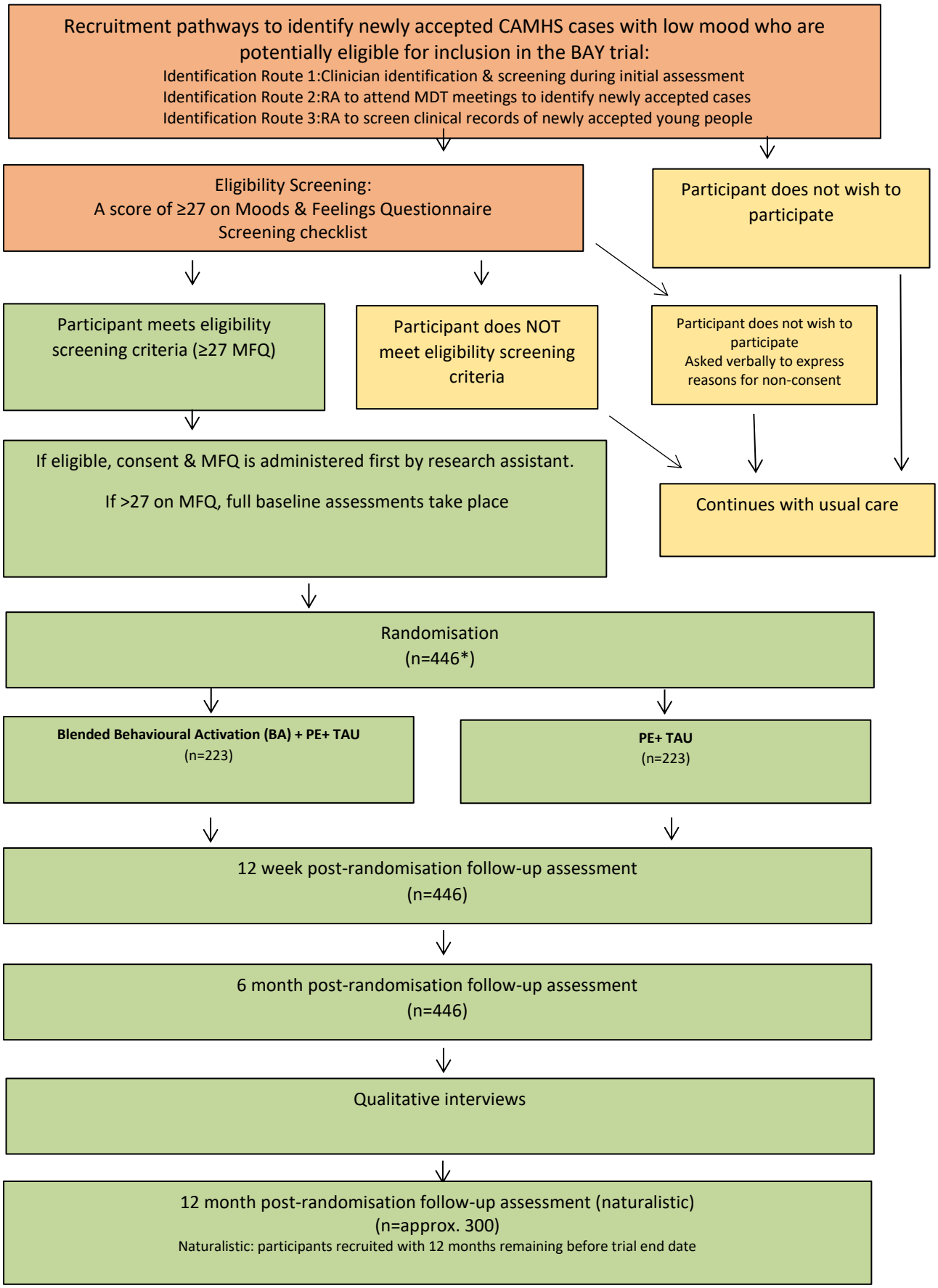
STUDY SUMMARY

Study title	Behavioural Activation for Young people with depression in specialist child and adolescent mental health services	
Short title	BAY: Randomised Controlled Trial	
Study design	Randomised Controlled Trial with internal pilot	
Participants	Young people aged 11 to 17 years with moderate to severe depression	
Planned sample size	446 young people	
Treatment duration	Behavioural Activation will be delivered weekly for up to 8 sessions +Treatment as Usual +psychoeducation	
Follow-up duration	12 weeks, 6 months, and 12 months post-randomisation (naturalistic follow up at 12 months)	
Planned study period	4 years (45 months)	
	Objectives	**Outcome Measures & Data Collection Tools**
Primary	Estimate the clinical and cost effectiveness of BA + psychoeducation (PE) + treatment as usual (TAU) on depressive symptoms compared to PE+TAU at 6 months post-randomisation	Primary outcome measure (primary endpoint 6-months post-randomisation) : Mood and Feelings Questionnaire (MFQ-C young person self-rated) Additional measures: Youth: DAWBA (baseline only), SDQ, RCADS, BADS, self-harm and suicidality questions, goal-based outcomes, CHU-9D, EQ-5D-Y, Healthcare service use schedule, Aspects of Care checklist, WAI-S Clinician: Session logs, End of Treatment questionnaire, adverse & serious adverse events Carer: DAWBA (baseline only), MFQ, SDQ, , Carer EQ-5D-5L- Childs mental health PHQ-9, GAD-7- Carers mental health RA completed: Treatment as usual form. Numbers discharged

		from CAMHS; n needing therapy; (treatment as usual questionnaire & end of treatment questionnaire) Adverse & Serious Adverse Events
Secondary	Co-design and develop our website with YP, to enhance the acceptability and effectiveness of remote delivery, and train therapists to deliver blended BA.	Feedback from young people and clinicians during development and training.
	Conduct an internal pilot to assess recruitment and acceptability in all sites.	Progression criteria to a full trial. Collect reasons for declining. Interview participants who initially consent and then refuse to take part (early exit participants, n=15)
	Examine immediate and longer-term acceptability, including blended delivery, potential barriers to uptake and engagement from multiple stakeholder perspectives.	Qualitative interviews with YP, carers, and clinicians End of treatment feedback forms for clinicians and YP. Website usage and engagement data
	Use the knowledge gained, from the perspective of all stakeholders, to make recommendations for depression treatment in CAMHS, including for delivery approaches.	Recommendations to be agreed with study team and service user and carer panels, and disseminated with a broad ranging dissemination strategy
Intervention	Blended Behavioural Activation (BA) + PE + TAU	
Comparator	Psychoeducation + TAU	
Method of delivery	Both groups will be supported by professionals based within NHS CAMHS. The intervention will be delivered using a blended approach of online and in-person behavioural activation sessions using a co-produced website, dependent on the young person's preference. BA will be delivered by Band 4 or 5 mental health professionals, depending on local service structures.	

Study Flowchart



*Internal pilot recruitment target: 176. Main trial recruitment target: 270

ABBREVIATIONS

BA	**Behavioural Activation**
CAMHS	**Child and Adolescent Mental Health Services**
CBT	**Cognitive Behavioural Therapy**
CCA	**Cost-Consequence Analysis**
CCG	**Clinical Commissioning Group**
CEAC	**Cost Effectiveness Acceptability Curves**
CWP	**Children's Wellbeing Practitioner**
CYP IAPT	**Children and Young People's Improving Access to Psychological Therapies**
DfE	**Department for Education**
DAWBA	**Development and Well-Being Assessment**
DHSC	**Department of Health & Social Care**
DMEC	**Data Management and Ethics Committee**
GDPR	**General Data Protection Regulation**
HRA	**Health Research Authority**
IAPT	**Improving Access to Psychological Therapies**
ICER	**Incremental Cost-Effectiveness Ratio**
IPT	**Interpersonal Therapy**
ITAX	**Intervention Taxonomy**
LA	**Local Authorities**
MAR	**Missing At Random**
MFQ	**Mood and Feelings Questionnaire**
MHSDS	**Mental Health Services Dataset**
MID	**Minimal Important Difference**
NDST	**Non-Directive Supportive Therapy**
NICE	**National Institute for Health and Care Excellence**
NIHR	**National Institute for Health Research**
PPI	**Patient and Public Involvement**
PSC	**Programme Steering Committee**
QALY	**Quality-Adjusted Life Years**
RA	**Research Assistant**
RAG	**Red-Amber-Green (rating for internal pilot)**
RCADS-SF25	**Revised Children's Anxiety and Depression Scale (25-items)**
RCI	**Reliable Change Index**
RCT	**Randomised Controlled Trial**
REC	**Research Ethics Committee**
SAE	**Serious Adverse Event**
SAP	**Statistical Analysis Plan**
SDQ	**Strengths and Difficulties Questionnaire**
SOP	**Standard Operating Procedure**
SPA	**Single Point of Access**
SQ	**Supplementary Questions**
SUS	**Service Use Schedule**
WAI-S	**Working Alliance Inventory Short Form**
WHO	**World Health Organisation**
YP	**Young People/Person**
YTU	**York Trials Unit**

1. BACKGROUND

Rates of emotional disorders in young people (YP) have been increasing (Sadler et al. 2018) and the covid 19 pandemic is disproportionately affecting the mental health of YP with record levels of demand (Newlove-Delgado et al. 2021; Young Minds, 2020). From 2017 to 2020, rates of probable mental health disorders in children and young people aged 7 to 16 rose from 1 in 9 (12.1%) to 1 in 6 (16.7%). Furthermore, between 2017 and 2022, rates in young people aged 17 to 19 rose from 1 in 10 (10.1%) to 1 in 4 (25.7%) (NHS, 2022). Consequently, the demand for CAMHS has continued to rise: the number of referrals of children and young people to services increased by around 77 per cent compared to before the pandemic (66,113 in February 2020 versus 37,432 in February 2022) (Plewes, 2022), and there has been a 47% increase in emergency referrals for young people under 18 to crisis care teams between December 2019 and April 2021 (Lavis, 2021). In England, it has been predicted that 1.5 million children and young people under the age of 18 will need extra mental health support as a result of the pandemic (O' Shea, 2020).

Even before the pandemic, only 25% of children and YP with mental health disorders accessed help (Office for National Statistics, 2004); those that do often have long waits for specialist therapy after assessment (Crenna-Jenning and Hutchinson, 2018; Hughes, 2019). The government Green Paper (Department for Education, 2017) offers help in schools for YP with mild to moderate problems. However, YP with more severe depression and high risk are still referred to specialist child and adolescent mental health services (CAMHS) where there is a significant shortage of skilled staff (Gilbert, 2019) and insufficient therapy skills (Lowe and Campbell, 2014; Care Quality Commission, 2019).

For some mental health services, the longest waiting times for mental health support for children and young people has been over 1 year, which significantly exceeds the UK government's goal of four weeks (Crenna-Jennings and Hutchinson, 2020). A Local Government Association report highlighted that during 2018, only 20% of young people received mental health support within 4 weeks (Local Government Association, 2022). A Care Quality Commission review found that referrals were "often" rejected due to thresholds for eligibility being too high, meaning that young people were only receiving treatment "at the point of crisis" (CQC, 2018). Due to this combination of long waiting lists and high thresholds to receive care, resources will continue to be further stretched, and young people may face an escalation in their mental health difficulties to the point of crisis before receiving support (House of Commons Health and Social Care Committee, 2021).

In response to Covid-19, delivery modes for therapy have changed with more remote working and blended therapy (Wessex Academic Health Science Network, 2020; Bhardwaj et al., 2021), which also offers an opportunity to increase access to services in the face of unprecedented demand. In response to this need, we developed a behavioural activation (BA) intervention with a brief training to clinicians without specialist therapy skills to deliver blended BA (Dubicka et al., 2021), and delivered this in a CAMHS clinic setting with young people aged 11-17 scoring 27 or above on the MFQ-C (Wood et al., 1995). Existing research demonstrates that BA is effective for adults (Stein et al., 2020) and cost effective compared to cognitive behavioural therapy (CBT) (Richards et al.,

2016). However, for YP the evidence is unclear. In developing this study, a rapid literature review was undertaken to search for relevant BA studies in depressed youths, using Psychinfo, Medline, and Cochrane reviews and trials databases (search terms: behavioural activation, depression; limits: adolescents, past 10 years, peer reviewed journals). Two systematic reviews (Martin and Oliver, 2018; Tindall et al., 2017) only found 4 small BA RCTs, with an effect size of 0.7. Only one of these, a US study (n=60) recruited YP with more severe depression, and compared BA with an active comparator; outcomes were similar with 21/27 YP completing BA no longer meeting criteria for depression (McCauley et al., 2015). In the UK, two studies in specialist CAMHS had similar findings to our feasibility work: a feasibility study and a small RCT (n=11) suggested an effectiveness signal (Pass, Lejuez and Reynolds, 2017; Kitchen et al., 2020).

Research currently underway

The most relevant UK study that is underway is the COMBAT trial of BA in school settings (NIHR201174). However, COMBAT will recruit adolescents with mild-moderate depression with minimal complexity and risk, unlike our proposed trial in specialist CAMHS, where we will provide routine specialist clinical care to address complexity and risk management. BAY will therefore complement COMBAT, and together these studies will enable us to understand the role of BA across the spectrum of severity of depression and in different settings.

A schools study is also underway in the Netherlands (van den Heuvel et al., 2019); this is a prevention trial in high school students with elevated depressive symptoms. A number of other recently published school studies have been identified: a small UK feasibility study of BA for depressed adolescents in 5 schools demonstrated acceptability (Pass et al., 2018), and a universal prevention program in Australian primary schools found that children in the BA condition showed increased resilience at 6 months (Johnstone et al., 2020). Therefore, to our knowledge, currently there is no similar trial of BA being undertaken in specialist CAMHS recruiting adolescents with higher levels of depression severity and risk. In our feasibility studies we developed an 8 session workbook ('Be-Active') and offered BA to depressed YP in specialist CAMHS after their initial assessment (Dubicka et al., 2021). We delivered BA to YP in a development phase (n=15), and then a mixed methods feasibility study (n=36). Our BA programme showed good acceptability with YP and professionals, and relatively junior clinicians (bands 4 and 5) used it with YP with complex problems (58% had one comorbidity or more). Depression scores fell from 43.2 to 27.6, and of 8 sessions offered, YP attended a median of 8 (mean 6.6). 16 (44%) were discharged and 25 (69%) were rated as improved by clinicians. At the end of our study, during covid-19, we delivered BA remotely, with website access to the BA workbooks, and received positive feedback from families and clinicians.

How will this research add knowledge to current NHS policy and practice

This mixed methods RCT will add much needed knowledge about BA as a first-line treatment for YP with more severe depression and risk in specialist CAMHS. NICE (NICE, 2019) recommends BA research for mild depression; we believe an RCT for those with more severe depression will provide NHS evidence about BA utility across all depression severities. 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 also 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.

Why is this research important and needed now?

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 (Sadler et al. 2018; Newlove-Delgado et al. 2021; Young Minds, 2020; Crenna-Jenning and Hutchinson, 2018; Hughes, 2019; Gilbert, 2019), and help address the profound mental health consequences of covid-19 on YP.

Even before the pandemic, rates of emotional disorders in YP were increasing (Sadler et al. 2018). The UK Millennium Cohort Study found that almost one in four girls (24%) and one in ten boys (9%) at age 14 self-reported high levels of depressive symptoms (Patalay and Fitzsimons, 2018). In their 2020 report, NHS Benchmarking noted a 15% increase in referrals to CAMHS over the past year, the highest rate of increase of any speciality in the NHS that year (Bell, 2022); this was reported to have reached an all time high in November 2020 (The Telegraph, 2021). Even more worryingly, suicide rates in YP were rising year on year before the pandemic (Bould et al., 2019). The covid-19 pandemic is further impacting on the mental health of YP, who have been disproportionately affected (Newlove-Delgado et al. 2021; Young Minds, 2020), including evidence of a rise in suicides (Disability Rights UK, 2022). Before the pandemic and subsequent increase in prevalence and demand, only 25% of children and YP with mental health disorders accessed help (Office for National Statistics, 2004), often with long waits for specialist therapy after assessment (Crenna-Jenning and Hutchinson, 2018; Hughes, 2019). In 2019, for routine cases, the average wait was 13 weeks to start treatment whilst 22% waited more than 18 weeks . Since the pandemic, the personal experience of our team suggests that increased demand and staffing challenges have continued to impact on timely access to treatment for young people.

The government Green Paper (Department for Education, 2017) offers help in schools for YP with mild and moderate problems. However, YP with more severe depression, complexity and high risk are still referred to specialist CAMHS. CAMHS have a significant shortage of skilled staff (Gilbert, 2019) to meet this demand, and the workforce is changing with employment of staff with less experience and therapy skills (Lowe and Campbell, 2014; Care Quality Commission, 2019): according to the CQC, 'the lack of availability of suitably skilled and qualified staff can mean interventions are often poorly targeted and ineffectively implemented.' YP with depression therefore need access to evidenced based psychological treatments delivered by trained staff.

Delivery modes have also changed with Covid-19 enforcing services to work remotely and offer blended therapy, taking into account patient preference, risk and needs. This way of working is likely to continue in the future to optimise access and capacity, but more research is urgently needed. Research into blended therapy for YP is limited (van der Zanden et al., 2012; Huguet et al., 2018), with some emerging evidence for adults (Ly

et al., 2015; Arjadi et al., 2018; Dahne et al., 2019) indicating effectiveness. Current NHS covid recovery protocols suggest blended approaches. An RCPsych survey (Williams et al., 2021) and a survey within our own services report that clinicians find virtual working works best once a therapeutic relationship has been established face to face. A rapid review showed both advantages and disadvantages of remote versus face-to-face work with YP, and that a personalised approach is optimal (James, 2020).

Similarly, NICE (NICE, 2019) recommends patient choice for treatment, since there is limited evidence of superiority of any particular therapy. Our HTA-funded IMPACT trial found outcomes to be similar across 3 therapies in specialist CAMHS, including a brief psychosocial intervention (BPI) that describes good clinical care; however, BPI recommends up to 16 sessions with experienced clinicians (Goodyer et al., 2017). Our BA intervention is briefer (8 sessions), and can be provided by less senior staff. Furthermore, there is evidence that therapy outcomes are similar with fewer sessions (O'Keeffe et al., 2019). BA may thus be a cost-effective first-line treatment in a stepped-care approach to YP presenting with more severe depression in CAMHS. It may also provide further patient choice, particularly as an initial alternative to antidepressants, which may not be acceptable to many YP and carers in specialist CAMHS.

In summary, if BA is effective and cost-effective, it would increase access to a treatment that can be delivered at scale in specialist CAMHS; this study would also give us information on the acceptability of different modes of delivery. BA could potentially free up more experienced staff, reduce waiting times for more specialist interventions, and provide an additional therapeutic response to the future mental health impacts of this pandemic.

2. RATIONALE

There is a current lack of fully powered RCTs and economic evaluations of the use of BA interventions with YP in the UK or elsewhere to date. UK-based feasibility studies, case reports and small RCTs have demonstrated promising results. We aim to build on this research by delivering and evaluating blended BA within specialist clinical services to complement the ComBAT school BA trial (NIHR201174). We have developed, and tested through a feasibility study, a standardised BA package to be delivered online or in-person for use within CAMHS for YP experiencing more severe depression and risk. The trial aims to enable Band 4 and Band 5 mental health practitioners within NHS CAMHS services, to deliver a clinically informed intervention for YP. A fully powered RCT will evaluate its effectiveness, cost-effectiveness and acceptability compared to psychoeducation within the context of treatment as usual.

3. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1. Aims and Objectives

The aim of the trial is to examine the effectiveness, cost-effectiveness and acceptability of blended BA + psychoeducation + treatment as usual (TAU) versus TAU + psychoeducation (PE) in newly referred depressed adolescents in specialist CAMHS.

3.1.1 Primary objective

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

3.1.2 Secondary objectives

1. Co-design and develop our website with YP, to enhance the acceptability and effectiveness of remote delivery, and train therapists to deliver blended BA.

2. 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.

3. Examine immediate and longer-term acceptability, including blended delivery, potential barriers to uptake and engagement from multiple stakeholder perspectives.

4. Use the knowledge gained, from the perspective of all stakeholders, to make recommendations for depression treatment in CAMHS, including for delivery approaches.

3.2. Internal Pilot

An internal pilot RCT will run for 8 months; at the end of the internal pilot, we will apply a red-amber-green (RAG) rating to assess whether the RCT can recruit and retain young people at the required rate and that it can be safely delivered within the timeframe and resources available. The criteria for a "green" rating will be:

We will aim to recruit a total of 176 participants across 5 NHS sites.

	Green	Amber	Red	Stop
Recruitment rate (Target 176)	100%	80-99%	50-79%	>50%

If the above criteria for a green rating are not met at the end of the pilot and the study is in the amber rating, the Trial Steering Committee (TSC) and the Sponsor will advise on how the risks can be mitigated, using information provided from our qualitative work.

Qualitative interviews during the internal pilot will be conducted with participants who consent to the trial, are allocated to BA and engage with their treatment, as well as those who do not begin treatment. This will be used to help inform recruitment and retention for the main trial.

Green: 100% randomisation, continue the trial.

Amber: 80-99% - 80% of target is 4.4 participants per site per month (80% total per site = 141). This would need 6 young people recruited per site per month for the remaining 16 months of the trial. Recruitment procedures will be reviewed, and strategies developed to address problems, including recruiting additional clinics; review in 6 months by the TSC/DMC/TMG. Consideration will be given to recruiting an additional site, as well as increasing clinics within existing sites.

Red: 50-79% - 50% target is 2.75 per site per month (50% total per site = 88). This would need 6.9 participants recruited per site per month for the remaining 16 months of the study. In addition to maximising the number of clinics for recruitment in each site, we will approach neighbouring trusts at each site. There will be close monitoring over 6 months by the TMG/TSC/DMC to assess progress and recruitment and retention strategies. Stop

Stop: in consultation with the funder we will consider close down of the trial.

3.3. Quantitative Outcomes

Measures will be administered to participants by a trained researcher at baseline (n=446), 12 weeks (n=446), 6 months (primary outcome, n=446), and 12 months post-randomisation (naturalistic follow up, n= approx. 300/participants recruited ≥12 months before trial end date). All measures and their time-points of completion are presented in Table 1.

Table 1: Summary of assessments

Assessment	Source	Method of Completion	TIMELINE				
			Screening	Baseline	12 Weeks	6 Months	12 Months *
PARTICIPANT- YOUNG PERSON							
Screening	Screening Log	Research Assistant (RA) /Site staff	X				
Mood and Feelings Questionnaire (MFQ-C)	Questionnaire	Self-completion	X	X	X	X	X
Contact Details	CRF	Research Assistant/Participant		X	YTU to be notified of changes to contact details		
Demographics	CRF	Self-completion/ RA assistance if requested		X			
Eligibility (including Inclusion and Exclusion Criteria)	CRF	PI/Research Assistant/PIs Delegate at site		X			
Consent	Paper/Online Consent Form/REDCap	Self-completion / Research Assistant		X			
Strengths & Difficulties Questionnaire (SDQ)	Questionnaire	Self-completion/ RA assistance if requested		X	X	X	X
Development and Well-Being Assessment (DAWBA)	Online	RA led alongside participant if requested		X			
Revised Children's Anxiety and Depression Scale (RCADS) Brief Version	Questionnaire	Self-completion/ RA assistance if requested		X	X	X	X

Behavioural Activation for Depression (BADS)	Questionnaire	Self-completion/ RA assistance if requested		X	X	X	X
Self- harm & suicidality questions	CRF	Self-completion/ RA assistance if requested		X	X	X	X
Goal based outcomes	CRF	Self-completion/ RA assistance if requested		X	X	X	X
Child Health Utility -9 Dimensions (CHU-9)	Questionnaire	Self-completion/ RA assistance if requested		X	X	X	X
EQ-5D-Y	Questionnaire	Self-completion/ RA assistance if requested		X		X	
Healthcare Service Use schedule	CRF	Self-completion (with assistance from carer)		X	X	X	X
Aspects of Care Contamination Checklist	CRF	Self-completion/ RA assistance if requested			X	X	X
Working Alliance Inventory (WAI-S)	Questionnaire	Self-completion	(Collected halfway through intervention delivery)				
End of BA treatment Questionnaire	Questionnaire	Self-completion	(Collected after final session of BA therapy)				
Optional Qualitative Interview	Semi-structured interview	Interview				X	
PARENT/CARER							
Consent	Paper/Online Consent Form/REDCap	Self-completion / Research Assistant		X			
Demographics	CRF	Self-completion/ RA assistance if requested		X			

Strengths & Difficulties Questionnaire (SDQ)- Parent version	Questionnaire	Self-completion/ RA assistance if requested		X	X	X	X
Development and Well-Being Assessment (DAWBA)	Online	RA led alongside participant if requested		X			
Mood and Feelings Questionnaire (MFQ) Parent version	Questionnaire	Self-completion/ RA assistance if requested		X	X	X	X
Carer EQ-5D-5L	Questionnaire	Self-completion/ RA assistance if requested		X		X	
Generalised Anxiety Disorder (GAD-7)	Questionnaire	Self-completion/ RA assistance if requested		X		X	
Patient Health Questionnaire (PHQ-9)	Questionnaire	Self-completion/ RA assistance if requested		X		X	
Optional Qualitative Interview	Semi-structured interview	Interview				X	
RESEARCH ASSISTANT/RESEARCH TEAM							
Treatment as Usual Questionnaire	Questionnaire	Self-completion/Clinical records				(X – IF PARTICIPANT IS NOT DUE A 12 MONTH FOLLOW-UP)	X
Safety Reporting	CRF	Research Assistant/PI/Clinician	X (collected throughout)				
BA Completion (Discharge Information)	CRF	Clinician/Research Team	X (collected throughout)				
Trial withdrawals	CRF	Research Assistant/PI/Clinician	X (collected throughout)				

Table 2: Summary of BAY therapist assessments.

Assessment	Source	Method of Completion	Pre-trial delivery	1st session	2nd session	3rd Session	4th Session	5th Session	6th Session	7th Session	8th Session	End of trial
BAY THERAPIST												
Demographics	CRF	Therapist	X									
BA Session Log	Questionnaire	Therapist		X	X	X	X	X	X	X	X	
Safety Reporting	CRF	Therapist	X (collected throughout)									
End of BA treatment Questionnaire	Questionnaire	Therapist									X (after final session)	
Fidelity to BA Checklist*	CRF	Independent Assessor										X
Qualitative Interview	Semi-structured interview	RA led										X

* Random selection of recordings based on pre-selection criteria: commence in year 2 of trial

3.3.1 Descriptions of outcome measures & assessments

A mixed methods approach will use quantitative and qualitative methods, and will involve trial participants, parents/carers, therapists delivering the BA intervention component, and researchers involved in recruitment for the trial.

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 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 sub-set of participants.

<u>Mood and Feelings Questionnaire (MFQ)</u>

- *Young people*

The Mood and Feelings Questionnaire (MFQ) (Angold et al., 1995; Costello & Angold, 1988) is a screening tool for depression in children and young people 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 Mood and Feelings Questionnaire to be a reliable and valid measure of depression in children in both clinical and non-clinical samples (Burleson Daviss et al., 2006; Sund, Larsson and Wichstrom., 2001; Wood et al., 1995).

- *Parents*

The MFQ Parent Report is a 34 item measure (Angold et al., 1987). 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

- *Young People*

On entry to the study, participating young people 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. Young people 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.

- *Carers*

On entry to the study, participating parents will be asked to complete a short demographic questionnaire to obtain information about their age, gender, ethnicity, religion, and socioeconomic status.

- *Therapists*

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)

-*Young people and parents/carers*

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 (Goodman et al., 2000). The DAWBA covers the common emotional, behavioural and hyperactivity disorders, without neglecting less but sometimes more severe disorders.

Information is collected from up to three sources:

- An interview with 11-17 year olds themselves (Included in the BAY Trial at baseline)
- An interview with the parents of 11-17 year olds (Included in the BAY Trial at baseline)
- A questionnaire completed by teachers of 11-17 year olds. (Not included in the BAY Trial as educational professionals are not involved in the study)

The interviews and questionnaires involve 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 (young people 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 (Goodman et. al., 2000).

Strengths & Difficulties Questionnaire (SDQ)

- *Young People*

The SDQ measures emotions and behaviours of YP and the SDQ (25 items) + impact scale will be used here (Goodman, 1997). 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'. Some items are reverse scored, and so a higher score on the SDQ indicates greater difficulties within the subscales.

The extended version of the SDQ asks whether the respondent thinks they have a problem, and if so, enquires further about chronicity, distress, social impairment, and burden to others. This provides useful additional information for clinicians and researchers with an interest in psychiatric caseness and the determinants of service use.

- *Parents*

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 (Chorpita et al., 2000) 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 (available on the measure's website https://www.childfirst.ucla.edu/resources/). 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.
This scale is routinely used in CAMHS and will provide information about anxiety, a common comorbid problem in YP with depression; it will also allow for direct comparisons with the other current UK BA trial taking place in school populations (COMBAT).

Self-harm and suicidality measures

A brief bespoke measure of self-harm and suicidality will be used to collect information directly from the young people 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. 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 9-item questionnaire, based on the longer, 25-item BADS (Kanter et al., 2007; Manos, Kanter and Luo, 2011) that measures levels of activity on 2 sub-scales: activation (goal-directed action and completion of scheduled activities) and avoidance (procrastination rather than active problem solving). The BADS-SF consists of 9 questions, each rated based on the previous week on a seven-point scale ranging from 0 (not at all) to 6 (completely); higher scores represent increased behavioural activation. Total scores on the BADS-SF range from 0 to 54. We will use the BADS-SF to monitor self-reported activity and avoidance. Although the scale has not been validated with an adolescent population, we will use it as 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 (Stevens, 2010) 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 young people valuation set will be used to derive the utility values (Stevens, 2012). 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 (EURO-QOL Research Group, 2018). 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 (EURO-QOL Research Group, 2018). 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 (CA-SUS) for completion by participants, with assistance from their parent/carer. Its purpose is to collect information about use of health and social care by each young person during the study period. This will be used to estimate costs for the economic evaluation. To incorporate a broader perspective, the schedule also captures information on the amount of time parents/carers spend with YP at health and social care contacts. The questionnaire has been reviewed by PPI panel members and revised based on their feedback.

Goal Based Outcome measure

Young people will be asked to work with the Research Assistant 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' (Law, 2013). This will evaluate clinical progress throughout either behavioural activation or treatment as usual. 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 (based on the COMBAT study measure) that has 4 items to help assess contamination, i.e. where an individual randomised to treatment as usual 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 treatment as usual would be expected to answer "no" or 'I don't know'.

Working Alliance Inventory (WAI-S)

The WAI-S 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 (Hatcher and

Gillaspy, 2006). 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. (Paap & Dijkstra, 2017).

End of treatment questionnaire

- *Young People*

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. Young people who withdraw from the intervention before their 8th session will be asked to complete this measure at the point they stop their BA sessions. The questionnaire will generate quantitative and qualitative data which will contribute to overall acceptability measures.

- *Therapists*

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 be distributed by an unblinded member of the research team and 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) (Kroenke, Spitzer and Williams, 2001). 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) (Spitzer er al., 2006). 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.

Serious Adverse Event Forms

Adverse event forms will be completed by a trial manager when they have been reported. Adverse event forms will detail what the event was, who reported it and the outcomes. The procedure for reporting and collecting data about adverse events is highlighted in Section 7.6

Fidelity to BA rating scale

Where consent has been provided from the participant, BA therapy sessions will be audio recorded. To assess the fidelity of the BA component, fidelity to BA principles will be assessed via the review of therapy recordings against the fidelity criteria by a clinician who has expertise in BA and who is external to the delivery of BA in the BAY trial. This procedure will occur once the last recruited participant has attended their final session. 10% of BA session recordings will be assessed and selected at random and a procedural fidelity checklist completed by the assessor whilst listening to the audio recording of the sessions.

Qualitative interviews

Refer to the Section 10: Qualitative Study for further details.

4. STUDY DESIGN

We will conduct a parallel two-group RCT, with an internal 8-month pilot to compare the effectiveness of BA +psychoeducation+TAU against TAU+psychoeducation. Nested within the study will be an embedded qualitative study to assess acceptability and implementation of behavioural activation, and economic evaluation (as described in section 10 & 11) of BA's cost-effectiveness relative to psychoeducation+TAU alone.

5. STUDY SETTINGS

The study will be conducted within CAMHS sites responsible for providing support to young people with moderate and severe depression. These sites will be involved in the identification of study participants and will be the locations for intervention delivery. The site must have a BAY trained therapist (trained by psychology leads based within each Trust, PI and psychologist PI from the study) and local supervisor to deliver the BA component. To allow for the option of remote delivery of BA, the site must also have access to the required software and technology to be able to deliver the BA sessions using

video conferencing software. Each CAMHS site will also provide treatment as usual for each participant, which will include access to any urgent care that may be required.

Research Assistants will be based either within CAMHS or their R&D unit within the NHS Trust, and they will be responsible for recruitment and data collection at all timepoints. Some measures will be collected by the trial managers to avoid unblinding the RAs.

6. PARTICIPANT ELIGIBILITY CRITERIA

6.1. Inclusion criteria

Young people will be eligible for the study if they:

1. Are aged 11-17 years at the date of consent.*

2. Score ≥27 on the Mood and Feelings Questionnaire (this is the standardised cut-off by which elevated symptoms of depression warrant further assessment and potential intervention).

3. Recently accepted into specialist CAMHS. (≤6 weeks)

4. Provide consent, or assent along with their carer's consent (if applicable), to participate in the study

*Up to 17 years and 6 months

6.2. Exclusion criteria

Young people will <u>not</u> be eligible for the study if they:

1. Have a severe mental illness that is not primarily depressive (e.g. schizophrenia, non-depressive psychosis, current mania, anorexia).

2. 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 (clinical judgement).

3. Cannot speak English to a sufficient level to understand the intervention and research materials.

4. Have an intellectual disability of a level which prevents adequate understanding of the study or intervention materials.

5. Have received 8 sessions of therapist-led CBT (including behavioural activation) in the previous 6 months.

6. If there is more than one eligible child in the family, only one child will be consented into the study and randomised and the same randomised treatment will be offered to the sibling.*

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

7. STUDY PROCEDURES

7.1. Recruitment

We will recruit participants through NHS CAMHS. CAMHS sites within 5 NHS Trusts will be invited to both promote the RCT and assist with identifying young people who may be suitable and interested in participating. BAY research team members will work closely with members of the CAMHS team to ensure that the professionals understand the study and its inclusion criteria. The study will be embedded within the CAMHS team to ensure all potential participants are aware of the opportunity. There will be 3 methods of recruitment through the CAMHS service: 1) Identification by clinician, 2) MDT Meetings, and 3) Screening records

1) Identification by clinician

CAMHS clinicians conducting 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 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 MFQ may have been conducted via routine clinical assessment and this score 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 young people 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.

2) MDT Meetings attended by the RA

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 due to low mood. RAs will attend this meeting on a regular basis to identify potentially eligible participants for the study. 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.

3) Screening records by the RA

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 young people with low mood who are potentially eligible young people. Search terms for screening patient records will be standardised across CAMHS sites. 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 will 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.

<u>Eligibility screening process</u>

Once a YP 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 YP 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 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. 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 treatment as usual (this will be explained to the participant prior to giving consent).

If an eligible YP declines to participate, they will be asked verbally their reason for this and the research assistant will complete a pro-forma based on their response.

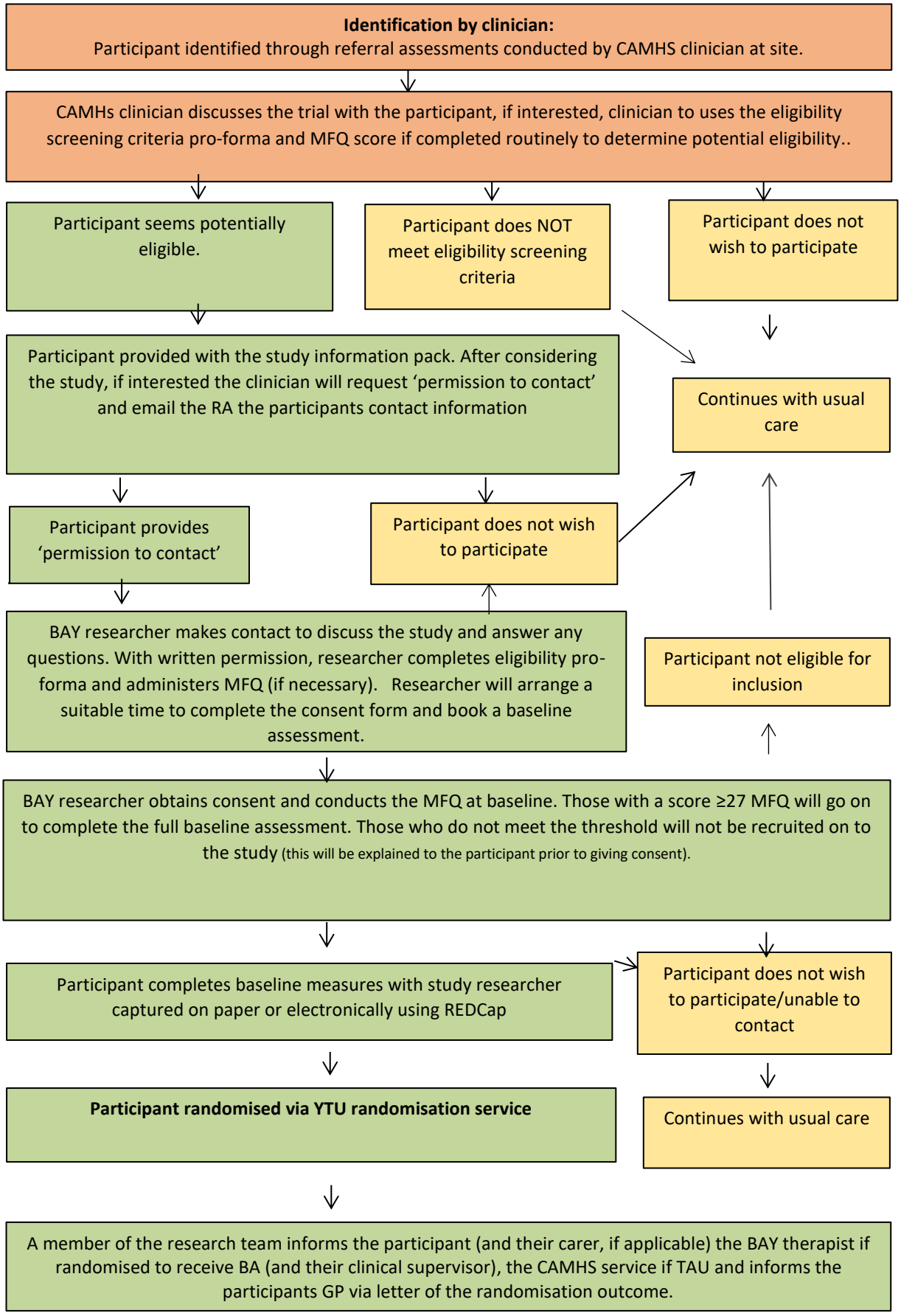
Baseline assessments will be offered face-to-face at CAMHS, NHS or affiliated University sites, in the family home, via video conferencing or another suitable location at a mutually agreed time and date with the young person and parent/guardian; however, these assessments can take place virtually if this is preferred by the YP. 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.

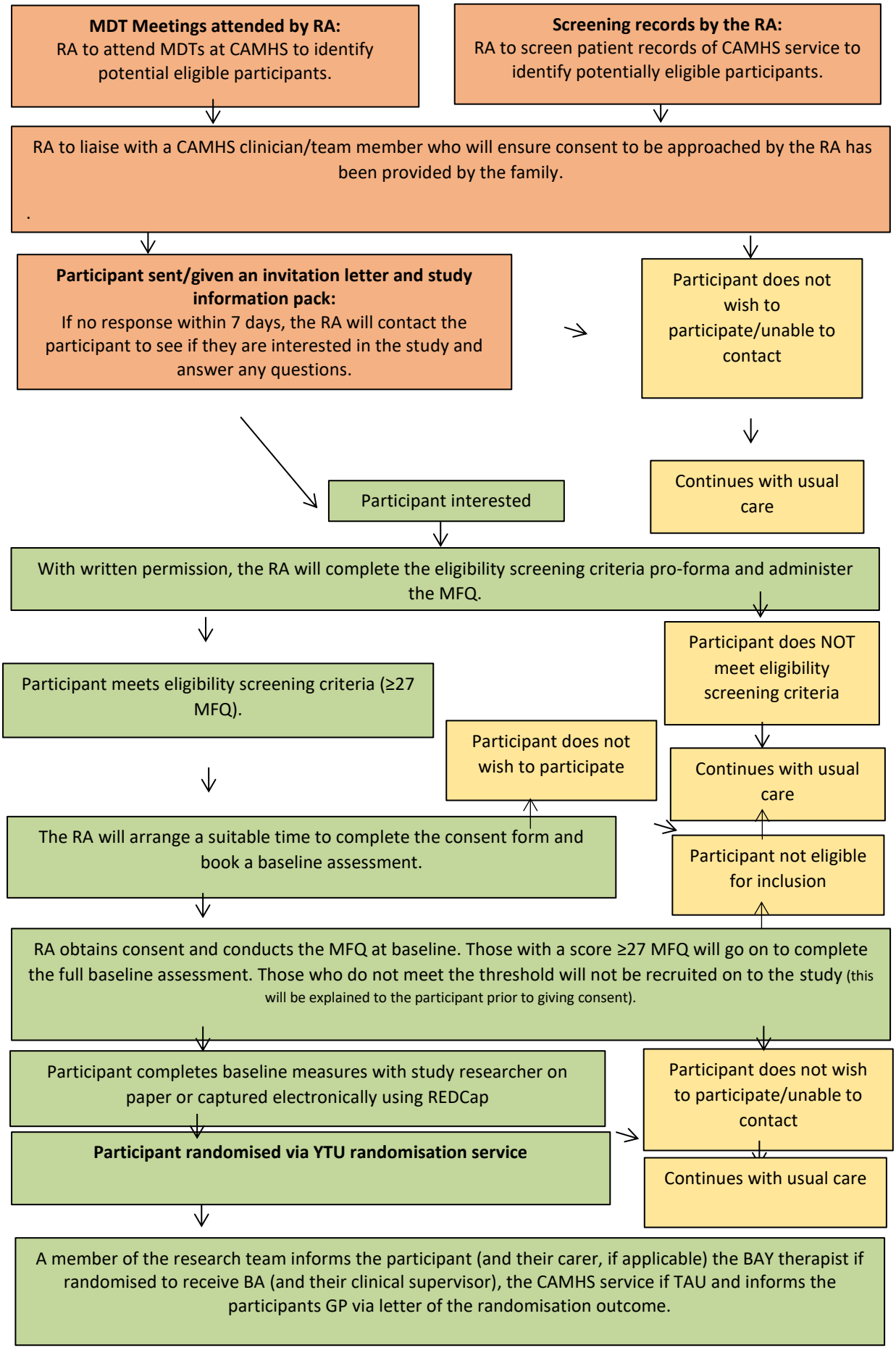
The study information that potential participants will receive includes:

- Invitation letter;
- Participant Information Sheet, including a step-by-step guide for how to participate and what is involved, together with the researchers contact details;
- Consent/Assent form.

Flow Diagram 1. Participant identification and Recruitment- Route 1



Flow Diagram 2. Participant identification and Recruitment- Route 2 & 3



7.2. Informed consent

Prior to the baseline visit the researcher will call the carer and/or young person to reiterate the trial aims, discuss what participation entails and answer any questions young people and/or their carers have regarding the research. If happy to proceed, informed consent/assent will be obtained from young people and carers. Throughout the trial, potential participants who decline to take part in the trial will be asked verbally by the researcher their reason for not taking part. The researcher will record this on a 'tick box' pro-forma with a list of potential reasons for declining, with an 'other' option and free text option. Potential reasons for refusal will be discussed with our advisory panels and will inform the main trial process.

Throughout the recruitment process the research assistant will attempt to contact the participant no more than four times.
Consent will be obtained on paper or via a secure online data capture system, where participants will be sent the link via email by the researcher and asked to tick all clauses that apply and then provide an electronic signature. Participants can complete the consent form independently before the baseline MFQ, or at the baseline appointment with the researcher. The consent process will vary depending upon the age of the young person.

<u>Young people aged 11 to 15 years</u>

Young people aged 11 to 15 years will be required to complete an assent form, alongside their carers consenting for them to be able to take part in the trial. The research assistant, with guidance if necessary from the clinician or PI at the local CAMHS site, will determine the participant's capacity to provide informed consent/assent (the YP can understand the information given to them about the study, retain the information, be able to relay the information back to the research assistant and can make a decision about participation). Training will be provided to RAs regarding assessing competence/capacity. As part of this, a carer will be required to confirm that they will support their child during their time in the trial. The carer will sign a consent form on the young person's behalf, including permission for their child to take part in the study as well as consent for themselves to take part in the study.

<u>Young people aged 16 to 17 years</u>

Young people aged 16 to 17 years will be required to complete a consent form to participate in the trial. Whilst carer consent will not be required, young people will be reminded that involving carers in the completion of BA may provide a useful form of additional support during their participation (e.g. in supporting activation attempts). Whether 16- to 17-year-old participants choose to involve carers in the completion of BA is based upon individual choice. 16-17 year olds will be informed that their parents will be asked to complete their own questionnaires if they choose for them to be involved in the study via the Participant Information Sheet and if in agreement the parent/carer will sign their own consent form.

7.3. Procedure

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

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

The full baseline assessment will include: demographic questionnaire, DAWBA, SDQ, RCADS, WAI-S, CHUD-9D, EQ-5D-Y, WHO scale, suicidality questions, service use, GBO.

The carer will complete: MFQ, DAWBA, SDQ, and EQ-5D-5L on behalf of their child's mental health and PHQ and GAD-7 to report their own mental health.

On completion of the baseline measures, participants will be randomised to either receive BA+PE+treatment as usual or treatment as usual +PE.

A member of the trial management research team will inform the participant (and their carer, if applicable) and the BAY therapist if randomised to receive BA (and their clinical supervisor) and inform the participants GP via letter of the randomisation outcome. Upon informing the participant of their allocation, the trial managers will distribute the psychoeducation leaflet to the participants.

If randomised to BA, treatment sessions will be arranged by the local BA therapist who will liaise with the young person and, if appropriate, their carer (e.g for children aged between 11-15 years). Trial Managers will distribute a session log for the BA therapist to complete online/ on paper upon completion of each BA session delivered. Session logs will collect information about 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.

If randomised to TAU+PE alone, the local manager will arrange treatment as usual as required. The researcher will arrange follow-up meetings at 12 weeks, 6 months and 12 months from the point of randomisation and will keep in contact with the young person before these meetings as needed. Participants will only be asked to complete the 12 month follow-up if they are recruited before July 2024 due to the study completion date (August 25).

Research assistants will screen clinical records at the end of the young person's participation to identify what other treatment and therapies they have been receiving from CAMHS. If there is any information about private care this will be noted too. Research assistants will use a treatment as usual questionnaire to record this information. This is a list of therapies and interventions offered by CAMHS, gathered from PPI panels and PIs at each site, an option for 'other' and discharge information.

7.4 Randomisation

Young people will be randomised in 1:1 ratio to either BA, psychoeducation and TAU or psychoeducation and TAU using stratified block randomisation. 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 and use randomly-varying blocks of randomly-varying sizes. The Trial Managers based at YTU will inform the behavioural activation therapists who has been allocated to receive behavioural activation.

7.5 Post Randomisation

7.5.1 Blinding

All research assistants collecting follow up data will be blind to participant group 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, with additional support from the qualitative researcher as required, who does 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.

If unblinding occurs all blind breaks including accidental unblinding will be recorded by the trial manager and reviewed by the Chief Investigator for patterns in unblindings and be reported to the TSC and DMEC. If unblinding occurs and if feasible an RA from another site will collect follow up data from the young person and carer (if applicable).

7.5.2 Withdrawal of consent

The right to refuse participation without giving reasons will be accepted. Participants are free to withdraw consent and leave the trial at any time without giving reasons and without affecting their care. If a patient withdraws consent to participate, clarification will be sought on whether withdrawal is from the intervention (BA), completing the questionnaires, or both. Data collected up to the date of withdrawal of consent will be used in the analyses.

7.5.3 Treatment discontinuation

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 trial if there is reason to believe that they have, after screening and consent, become unsuitable

for the study such that 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 the capacity to consent to participate in the trial;
- 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.

7.5.4 End of Trial

The end of trial is defined by the last visit and completion of data collection of the last participant undergoing the trial. The sponsor, or delegated individual in the study team must notify the NIHR and HRA of the end of a clinical trial within 90 days of its completion.

7.6 Monitoring and reporting Adverse Events (AE) and Serious Adverse Events (SAE)

Table 3: Definitions of AE and SAE

Term	Definition
Adverse Event (AE)	An adverse event is; • any unintentional, unfavourable clinical sign or symptom • any new illness or disease or the deterioration of existing disease or illness
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: (a) results in death (b) is life-threatening (c) requires inpatient hospitalisation or prolongation of existing hospitalisation (d) results in persistent or significant disability/incapacity (e) consists of a congenital anomaly or birth defect (f) is otherwise considered medically significant by the investigator Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

	NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
Related Unexpected Serious Adverse Event (RUSAE)	The National Research Ethics Service (NRES) defines related and unexpected SAEs as follows: ● 'Related' – that is, it resulted from administration of any research procedures; and ● 'Unexpected' – that is, the type of event is not listed in the protocol as an expected occurrence.

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).

Clinical teams will be trained to report the serious adverse events outlined above to the Trial Managers from the York Trials Unit. Clinical professionals will be asked to complete a serious adverse events form and send it to the Trial Managers, who will process it at the trials unit.

Items relating to hospitalisation on the CA-SUS as well as concerning responses on the self-harm and suicidality questions will be flagged up at all follow-up timepoints in both arms and the Trial Manager 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 research assistant or BAY therapist, or the site team become aware of such an event in the TAU arm, it will be reported to the Trial Manager as soon as possible and the same above process will occur.

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 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.

7.7 Protocol Deviations/ Violations

7.7.1 Protocol Deviation

A protocol deviation can be defined as any accidental or unintentional change to, or non-compliance with the research protocol that **does not** increase risk or decrease benefit or, **does not** have a significant effect on the participant's rights, safety or welfare; and/or on the integrity of the data. Deviations may result from the action of the participant, researcher, or research staff.

A deviation may be due to the participant's non-adherence, or an unintentional change to or non-compliance with the research protocol on the part of a researcher.

Examples of a deviation include, but are not restricted to:

- A rescheduled trial visit.
- Participant refusal to complete scheduled research activities.

Deviations will be documented on a trial specific CRF and reported to the TMG and TSC as agreed in the Trial Monitoring Plan (TMP).

7.7.2 Protocol Violation

A protocol violation can be defined as any accidental or unintentional change to, or non-compliance with the protocol that **does** increase risk or decrease benefit, or has a significant effect on the participant's rights, safety, or welfare, or on the integrity of the data.

Examples of a violation include, but are not restricted to:

- Failure to obtain valid informed consent.
- Breaches of eligibility criteria.

8. INTERVENTION AND COMPARATOR

8.1. Intervention: Blended Behavioural Activation

8.1.1 Content

"Be Active" (13) workbooks (8 sessions) have been developed to include blended delivery plus TAU+psychoeducation versus TAU+psychoeducation. The BA program is designed to be structured, yet flexible in delivery. 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. The first 4 sessions focus on introducing BA, goals, values, and activity scheduling (See Table 4)

The BAY 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 days led by local therapy leads which will include practice case discussion); and required reading of existing material on behavioural activation and depression (RCPsych/minded.org).

A website for blended delivery will be developed in order to enhance our current basic website in order to improve the experience of remote therapy, and will include animations. Young people fed back that our original website was easy to use, but would benefit from more functionality and improved design. Therefore, 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.

Table 4: Eight BA modules in BAY

Module	Topics covered
Module 1: Goal setting, Psychoeducation and Recording	• Engagement, personalisation, getting to know the young people and 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 enjoyment and achievement • 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 behavioural activation 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

8.2 COMPARATOR: Psychoeducation plus Treatment as Usual

Following randomisation, all young people will receive a website link to a psychoeducation leaflet from the Royal College of Psychiatrists. The leaflet provides information about depression and signposting to where young people can find extra support. Carers (if involved) will also receive carer information regarding depression in young people, as well as signposting for carers.

Usual practice in CAMHS can vary widely (experience of the trial team and in national reports eg CQC 2018). Treatment as usual may be no intervention whilst on an internal CAMHS pathway waiting list; signposting to alternative sources of support; risk and case management; referral to a psychiatrist for medication review; or referral for psychological therapy, however, these generally have long waiting lists. Currently waiting lists for therapy in CAMHS services vary and can be months.

We will record and monitor what treatment as usual means for each young person recruited into the study. We will devise a pro-forma for RAs to complete using clinical records. This will capture all interventions that were delivered in CAMHS, including BA, and recording of risk issues such as attendance at A&E.

When reviewing clinical records we will particularly look for any aspects of treatment as usual that are similar to BA e.g. rating and structuring activities. Even in sites where BA-type interventions may be included in treatment as usual (such as brief psychosocial support), from experience within the associated teams, it is expected that these interventions are sufficiently different to our BA. For example, they are not standardised or do not include key components such as activity scoring.

8.3 Delivery

The BAY therapist will be the first point of contact within the CAMHS team for the Trial Managers. Therefore, immediately after randomisation, the Trial Managers from YTU will contact the BAY therapists (and their clinical supervisor) to inform them of the young person's allocation. The Trial Managers will also inform the young person and their carer (if applicable) of their allocation. For the intervention arm, the BAY therapist will then contact the YP to arrange the first session and begin delivering behavioural activation.

BA will be delivered by trained members of staff based within CAMHS. Given that part of our study's rationale is that BA can be disseminated by professionals with less therapy training and who are less expensive to employ, we will exclude professionals on or above NHS pay grade 6 who are usually experienced qualified clinicians. Professionals in CAMHS whose role is to work with young people with mental health and emotional difficulties and who are below grade 6, include: assistant psychologists (APs), education mental health practitioners (EMHPs), children's wellbeing practitioners (CWPs), newly qualified nurses. These will be supported by a grade 7 supervisor within CAMHS, including clinical psychologists and experienced CBT therapists. A lead psychologist and co-applicant on the trial will oversee all supervision for BAY therapists and their supervisors.

There will be at least two trained BAY therapists within each NHS Trust. If one therapist cannot continue delivering BA with a young person, the other trained therapist will be allocated to that young person. If a therapist ceases to be involved in BA delivery, the PI

and psychology lead at the site will identify whether there are any other suitable Band 4 or 5 clinical professionals within the CAMHS service. If so, they will be trained to deliver BA. If not, a band 4 or 5 clinical professional will be recruited internally or externally and trained to deliver BA. This will ensure there are two BA therapists at site.

To enable the collection of data on procedural fidelity, we will ask therapists to complete a procedural fidelity checklist at the end of each session. With the participants consent all therapy sessions will be audio recorded to enable assessment of BA fidelity on 10% of sessions at the end of the trial.

8.4 Identifying and mitigating contamination

Pathways to, and sources of, contamination

Contamination would occur if young people randomised to treatment as usual receive elements of BA. This may happen for the following reasons:

- At service level: Treatment as usual services offer BA as a standalone intervention or elements of BA as part of another intervention, such as cognitive behaviour therapy.
- At professional/therapist level: Professionals supporting young people in treatment as usual inadvertently or deliberately deliver BA. This can happen if professionals: have previously been trained in BA; received BA training as part of BAY and support participants in both BA and treatment as usual arms; access BA resources on their own accord online or publicly available treatment manuals (e.g. prompted by reading about BA in the BAY protocol).
- At participant level: Participants randomised to treatment as usual access BA materials.

Preventing contamination

- Where possible, sites will identify separate professionals to support BA and treatment as usual for participants in the trial. If the same professional delivers both BA and treatment as usual, the BA trainer and supervisor will ask the professional to avoid using any resources, principles or techniques of BA as part of treatment as usual .
- Access to the BAY manual alone, previous training, or self-directed learning are not sufficient to deliver BA at a standard that will be considered 'contamination in BAY'; this requires training by the research team plus consistent supervision to be able to deliver BA with fidelity.
- A Contamination Information Sheet (CIS) outlining what 'contamination' of treatment as usual is, why it is important to prevent it in BAY, how to prevent it, and what to do if it happens. The CIS will be included in the local information pack sent to the participating sites and in the BA training pack for professionals.
- The importance of avoiding contamination will be covered in detail at the two-day training event for BAY therapists. BAY therapists and their supervisors who attend the training will be asked to disseminate this information to their CAMHS service.

Monitoring Contamination

- Training: Therapists and supervisors will be informed at the BA initial training event about the importance of avoiding contamination in the TAU arm post randomisation. BAY leads will then disseminate information to clinics and managers and regularly remind them of this.
- At sites: BA therapists will avoid delivering regular sessions to young people allocated to treatment as usual alone post randomisation, in conjunction with managers/site leads.
- Aspects of care questionnaire: All YP to complete an 'aspects of care questionnaire' which asks about BA elements of their treatment from any source at follow up (including external to CAMHS).

Addressing Contamination

- We will assess contamination as above as part of the 8 month internal pilot by reviewing the Aspects of Care questionnaire.
- If contamination is present (or suspected) in a site, the research team will contact the site and discuss ways to mitigate this e.g. identifying alternative professionals to deliver treatment.

9. STATISTICAL AND DATA ANALYSIS

9.1 Sample Size

For 90% power to detect an effect size of 0.3125 we will require 8 groups of 28 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(Wood et al., 1995) 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 (Goodyer et al., 2017; Goodyer et al., 2007,). 7% attrition was observed at 6 months in the HTA ADAPT trial and 16% in IMPACT, however this was at 18 months. Conservatively inflating the current sample size by 15%, we will recruit a total sample size of 528.

On 28th April 2025the funder approved a request from the study team for a costed extension, under the condition that the sample size be recalculated to provide 80% power. Assuming based on the trial data collected so far an updated baseline-follow-up correlation of 0.45, 13 groups of 12 participants in the intervention arm, a 70% retention rate, an effect size of 0.30 and keeping all other parameters the same, 446 participants (223 per group) are required for 80% power to detect a minimum clinically important difference of five points on the MFQ-C.

9.2 Statistical Analysis

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 by trial arm will be given in terms of the mean and standard deviation (or median and inter quartile range as appropriate). Descriptive summaries of categorical data will be given 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 therapist (nested within treatment arm). The primary analysis will compare the groups at 6-months post-randomisation. Secondary analyses will compare the groups at 12-weeks and 12-months post-randomisation. 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.

Sensitivity analyses assessing the robustness of results to deviations from the missing at random assumption will be carried out. We will also explore potential associations between therapist characteristics and outcomes. If any such associations are found, a sensitivity analysis will be carried out repeating the primary analysis with the addition of any confounding therapist characteristics as fixed effects.

The efficacy of the intervention in participants who complied with the intervention will be assessed using Complier-Average-Causal-Effect (CACE) analysis.

Any planned subgroup analyses will be pre-specified in the statistical analysis plan.

10. QUALITATIVE STUDY

10.1. Study design

An embedded qualitative study will capture and compare the experiences of young people and professionals participating in the RCT as a means of assessing BA's acceptability, but also as a way of understanding some of the contextual, implementation and mechanistic factors that may influence intervention use and outcomes.

10.2. Participants and sample size

Young people and Carers

During the internal pilot, we will seek to identify and recruit 15 'early exit' participants who initially consent but who do not commence the BAY intervention. These young people and/or their designated carer (where available) will be invited to participate in a qualitative interview to explore potential barriers and enablers to intervention commencement.

Across the internal pilot and main trial phases, we will complete one-to-one qualitative interviews with 25-30 young people and 25-30 carers per arm (~120 interviews) to explore intervention acceptability. Participants recruited in the internal pilot phase (max n=10-12) will additionally be asked about their experiences of trial recruitment and research processes.

Eligible participants will be the cohort of participants who consented at trial recruitment/baseline to be contacted about an interview, as recorded on the YTU database. We will purposefully sample across sites, and intervention engagement levels (<4, 4+ sessions), and use maximum variation sampling to ensure a spread of participants in terms of age, gender, SES and baseline depression severity.

The final sample sizes for the young people and carer samples will be determined by data saturation; we will continue to recruit until team consensus suggests saturation has been achieved. Participants may include but not depend upon, recruiting young people-carer dyads.

Professionals:

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 Behavioural Activation) 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.

10.3. Recruitment

Young person and carer 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.

Immediately after participants' 6-month follow-up date, a qualitative researcher from the research team will provide participants with a qualitative interview information sheet and invite a young people and/or their carers (where appropriate) to an interview. Participants will have at least 24 hours to decide whether to take part in the interview after receiving the information. After this point, a researcher will re-contact the participants to discuss any questions, complete an additional consent/assent form and arrange the interview. Interviews will be conducted within 4-6 weeks post primary outcome point in both internal pilot and main trial phase.

Professional recruitment

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.

Additionally, 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. Professionals will be provided with an information sheet outlining the aims of the interview and what participation will entail. Those interested in taking part will be asked to complete a consent form.

10.4. Procedure

All 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... In exceptional cases where remote interviews cannot be facilitated, on participant preference, they will be held in-person in a mutually convenient private location.

Interviews recorded on MS teams will be stored on Microsoft Office 365 cloud and subsequently downloaded and saved in a folder on the secure network on an NHS or University computer with access restricted to the study team. Recordings will be deleted from Microsoft Office 365 once downloaded. Participants will be given the option to switch their camera off so only an audio recording will be made.

Interviews recorded on Zoom will be audio recorded only and will be saved directly in a folder on the secure network on an NHS or University computer with access restricted to the study team. Interviews recorded on an encrypted Dictaphone will be securely transferred to a secure folder on the secure network on an NHS or University computer,

and will be deleted from the Dictaphone. Access to recordings will be restricted to the study team.

Topic guides for YP and parents will be co-developed with the PPI panel members' feedback to ensure the questions are appropriate and suitable for the participants.

All interviews will last 60-90 minutes and will be audio recorded and transcribed verbatim, to which participants would have given permission when signing the assent/consent form. Participants will be reminded that the discussion will be recorded before it starts. All recordings will be transcribed by a sponsor approved transcription company. When the transcriptions have been checked for accuracy by the research team, all audio-recordings will be erased. Interview transcripts will each be given an individual linking identifier to maintain participant confidentiality.

Interview schedules for parents and YP will be codeveloped with the PPI panel members and informed by the Theoretical Framework for Intervention Acceptability (TFA; Sekhon, Cartwright and Francis, 2017) Professional interviews will be informed by the TFA and the Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2009)

10.5. Data analysis

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; Sekhon, Cartwright and Frances, 2017) and Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2009). Each dataset will be analysed separately and combined in a data synthesis. Analysis will be led by a qualitative researcher, together with the YP co-researcher (for YP data) under the supervision of PB. Data interpretation will be discussed regularly, and a shared coding scheme agreed. New codes will be added, and duplicate or superfluous codes removed as analysis progresses. Excerpts of data analysis and preliminary study interpretations will be fed back to the project's PPI advisory panels and the research team for verification.

10.6. Ethical considerations

Confidentiality of participants and the data obtained during interviews will be maintained throughout. All interview transcripts will be assigned an identifier with no personal information and pseudonyms will be used when reporting all results. Personal information will be collected in the trial and linked to describe the sample. All recordings will be made using encrypted devices with recordings deleted immediately following transcription. A trained researcher will conduct all interviews and will have a relevant educational background and DBS check.

11. ECONOMIC EVALUATION & MODELLING

The health economic analyses will be conducted following intention-to-treat principles and will follow a pre-specified health economics analysis plan (HEAP). All costs will be presented in Pound Sterling in a single cost year.

11.1 Cost-Utility & Cost-Effectiveness: trial-based analysis

The cost to train the BAY therapists and the cost of their time to deliver the intervention therapy sessions will be estimated as the intervention cost. This will be added to the cost of health and social care resources used by YP in the intervention arm to generate an overall cost for that treatment group. For the TAU+PE group, their overall cost will be generated from their use of health and social resources only. The primary analysis will take the health and social care perspective and so will only include these costs. A secondary analysis will include the cost of 'lost productivity' for parents/carers during the time they spend with YP at (and travelling to) healthcare contacts. Unit costs will be derived from published sources (e.g. NHS Schedule of Reference Costs; PSSRU Unit Costs of Health and Social Care) using the most up-to-date versions at the time of the analysis.

The measure of health benefit in the primary analysis will be YP's QALYs derived from the CHU-9D at baseline and 6-month follow-up. A secondary analysis will derive YP's QALYs from the EQ-5D-Y at these timepoints. QALYs will be estimated using an area under the curve approach.

The difference in costs between the treatment groups will be calculated using a glm regression model with log link and gamma family to account for the typically skewed nature of cost data. The difference in QALYs between the groups will be estimated using a linear regression model. Both regression models will include key covariates, as specified in the statistical analysis. An incremental cost-effectiveness ratio (ICER) will be calculated by dividing the difference in costs by the difference in QALYs between the treatment groups. This will be reported as a cost per QALY. Non-parametric bootstrapping will be used to produce a cost-effectiveness plane to demonstrate uncertainty in the results. A cost-effectiveness acceptability curve (CEAC) will also be generated to illustrate the probability that either treatment is cost-effective at a range of willingness to pay (WTP) thresholds.

The health utility of parents/carers during the study period will be derived from the EQ-5D-5L and compared between the treatment groups.

The time horizon for the primary analysis will be 6 months. An exploratory analysis over 12 months will also be conducted. As the study period does not extend beyond 12 months, no discounting will be applied to costs or health benefits.

11.2 Long-term cost-effectiveness: model-based analysis

If there is evidence that the intervention is cost-effective during the study period, then a decision model will be constructed to explore the costs and health benefits over a longer time period. Due to the remitting and relapsing nature of depression, a Markov model is

appropriate for this population. Two alternative scenarios will be modelled for the long-term benefit of the intervention: continuing what was observed in the trial, and attenuating. Targeted literature searches will be conducted to estimate the probability of relapse and remission of symptoms over time in YP. Costs and QALYs will be derived from data collected as part of the trial. Where published or trial data cannot be used to derive model parameters, they will be identified through consultation with experts (clinical and expert by lived experience). ICERs will be generated to estimate the cost-effectiveness of the intervention versus TAU+PE over time. The time horizon for the model will be determined by the mean age of participants at study entry and the likely age they will leave CAMHS services and enter adult mental health services. A discount rate of 3.5% will be applied to costs and health benefits accrued after 12 months, as per current standard practice in England. One-way and probabilistic sensitivity analyses will be conducted to explore uncertainty in the model structure and parameters.

12. STUDY WITHIN A TRIAL (SWAT)

12.1 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.

12.2 Retention SWAT

The York Trials Unit 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.

13. 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. A broad range of YP with experience of depression and carers will be recruited to our PPI activities:

1. Digital panel for website development (8 YP): co-design workshops with the YP Trial Advisory Panel and an active Greater Manchester Mental Health digital PPI group led by PW. Our expert by experience (NR or EW) will join the co-design workshops. Additional co-design workshops will take place during website development with members of the research team.

2. Young Person Trial Advisory Panel (8 YP): co-led by PPI leads, SY, EW and NR, will meet throughout the project; additional oversight will be provided by a senior PPI expert. This panel will actively contribute to all aspects of the research, e.g. ethics approval, website co-design, reviewing the content of BA training, participating in training events, participant information, co-producing trial updates for participants eg newsletter, social media, video blogs; evaluating and disseminating findings.

3. Carer Panel: led by the carer lead, TW, and SY. 5 additional carers will be recruited across the sites.

4. Qualitative PPI: a YP will co-design the qualitative interview schedules and contribute to qualitative analysis workshops (led by PB).

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. Throughout the trial there will be additional opportunities to get involved, for example creating and reviewing content for our social media pages and providing feedback on digital elements of the intervention. There will be a range of opportunities for participating in project dissemination activities including cofacilitating and presenting at the dissemination meeting, video-blogs, publication authorship as peer researcher and presenting at conferences.

14. MONITORING, AUDIT AND INSPECTION

We will follow trial monitoring and site monitoring procedures in accordance with the standard operating procedures of both the study trials unit (York Trials Unit) 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.

15. ETHICAL AND REGULATORY CONSIDERATIONS

15.1. Health Research Authority (HRA) review

Ethical approval in line with NHS Research Ethics Committee (REC) and HRA guidance will be sought for the completion of this trial. Both the REC and HRA will be notified of, and asked to review, any proposed changes to the procedures and/or documentation made during the trial. As no pharmaceutical compounds or medical devices will be used in the study Clinical Trials Authorisation will not be required.

15.2. Ethical considerations

Several ethical issues have been considered to enable the safe running of this trial. First, young people with depression can be vulnerable and may experience distress or worsening symptoms during their participation. All participants entering the trial will be provided with information outlining who to contact if they (or their carer, if applicable) have any concerns or worsening symptoms during participation. This will include providing individuals with the contact information of their local NHS CAMHS duty clinician service which provides urgent assessments during office hours on weekdays. If a participant feels at risk outside of these hours they will be signposted to the out of hours on-call service provided by their local NHS mental health trust which is available 24 hours a day, 7-days per week. In serious situations young people will be directed to present at their local A&E department or call 999. This will be made clear within the participant information sheets and reiterated during the baseline visit with the researcher.

Throughout the research, any potential adverse events (e.g. distress, misunderstandings, deteriorating mental state) will be monitored closely by the research team. We will encourage all participants to speak to their clinical team if they are unhappy about their participation in the research. We will explicitly state in the study information sheets that participants can withdraw from the project at any time and do not have to give a reason. Withdrawal from the research will not impact upon any therapies they may receive now or in the future.

All data collected from participants during the trial will be confidential and will not contain any information that may lead to the identification of an individual. All participants will be assigned with an ID number which will be used on any questionnaires they complete. All ID numbers will be randomly generated and not be based upon any participant identifiable information. All information will be stored securely and adhere to GDPR regulations and the principles of the Data Protection Act (2018) (as described in section 16.3 for more information about data storage).

Finally, as some participants may prefer their baseline and follow-up assessments to be conducted face-to-face, we will adhere to the individual NHS Trust's lone worker policy in these instances, depending on where the researcher is located. This will be adhered to if visits are conducted in non-public locations (e.g. participant homes). This will include enacting a 'buddy system' whereby any researcher conducting a face-to-face visit will inform colleagues appointment times and expected end time. All researchers will ensure

that they inform a colleague of their arrival at a visit and also at their departure. Non-public locations will be avoided where possible, and the first suggestion for an in-person meeting will be at the CAMHS site.

15.3 Data storage

All data collected during the trial will be stored in accordance with GDPR principles and will adhere to the Data Protection Act 2018 at all times. Physical data will be stored in locked filing cabinets, in a locked office at the University of York and NHS sites and only accessible to members of the immediate research team. Any personally identifiable data will be stored separately from non-identifiable study data. Any electronic data will be password-protected, stored on secure servers at the University of York and only transferred (where necessary) using encrypted and GDPR-compliant methods.

Electronic Data will be held securely on a cloud-hosted REDCap server. Access to the study interface will be restricted to named authorised individuals granted user rights by a REDCap administrator at York CTU. All data will be kept secure at all times and maintained in accordance with the requirements of GDPR and archived according to GCP regulations. Data will be held securely on paper and electronically at York Clinical Trials Unit and appropriate processes put in place for the transfer, storage, restricted access, and disposal of personal information. Relevant Standard Operating Procedures, Guidelines, and Work Instructions in relation to data management, processing, and analysis of data will be followed.

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). Website data 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.

All BA therapy sessions will be recorded with the consent of the participant by the therapist via a Trust-approved platform. The sessions will be downloaded from the platform and stored securely at each local NHS Trust. Recordings will be deleted from the video platform used once downloaded and stored securely. A sample of these (10%) will be accessed at the end of the treatment period by a researcher to assess treatment fidelity up to the end of the study period.

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.

15.4 Statement of Indemnity

The proposed 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.

16. OUTPUTS AND DISSEMINATION

16.1. Intended outputs

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. Research team members have led such events e.g. for the HTA 'IMPACT' trial.

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. Our research team has links regionally and nationally, which will assist in implementing the findings into practice e.g. KS & BD are editors of the clinician and service-oriented journal 'Child & Adolescent Mental Health' which commissions editorial perspectives from national and international leaders; BD was previously Chair of the RCPsych Child and Adolescent Faculty and has ongoing links with the college and allied organisations; the NHSE CAMHS National Clinical Director is based in trust, PCFT; BD is an advisor to the Health Innovation Greater Manchester Mental Health Network (GM HIM); both BD and KS work closely with their local Applied Research Collaboratives (ARCs).

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 'Be-Active', 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

16.2. Communication with stakeholders and the wider public

Some of the ways in which we plan to inform and engage wider and targeted audiences about the BAY trial include:

- Using social media to regularly detail the work being undertaken with progress reports.
- Arranging a series of stakeholder events to present the evolving versions of BAY materials and to discuss evaluation results.
- Using the networks of universities, the NHS and the third sector to engage commissioners and service providers.
- Publishing lay summaries and evidence briefings of the project's findings through our partner networks in CAMHS.
- Presenting at national and international conferences for non-governmental organisations, policy makers and those responsible for children and young people's service commissioning and delivery.
- Publishing the results in a variety of scientific journals for different professional groups including mental health, social work and education.

On completion of the project, we will work with our NHS sites to ensure that BAY resources can be accessed freely. The University of York and Greater Manchester Mental Health NHS Trust will work together with press offices from contributing organisations to carry out dissemination and marketing activities. We will support such activities by continuously applying for impact and innovation funds available to the NHS and Universities. We will approach universities and other organisations that offer training and continuous professional development (CPD) to psychological wellbeing practitioners and mental health professionals to explore the most appropriate ways of using the BA within their current and future practice in CAMHS services.

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