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

Short title: ComBAT feasibility study and survey

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Sponsor: Tees, Esk and Wear Valleys NHS Foundation Trust

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TABLE OF CONTENTS

RESEARCH REFERENCE NUMBERS

Governing body or organisation	Reference
Integrated Research Application System (IRAS)	302389
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Research Ethics Committee (REC)	21/NE/0182

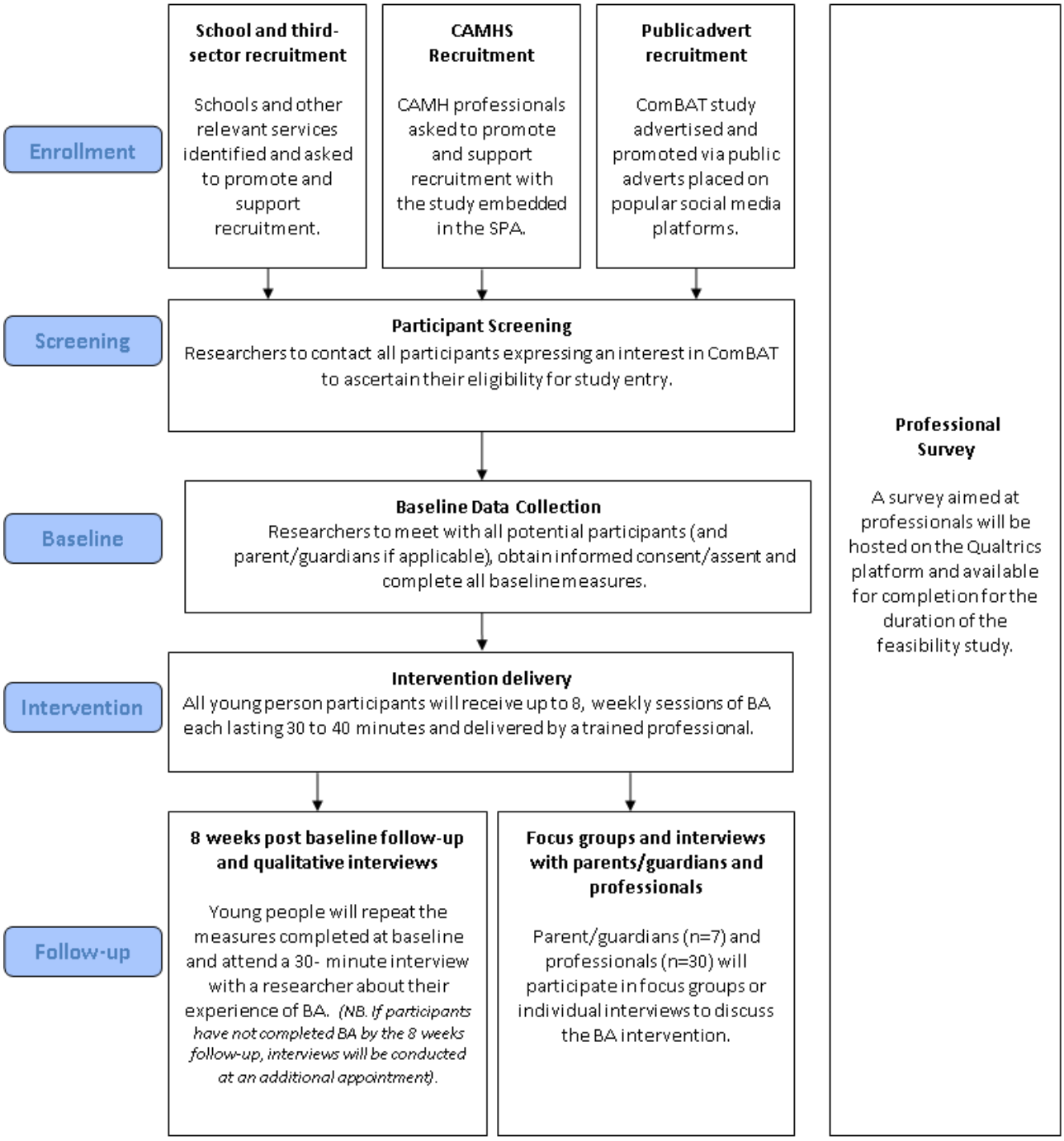
STUDY SUMMARY

Study title	Community-based Behavioural Activation Training (ComBAT) for Depression in Young people: A single-group pre-post feasibility study with an embedded qualitative study and a parallel professional survey	
Short title	ComBAT feasibility study and survey	
Study design	A single-group pre-post feasibility study, with an embedded qualitative study and a parallel professional survey	
Participants	Young people aged 12 to 18 years with mild to moderate depression, parents/guardians of young people with mild to moderate depression, professionals involved in the treatment of young people with mild to moderate depression.	
Planned sample size	37 (20 young people, 7 parent/guardians, 10 professionals)	
Follow-up duration	8 weeks from baseline	
Planned study period	6 months	
	Objectives	**Outcome Measures**
Primary	1. To produce a suite of standardised ComBAT resources, including: a) a session-by-session guide for mental health support workers who deliver the BA intervention b) materials for young people and their parents who use the BA intervention c) a "training the trainers" package for specialists who teach and supervise the BA intervention 2. Map what "usual care" means - and plan the potential delivery models for the BA intervention (who, when, where and how) that fit usual care - across the range of community settings where young people may seek support for depression.	Interviews and focus groups with stakeholders including: - Young people - Parents/guardians - Professionals Circulation of an online survey to map service provision for young people with mild to moderate depression Outcome measures (completed at baseline and 8 weeks from baseline) including: - Revised Children's Anxiety and Depression Scale (RCADS) - Children's Depression Rating Scale-Revised (CDRS-R) - Behavioural Activation for Depression Scale- Short Form (BADS-SF) - Child Health Utility-9 Dimensions (CHU-9D) - Resource Utilisation Questionnaire for Adolescents (RUQ-A)

	3. Road-test the BA intervention resources and arrive at a final iteration of the intervention and a protocol for its at-scale delivery. 4. Develop the Resource Utilisation Questionnaire for Adolescents (RUQ-A). 5. Measure intervention uptake, adherence, completion of follow-up measures and data missingness in the questionnaires. 6. Capture the experiences of young people and parents who participated in the intervention and of professionals who supported them.	
Intervention	Behavioural Activation (BA)	
Method of delivery	BA will be delivered by professionals based within schools, third sector organisations or CAMHS. Staff groups delivering ComBAT include school counsellors, family support workers, emotional literacy support assistants, wellbeing practitioners, social workers, youth workers, counsellors and family advisors.	

1.

FLOWCHART


Enrollment
School and third-sector recruitment
Schools and other relevant services identified and asked to promote and support recruitment.
CAMHS Recruitment
CAMH professionals asked to promote and support recruitment with the study embedded in the SPA.
Public advert recruitment
ComBAT study advertised and promoted via public adverts placed on popular social media platforms.
Screening
Participant Screening
Researchers to contact all participants expressing an interest in ComBAT to ascertain their eligibility for study entry.
Baseline
Baseline Data Collection
Researchers to meet with all potential participants (and parent/guardians if applicable), obtain informed consent/assent and complete all baseline measures.
Intervention
Intervention delivery
All young person participants will receive up to 8, weekly sessions of BA each lasting 30 to 40 minutes and delivered by a trained professional.
Follow-up
8 weeks post baseline follow-up and qualitative interviews
Young people will repeat the measures completed at baseline and attend a 30- minute interview with a researcher about their experience of BA. (NB. If participants have not completed BA by the 8 weeks follow-up, interviews will be conducted at an additional appointment).
Focus groups and interviews with parents/guardians and professionals
Parent/guardians (n=7) and professionals (n=30) will participate in focus groups or individual interviews to discuss the BA intervention.
Professional Survey
A survey aimed at professionals will be hosted on the Qualtrics platform and available for completion for the duration of the feasibility study.

ABBREVIATIONS

BA	Behavioural Activation
BADS-SF	Behavioural Activation for Depression Scale Short Form
CAMHS	Child and Adolescent Mental Health Services
CBT	Cognitive Behavioural Therapy
CCG	Clinical Commissioning Group
CDRS-R	Children's Depression Rating Scale-Revised
CHU-9D	Child Health Utility-9 Dimensions
ComBAT	Community-based Behavioural Activation Training
CWP	Children's Wellbeing Practitioner
CYP IAPT	Children and Young People's Improving Access to Psychological Therapies
DfE	Department for Education
DHSC	Department of Health & Social Care
GDPR	General Data Protection Regulation
HRA	Health Research Authority
IAPT	Improving Access to Psychological Therapies
IPT	Interpersonal Therapy
ITAX	Intervention Taxonomy
MHSDS	Mental Health Services Dataset
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
RCADS	Revised Children's Anxiety and Depression Scale
RCI	Reliable Change Index
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RUQ-A	Resource Utilisation Questionnaire for Adolescents
SPA	Single Point of Access
TEWV	Tees Esk and Wear Valleys NHS Foundation Trust
WHO	World Health Organisation

3. BACKGROUND

It is expected that depression will be the most burdensome disease in the world by the year 2030 (World Health Organisation (WHO), 2008). Globally, depression is the fourth leading cause of illness and disability among adolescents aged 15-19 years and fifteenth for those aged 10-14 years (WHO, 2021). Yearly prevalence rates are estimated from 7.1% to 19.4% across 11 European countries (Balazs et al, 2012) and 13.3% in the US (in the year 2017) with a strong female preponderance (20% female, 6.8% male) (National Institute of Mental Health, 2019). In the UK, The Millennium Cohort Study (Patalay & Fitzsimons, 2017) found that almost one in four girls (24%) and one in ten boys (9%) at age 14 self-reported high levels of depressive symptoms; with two-thirds of them likely to have diagnosable depression. Key symptoms of depression in young people include sadness and irritability, loss of interest and pleasure, persistent fatigue or lack of energy, loss of confidence, trouble with concentration and sleep, and changes in appetite. Depression is more likely to be under-diagnosed and under-treated in young people than in adults (Grover & Avasthi, 2019), because symptoms are dismissed as being a normal mood variation and reactivity often seen in adolescence (Thapar et al, 2012).

In the UK, Child and Adolescent Mental Health Services (CAMHS) provide evidence-based psychological interventions for young people with depression as part of their stepped care model (National Institute of Health and Care Excellence (NICE), 2019). These include watchful waiting, antidepressant medication, digital/group/individual cognitive behaviour therapy (CBT), interpersonal therapy (IPT), non-directive supportive therapy (NDST), family therapy, brief psychosocial intervention or psychodynamic psychotherapy. However, owing to increased demand and limited resources, waiting lists are frequently long and entry thresholds are high creating evident gaps between treatment provision and need (Crenna-Jennings & Hutchinson, 2020). As a result, many young people with mild to moderate depression do not meet the threshold for entry into CAMHS.

In a 2018 Green Paper, the Department of Health & Social Care (DHSC) and the Department for Education (DfE) in England put forward plans for the provision of school-led interventions for children and young people experiencing mild to moderate mental health problems to prevent their escalation to a point where higher intensity interventions are needed. Due to this, schools, as well as other community-based settings are increasingly involved in mental health care provision. Historically, the delivery of evidence-based interventions in schools and community settings has been limited. In a cross-sectional survey of UK primary and secondary schools (n=736), Vostanis et al. (2013) reported that most settings delivered locally developed interventions with only a third using evidence-based practices and only a few staff receiving specialist training. The pastoral care provided in these settings (e.g. discussion, consultation, relaxation) provides emotional support to young people, but is often not sufficient to reduce symptoms and change the trajectory of depression.

In 2019 NICE made recommendations for research to examine the effectiveness of a psychological therapy, Behavioural Activation (BA) for treating young people. BA is a depression-specific brief psychological intervention which aims to restore and increase stable sources of positive reinforcement in a person's environment through purposeful and rewarding activities that have a positive emotional impact on the person's mood, interest in people and life, and energy levels (Kanter et al, 2010).

BA is a recommended treatment approach for adults experiencing depression (NICE, 2016) following its effective delivery with this population but does not currently feature in any national (NICE, 2019) or international (WHO, 2017) recommendations for depression in young people. However, BA's focus on withdrawal, inactivity and avoidance, which are common symptoms of depression in young people may make it a suitable alternative for this group also. In addition, as

demonstrated within adult services (e.g. Ekers et al, 2011, Richards et al, 2016) it may have important resource implications and be a potential cost-saving alternative therapy within CAMHS. BA provides a leaner and less-resource intensive alternative to several established psychological therapies (e.g. CBT, IPT) owing to its requirement of fewer sessions and shorter training. Furthermore, BA can be delivered within varied settings and by professionals of different levels of expertise (McCauley et al., 2016a) including non-specialists outside clinical services (Ekers et al 2011, 2014; Richards et al, 2016). BA's brevity is also important in the context of young people, because drop-out from therapy can range for 16-75% for young people and the briefer the intervention, the more likely that young people will adhere to it and complete it (De Haan et al, 2013).

Although most research has focused upon the delivery of BA with adult populations, recent years have seen increased focus upon its use with young people, providing preliminary support in this context. Martin and Oliver (2019) conducted a meta-analysis of 4 BA-focused Randomised Controlled Trials (RCT) and reported a large effect in favour of BA vs. controls (1 active intervention, 1 signposting and 2 no treatment) with a pooled standardized mean difference of -0.7 (95% CI -1.20, -0.20). An earlier meta-analysis (Tindall et al, 2017) pooled together 3 RCTs, including an unpublished PhD thesis (Stark, 1985), and favoured BA over its comparators with a moderate effect but a wide confidence interval (95% CI -8.25, -0.09).

Several studies have also examined the delivery of BA with young people experiencing depression. This work has included two single-group pilot studies conducted within the UK, one delivered in CAMHS (Pass et al., 2017) and one in secondary schools (Pass et al., 2018). The CAMHS pilot showed promising results with 20 young people, whereas the one in secondary schools had no outcome data or any information about the impact of the intervention on the participating young people. This study did however find BA to be considered acceptable by young people, parents and school staff and found high treatment adherence, providing preliminary support for delivering BA within school settings. McCauley et al. (2016b) conducted an RCT with the largest total sample of young people than any other similar intervention. The RCT was conducted in the US with 60 young people (aged 12 to 18 years) with major depressive disorder who received either 14 sessions of therapist-delivered BA (delivered over 12-weeks) or "gold standard" evidence-based therapy (e.g. CBT or IPT) at a university hospital. Both groups showed large and similar improvement in depression and functioning, mediated by increased activation and reduced avoidance.

As part of their work McCauley et al (2016a) produced a manual to support the delivery of their BA intervention known as 'Behavioral Activation with Adolescents: A Clinicians Guide'. The manual provides a session-by-session guide for clinicians and includes handouts for young people and parents. This manual has the best published evidence in terms of the feasibility, acceptability and clinical outcomes of BA for young people to date. Owing to this, our wider research team have adapted and used McCauley et al's (2016a) BA manual in three feasibility studies conducted to examine its delivery within UK adolescent populations.

The first, the Body and Mind study (Arnott et al, 2020) examined the delivery of BA with young people who were overweight/obese and had clinical depression. The study, conducted in a school setting, recruited 8 young people (aged 13 to 15 years) who all received manualised BA either immediately or after 4 to 6 weeks as a wait-list control group. Support was provided by a research assistant who had no clinical or therapy qualifications but who received appropriate BA training and supervision. BA took place weekly and the number of sessions ranged from 8 to 11 (with a maximum of 12). Scores showed a large change in a positive direction for depressive symptoms and functioning for the 7/8 participants for whom we had follow-up data; 5/7 young people were depression-free after the intervention (below the cut-off score for remission). An embedded qualitative study, comprising exit interviews with 7 young people and their parents reflected high

satisfaction with BA, but highlighted difficulties with scheduling weekly appointments in schools (e.g. during school hours or school holidays). This led to frustration with the disruption in the flow of the intervention. Parents found it difficult to take an active role in BA due to other commitments, despite being perceived as the 'gatekeepers', who held the power to restrict or provide opportunities for the young person to carry out BA.

The BAY-F study (Kitchen, 2018) recruited 7 young people (aged 12 to 18 years) with depression from GP surgeries by two general nurse practitioners who received training to deliver up to 12 one-hour weekly BA sessions. Four (4) participants completed all BA sessions and reported lower depression scores at follow-up and high satisfaction. The remaining 3 participants stopped attending after the first three BA sessions and did not complete follow-up outcome measures. Informal feedback from the two nurse practitioners (who routinely saw all young people at the GP surgery outside the study) suggested that young people dropped out because their mood improved and no longer wanted to be part of the study. For the young people who completed the intervention, the nurses reported that they observed rapid improvements in depressive symptoms early on. One of the difficulties highlighted by the nurses was that the one-hour BA sessions did not fit with their usual 20-minute appointment slots, so they had to accommodate the research in their own time. The nurses also identified the need for greater flexibility within the manual to better tailor the intervention to each young person. Feedback from young people indicated difficulties in commuting to the GP practice, both in terms of time around their other commitments (i.e. college, school, social), and financially.

The Buddy Study (Kitchen et al, 2020) is the only known European RCT of BA with young people to date. Twenty-two (22) young people (aged 12 to 17 years) with major depressive disorder were recruited from CAMHS and randomised 1:1 to either 8 sessions of manualised BA or usual care. At 3 months post-randomisation, 7/11 BA participants and 8/11 usual care participants gave follow-up data; of those, 4/7 BA participants no longer met criteria for major depressive disorder compared to 1/8 participants in the usual care group. The number of completed BA sessions was high (mean 5.7; median 7 out of the total 8). There was a large change in a positive direction for the BA group but not for usual care, assessed by visual comparisons of mean scores on measures on depression, self-esteem and functioning. No adverse events were reported. An embedded qualitative study, carried out with 6 young people, 5 of their parents and 6 CAMHS professionals demonstrated overwhelming support for the weekly mode of BA delivery. However, concern was expressed about the need for greater flexibility in the number of BA sessions because of the complexity of need (including comorbidities) in young people who are under the care of CAMHS.

4. RATIONALE

The published work presented in the 'Background' section adds support to BA as a promising intervention for depression in young people. Yet, neither fully powered RCTs nor economic evaluations on BA with young people have been conducted in the UK or elsewhere to-date. Furthermore, feasibility studies, case reports and small RCTs conducted in the UK have been predominantly conducted within specialist clinical services. To evaluate the utility of BA beyond specialist clinical services, we are developing a new BA intervention for use within schools and third sector organisations for young people experiencing mild to moderate depression before they enter specialist services. Our aim is to enable schools and third sector organisations to deliver a problem-specific and clinically informed intervention for young people at the earliest opportunity, before their depression escalates to a point that needs specialist psychiatric services. In addition, this project seeks to strengthen the working connections between CAMHS, schools and the third sector, and among different professionals who may support young people with depression.

5. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1. Aims and Objectives

This study is part of a larger, 5-year programme of research called ComBAT. The current study is the first of several work packages which will be completed as part of ComBAT and aims to adapt and standardise BA to be delivered by mental health support workers in community settings, such as schools and youth centres.

To ensure that new interventions are developed to accommodate the needs and preferences of their target users, co-production is increasingly used within this context (Jones et al., 2020; Boyd et al., 2012). This approach recognises the importance of collaborating with important stakeholder groups and end users when developing interventions to increase the likelihood of them being considered useful, engaging and satisfying (Thabrew et al., 2018). This initial work package focuses upon co-production and road mapping and seeks to involve a range of stakeholders to evaluate the first version of the new BA intervention. The information provided will be used to refine the intervention ahead of testing in a full-scale RCT.

A single-group pre-post feasibility study, with an embedded qualitative study and a parallel professional survey, have six objectives:

1. Produce a suite of standardised ComBAT resources, including:

    a. a session-by-session guide for professionals who deliver the BA intervention
    b. materials for young people and their parents who use the BA intervention
    c. a "training the trainers" package for specialists who teach and supervise the BA intervention

2. Map what "usual care" means - and plan the potential delivery models for the BA intervention (who, when, where and how) that fit usual care - across the range of community settings where young people may seek support for depression.

3. Road-test the BA intervention resources and arrive at a final iteration of the intervention and a protocol for its at-scale delivery.

4. Develop the Resource Utilisation Questionnaires for Adolescents (RUQ-A).

5. Measure intervention uptake, adherence, completion of follow-up measures and data missingness in the questionnaires.

6. Capture the experiences of young people and parents who participated in the intervention and of professionals who supported them.

3.2. Outcome and end points

Throughout this feasibility study, a range of data collection tools will be used as part of screening, at baseline and at a follow-up point 8 weeks from baseline. Each measure will be administered by a trained researcher. All measures and their time-points of completion can be seen in Table 1 with additional information about their administration provided.

Table 1: Outcome measures and timepoints of completion

Measure	Time point completed	Completed by
Revised Children's Anxiety and Depression Scale (RCADS) depression subscale	Screening	Young person participant
Revised Children's Anxiety and Depression Scale (RCADS) – Brief Version	Baseline 8 weeks from baseline	Young person participant Young person participant
Demographics Questionnaire (Young person participant)	Baseline	Young person participant
Demographics Questionnaire (Parent/guardian)	Pre-focus group/interview	Parent/guardian
Demographics Questionnaire (Professional)	Pre-focus group/interview	Professional
Children's Depression Rating Scale-Revised (CDRS-R)	Baseline 8 weeks from baseline	Young person participant Young person participant
Behavioural Activation for Depression Scale – Short Form (BADS-SF)	Baseline 8 weeks from baseline	Young person participant Young person participant
Child Health Utility-9 Dimensions (CHU-9D)	Baseline 8 weeks from baseline	Young person participant Young person participant
Resource Utilisation Questionnaire for Adolescents (RUQ-A)	Baseline 8 weeks from baseline	Young person participant Young person participant

Demographics questionnaire

On entry to the study, participating young people will be invited to complete a short demographic questionnaire to obtain information about their age, sex, ethnicity, religion, family circumstances (who they live with) and education or work.

Revised Children's Anxiety and Depression Scale (RCADS) – Brief Version (Chorpita et al., 2005)

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 8-18-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.

The RCADS depression sub-scale includes the following 10 items: *1. I feel sad or empty; 2. Nothing is much fun anymore; 3. I have trouble sleeping; 4. I have problems with my appetite; 5. I have no energy for things; 6. I cannot think clearly; 7. I feel worthless; 8. I feel like I don't want to move; 9. I am tired a lot; 10. I feel restless.* The depression sub-scale is the same on both the 25-item and the 47-item versions of the RCADS. The sub-scale has the same clinical cut-off that indicates borderline or diagnosable depression as the overall scale (i.e. 0-64 non-clinical range, 65-69 borderline clinical range, and ≥70 clinical range) and has a high correlation with other depression-specific scales like the Children's Depression Inventory (de Ross et al, 2002). Based on the UK's national dataset of Children and Young People's Improving Access to Psychological Therapies (CYP IAPT) data, the Reliable Change Index (RCI), i.e. the amount scores have to change between a first and a last time point for the change to be considered reliable, for the child-reported RCADS depression sub-scale is 17.73 (for the T-scores) (Wolpert et al, 2016).

The 15 remaining items of the RCADS brief version relate to five anxiety problems. For example, generalised anxiety disorder: "I worry that something awful will happen to someone in my family"; panic disorder: "I am afraid of being in crowded places (like shopping centers, the movies, buses, busy playgrounds); social anxiety: "I worry what other people think of me"; separation anxiety; " I feel scared if I have to sleep on my own"; obsessive compulsive disorder: "I have to do some things in just the right way to stop bad things from happening".

The RCADS is a nationally recommended outcome measure as part of the Mental Health Services Dataset (MHSDS) in the UK. It is routinely collected by CAMHS / CYP IAPT practitioners and CWPs in clinical services with children and young people and it is used by commissioners for service evaluation and benchmarking. This means that our findings can be interpreted in the context of UK national datasets for our population. The RCADS is more sensitive to change compared to other measures (Wolpert, Cheng, Deighton, 2015), so it is particularly useful as an outcome measure of an intervention's effectiveness.

We will use the RCADS depression subscale to ascertain whether an individual is eligible to enter the study. The 25-item RCADS (including both anxiety and depression subscales) will then be completed at baseline and repeated 8 weeks from baseline.

Children's Depression Rating Scale-Revised (CDRS-R) (Poznanski & Mokros, 1996)

This 17-item researcher-administered interview is widely used in clinical research trials to assess severity of, and change in, symptoms of depression in children and adolescents. The CDRS-R covers seventeen symptom areas, including dysfunction relating to schoolwork, interpersonal relationships, psychosomatic complaints, and other thoughts and feelings commonly experienced by depressed young people. The researcher who conducts the interview scores each item on a scale from 1 to 5 or 1 to 7, yielding a total score between 17 and 113, with higher scores denoting more depressive symptoms. Scores ≥40 indicate diagnosable depression (Mayes et al 2010), whereas a score between 35 and 40 is interpreted as emerging or early depression (Plener et al, 2012). We will use the scale's continuous scores in our main analysis for this outcome. We will carry out a secondary analysis by grouping the participants in 3 categories according to the scale's interpretation of the 3 cut-off scores (no depression, emerging or early depression, diagnosable depression).

Behavioural Activation for Depression Scale Short Form (BADS-SF) (Kanter et al, 2012)

The BADS-SF is a 9-item questionnaire, based upon the longer, 25-item BADS (Kanter et al, 2007; Manos et al, 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 BADS-SF to monitor self-reported activity and avoidance for individual young people. Although the scale has not been validated with an adolescent population, we will use it as there are no alternative similar tools measuring behavioural activation that could mediate changes in depression.

Child Health Utility-9 Dimensions (CHU-9D) (Stevens & Ratcliffe, 2012)

We will use the CHU-9D (Stevens & Ratcliffe, 2012) to estimate incremental health gain in 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 "today" across domains of worry, sadness, pain, tiredness, annoyance, school, sleep, daily routine and activities. 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). There are many different health states based on this descriptive system, because of the different combinations of responses across the 9 dimensions. Each of these health states has a utility value on a 0–1 scale, where 1 is perfect health and 0 is a state equivalent to being dead.

Resource Utilisation Questionnaire for Adolescents (RUQ-A) (newly developed)

We have developed a Resource Utilisation Questionnaire for self-completion by adolescents (RUQ-A). Its purpose is to collect information about use of healthcare and other resources by each young person over the previous 8 weeks which will be used for the economic evaluation. We have conducted a literature search (including the Database of Instruments for Resource Use Measurement - DIRUM - database) for questionnaires previously used in economic evaluations in this population. In addition to the literature search, the RUQ-A was informed by previous RUQs developed by our team for mental health interventions with young people.

6. STUDY DESIGN

This 6-month pre-post single group feasibility study is being conducted to test the first version of the newly developed BA intervention. The data obtained as part of this will allow us to refine the intervention and produce its final iteration and a protocol for its delivery on a large scale before we conduct an RCT of its effectiveness (at which point we will no longer be able to change the intervention). Completion of the feasibility study will also allow us to recruit community sites, support staff within each site and CAMHS liaison staff.

7. STUDY SETTINGS

The study will be conducted within a variety of services responsible for providing support to young people with mild to moderate depression. These may include CAMHS, school-based or other community-based services. These sites will be involved in the identification of study participants (see 7.1) and will be the locations for intervention delivery.

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8. PARTICIPANT ELIGIBILITY CRITERIA

6.1. Inclusion criteria

Young people will be considered eligible for the study if they:

- Are aged 12-18 years at the date of consent (this captures the youngest and oldest age in secondary schools, but is not restricted to young people who attend secondary schools).

- Score ≥65 on the depression subscale (10-items) of the Brief Revised Children's Anxiety and Depression Scale (RCADS) (this is the standardised cut-off by which elevated symptoms of depression warrant further assessment and potential intervention)

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

6.2. Exclusion criteria

Young people will not be considered for the study if they are:

- Eligible for secondary care (tier 3 / high intensity therapy) in CAMHS based on local service entry criteria, which are usually: risk of suicide, inability to function because of the severity of the depressive symptoms, complex circumstances such as learning disability.

9. STUDY PROCEDURES

7.1. Recruitment

We will recruit participants through three main pathways: a) schools and third sector organisations; b) CAMHS and c) public adverts.

(a) Schools and third sector organisations

Different schools have different arrangements for assessing and helping young people with depression, but usually there are key points of contact (gatekeepers) within each school and

across clusters of schools within each area. We will approach these gatekeepers and ask them to identify any young people who they feel may be suitable and interested in participating. We will also work with the gatekeepers to promote active recruitment by raising awareness about the study to pupils and parent groups (e.g. governors, parent-teacher associations) and among their colleagues.

(b) CAMHS

CAMH services based within the sponsor's NHS Trust (Tees Esk and Wear Valleys NHS Foundation Trust (TEWV)) will be contacted and asked to both promote the feasibility study and assist with identifying young people who may be suitable and interested in participating. ComBAT team members will attend regular team meetings in these locations to remind professionals of the study and its inclusion criteria and will ask team secretaries to send study information to all professionals who may be able to support recruitment. TEWV CAMH services have an embedded single point of access (SPA) where assessments and signposting of referrals are carried out by trained staff. We will work with the SPA gatekeepers to capture referrals as they emerge.

(c) Public Adverts

To further support recruitment, we will promote the feasibility study via public adverts placed on social media popular among young people (e.g. Instagram). Any young person who sees an advert and is interested in participating will be asked to contact the research team directly. The research team will then direct the young person to their local gatekeeper (e.g. either school or CAMHS SPA). Although we will promote the study using public adverts, we will not have a self-referral option.

Any gatekeeper who identifies a young person as potentially suitable for participation will be asked to provide them with a study information pack. This will include participant information sheets (both a brief and a more detailed version for young people and ones for parents/guardians) an expression of interest form and a copy of the depression subscale from the Revised Children's Anxiety and Depression Scale (RCADS) – Brief version (Ebesutani et al., 2012). Having read the study information, if a young person is interested in taking part in the research, they will be asked to return a completed copy of the expression of interest form to the research team (either directly or via the person who gave them the study information) as well as their completed brief RCADS questions. The RCADS depression sub-scale comprises 10 items that assess children's depression and is included in both the 25-item and 47-item versions of the RCADS (see section 3.2).

On receipt of an expression of interest form, the research team will determine whether a young person is eligible for participation (i.e. attaining a score of ≥65 on the RCADS depression subscale). If eligible, a researcher will contact the young person and their parent/guardian (if applicable) and arrange a suitable time to conduct a baseline visit with them. Baseline visits may be held online, via video conferencing, or face-to-face at a mutually convenient location, depending on participant preference. Any young person expressing interest in the study but not meeting the eligibility criteria will be contacted and informed of this. All information provided by non-eligible participants will be securely destroyed and not included in any analyses. 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.

7.2. Informed consent

At the baseline visit the researcher will reiterate the study aims, discuss what participation entails and answer any questions young people and/or their parents have regarding the study. If happy to proceed, informed consent/assent will be obtained from young people and parents/guardians (where applicable). The consent process will vary depending upon the age of the young person.

Young people aged 12 to 15 years

Young people aged 12 to 15 years will be required to complete an assent form, alongside their parents consenting for them to be able to take part in the study. As part of this, a parent/guardian will be required to confirm that they will support their son/daughter during their time in the study.

Young people aged 16 to 18 years

Young people aged 16 to 18 years will be required to complete a consent form to participate in the study. Whilst parental consent will not be required, young people will be reminded that involving parents 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 18-year-old participants choose to involve parents in the completion of BA is based upon individual choice. As we will be seeking to recruit a sample of parents/guardians to take part in the embedded qualitative study, all 16- to 18-year-old participants will be asked whether they would be happy for their parents/guardians to receive information about this (see section 10.3). Their response will be marked on their consent form but will not impact upon their study participation in any way.

During the consent process all participants will be asked for the contact details of their GP but the GP will not be contacted unless there is a reason to do so (e.g. medication) and with permission from the young person or the parent/guardian as appropriate before the GP is contacted.

7.3. Procedure

Following informed consent/assent the young person participant will complete a series of standardised questionnaires with a trained researcher. These will include a demographic questionnaire, RCADS, CDRS-R, BADS-SF, CHU-9D and RUQ-A (for questionnaire description see section 3.2). On completion of the baseline measures, participants will be offered the BA intervention. Treatment sessions will be arranged by the supporting professional who will liaise with the young person and, if appropriate, their parent/guardian. The researcher will arrange a follow-up session at 8 weeks from baseline and will keep in contact with the young people before the 8 weeks as needed.

10. INTERVENTION

8.1. Content

All young people enrolled on the study will receive behavioural activation (BA) based on the BA model by McCauley et al (2016a), and on the manuals and operating procedures we developed and evaluated in our previous three feasibility studies (see section 1.1), which were also informed by McCauley's model. The preliminary version of our BA intervention will comprise up to 8 weekly sessions of 30-40 minutes each in a blended model of professional-guided and self-directed sessions.

In day-to-day life, activities fulfil different **purposes** and lead to different emotional **rewards**. There are things that we like and want to do **(pleasures**): the subsequent emotional reward is **enjoyment**. There are activities we need to do or have a duty to do **(routine tasks)**, which tend to reward us with a sense of **achievement** or at least a satisfaction and relief that they are done. Finally, there are activities that serve a bigger or future purpose, intention or aspiration **(challenges)**, which also add to our sense of achievement.

Daily activities can take different amounts of effort to complete depending on 1. how difficult they are, and 2. how well and ready we feel to complete them. **The greater the difficulty, the greater the sense of achievement**; still, effortless things are also helpful to either help us pick up momentum or slow us down as needed. Doing something that is difficult and challenging should not get in the way of completing it. We can still complete challenges if we break them down properly.

A crucial element of BA is that the scheduled activities are **meaningful**, i.e. they connect with what young people value in themselves, people who matter to them, and things that matter in their lives - and not what others think "should" be important. These areas of life include family, friends, intimate relationships, education/personal growth, work/career, hobbies/recreation, physical health, citizenship, spirituality/religion, moral principles/ethics, mental health, image. In Behavioural Activation, pleasures, tasks and challenges have to connect with what is important to us.

The BA intervention in ComBAT will include 6 elements, described under the acronym MASTER.

1. **M: Make a Menu** of pleasures, tasks and challenges that connect with what young people value in themselves, people who matter to them, and things that matter in their lives.

2. **A: Anticipate** activities that young people may avoid or delay doing (black holes), activities that make no difference to how they feel or make them feel down (grey clouds), and activities that are destructive or harmful to themselves or others (red zones). Also anticipate obstacles and helpers in completing activities.

3. **S: Schedule** on a weekly timetable a balance of pleasures, tasks and challenges in each important area of life, by describing what, where, with whom, when and how these will be done in the coming week.

4. **T: Track** a) each activity as it was completed, both scheduled and unplanned, and score enjoyment and achievement for this activity on a 0-10 scale (0=no enjoyment/achievement, 10=great enjoyment/achievement); b) activities that were not completed and what stopped the young person from completing them; c) any black holes, grey clouds and red zones; d) any obstacles and helpers.

5. **E: Evaluate** the impact of the activities on symptoms of depression on a weekly basis. This will be done in two ways. First, by rating two key symptoms associated with depression that BA targets (i.e. low mood/irritability and diminished interest and pleasure in daily activities) by attributing a score (0=not at all, 10=all the time) to these two statements: "Over the last week, I felt happy and fulfilled" and "Over the last week, I took interest and pleasure in doing things in day-to-day life".. Second, by getting an overall picture of the number of activities completed and their mean enjoyment and achievement scores over the previous week: we would expect that if depression improves, scores of enjoyment and achievement will increase too.

6. **R: Resolve** problems **and Revise** activities (e.g. tackle black holes, grey clouds, red zones and obstacles; add new pleasures, tasks or challenges; grade the difficulty of activities up or down).

The content of our BA intervention covers 5 "modules" which can be completed across multiple sessions. These, as adapted from McCauley et al's (2016a) guide, pp. 12-13, are presented in Table 2.

Table 2: Five BA modules as developed by McCauley et al. (2016a)

Module	Topics covered
Module 1: Getting Started	- Introduction to BA model/situation-activity-mood model - Understanding what an individual considers to be meaningful, challenging and enjoyable - Introduction to activity monitoring - Parental psychoeducation (e.g. information about depression in young people, how to create opportunities and facilitate BA)
Module 2: Getting Active	- Concepts that mood can be regulated by activity and activities make up "behaviour" - Differences between mood-driven vs. goal-driven behaviour. - Role of reinforcement in maintaining behaviour and choices between helpful vs unhelpful behaviour for depression. - Discuss short-term vs. long-term consequences of behaviour choices - Activity-mood monitoring - "Pump you up" and "bring you down" activities. - Making the most of good feelings - Parental inclusion by discussing their concerns or latest observations of behaviour
Module 3: Skills Building	- Role of stress as a trigger for depression - Problem-solving skills for stressful situations - SMART goals - Graded task assignment to reach each goal - Parental involvement in communication and monitoring
Module 4: Practice	- Introduction of the concepts of internal and external barriers to accomplishing goals - Importance of avoidance as an internal barrier in all its forms: procrastinating, brooding, bursting and hibernating - Trigger-Response-Avoidance Pattern (TRAP) vs. Trigger-Response-Alternative Coping (TRAC) - Goal-setting practice - Review parental support
Module 5: Moving Forward	- Review of young person's status, goals and skills acquired over the BA course - Develop a list of priorities, goals and activities to focus on in the short-term

	- Generate a relapse prevention plan (doing what works) to manage triggers and signs of depression in the long-term. - Review with the young person and parent together the next steps for avoiding relapse

8.2. Delivery

The BA intervention will be delivered by members of staff based within schools, third sector organisations or CAMHS (depending on where a young person is recruited from). Professionals within schools whose role is to work with young people with mental health and emotional difficulties include: school counsellors, family support workers, emotional literacy support assistants and school wellbeing practitioners. Counterpart professionals who work within third sector organisations may be social workers, youth workers, counsellors and family advisors. In CAMHs, these may include children's wellbeing practitioners (CWPs).

Prior to the delivery of BA all supporting professionals will receive training by the study's chief investigator and other clinically trained co-investigators and research personnel. Although this work seeks to inform the development of training resources for the wider ComBAT programme of research, the initial training for the feasibility study will comprise 2 full days of training, some of which will be self-guided. We will assess specific competencies in delivering BA at the end of the training through simulated practice using standardised role plays and scoring tools. Training will be delivered using a digital platform or face-to-face depending on clinician preference and availability. Weekly supervision will also be provided to support professionals during their participation in ComBAT.

11. STATISTICAL AND DATA ANALYSIS

9.1. Sample size

There is limited guidance available regarding the optimum sample sizes for feasibility studies (Billingham, Whitehead & Julious, 2013). Julious (2005) recommends, as a rule of thumb, recruiting a minimum of n=12 for a single-group feasibility study. We will therefore seek to recruit n=20 young people, this is based upon the recommendation made by Julious (2005) yet inflated to account for attrition.

9.2. Data analysis

We will tabulate the demographic information and data on each outcome measure at baseline and post-treatment for each participant (like a case series). We will also describe the data collected from the RUQ-A to identify the main costs associated with depression for NHS and non-NHS organisations and to assess whether the tool needs to be revised to inform data collection methods in a future trial. As this is a feasibility study, we will not conduct any statistical analysis or use the outcome data as a measure of effect.

For our primary outcome measure (RCADS brief version), we will present raw and T-scores for each participant on the depression and anxiety sub-scales and in total. We will also indicate, based on the established clinical cut-offs, in which severity group participants belonged at baseline and post-intervention (clinical, sub-clinical and non-clinical). For our main secondary outcome, the CDRS-R, we will present both the continuous scores and the categories according

to the scale's cut-off scores (no depression, emerging or early depression, diagnosable depression).

We will report intervention uptake (percentage of those eligible who consented to the study), adherence (session attendance and number of participants who withdraw and the reasons for withdrawal), completion of follow-up measures (number of participants who completed the questionnaires at 8 weeks from baseline including those who did not adhere to the intervention) and data missingness in the questionnaires (number of items missing and which items received no responses).

12. EMBEDDED QUALITATIVE STUDY

10.1. Study design

A qualitative study will identify elements of the intervention that the participants found most and least useful, and will lead to the refinement of the content and format of the intervention before it is tested in a large RCT. We will hold a series of focus groups and individual interviews with three stakeholder groups: young people who have used BA, parents who have supported their child in using BA, and professionals involved in the delivery of BA. The focus groups and interviews will be conducted after young people have received BA in the feasibility study and will cover the following topics:

- how BA needs to be different in community settings compared to clinical services.
- how we can best harness the resources and skills available within community settings.
- how we can overcome barriers in engaging young people with mild to moderate depressive symptoms to take up and complete BA.
- how we can enable parents to offer opportunities for and facilitate BA tasks with their young person children.
- how a standardised BA programme can be tailored to meet different needs and preferences for different young person groups.
- with what method and how often supervision should be offered by clinicians to support workers so that BA is applied safely and competently.
- what the depression-associated costs are for NHS and non-NHS organisations, as well as for young people and their families.
- what CAMHS, schools and third sector organisations would like to see as a return for their investment.

10.2. Participants and sample size

We will invite all young person participants recruited to our feasibility study (n=20) to take part in an individual interview about their experience of BA. We will also seek to recruit up to 7 parents/guardians who have supported their son/daughter when using BA; if more than 7 parents/guardians come forward, we will accept all those interested. Finally, we will recruit up to 10 professionals from a variety of settings, some of whom would have participated in the feasibility study and some who are interested in being trained in BA as part of ComBAT. Our proposed sample sizes are based upon the ones we recruited to co-produce another intervention for an NIHR-funded project, Young SMILES (Gellatly et al, 2019). We will endeavour to capture a wide representation of participants in terms of age, gender, geography and background and, for professionals, roles and services, within the time constraints of the feasibility study.

10.3. Recruitment

Young person recruitment

All young people recruited to the feasibility study will be asked to attend an individual interview with a ComBAT researcher following their completion of sessions. Interviews will be held following the final session of ComBAT or the last session attended (if a participant withdraws before the end). Consent/assent for young people to take part in interviews will be obtained during their baseline visit with the researcher.

Parent/guardian recruitment

We will also seek to recruit a sample of parents/guardians to take part in our embedded qualitative study to explore how they have found supporting their son/daughter during BA. How parents/guardians will be recruited and consented to this will be dependent on the age of their son/daughter:

The parents/guardians of young person participants aged 12 to 15 years

As outlined in section 7.2 all young people entering the research and aged between 12 and 15 years will be required to provide parental consent (alongside their own assent) to be able to participate. This will be obtained during the baseline visit with the research team, during which parents/guardians will be provided with information about the qualitative study. Any parents agreeing to take part in the qualitative study will be asked to complete an additional consent form confirming this during this meeting.

The parents/guardians of young person participants aged 16 to 18 years

To ensure the representativeness of our parent/guardian sample, we will also seek to recruit some parents/guardians of participants aged 16 to 18 years to take part in the qualitative study. To enable this, any potential participants aged 16 to 18 years (who do not require parental consent to participate in the feasibility study) will be asked whether they would be happy for their parents/guardians to be involved in the qualitative study during their baseline visit with the researcher. If they are happy, we will ask young people to tick a box confirming this on their consent form (see section 7.2) and will provide them with information to pass on to their parents/guardians about the study as well as an expression of interest form. Any parents/guardians interested in taking part will be asked to return their expression of interest form to the research team directly. On receipt of an expression of interest form, the research team will arrange to meet the parent/guardian (online, via telephone or face-to-face), to discuss the research in more detail and obtain consent.

Whilst all interested parents/guardians will be invited to attend a focus group in the first instance, if attendance at an individual interview is preferred or more practical, this will be arranged instead. Information about both interviews and focus groups will be provided to parent/guardians when deciding whether to participate in the qualitative work.

Professional recruitment

Professionals who delivered BA as part of the feasibility study will be invited to attend a focus group to discuss their experiences of delivering the intervention. If professionals prefer an individual interview rather than attend a focus group, we will arrange an interview instead. Apart from the professionals who participated in the feasibility study, we will also invite professionals who are interested in joining the ComBAT research programme, as well as their managers, to participate in further focus groups. Information about the qualitative study and an expression of interest form will be emailed to these professionals via the relevant gatekeeper from a variety of

services including the NHS, schools and the third sector. Potential participants will be invited to return an expression of interest form or contact the study team directly if they are interested in taking part or need further information. As part of their expression of interest, professionals will note whether they prefer to join a discussion group or have an individual interview.

10.4. Procedure

We will ask parents/guardians who are interested in participating to complete three introductory questions about their sex, age and relationship with the young people. Professionals will complete a brief questionnaire that asks their sex, age, professional role, service they work with, and whether they have delivered BA previously.

Focus groups and interviews will be held online using a video conferencing platform approved by the study sponsor. To accommodate the needs of all participants, the option to attend an interview face-to-face or via telephone will be offered in place of video conferencing if preferred or more practical. Any interviews conducted face-to-face will be completed in a mutually convenient location. If several participants per sample would prefer to attend a focus group face-to-face these will be held in a suitable space within the recruiting site.

All focus groups and interviews will follow a structured topic guide. Focus groups (with professionals and parents) will last up to 90 minutes and interviews (with young people and parents/professionals if requested) will last up to 30 minutes. The topic guides include how we can tailor the BA intervention to meet the needs and preferences of young people, how we can successfully incorporate parental support into the intervention and how we may overcome the barriers of engaging young people with mild to moderate depression to complete BA. We will ask professionals about the best methods of providing clinical supervision to ensure the safe delivery of BA and what costs are associated with care for depression in the NHS and in non-NHS organisations, as well as costs incurred by young people and their families.

All interviews and focus groups will be audio recorded and transcribed verbatim, to which participants would have given permission when signing the consent form. They will be reminded that the discussion will be recorded before it starts. All study materials (i.e. demographic questionnaires, transcripts) will each be given an individual identifier as to maintain participant confidentiality.

Participants will be reminded of their right to withdraw before the interview or focus group. However, any data collected at the point of withdrawal will be included in the analysis as agreed during the consent process.

10.5. Data analysis

All interview and focus group transcripts will be analysed using a template analysis because this allows for both deductive and inductive coding. The deductive coding will be guided by the items on the Intervention Taxonomy (ITAX; Schulz et al., 2010); a classification system which can be used to describe the main characteristics of an intervention. The ITAX comprises two tables, the first of which outlines characteristics associated with intervention delivery (e.g. delivery mode, materials, location) whilst the second describes content and goals (e.g delivery strategies, processes). Inductive coding will produce de novo themes emerging from the narrative data. Two researchers (who will have received training in template analysis) will carry out independent coding. The two coders will have regular meetings to ensure that the emerging codes remain grounded in the original data.

We will hold 2 synthesis workshops with our 2 PPI advisory groups (one with young people and one with adults – parents/guardians and professionals) where we will present the final coding framework and example quotes (anonymised) to arrive at a provisional content and delivery details for our proposed BA intervention. Following the 2 synthesis workshops, we will make iterative changes to our coding framework and produce the following resources: a session-by-session guide for mental health support workers, materials for young people and their parents to use at home, and a "training the trainers" package for specialists who will teach and supervise BA.

10.6. Ethical considerations

Although this qualitative work seeks to obtain information about the development of an intervention and does not seek to explore personal experiences in depth, several ethical considerations are required.

Firstly, during interviews and focus groups some participants may choose to discuss sensitive topics which they, or others may find upsetting. In the event of a participant becoming distressed, several measures may be taken depending on whether this occurs during an interview or focus group discussion. If a person becomes distressed during an interview, the interviewer will offer to pause the interview and recording and suggest taking a break. Following a break, the option to continue the interview will be offered as well as the option to postpone or, if required, cease their involvement in the study. If a person feels like they require additional support, the researcher will arrange this and liaise with the relevant professionals (e.g. CAMHS clinicians, ComBAT chief investigator and co-applicants trained in supporting distressed individuals). This will be explained to all participants in the participant information sheet and reiterated prior to the interview start.

If a person becomes distressed during a focus group, the facilitator will offer to pause the discussion and recording and suggest taking a break or will ask the participant whether they would like to temporarily leave the discussion. The facilitator will determine the best approach to be taken on a case-by-case basis. Outside of the discussion (either in person or via video conferencing as appropriate) the participant will be given the option to re-enter the discussion, arrange an interview at a different time for them to complete their involvement or, if required, cease their involvement in the study. If a person feels like they require additional support, the researcher will arrange this and liaise with the relevant professionals (e.g. CAMHS clinicians, ComBAT chief investigator and co-applicants trained in supporting distressed individuals). This will be explained to all participants in the participant information sheet and reiterated prior to focus group start.

All researchers conducting interviews and facilitating focus groups have experience of supporting people in distress and will receive additional training to enable them to enact these measures if they feel it necessary. Following all interviews and focus groups all participants will be provided with information about services that they are able to contact for additional support if required.

Confidentiality of participants and the data obtained will be maintained throughout. All data obtained from participants will be assigned an identifier with no personal information collected and pseudonyms will be used when reporting all results. All recordings will be made using encrypted devices with recordings deleted immediately following transcription. We will also ensure that ground rules are set prior to all interviews and focus groups whereby we will ask participants to refrain from disclosing any personal or family information. We will follow a structured topic guide and keep discussions focused on the research objectives. All group facilitators will have a health, social care or educational background and relevant DBS checks.

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13. EMBEDDED PROFESSIONALS' SURVEY

11.1. Study design

Alongside the feasibility study we will conduct a short survey to find out what path young people with mild to moderate depression may take to access help in different settings and locations. The survey questions are based on the ITAX (Schulz et al., 2010, see section 10.5). All survey questions will be interpreted with flexibility for 'usual care' which may not involve a specific intervention, but rather a less directive and less defined process of support.

11.2. Participants and recruitment

Professionals working with young people experiencing mild to moderate depression and based within local and specialist CAMHS, mainstream and special schools, improving access to psychological therapies (IAPT) services, voluntary agencies for young people, community paediatrics, residential social care settings, and other specialist local authority services will be invited to complete the survey. A link will be distributed to whole teams via secretaries with all professionals asked to share the link with other, relevant colleagues.

11.3. Procedure

The survey will be hosted on the Qualtrics Platform with individuals able to complete it online or via telephone with a member of the research team, depending on preference. If any individuals/sites express that they would be happy to elaborate on their survey answers or they would like to find out more about the research, a telephone or face-to-face conversation will be arranged. The survey has been designed to be brief and take approximately 10 minutes to complete.

To complete the survey all professionals will need to agree to a consent statement. This reiterates the study aims, explains data storage arrangements and provides important information about principles of General Data Protection Regulation (GDPR).

The survey comprises a combination of short answer questions with drop-down boxes embedded (where possible) for ease of completion. Survey questions explore the services to which participants belong, the treatments (if applicable) offered to young people (including their duration, session number and length), the professionals responsible for delivering interventions to young people, any thresholds in place for service acceptance, how young people reach services (i.e. self-referral, GP referral) and whether services signpost young people with mild to moderate depression elsewhere. No personal information is collected as part of the survey with all responses being anonymous. However, if a participant wishes to arrange a further follow-up call to discuss the study or their responses in further detail, they will be required to provide their contact details. All participants will be informed of their right to withdraw as part of the consent statement, however any data obtained prior to withdrawal will be retained as agreed when consenting to participate.

Two fortnightly automated reminders will be sent to the professionals to encourage survey completion.

11.4. Sample size

We will recruit professionals until we reach data saturation, i.e. where we feel additional data collection does not add substantially to the findings. The responses to the survey questionnaire

will be reviewed weekly in order to ascertain this. If the response rate is poor, we will contact key individuals (e.g. the CCG and local authority commissioners) to facilitate communications with their local NHS and non-NHS agencies and organisations.

11.5. Data analysis

All survey responses will be analysed by themes using the ITAX (Schulz et al., 2010). This will produce a roadmap of the different "journeys" that young people with depression may take in order to access evidence-based interventions across different sites. This information will be used for two purposes. First, to understand what 'usual care' options we are likely to encounter in our subsequent RCT. Particularly, it is important for us to identify sites where usual care includes BA, or sites where no support is in place for young people randomised to usual care. Second, the roadmap will help us plan different delivery models for our BA intervention that fit different types of usual care. We need to ensure that the ComBAT research is provided in schools and the third sector in a way that fits, as much as possible, with existing and evolving ways of working.

14. MONITORING, AUDIT AND INSPECTION

Throughout completion of the feasibility study, as well as the subsequent RCT, trial monitoring and site monitoring procedures will be followed in accordance with the standard operating procedures of both the study trials unit (York Trials Unit) and the study sponsor (TEWV). The conduct of the study will be governed by a Programme Steering Committee (PSC) which has been established as part of the wider 5-year ComBAT research programme. This committee comprises an independent chair, two independent senior academics, two representative of young service users and two parents/carers. The PSC will meet once a year and will monitor progress, protocol adherence and will provide advice to the Chief Investigator, the NIHR, the University of York and TEWV. All resources produced from the findings of the feasibility study will be presented to the PSC ahead of testing in the larger RCT.

15. ETHICAL AND REGULATORY CONSIDERATIONS

13.1. 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 feasibility study. Both the REC and HRA will be notified of, and asked to review, any proposed changes to the procedures and/or study documentation made during the study. As no pharmaceutical compounds or medical devices will be used in the study Clinical Trials Authorisation will not be required.

13.2. Ethical considerations

Several ethical issues have been considered to enable the safe running of this feasibility study. First, young people with depression can be vulnerable and may experience distress or worsening symptoms during their participation. All participants entering the study will be provided with information outlining who to contact if they (or their parent/guardian, if applicable) have any concerns or worsening symptoms during participation. This will include providing individuals with the contact information of their local CAMHS duty clinician service which provides urgent assessments during office hours on weekdays. In the event that a participant feels at risk outside of these hours they will be signposted to the out of hours on-call service provided by consultant psychiatrists 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 visit (baseline) with the researcher. Agreement to seek additional support if required will be a requisite of study entry.

During any contact with the research team, if we consider a young person to be at risk we will ask the parent/guardian, and the young person, for permission to liaise with the relevant support services (e.g. social care/child protection/mental health). If the level of risk warrants it, the research team will directly contact the relevant services, having obtained informed consent from the participants before they entered the project (the consent form will state "risk" as a criterion for breaching confidentiality). During their participation, all young people will have access to usual care with this communicated to them clearly. If a professional delivering BA feels that the complexity or severity of the depression or other problems warrants more high-intensity treatment, they may decide to discontinue the participant from the research.

Throughout the research, any 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 support workers if they are unhappy about their participation in the research. We will explicitly state in the study information sheet 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 feasibility study 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) (see section 3 for more information about data storage).

Finally, as some participants may prefer for their baseline and follow-up assessments to be conducted face-to-face, we will adhere to the University of York's lone worker policy in these instances. 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 of their location, 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.

We acknowledge that taking part in this feasibility study will require young person participants to attend treatment sessions over a period of up to 8 weeks, complete a series of outcome measures at baseline and follow-up and attend an interview about their experiences. As a thank you, all young person participants will receive a £25 Love to Shop voucher following their interview in recognition of their contribution.

13.3. Data storage

All data collected during the feasibility study 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 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. All personal identifiable information will be destroyed at the end of the ComBAT 5-year programme of research and the rest of the information from the study will be

destroyed after 10 years as per the requirements of the National Institute for Health Research (NIHR).

16. DISSEMINATION POLICY

The results of this work will be disseminated to our 2 PPI advisory groups. We will hold 2 consensus workshops (one with each PPI group) where we will present the final BA resources that will have been developed based upon the data collected in the feasibility study. The data obtained from the survey completed with healthcare professionals will ensure the developed resources are 'pragmatic'. More broadly, we will produce academic papers to describe the methods and findings of our research. We will also create non-academic materials for workshops, seminars, podcasts, posters and other digital and physical media. Through our varied dissemination strategies our research will be accessed by several stakeholder groups including healthcare professionals, other allied professionals, educational establishments, young people and their families.

17. REFERENCES

Arnott B, Kitchen CEW, Ekers D, Gega L, Tiffin P. (2020) Behavioural activation for overweight and obese adolescents with low mood delivered in a community setting: feasibility study. *BMJ Paediatrics Open*;4:e000624. doi: 10.1136/bmjpo-2019-000624

Balazs, J., Miklósi, M., Keresztény, Á., Apter, A., Bobes, J., Brunner, R., Corcoran, P., Cosman, D., Haring, C., Kahn, J.P. and Postuvan, V. (2012). P-259-Prevalence of adolescent depression in Europe. *European Psychiatry*, 27(S1), 1-1.

Billingham, S.A., Whitehead, A.L. & Julious, S.A. (2013). An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. BMC medical research methodology, 13(1), 1-6.

Boyd, H., McKernon, S., Mullen, B. & Old, A. (2012). Improving healthcare through the use of co-design. New Zealand Medical Journal, 125(1357),76–87.

Chorpita, B. F., Yim, L., Moffitt, C., Umemoto, L. A., & Francis, S. E. (2000). Assessment of symptoms of DSM-IV anxiety and depression in children: A revised child anxiety and depression scale. *Behavior Research and Therapy*, 38, 835-855.

Chorpita BF, Moffitt CE, Gray J (2005) Psychometric properties of the Revised Child Anxiety and Depression Scale in a clinical sample. *Behaviour Research and Therapy*, 43:309-22.

Crenna-Jennings, W. & Hutchinson, J. (2020). Access to Child and Adolescent Mental Health Services in 2019. [Online]. Education Policy Institute. Available at: https://epi.org.uk/wp-content/uploads/2020/01/Access-to-CAMHS-in-2019_EPI.pdf [Accessed at: 13.07.2021].

De Haan, A.M., Boon, A.E., de Jong, J.T., Hoeve, M. & Vermeiren, R.R. (2013). A meta-analytic review on treatment drop-out in child and adolescent outpatient mental health care. Clinical Psychology Review, 33, 698-711.

Department of Health and Social Care and Department for Education. (2017). Transforming children and young people's mental health provision: a green paper. [Online] Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachmentdata/file/664855/Transforming_children_and_young_peoples_mental_health_provision.pdf [Accessed 13.07.2021].

de Ross, R.L., Gullone, E., & Chorpita, B.F. (2002). The Revised Child Anxiety and Depression Scale: A psychometric investigation with Australian youth. Behaviour Change, 19, 90–101.

Ebesutani, C., Reise, S. P., Chorpita, B. F., Ale, C., Regan, J., Young, J., ... & Weisz, J. R. (2012). The Revised Child Anxiety and Depression Scale-Short Version: scale reduction via exploratory bifactor modeling of the broad anxiety factor. *Psychological Assessment*, 24(4), 833.

Ekers, D., Webster, L., Van Straten, A., Cuijpers, P., Richards, D. & Gilbody, S. (2014). Behavioural Activation for depression: An update of a meta-analysis of effectiveness and sub-group analysis. *PLoS One*, 19(6), e100100.

Ekers, D., Richards, D., McMillan, D., Bland, J. M. & Gilbody, S. (2011) Behavioural activation delivered by the non-specialist: phase II randomised controlled trial. *British Journal of Psychiatry*, 198(1), 66-72.

Gellatly, J., Bee, P., Kolade, A., Hunter, D., Gega, L., Callender, C., Hope, H. & Abel, K.M. (2019). Developing an intervention to improve the health related quality of life in children and young people with serious parental mental illness. *Frontiers in Psychiatry*, 10, 155.

Grover, S. & Avasthi, A. (2019). Clinical practice guidelines for the management of depression in children and adolescents. *Indian Journal of Psychiatry*, 61(S2), 226.

Jones, R.B., Stallard, P., Agha, S. S., Rice, S., Werner-Seidler, A., Stasiak, K. ... & Evans, R. (2020). Practitioner review: Co-design of digital mental health technologies with children and young people. Journal of Child Psychology and Psychiatry, 61(8), 928-940.

Julious, S.A. (2005). Sample size of 12 per group rule of thumb for a pilot study. Pharmaceutical Statistics: The Journal of Applied Statistics in the Pharmaceutical Industry, 4(4), 287-291.

Kanter, J. W., Mulick, P. S., Busch, A. M., Berlin, K. S., & Martell, C. R. . (2012) . Behavioral Activation for Depression Scale (BADS) (Long and Short Form). Measurement Instrument Database for the Social Science. Available at: www.midss.ie [Accessed 17.02.2022].

Kanter, J.W., Manos, R.C., Bowe, W.M., Baruch, D.E., Busch, A.M. & Rusch, L.C. (2010). What is behavioral activation? Clinical Psychology Review, 30, 608-20.

Kanter, J. W., Mulick, P. S., Busch, A. M., Berlin, K. S. & Martell, C. R. (2007). The Behavioral Activation for Depression Scale (BADS): Psychometric properties and factor structure. Journal of Psychopathology and Behavioral Assessment, 29, 191–202.

Kitchen, C. E., Tiffin, P. A., Lewis, S., Gega, L. & Ekers, D. (2020). Innovations in Practice: A randomised controlled feasibility trial of Behavioural Activation as a treatment for young people with depression. *Child and Adolescent Mental Health*.

Manos, R. C., Kanter, J. W., & Luo, W. (2011). The behavioural activation for depression scale-short form: development and validation. *Behavior Therapy*, 42, 726-739.

Martin, F. & Oliver, T. (2019). Behavioral activation for children and adolescents: a systematic review of progress and promise. *European Child & Adolescent Psychiatry*, 28(4),427-441.

Mayes, T.L., Bernstein, I.H., Haley, C.L., Kennard, B.D. & Emslie, G.J. (2010). Psychometric properties of the Children's Depression Rating Scale – Revised in adolescents. *Journal of Child and Adolescent Psychopharmacology*, 20(6), 513-516.

McCauley, E., Schloredt, K.A., Gudmundsen, G.R., Martell, C.R. & Dimidjian, S. (2016a). Behavioral activation with adolescents: A clinician's guide. New York: Guilford Press.

McCauley, E., Gudmundsen, G., Schloredt, K., Martell, C. Rhew, I., Hubley, S. & Dimidjian, S. (2016b). The Adolescent Behavioral Activation Program: Adapting Behavioral Activation as a Treatment for Depression in Adolescence. *Journal of Clinical Child & Adolescent Psychology*, 0(0), 1–14.

National Institute for Health and Care Excellence (2019). NG134: Depression in children and young people: Identification and management in primary, community and secondary care. NICE clinical guideline 28, September 2005. [Online]. Updated June 2019. Available at: https://www.nice.org.uk/guidance/ng134 [Accessed 13.07.2021].

National Institute for Health and Care Excellence (2016). CG90: Depression in adults: Recognition and management. NICE clinical guideline 90, October 2009; updated April 2016. Retrieved from: http://www.nice.org.uk/guidance/cg90.

National Institute for Mental Health (2019) Major Depression: Prevalence of Major Depressive Episode Among Adolescents. Available online: https://www.nimh.nih.gov/health/statistics/major-depression. [acesssed 08/08/2021]

Pass, L., Sancho, M., Brett, S., Jones, M.& Reynolds, S. (2018). Brief Behavioural Activation (Brief BA) in secondary schools: a feasibility study examining acceptability and practical considerations. Educational and Child Psychology, 35(2), 10-20.

Pass, L., Lejuez, C. W. & Reynolds, S. (2017). Brief Behavioural Activation (Brief BA) for Adolescent Depression: A Pilot Study. Behavioural and Cognitive Psychotherapy, 1-13.

Patalay, P. and Fitzsimons, E., 2017. Mental ill-health among children of the new century: trends across childhood with a focus on age 14. London: Centre for Longitudinal Studies, pp.1-6.

Plener, P.L., Grieb, J., Spröber, N., Straub, J., Schneider, A., Keller, F. & Kölch, M.G. (2012). Convergence of children's depression rating scale-revised scores and clinical diagnosis in rating adolescent depressive symptomatology. Mental Illness.

Poznanski, E.O. & Mokros, H.B. (1996). Children's Depression Rating Scale-Revised Manual. Los Angeles: Western Psychological Services.

Richards, D. A., Ekers, D., McMillan, D., Taylor, R. S., Byford, S., Warren, F. C. et al. (2016). Cost and Outcome of Behavioural Activation versus Cognitive Behavioural Therapy for Depression (COBRA): a randomised, controlled, non-inferiority trial. The Lancet, 27, 388(10047), 871-80.

Schulz, R., Czaja, S.J., McKay, J.R., Ory, M.G. & Belle, S.H. (2010). Intervention Taxonomy (ITAX): describing essential features of interventions. American Journal of Health Behavior, 34, 811–821.

Stevens, K. & Ratcliffe, J. (2012). Measuring and valuing health benefits for economic evaluation in adolescence: An assessment of the practicality and validity of the child health utility 9d in the australian adolescent population. *Value in Health*, 15(8):1092-99.

Thabrew, H., Fleming, T., Hetrick, S. & Merry, S. (2018). Co-design of eHealth interventions with children and young people. Frontiers in Psychiatry, 9, 481.

Thapar, A., Collishaw, S., Pine, D.S. & Thapar, A.K. (2012). Depression in adolescence. The Lancet, 379, 1056–67.

Tindall, L., Mikocka-Walus, A., McMillan, D., Wright, B., Hewitt, C. & Gascoyne, S. (2017). Is Behavioural Activation effective in the treatment of depression in young people? A Systematic Review and Meta-analysis. Psychology and Psychotherapy: Theory, Research and Practice, 90(4), 770-796.

Vostanis, P., Humphrey, N., Fitzgerald, N., Deighton, J. & Wolpert, M. (2013). How do schools promote emotional well-being among their pupils? Findings from a national scoping survey of mental health provision in English schools. Child and Adolescent Mental Health, 18(3), 151-157

Wolpert, M., Cheng, H. and Deighton, J. (2015), Measurement Issues: Review of four patient reported outcome measures: SDQ, RCADS, C/ORS and GBO – their strengths and limitations for clinical use and service evaluation. Child and Adolescent Mental Health, 20: 63-70. https://doi.org/10.1111/camh.12065

Wolpert, M., Jacob, J., Napoleone, E., Whale, A., Calderon, A., & Edbrooke-Childs, J. (2016). Child- and Parent-reported Outcomes and Experience from Child and Young People's Mental Health Services 2011–2015. London: CAMHS Press.

World Health Organization (2008). The Global Burden of Disease: 2004 Update. Geneva: World Health Organisation.

World Health Organisation (2021) Adolescent mental health: Emotional Disorders. Available from: https://www.who.int/news-room/fact-sheets/detail/adolescent-mental-health. [Accessed 08/08/2021]