ATTEND (Adolescents and carers using mindfulness Therapy To END depression)

A mindfulness-based approach for adolescent non-responders to first-line treatments of depression and their carers: establishing feasibility of implementation and delivery

Chief Investigator	Professor Tamsin Ford
Sponsor	Co-sponsors: Cambridge and Peterborough NHS Foundation Trust & University of Cambridge
Funder	National Institute for Health Research Programme Development Grant
NIHR Portfolio number	NIHR201024
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Children & Family Health Devon

KING'S College LONDON

Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol.

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 investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly 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 from the trial as planned in this protocol will be explained.

	Name	Position	Signature	Date
Trial sponsor	Stephen Kelleher	Senior R&D Manager		
Chief Investigator	Tamsin Ford	Professor of Child and Adolescent Psychiatry		
London Principal Investigator	Dr Patrick Smith	Reader in Clinical Psychology		
Devon Principal Investigator	Caroline Clunies-Ross	Principal Clinical Psychologist and Clinical Lead, JACAT Professional Lead for CBT		

General Information This protocol describes the ATTEND study and provides information about the procedures for entering participants into the trial. Every

care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the trial. Problems relating to the trial should be referred, in the first instance to the Study Manager Dr Rachel Hayes (R.A.Hayes@exeter.ac.uk).

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Study Co-Ordination

The ATTEND study is being coordinated by Dr Rachel Hayes. This protocol has been developed by the ATTEND Study Management Group (SMG). For all queries please contact Rachel Hayes (R.A.Hayes@exeter.ac.uk).

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Study Summary

Short title	A combined mindfulness-based approach for adolescent non-responders to first-line treatments of depression and their carers: establishing feasibility of implementation and delivery
Subtitle	ATTEND (Adolescents and carers using mindfulness Therapy To END depression)
Funder and ref.	National Institute for Health Research (NIHR) Programme Development Grant (PDG) NIHR201024
Study Sponsor	Joint sponsors: Cambridge and Peterborough NHS Foundation Trust & University of Cambridge
Study Design and Objectives	This study comprises three separate work packages to address four areas of uncertainty: (1) develop the delivery of our training and supervision programme for therapists; (2) describe the current care pathways of young patients who have not responded to treatments delivered by CAMHS services and develop a detailed understanding of what Treatment As Usual (TAU) comprises; (3) explore and operationalise the identification of eligible young people and to estimate the proportion of eligible young people who are willing to be randomised in order to underpin the calculation of the number of participating sites required in a definitive trial to provide an adequately powered sample; (4) Build therapist experience by delivering the intervention to two groups of young people and their parents; The findings of these linked work packages will feed into the development of the proposed Programme Grant for Applied Research PGfAR) protocol which will include a fully powered

	definitive multicentre randomised controlled trial comparing MAC with TAU for the treatment of patients within CAMHS.
Study participants	Young People Young people who have completed at least one NICE recommended treatment for depression in a CAMHS service, and 1. have not recovered sufficiently to be discharged, OR 2. have previously recovered from depression and been discharged but subsequently relapsed and been re-referred will be eligible for participation in the study. Carers When a young person consents to take part in the study their parent or another adult carer will also be invited to take part.
Planned sample size	40 young people
Planned number of sites	2: Devon and London
Inclusion criteria	Young People Inclusion • CAMHS patients with a primary diagnosis of depression • Aged 14-17 years at the time of recruitment • Completed at least one NICE recommended treatment for depression • Not recovered sufficiently to be discharged, or who have subsequently relapsed and been re-referred Carer Inclusion • A carer of a young person who has consented to take part in the study
Exclusion criteria	Young People Exclusion

<table>
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- A primary presenting problem of eating disorder, post-traumatic stress disorder or psychosis
- Self-harming behaviour or substance misuse necessitating current active clinical management

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<tr><td>Intervention duration</td><td>9 weeks</td></tr>
<tr><td>Follow-up duration</td><td>Two follow-up assessments will be completed at one- and four-months post-treatment, or the equivalent timeframe for TAU</td></tr>
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<tr><td>Intervention</td><td>Mindfulness for Adolescents and their Carers (MAC)

Mindfulness-based cognitive therapy (MBCT) for adults was designed to prevent depressive relapse by reducing unhelpful ways of reacting to stress and negative mood, including</td></tr>
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	maladaptive patterns of repetitive thinking; it aims to teach people to recognise these patterns and to respond in more adaptive ways. We have developed and piloted a 9-session mindfulness-based cognitive therapy programme for young people who have completed a first line psychological intervention for depression within CAMHS, but are not sufficiently well enough to be discharged. Given the importance of family context in influencing young people's recovery, we have included a parallel version of the intervention for carers.

Plain English Summary

Background. Depression in teenagers can knock normal development off course and disrupt family relationships. Even after treatment, many young people still have symptoms, so we need more treatment options for this group who suffer greatly. We have developed a new treatment, 'Mindfulness for Adolescents and Carers' (MAC), in which young people and carers learn to recognise unhelpful patterns of thoughts and feelings and to find new ways of dealing with distress. Earlier work shows that carers and young people were willing to take part in treatment sessions. They found mindfulness helpful and young people's symptoms reduced.

Aims. Before we can test whether MAC works and is value for money, we need to answer four questions:-.

1. Who should be trained to deliver mindfulness, and how should they be trained? We need to establish the capacity Child and Adolescent Mental Health Services (CAMHS) has for delivering mindfulness interventions. We need to develop a training programme that can accommodate therapists who may be skilled in working with young people but not mindfulness and vice versa.

2. What does 'usual' treatment look like for this group of young people? We will interview young people, carers and therapists in CAMHS and analyse case notes. This will help us understand how people in this group are currently treated by CAMHS so we can make sure that we target those young people most likely to benefit from mindfulness and plan a larger trial that has the most appropriate comparator.

3. How can young people and their carers best be recruited to a study on mindfulness? We will run one mindfulness group in London and one in Devon with the new therapists we have trained. Young people and carers will be selected at random to either receive mindfulness or not. This will allow us to try out ways of inviting people to this kind of research and to understand how many clinics we need to work with when we test if MAC is effective.

4. How many young people would agree to provide blood and saliva samples? This will help us to test whether biological changes might occur as a result of MAC, which in turn explain how the mindfulness treatment works or who is most likely to respond.

What will this study produce? We will use what we have learned to plan a future programme of work that will definitively test whether MAC works, is value for money, whom it might work best for and how we can best identify, train and support clinicians to deliver MAC.

Involvement of patients: Young people and carers were involved in the design of this study from its conception. They will help us design the interview questions, understand our findings and explain our results to others.

Introduction

Background and Rationale

Depressive disorders are increasingly common among young people and frequently comorbid with anxiety, with a prevalence of 9% among 11-16 year olds and 15% among 17-19 year olds in the most recent national survey (Vizard et al., 2018). Psychological treatments for depression in young people improve symptoms but gains are often not maintained, and between 34% and 75% of young people relapse within one to five years (Kennard et al., 2009). A significant number of young people attending Child and Adolescent Mental Health Services (CAMHS) are therefore at risk for a lifetime of recurrent emotional disorder (Costello & Maughan, 2015). The risk of relapse is significantly increased among young people with residual symptoms and increases with each new episode (Alliance & Health, 2016; Cox et al., 2012; Kennard et al., 2009; Weisz et al., 2017).

Mindfulness-based cognitive therapy (MBCT) for adults was designed to prevent depressive relapse by reducing unhelpful ways of reacting to stress and negative mood, including maladaptive patterns of repetitive thinking; it comprises an 8-week group-based programme that combines mindfulness practice with cognitive behavioural elements (Kuyken et al., 2016). MBCT aims to teach people to recognise these unhelpful reactive patterns and to respond to stress and low mood in more adaptive ways. There is now a substantial body of evidence for its effectiveness and cost-effectiveness in relapse prevention for depression among adults (Glodberg Tucker, R.P., Greene, P.A., Davidson, R.J., Wampold, B.E., Kearney, D.J. & Simpson, T.L. et al., 2018; Kuyken et al., 2016); these meta-analyses suggest that the preventative effects of the intervention are increased among people who are suffering from residual symptoms. Importantly, research shows that the utilisation of core skills is maintained, and often increases, after the completion of MBCT, which suggests a lasting potential for buffering responses to stress and negative mood (Farb et al., 2018). There is growing interest in the application of mindfulness- based approaches with young people including a recent meta-analysis which demonstrated that

Mindfulness Based Interventions (MBIs) had a significant positive impact on children and young people's reported levels of depression (d = .47) and anxiety/stress (d = .18) (Dunning et al., 2018).

Drawing on the above evidence and theory, we have developed and piloted a 9-session mindfulness-based cognitive therapy programme for young people who have completed a first line psychological intervention for depression within CAMHS, but are not sufficiently well enough to be discharged. Given the importance of family context in influencing young people's recovery (Sander & Mccarty, 2005), we included a parallel version of the intervention for carers. Our theory of change is illustrated in Figure 1.

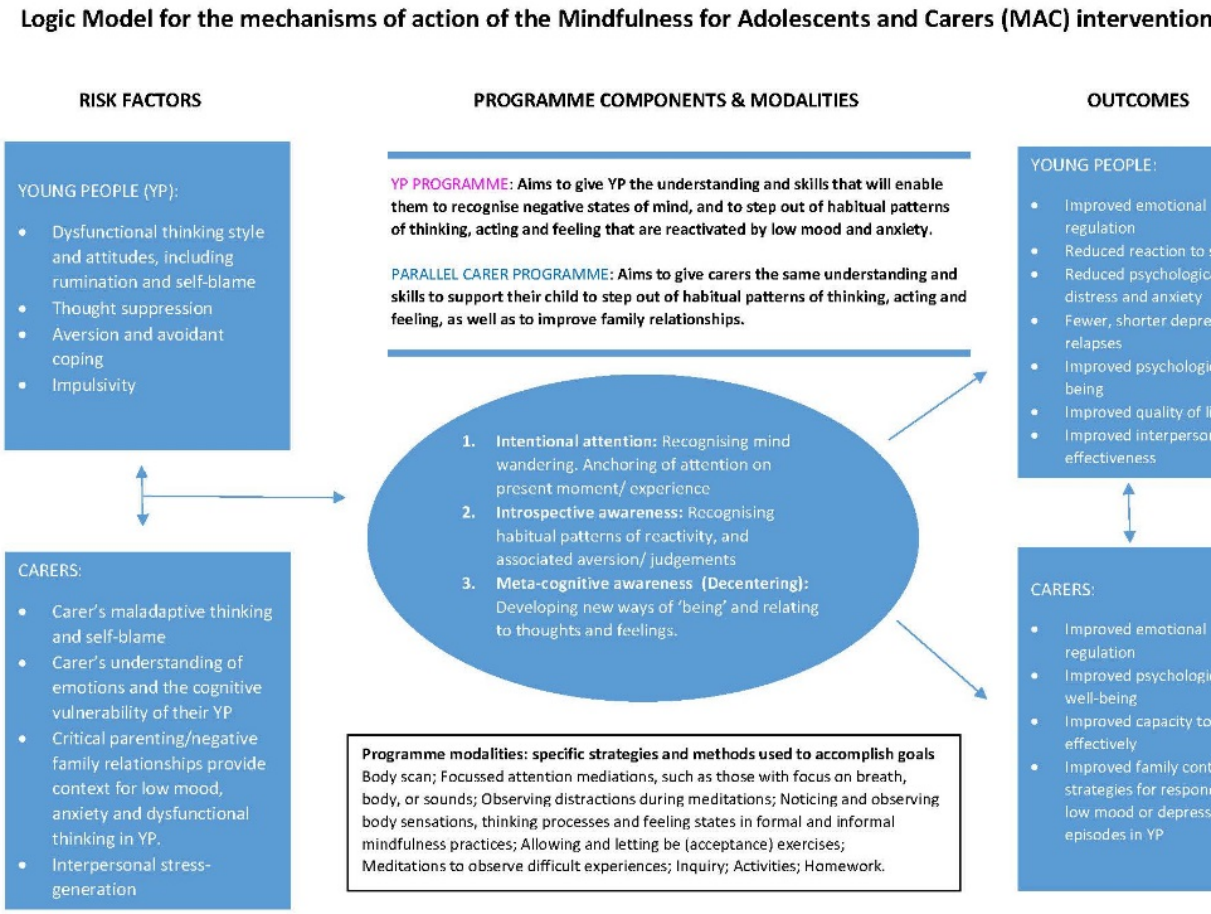

Figure 1: Logic model for the mechanisms of action of the MAC intervention

Our pilot work with this intervention, Mindfulness for Adolescents and Carers (MAC), comprises six cohorts at two sites (Exeter University and King's College London), and shows that the intervention is both acceptable and feasible (Ames et al., 2014; Racey et al., 2018). Carer involvement was strongly endorsed by young people, carers and the referring clinicians (Racey et al., 2018). Although primarily designed to support young people's mindfulness practice, which predicts response to MBCT (C. Crane et al., 2014; Parsons et al., 2016), carers reported that the parallel group supported them through the emotional impact of caring for a child with poor mental health. More than half of the carers had a personal history of depression, and approximately a quarter were taking antidepressants (Racey et al., 2018). Both young people and carers reported significantly improved family relationships after attendance at MAC (Racey et al., 2018). Carers as well as young people reported statistically significant reductions in rumination and improvements in self-compassion and decentring (Racey et al., 2018). The addition of the parallel carers' group would, therefore, seem to be a particularly powerful approach in highly vulnerable young people who have relapsed or not responded fully to initial treatment, and for whom intergenerational transmission is likely to have played a significant role in their presentation to CAMHS. It may also improve the mental health of carers as previous work by our team suggests a bi-directional relationship between parent and child mental health (Wilkinson et al., 2020).

Importantly, our audits in the development sites suggest a lack of access to evidence-based alternatives to MAC for young people for second-line interventions. For example, only 38% of 14-17 year olds referred to the Depression and Anxiety pathway in Exeter CAMHS were offered one of the following evidence based treatments: Cognitive Behavioural Therapy (CBT), Family Therapy, Supportive Therapy or antidepressants. Furthermore, 47% remained in treatment at 12 months, and an additional further 20% were transferred to adult mental health services (Apostu et al., 2018).

Finding ways to identify the young people most at risk of repeated and prolonged episodes of emotional disorders as well as more effective and timely treatment of residual symptoms to prevent relapse is therefore imperative, and is among the top 10 priorities for research in depression according to a prioritisation process led by the James Lind Alliance (Alliance & Health, 2016). Indeed, mental health remains a named priority area for NIHR and the National Institute of Health and Care Excellence (NICE) guidelines on the identification and management of depression among children and young people recommend research into the effectiveness of group mindfulness therapy in the most recent update, published in June 2019 (NICE, 2015).

Aims and objectives

Our previous research suggests that MAC is feasible and acceptable, but to enable a definitive programme of research into the effectiveness, cost-effectiveness, and mechanisms of action and implementation, we need to address four key areas of uncertainty.

1. We need a sufficient number of trained mindfulness and CAMHS therapists to deliver MAC in a definitive trial and any subsequent implementation programme, and **we need to understand how best to train and supervise them to optimise intervention delivery**.
2. We need to **improve our understanding of the current care pathways** to both inform recruitment to a definitive study and to be able to fully document what TAU is likely to involve, as well as whether access to MAC influences TAU.
3. We need to understand the **recruitment pathway for a larger definitive trial**. This will include understanding **how to support clinicians to identify appropriate young people** for inclusion in the trial and to operationalise this procedure and to establish that young people and their carers are **willing to take part in a randomised trial of MAC** and we need to estimate **how many people we will need to invite** to take part in order for us to reach our target recruitment.

4. If we are to evaluate biological as well as psychological and social mechanisms of action, we need to understand how best to invite participation in such studies and what proportion of young people would be willing to provide **biological samples (blood and saliva)**.

Study design

These objectives will be met through three separate work packages; 1) refining the training and supervision procedures (WP1), developing the recruitment and randomisation protocol (WP2) and standardising the measurement of Treatment As Usual (TAU) (WP3). The findings of these linked work packages will feed into the development of the proposed Programme Grant for Applied Research (PGfAR) protocol which will include a fully powered definitive multicentre randomised controlled trial comparing MAC with TAU for the treatment of patients within CAMHS, to evaluate effectiveness, cost-effectiveness, and how best to target MAC to those most likely to benefit.

WP1 Refinement of the training process

We will scope the potential for recruiting therapists with a) a core professional qualification that would enable them to work with young people, and some experience of leading or co-leading a Mindfulness Based Intervention (MBI) and ideally with a level 1 teacher training certificate. In December 2020 and January 2021 we will train up to 20 therapists from 2 sites, six of whom would deliver their first MAC groups under supervision. We will then adapt our training model to make it suitable for training a larger number of MAC therapists for delivery of the definitive randomised controlled trial.

WP2 Developing the recruitment and randomisation protocol: Feasibility Trial

We will test the feasibility of randomising young people and their carers to either MAC or TAU by identifying and recruiting 20 young people from CAMHS settings in each site

(London and Exeter) and randomly allocating them a treatment. We will monitor eligibility, willingness to be randomised, recruitment, retention, and data completeness and seek to understand the acceptability of our choice of outcome measures. We will scope the acceptability of repeated mechanism questionnaire measures during the feasibility study. Whilst we do not intend to collect blood or salvia samples in this study, we will explore with participants how acceptable they feel it would be to do so in a definitive trial. The results from this feasibility study will inform the design of the definitive randomised controlled trial.

WP3 Standardising the measurement of treatment as usual (TAU)

This stream of work will identify and characterise the treatment experiences of young people considered suitable for MAC by services, as well as the TAU comparator across sites for those who are not allocated to receive MAC. We will conduct an audit in each participating site exploring treatment/s received by eligible young people. We will also test a Treatment Recording Sheet (TRS) for use in the definitive trial.

Methods

Participants

Young People

Young people who are being treated for depression in a CAMHS setting who have completed at least one NICE recommended treatment but are not recovered sufficiently to be discharged, or who have subsequently relapsed and been re-referred for the same condition will be eligible for participation in the study.

Parent/Carers

When a young person expresses an interest in the study we will invite one of their parents or carers to take part as well.

Inclusion and exclusion criteria

Young People Inclusion

- CAMHS patients with a primary diagnosis of depression
- Aged 14-17 years at the time of recruitment
- Completed at least one NICE recommended treatment for depression
- Not recovered sufficiently to be discharged, or who have subsequently relapsed and been re-referred

Young People Exclusion

- A primary presenting problem of eating disorder, post-traumatic stress disorder or psychosis
- Self-harming behaviour or substance misuse necessitating current active clinical management

Carer Inclusion

- A carer of a young person who has consented to take part in the study

Interventions

Mindfulness for Adolescents and their Carers (MAC)

Mindfulness-based cognitive therapy (MBCT) for adults was designed to prevent depressive relapse by reducing unhelpful ways of reacting to stress and negative mood, including maladaptive patterns of repetitive thinking; it comprises an 8-week group-based programme that combines mindfulness practice with cognitive behavioural elements (Kuyken et al., 2016). MBCT aims to teach people to recognise these patterns and to respond in more adaptive ways. There is now a substantial body of evidence for its effectiveness and cost-effectiveness in relapse prevention for depression among adults (Glodberg Tucker, R.P., Greene, P.A., Davidson, R.J., Wampold, B.E., Kearney, D.J. & Simpson, T.L. et al., 2018;

Kuyken et al., 2016); these meta-analyses suggest that the preventative effects of the intervention are increased among people who are suffering from residual symptoms. Importantly, research shows that the utilisation of core skills is maintained, and often increases, after the completion of MBCT, which suggests a lasting potential for buffering responses to negative mood and stress (Farb et al., 2018). There is growing interest in the application of mindfulness-based approaches with young people and some tentative but low-quality evidence to support their use in clinical populations (Tan, 2016).

Drawing on the above evidence and theory, we have developed and piloted a 9-session programme for young people who have completed a first line psychological intervention for depression within CAMHS, but are not sufficiently well enough to be discharged. Given the importance of family context in influencing young people's recovery (Sander & Mccarty, 2005), we have included a parallel version of the intervention for carers. Our theory of change is illustrated in our Logic Model (Figure 1).

The interventions will consist of 9 weekly group-based sessions of 2 hours duration and a pre-class interview of 1 hour duration conducted with each dyad of a young person and their carer and allowing for individual therapist contact with both of them. Participants of both groups will be asked to engage in regular daily home practice consisting of guided meditation and generalisation exercises aimed at helping participants utilise mindfulness skills in daily life. Both interventions will be delivered using videoconferencing and scheduled so that classes for young people and their carers will run in parallel.

The therapists and training

MAC therapists will require competency in both mindfulness and working with young people and their carers and therefore we will invite therapists who meet the following minimum criteria; i) have a core professional training (NHS band 6 and above) meaning they can work therapeutically with depressed children and young people, ii) have their own personal mindfulness practice following attendance at either an 8-week MBCT or MBSR group, and iii) have experience leading or co-leading a

Mindfulness Based Intervention (MBI), ideally with level 1 MBI teacher training. The MAC training will involve a 4-day training workshop in the MAC manuals with built-in practice and feedback sessions.

Detailed data about applicants' previous experience of work within CAMHS and mindfulness will be gathered in order to judge suitability of the candidates for the training. We will deliver the intervention once in both sites, which will comprise one group of young people and one group of carers at each site. The young person's group will be facilitated by one experienced MAC therapist and one newly trained MAC therapist and the carers group will be facilitated by two newly trained MAC therapists.

Supervision

Therapists will take part in 10 supervision sessions: Week 0 before orientation and session 1 begins through to week 10 after the final session has been delivered. Therapists will access remote group supervision with experienced MAC therapists. The 90-minute supervision would comprise 1 hour on the young person intervention (with at least 1 of the therapist pair attending) and ½ hour on carer intervention, with strong focus on overlap. A brief pre-supervision form will be developed, which therapists will complete to highlight demands to discuss at supervision. Competence and fidelity will be assessed by Thorsten Barnhofer applying the MBI-TAC (R. S. Crane et al., 2012) to video recordings of the workshops. In addition, session checklists and semi-structured interviews with the therapists will be used to identify elements of the manual that the therapists found challenging. The training manual, supervision and checklists may then be revised accordingly.

Treatment As Usual (TAU)

This stream of work aims to inform the PGfAR trial recruitment by indicating the characteristics and treatment experience of young people considered suitable for MAC by services, as well as the TAU comparator across sites for those who are not allocated to receive MAC. The audits conducted as part of our feasibility work strongly

suggest that discrete second-line interventions that resemble MAC are not currently offered. Furthermore, availability or offer of treatments is not consistent across CAMHS sites, which is problematic in a definitive trial. Given that MAC is an intense intervention and would provide 9 weekly highly structured sessions for the young person and separately for their carer, it seems likely that allocation to MAC may reduce the offer of alternative provision by CAMHS. If we can demonstrate this by measuring CAMHS provision during the PDG, it would suggest that the definitive trial would test MAC versus TAU rather than MAC + TAU versus TAU.

We will explore whether young people who received MAC continued, in addition, to receive similar input to those allocated to receive TAU. We will ask therapists to complete a Treatment Recording Sheet (TRS;(Bearsley-Smith et al., 2008)) for any other non-specified therapy or psychological intervention provided, to allow for comparison across sites of treatment strategies and intervention content for all those randomised to MAC or TAU (n=40). TRS is a currently non-validated measure collecting clinicians' report on a monthly basis for each young person, and is used to record specific intervention strategies (e.g. goal setting, supportive listening, family therapy) provided to young people and /or parents/families during sessions, and the frequency with which they are provided. We will ask the lead clinician for every young person involved in the trial to complete TRS reports at each data collection point. This work will allow us to test the acceptability and feasibility of the TRS and to validate its predictive accuracy and specificity against case notes, practitioners' and family reports via interviews and second-rated blinded completion. If the TRS is not suitable, we will use these data to develop an alternative procedure for the PGfAR.

Outcomes

Eligibility outcomes

Children's Revised Impact of Event Scale (CRIES-8)

The CRIES-8 is a brief child-friendly measure designed to screen children at risk for Posttraumatic Stress Disorder (PTSD) (Perrin et al., 2005). Each item is rated on a four-

point scale (Not at all, Rarely, Sometimes, Often), scored 0, 1, 3, 5. The total score indicates the severity of a child's posttraumatic stress reactions with a range from 0 to 65. Perrin et al. (2005) reported Cronbach's alpha to be 0.80 for the total scale and 0.70, 0.73, and 0.60 for the intrusion, avoidance and arousal subscales, respectively (Perrin et al., 2005). A score of 30 and above has been suggested as the most effective cut-off score for screening cases of PTSD (Perrin et al., 2005).

SCOFF

The SCOFF addresses the core features of anorexia nervosa and bulimia nervosa and was developed to detect cases of eating disorders (Morgan et al., 1999). Response options ('Yes'/'No') are scored by giving one point for a positive answer and zero points for a negative answer. Scoring two or more points was initially taken as the threshold for a suspicion of an eating disorder (Hautala et al., 2009). Some studies of adolescents lowered the threshold to 1 or more points to afford greater opportunity for early intervention (Mond et al., 2008) as the threshold of 2 points demonstrated sensitivity of 76– 82% and specificity of 79–97% (Leung et al., 2009; Rueda et al., 2005), but using a cut-point of one or more positive responses has provided sensitivity of 92% and specificity of 56% (Mond et al., 2008).

Self-Harm Questionnaire (SHQ)

The Self Harm Questionnaire (SHQ)(Ougrin & Boege, 2013) is a short questionnaire consisting of 3 screening questions which are followed by 12 follow-up questions assessing the severity, function and consequences of self-harm in adolescents. In a clinical setting, 20% of adolescents endorsed self-harming behaviours that were otherwise unknown from previous clinical examinations (Ougrin & Boege, 2013). However, in this same study, 3% of adolescents whose self-harming behaviour was already disclosed to the clinical team, chose not to report self-harm when completing the SHQ. To assess eligibility and ensure that potential participants are not currently self-harming in a way that necessitates active clinical management, all young people will complete the first three screening questions of the SHQ followed by the first follow-up question asking about how long ago the last episode of self-harm was. Any

young person who reports self-harming behaviours within the last 12 months will complete the full SHQ and their responses will be assessed in order to determine eligibility.

Primary Outcome – Young Person Reported

Revised Child Anxiety and Depression Scale – Short Form (RCAD-SF)

The RCAD-SF (Ebesutani et al., 2012) is a 25 item questionnaire that measures anxiety (15 items) and depression (10 items). Items are scored on a 4-point Likert scale (Never, Sometimes, Often or Always) with higher scores indicating greater levels of psychopathology. Both the depression and anxiety sub-scales show good internal and external validity with good reliability in both a clinical and school based sample (Ebesutani et al., 2017).

Secondary Outcome Measures

There are a number of psychological constructs that we wish to examine in both young people and their parents/carers. Table 1shows which outcome measure is being used to examine which construct alongside detailing who the respondent for each measure will be. Each measure is described in full below.

Table 1: The choice of outcome measures given to young people and carers to measure the following constructs

Construct	Young Person Completed	Parent or Carer Completed
Respondent Background	Background Questionnaire	Background Questionnaire
Depression	RCADS-SF (Primary Outcome)	GAD & PHQ-8
Quality of Life	CHU-9D	EQ-5D
Coping	1 bespoke question	1 bespoke question
Family Dynamics	Score-15	Score-15
Mindfulness	CAMM	FFMQ-SF
Self-Compassion	SCS-SF	SCS-SF

Emotional Regulation	ERQ	ERQ
Decentering	EQ Decentering Scale	EQ Decentering Scale
Rumination	CRSQ	RRS

Background and ability to 'cope'

To gather important information about participants' backgrounds we will ask about background characteristics such as presenting issues, current and previous treatments, previous experience of emotional disorders, current living situation, parental education and family history. Following consultation with our Patient and Public Intervention (PPI) group, we will ask a bespoke question about participants' perception of their ability to cope with life on a 5-pint Likert scale.

Generalized Anxiety Disorder Screener-7 (GAD 7)

The GAD-7 (Spitzer et al., 2006) (Spitzer et al., 2006) is a 7-item scale measuring symptoms of anxiety and worry. Items are rated on a 4-point Likert scale (0-3; maximum score 21), with higher scores reflecting greater symptom severity. Scores ≥10 indicate clinical levels of anxiety. The scale is reported to have excellent internal consistency (α = .89) and good convergent validity (S. U. Johnson et al., 2019; Löwe et al., 2008). Sensitivity and specificity are between 89-74% and 82-54%, respectively when a cut off of 10 is used (Beard & Björgvinsson, 2014; Spitzer et al., 2006).

Patient Health Questionnaire eight-item depression scale (PHQ-8)

The PHQ-8 (Kroenke et al., 2009; Kroenke & Spitzer, 2002) evaluates 8 of the 9 DSM-IV depression diagnostic criteria, omitting the question about suicide and self harm. Patients are asked how many days in the last 2 weeks they experienced different symptoms (0-1 days = 0, 2-6 days = 1, 7-11 days = 2, 12-14 days = 3). The maximum score is 24, with higher scores indicating greater symptom severity. Scores ≥10 are taken to signify clinical level major depression and when this cut off is used, sensitivity and specificity are both 88% (Corson et al., 2004; Kroenke et al., 2001; Kroenke & Spitzer, 2002).

Child health utility 9D (CHU-9D)

The CHU-9D is a measure of health-related quality of life, created through qualitative interviews with children to identify health dimensions that are important to them (K. Stevens, 2011; K. J. Stevens, 2010). Each of the 9 dimensions have 5 severity levels (5 being most severe) which are scored and converted into utility values from 0.33-1 (perfect health). The CHU-9D has fair to moderate test-retest reliability and good convergent and construct validity (Canaway & Frew, 2013; Ratcliffe et al., 2012).

Emotion Regulation Questionnaire (ERQ)

The ERQ (Gross & John, 2003) uses a 10-item scale to measure 2 different emotion regulation strategies: cognitive reappraisal (6 items) and expressive suppression (4 items). Items are rated on a 7-point Likert scale from 1–7, with higher scores indicating greater agreement with items. The cognitive reappraisal facet negatively predicts psychological distress and alexithymia, whilst expressive suppression is positively correlated with these characteristics (Preece et al., 2020). Across samples, the two ERQ facets show adequate to excellent internal consistency (cognitive reappraisal α = .89-.90; expressive suppression α = .76-.80; (Preece et al., 2020).

EQ-5D

The EQ-5D (Rabin & De Charro, 2001) assesses 5 health dimensions, with 3 levels of problems each. The patient responds based on their present health state by ticking any problems that currently apply to them. They then rate their current health state from 0-100 (best possible health state). This measure has good convergent and divergent validity with other health questionnaires (J. A. Johnson & Pickard, 2000).

SCORE-15

The SCORE-15 (Stratton et al., 2010) is a measure of familial quality of life. The questionnaire includes a 15-item scale (rated as 1-5; 1 being very characteristic of the respondent's family life) and 2 open and 3 sliding scale questions about the reason for seeking therapy. The SCORE-15 is sensitive to change in family functioning and has

excellent internal consistency (α = .89). It also appears to have good divergent validity, although responses may be influenced by gender of the scorer (Stratton et al., 2014).

Child and Adolescent Mindfulness Measure (CAMM)

The CAMM (Greco et al., 2011) measures awareness of the present moment and non-avoidance and non-judgement of one's own thoughts and feelings. Its 10 items are rated on a 5-point scale. The measure has good internal consistency (α = .80-.81) and CAMM scores are positively associated with quality of life and social and academic proficiency and negatively correlated with mental and physical health problems (de Bruin et al., 2014; Greco et al., 2011; Kuby et al., 2015).

Five Facet Mindfulness Questionnaire – short form (FFMQ-SF)

The FFMQ-SF (Bohlmeijer et al., 2011) assesses 5 facets of mindfulness (observing, describing, acting with awareness, non-judging and non-reactivity) with 24 items rated on a 5-point Likert scale. It has good adequate internal consistency with Cronbach's alpha values ranging from .73-.93 across facets, has good convergent and divergent validity and is sensitive to treatment-related changes in mindfulness (Bohlmeijer et al., 2011).

Self-Compassion Scale - short form (SCS-SF)

The SCS-SF (Raes et al., 2011) is a 12 item self-report measure of self-compassionate responding in the event of failure and distress. Items are rated on a five-point scale from 1 (almost never) to 5 (almost always). The measure has excellent internal consistency (α = .89) as well as good convergent, divergent, content and face validity (Neff, 2016; Raes et al., 2011).

Experiences Questionnaire (EQ Decentering Scale)

The EQ Decentering Scale (Fresco et al., 2007) measures decentering, the ability to understand mental states as temporary and objective events in the mind rather than as definitive reflections of the self. The scale consists of 10 items that are rated on a 5-point Likert scale from 1 (never) to 5 (all the time) and assess three facets: the

ability to separate oneself from one's thoughts, the ability not to react to negative experiences, and self-compassion. The questionnaire has good convergent and divergent validity (Fresco et al., 2007).

Children's Response Styles Questionnaire (CRSQ)

The CRSQ (John R.Z. Abela et al., 2004) is a 25-item scale measuring responses to depressive symptoms. It includes 3 scales (ruminative, distractive and problem-solving responses) which are scored individually by taking the mean (1-4) of items from that scale. Higher scores indicate a higher likelihood of responding in a given manner to depressive symptoms. Internal consistency across subscales is moderate to high (α = .51-.84) and scores are predictive of level of depressive symptoms, self-control and perceived helplessness, (J R Z Abela et al., 2002; Treynor et al., 2003).

Ruminative Responses Scale (RRS) – Brooding and Reflection Sub-Scale

The RRS (Nolen-Hoeksema & Morrow, 1991) is a 22-item scale to measure-symptom focused, self-focused and cause-focused responses to depressive mood. Since depressive mood is being measures elsewhere, we will only use the brooding and reflection sub-scales which comprise 10 items in total. Items are rated from 1 (almost never) to 4 (almost always). Internal consistency is excellent (α = .90) and test-retest reliability is adequate (r = .67; (Treynor et al., 2003).

Qualitative Interviews

We will conduct semi-structured interviews with key referring clinicians, MAC therapists, young people and carers to standardise the eligibility criteria and identification pathways for the subsequent trial. Our previous feasibility work has included a great deal of testing of possible questionnaires and measures, and we have benefitted greatly from our Patient and Carer Advisory Group input in our selection of the most important outcomes to measure, as well as the questionnaires that best tap their experience of MAC. However, we would use this opportunity for final testing of outcome measures and data management processes.

CAMHS practitioners

After meetings in both sites with researchers and the Patient and Young People Advisory Group to co-design topic guides, we will conduct semi-structured interviews with 5-10 CAMHS practitioners and/or managers in each site to understand the local emotional disorders care pathway. Referring clinicians will be asked to describe what first-line treatment the young person has received and for what duration.

Families

In-depth interviews with 5-10 families in each site will be used to understand what TAU comprises, which will be supplemented with a more comprehensive analysis of all participants' case notes to test the generalisability of themes that emerge from the interviews. Families will be purposively sampled to reflect a range of socio-demographic characteristics and prior treatment experience, such as first episodes or relapse, antidepressant medication, ethnicity and gender. For each participant we will explore what intervention (therapy and/or medication) they had received prior to being referred for MAC, including input from primary care, education and community settings, as well as what subsequent intervention and contact they received from CAMHS after referral to MAC.

We will triangulate quantitative data from the audit of case notes with content analysis of interviews to compare the findings with current best-practice recommendations from NICE.

Clinician survey

We will scope the potential for recruiting therapists with a) a core professional qualification that would enable them to work with young people, and some experience of leading or co-leading a Mindfulness Based Intervention (MBI) and ideally with a level 1 teacher training certificate with the use of an online survey. This will be an opportunistic sampling with a self-selecting participation of child mental health practitioners and mindfulness teachers. The questionnaire will collect data about respondents current CAMHS experience, mindfulness experience as well as

mindfulness teaching experience. Gathering also interest on future mindfulness-based training for young people. The survey will be fully anonymised since we are not requesting any identifying data.

Participant timeline

Recruitment

Potential young people will be identified by their CAMHS team or local clinical research network through case note screening who will provide the young person with an information sheet and permission to contact form prepared by the study team. If a young person expresses an interest the case worker will ask a parent/carer to return a permission to contact form either directly to the study team or provide permission for CAMHS return it. When a permission to contact form is received by the study team a research officer will contact the young person and carer to explain more about the study and answer any questions. If families wish to take part in the study, informed written consent will be provided by parents or carers for their own participation and that of their child if aged 15 or under. However, as many of the younger teenagers will be Gillick competent and because it is good practice, young people aged 15 or under will also be asked to provide informed written assent. Young people aged 16 or 17 will be able to provide informed written consent for their own participation without the need for parent/carer written consent.

We will collect detailed data about the rate at which young people are identified as suitable for the study to establish the expected number of such referrals per month, the proportion of identified young people who would be eligible and then who subsequently accept randomisation. We will also report the number who then go on to attend at least one MAC session as well as retention to the two follow-up timepoints (one month and four months post-treatment, or equivalent timeframe for TAU). This would provide an empirical foundation to refine our power calculation as well as provide information on which to base the number of required research sites.

While we will encourage the young person and their carer to both consent to the study, it would be unethical to refuse a willing young person access to the study if their carer was unable or unwilling to consent to their own involvement in the research study. If a young person aged 15 or under wishes to participate in the research study without the involvement of their carer, it will still be necessary for the carer to provide written consent that their child is able to enrol in the study. Carers are only eligible for the study if their child enrols, since the parent group is primarily about supporting the young people's mindfulness practice (See Figure 2).

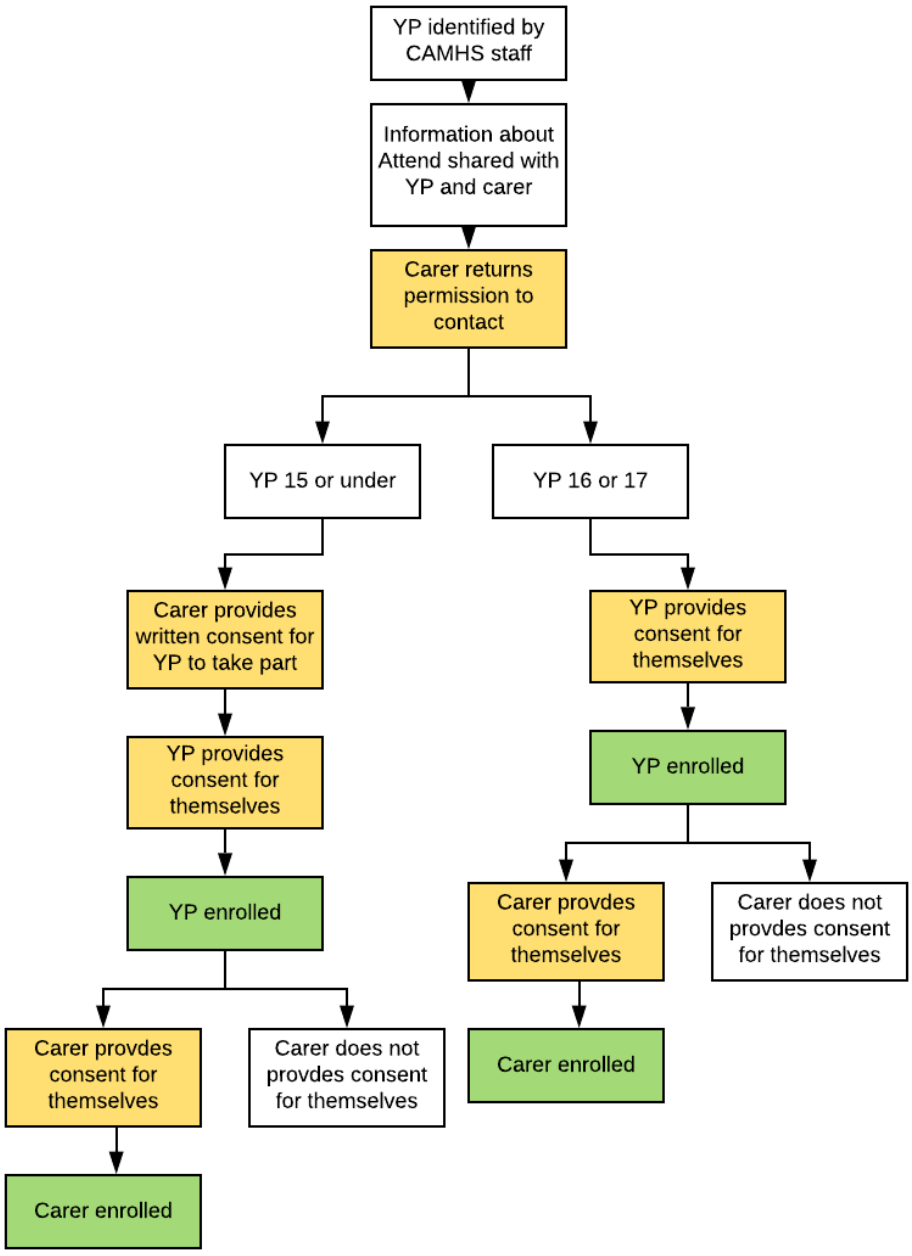

Figure 2: Pathway to enrolment in the Attend study

Consent for data linkage to key administrative datasets to permit longer-term follow up beyond the trial, such as the National Pupil Database and Hospital Episode Statistics data for attendance at Accident and Emergency with self-harm will also be sought.

Eligibility and Baseline Assessment

Eligibility will be established through the use of the screening measures with the following cut-points indicating a young person is eligible for inclusion in the study; CRIES-8 (score less than 30), SCOFF (score less than 2) and SHQ indicating no significant self-harming behaviour within the last 12 months. All eligible young people and consenting cares will then be invited to complete the baseline measures via an online portal. Paper copies of the baseline measures can be provided if preferred.

Randomisation

Given that this is a feasibility trial, the randomisation ratio will depend on how recruitment progresses, so that we can run groups with sufficient young people (between 8 and 10), and test retention for those randomised to treatment as usual. This ratio will be between 1:1 and 4:1 favouring the intervention, therefore the chances of access to MAC treatment will be at least 50%.~~We propose to randomise 20 young people at each site using block randomisation with 1:1 ratio to MAC (n=10) or Treatment As Usual (TAU) (n=10) using~~ We will use block randomisation, and Stata to generate the random sequence. The randomisation sequence would be known only to the Study Manager who will inform participants of their randomised treatment independently of the remaining research team to ensure recruiting researchers are unable to predict a participant's randomisation outcome.

Follow-up Assessments

Two further assessments will be completed one- and four-months post-treatment, or the equivalent timeframe for TAU. Table 2 details which outcome measures are collected at which assessment point.

Table 2: Details of the outcomes collected for each respondent at each timepoint

Assessment	Young Person Outcomes	Parent/Carer Outcomes
Eligibility	CRIES SCOFF APLSS SHQ	
Baseline	Background questionnaire, RCADS - Short Version, CHU-9D Coping Question Score-15 CAMM SCS-SF ERQ EQ (Decentering Scale) CRSQ	Background questionnaire GAD & PHQ-8 EQ-5D Coping Question Score-15 FFMQ-SF SCS-SF ERQ EQ (Decentering Scale) RRS
4-month	RCADS - Short Version CHU-9D Coping Question Score-15 CAMM SCS-SF ERQ EQ (Decentering Scale) CRSQ	GAD & PHQ-8 EQ-5D Coping Question Score-15 FFMQ-SF SCS-SF ERQ EQ (Decentering Scale) RRS
9-month	RCADS - Short Version CHU-9D Coping Question Score-15 CAMM SCS-SF ERQ EQ (Decentering Scale) CRSQ	GAD & PHQ-8 EQ-5D Coping Question Score-15 FFMQ-SF SCS-SF ERQ EQ (Decentering Scale) RRS

Reporting of Outcomes

The primary purpose of this study is to explore the key areas of uncertainty, namely is our training program suitable for currently employed CAMHS staff, what is the standard 'treatment as usual', how many young people are identified as suitable for inclusion, what proportion ultimately consent to be randomised, how many in principle would consent to biological samples being taken and subsequently how many are still engaged 9 months later at the final follow-up? Figure 3 depicts the CONSORT diagram showing the recruitment and retention pathway.

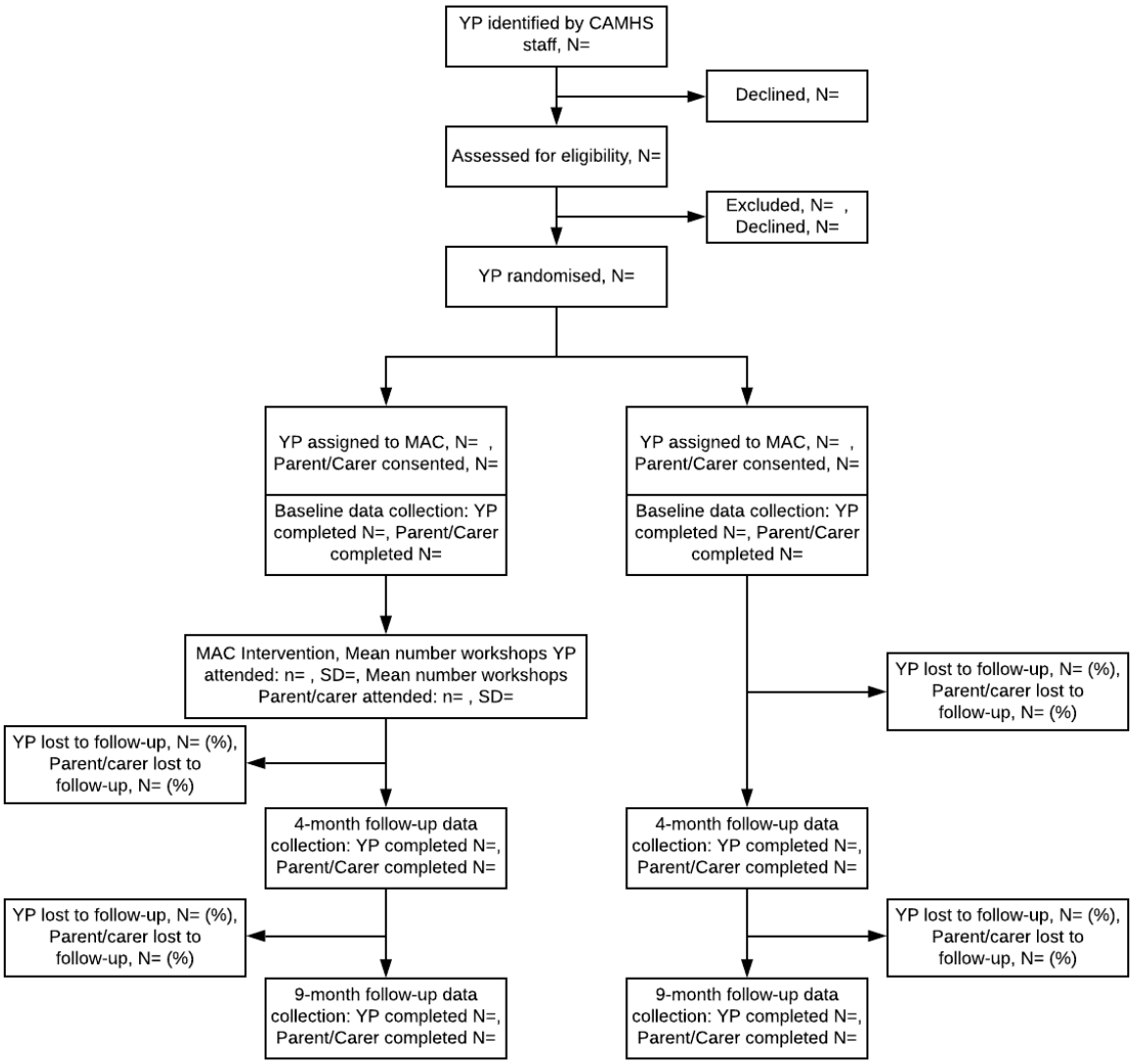

Figure 3: CONSORT diagram

Feasibility of training MAC therapists

In each site, we will report the number of therapists who were identified as being suitable to attend MAC training, how many of these chose to attend training, and what their actual attendance was. We will use a mixture of written feedback and qualitative interviews with both the trainers and the trainees to establish the acceptability of the training and the MBI-TAC will assess the competency of the trial therapists.

Choice of comparator for definitive trial

We will report the number, duration and type of treatment that participants received in each arm of the study. This data combined with a wider audit of care records in Devon and SLAM will inform if there is a standard 'Treatment as Usual' for this population of patients. If treatments vary significantly between areas, it will be necessary for us to devise a standardised comparator in the definitive trial.

Feasibility of recruitment to definitive trial

To inform the power calculation in the definitive trial, we will report the number of potentially eligible patients identified by the CAMHS care team, the number who permitted contact with the research team as well as the number who ultimately consented to take part in the study. We will then report the number of parents or carers who also consented to take part in the study. We will report the percentage of participants who were contactable at both follow-up timepoints along with the percentage of completed data. For those randomised to the intervention, we will report the percentage attendance and retention at the workshops, as well as their adherence to practice protocols using homework recording sheets. Where possible, we will explore the reasons why young people or parents do not accept the offer of MAC and examine the characteristics of young people who refuse the intervention, drop out of treatment or do not adhere to practice protocols.

Acceptance of the collection of biological samples

We will report the percentage of participants that said they would be willing for a blood and/or salvia sample to be taken. During the qualitative interviews we will explore any barriers to consent for the taking of biological samples.

Qualitative data

All audio-taped qualitative data will be transcribed verbatim, anonymised and password protected. Directed content analysis (Hsieh & Shannon, 2005) of interview

data will be framed by research questions that will help explain the experience and views of young people, parents/carers, therapists and referring clinicians. The senior clinicians' interviews (Topic Guide 1) will be coded to look for common pathways of intervention across research sites to the management and treatment of depression. This will inform our understanding of TAU for the main trial. Similarly, we will use qualitative content analysis to code and explore interviews with case-managing clinicians (Topic Guide 2) to identify common and distinct experiences across sites in YP's service receipt. Finally, we will undertake a qualitative thematic analysis to understand families' (Topic Guide 3) experience of the interventions they received and to explore their perceptions of intervention impact or progress over the duration of the study.

Study management

TF as Chief Investigator will assume responsibility for the financial management and delivery of the work, supported by RH as Project Manager. TF will lead the Core Research Team (all co-applicants and junior researchers) who will meet monthly via teleconference with input from the wider team of collaborators and representatives from the Parent and Carer Advisory Group and our named collaborators at quarterly Project Management Group meetings. Our independent Steering Committee is chaired by Clara Strauss from the Sussex Mindfulness Centre and University of Sussex. The role of the Steering Committee will be to provide critical scrutiny to the conduct of the current proposal and to the development of PGfAR. Both team and project meetings will be used to monitor progress against the proposed timeline, to discuss results and coordinate findings between the different work-streams as they arise and to discuss and solve possible risks or barriers to the delivery of the project.

Each work stream will proceed independently, with weekly meetings of those directly involved to monitor progress. PS will lead the training component with TB, JF and JR; TB will lead the quality assurance in relation to the therapists' delivery of

MAC while RH will coordinate the recruitment and delivery of MAC at both sites supported by PS and JR in London and JF in Exeter. VB will lead the investigation of TAU supported by RH, TF and the junior researchers. TF will take the lead in writing the PGfAR application. KL will facilitate the involvement of LF, our parent co-applicant and together they will coordinate the Patient and Carer Advisory Group as described in greater detail below.

Risk Management

This study will inevitably involve participants who are vulnerable by virtue of their age and mental health. The latter may also apply to carers. It is therefore essential that we have strong standardised operational procedures to ensure participant safety should risk of harm to self or others become evident, or if safe-guarding concerns emerge. Clinical responsibility for all young people will remain with CAMHS. We will ensure that one person with Level 3 child protection training is available during office hours at all times to support junior researchers who are concerned about participants, as well as liaising closely with the referring CAMHS teams.

Should young people or carers disclose a risk of harm to self or others a separate risk protocol will be actioned. This risk protocol will involve the completion of a standardised pro forma which will be signed by the local PI and sent to the study manager within 48 hours. The study manager will complete a serious adverse event form (SAE) sending a copy to the Trial Steering Committee and approving ethics board. The Participant Information Sheet informs young people and carers that if they disclose information of potential harm to themselves or someone else, we would need to break confidentiality.

Ethics

Research ethics approval

We have received multi-centre ethical approval from the East of England – Cambridge South Research Ethics Committee (ref number 20/EE/0246). and

local research governance approval for all sites (Devon Partnership Trust and South London and Maudsley Trust) . The study personnel, management group and independent Trial Steering Committee, chaired by Clara Strauss will ensure that the study is conducted within appropriate NHS and professional ethical guidelines, ensuring that Good Clinical Practice guidelines are observed at all times.

Confidentiality/Data Management

All data will be held in accordance with GDPR. Each young person, carer and therapist will be assigned a unique identifier and all data will be stored without identifying details. Data will be held on a secure database on a password-protected computer at the University of Cambridge. Access to data will be restricted to the research team. It is envisaged that all participants will complete measures using a web-based tool, however, paper copies will be made available should participants prefer this.

Project timescale

The project will take place over 15~~2~~ months from October 2020, starting with the training of therapists and following on to the feasibility study. The study of care pathways and treatment as usual will be undertaken throughout (Figure 4).

	Prior	2020			2021											
		Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
WP1 Refinement of the training process																
Develop training programme																
MAC therapist training																
Refinement of training programme following feedback																
WP2 Developing the recruitment and randomisation protocol: Feasibility Trial																
Recruitment and randomisation of young people and their carers																
Baseline testing																
Delivery of MAC treatment																
Follow-up testing																
Data cleaning																
WP3 Standardising the measurement of treatment as usual (TAU)																
Audit CAMHS notes																
Qualitative interviews with families, clinicians and MAC therapists																
Qualitative analysis																

Project management work stream																
Ethics application																
Write Program Grant Application																
Write Final Report																

Figure 4: Project Timescales

Patient and Participant Involvement:

To date the bulk of this work has taken place in Exeter, with parents and their young adult children who attended mindfulness delivered via CAMHS there. Given the difference between the two sites (predominantly White British, rural and semi-rural versus metropolitan and diverse), which may lead to very different experiences or issues with MAC delivery, we are now also working with a parallel group of CAMHS experienced young people in London at King's College. The two groups advise the researchers on protocol development in terms of recruitment, screening, and data collection, as well as relevant documents for the ethics application and safe-guarding and risk management standardised operating procedures.

The groups will continue to assist the researchers, particularly in the interpretation of themes emerging from our study of TAU (one meeting at each site) and will be invited to discuss the interpretation, application and dissemination of the findings at a sense-making workshop. As with the current group, we would hope to include at least one person with lived experience of emotional disorder and the MAC programme as a co-applicant.

Amendment History

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

Amendment No.	Protocol version No.	Date issued	Summary of changes made
1	V1.2	28/1/2021	The removal of the AD-SUS as an outcome measure in Study Summary table and Table 1. Further detail about the clinician survey has been added.
2	V1.3	06/04/2021	Randomisation ratio plan changed

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List of Abbreviations

APLSS--Adolescent Psychotic-Like Symptom Screen

CAMHS- Child and Adolescent Mental Health Services

CAMM--Child and Adolescent Mindfulness Measure

CBT- Cognitive Behavioural Therapy

CHU-9D--Child health utility 9D

CRIES- Children's Revised Impact Event Scale

CRSQ --Children's Response Styles Questionnaire.

EQ -- Experiences Questionnaire

ERQ-- Emotion Regulation Questionnaire

FFMQ-SF --Five Facet Mindfulness Questionnaire – short form

GAD-7--Generalized Anxiety Disorder Screener-7

MAC- Mindfulness for Adolescents and Carers

MBCT- Mindfulness-based cognitive therapy

MCID- Minimum Clinically Important Difference

NICE- National Institute of Health and Care Excellence

PHQ-8--Patient Health Questionnaire eight-item depression scale

RCADS-SF--Revised Child Anxiety and Depression Scale – Short Form

RSS--Ruminative Responses Scale

RT- Risk taking

SCOFF - **S**ick,**C**ontrol **O**ne stone **F**at **F**ood

SCS-SF --Self-Compassion Scale - short form

SH- Self-harm

SLAM--South London and Maudsley Trust

TAU- Treatment As Usual