Study Title: A cluster randomised controlled trial of the effectiveness and cost-effectiveness of a mindfulness training programme in schools compared with normal school provision: the MYRIAD trial

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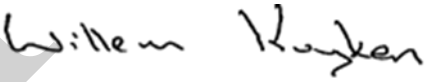
Chief Investigator Signature:	

Declaration of interests

WK is Director of the University of Oxford Mindfulness Centre. MW is co-author of *Mindfulness-based Cognitive Therapy* and *Mindfulness, Finding Peace in a Frantic World* and receives royalties from their sales.

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Abbreviations

BRIEF	Behaviour Rating Inventory of Executive Function
CAMM	Child-Adolescent Mindfulness Measure
CA-SUS	Child and Adolescent Service Use Schedule
CBT	Cognitive Behavioural Therapy
CES-D	Centre for Epidemiologic Studies Depression Scale
CHU-9D	The Child Health Utility 9D
CONSORT	Consolidated Standards of Reporting Trials
DMC	Data Monitoring Committee
GAD7	Generalised Anxiety Disorder 7
GEE	Generalised Estimating Equations
ICC	Intra-cluster Correlation Coefficient
MBCT	Mindfulness-based Cognitive Therapy
MBI	Maslach Burnout Inventory
MTS	Mindfulness in Teaching Scale
MT	Mindfulness Training
MYRIAD	My Resilience in Adolescence
NICE	National Institute for Care and Health Excellence
OFSTED	Office for Standards in Education
PenCTU	Peninsula Clinical Trials Unit
PHQ9	Patient Health Questionnaire 9
PSS	Perceived Stress Scale
QALYs	Quality Adjusted Life Years
RCADS	Revised Child Anxiety and Depression Scale
RPIS	Resistance to Peer Influence Scale
RCT	Randomised Controlled Trial
SCCS	School Climate and Connectedness Survey
SDQ	Strengths and Difficulties Questionnaire
SEL	Social and Emotional Learning
SOP	Standard Operating Procedure

SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SQL	Structured Query Language
SSL	Secure Socket Layer
TAU	Teaching As Usual
TiDier	Template for Intervention Description and Replication
TMG	Trial Management Group
TSC	Trial Steering Committee
TSES	Teacher's Self-efficacy Scale
WEMWBS	Warwick-Edinburgh Mental Well-being Scale

Project Synopsis

Abstract

Background

Mindfulness-based approaches for adults are effective at enhancing mental health, but few controlled trials have evaluated their effectiveness or cost-effectiveness for young people. The primary aim is to evaluate the effectiveness and cost-effectiveness of a mindfulness training (MT) programme, across the spectrum of mental health/well-being/functioning, as a universal schools-based intervention.

Methods/design

To address this aim, the design will be a superiority cluster randomised controlled parallel group trial in which schools offering social and emotional provision in line with good practice[17,90,91] will be randomised to either continue this provision (control) or to include MT in this provision (intervention). The study will recruit and randomise 76 schools and 5700 school students aged 12 to 14, followed up for two years.

Discussion

The study will establish if MT is an effective and cost-effective approach to enhancing mental health, well-being and social-emotional-behavioural functioning in adolescence.

1 Background

1.1 The social and economic challenge of mental ill health

In the UK, the annual economic cost of mental health problems has been estimated at £105 billion[1-,2]. Mental health problems commonly have their first onset in adolescence, which is a period of heightened vulnerability associated with reduced attentional, emotional and behavioural regulation in the face of growing demands [3-4]. In fact, 50 % of adults with psychiatric disorders experience clinically impairing psychopathology by age 18, and 75 % by age 24[5].

Of all mental health disorders that emerge during adolescence, depression is the one with the largest impact on health throughout the lifespan in terms of Years Lost to Disability[6]. Among adults with recurrent depression, the earlier their depression first develops, the more severe its subsequent clinical course[7]. Onset in childhood or adolescence is associated with greater impairments in social and occupational functioning and reduced quality of life, with adolescent depression associated with poor academic performance, family and social difficulties, physical ill-health, suicide attempts and completed suicide[8-11]. Such increased severity of early onset depression is also reflected in the fact that within child and adolescent samples, depression is often co-morbid with other disorders; more than a third of these young people have a disruptive behavioural disorder, anxiety disorder or both[12-13]. It is, therefore, vital that effective interventions are developed to tackle these vulnerability processes and to target those interventions during this critical window of adolescence.

1.2 Existing programmes to reduce risk and promote mental health

There have been many calls to develop programmes for adolescents to reduce risk of mental ill health, promote well-being and develop life skills across the spectrum of well-being and functioning[14-15]. Because of their broad reach and central role in the lives of children and families, schools are seen as the primary setting where such efforts should be focused[16]. However, there are many challenges to implement such schools-based programmes. In particular, targeted interventions, selectively offered only to

adolescents deemed at risk of later mental health problems, face substantial costs associated with screening and can be stigmatising. Critically, they also miss those currently deemed at lower risk, but whose risk profile changes later.

As an alternative, recent systematic reviews and governmental reports suggest that schools-based universal approaches, offered to the whole population, have the most potential to promote the mental health of young people[17-19]. However, the current research highlights that for such universal interventions to succeed, several key pragmatic and theoretical issues need to be considered[20]. At the pragmatic level, many programmes do not consider fully how best to support teachers to deliver the intervention competently[18] or try to implement programmes without due attention to known implementation facilitators and barriers[21].

However, even if these pragmatic concerns are resolved, more fundamental theoretical issues still remain. Many existing universal interventions, aimed at reducing the risk of depression in young people, are based on theoretical models originally developed to address established psychopathology (e.g., cognitive theory and therapy) – *that is, they are designed to be used when people are unwell.* They therefore lack relevance, both for low-risk adolescents and for those who are at high-risk, but not currently showing symptoms. To illustrate, a recent fully-powered large-scale UK cluster randomised controlled trial (RCT) based on cognitive-behavioural therapy (CBT) principles had good reach, but low acceptability[22]. The study found the intervention had no effect compared to usual school provision or attention control conditions[22], consistent with other recent well-designed RCTs[14,23-24].

This suggests that the theoretical basis for an effective universal intervention needs to focus on those critical psychological mechanisms that are universally relevant for the whole spectrum of mental health, from risk at one end, through resilience, to flourishing at the other end. The proposed trial is grounded in such a framework and evaluates a method of mental training (*mindfulness*) to modify these core mechanisms, which can be used by all young people.

1.3 Theoretical framework

Our key theoretical premise is that mental health and well-being are compromised when there is diminished ability to effectively harness top-down executive control to pursue goals and plans when faced with salient, competing distraction from bottom-up processes[25-29]. The significance of this premise is that this proposed central cognitive mechanism applies not only to those at risk, but also across the well-being spectrum.

For individuals at risk of *internalising* problems such as depression and anxiety, deficits in executive control manifest as difficulty in regulating cognition, affect and behaviour in the face of distracting, intrusive, negative thoughts and feelings[30-36]. For those at risk of *externalising* problems (conduct and antisocial/disruptive behaviour), deficits in executive control manifest as impaired impulse regulation, a problem that is associated with long-term impairments across multiple domains of functioning[37-38].

For those who are *resilient or flourishing*, executive control enables the effective deployment of attention in the face of relatively innocuous, but habitual, patterns of thought (e.g., rumination) that can distract from current plans, exacerbate everyday stresses (affecting test-taking, sports performance and sleep) and undermine well-being[39-40]. In sum, the hypothesis is that enhancing executive control in the face of these diverse challenges will both reduce risk for vulnerable adolescents as well as promote flourishing among those who are already resilient.

Our theoretical framework points us towards a training method that focuses on modifying key executive processes, instead of focusing on reducing pathology-specific negative patterns of thinking and behaviour. Our programme aims to examine one such method, mindfulness training (MT), which is specifically designed to address such processes[29] and be used when people are well [41-42].

1.4 Mindfulness training (MT)

MT involves systematic practice in focusing attention in a sustained and intentional way. It augments the ability to exercise top-down executive control in the face of

motivationally compelling distractions[43-46]. It also reduces intrusive thoughts and ensuing ruminative responses[47-50] and behavioural impulses[51]. MT has been developed as a preventive intervention for those who already have enduring mental health problems. For example, mindfulness-based cognitive therapy (MBCT) was developed for people with a depression history but who are currently well, to prevent future depressive relapse[52]. The evidence base for its effectiveness and cost-effectiveness is growing[53-55], and it is now recommended by National Institute for Health and Care Excellence (NICE) (2009) as a first line psychosocial treatment for secondary prevention of recurrent depression. Early studies suggest that MBCT's preventive effect was greatest in those who had experienced three or more prior episodes. However, we now know that the number of episodes predicts good response because it is a marker for those with greater vulnerability due to pre-adult onset of depression and early adversity[56]. The effects of MT are not, however, confined to vulnerable groups. It has been found to have beneficial effects, via executive function changes, in non-clinical populations[47,57]. This suggests that MT is not only acceptable to non-clinical populations, but also has huge promise for *primary* prevention of depression because it enables intervention in early adolescence, the point at which such vulnerability first emerges.

The research question is:

"*Does MT have the potential in adolescents to shift the population away from psychopathology and towards improved mental health and well-being by addressing key processes of mental regulation and executive control that operate across the spectrum of risk/resilience?*"

The acceptability and feasibility of MT in young people appears promising[58-62]. However, there are many unanswered questions about its ability to prevent future depression and other mental health problems in adolescence, its mechanisms of action and what moderates its effectiveness. Also, there are no robust randomised controlled trials – grounded in theory and using an adequate follow-up period – that have evaluated the benefits of MT across the whole spectrum of risk/resilience in adolescence[60].

A prototype of a schools-based MT programme has been developed by classroom teachers to teach mindfulness skills in a UK context as an integral part of the school curriculum[63]. This MT programme was piloted (against matched comparison schools, including some schools with higher than average deprivation scores and more children with special needs). Not only was MT acceptable to secondary school children and teachers, but compared with normal school provision of social and emotional teaching, MT also reduced children's depressive symptoms and increased their well-being. This was maintained at three-month follow-up (adjusted mean differences: depression, Centre for Epidemiologic Studies for Depression Scale, CES-D[64], -1.4, 95 % CI -2.3 to -0.05, p=0.005; well-being, Warwick-Edinburgh Mental Well-being Scale; WEMWBS[65], 3.0, 95 % CI 0 .0 to 6.0, p=0.05). Effects on well-being and depressive symptoms were most marked at times of highest stress, and greater use of mindfulness skills was associated with stronger effects[66].

Provisional evidence from this non-randomised feasibility trial is encouraging. Moreover, interventions that are designed with implementation in mind are likely to prove more acceptable[21,67]. When adapted appropriately, MT is acceptable in more deprived and culturally diverse settings[68], and among young people with attention and conduct disorders[69]. Importantly, preliminary evidence suggests that MT in schools benefits not only young people, but also shows promise in enhancing teachers' self-efficacy and well-being[58,70-71]. There is a need for an adequately powered RCT - that uses validated outcomes assessed over meaningful time frames - of a theory-based and thoughtfully implemented MT programme. Moreover, as the MT is delivered as a universal school intervention, a cluster RCT is required where schools are the units of allocation.

2 Objectives

This study protocol describes a cluster randomised controlled trial (RCT) designed to evaluate the effectiveness and cost-effectiveness of including an MT programme within provision of social-emotional teaching compared with social-emotional teaching as usual for young people aged 11-14 within secondary schools. This protocol has

been informed by learning from two feasibility studies[66,72] and several large-scale schools-based studies [12,16,67,73-77]. The protocol is written in conjunction with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidance for protocols[78], the 2010 Consolidated Standards for Reporting Trials (CONSORT) statement for reporting results from RCTs[79] (including its extension to cluster RCTs[80]) and will comply with the Ottawa Statement on the ethical conduct and design of cluster RCTs[81].

2.1 Primary Objectives

The primary aim is to determine the effectiveness and cost-effectiveness of the MT programme on three co-primary self-report outcomes at 1 year follow up measured at the level of the individual young person:

1. Risk for depression,
2. Socio-emotional and behavioural functioning and,
3. Well-being.

2.2 Secondary Objectives

Broader secondary individual level outcomes for students will include executive functioning, drug use, , anxiety, attainment and mindfulness skills. Teachers will also rate the pupils on socio-emotional and behavioural functioning.

For teachers secondary objectives will include stress, anxiety, depression, burnout and classroom mindfulness.

Secondary cluster-level outcomes will include school ecology/climate.

3 Methods/Design

3.1 Study design

The **design** will be a superiority cluster randomised controlled parallel group trial in which inclusion of the MT programme within school social-emotional teaching provision will be compared with provision of school social-emotional teaching as usual (teaching as usual, TAU)], in 76 schools (clusters); 6840 school students (ages 12-14) will be approached to recruit 5700 (Figure 1, CONSORT diagram). To ensure baseline measures are collected prior to randomisation all Year 7 and 8 pupils (or equivalent) (approximately 25000) will be enrolled into the study to provide baseline assessments (primary measures only), with only a subset of these pupils moving on to become full trial participants the following year.

The definition of a trial participant will be those who provide data at the baseline assessment and are members of one of the classes subsequently selected for continued trial participation Those providing baseline assessments only will be defined as study participants.

A two-arm trial is employed for several reasons. First, the research question addresses the key remaining uncertainty: does MT add value over current UK good practice in relation to social-emotional teaching? Second, MT's mechanisms of action are examined through a separate programme of work. Third, cluster RCTs on this scale are most likely to be a rigorous test of effectiveness/cost-effectiveness when they are as simple as possible and when school heads, teachers and pupils perceive there to be equipoise between the two arms.

3.2 Setting

Secondary schools will be recruited that are broadly representative of UK secondary schools, which offer social and emotional teaching in line with good practice guidance and are open to having the content and quality of their provision monitored.

3.3 Participants and eligibility criteria

A sample of mainstream UK secondary schools will be recruited that is representative of such schools, both with respect to the population served (on key variables such as deprivation, operationalised as eligibility for free school meals) and the type of school (e.g., selective/non-selective, urban/rural, large/small, mixed/single gender, state maintained/independent). We will not include special schools or alternative provision settingsTo avoid contamination between the trial arms, if a school was part of an academy chain, only one school per academy would be normally recruited, and schools part of academy chains already teaching mindfulness programmes were excluded from taking part in the trial for similar reasons.Only schools that offer social and emotional teaching in line with good practice will be eligible for participation, determined using a measure designed for this study to benchmark against key dimensions (e.g., leadership and strategy, curriculum content and delivery and assessment / evaluation in social-emotional teaching; this measure will be developed in the trial set up phase). Schools must also be willing to commit to the Mindfulness and resilience in adolescence (MYRIAD) study, including the teacher training required in schools randomised to MT and teacher and pupil assessments and follow-ups. To mitigate risk to implementation, schools with an inadequate rating, or where there is no substantive head, will be excluded. Within schools, classes from Years 8 and 9 (or equivalent) will be selected for pupil recruitment. To mitigate risk of selection bias, classes will be randomly selected from amongst the pool of classes configured for the school year in question. All children in selected classes will be invited to take part in the research. Where children with special educational needs are included in mainstream classes they will be invited to participate along with their classmates (with appropriate support and a limited set of research measures where appropriate).

Within schools, participating teachers will be qualified/experienced teachers who have given their consent to participate in the research and to complete the training in the delivery of the MT programme and subsequently to deliver the MT programme, should their school be randomised to the MT arm of the trial. Should the school be randomised to the TAU arm these teachers will be assessed as “controls”. They will normally be on substantive teaching contracts to increase the likelihood that they will remain teaching within the school during the research period.

3.4 Recruitment

Recruitment of schools, teachers and pupils will occur in at least two recruitment cohorts with each new cohort starting at the beginning of a school year. In the first recruitment year the aim will be to enrol a relatively small number of schools (approximately 16), with the remainder recruited in the following year.

(1) Seventy-six secondary schools will be recruited using a recruitment strategy devised to obtain a representative selection of UK schools. Schools must agree to randomisation, be open to either continuing to offer social and emotional teaching in line with good practice guidance or training teachers to deliver the MT programme and to delivering the MT programme as part of their ongoing social and emotional teaching provision.

(2) Pre-written standard letters or emails will be sent to parents/caregivers of children in Years 7 and 8 (years 8 and 9 in Northern Ireland and year S1 in Scotland) giving them an opportunity to opt-out their children from the research trial, namely the baseline study measures and the potential further data collection in the following years, if their child's class moves into the full trial.

(3) Prior to randomisation, all pupils in the current Year 7 and 8 (or equivalent) in eligible schools will be invited to assent to the trial. At this point they become a study participant with the potential to move onto the full trial the following year. After this they will be asked to complete the primary outcome measures for the study. This data will provide baseline data for those pupils in the classes who subsequently proceed into the full randomised controlled trial, and will be used to assess the representativeness of this subset of pupils relative to all pupils of their age within the school. This method of obtaining baseline data is required because class configuration may not be stable within a school from one academic year to the next. In order to be sure that all pupils within a selected class have baseline data we need to obtain this data from all pupils in the year group.

(3) Prior to randomisation, teachers who would deliver the MT, should the school be randomised to MT, will be identified. If allocated to the control school these teachers will be "controls." Following randomisation of schools to intervention/control arms, the participating teachers in schools randomised to MT will begin their programme of training. Participating teachers in both arms will complete research outcomes during this training phase.

(4) Once MT teacher training is complete, a random sample of at least 3 classes will be selected within each intervention and control school, using an approach to ensure class selection is not biased based on a standard algorithm.

(5) Letters will be sent to parents/caregivers of children in the selected classes reminding them of the next step for their child. At this point this would relate to the full randomised controlled trial. The same letter/email containing the same information will sent to all parents/caregivers irrespective of intervention.

(6) All eligible pupils in the selected classes will then be asked to provide continued informed assent to data collection at each time point

(7) Letters will be sent to parents/caregivers of children in classes that are not selected to proceed to trial participation informing them that their child's involvement in the study has ended.

Where schools decide to participate in the trial they will agree to offer the MT programme as part of the standard school curriculum. That is to say parental opt out and child assent relates to the research (baseline and full randomised control trial assessments) and not the MT or TAU. Consent to participation in MT or TAU curricula is at school level. Schools will be free to teach the MT programme to non-trial classes as they wish, but we will not collect data from these pupils.

3.5 Randomisation procedure and blinding

Randomisation of schools to intervention and control arms will be stratified and will be carried out by an independent statistician. The following stratification variables will be

considered, with final decisions taken once schools have been recruited: School size (large/small), type of school (selective/non-selective, independent/non-independent, mixed/single gender, school quality measure e.g. OFSTED), geographic location (urban/rural and region) and level of deprivation (below or above median of children eligible for free school meals)

All participating children will be recruited from the schools in the autumn term of the school recruitment years (September through December) [82].

Attempts will be made for researchers collecting follow-up data to be blind to allocation, but teachers and pupils involved in the intervention cannot be blind.

3.6 Interventions

The MT programme and TAU will be delivered at school (cluster) level. Both will be mapped as far as possible using a template for intervention description and replication (TIDieR) checklist and guide for reporting complex interventions; namely articulating the interventions' name, theory, what (materials), how (procedures), who provides it, modes of delivery, place of delivery, any tailoring and fidelity[83]. UK schools deliver social-emotional teaching in different ways and will likewise choose to integrate MT within their existing provision in different ways. Thus the trial cannot be categorized as either purely additive (MT+ existing social-emotional teaching provision) or substitutive (MT replacing existing social-emotional teaching provision) in its design. Rather different schools will be at different points on this hypothetical continuum and we will report provision of social emotional teaching in schools across both arms of the trial.

3.6.1 MT programme[63].

The MT goals are to enable adolescents to learn mindfulness skills that enhance mental regulation and executive control across the spectrum of risk/resilience. The MT programme is drawn primarily from MBCT[52]. A unique feature of the MT programme is its focus on the full spectrum of functioning from mental health problems to flourishing, enabling all young people to use mindfulness skills to manage emotions, academic study, sport, sleep and relationships. It was developed over more than 5 years by three classroom teachers (Richard Burnett, Chris Cullen and Chris O'Neill)

who are also experienced mindfulness practitioners. This has included ensuring the programme can be taught in mainstream schools, how best to engage hard to reach children and how to manage challenging classroom behaviour. It has been developed and adapted to ensure it is acceptable to diverse school contexts and student populations. Latterly the programme has been enhanced to support children to practice mindfulness during and beyond the course (including digital resources such as animations).

The MT programme comprises several elements, delivered through the school curriculum, over several years, supported by teacher training. The bulk of the MT programme is taught to students in a set of 10 scripted lessons (taught in year 8 and 9 or equivalent). The MT programme will normally be delivered in the spring terms (January through April), with support to continue use of mindfulness skills into the summer term. In the following school years, there are follow-on lessons intended to continue and support further learning and ongoing mindfulness practice (e.g., lunchtime clubs or drop in sessions). This follow-on training in subsequent school years aims to sustain, deepen and begin to apply students' learning and embed mindfulness in the school ecology/climate.

The MT programme includes a combination of psycho-education and practical skills involved in training the mind, learned in an experiential way, through short mindfulness practices which focus on the breath, body and immediate experience. There is also classroom discussion of the application of new skills in everyday life. Its design aligns with principles identified as important for effectiveness in several reviews of schools-based programmes that promote mental health and well-being and teach social and emotional competence[19]. These principles include: explicitly teaching skills and attitudes; tailoring components and approaches to the needs of young people; using a range of age-appropriate, interactive, experiential and lively teaching methods; providing age appropriate resources, for example in this context resources that bring mindfulness to life (including a course booklet and a set of mindfulness exercises provided online and/or as CD / mp3 audio files); intensive, focused teacher education to build teachers' self-efficacy and well-being; and programme implementation which pays close attention to clarity and fidelity, in this case supported by a manual and indicative script[19,21,58]. Building on data that greater practice is associated with better

outcomes[84-85], the MT programme includes strategies to support teachers in keeping mindfulness integral to the culture of their year group/the school as a whole. Examples of good practice in this area could include teacher catch-up days/support events, suggested schedules for progressive, regular mindfulness input throughout year groups, suggested smart phone apps and using parts of the MT programme in core curriculum subjects.

Whilst all participating schools randomised to MT will have agreed to deliver the MT programme to a minimum of three classes within years 8 and 9,(or equivalent) they will be encouraged to consider how they might introduce mindfulness into the curriculum more broadly, for the potential benefit of other school pupils and the wider school climate.

Because implementation affects both reach and outcomes[86], all schools will be supported with implementation guidance to increase the likelihood that MT is introduced into the schools in ways that maintain its integrity and are sustainable. For example, implementation of MT will require engagement with school leadership teams, teachers and pupils, as identified, for example, in research in disadvantaged urban schools in the US [77,87].

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3.6.1.1 Training teachers to deliver the MT programme.

The training programme to deliver the MT programme involves teachers first participating in an 8-week MBCT programme, adapted for the general (non-clinical) population, to support the development of their resilience and mindfulness skills (eight 2 hour sessions per week, with an all-day mindfulness session supported by a digital app to facilitate mindfulness practice during and after the 8 week course). Selected teachers will then attend a 4-day training workshop to learn how to deliver the MT in schools, with support where needed when they move onto teach themselves. Within participating schools, as large a pool of teachers as possible, will be trained to build in redundancy should teachers either not achieve required levels of competency or leave the school. Training a larger group of teachers will also support greater implementation of the MT programme within the school, outside trial classes, as well as offering peer support throughout the project.

3.6.1.2 Fidelity of the MT programme

To test the effectiveness of the MT programme we need to ensure it is delivered with fidelity. The teacher training and MT programme are highly structured and standardised to maximise fidelity. Through teacher selection and teacher training we will endeavour, as far as posisble, to ensure teachers reach an adequate standard before they teach trial classes. During the trial classes, competency/adherence will be monitored. Independent raters will rate a randomly selected subset of videotapes of MT programme classes for fidelity (adherence and competence) using a standardised measure developed by the applicant team with adaptations made for MT in schools[88],[89].

3.6.2 Teaching as usual in line with good practice.

The trial aim is to establish if MT when integrated into current good practice in social and emotional teaching in secondary schools adds value over and above current good practice in social and emotional teaching in secondary schools. Therefore, all participating schools will be selected only if they are currently offering social and emotional teaching in line with good practice[17,90,91]. A Department of Education Report suggests 70 % of secondary schools offer social-emotional teaching, usually through a variety of methods (e.g., citizenship or Personal, Social and Health education lessons, drop down days, within other subjects, and in tutor/form time) and taught through ages 11-16 (Key Stages 3 and 4)[17]. TAU schools will agree not to provide the MT programme (or other curricula that include mindfulness training) until study completion. This approach ensures that MT's effectiveness is tested against current good practice.

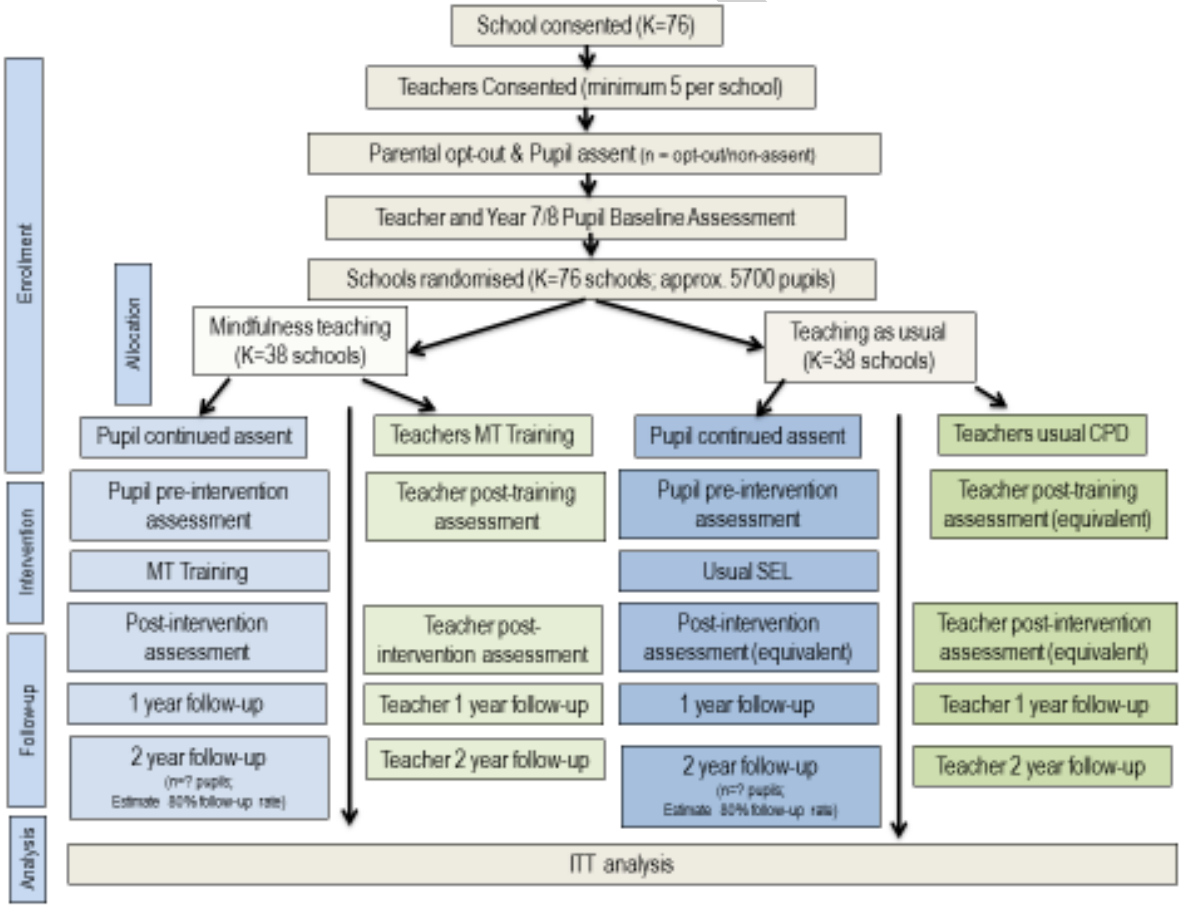
3.7 Audit of teaching as usual in both trial arms

Following randomisation, the current provision of social emotional teaching will be mapped using a bespoke audit tool developed for the MYRIAD trial[17]. The mapping

will enable us to fully describe current practice with respect to social-emotional teaching in all randomised schools, at the school-level and for study pupils within each school, and compare the two trial arms. It will further provide information on how the MT curriculum is integrated into wider social-emotional teaching provision in intervention schools.

3.8 Baseline assessment and follow-ups

Study outcomes will be measured at school consent/baseline (prior to randomisation[1]), pre-intervention, post-intervention (within 30 days of the end of the MT programme or equivalent time in the TAU arm), 1-year follow-up (1 year after pre-intervention measures and again at 2-year follow-up (2 years after pre-intervention measures). (See Figure 1). The experience of a young person, teacher and school going through the trial is shown in Appendix 1.



[1] For pragmatic reasons at this time-point only the primary outcome measures for the pupils will be measured.

Figure 1 Participant flow CONSORT diagram.

3.9 Sample size

The study requires 76 schools, with the intention that 5700 proceed to full trial participation, and that 4560 ultimately complete the trial at 2-year follow-up. Extra schools will be recruited to allow for dropout at the cluster level, predicting around 4 schools per study arm to drop put. These pupils will be a subset of the approximately 25000 pupils enrolled into the study that provided baseline assessments (primary measures only). At least three classes from each school will be included in the study. Drawing on the two feasibility studies[66,72], a conservative assumption is made that in each class of 30, 25 children will have assented to participate and 20 of these will be followed-up over two years. However because opt-out assent will have been obtained prior to class selection where levels of assent are lower than expected we will have the flexibility to include more classes within a school, in order to ensure that the required number of participants proceed to full trial participation. However, as this sampling approach yielded a lower number of pupils in some schools in Cohort 1, it was revised from three to four classes or more per school where possible in the second and larger Cohort 2, with the aim to have approximately 100 pupils per school. The 38 schools (clusters) and 2280 children in each trial arm at follow-up (76 schools and 4560 children altogether) is a large enough sample to detect a difference of 0.2 standard deviation units (effect size) on our continuous co-primary outcomes. The sample size has been inflated to allow for multiple testing, setting the 2-tailed significance level (alpha) for comparing each individual outcome between the trial arms to 0.0167 to preserve the overall family-wide Type I error rate at 0.05. The study has 90 % power to detect the specified effect size for each co-primary outcome as statistically significant. The sample size also allows for: (i) clustering of outcomes within schools, assuming an intra-cluster (intra-school) correlation coefficient (ICC) of 0.04; and (ii) 20 % drop-out, with 60 of the 75 children consenting to participate in the trial providing full follow-up data within each school. Relevant literature suggests our assumed value of the ICC is conservative. The largest ICC in one of our feasibility

studies[66] was 0.037. The ICC for the same measure of depression as used here (CES-D) has been estimated to be 0.033 from a previous study in Quebec based on around 5000 children from across 71 schools drawn from relatively disadvantaged communities[92] and to be 0.009, 0.015 and 0.017 for different Year levels (Year 8, Year 9 and Year 10 respectively) based on around 2500 children from across 25 state-funded schools in South Australia spanning the full socioeconomic spectrum[93].

3.10 Outcome measures

Multi-method and multi-informant measures will be used that have established sensitivity to change, reliability and validity, balanced with consideration to minimising burden on both participants and researchers and maximising data quality. All measures will be completed either on paper or via an online system. The pupils will complete the measures in a classroom setting where possible.

3.10.1 Primary outcomes (pupil completed):

Our aim is to determine the effectiveness of the MT programme based on three **co-primary** outcomes at 1-year follow-up: **risk for depression** (Centre for Epidemiologic Studies for Depression Scale; CES-D; [64]); **social/emotional/behavioural functioning** (Strengths and Difficulties Questionnaire, SDQ; [94]); and **well-being** (Warwick-Edinburgh Mental Well-being Scale; WEMWBS; [65]). There was consideration of selecting just one primary outcome but the research team, experts in the field who were consulted and peer review concluded that all three co-primary outcomes are critically important. The research team also considered combining the three co-primaries into a composite outcome. However, as the research question includes the specific effect of the intervention on each of the three aspects, not just the overall effect, it was decided to retain the primary outcomes in their natural form. Composite measures can obscure variation that would convey interesting and important information in our proposed work[95].

There are a number of reasons for the choice of primary outcomes. First, adult depression (like mental health generally) is predicted by a range of difficulties in

adolescence, including not only low-grade depressive symptomatology, but also social/emotional/behavioural functioning[13,96-98]. Second, MT is a complex intervention that is specifically designed for young people along the full spectrum of risk/resilience and mental health. The outcome measures, therefore, needed to assess both problems (e.g., depressive symptoms) and also positive mental health. In such instances, and in line with the Medical Research Council (MRC) Complex Interventions Framework[99] and evolving guidance in the literature[100-101], a number of critical outcomes were chosen as co-primary outcomes that: (a) are targeted by MT; (b) cover the full spectrum of mental health risk/resilience; and (c) predict later psychopathology / mental health.

3.10.2 Secondary outcomes (pupil, teacher and school based):

A range of individual level ***secondary outcome measures*** have been chosen based on their value to education policy makers, school heads and pupils themselves. Secondary outcomes are: students' executive processing (Behaviour Rating Inventory of Executive Function, self and teacher rated versions; BRIEF[102]); drug and alcohol use; anxiety (anxiety subscales from the Revised Child Anxiety and Depression Scale; RCADS[104]); Strengths and Difficulties Questionnaire, SDQ), teacher-rated version; SDQ [94]; student level attainment and attendance(National Pupil Database); [105-106]; self-harm and suicidal ideation and mindfulness skills (Child-Adolescent Mindfulness Measure, CAMM[107]). To support resource allocation decision making and guideline development by bodies such as NICE [108]; the CHU-9D measure of health-related quality of life[134,135] suitable for the calculation of Quality Adjusted Life Years (QALYs) and application to economic evaluation, will also be included, alongside the Child and Adolescent Service Use Schedule (CA-SUS). Given the high rates of teacher stress and burnout, the importance of school ecology/climate, and the potential of MT to address these variables, the following will also be secondary outcomes: teachers' well-being (Maslach Burnout Inventory, MBI Educator version[110]); self-efficacy (Teacher's Self-efficacy Scale, TSES[111]), classroom mindfulness (Mindfulness in Teaching Scale [112]), stress (Perceived Stress Scale, PSS[113]), depression (Patient Health Questionnaire, PHQ9[114]) and anxiety (Generalised Anxiety Disorder, GAD7[115]). Teacher level variables will be measured for those teachers within schools identified to teach the intervention pre-randomisation. School (cluster) level outcomes will

include school ecology/climate ([sub-scales most relevant to the intervention from the School Climate and Connectedness Survey (SCCS)[133]] and school level attainment, for example GSCE results (National Pupil Database)

Study outcomes will be measured at five time points: baseline (school and teacher as well as primary measures for all pupils from Years 7 and 8 or equivalent); pre-intervention; three-months post-intervention (or equivalent); one-year (1 year after pre-intervention) follow-up; and again at two-year follow-up (2 years after pre-intervention). It is important that outcomes are measured over a short enough period to enhance data completeness as well as over a long enough period to examine emergent risk/resilience over time

3.11 Economic data

The economic evaluation will take a health and social care perspective, as preferred by NICE [108], but will additionally include education-based services, since evidence suggests that health and education make up the majority of the costs of caring for young people with depression[116].

Service use will be recorded using a brief version of CA-SUS, successfully applied in previous adolescent depression populations[116]. A brief version focusing on key services (high cost and high volume of use) suitable for self-completion by parents of primary school children is currently being applied in a similar school-based cluster RCT[73]. This measure will be adapted for application to an older population and for self-completion by the young people. Economic data will be collected at baseline, pre and post intervention as well as one and two-year follow-up. The pre-intervention measure will collect information covering the previous 3 months; at follow-up the service use will be collected in the last 3 months at which economic data were collected will be recorded.

Resource inputs into MT training and delivery will be recorded as part of the trial and will be costed using a micro-costing approach. This will involve calculation of the cost of all individual elements (teaching and training staff time, any supply teaching expenses, training and intervention materials, etc.), as well as relevant overheads

(administration, managerial, capital etc.) and adjustment for indirect time (non-face-to-face working time which cannot easily be allocated to specific individuals). All other services used will be costed by applying nationally applicable unit costs, including National Health Service Reference costs for secondary care services, as well as published costs for primary care, social care and education services[117].

Outcomes for the economic evaluation will be measured using the CHU-9D[134, 135] measure of health-related quality of life, shown to be valid and responsive to change in adolescent populations[118].

4 Analysis plan

Analyses will be conducted / supervised by the co-investigator trial statistician (Obioha Ukoumunne) and trial health economist (Sarah Byford) following CONSORT standards, overseen by the Data Monitoring Committee (DMC) and documented in a full pre-specified Statistical Analysis Plan. Analyses will be conducted on an intention-to-treat basis, with participants analysed according to the trial arm they were randomised to, using multiple imputation to "fill in" missing data. Comparisons will also be made between the trial arms, based on those with complete data in a sensitivity analysis. All between-arm comparisons will be run first as crude analyses (unadjusted) and then adjusted for baseline prognostic factors, chosen *a-priori*, but certainly including the factors used to stratify the randomisation. The adjusted analysis will be considered to be the main analysis.

The approach to evaluating the intervention emphasises estimation of the intervention effect (confidence intervals), rather than strictly hypothesis testing. In recognition of the multiple testing, we will use an adjusted critical level for significance testing of 0.0167 for each of the three primary outcomes to maintain the overall Type I error rate at 0.05. The confidence intervals will not be adjusted for multiple comparisons. No adjustments will be made to the critical levels for testing the secondary outcomes, as these are more exploratory in nature. The study sets out to establish the superior effectiveness and cost-effectiveness of MT compared with TAU. As set out above, all the co-primary outcomes are deemed important in their own right, such that each will be reported independently. Interpretation of the effect sizes will be across the primary

and secondary child, teacher and whole school outcomes, examining the overall profile of effect sizes as well as specific effect sizes for specific outcomes.

The main reported clinical analysis will use the intention-to-treat principle. The definition of a trial participant will be those who provide data at the baseline assessment and are members of one of the classes subsequently selected for continued trial participation. Those providing baseline assessments only will be defined as study participants. In ancillary exploratory analyses we will also examine whether the effectiveness of the intervention is greater for those that adhere to the curriculum (i.e., engage with intervention, and in the case of the MT use the mindfulness practices). Because adherence is likely to be associated with factors that impact on the outcomes, we will account for this confounding using instrumental variable methods[120].

All analyses will account for clustering within schools, as this is a cluster-randomised design. Continuous outcomes will be compared using random effects ("multilevel") linear regression and binary outcomes will be compared using marginal logistic regression models using Generalised Estimating Equations (GEEs) with robust estimates of standard error, specifying an exchangeable correlation structure within clusters. Continuous outcomes will be summarised for each trial arm using means and standard deviations and binary outcomes will be summarised for each trial arm using numbers and percentages.

We will use tests of interaction to explore potential moderators of outcome, including, but not exclusive to: the children's age/year group; the stratification variables and baseline risk for depression; well-being; and social/emotional/behavioural functioning. The latter is particularly important, as it is key to engagement with MT. These analyses are exploratory and hypothesis generating in nature[121]. We acknowledge the issue of multiple testing and the need to cautiously interpret significant findings that will require replication in subsequent studies to have credence. We also acknowledge the low statistical power of tests of interaction in comparison to the power for detecting main effects[122].

Whilst mechanisms of action and potential mediators are examined in detail in a separate programme of work, we will explore potential mechanism variables pre- and

post-MT in both trial arms and key outcomes at one- and two-year follow-up. We will ask if the change in mechanisms is specific to MT, changes as a function of use of mindfulness skills, precedes changes in the outcomes, and explains changes in key outcomes at follow-up, over and above changes in those outcomes from baseline-to-post-treatment[123] and through moderated mediation explore what works for whom. Methods for the analysis of mediation using clustered data are in the infancy of their development[124]. We will keep abreast of on-going methodological research in this area and these analyses will be exploratory and hypothesis generating in nature.

Cost-effectiveness will be assessed in terms of quality-adjusted life years using the CHU-9D. Secondary analyses will explore cost-effectiveness in terms of the three co-primary outcomes, to assess the sensitivity of analyses to the alternative outcomes of interest. We will employ standard methods of analysis, including multiple imputation for missing data , adjustment for baseline prognostic factors, in line with the clinical analyses, and standard parametric tests for differences in costs, with the robustness of the parametric tests confirmed using bias-corrected, nonparametric bootstrapping[125]. Cost-effectiveness will be assessed using the net benefit approach, with uncertainty explored through the presentation of cost-effectiveness acceptability curves[126]. A within-trial analysis will be undertaken at 1-year follow-up.

The lifestyle choices and behaviour of young people on the threshold of adulthood can lead to short- and long-term adverse outcomes that are expensive for society and damaging to them[127,128]. To this end, longer-term outcomes and costs will be explored using decision analytic modelling[129]. The model will be populated using data from our ongoing programme of work, including trial data and research on teacher training models, as well as evidence from the literature and relevant longitudinal cohort databases. The most suitable modelling framework in which to carry out the analysis will be dependent upon the results of the RCT, and thus will be finalised at a later point. Markov modelling is likely to be the most appropriate for extrapolation over the longer-term since it is able to deal with relatively complex care pathways. The cost-effectiveness model will be analysed using incremental analysis and probabilistic sensitivity analysis. The time period over which the model will be run will be determined after review of the literature, since data availability is the key limiting factor. These analyses are exploratory and hypothesis generating in nature[121].

4.1 Minimising bias

To maximise ***generalisability***, we will actively recruit schools that are representative of the UK population, with particular, but not exclusive, attention to key variables such as deprivation, operationalised as eligibility for free school meals and region and the type of school (e.g., selective/non-selective, urban/rural, large/small, mixed/single gender, state maintained/independent). As recruitment progresses we will, as far as possible, monitor recruited schools and teaching staff within these schools in terms of their match to these variable, actively seeking schools with variables that will improve the representativeness of the sample. In the event that we have more interested schools than we are able to recruit, we will make decisions on suitability based partly on the intention of achieving a representative sample of schools

To minimise ***contamination across clusters*** we will randomise at the level of school, and secure schools' agreement to adhere to the regime of the trial arm to which they are allocated. ***Attrition bias*** will be minimised by building on robust trial procedures developed in our feasibility trials[66,130]. Retention of pupils is predicted to be > 80 % at follow-up. We have demonstrated that we can achieve close to 97 % data from pupils and 100 % retention of schools/teachers completion in our feasibility studies, albeit it with shorter follow-ups[66,130]. As randomisation is at the level of school, if teachers leave, provision can be made within schools for cover by allocating another teacher able to offer the interventions. We will exclude schools from the study with an inadequate school quality rating or without a substantive head because of the risk to implementation. Trial newsletters and social networking will be used as a way of keeping in touch with schools and participants between follow-up points.

Robust randomisation procedures conducted by an independent statistician and pre-publication of the trial protocol will minimise ***subversion bias***.

Blinding. Attempts will be made for researchers collecting follow-up primary and secondary outcome data that may be prone to researcher-expectancy effects to remain blind. The Trial Manager and Administrators will not be blind, to enable good trial governance and communication with schools. Researchers engaged with blind data collection will be asked to guess the trial arm at each follow-up point.

To ***maximise data completeness***, data will be collected either through an online portal using tablets/laptops or through paper and pencil measures, whichever is preferred by the school/teacher students. Pupils who are absent from school will normally be contacted through their school. Teachers will be remunerated for completion of student and self-report measures. Time windows for the follow-up assessments will be large enough to maximise data completeness. ***Data management and integrity*** will be maximised by using protocols established in our previous trials including using online data entry and, where appropriate, through double entry. Finally, ***analytical biases*** will be minimised by pre-publishing the Study Protocol prior to data collection and the Statistical Analysis Plan prior to analysis.

Measurement of preference: In line with guidance for the design of randomised controlled trials[131], we will write our study materials to ensure they provide clear information about the two trial arms. We will assess head teachers preferences at baseline. We will ask pupils about the credibility and usefulness of the MT and social and emotional learning (SEL) curricula.

5 Trial governance and ethics and safeguarding

Ethical and Regulatory considerations:

Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki

(http://www.wma.net/en/30publications/10policies/b3/)

Guidelines for Good Clinical Practice

The Investigators will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice. Researchers who will be obtaining informed consent will complete relevant components of Good Clinical Practice training.

All members of the research team will undergo clearance through the disclosure and barring service.

Trial Governance:

The management structure will ensure that the scientific aims are delivered and provide robust governance and oversight. Oxford University will sponsor and host the study and we will seek ethics approval from the University of Oxford Central Research Ethics Committee.

A Trial Management Group (TMG) comprising the co-investigators and Trial Manager will provide day-to-day management of the project. Quarterly TMG meetings will review progress against study milestones, plan work, discuss methods, keep a risk register and anticipate/resolve any problems. The first meeting will be face-to-face and then via video/teleconferencing throughout the project, with face-to-face meetings at least once a year. They will seek input from collaborators and others, as needed.

A Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) will be established to provide oversight of the trial. They will be independent of the study team and chaired and constituted by people with the requisite specialist expertise and experience. The PenCTU will support the trial in terms of database development, randomisation, methodology, and statistics.

5.1 Ethics and Safeguarding

Ethics procedures build on our feasibility trials and other schools-based trials[73]. We will ensure consent at the school level from head teachers. We will then seek parental/caregiver opt-out and child assent. Cluster RCTs present particular ethical issues and we therefore follow the Ottawa group 15 consensus recommendations for cluster RCTs, with school headteachers identified as the "gatekeepers"[81]. Child welfare and safeguarding procedures have been developed with input through our stakeholders (headteachers, teachers and young people).

The recruitment and research governance procedures developed in the STARS (Supporting Teachers And childRen in Schools) trial[73] and our feasibility study will be used[66]. Our feasibility study did not identify any risks to young people arising from the research procedures or MT itself. However, a protocol or Risk Management has been

developed to provide a consistent approach to identification and reporting of risk. This protocol will be discussed and agreed with the headteachers/safeguarding leads at each participating school and builds on the protocol developed in our earlier trials. The protocol will ensure that, where young people are identified as at risk of abuse, appropriate safeguards are put in place in a timely way. Young people who disclose concerns directly to the research team in person, or via another means of direct communication rather than through case report forms, will be followed up to ensure that they receive appropriate support. All young people will be provided with bespoke information on local and national sources of support, the content of which will be agreed with participating schools. Likewise participating teachers who are identified as at risk of harm will be followed up in accordance with the protocol for Risk Management. Data on Serious Adverse Events (death, overnight hospitalisation, prolongation of existing hospitalisation, persistent or significant disability/incapacity, life threatening situations and attendance at A+E) will be collected both as they arise and as part of routine data collection at each assessment point and will be reported to the DMEC within seven days of the research team becoming aware of them. Adverse events will be logged and reported via the DMEC and TSC, and the DMEC will review aggregate data on child mental health and self-harm outcomes to ensure there is no excess of such outcomes in the active arm. As we are collecting data in two cohorts, the end of the first cohort provides an opportunity for the DMEC and TSC to review this data and the robustness of these procedures once the first wave of intervention has been completed.

5.2 Public engagement

Public engagement has been established for three aims: integrate stakeholders' perspectives, maximise impact of dissemination, and as an end in itself. In relation to stakeholder engagement, a process of engaging secondary school heads, teachers and student councils was used to inform the protocol. Our consultation resulted in: including more visits and on-going communication with schools; ensuring appropriate remuneration for teachers completing assessments of their students; planning best scheduling of assessments/MT intervention; and creating robust procedures for ensuring participant safety. Our public engagement will be supported by a Public

Engagement Group chaired by Geraldine Davies, Head Teacher, UCL Academy; that will meet bi-annually (at least initially), feeding into the Trial Management Group and the comprising key stakeholders who can to some degree represent their stakeholder group, including young people, teachers, parents and school mindfulness teachers.

6 Electronic data storage, confidentiality, security, archiving and dissemination

Electronic study records will be stored in a Structured Query Language (SQL) server database, stored on a restricted access and secure server, maintained by Plymouth University. Data will be entered into the database via a bespoke web-based data entry system encrypted using Secure Socket Layer (SSL). Data entered onto the database will be backed up according to PenCTU Standard Operating Procedures (SOPs). Data will be collected and stored in accordance with the Data Protection Act, 1998.

Double-entered data will be compared for discrepancies using a stored procedure. The results will be available, via a web-based report, to the study team who may choose to verify discrepant data using the original paper data sheets.

Access to the database will be permission based and user accounts will be requested by the trial manager and managed by the PenCTU data manager and PenCTU programmer.

Following completion of data analysis and submission of the end of study report, the Sponsor will be responsible for archiving the study data and essential documentation in a secure location for a period. No trial-related records should be destroyed unless or until the Sponsor gives authorisation to do so. On completion of the trial the University of Oxford will continue to safeguard the master file and enable access to the data in line with its policies. Dissemination is guided by the MYRIAD Dissemination Protocol, which provides guidelines on authorship, planned outputs and mechanisms for additional papers and access to the trial dataset. School summary data will be offered to the schools at the end of the trial.

6.1 Data held by 3rd parties

Where rules, in the license agreements of questionnaire scales, require the use of external websites to perform data collection the storage and security of these data becomes the responsibility of the 3rd party. Where possible an anonymised identifier will be stored in the PenCTU database and this will be used by the 3rd party websites.

6.2 Current study status

6.3 Recruitment of schools was completed in Autumn 2017. The first cohort of schools (12) completed their 2 year follow-up visits in January 2020. The second cohort of schools (72) completed the 1-year follow-up of the project during the Autumn term of 2019 with some schools finishing in January 2020. The final 2-year follow-up is planned to take place in Autumn 2020, however, due to the outbreak of COVID-19, at the time of writing the timing of this phase of data collection remain uncertain and may be moved to a later time point.Protocol updates

Protocol update	Person making update	Date and protocol version number
Minor changes to clarify protocol	E. Nuthall	1.1 18/05/2016
Change of primary endpoint from 2 year follow up to 1 year follow up. Update to questionnaires used and table in appendix 1. Items changes for clarity	E. Nuthall	2.0 27/07/2020

7 Discussion

This cluster RCT aims to provide a rigorous evaluation of the effectiveness and cost-effectiveness of a MT programme, compared with good practice teaching of social-emotional curricula, for young people aged 11-14 within secondary schools. It will answer a question with significant public health implications; namely “can a universal school-based intervention, in this case MT, shift the population away from mental ill health and towards improved mental health and well-being?”

If the trial suggests MT is cost-effective, this could enable schools to offer a relatively low cost, scalable intervention to improve young people’s short and longer-term social, emotional and mental health outcomes. This would have implications in terms of preventing mental health problems before they can take root and become a lifelong recurring problem. Moreover, there are prospective studies suggesting that the executive control skills MT seeks to develop are associated with a range of long-term health, social, and economic outcomes[37]. This study will examine whether integrating MT into social-emotional teaching as usual, when compared with continuing social-emotional teaching aloneso positively affects these short-term 1-year outcomes. To assess longer-term outcomes we plan to establish a cohort, to follow participants up into adulthood, linked to the National Pupil Database. There are also significant potential benefits for schools in terms of teacher mental health, well-being and functioning and school ecology/culture. Finally, alongside our other programmatic work, the trial will contribute to our understanding of for whom and when MT is best delivered, its mechanism of action and the most scalable approach to training teachers to deliver the MT programme.

8 Appendices

Appendix 1**:** Table to show the experience and measurements of a young person, teacher and schools going through the trial:

	STUDY PERIOD								
	Enrolment		**Allocation**	**Post – Allocation**					
TIMEPOINT	**-T1**	**T0**	**Allocation**	**Training**	**T1**	**Intervention**	**T2**	**T3**	**T4**
Months relative to pre-intervention (T1) assessment	**-20 to -15**	**-15 to -10**	**-12**	**-6**	**0**	**1-5**	**4-10**	**12 (+/-2)**	**24 (+/-9)**
ENROLMENT									
School Eligibility Screen	✓								
Headteacher Consent	✓								
Teacher Consent	✓								
New Teacher Consent				✓					

Parental opt-out consent	✓				✓				
Pupil Assent		✓			✓				
Randomisation			✓						
INTERVENTIONS									
Mindfulness Training (MT) *those allocated to MT arm*						✓			
MT Booster Sessions *those allocated to MT arm*								✓	✓
Teaching as Usual (TAU) *all schools*						✓	✓	✓	✓
PUPIL SELF-REPORT									
Sociodemographic Information		✓							
CES-D		✓			✓		✓	✓	✓
SDQ (youth version)		✓			✓		✓	✓	✓
WEMWBS		✓			✓		✓	✓	✓
PDS					✓		✓	✓	✓
CAMM					✓		✓	✓	✓
RCADS					✓		✓	✓	✓
Mindfulness Practice* *those allocated to MT arm*							✓	✓	✓
BRIEF-2					✓		✓	✓	✓

Drug and Alcohol Use*					✓		✓	✓	✓
CHU-9D					✓		✓	✓	✓
Self-Harm / Suicidal Ideation*					✓		✓	✓	✓
Adapted CA-SUS *					✓		✓	✓	✓
Assessment of Curriculum, PSHE					✓		✓	✓	✓
Assessment of Mindfulness Curriculum *					✓		✓		
Questions designed by pupils as part of the 'Co-Researcher Challenge' exercise (note will be either T3 or T4 depending on which cohort the school is in)								✓	✓
PUPIL ASSESSMENT OF SCHOOL									
SCCS					✓		✓	✓	✓
TEACHER ASSESSMENT OF PUPILS									
Consent to provide pupil data					✓				
SDQ (teacher rated)					✓		✓	✓	✓
BRIEF-2 (teacher rated)					✓		✓	✓	✓
TEACHER SELF-REPORT									
Sociodemographic Information		✓							

MBI		✓			✓		✓	✓	✓
TSES		✓			✓		✓	✓	✓
PSS		✓			✓		✓	✓	✓
PHQ9		✓			✓		✓	✓	✓
GAD7		✓			✓		✓	✓	✓
FFMQ-SF		✓			✓		✓	✓	✓
MTS		✓			✓		✓	✓	✓
Mindfulness practice* *those allocated to MT arm*					✓		✓	✓	✓
Feedback on programme* *those allocated to MT arm*					✓		✓		
TEACHER ASSESSMENT OF SCHOOL									
SCCS		✓			✓		✓	✓	✓
HEADTEACHER SELF-REPORT									
Descriptives		✓							
Preference (MT or TAU)*		✓							
SCHOOL LEVEL MEASURES									
PSHE (Personal, Social and Health Education)		✓					✓	✓	✓
School mindfulness implementation*							✓	✓	✓

those allocated to MT arm									

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