Title: Learning Together to promote mental health and wellbeing (LTMH)

Subtitle: Refinement and feasibility study of the Learning Together to promote mental health and wellbeing intervention (LTMH) in English secondary schools

Version control table

Version	Date	Summary of changes
1.0	15 September 2021	-
1.1	15 November 2021	Funding details and version control table included
1.2	23 June 2022	Revision of primary and secondary outcomes (before commencement of data collection)

Funding

This study/project is funded by the UK National Institute for Health Research (NIHR) [Public Health Research programme (PHR Project:NIHR131594). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Background

Young people's mental health: Mental health problems are the largest cause of disability in the UK(1) with around three-quarters starting before age 24 and half before 14.(2) Among those aged 5-19, 13% have at least one mental health disorder.(3) About 40% of adolescent girls have disordered eating(4) and 20% report self-harming.(5) Healthcare systems are stretched(6) and focus has turned to prevention.(7) In the UK, the green paper 'Transforming Children and Young People's Mental Health Provision' has identified a central role for schools in promoting mental health.(7) Schools aim to implement effective programmes but lack specialist expertise, access to evidence-based interventions and resources. This will change over the next five years as schools gain new funding and staff dedicated to mental health. All schools will be part of Mental Health Support Teams (MHST) with access to a new workforce of Educational Mental Health Practitioners(EMHP)(7) and all schools will be required to deliver statutory Relationships, Sex and Health Education from Sept 2020. This resource will be finite and have limited focus on universal prevention, thus understanding priorities for universal interventions is important and requires an evidence base.(8) There is a window of opportunity to produce rigorous intervention evidence for

whole-school universal interventions to promote mental health and wellbeing that are feasible to implement, work with the grain of school systems and require minimal resources. Such interventions are of even greater importance post-COVID-19. There is emerging evidence that population mental health in young people worsened during the pandemic and the lockdown response,(9, 10) although robust data are still awaited.

Schools influence mental health in multiple ways. School environments affect mental health through exposure to prosocial or antisocial peers, bullying, social-support networks and exposure to other aspects of school culture.(11, 12) The most effective interventions in schools are those that address multiple mechanisms operating at multiple levels. Such 'whole-school' interventions include environmental and curriculum components and have broad effectiveness against a range of health outcomes and are popular with schools.(8) School environment components address school culture and systems, and impact on a range of health outcomes and behaviours.(13) A key aspect is increasing student engagement with school, particularly the most disadvantaged and those with highest baseline need.(14, 15) Schools promote health most effectively when they are recognised as physical and social environments that can actively support healthy behaviours.(16) Health outcomes in young people cluster together and have common underlying causes.(17) Modifying the way in which schools manage their 'core business' (teaching, pastoral care and discipline) can promote student health and potentially reduce health inequalities across a range of outcomes, including mental health.(12)

Multiple reviews support a role for school programmes in improving young people's mental health,(18-21) with evidence across anxiety and depression(19, 22) body image and disordered eating,(23) self-harm and supportive capacities such as self-regulation.(24) There are major limitations to this evidence including: small effect sizes;(18, 21) sample sizes;(25) intervention focus on single elements of mental health;(26) lack of interventions being co-created with young people; lack of addressing the digital environment; promising interventions failing to be effective at scale;(8) interventions failing to work with the grain of school system;(8) and interventions not meeting schools' need for guidance but flexibility in implementation.(27)

As school environment interventions are inherently universal in reach and impact,(28) they offer the most parsimonious method for intervening in schools. Yet existing school environment interventions have largely focused on risk behaviour such as bullying and substance use and have only examined mental health as a secondary outcome.(29)

Refining the Learning Together intervention

We previously led the Inclusive cluster-randomised trial of the Learning Together intervention across 40 English secondary schools 2014-17.(28) Learning Together is a multi-component intervention which aims to modify the school environment to reduce bullying and anti-social behaviour. The key elements of original LT are: survey of students to identify areas of need;

Action Groups comprising staff and students to review needs data and use this to plan and coordinate local delivery and rewrite school behaviour policies and rules supported by an external facilitator; training of all school staff in restorative practices (identifying harm and restoring relationships in response to conflict within the school); and a social and emotional skills classroom curriculum. We found significant benefits for the intervention reducing bullying victimisation (primary outcome) as well as improved mental wellbeing and health-related quality of life, and reduced psychological distress and substance use (secondary outcomes), with high cost-effectiveness comparable to other school-based interventions.(28) Learning Together is now being assessed for scale-up across Wales and has been accredited for delivery at scale by Blueprints for Positive Youth Development in the USA and the Early Intervention Foundation in the UK. Despite the fact that the intervention's primary aim did not include mental health per se, the effect sizes for impacts on mental health and wellbeing were approximately 0.1SD. These impacts on mental health related outcomes occurred despite the intervention not including activities directly addressing mental health. This suggests the possibility that modification of Learning Together to address mental health directly may enable greater impact upon such outcomes, particularly on emotional domains of mental health.

We will refine Learning Together for Mental Health (LTMH) to focus more directly on improving other aspects of mental health and wellbeing, including emotional issues, self-esteem, body image and eating problems substance use and self-harm. LTMH will retain the proven elements of LT but also give schools new tools to make locally-owned needs-driven choices from a package of evidence-based practices: approaches that are effective and valued by schools.(30) A modified LTMH would build mental health skills at a time when schools are developing a new workforce with capacity to deliver interventions. This would build on and add value, given previous investments in LT and its proven effectiveness and cost-effectiveness. In the LT-MH intervention: the needs assessment surveys will focus on mental health and wellbeing and produce a guide for schools to assess the prevalence of mental health problems and identify local need; the Action Group will focus on reviewing and revising school policies and systems to promote mental health and wellbeing, choosing options from a new menu of actions that have previously been shown to work in schools; and the curriculum element will be modified to focus on social and emotional learning using an updated curriculum.

We propose a refinement and feasibility study to modify the intervention to increase its focus on mental health and wellbeing among young people in secondary schools, prior to a future study to evaluate the effectiveness of the intervention in a phase III cluster-randomised trial. We do not aim to conduct a pilot RCT of the intervention in the interests of costs and timeliness given we are building on existing evidence.

Our refinement and feasibility study of LT-MH would be the first UK study of a whole-school mental health intervention. There are major potential public health benefits arising from the

prevention of adolescent mental health problems. Our study fits alongside a national programme of embedding mental health within schools, and will contribute to the evidence for this. Refinement of Learning Together to address mental health and wellbeing shuld be an efficient means to address these problems and will be informed by patient and public involvement and engagement (PPIE). Participants are unlikely to experience any physical or psychological risks, either because of the intervention or the research study. Any potential harmful effects of the intervention will be explored in the process evaluation. Participating schools will facilitate data collection with students. Participants will be informed that participation is voluntary and they may withdraw at any point. We will maximise retention, minimise disruption to schools and ensure data quality by employing strategies we have previously used, such as: close liaison between a named researcher and school day-to-day lead to identify convenient times and places for research, and identify problems early; and compensating schools for the costs arising from their participation in research activities.

Research aims, questions and objectives

Aims

1. To refine LT, with the mental health charity Place2Be, a secondary school and other stakeholders, to promote mental wellbeing and address health inequalities in England.
2. To assess the feasibility and acceptability of delivery of LT-MH in secondary schools in England.

Research questions

REFINEMENT PHASE

Is it possible to refine LT to promote mental health wellbeing (to develop LT-MH)?

FEASIBILITY STUDY

1. What is the feasibility and acceptability of delivery of LT-MH in secondary schools in England?
2. Is progression to a phase III trial justified in terms of pre-specified criteria (see below).
3. What level of student awareness does the intervention achieve among year-10 students at follow-up?
4. What do qualitative data suggest in terms of intervention mechanisms and refinements to programme theory and theory of change?
5. How do contextual factors appear to influence implementation, receipt and mechanisms of action?
6. Are any potential harms suggested and how might these be reduced?
7. Is an economic evaluation feasible?

A future phase III trial would be focused on the question of what is the effectiveness and cost-effectiveness of LH-MH in improving mental health and wellbeing among young people in English secondary schools.

Research objectives and timescale

We will undertake a 25 month project from 1 November 2021 to 30 November 2023.

i) To refine LT-MH in collaboration with Place2Be, the staff and students from one secondary school, the National Children's Bureau (NCB) Young Research Advisors and other stakeholders (Nov 2021 - Sept 2022).
ii) To recruit four schools for the feasibility study and undertake baseline surveys of students at the end of year 7 (age 11-12) (Nov 2021-July 2022).
iii) To implement the intervention (Sept 2022-July 2023).
iv) To conduct quantitative and qualitative elements of the process evaluation (Sept 22-July 23).
v) To undertake follow-up surveys at 12 months post baseline with students in year 10 age 14-15 (June-July 2023).
vi) To conduct data analysis addressing all of the above research questions and draft a report of the pilot evaluation (July-Nov 2023).
vii) To disseminate findings and determine whether progression to a phase III trial is justified (post study).

Research design

The research has 2 phases:

A. Intervention refinement involving PPIE.
B. Feasibility study

Figure 1 outlines the intervention flow.

A. Intervention refinement phase: We will work with Place2Be, the NCB Young Research Advisors, the staff and students of one school and other health/education stakeholders in a period of co-creation and refinement, co-producing an intervention that is likely to be acceptable in schools. Key elements of the theory of change adaptations as well as the basic outline of the core components have already been determined. Further work is required to elaborate this and optimise the intervention, developing in detail the intervention components and materials.

Optimisation will be informed by existing frameworks (31) and occur in phases:

1. Elaboration of the intervention theory of change, logic model and overall approaches.

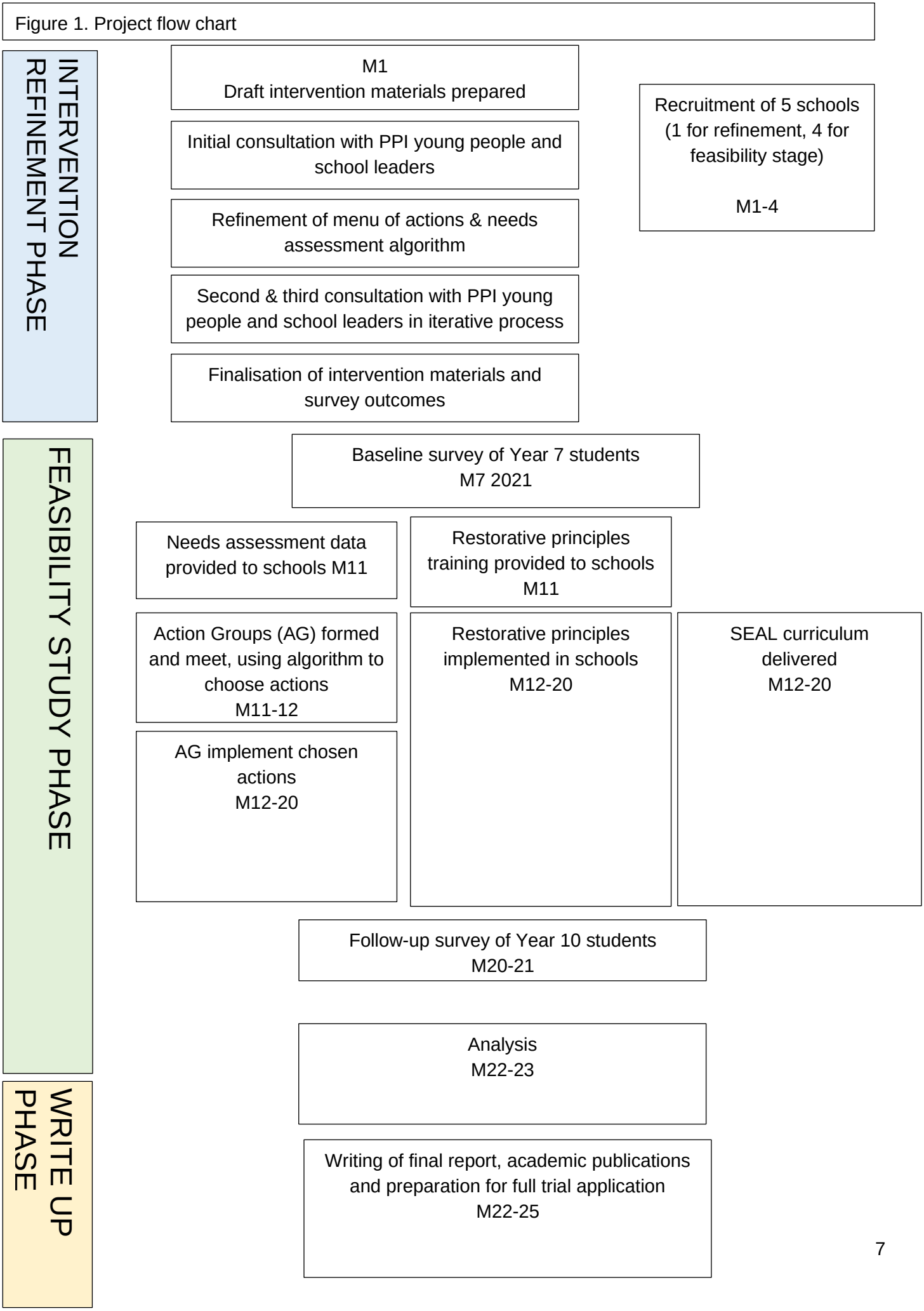
2. Refinement of the student needs survey, manual guiding the Action Group (including menu of actions) and needs assessment guide/algorithm.
3. Identify best-evidenced SEAL curriculum.

For each, optimisation will occur through a systematic process:

1. Review of existing systematic reviews and, where appropriate, evaluations of intervention materials from identified actions with two waves of PPI discussion.
2. Drafting of the above resources 1-3 by the research team in consultation with staff and students from all schools.
3. Refinement of these resources.

We will set internal progression criteria to move from the refinement phase to the feasibility study phase: i.e. that intervention materials, algorithms, menus and processes are generated and focused on mental health and wellbeing outcomes to the satisfaction of the research team, Place2Be, all other PPIE stakeholders and the steering committee.

Figure 1. Project flow chart



B. Feasibility study phase: We will undertake a feasibility study in four schools to test the intervention for one school year. All schools will receive the intervention in order to assess feasibility of implementation across schools varying by need (measured by deprivation level (using free school meal proportions as a proxy) and by school capacity (measured by Ofsted rating as a proxy).

Design: Feasibility study.

Setting: Four state secondary schools in southern/central England.

Population: The intervention will target all young people in years 7-11 (age 11-16) in participating schools. The research evaluation will focus on students in year 7 at baseline but on year 10 at 12-month follow-up in order to pilot response rates and measures for a future full trial rather than to estimate intervention effects (the feasibility study is not powered or designed to estimate intervention effects). We estimate approximately 670 students per wave will complete the surveys (informed by a mean 167 per school in the Learning Together trial).

Allocation: All to intervention.

Recruitment

The refinement phase will involve one purposively sampled secondary school with a high rate of free school meals (as a proxy for need) and Ofsted inspection rating of good or excellent (as a proxy for the school having good organisational capacity to participate actively in refinement). This school will be recruited via our existing contacts to ensure the school has the capacity to participate.

In the feasibility study, four state secondary schools in southern/central England will participate, purposively recruiting schools from a broad range of backgrounds. All schools will be mixed sex and with an Ofsted inspection rating of 'requires improvement' or higher and with a non-temporary head-teacher. Schools will vary by free school meal rates (above and below the national average) and Ofsted rating (requires improvement or good versus excellent) as proxy measures of need and capacity for implementation (purposive criteria described above). As with our previous pilots and feasibility studies, this small number of schools can and will be recruited by a low-intensity combination of mail outs, phone calls and prior networks. Head-teachers and chairs of governors will be asked to give informed consent to each school's participation. Information will indicate the workload required of the intervention to ensure that schools know what they are signing up to, to minimise later drop-out. Other methods to maximise retention are discussed above. Response rates will be recorded, as will any stated reasons for non-participation.

We will recruit schools through linked networks and collaborators. Our PPI partner (National Children's Bureau (NCB)) has a schools network that will be used for recruitment (see

upload). Our collaborator Place2B (P2B) works with large numbers of schools nationally and will assist with recruitment (see upload). Our project begins in November 2021 and our timescale allows for recruitment of schools between Jan and April 2022. We do not believe it is useful to pre-recruit schools currently given the circumstances of the return to schooling post COVID.

Intervention

Theory of change

The intervention is underpinned by a theory of change based on that used in the LT intervention, which we have previously shown is effective in a large randomised controlled trial in secondary schools. Drawing on the theory of human functioning and school organisation,(32) this theorised that engagement in risk behaviours could be reduced and mental wellbeing enhanced by building student sense of belonging and engagement with learning in school, which in turn contribute to students developing 'practical reasoning' skills and peer affiliations supportive of healthier decisions and wellbeing. There is strong support in the mental health literature that improving relationships between and among students and staff, and increasing connections between students and school will actively promote multiple aspects of mental health and wellbeing.(33, 34)

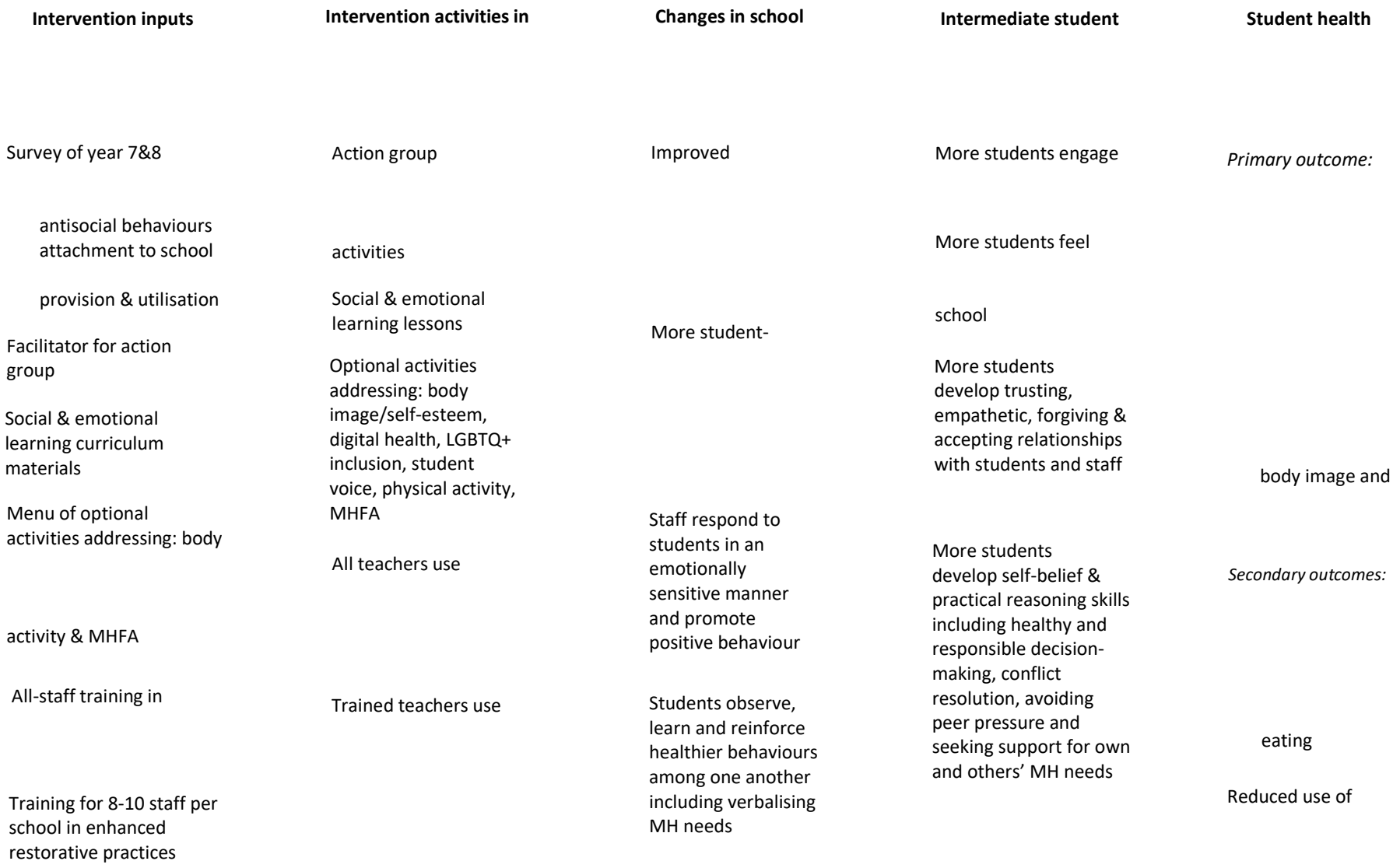
Our intervention inputs aim to enable schools to convene action groups involving staff and students who cooperate to review survey needs data and plan and oversee core intervention components and locally chosen options. These options come from a menu of evidence-based interventions focused on primary and early intervention within the school relating to body image/self-esteem, digital health, LGBTQ+ inclusion, student voice, physical activity for mental wellbeing and mental health first aid. In addition, universal core intervention components include schools delivering social and emotional skills lessons, and teachers being trained in use of the language of restorative practice and, for a subset of teachers, in-depth training in restorative conferencing to address serious conflict. Restorative practice enables students to resolve conflict, take responsibility for behaviour, and engage in acts of empathy and forgiveness, supported by enhanced connection with school. Together these core and optional activities modify schools' social environments so these are characterised by: improved communication among and between students and staff; more student-centred teaching, behaviour management and social support for mental wellbeing. Staff are able to respond to students in an emotionally sensitive manner and promote positive behaviours supportive of mental wellbeing. Through social and emotional skills lessons, restorative practice, action groups and other intervention activities, students observe, learn and reinforce healthier behaviours among one another including being able to verbalise mental health challenges and needs.(35)

These changes in the social environment result in intermediate student outcomes of increased engagement in learning; increased sense of belonging and emotional security in school; more trusting, empathetic, forgiving and accepting relationships with students and staff; increased self-belief (including belief in the ability to manage and resolve difficulties when they arise) and 'practical reasoning' skills relating to conflict resolution, avoiding peer pressure (e.g., in relation to anti-social behaviour, restricted eating, self-harm and perfectionism) and seeking support for own

and others' mental health needs. These changes mediate intervention impacts on improved mental health with fewer emotional problems and less disruptive behaviour; improved wellbeing and quality of life; improved body image and self esteem; reduced antisocial behaviour, self-harm, substance use and disordered eating; and reduced use of NHS crisis services.

Based upon this theory of change, our Logic Model (Figure 2) outlines the intervention inputs and processes we anticipate will lead to improved outcomes. The structure of inputs and processes from the original LT will be retained, with most inputs/processes modified to focus on mental health promotion.

Figure 2. Intervention logic model



A. Inputs: The intervention will provide the following inputs in each school

i) Needs assessment: Intervention actions in each school will be guided by a needs assessment, based on data obtained during baseline surveys. We will retain the original Learning Together needs assessment focus on antisocial behaviours and: a) strengthen assessment of a wide range of mental health issues as described above; b) strengthen translation of assessment into actions through use of an algorithm to guide schools on matching needs to actions; and c) guide and enable the Action Group to draw on existing data to audit existing mental health and wellbeing provision in the school.(36)

ii) Facilitator: We will modify the external facilitation of the Action Group (identified as being critically important in the process evaluation of Learning Together(37)) to involve predominantly online support, reducing costs. Facilitation will include three days' time per school provided by Place2Be to prepare for intervention delivery followed by one-hour meetings before each Action Group.

iii) Whole-school training in empathic and respectful communication and restorative practice. This will remain unmodified because this was identified as highly valued in the trial of Learning Together trial and process evaluation. We will explore the provision of some online as well as face-to-face training.

iv) Curriculum: This will be retained because of evidence for the effectiveness of social and emotional skills curricula on mental wellbeing(38) but with a new evidence-based social and emotional skills curriculum identified in the intervention refinement phase. The process evaluation within the process evaluation of the Learning Together trial reported that the original curriculum was overly grounded in cognitive behavioural theory with outdated materials not well suited to English schools.

B. School processes i.e. interventions implemented by schools

a) **Action Group**: In each school, an Action Group (AG) will be convened which will enable staff and students to work together on planning and co-ordinating intervention delivery, locally identifying need, taking ownership for intervention elements and enabling student agency. The facilitator will assist the school in convening the AG, understanding the school's needs assessment data, setting initial priorities for action and facilitating initial meetings and functions. In this the AG will follow the form/function developed in the original LT. The AG will draw on local needs assessment data (input) to set priorities for improving mental health/wellbeing in school and guide decisions for actions to be implemented in school. For LT-MH, the AG will be modified so that they will choose intervention activities from a set 'menu' of possible actions for schools to implement. Actions included on the menu will be those that are evidence-based to improve aspects of mental health/wellbeing in young people, and are practical and free/minimal cost to implement in schools (costs will be borne by schools). AG will be provided with a simple

guide/algorithm linking identified needs to potential actions. The menu of actions and the guide/algorithm will be co-produced during the refinement stage, based upon systematic reviews. Actions will be predominantly universal, i.e. based at the whole-school level, however schools will also have options to implement some more individual-level actions.

We have undertaken brief reviews and initial consultations with young people from the NCB Young Research Advisors to identify areas and actions likely to be relevant. These will be finalised during the refinement stage from relevant systematic reviews and by consultation with relevant experts, but are likely to include:

1. Self-esteem and body image: There are a range of evidenced actions to improve self-image and body dissatisfaction, from single session curriculum interventions(39) to multi-session interventions.(40)
2. Anxiety and depression: Multiple interventions are available with effect sizes for depression around 0.2SD(41) and for anxiety up to 0.6 in meta-analyses.(22, 42); interventions include teacher-delivered curricula covering strategies to deal with unhelpful thoughts, problem-solving and coping skills.(26) Even single session interventions show promise in reducing anxiety and depression in young people.(43)
3. Digital health including social media, a key area identified by the NCB Young Research Advisors: this is a rapidly developing area although little trial evidence currently exists.
4. Promotion of social and emotional learning in addition to the curriculum element of the intervention.(44, 45)
5. Promotion of inclusion of LGBT+ young people (via inclusion policies; champions; and support groups)(46)).
6. Increasing student voice, identified as key by our Young Research Advisors, and peer mentoring programmes.
7. Mental health awareness sessions: Young people felt that these would be valuable to raise awareness and improve help-seeking.
8. Increasing the extent and range of physical activity opportunities including alternative opportunities (e.g. boxing) and non-sport activities (e.g. dance).(47)
9. Mental health first aid training for students, which was identified as important by Young Research Advisors.
10. Other activities identified by Young Research Advisors such as: wellbeing workshops; sports activities; mental health monitoring; ongoing mental health literacy education; support for exam stress and signposting services.
11. COVID-19: we will explore the literature and work with stakeholders to examine whether there are evidenced actions that are useful or necessary to address issues such as pandemic anxiety and isolation.

b). **Restorative practice** – this will be implemented largely unchanged from LT, but will be situated within a broader focus on improving mental health/wellbeing rather than a narrower disciplinary focus. Use of language for restorative practice will be explored during the refinement phase to ensure it fits for young people and schools, e.g. circle-time will be positioned as class group activities that promote positive behaviour and peer to peer support.

In summary, the following elements of LT will be modified:

- Needs assessment survey – this will now be undertaken with year 7 students and will focus on mental health needs.
- Curriculum – the curriculum as used in LT will be dropped as it was poorly rated and delivered by schools. This will be replaced by an evidence-based curriculum identified in the refinement phase.
- Action groups – the ability for action groups to decide locally appropriate actions from a blank slate in LT will be replaced by the action group making choices from a menu of evidence-based options (developed in refinement phase).
- Action groups –action groups rewriting school rules in LT will be modified. Given that the focus of LT-MH is on mental health rather than bullying and aggression, the action group will focus on broader activities addressing mental health.

Intervention provider

The intervention will be delivered by schools with intervention inputs provided by our collaborator Place2Be (facilitation; curriculum resources) and restorative training provided by the same team of restorative training specialists who trained schools so successfully in the trial of LT.

Outcome measures

The **primary outcomes** for the feasibility study are feasibility and acceptability. Feasibility and acceptability will be assessed by data collected from the process evaluation (interviews, focus groups, Action Group minutes) across the 1 school year of the intervention, collated at the end of the study (1 year).

Lack of feasibility or acceptability will be defined by meeting any one of the following criteria:

a. Intervention feasibility

1. three or more schools had a response rate lower than 60% in the baseline (needs) survey

2. three or more schools did not have at least three meetings of action groups *regardless of quoracy*

3. three or more schools had fewer than *two* staff complete the in-depth training

4. three or more schools completed *no locally decided actions*

5. three or more schools had fewer than 2 staff trained in-depth in restorative practice (RP) regularly implementing RP

6. three or more schools implemented the curriculum with lower than 50% fidelity

7. three or more schools did not choose *any actions* from a menu of evidence-based options

b. Intervention acceptability

1. three or more schools had less than half of senior leadership and action group members finding the intervention acceptable

c. Trial feasibility

1. three or more schools achieved a response rate of less than 60% at follow-up

Failure on one or more of the intervention (feasibility or acceptability) criteria would imply the intervention was not sufficiently feasible or acceptable to evaluate the intervention in a full trial. Failure on the trial feasibility criteria would not speak directly to intervention feasibility/acceptability but require reconsideration of trial design in any future full trial.

We will also pilot indicative primary and secondary outcomes for a future full trial:
a. Indicative Primary outcome – Strengths and Difficulties Questionnaire (SDQ):(48) the SDQ is the most commonly-used mental health outcome measure for children and young people in the UK, extensively validated in population-samples of the relevant age and used in the most recent national mental health survey.(3) It also provides a measure of positive mental health. We will use

the total difficulties score as the primary outcome, with other subscales as secondary outcomes. Note that the SDQ was used as a secondary outcome in LT, allowing some comparability.

b. Indicative Secondary outcomes will include:

1. SDQ subscales(48). We will restrict analyses to the prosocial, conduct problems, peer problems and hyperactivity subscales as these provide additional data to other secondary outcomes.
2. Wellbeing: Warwick-Edinburgh Mental Well-being Scale (WEMWBS),(49)
3. Depressive symptoms: Short Moods and Feelings Questionnaire (SMFQ) (50)
4. Anxiety, measured using the 7-item Generalized Anxiety Disorder (GAD7) scale(51)
5. Eating behaviour including disordered eating, measured using the Eating Disorders Examination Questionnaire (EDEQ), which has measures of weight and shape concerns.(52)
6. Self-harm: using one question derived from the Health Behaviour in School-aged Children (HBSC) study.
7. Bullying (victimization) measured using the Gatehouse Bullying Scale(53)
8. Cyberbullying, assessed using two items adapted from the DAPHNE II questionnaire(54) [asking whether the participant was bullied (victim) and/or bullied someone else (perpetrator) through mobile phone use or the internet
9. Substance use(55)
10. Student report of School climate, using the Beyond Blue school climate scale(56)

Longer-term outcomes: During the refinement phase, we will work with young people and stakeholders to investigate whether in a future full trial we should request consent for National Pupil Database (NPD) linkage to enable assessment of impact upon attainments (as we did in LT), whether further linkage might be attractive (e.g. to NHS sources) and examine procedures used by other school trials to obtain consent for additional later follow-up.

c. Economic outcomes: Outcomes for the economic analysis within a future phase III RCT would include the above primary and secondary outcomes and costs (see Health Economic analysis section). The Child Health Utility (CHU) 9D measure(57) will be used to assess health-related quality of life. This measure has been chosen because it is a utility measure specifically developed for young people and used in our previous LT trial. The CHU-9D includes nine dimensions (worried, sad, pain, tired, annoyed, sleep, school, daily routine and activities), with each represented by a single question with five response options. Health service use focusing on mental health service use will be assessed using the CASUS questionnaire as used in the Myriad trial.(58) Data on costs of the intervention in terms of staff and facilitator time will be estimated from process evaluation data including Action Group minutes and interviews with school staff.

Data and outcome collection

Surveys: Baseline surveys (which also provide data for needs assessment reports for schools) will involve students at the end of year 7 (age 11-12) in June-July 2022. Follow-up surveys will occur at 12 months post baseline with students in year 10 age 14-15 in June-July 2023. This will enable us to pilot the surveys that will be conducted within a phase III trial but within the shorter timescale necessary within a feasibility study. Consent procedures are described under ethics below. Paper questionnaires will be completed confidentially in classrooms supervised by fieldworkers, with teachers remaining at the front of the class to maintain quiet and order, but unable to see student responses. Previous experience indicates that paper questionnaires are acceptable and logistically more straightforward than electronic/tablet surveys. We will survey absent students by leaving questionnaires and stamped addressed envelopes with schools, and liaising with schools to maximise returns. Fieldworkers, but not students, will be blind to allocation. Based on past studies,(28, 59-61) we expect at least 80% survey response rates at baseline and follow-up.

Process evaluation (PE) : Integral PE informed by existing frameworks(62-64) aims to examine intervention feasibility, fidelity, reach and acceptability, and to explore context and potential mechanisms of action including potential unintended effects, in order to refine the intervention theory of change and design. In addition to assessing the 'progression criteria' relating to intervention feasibility and acceptability, we will also examine reach via qualitative research as well as questionnaire survey items at follow-up. The information collected on socio-demographic characteristics in the student surveys will also allow us to examine reach according to these measures. We will also assess the fidelity, reach and perceived impacts of staff training activities. Data will be collected via: audio-recording of training for school staff; surveys of school staff receiving training; web surveys of Action Group members and senior leadership teams; diaries (including time logbooks) of school staff implementing Action Groups, restorative practice and the curriculum; and structured observations of randomly selected session per school of action groups and curriculum lessons.

We will collect rich, contextual qualitative data and analyse this in order to explore potential mechanisms of action and thus refine our theory of change. These qualitative analyses will also examine how mechanisms may vary with context, students' socio-demographic characteristics and/or other factors, in order to refine and optimise the intervention's theory of change. We will also analyse qualitative data to explore any mechanisms that might give rise to unintended, potentially harmful consequences. Data will be collected via:

a. student surveys;

b. interviews with one Place2Be facilitator and one restorative practice trainer;

c. two focus groups with four staff per school (purposive by seniority/activity involved in);

d. one focus group with year 8 and one with year 10 students per school. Each will involve about 6-8 students and be diverse to reflect school profile in terms of gender, school engagement and ethnicity.

PE data need to be collected in each school. Whilst the framework of the intervention is not new (inputs and process), the content of many of the processes is new. Additionally, we need qualitative data on factors affecting acceptability and feasibility of the modified intervention in each school.

Economic evaluation: We will perform a cost-consequence analysis as the 'primary analysis', as recommended by NICE's public health methods guidance.(65) We also plan to assess the feasibility of a cost-utility analysis. For these we will draw upon our experience of similar analyses for the full LT trial.(66)

The cost analyses will take a public-sector perspective following NICE's methods guidance and will cover education, NHS and police costs. Detailed data will be collected linked with the PE on the costs of delivering the intervention as incurred during the trial. Costs such as the trainers' and facilitators' time will be available from invoices. Staff time includes the time staff spent dealing with mental health and will be identified in the teacher survey. The amount of time staff spend with action groups will be collected in facilitator diaries. The staff time involved in curriculum delivery will be taken from logs to be completed by teachers delivering the curriculum. The amount of time spent training will be taken from diaries kept by the trainers and the number of teachers attending training will be recorded on attendance sheets. Teacher salaries will be obtained through the Department for Education (DfE) website. To estimate an hourly rate, we will divide salaries by the DfE statutory guidance on school teachers' pay and conditions document detailing the annual hours of work. NHS and police costs will be incorporated with questions in the student surveys on NHS resource use in terms of visits and hospital stays, and policing costs associated with stops and arrests. These will be costed using standard NHS tariffs and data from the literature on police costs. As above, we will use CHU-9D to capture health related quality of life.

Data analysis

Our main analyses will determine whether criteria for progression to a phase III trial are met. Descriptive statistics on fidelity will draw on Action Group minutes, records of staff training; staff diaries; and web survey of senior leadership team and Action Group members.

Other analyses will address our other research questions. Descriptive summaries of baseline and follow-up data by arm will be tabulated and the reliability of outcome measures be examined via Cronbach's alpha where appropriate. Quantitative analyses will examine

intervention awareness among year 10 students at follow-up, and how this varies by student socioeconomic status, gender and ethnicity. Qualitative data will be subject to thematic content analysis (in vivo/axial codes; constant comparison(67)) informed by realist approaches to evaluation(68) and May's implementation theory(63) to: examine potential mechanisms of action and of harm (to inform selection of quantitative measures of harm within a phase III RCT), and how contextual factors influence implementation and mechanisms; and refine our programme theory and theory of change. Analysis of qualitative data on the impact of context on implementation and mechanisms will be used to inform hypotheses to be tested within a phase III RCT, which will in turn provide empirical data on the potential scale-up and transferability of the intervention across different settings.

Protecting against bias

Although the aim of this study is to refine the intervention and assess feasibility, rather than estimate intervention effects, we will pilot methods aimed at minimising bias. The investigator team and the intervention delivery team will be separately managed, with the intervention managed by our collaborator Place2Be. We will aim to maximise response rates at baseline and follow-up to minimise non-response and attrition bias, for example following up those individuals not present during survey sessions. Response rates and qualitative data will be analysed to refine data collection methods prior to a phase III trial examining effectiveness.

Socioeconomic position and inequalities

School-environment interventions such as planned here have reach across the whole school to influence all students regardless of socioeconomic status. This universal reach avoids the tendency for individual-level interventions to have greater uptake and benefits amongst the more educated and affluent. Given our previous LT intervention had greater impact on those with greater behavioural problems, this intervention may particularly benefit those from more deprived families, given the strong association between deprivation and mental health problems.

All intervention materials will be designed to be accessible and appropriate for individuals regardless of socioeconomic status, gender, ethnicity and sexual identity. The intervention is universal but aims to benefit those with most baseline need. The evaluation will assess how socioeconomic status as well as other characteristics affect the experience of implementation and receipt. We will purposively recruit schools that vary by free school meal rates (above and below the national average) as a proxy measures of the socioeconomic profile of students. This is in order to assess whether the intervention is as feasible and acceptable across schools that differ by socioeconomic status. Awareness will also be assessed against student sociodemographic characteristics (socioeconomic status, gender, ethnicity and sexual identity). Our process evaluation will assess how implementation and intervention mechanisms appears to vary by school and student characteristics. In a phase III trial, we would examine the extent to which

effects vary and are moderated by student socio-demographic measures (gender, parental SES, ethnicity), school-level GCSE attainment and area-level deprivation.

Ethical issues

Ethical approval for the study will be obtained from the UCL and LSHTM ethics committees. Any member of the research/fieldwork team visiting a school will be required to have a full Disclosure and Barring Services (DBS) check. All work will be carried out in accordance with guidelines laid down by the Economic and Social Research Council (ESRC), the Data Protection Act 1998, and the latest Directive on GCP (2005/28/EC).

Head teachers as gatekeepers will be asked for informed consent for intervention. As is normal within public health and educational research in secondary schools in the UK (e.g. RIPPLE, SHARE, ASSIST trials), informed written opt-in consent will be sought from all research participants, including students, judged competent to provide this. In all cases of data collection including surveys, interviews and focus groups, observations and audio-recordings, except where practically impossible, participants will be given an information sheet several days before data collection. In addition, students' parents will be contacted by letter one week prior to any specific research fieldwork informing them about this and providing them with the option of withdrawing (opting out) their child by contacting the school or the research team. Just before data collection participants will also receive an oral description of the study, and have the chance to ask questions. Participants will then be advised that participation is voluntary and they may withdraw at any point. All participants will be advised that they are free to withhold consent and this matter will not be fed back to teachers or, in the case of staff participants, their managers. Students opting not to participate in surveys will be offered alternative activities in the classroom. Those opting out of other data collection will be free to continue with their normal activities.

All participants, including students, will be informed in consent materials of the confidentiality with which the information they provide will be treated as well as the circumstances in which we would need to breach confidentiality. We will develop and maintain standard operating procedures for dealing with safeguarding concerns and reporting serious adverse events. In collaboration with the National Children's Bureau, we will develop a priori categories of abuse reported through the research that necessitate our breaching confidentiality to ensure individuals are offered care and protection. These criteria will be established so that we balance our ethical duty of promoting participant autonomy by respecting confidentiality and our ethical duty of promoting participant wellbeing when we determine that we need to breach confidentiality to address abuse that appears to be serious and ongoing. Where such abuse is reported through a questionnaire, we will contact the safeguarding lead in the school. Where it occurs directly to research staff we will first discuss the need for a response with the research participant prior to contacting the school safeguarding lead.

The study steering group (which because this is a feasibility study not a phase III RCT will undertake data monitoring and ethics duties) and LSHTM ethics committee will be provided with anonymised reports of all disclosures of serious abuse and any other serious adverse events. These will categorised by type, circumstances and the extent of any possible connection with intervention or research activities.

In each school, a senior member of staff will be identified who is not directly involved with the intervention and whom staff or students may go to if they have complaints about any elements of the research study. This will be communicated to students outside of the research process to increase trust that this is truly independent.

Quantitative and qualitative data will be managed by project staff using secure data management systems and stored anonymously using participant identification numbers. Quantitative data will be managed by LSHTM, an accredited clinical trials unit (CTU). Where collected, participant identification numbers and corresponding participant names will be held in separate files; these files will be password-protected folders. The names used in qualitative data will be replaced with pseudonyms in interview/focus group transcripts. In reporting the results of the process evaluation, care will be taken to use quotations which do not reveal the identity of respondents.

In line with MRC guidance on personal information in medical research, we will retain all research data for 20 years after the end of the study.

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