PROTOCOL

Adaptation and pilot trial of Learning Together Primary Schools, a whole-school restorative practice intervention to reduce bullying and promote mental health

Short title: The Learning Together Primary Schools pilot trial of a whole-school intervention to prevent bullying.

This protocol has regard for the HRA guidance

Protocol version: 1.5 (8/11/24)

Trial registration: ISRCTN

Disclaimer: This study/project is funded by the National Institute for Health Research (NIHR) Public Health Research Programme (NIHR153932). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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Competing interests: The investigators declare that they have no competing interests.

Sponsor: London School of Hygiene and Tropical Medicine Research Governance and Integrity Office, Keppel St, London WC1E 7HT. rgio@lshtm.ac.uk. This research will adhere to the principles outlined in the International Council for Harmonisation Good Clinical Practice (ICH GCP). The study

may be subject audit by the London School of Hygiene & Tropical Medicine under their remit as sponsor, the Study Coordination Centre and other regulatory bodies to ensure adherence to GCP.

Governance: An independent study steering committee (SSC) and data monitoring and ethics committee (DMEC) are appointed by the funder with oversight of trial design and conduct, and data integrity, ethics and participant safety. Composition available on request.

Trial status: Schools will be recruited December 2023-March 2024 and students will be recruited May-July 2024.

Version control

Version	Date	Note of changes
1.0	16.10.23	N.A.
1.1	06.02.24	1. School recruitment period is extended until Mar 2024 to allow time for ethics review. The baseline survey and randomisation will now be done Apr-Jul 2024. 2. Data collection from students will be with students from year 3 to 6. Based on PPIE with primary school teachers and researchers who have conducted trials of similar interventions in primary schools, we concluded that data collection from year 2 students is not feasible. 3. PPIE with policy stakeholders will be conducted in phase 2 of the study, not phase 1, as the focus of those meetings with policy stakeholders is on interpretation and dissemination of results. The policy group will be consulted twice rather than the original three times as it was felt that three times would be a poor use of these busy professionals' time. We will no longer consult with the children's group in phase 2 as the key area of discussion with this group is in refining our intervention and evaluation methods, which occurs in phase 1. 4. Informed by PPIE with primary school teachers and researchers who have conducted trials of similar interventions in primary schools, students will not be given a written information sheet in advance. However, the study and process will be explained in detailed by researchers and this process and obtaining assent will be

		observed by a member of school staff or another independent observer. 5. We are no longer inviting a policy stakeholder onto the SSC. This is because we were requested to convene a DMEC in addition to an SSC. Therefore, we wished to keep the numbers participating on these two committees to a manageable number. Given policy stakeholders are represented on a specific group, we did not think it was also necessary to involve them in the SSC. The membership of the SSC and DMEC have been approved by NIHR.
1.2	01.05.24	The measure of cyberbullying victimisation has been changed to the DAPHNE measure because this is shorter and more straightforward for this age-group to complete. Student recruitment will begin in May not April 2024.
1.3	17.05.24	On the advice of the SSC, we have amended the progression criteria so that these use a red/amber/green system rather than a stop/go system. These have been approved by the SSC and DMEC.
1.4	25.6.24	We realised that we had not deleted reference to using the Family Affluence Scale (FAS) when describing plans to assess reach and acceptability of the intervention by student subgroup and also when referring to planned analyses of sub-group effects in a phase III trial. These were drafting error in the original funding proposal; the FAS is not suitable for use with primary school children. We have amended the protocol so that when describing the above analyses, student entitlement to free school meals is referred to as a measure of socio-economic disadvantage. We have corrected a typo that follow-up will occur at 17 months post-baseline; as a result of amendment 1 above this is actually 12 months. We have also ensured we are consistent when referring to the months when baseline and follow-up surveys will be done (May-July in both cases).
1.5	8/11/24	Russell Viner removed as co-investigator.

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Abbreviations

CHU9D - Child Health Utility 9D measure

CI – confidence interval

ICC - Intra-cluster correlation coefficient

LSHTM - London School of Hygiene and Tropical Medicine

NICE - National Institute for Health and Clinical Excellence

Ofsted - Office for Standards in Education, Children's Services and Skills

OR - Odds ratio

P – probability

PI – principal investigator

PPIE – Public and policy involvement and engagement

RCT - Randomised controlled trial

RQ - Research question

SDQ – strengths and difficulties questionnaire

SWEMWBS – short Warwick Edinburgh mental wellbeing scale

UK - United Kingdom

Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

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

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

For and on behalf of the Trial Sponsor:

Signature: Date: 19/10/2021

See sponsor letter
19/10/23.....

Name (please print):

Naomi Panteli.....

Position: Research facilitator, Research Governance and Integrity Office, London School of Hygiene and Tropical Medicine....

Chief Investigator:

Signature: Date: 16/10/2023
.....

Name: (please print):

Chris Bonell.....

Position: Professor of Public Health & Sociology, London School of Hygiene and Tropical Medicine.

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Study steering committee chair	Nick Axford	nick.axford@plymouth.ac.uk

Funding

Funder	**Support**
NIHR Public Health Research Programme	£483,454.30

Roles

Sponsor

To be responsible for the initiation, management, and/or financing of the trial.

Through the Chief Investigator to be responsible for ensuring that members of the research team comply with all regulations applicable to the performance of the project, including, but not limited to: Good Clinical Practice (the ICH GCP R2 (2016) guidelines are recommended as internationally recognised), the Declaration of Helsinki (2013), and for projects conducted in the UK: the Medicines for Human Use (Clinical Trials) Regulations (2004), the Data Protection Act (2018), the Human Tissue Act (2004), and the UK Policy Framework for Health and Social Care Research (2017).

To provide Clinical Trial/Non-Negligent Harm Insurance and Medical Malpractice Insurance applicable to this study, confirming that this study does not fall under any exclusion criteria in the policy.

Sponsorship is conditional on the project receiving applicable ethical and regulatory approval, complying with LSHTM / MRC Unit at LSHTM policies and procedures, as well as successful contract and agreement negotiations before the study commences.

Study steering committee

The role of the SSC

The role of the SSC is to provide overall supervision for a project on behalf of the Project Sponsor and Project Funder and to ensure that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. It should be noted that the day-to-day management of the project is the responsibility of the Chief Investigator.

The main features of the SSC are as follows:

To provide advice, through its Chair, to the Funder, the Sponsor, the Chief Investigator, the Host Institution and the Contractor on all appropriate aspects of the project.

To concentrate on progress of the trial/project, adherence to the protocol, patient safety (where appropriate) and the consideration of new information of relevance to the research question.

The rights, safety and well-being of the participants are the most important considerations and should prevail over the interests of science and society.

To ensure appropriate ethical and other approvals are obtained in line with the project plan.

To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments.

To provide advice to the investigators on all aspects of the trial/project.

Constitution of a SSC

The relevant NIHR Programme Director will review the nominees and appoint the Chair and members.

Independent * members must make up a minimum of 75% of the SSC membership.

The minimum quoracy for any SSC meeting to conduct business is 67% (two thirds) of the appointed membership.

Only appointed members will be entitled to vote and the Chair will have a casting vote.

The Chair and members to sign and maintain a log of potential conflicts and/or interests.

Attendance at SSC meetings by non-members is at the discretion of the Chair.

The primary SSC reporting line is via the Chair to the relevant NIHR Programme Director; however communication is likely to be between the Chair and the NIHR Research Manager who has day to day responsibility for the project.

* Independence is defined as follows:

Not part of the same institution as any of the applicants or members of the project team.

Not part of the same institution that is acting as a recruitment or investigative centre, including Patient Identification Centres (PIC), identifying and referring patients to a recruitment or investigative centre.
(In both cases above 'not part of the same institution' means holding neither a substantive nor honorary contract or title with said institution).

Not related to any of the applicants or project team members.

No other perceived conflicts of interest.

For the Chair only; not an applicant on a rival proposal.

It is recognised that independence status may change during the duration of the trial.

Composition of the SSC

An Independent* Chair (UK based and/or holding a substantive UK based appointment)

An Independent* statistician (where relevant)

At least one PPI member

Others with expertise relevant to the project, such as health economist and clinician(s)

Ideally, the SSC should invite observers, including a representative of the sponsor and a representative from the research network to meetings.

An indication of any proposed overseas members should have been given at the full application stage and feedback on such proposals supplied following the Funding Board's consideration of the application.

SSC meetings

Although there may be periods when more frequent meetings are necessary, the SSC should meet at least annually.

SSC meetings should be scheduled to follow shortly after DMEC meetings so that reports from that group can be considered if appropriate.

Minutes of meetings should be sent to all members, the sponsor, and the funder and be retained in the study master file.

The responsibility for calling and organising SSC meetings lies with the Chief Investigator, in association with the Chair.

There may be occasions when the Sponsor or the Funder will wish to organise and administer these meetings for particular projects. This is unlikely, but the NIHR reserves the right to attend any meeting therefore should be included in relevant invitations and also reserves the right to convene a meeting of the SSC in exceptional circumstances.

The Role of the Chair of SSC

The Chair of the SSC is directly answerable to the relevant NIHR programme, as funder. The Chair's responsibilities include:

Liaising with the Chief Investigator to arrange a meeting to finalise the protocol and to set up a schedule of meetings to align with the project plan.

Establishing clear reporting lines to the Funder, Sponsor, etc.

Being familiar with relevant guidance documents and with the role of the DMEC if appropriate.

Providing an independent*, experienced opinion if conflicts arise between the needs of the research team, the funder, the sponsor, the participating organisations and/or any other agencies.

Leading the SSC to provide regular, impartial oversight of the study, especially to identify and pre-empt problems.

Ensuring that changes to the protocol are debated and endorsed by the SSC; letters of endorsement should be made available to the project team when requesting approval from the funder and sponsor for matters such as changes to protocol.

Being available to provide independent* advice as required, not just when SSC meetings are scheduled.

Commenting on any extension requests and, where appropriate, providing a letter to the funder commenting on whether the extension request is supported or otherwise by the independent* members of the SSC.

Commenting in detail (when appropriate) regarding the continuation, extension or termination of the project. NB: The SSC Chair does not need to be a content expert him/herself but needs to ensure that sufficient content expertise is available for the group to perform its oversight function effectively.

Data monitoring and ethics committee

The study will also have a Data Monitoring and Ethics Committee.

The role of the DMEC

The Data Monitoring and Ethics Committee's main role is as follows:

- In the case of a study with blinded/masked data, the DMEC is the only body involved that may have access to the unblinded comparative data. For other study types it has oversight of any primary data collected from participants, including qualitative data
- The role of DMEC members is to monitor these data and make recommendations to the Steering Committee on whether there are any ethical or safety reasons why the study should not continue
- The DMEC should uphold the safety, rights and well-being of the study participants: these are paramount considerations
- The DMEC should consider the need for any interim analysis advising the Steering Committee regarding the release of data and/or information
- The DMEC may be asked by the Steering Committee, Study Sponsor or Study Funder to consider data emerging from other related studies
- There are also rare occasions when the DMEC chair might be asked by the Study Funder, through the chair of the Steering Committee, to provide advice based on a confidential interim or futility analysis if serious concerns are raised about the viability of the study or if the research team are requesting significant extensions
- Criteria should be agreed (where appropriate) relating to the point at which continuation of the study is considered futile, and in the case of a randomised trial, the DMEC would only indicate if these had been passed or not as this would limit the potential for un-blinding.

Constitution of a DMEC

- The relevant NIHR Programme Director will review the nominees and appoint the Chair and members
- Only appointed members will be entitled to vote and the Chair will have a casting vote
- The minimum quoracy for a meeting to conduct business is 67% (two thirds) of appointed members
- The Chair and members must sign and maintain a log of potential conflicts and/or interests
- Attendance at DMEC meetings by non-members is at the discretion of the Chair
- The primary DMEC reporting line is via the Chair to the Steering Committee.

Composition of a DMEC

- All DMEC members are to be independent (with at least one member being UK based and/or holding a substantive UK based appointment)
- Membership of the DMEC should be small (3- 4 members) and comprise experts in the field, e.g. a clinician with experience in the relevant area and expert statistician. Membership might, on occasion, include members of the public.

DMEC meetings

- Responsibility for calling and organising DMEC meetings lies with the Chief Investigator, in association with the Chair of the DMEC. The study team should provide the DMEC with a comprehensive report, the content of which should be agreed in advance by the Chair of the DMEC
- The DMEC should meet at least annually, or more often as appropriate, and meetings should be timed so that reports can be fed into the Steering Committee
- Minutes of meetings should be sent to all members, the sponsor, the funder, and the Steering Committee, and a copy should be placed in the study master file. It should be noted that the minutes may have 'in camera' items redacted from some copies.

Adaptation and pilot RCT of Learning Together Primary Schools, a whole-school restorative practice intervention to reduce bullying and promote mental health

BACKGROUND AND RATIONALE

This section is informed by literature identified through searches for our recent NIHR-funded systematic review of whole-school interventions promoting student commitment to school to prevent violence (17/151/05), in which we searched multiple databases and websites using terms relating to whole-school interventions, children/young people and evaluation.[1]

What is the problem being addressed?

Bullying is repeated behaviour by an individual or group that intentionally hurts another physically or emotionally.[2] It has been rising in England since 2010. Among 11 year-olds, one third report victimisation in the previous two months with a sixth reporting cyberbullying victimisation. Bullying victimisation increases with age during primary school before peaking in mid-adolescence, and is more common among disadvantaged students.[3 4] Bullying causes multiple physical/mental health harms in childhood and adulthood,[5-10] and lower educational attainment.[11] Through lifetime impact on healthcare, crime, lost income and productivity, it generates £17.9 million costs per year in the UK.[12] Student misbehaviour including bullying is a key reason why people leave[13] or do not enter the teaching profession.[14] Bullying prevention has a return of £7 per £1 invested (public-sector perspective) or £140 (when including individual costs by age 50).[15]

There have been repeated calls that bullying prevention is a priority for which evidence is required, including on the effectiveness of restorative practice in primary schools.[2 16 17] Schools increasingly use zero-tolerance/punitive approaches[18] despite evidence these are ineffective.[19] An alternative approach, restorative practice, aims to prevent or resolve conflicts between/among students or staff.[20] Victims communicate the impact of harm. Perpetrators acknowledge and amend their behaviour. Restorative practice involves primary prevention via 'circle-time' (gatherings to discuss feelings and relationships to prevent conflict before it arises) and/or secondary prevention via conferencing (parties in conflict develop strategies to avoid future harms).

Deficits in socio-emotional wellbeing also commonly manifest during the primary school years,[21] associated with bullying,[4] and with mental illness, risk behaviours, criminal convictions and educational failure in adulthood,[22] incurring high costs to individuals and society.[23]

Why is the research important in improving health?

We propose to take the 'Learning Together' whole-school restorative practice intervention (with proven effectiveness in preventing bullying and promoting mental/physical health in secondary schools), and adapt and pilot this for primary schools. Learning Together for secondary schools comprises: training for school staff to conduct restorative practice to resolve student conflict; an action group comprising staff and students to oversee delivery and build student sense of school belonging; and a classroom social/emotional skills curriculum. Whole-school approaches to restorative practice ensure the practice is supported by changes to school policies and systems. The Learning Together intervention adapted for use in primary schools could make a major contribution to preventing bullying and improving socio-emotional wellbeing with the potential for a large public-health dividend. Most bullying prevention has to date focused on secondary school and has largely ignored the fact that experience of bullying increases during the primary school years. Public and policy involvement and engagement (PPIE) suggests that UK primary schools lack effective bullying prevention interventions. Early intervention in primary schools (when bullying

behaviours increase) is likely to have greater impacts than when delivered in secondary schools given that there is recent evidence that bullying prevention is more effective among younger students.[24] Given primary school commitment to preventing bullying, and social and emotional problems, this intervention - if effective - is likely scalable. This study will assess the value of conducting a phase III randomised controlled trial (RCT) of effectiveness and cost-effectiveness. The Ending Youth Violence Lab is considering co-funding the adaptation phase. The Youth Endowment Fund is interested in co-funding a full RCT.

Review of existing evidence

A recent Campbell review of school-based bullying prevention reported effectiveness in reducing perpetration (OR=1.31: 95% confidence interval (CI) 1.24, 1.38) and victimization (OR=1.24: 95% CI 1.19, 1.31).[25] The review included no RCTs of restorative practice in primary/elementary schools but three quasi-experimental studies of restorative practice in these settings. A US study of 'Bullyproofing Your School' (comprising restorative practice, changes to rules and to school environment) reported decreased bullying victimisation/ perpetration.[26] A replication study found no impact.[27] A Norwegian study of the 'Zero Program' (comprising restorative practice, changes to rules and staff visibility in playgrounds) reported decreased victimisation/perpetration.[28] Recent systematic reviews focused specifically on school restorative practice were poorly conducted and lack meta-analyses, but include two US RCTs of restorative practice among primary school age children.[29-31] An RCT of 'Safer Saner Schools' (whole-school restorative practice) reported reductions in school suspensions.[32] An RCT of a non-whole-school restorative practice intervention reported reduced bullying victimisation among those reporting exposure to the intervention but no overall intention-to-treat effect.[33] These systematic reviews of restorative practice conclude, largely on the basis of quasi-experimental studies, that it is effective in reducing bullying among primary school aged children.[29-31] Restorative practice is likely to be more feasible to implement in primary schools than curriculum-based interventions because unlike the former they do not require classroom learning time for delivery. Curriculum-based bullying prevention has proven challenging to deliver with fidelity in the UK and elsewhere because of lack of space in school timetables.[34 35]

Our previous NIHR-funded RCT examined Learning Together in English secondary schools, reporting reduced bullying victimisation (primary outcome), as well as reduced social and emotional problems (Strengths and Difficulties Questionnaire, SDQ), improved mental wellbeing (Short Warwick Edinburgh Mental Wellbeing Scale, SWEMWBS), improved health-related quality of life, and reduced substance use (secondary outcomes).[36] Mean differences were -0.08 (P=0.044) for bullying victimisation, -0.14 (P=0.0002) for SDQ and 0.07 (P=0.048) for SWEMWBS), indicating significant intervention benefits. The intervention also had significant effects improving student educational attainment in GCSE exams.

The intervention cost £58 per student and was highly cost-effective, with cost-per quality-adjusted life year thresholds of £13,284 and £1,875 at 24 and 36 months respectively.[37] Learning Together has been accredited for scale-up in the USA and UK, and has informed scale-ups in Wales and various English local authorities. Exploratory analyses suggest that, in schools with high management capacity, student participation in decision-making was key to a causal mechanism involving increased sense of belonging. In other schools, similar reductions in bullying occurred but via restorative practice curtailing conflicts.[38 39] The curriculum was poorly implemented and so cannot account for mechanisms of impact. More generally, there is international evidence that whole-school approaches are effective in reducing bullying and promoting mental wellbeing in primary schools.[40-42] Our own recent systematic review of whole-school interventions to prevent violence found reductions in violence perpetration at up to one year post baseline (OR=0.85, 95% CI 0.76, 0.96) and more than one year post baseline (OR=0.79, 95% CI 0.65, 0.98) across school phases.[1] Interventions led to reductions in violence victimisation at up to one year post baseline

(OR=0.84, 95% CI 0.72, 0.98) and more than one year post baseline (OR=0.85, 95% CI 0.73, 0.99). A meta-analysis of school-based bullying interventions identified whole-school elements associated with decreased bullying, all of which are integral components of Learning Together: improved disciplinary methods; staff training; anti-bullying policy; and cooperative group-work.[42]

RESEARCH QUESTIONS

1) Is it possible to adapt Learning Together for primary schools?
2) Is progression to a phase III RCT justified in terms of pre-specified criteria?
3) Are outcome and covariate measures well completed and reliable?
4) Which methods to survey teachers are most feasible?
5) With what rates are schools recruited and retained?
6) What do qualitative data suggest about how context influences implementation and about refinements to the theory of change?
7) Are any potential harms suggested and how might these be mitigated?
8) What is treatment as usual in control schools and is there any evidence of contamination between arms?
9) Are methods for economic evaluation feasible?

PUBLIC AND POLICY INVOLVEMENT AND ENGAGEMENT

PPIE is central to the project. The PPIE lead for the project will be Miranda Perry who is an ex-teacher and mother of two school children. She previously worked as lead facilitator on Learning Together and is now freelance. She has experience facilitating workshops and coaching with children and teachers as well as community volunteering. We wanted to list Miranda as a co-investigator but the online system did not enable this.

PPIE conducted so far with senior leaders and teachers from five primary schools in south-east England indicates that: bullying and poor mental wellbeing are highly prevalent and worse post-pandemic; schools lack scalable, effective bullying prevention interventions; schools would struggle to implement curriculum-based interventions because of lack of timetable space; interest in restorative practice is high; some schools are already conducting restorative practice but without training or support materials so fidelity to restorative practice best practice is likely to be poor; schools need training and guidance materials to deliver restorative practice properly; and schools are enthusiastic about using action groups, student involvement and data on student needs to inform action.

Phase 1 will involve PPIE-based adaptation involving two schools, plus a group of children recruited from other primary schools and a group of parents to provide broader views. The approach to PPIE in phase 1 is described in detail in the relevant section below. One teacher not working at a school involved in the pilot RCT will be invited to sit on the study steering committee. Phase 1 will also involve us consulting with the above teachers and students to inform how we conduct student surveys, which we anticipate will be via paper questionnaires with fieldworkers reading out questions and response options.

In phase 2, we will consult twice with a group of policy stakeholders about our emerging findings and methods. We include letters of support from organisations indicating that they are already willing to participate in these groups. One meeting in the middle of the project will review emergent finding from the process evaluation and critically appraise drafts of the follow-up questionnaires. The meeting near the end will focus on interpretation and dissemination of our results, and the value of proceeding to a phase III RCT of the intervention.

RESEARCH PLAN/METHODS

Project objectives and timetable

1. To undertake PPIE with various stakeholders, evidence review and a survey of schools in south-east England to inform adaptation of Learning Together for primary schools (Dec 2023-Sep 2024).
2. To recruit six schools for the pilot RCT, conduct baseline student and teacher surveys, and randomise schools (May-July 2024).
3. To implement the intervention to all students in the four intervention schools (Sep 2024-Jul 2025).
4. To conduct process evaluation (Sep 2024-Jul 2025).
5. To conduct follow-up student and teacher surveys (repeat cross-sectional design) 12 months post-baseline (May-July 2025).
6. To analyse data (Aug-Sep 2025).
7. To disseminate findings and assess progression to phase III RCT (from Oct 2025).

Timing of the pilot trial allows a start-up phase between allocation and delivery so schools can organise staffing and activities, as suggested by previous trials.[43 44]

Phase 1: Adaptation

Adaptation of the Learning Together intervention for primary schools will occur from December 2023 to September 2024. This will be underpinned by PPIE with various stakeholders, a review of systematic reviews of whole-school and restorative practice interventions in primary schools and an online survey of schools in SE England.

Phase 1 will involve PPIE-based adaptation involving staff and students from 2 primary schools. These schools will have high free school meal entitlement (indicating high need) and good/outstanding Ofsted ratings (indicating high capacity to collaborate). Adaptation will involve 3 sessions at each school reviewing existing Learning Together materials (December 2023) and successive drafts of adapted materials (March and April 2024). Each session will involve a workshop with 10 year-5/6 students (diverse by gender, ethnicity and school engagement) and a workshop with 5 staff (diverse by role/seniority). Adaptation will also involve: two meetings with another group of 10 children recruited from other primary schools; and one meeting with a group of parents. Children will be recruited in pairs from 5 different schools. One teacher not working at a school involved in the pilot RCT will be invited to sit on the study steering committee. Phase 1 will also involve us consulting with the above teachers and students to inform how we conduct teacher and student surveys.

The review of systematic reviews will address the following questions: (1) are there additional intervention components (including social and emotional skills curricula) that are elements of effective primary school bullying prevention interventions, which are consistent with the theory of change for the Learning Together Primary Schools intervention and which could be feasibly and usefully incorporated into the intervention?; (2) are there factors influencing the feasibility, acceptability, reach or effectiveness of primary school bullying prevention interventions that should be considered in adapting Learning Together for primary schools; (3) are there feasible, acceptable and reliable methods of surveying primary school teachers and students reported in evaluations of primary school bullying prevention interventions that could usefully inform the choice of methods for the pilot trial?; (4) do evaluations of primary school bullying prevention interventions use parental opt-out or opt-in consent?; and (5) do evaluations of primary school bullying prevention interventions suggest any amendments to the proposed methods for the pilot RCT?

The online survey of primary schools in SE England will address the following questions: (1) are the intervention components and methods we propose to include in Learning Together

Primary schools feasible and acceptable to implement in English primary schools?; (2) do English primary schools already deliver any of these components and if so with what training, facilitation or other support?; (3) do English primary schools deliver social and emotional skills curricula and, if so, which ones, comprising how many lessons and targeting which students?; (4) how much would English primary schools be prepared to pay for an effective bullying prevention intervention?; (5) are the evaluation methods proposed for the pilot RCT feasible and acceptable to conduct; and (6) would schools potentially be interested in participating in a pilot or phase III trial of this intervention?

The study will then progress to phase 2 dependant on the following criteria being met: (to be judged by the study steering committee): (1) have feasible and acceptable methods for surveying students and teachers in the pilot RCT been identified?; (2) has a decision been made as to whether parental opt-in or opt-out consent is appropriate for the pilot RCT?; (3) have fidelity and acceptability metrics been developed which will inform the evaluation methods and progression criteria for the pilot RCT?; (4) have all other evaluation methods for the pilot RCT been finalised?; (5) has a decision been made as to whether or not the intervention to be piloted should include a social and emotional skills curriculum?; (6) has the intervention to be piloted been adapted for primary schools?; (7) have all intervention materials and processes been elaborated?; (8) have PPIE members been recruited to sit on the study steering committee for the pilot RCT?; and (9) have all of the above questions been appropriately informed by the evidence review, schools survey and PPIE?

Phase 2: External pilot cluster RCT

Design overview

The external pilot cluster RCT will occur in six primary schools (four intervention, two control). Recruitment, baseline surveys of students and teachers, and randomisation will occur in April-July 2024. Schools will be randomly allocated 2:1 to intervention/control (1:1 in phase III RCT) stratified by free school meals (plus Ofsted rating in phase III RCT) in June/July 2024.[3 4] A 2:1 allocation will allow us to pilot randomisation while ensuring diversity across four schools for intervention piloting. The intervention will be implemented in the four intervention schools from September 2024 to July 2025. The pilot RCT will include an integral process evaluation and economic evaluation feasibility study (figure 2) occurring during this time. Follow-up surveys will occur in June/July 2025. The primary outcome for the pilot RCT will be assessing criteria for progression to a phase III RCT. Primary and secondary outcome measures for a phase III RCT will be assessed for completion and reliability but effects on these outcomes will not be assessed. These outcomes are described in detail below but consist of twin primary outcome measures assessing student-reported bullying victimisation and perpetration in the past two months, plus secondary outcomes consisting of: adult-reported social and emotional problems; student-reported cyber-bullying victimisation; student-reported wellbeing at school; routine data on student attendance/attainment; teacher-reported student behaviour; teacher-reported self-efficacy; and teacher-reported burnout.

Any future phase III RCT would involve a repeat cross-sectional RCT design drawing on data from students in years 3-6 (age 7-11) at baseline and follow-up. This design is chosen rather than a longitudinal cohort-based RCT for three reasons. First, the design allows for 36-month follow-up (which is the time period over which impacts are likely to be generated according to the trial of Learning Together[36]) without the need to track older students into secondary school (which would result in significant attrition). Second, literature suggests that, in school cluster RCTs with significant in/out migration, the baseline cohort will not remain representative and this is a greater issue in primary than secondary schools.[45-47] Third, statistically this design offers comparable power in analysis of binary outcomes. A final decision on phase III design will be made in light of the pilot.

Settings/context
Learning Together Primary Schools is intended to be deliverable in all English primary schools (including faith schools, free schools, academies and private schools) excluding pupil referral units, schools for those with special educational needs and disabilities, and schools with 'inadequate' Ofsted inspections (which previous studies indicate lack the capacity to deliver until they gain an improved inspection report[43 48]). We will recruit primary schools in south-east England which include years 3-6. This geographical spread is appropriate for the pilot RCT to reduce travel time and costs. Schools will vary by free school meals (measure of poverty), Ofsted rating (measure of school capacity) and school type so we can assess feasibility across factors likely to affect this.[49] Any future phase III RCT would be national in scope and would also include a representative variety of school types.

Study population
The study population is defined as students in years 3-6 (aged 7-11 years) as well as their teachers at baseline and follow-up during the trial. All student-reported measures are suitable for students in the age range being examined here (see outcome measures below). No students deemed competent to complete data collection will be excluded from research recruitment unless they do not assent to the research or parents withdraw them from the research. Those who have mild learning disabilities or limited English will be supported to complete the questionnaire by researchers.

Analytic sample and sample size
The pilot focuses on feasibility and no power calculation is performed. Instead, the pilot RCT aims to include sufficient diversity of schools in terms of free school meals and Ofsted rating to allow piloting of the feasibility and acceptability of the intervention in a diverse range of contexts.

For the phase III RCT, to detect an effect of RR=0.8 on bullying victimisation at 80% power and 5% significance will require 30 schools per arm assuming 160 students per school, drop-out of one school per arm, 25% bullying victimisation in control schools and an intra-cluster correlation coefficient (ICC) of 0.02 for victimisation. Our effect size is a relatively conservative one, slightly larger than that detected in the Learning Together trial but smaller than the effect sizes reported in recent systematic reviews of school-based bullying prevention on bullying perpetration (OR=1.31: 95% confidence interval (CI) 1.24, 1.38) and victimization (OR=1.24: 95% CI 1.19, 1.31)[25] across school settings. Our estimated effect size is certainly of policy significance.[25] The effect size takes into account recent evidence that bullying prevention is more effective when delivered to younger students,[24] which is plausible given that early intervention in primary schools, as bullying behaviours manifest, would be expected to be more effective than prevention in secondary schools. Student numbers per school, prevalence and ICC are now informed by recent UK research and in line with broader estimates.[25 34 50] Our pilot will provide a check on our assumptions about prevalence of the outcome and ICC while acknowledging small sample limitations. Our pilot will not assess preliminary intervention effects since it is not powered to do so.

Recruitment and randomisation
We will recruit primary schools in south-east England inclusive of years 3-6. Schools will vary by free school meals (measure of poverty), Ofsted rating (measure of school capacity) and school type so we can assess feasibility across factors likely to affect this.[49]As with our previous trials, schools will be recruited by a combination of emails and phone calls to schools, local authorities, school networks and academy chains. Response rates will be recorded, as will any stated reasons for non-participation.

As explained above, after baselines, schools will be randomly allocated 2:1 to intervention/control (1:1 in phase III RCT) by LSHTM clinical trials unit (CTU), stratified by free school meals (plus Ofsted rating in phase III RCT).[3 4] A 2:1 allocation in the pilot RCT

will enable us to pilot randomisation while ensuring sufficient diversity of schools in the intervention arm for intervention piloting. Piloting randomisation is necessary given the paucity of UK RCTs of primary school bullying prevention. Schools will be given unique study numbers to preserve allocation concealment within the CTU. The CTU will inform the fieldwork team of allocations who will then inform schools. Informed by the Positive Choices and 'If I Were Jack' RCTs,[48 51] we will incentivise recruitment and retention by offering a £500 payment to all schools with an additional £1,000 for those allocated to the intervention group, reflecting the greater research load on such schools. Previous studies suggest that payment is now absolutely essential for maintaining school participation in research[48 51] particularly in the current context of current stretched school budgets and institution strain. Each school will be allocated a named research liaison contact to facilitate retention.

Intervention and comparator

The **Learning Together Primary Schools** intervention is described below using the TIDieR framework[52] and in figure 1.

Theory of change: Learning Together is a whole-school restorative practice intervention the theory of change of which is informed by the theory of human functioning and school organisation.[53] Restorative practice aims to prevent/resolve face-to-face and online conflicts between students or conflicts between staff and students to prevent further harms and improve student/student and student/staff relationships.[20] Learning Together aims to reduce bullying and social and emotional problems via two mechanisms: a) using restorative practice to improve relationships and prevent/de-escalate conflict; and b) using an action group to involve students in school decisions and build school belonging. Existing studies suggest mechanism a) will be key in schools with lower capacity while b) will be key in schools with higher capacity.[38 39]

Materials: Schools will receive an anonymised report on overall student needs (drawing on baseline survey), an intervention manual and a workbook to help teachers run restorative practice sessions. In the previous RCT, the curriculum was poorly implemented and did not contribute to effectiveness. Initial PPIE to inform this proposal suggests that primary schools already deliver classroom social and emotional learning. Not including this component would also enable the study to better establish the specific effectiveness of restorative practice. However, including this component may increase the potential effectiveness of the overall intervention.[54] Consultation will inform a final decision on whether the intervention in a phase III RCT should include a curriculum component in phase 1. If it is determined in the adaptation phase that the intervention should involve a curriculum, schools will be provided with lesson plans and slides.

Training/facilitation: All school staff will receive a two-hour introductory training in restorative practice. Selected 4-5 staff per school will receive three-day in-depth training provided by L30 Relational Systems (training partner in previous Learning Together RCT). The Place2Be charity will facilitate action groups. If it is determined in the adaptation phase that the intervention should involve a curriculum, schools will be provided with additional training for this.

Procedures, delivery & dose: All staff will undertake restorative practice in their tutor groups and classrooms to prevent conflict and respond to minor incidents coming to their attention. Selected staff will facilitate restorative practice conferences in response to more serious incidents which they identify. The action group will meet termly and: review needs data to decide local priorities; identify staff to be trained; revise rules/policies to support restorative practice; and plan communications to students/parents. The action group will include approx. six staff (diverse by seniority/role) and eight students from years 3-6 (also diverse by gender, ethnicity, school engagement). If it is determined in the adaptation phase that the intervention should involve a curriculum, schools will deliver this in lesson time.

Planned adaptations: Guided by the manual and needs data, schools will identify local priorities re. the forms of bullying to be addressed and the student groups most affected.

Cost: £1500 per school met from sources other than schools for the pilot.

The intervention described above complements existing activities.

The **comparator** will be treatment as usual with schools continuing with existing activities to prevent bullying and student social and emotional problems. Process evaluation will describe this. Initial PPIE suggests that some schools already use restorative practice but few use a whole-school approach or are guided by training/materials.

Outcome measures

Pilot outcomes
For this pilot trial, the primary outcome is assessment of criteria for progression to phase III RCT according to the following criteria:

Criterion number	**Red/amber/green criteria**		
1.	***Red****	***Amber****	***Green****
	Recruitment and randomisation do not occur within the allocated timescales	Recruitment and randomisation occur within the allocated timescales	Recruitment and randomisation occur within the allocated timescales
2.	<4 schools are retained in study	4 schools are retained in study	≥5 schools are retained in study
3.	Intervention is implemented with <70% fidelity in ≥2 schools retained in intervention arm	Intervention is implemented with <70% fidelity in 1 school retained in the intervention arm	Intervention is implemented with ≥70% fidelity in all schools retained in the intervention arm
4.	Intervention is acceptable to <70% of teachers and students responding to the survey in ≥2 schools retained in intervention arm	Intervention is acceptable to <70% of teachers and/or students responding to the survey in 1 school retained in the intervention arm	Intervention is acceptable to ≥70% of teachers and students responding to the survey in all schools retained in the intervention arm
5.	Student response rates and completion of outcome measures are	Student response rates and completion of outcome measures are	Student response rates and completion of outcome measures are

	<80% in ≥3 schools retained in the study	<80% in 1-2 schools retained in the study	≥80% in all schools retained in the study
6.	Staff response rates and completion of outcome measures are <70% in ≥3 schools retained in the study	Staff response rates and completion of outcome measures are <70% in 1-2 schools retained in the study	Staff response rates and completion of outcome measures are ≥70% in all schools retained in the study
7.	There is evidence of substantial contamination between arms	There is evidence of some contamination between arms	There is no evidence of any contamination between arms

* Any red criteria indicate that the study will not progress to a phase III trial.
** Any amber criteria indicate that the study might be able to progress to a funding proposal for a phase III trial if mitigating factors are identified and implemented.
*** Indicating the study should be recommended to progress to a funding proposal for a phase III trial.

The precise metrics that will be used to assess implementation fidelity and acceptability will be defined in phase one when the intervention is finalised. These will be shared with the study steering committee and with NIHR for approval. The NIHR will make judgements about how the study has met the above criteria informed by assessments made by the study steering committee.

Trial outcomes to be piloted

The twin primary outcome measures for a future phase III RCT to be assessed for completion in the pilot are binary measures of student-reported bullying victimisation and perpetration in the past 2 months (Revised Olweus Bully/Victim Questionnaire), which have previously been used in existing trials including students age 6-11[25 34] with strong reliability/validity.[55]

Secondary student-level outcomes will be:

- teacher-reported social and emotional problems for each student (Strengths and Difficulties Questionnaire total difficulties score[56]);
- student reported cyber-bullying victimisation (DAPHNE measure)[57];
- student-reported wellbeing at school (Adapted How I Feel About My School questionnaire[58]); and
- student attendance/attainment (routine data).

All student-reported measures are suitable for students in the age range being examined here. They will be collected via paper surveys in schools (see below). The pilot RCT will assess the feasibility of collecting teacher-reported data on each student's social and emotional problems by surveying children's classroom teachers using the teacher-completed SDQ.

Secondary teacher-level outcomes will be:

- perceived behaviour of students in their class (Pupil Behaviour Questionnaire[59]);
- self-efficacy (Teacher Sense of Efficacy scale[60]); and
- burnout (Maslach Burnout Inventory).[61]

Economic analysis will include the above outcomes (cost-consequence analyses) and the Child Health Utility (CHU) 9D measure (cost-utility analysis) which was developed using children's input and is validated for use in this age range.[62]

Assessment and follow up

Baseline surveys will be done before randomisation with students in years 3-6 (age 7-11) and their class teachers in May-July 2024 and will collect data on socio-demographic characteristics, baseline values of outcomes and other covariates, drawing on existing survey items. Consent procedures are described under ethics below.

For students, paper questionnaires will be completed confidentially by students supervised by trained fieldworkers. In the adaptation phase, we will consult with teachers to determine the most appropriate means of surveying students of different ages: either in whole classes, smaller groups or individually. Whichever method is chosen, fieldworkers will read out questions and responses options to students with students then completing their answers. Students will be asked to skip questions they do not understand or do not wish to answer. Students will be advised to contact their school safeguarding lead or other trust staff-member for support should they feel confused or upset as a result of completing the questionnaire, with the team briefing safeguarding leads about this and liaising with them to record where this has occurred. Previous experience indicates that paper questionnaires are acceptable and logistically more straightforward than tablet surveys. We will survey absent students by leaving questionnaires and stamped addressed envelopes with schools, and liaising with schools to maximise returns.

For teacher surveys, we will consult with schools in the adaptation phase to identify the most feasible means of achieving a high response rate. We will then pilot this approach in the pilot RCT phase. We anticipate that the most feasible method for teachers will be to conduct paper-based surveys face to face in specific sessions in school staff rooms.

We will conduct follow-up surveys of students and their teachers at 12 months (May-July 2025). This period is sufficient to assess the feasibility of follow-up in the next academic year after baselines but is not intended to assess impacts of the intervention in this pilot RCT. In a phase III RCT, we would undertake follow-up surveys with students in years 3-6 and teachers at 36 months post-baseline, the likely time required to generate outcomes according to the original Learning Together trial and other research on whole-school interventions.[36 63] Survey fieldworkers but not students or teachers will be blind to allocation.

Process evaluation data collection

In addition to assessing progression criteria and informed by existing frameworks,[64-67] we will examine: levels of intervention fidelity, reach and acceptability and how these vary between schools and students; what is usual treatment in control schools and potential contamination between arms; and implementation processes and intervention mechanisms and how these vary between schools/students.

Intervention fidelity, reach, acceptability and context

Fidelity of implementation of all intervention components by schools as well as preparatory training will be assessed quantitatively using bespoke measures developed in phase 1 and informed by measures used in the original Learning Together trial.[36] Data will be collected via: audio-recording of all training for school staff; surveys of all school staff undergoing training; logbooks of all school staff implementing action groups and restorative practice

(plus the curriculum if this is delivered as part of the pilot); and structured researcher observations of one randomly selected action group (and curriculum lesson if delivered) meeting per school. Observations will act as a check on the reliability of data from log-books. Restorative practice sessions will not be observed for logistic (they will generally occur at short notice) and sensitivity reasons. We will primarily assess fidelity of form (i.e. of the activities as planned) but, where local adaptations are made, we will assess whether these are consistent or not with the intervention theory of change in order to provide a qualitative assessment of fidelity of function (i.e. alignment of implementation with the theory of change).[68] We will examine reach and acceptability to staff, students (overall and by student gender, ethnicity and free school meal entitlement), and by school-level Ofsted rating and free school meals entitlement. Reach and acceptability will be assessed quantitatively via questionnaire survey items at follow-up.

Comparator and potential contamination

We will undertake a structured interview with one staff-member (informed by questions from the School Health Research Network Questionnaire[69]) per control school and draw on student and staff surveys to assess treatment as usual in terms of behaviour management, bullying prevention and mental health provision. The individual sampled will be a member of the senior leadership team with an overview of these areas of provision. We will examine the potential for contamination across arms to assess whether this is a threat to internal validity. We will collect qualitative data to explore implementation and mechanisms, and how these vary between schools and students.

Implementation processes/intervention mechanisms and context

Informed by May's implementation theory and realist evaluation,[65 67] we will collect qualitative data and analyse these in order to explore implementation processes and intervention mechanisms, and how these vary between schools and students. Informed by 'dark logic' methods, we will explore whether any hypothesised mechanisms of harm appear plausible.[70] Data will be collected from intervention schools via: interview with one staff-member and one parent per school, and focus groups with 4-8 staff (purposive by seniority and role) and 4-8 students per school (purposive by involvement in intervention activities, ethnicity and gender) per school. We will also interview staff from Place2Be and L30 Relational Systems. It will not be feasible in schools to purposively sample by student socio-economic status but we will strive to be inclusive of a diverse range of students. Purposive sampling will be used to explore a range of perspectives and experiences according to factors likely to be associated with differences in these.

Economic evaluation data collection

The pilot RCT will examine whether it is feasible to assess cost effectiveness using cost-consequence and cost-utility analyses within a phase III trial.[62] The use of CHU-9D is described above. We will assess the feasibility of estimating costs within the trial period arising from primary and secondary outcomes. Within the pilot, study methods to measure the incremental cost of the intervention in a phase-III trial study will be developed and piloted. With use of a broad public and third-sector perspective, resources to be measured will include: resources used by trainers, Place2Be and schools. Within this, key interventional resources will include Place2Be, L30 Relational Systems and school staff time, training events, meetings and consumables. Measures will include: standardised sessional checklists to monitor and document attendance, preparation and delivery time for key training events, action group meetings and restorative practice meetings (as well as the curriculum if this is part of the intervention); and the completion of surveys and log-books by school staff charged with intervention delivery, assessing time spent on tasks relating to intervention, staff travel and other expenses relating to the intervention charged to a specific project grant code.

Data management

Anonymised linked student and teacher survey data will be managed by LSHTM's accredited CTU with linkage to unique identifier codes (not names) in password-protected files on drives accessible only by named CTU staff. The (institutionally separate) fieldwork team will manage a separate data-file linking names to unique identifiers, in similarly protected files and drives, and will not have access to self-report survey data. This will maintain separation of identifiers and self-report data. Audio-recordings made during the qualitative research will use secure password-protected recorders. These will be transcribed in full by LSHTM-approved contractors with secure data transfer and management processes. Transcripts will be anonymised and stored in secure files and drives by the fieldwork team. All reporting will be fully anonymised to prevent explicit or implicit identification. In line with MRC guidance on personal information in medical research, we will retain all anonymised research data for 20 years after the end of the study. This is to allow secondary analyses and further research to take place, and to allow any queries or concerns about the conduct of the study to be addressed.

Data analysis

Adaptation phase

Most activities in the adaptation phase will be PPIE rather than research. Such activities will be summarised but not subject to research analysis. The review of reviews will present a narrative summary of evidence pertinent to adapting the Learning Together intervention to primary schools, including any evidence of potential harms and how these might be mitigated. Research data from the survey of schools in south-east England will be analysed to descriptively summarise need for, and feasibility and acceptability of the intervention and its components, including whether a curriculum component should be included.

We will report to the study steering committee and NIHR on whether we recommend that the study should progress to phase 2 based on whether the intervention has been finalised to the satisfaction of the two participating schools, and whether the fidelity and acceptability metrics for the pilot phase have been defined (RQ1). The adaptation phase will also make recommendations as to how best to survey teachers.

Pilot RCT

Our main analyses will determine whether criteria for progression to a phase III trial are met (RQ2). School randomisation and retention, and survey response rates will be described using a CONSORT diagram.[71] Descriptive statistics on fidelity will draw on audio-recordings of training, log-books of providers and structured observations of action groups (and curriculum lessons if included). Statistics on acceptability will draw on surveys of students and staff. Qualitative data will be analysed to describe relevant activities in and around intervention and control schools; and assess evidence of contamination.

Other analyses will address our other research questions. We will assess the reliability of scaled outcome measures by reporting Cronbach's alpha statistics (RQ3). Descriptive summaries of baseline and follow-up data by arm will be tabulated, reporting completion rates by measure (RQ3-5). We will determine which methods are most feasible to survey teachers (RQ4).

Qualitative data will be subject to thematic content analysis (in vivo/axial codes; constant comparison[72]) informed by May's implementation theory,[65] realist approaches to evaluation[67] and dark logic methods[70] to examine: how contextual factors including school type influence implementation and mechanisms, and refine our theory of change (RQ6); and examine potential mechanisms of action and of harm (RQ7). Qualitative research will describe treatment as usual in control schools (RQ8). Our economic feasibility study will pilot collection of CHU-9D and cost data, and assess the feasibility of methods to be used within a full trial to conduct cost-consequence and cost-utility analyses (RQ9).

A future phase III RCT would undertake intention-to-treat analyses to assess intervention effects on our primary and secondary outcome measures. Additional, secondary analyses would examine on-treatment effects according to school-level fidelity, as well as examine moderation of intervention effects by school-level (free school meals rates, Ofsted rating), student-level (gender, ethnicity, socio-economic disadvantage and school engagement) and teacher-level (gender, role) characteristics. Alongside insights from the process evaluation of how context influenced implementation and receipt, such analyses would provide empirical evidence about the potential transferability of the intervention to different schools and its relevance to addressing different student needs.

Ethical issues, safeguarding and serious adverse events

Ethical approval for the study will be obtained from the London School of Hygiene & Tropical Medicine (LSHTM) Research Ethics Committee. Any member of the research/fieldwork team working with students without supervision by school staff will be required to have a full disclosure and barring services check. All work will be carried out in accordance with the research ethics framework laid down by the Economic and Social Research Council and the General Data Protection Regulation 2016. Data processing will operate on the basis of the public task legal basis.[73]

Head teachers as gatekeepers will be asked for informed consent for random allocation and intervention. We will liaise with LSHTM ethics committee during the adaptation phase to determine if it will approve an approach to students' participation in research activities consisting of students' informed active (opt-in) written assent and parents' passive consent (whereby parents would be sent written information about the research and have the right to opt out their children if they wish). Parental opt-in consent is not a legal requirement for non-medical research with children of primary school age.[74] We are aware of a number of trials of public health interventions conducted in primary schools which have used opt-out parental consent.[34 75 76] Informed by our review of the law and guidance on research ethics and school-based studies, we anticipate that this is a viable option for our study. However, if we are instructed by our ethics committee that parental opt-in consent is required, we will examine in the adaptation phase the most appropriate means to maximise parental responses to this, for example via using multiple communication routes including parental meetings, attending parents' evening and electronic communications.

In all cases of data collection, adult participants and the parents of students will be given via an information sheet one week before data collection and will be able to opt themselves/their children out of this should they wish. Just before data collection, adult participants who have not previously opted or been opted out will receive a plain English, written description of the study. Student participants will receive an oral description of the study and process, and chance to ask questions of trained fieldworkers just before data collection. This process of providing oral information to students and obtaining verbal assent from students will be witnessed by a member of school staff or another independent observer. Participants will be advised that participation is voluntary and they may withdraw at any point or not answer questions which they do not wish to. All participants will be advised that they are free to withhold consent and this will not be communicated to others within the school or family. Participants will then be asked for their written consent (or, in the case of students, assent) to participate. Students opting not to participate in research activities will continue with normal school activities.

All participants will be informed in consent materials that the information they provide will be treated with anonymity and confidentiality, as well as the circumstances in which we would need to breach confidentiality. With Place2Be, we will develop standard operating procedures for dealing with safeguarding concerns. We will define age-appropriate defined

categories of abuse reported through the research that would necessitate our breaching confidentiality to ensure individuals are offered care and protection, informed by existing clinical guidelines. We will ensure balance between our ethical duty of promoting participant autonomy and wellbeing. Where defined categories of abuse are indicated in questionnaires, we will contact the safeguarding lead in the school. Where these are reported directly to research staff during data collection, we will discuss with the student that there is a need for a response prior to contacting the school safeguarding lead. In each school, a senior member of staff will be identified who is not directly involved with the intervention and to whom staff or students may go if they have complaints about any elements of the intervention or research.

Interviews, focus groups and observations will not aim to explore personal experiences of bullying or mental health problems. In the case of focus groups, our researchers will be trained to ensure that discussions do not move in the direction of personal disclosures since this is not the purpose of the groups and it would be very difficult to ensure that other participants do not communicate such disclosures outside the group. However, if participants in interviews or focus groups describe any abuse, bullying or mental health problems they have experienced, or become upset in any way, our researchers will be trained in how to respond. In interviews, researchers will stop the interview and determine the need for a referral to support within the school. In focus groups, researchers will aim to stop sensitive discussions, and assess the need for individual support at the end or stop the focus group if the assessment is that immediate support is needed.

We will monitor safeguarding concerns and standard categories of serious adverse events via regular consultation with schools. The study steering committee and LSHTM ethics committee will be provided with anonymised reports of safeguarding concerns and serious adverse events, categorised by type, circumstances and the plausibility that these are related to intervention or research activities. Because all follow-ups occur at 12 months, there will be no interim analyses. The study steering committee will consider stopping the pilot RCT if there is any suggestion of an association between the number of safeguarding concerns and serious adverse events plausibly associated with the intervention or trial.

SOCIOECONOMIC POSITION AND INEQUALITIES

Learning Together Primary Schools is a universal intervention which aims to disproportionately benefit disadvantaged and minority students by addressing structural influences on bullying and social and emotional problems, which are likely to be particularly implicated in adverse outcomes among disadvantaged and minority students. These include the experience of school systems and sense of belonging in school.[77] The intervention aims to ensure such students are active participants in intervention planning, and reached by intervention activities such as action groups and restorative practice.

PPIE and research methods will be inclusive for disadvantaged and minority students, for example by using fieldworkers from diverse backgrounds, using plain written English materials and supporting all students who need help in surveys and other data collection. Schools recruited to the adaptation phase will all have high rates of free school meal entitlement (measure of poverty). Schools recruited to the pilot RCT will vary by free school meals and Ofsted rating. The pilot RCT will focus recruitment on south-east England but within this include areas of high and low deprivation. A phase III RCT would be national in focus and aim to be representative in terms of school free school meal entitlement.

In the pilot RCT, we will assess how intervention reach and acceptability vary by student gender, ethnicity, socio-economic disadvantage and school engagement, and by school-level measures of free school meal entitlement. Student recruitment to qualitative research will be purposive by gender and ethnicity. It will not be feasible in schools to purposively

sample students by socio-economic position but we will strive to be inclusive of a diverse range of students. In a phase III RCT, we would examine moderation of intervention effects by student gender, free school meal entitlement (as a marker of socio-economic disadvantage), ethnicity and school engagement to assess impacts on health inequalities.

DISSEMINATION, OUTPUTS AND ANTICIPATED IMPACT

Knowledge exchange will target public health and education policy-makers, school staff and students, and the public. The purpose of dissemination at this stage is to raise awareness of the intervention approach and share findings about its feasibility, rather than to support immediate scale-up. Knowledge exchange is built into the proposed work from the outset via the policy stakeholder group. As well as reporting in the NIHR Public Health Research journal, we will submit at least two open-access papers, and present at the Science Media Centre and two conferences (European Society for Prevention Research; Lancet UK Public Health Science). We will develop plain English research summaries for participating schools, the children's and policy stakeholder groups, and various national and regional school health research networks. We will offer webinars to support this communication. This engagement aims to recognise the contribution of organisations and individuals that we have involved in the pilot RCT, continue the collaboration via two-way communication, and ensure these groups are willing to continue the collaboration into a future phase III RCT. We will draft an article for the Times Education Supplement about the research. We will use social media to increase public awareness. We will present emerging findings at two meetings with policy-makers (including health and social care and education department officials, and public health agencies in the UK nations) and via the Mental Elf website. This is intended to maintain policy interest in the intervention so that policy stakeholders would be supportive of a phase III RCT should this pilot RCT suggests its feasibility. Some of this dissemination activity will continue beyond the pilot RCT period, supported by the work of institutionally funded staff.

Learning Together Primary Schools will be developed as a potentially scalable programme for schools. The most important scientific outputs generated by this project will be increased knowledge about the feasibility and acceptability of delivering and trialling this intervention. This will inform the development of a subsequent proposal to NIHR for a phase III effectiveness trial. Within this effectiveness trial, schools would fund the intervention as they will in the pilot RCT. We will assess in this pilot RCT whether this funding model is likely to remain feasible in the near future. If the phase III trial found the intervention to be effective, this would be scaled up, marketing the intervention to schools, local authorities and school networks. Accreditation for the intervention would then be sought from Blueprints for Positive Youth Development and Early Intervention Foundation to promote scale-up, as it has done with the original Learning Together intervention. As described above, the phase III trial would conduct several analyses of implementation, moderation aiming to inform and contribute to the scalability and transferability of the intervention. Intellectual property newly generated by the study will be held by LSHTM which will grant a license for collaborating institutions and organisations to use this appropriately. Existing third-party intellectual property (restorative practice training materials, survey measures) will be used with permission in this study.

PROJECT MANAGEMENT

Governance

The principal investigator (PI) will have overall responsibility for the conduct of the study. The day-to-day management of the study will be coordinated by the trial manager. A study executive group will meet monthly attended by the PI, trial manager, lead statistician and, where appropriate, other staff. Statisticians will not participate in discussions that would

unblind them to allocation. A trial investigators' group will meet quarterly attended by all investigators.

An independent SSC and DMEC will be established to oversee the study. These will meet three times during the study period. Dr Nick Axford, who has led a previous study of bullying prevention in primary schools,[34] will be invited to chair the study steering committee. The study steering committee and data monitoring and ethics committee will also involve other independent researchers including statisticians and PPIE representatives.

The study will use standard operating procedures for consent and fieldwork procedures, safeguarding, serious adverse events and data management, agreed with the study steering committee. The study protocol will be registered at www.clinicaltrials.gov and published in Trials. The trial sponsor will be the Research Governance and Integrity Office at LSHTM.

Success criteria and barriers to proposed work

Research success will be defined in terms of achieving the deliverables specified in the research objectives listed above, and the study achieving the progression criteria for progression from adaptation to pilot RCT and from pilot to phase III RCT as described above.

The key risks to the proposed research and how these will be mitigated are described below.

Risk	**Mitigation**
It is not possible to recruit PPIE partners for the study.	There will be a specific PPIE lead who will ensure recruitment is an early focus for action. PPIE collaborators will be recruited via multiple mechanisms including existing school networks as well as emails and social media. Where PPIE occurs in their non-work time, collaborators will receive compensation for their time.
It is not possible to recruit schools for the pilot RCT.	Multiple recruitment methods will be used as specified under recruitment above. Schools will be offered proper funding to offset the costs and burden associated with the study. Each school will have a dedicated researcher who will be their sole point of liaison with the research team. Research burden will be minimised through efficient working methods developed by the team through their previous studies.
Parental lack of responses undermines the response rate for the student surveys.	We will consult with our ethics committee in phase 1 to establish that parental opt-out consent is appropriate to this study given the legal framework, previous studies using this approach and the low risk to participants of taking part. Responses to the parent survey will be maximised via using multiple communication channels as advised by schools.
Teacher survey responses are low.	We will consult with schools in the adaptation phase to identify the most promising means of achieving a high response rate to teacher surveys. We will then pilot this approach in the pilot RCT phase. We anticipate that it may well be feasible to conduct paper-based surveys of staff face to face in primary schools, and that this represents the best way to achieve a high response rate.
Outcome measures are poorly understood and completed by students.	We have chosen measures which were developed and validated for the age range being surveyed. We will use paper questionnaires as these are most accessible to this age-group. Fieldworkers will read out questions and response options then

	giving students time to answer each question. We will assess the feasibility of these methods via PPIE in phase 1.
Intervention fidelity is poor.	The intervention is supported by a specialist charity with a track record of intervention delivery in schools. The intervention is based on adapting the existing Learning Together intervention for which fidelity of delivery in secondary schools was adequate. Fidelity is likely to be even better in secondary schools because of their greater flexibility in scheduling activities.[49]
Even if found to be effective in a phase III RCT, the intervention is not scaled up.	The intervention is designed from the outset with scalability in mind. The intervention is supported by a specialist charity with the capacity to scale up the intervention within a sustainable model of reasonable school charges.

PROJECT / RESEARCH EXPERTISE

Professor Chris Bonell will oversee all aspects of the research. He is an NIHR Senior Investigator, has led on multiple NIHR-funded evaluations of school-based interventions including being co-PI of the original Learning Together trial, and is expert in school-based health promotion, child health and evaluation methods. He will supervise the research fellow and research assistant working on the study via weekly one-to-one and team meetings. He will liaise with Place2Be and L30 Relational Systems which lead on intervention support via monthly meetings.

Miranda Perry will lead PPE. She is an ex-teacher and mother of two children with previous experience implementing Learning Together, and leading workshops and coaching teachers and children.

Professor Elizabeth Allen will oversee the LSHTM clinical trials unit work on the study including data management, random allocation and statistical analyses planning and reporting. She is an expert on pilot RCTs, evaluations of school-based interventions and cluster RCT.

Professor G.J. Melendez-Torres will advise on quantitative analyses and oversee qualitative analyses. He is an expert on advanced statistical and qualitative analysis methods, school-based interventions and evaluation methods.

Dr Rosa Legood will conduct the economic evaluation feasibility study. She is an expert on the economic evaluation of school-based health interventions and led the economic work within the original Learning Together trial.

Joanna Sturgess will lead on data management and implement the statistical analyses under the supervision of Professor Allen. She is a highly experienced data manager and statistician who has worked on multiple school-based trials.

Hannah Wilkinson will lead Place2Be's contribution to the study, liaising with Place2Be's staff providing training and support to schools. She is an expert in children's mental health and evaluation methods.

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