PROTOCOL

Optimisation and pilot RCT of the 'Belonging' brief intervention to build school belonging, promote mental health and prevent violence in secondary schools

Short title: The Belonging pilot trial of a brief intervention to promote mental health and prevent violence.

This protocol has regard for the HRA guidance

Protocol version: 1.0 (17/01/25)

Trial registration: **ISRCTN**

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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 January-March 2025 and students will be recruited May-July 2025.

Version control

Version	Date	Note of changes
1.0	16.10.23	N.A.

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Abbreviations

CHU9D - Child Health Utility 9D measure

CI – confidence interval

EEF – Education Endowment Foundation

ICC - Intra-cluster correlation coefficient

LSHTM - London School of Hygiene and Tropical Medicine

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

RSHE – relationships, sex and health education

SDQ – strengths and difficulties questionnaire

SEND – special educational needs and disabilities

TIDieR - template for intervention description and replication

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):

.....

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

Chief Investigator:

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

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Study steering committee chair		

Funding

Funder	**Support**
NIHR Public Health Research Programme	£445,038

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.

Optimisation and pilot RCT of the 'Belonging' brief intervention to build school belonging, promote mental health and prevent violence in secondary schools

BACKGROUND & RATIONALE

This section is informed by evidence identified through 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 databases and websites using terms for whole-school interventions, children/young people and evaluation.(1)

What are the problems being addressed?

Regarding our primary outcomes, mental ill health and violence are inter-related problems often arising from young people feeling low sense of school belonging.(2-4) Mental ill health is the largest cause of disability in the UK (5) with around half of disorders starting by age 14(6) and 17.4% of 6-16 year-olds having a mental health disorder.(7) Mental health in young people worsened and inequalities widened during the pandemic.(8, 9) Regarding our secondary outcomes, 17% of young people age 11-15 report being in a fight 2+ times in the previous year with boys more likely to report this than girls.(10) Youth violence predicts violent crime in adulthood.(11, 12) Bullying victimisation peaks in mid-adolescence and is more common among disadvantaged students.(13, 14) Bullying causes multiple physical and mental health harms in childhood and adulthood,(15-20) and lower educational attainment.(21) The cost of youth violence is high; for example the cost of crime attributable to conduct problems in childhood is estimated at £60 billion per year in England and Wales.(22) Temporary and permanent school exclusions are common, harmful to health and costly, with increased rates post-pandemic.(23) Rates in secondary schools are 4.05% and 0.06%, and higher among students from poorer families and some ethnic groups.(24, 25) Exclusions are associated with psychological distress, violence, crime and anti-social behaviour, educational failure and worse physical and mental health in adulthood.(25-30) Lifetime societal costs in the UK are estimated as £63,851 per exclusion.(31) Young people's substance use remains at high levels.(32)

Review of existing evidence

The Learning Together intervention was effective in reducing bullying victimisation (primary outcome), promoting mental wellbeing and psychological functioning, and reducing substance use (secondary outcomes) among English secondary school students.(33) The intervention worked by building student sense of school belonging.(34, 35) There is broader, consistent evidence, including from systematic reviews, that promoting school belonging is a key way that school interventions promote mental health, and prevent violence and substance use.(4, 36-40) But Learning Together was a complex intervention placing burdens on staff.(33) Post-Covid, schools are struggling to balance academic catch-up and support for mental wellbeing, and complex interventions are harder to implement.(41) There is a need for simpler, brief interventions to promote mental health and prevent violence, exclusions and substance use via promoting school belonging. Learning Together was also limited in the extent to which it ameliorated health inequalities.(33) So there is a need to develop interventions with enhanced reach and effectiveness for disadvantaged students.

The most promising brief interventions to promote school belonging, with strong reach to disadvantaged students and impacts on a range of outcomes, are two recent interventions led by US researchers, which have a shared theoretical basis in promoting student belonging. The first, the 'Student Belonging' intervention, focuses on high school students and aims to educationally engage them via 2 x 15-20-minute classroom sessions(42) aiming to reduce anxiety about school belonging.(43) The intervention presents students with a booklet providing survey results and stories from older students conveying that challenges

and worries about school are normal and improve with time, rather than indicating students do not belong in a school. The theory of change is that students are helped to reflect on their experiences and how these reflect processes of change rather than fixed personal limitations. This gives students a more adaptive narrative to interpret adversities, helping students sustain a sense of belonging, stay academically engaged, and build more trusting relationships and interactions with teachers. In a randomised trial, the intervention reduced disciplinary incidents (z=-2.89, P=0.016, B=-0.3), reduced academic test anxiety (z=-2.74, P=0.005, B=-0.07), improved sense of school belonging (z=3.37, P=0.001, B=0.06) and improved educational attainment (z=2.08, P=0.038, B=0.03) with the greatest benefits for male, Black students. Intervention cost was $1.35 per student per year.

The second intervention, the 'Teacher Empathetic Discipline' intervention, focuses on high school teachers, helping them take a more empathic approach to misbehaving students via a 2-session teacher-directed online reading and reflection exercise. The theory of change involves teachers reflecting on the opportunities they have to help students grow and learn, even when students misbehave, listening to students, and taking an empathetic approach to understanding and responding to them, thereby sustaining positive relationships, and building student trust in school staff and sense of school belonging. The intervention uses narratives and written reflection exercises to represent this approach as normative, optimal and intuitive, informed by research. Teachers are asked to reflect on what they have reviewed and their own experiences to write advice to a new teacher to help them navigate relationships with students. This task helps participants articulate a psychological message for themselves, connect it to their own experience and use it in future. An initial randomised controlled trial (RCT) reported fewer suspensions for violence and other anti-social behaviour among students age 11-13 with no differences by ethnicity or gender (odds ratio (OR)= 0.42, P=0.001).(44) A large replication trial yielded a similar reduction, with effects greatest for ethnic-minority and educationally disabled students, with reductions persisting through the next school year. Intervention costs were very low, involving only teacher time for training.(45)

These Student Belonging intervention and the Teacher Empathetic Discipline intervention have been subject to replication studies in the USA, with sustained effectiveness addressing school belonging, disciplinary incidents, suspensions, attendance, social support and educational attainment.(42, 45-47) While studies with high school students have not examined impacts on general health beyond the above measures, studies of such interventions with university students report significant impacts on general health, mental wellbeing and medical attendances.(48, 49) The consistent impact of these interventions is particularly notable given their simplicity and brevity. This has been attributed to the 'psychologically precise' way they target student and teacher determinants of student sense of school belonging and risk behaviours.(4, 43)

Why is the research important in improving health?

No studies have yet examined the impacts of these interventions beyond the USA or on secondary-school-age students' mental health, violence or substance use, hence the need for a new trial. Discussion with the US investigators suggests the student and teacher interventions are complementary and may be combined. Given this, together with the consistent impacts of these interventions on school belonging and reduced anti-social behaviours, their impacts on university students' health, and the evidenced importance of student sense of school belonging for mental and physical wellbeing and development, it is appropriate to test the effectiveness and cost-effectiveness of a combined intervention for key public health outcomes in the UK.

We therefore propose to combine the US Student Belonging intervention and the Teacher Empathetic Discipline intervention (together branded the 'Belonging' intervention). We will

first culturally optimise their materials for English secondary schools and inclusivity. We will then pilot a 2-arm school cluster trial design comparing the Belonging combined intervention with usual practice comparator. The student and teacher elements will be as described above, retaining their original theories of change. A pilot RCT is justified because, although school randomisation has proven feasible previously, this cannot be so easily assumed post-pandemic.

RESEARCH QUESTIONS

1) Is it possible to combine the US Student Belonging intervention and the Teacher Empathetic Discipline interventions, culturally optimised for English secondary schools and branded as the Belonging intervention?
2) Is progression to a phase III RCT justified in terms of pre-specified criteria concerning intervention and trial feasibility and acceptability?
3) Are outcome and covariate measures well completed and reliable?
4) With what rates are schools recruited and retained?
5) What do qualitative data suggest about how context influences implementation and interacts with intervention mechanisms?
6) Are any potential harms suggested and how might these be mitigated?
7) What is usual practice in control schools?
8) Are methods for economic evaluation feasible?

PUBLIC AND POLICY INVOLVEMENT AND ENGAGEMENT

Public and policy involvement and education (PPIE) is central to the project. The PPIE lead for the project will be Miranda Perry who is an ex-secondary school teacher and was lead facilitator on Learning Together. She has experience facilitating workshops with young people and teachers.

We contacted ten leads of relationships, sex and health education (RSHE) in secondary schools. All indicated that student mental health is worse post-pandemic. All said their school would be interested in an intervention that improved student sense of belonging via brief intervention. Participants thought that year-9 students would particularly benefit. PPIE with DHSC, DfE, EEF and teaching union stakeholders focused on the importance of evaluating how implementation varies by school and could be integrated into school practices. DfE requested we include life satisfaction as an outcome.

Phase 1 will involve PPIE-based cultural optimisation with students, teachers, parents and policy stakeholders (see below). We include letters of support from organisations indicating that they are already willing to participate in the stakeholder group. We will also consult with schools about our questionnaires and survey methods for phase 2.

RESEARCH PLAN AND METHODS

Project objectives

1. To combine the US Student Belonging intervention and the Teacher Empathetic Discipline intervention and culturally optimise materials for English secondary schools (branded together as the ‘Belonging’ intervention) with the US researchers, staff and students from two schools, and other young people, parents and policy stakeholders (Mar 2025-Aug 2025).
2. To recruit six schools for the pilot RCT (Mar 2025), and conduct baseline year-8 student and teacher surveys, and randomise four schools to intervention and two to comparator (May-Jul 2025).
3. To implement the interventions to year-9 students and teachers in four intervention schools (Sep 2025-Jul 2026).

4. To conduct process evaluation (Sep 2025-Jul 2026).
5. To conduct follow-up year-9 student and teacher surveys 12 months post-baseline (May-Jul 2026).
6. To analyse data (Dec 2025-Sep 2026).
7. To write outputs (Feb-Sep 2026)
8. To disseminate findings and assess progression to phase III RCT (from Sep 2026).

See flow chart (figure 1). Timing of the pilot trial allows a short start-up period between allocation and delivery so schools can organise staffing and activities, as suggested by previous trials.(50, 51) This can be short given the brief nature of the intervention.

Phase 1: Cultural optimisation

PPIE-informed cultural optimisation will occur from March to September 2025 (figure 1). This will combine the US Student Belonging intervention and the Teacher Empathetic Discipline intervention into a single intervention with student and teacher components. The theories of change for these interventions are complementary and these and intervention procedures will remain unchanged. In the section below on 'Intervention and comparator' and in the logic model (figure 2), we integrate the original theories of change into a single theory of change (for presentational purposes to show how the two combined will work). Intervention materials will be adapted purely to be culturally appropriate for England and inclusive for all students including those with special educational needs and disabilities (SEND) informed by existing frameworks.(52, 53) At the same time, we will develop fidelity and acceptability metrics to use in phase 2 that reflect the optimised intervention. We will work with the US researchers (Walton, Okonofua, Goyer) closely at all points to ensure we remain consistent with the original theories of change and approaches that proved effective in the USA.

Optimisation will involve two schools, both with high free-school-meals entitlement and Ofsted (Office for Standards in Education, Children's Services and Skills) ratings (respectively indicating high need and high capacity to collaborate) and varying by ethnic mix and urban/peri-urban status. These schools will have large numbers of disengaged students. In each school, we will convene two meetings with a group of around 10 year-9 students (varying by gender, ethnicity, school engagement and SEND) and a group of around five staff (varying by seniority and role). We will include disengaged students by asking schools to identify such students based on unauthorised absences and declines in academic attainment. Where possible, we will recruit students in friendship groups so students feel more comfortable joining and contributing. We will also convene one meeting each with an additional group of young people with low school engagement (recruited from other schools using the same criteria regarding attendance and attainment as above), a group of parents and a group of policy stakeholders.

The first meeting with school students and staff will examine the original theories of change and assess the intervention materials for cultural fit and inclusivity (Mar 2025). We will also use it to get student and staff comments on the baseline questionnaires. The second meeting will comment on revised intervention materials to ensure cultural appropriateness and inclusivity while staying true to the original interventions and their theories of change (May 2025). We will also use it to get student and staff comments on survey methods. The refined intervention materials will then be reviewed for broader appropriateness in meetings with disengaged students from other schools, parents and policy stakeholders (Jun-July 2025). Our PPIE facilitator has experience working with teachers, students and parents to optimise interventions, and will ensure that optimisation is participative and inclusive of SEND and disadvantaged students with low school belonging and engagement. Meetings with students will use participative methods (such as small group work, paired discussions and ranking exercises) to ensure all students including disengaged students shared their expertise and views based on their lived experiences.

The study will then progress to phase 2 if the study steering committee judges that: the intervention materials have been culturally optimised for English schools while staying true to the original interventions and their theories of change; fidelity and acceptability metrics have been developed which will inform the evaluation methods and progression criteria for the pilot RCT; all other evaluation methods for the pilot RCT have been finalised; and all of the above have been appropriately informed by PPIE.

Phase 2: Pilot cluster RCT

Design overview

The pilot cluster RCT will occur in six secondary schools (four intervention, two control). Recruitment, baseline surveys of students and teachers, and randomisation will occur in March-July 2025. Schools will be randomly allocated 2:1 (1:1 in any future phase III RCT) to intervention/control stratified by free school meals (plus single/mixed sex school in phase III) in June/July 2025.(13, 14) 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 2025 to July 2026 accompanied by integral process evaluation and economic evaluation feasibility study (figure 1). Follow-up surveys will occur in May-July 2026. The primary outcome for the pilot RCT will be assessing criteria for progression to a phase III RCT. Indicative primary and secondary outcome measures (described below) for a phase III RCT will be assessed for completion and reliability but intervention effects on these outcomes will not be assessed. A future phase III RCT would involve 1:1 allocation to intervention and control, and 12- and 24-month follow-up.

Settings/context

The Belonging intervention is intended to be deliverable in all English secondary schools (including faith schools, free schools, academies and private schools) excluding pupil referral units and schools exclusively for SEND students. A future phase III RCT would be national in scope and include a representative sample of schools. The pilot will recruit schools in south-east England, appropriate to reduce travel time and costs. Pilot schools will be purposively recruited to vary by free-school-meals entitlement (poverty), Ofsted rating (school capacity), urban/peri-urban and ethnic make-up so that we can pilot the intervention across factors potentially affecting feasibility, reach and acceptability.(54)

Study population

The study population is defined as students in year 8 (aged 12-13 years) at baseline (so in year 9 for intervention) plus all teachers. All student-reported measures are suitable for students in this age-group (see outcome measures below). The research will be inclusive, including of SEND students. No students deemed competent by teachers to complete data collection will be excluded from recruitment unless they do not consent to, or their parents withdraw them from, the research. Those who have mild learning disabilities or limited English will be supported to complete the questionnaire by researchers.

Analytical sample and sample size

The pilot focuses on resolving uncertainties before a phase III RCT rather than estimating effects, with no power calculation. The sample will involve approximately 140 students and 60 teachers per school (840 and 360 overall). The pilot RCT aims to include sufficient diversity of schools in terms of free school meals, Ofsted rating, urban/peri-urban location and ethnic make-up to allow piloting of the feasibility and acceptability of the intervention in diverse contexts. We judge six schools in total and four in the intervention arm is sufficient

for this because what we seek is overall diversity for the above factors rather than a school with every combination of the factors.

For the phase III RCT to detect a standardised effect of 0.2 SDs on our primary outcome, the Strengths and Difficulties Questionnaire (SDQ), at 90% power and 5% significance will require 16 schools per arm assuming 140 year-9 students surveyed per school, drop-out of 1 school per arm and an intra-cluster correlation coefficient (ICC) of 0.02. Our effect size has previously been defined as of policy significance.(55) We conservatively focus on SDQ in this calculation because its ICC is larger than that of our other primary outcome. Our estimate for the ICC for SDQ is conservative compared to estimates from recent UK research.(55) Our pilot will assess our estimates while acknowledging small-sample limitations. Our pilot will not assess preliminary intervention effects since it is not powered to do so.

Recruitment and random allocation

We will recruit secondary schools in south-east England (all England in phase III) of all types except those exclusively for SEND students and pupil referral units. Schools in the pilot will vary by free-school-meals entitlement (poverty), Ofsted rating (school capacity), urban/peri-urban location and ethnic make-up so that we can pilot across factors likely to affect feasibility, reach and acceptability.(54) As with our previous trials, schools will be recruited by a combination of emails and then 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 and control (1:1 in phase III RCT) by LSHTM clinical trials unit (CTU), stratified by free school meals (plus single/mixed sex school in phase III).(13, 14) 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. Schools will be given unique study numbers to preserve allocation concealment within the CTU. The CTU will pass on allocations to the fieldwork team who will then inform schools. Informed by the Positive Choices and ‘If I Were Jack’ RCTs,(56, 57) we will facilitate recruitment and retention by offering a £500 payment to all schools. Previous studies suggest that payment is now essential for maintaining school participation in research(56, 57) particularly in the post-pandemic context. Each school will be allocated a named research liaison contact to facilitate retention.

Planned intervention and comparator

The Belonging intervention combines the US Student Belonging intervention and the Teacher Empathetic Discipline intervention (see ‘Review of existing evidence’ above) culturally optimised for English secondary schools but retaining original procedures and theories of change. Our logic model (figure 2) integrates these original theories of change for presentation purposes to show how they work together (figure 2). The intervention is described below using the Template for Intervention Description and Replication (TIDieR) framework.(58)

Theory of change: The theory of change simply integrates those of the US Student Belonging intervention and the Teacher Empathetic Discipline intervention summarised earlier. Students are helped to reflect on their experiences and how these reflect processes of change, which gives them a more adaptive narrative to interpret adversities. This helps them sustain sense of belonging and academic engagement, and build trusting relationships and interactions with teachers. Teachers reflect on their opportunities to help misbehaving students grow and learn, listening to students, and taking an empathetic approach to

understanding and responding to them. This sustains positive relationships, and builds student trust in school staff and sense of school belonging. Together these student and staff mechanisms are theorised to improve student mental health and reduce aggression, bullying and substance use.(59)

Training/facilitation: School leads provide a brief introduction to other teachers on the intervention materials, guided by intervention resources. Teachers receive online training.

Materials: Student curriculum booklet presenting survey results and student stories plus online teacher training involving reading and reflection exercises.

Procedures, delivery & dose: All year-9 students receive two x 15-20-minute classroom sessions early in year 9 working through the student booklet. Students are offered the idea that educational challenges and worries are normal, and not indicative of a lack of belonging. Student absent on the day of the lesson will receive it individually when they return to school, facilitated by receiving the student booklets. Teachers complete two x online sessions (45, 25 minutes). In the first, teachers read an introduction and student stories describing their experiences in school and relationships with teachers, then respond to writing prompts. In the second, they read a teacher's story and respond to writing prompts. Our training materials will encourage as many teachers as possible to participate as all are likely to have some contacts with year-9 students. The intervention complements existing activities.

Cost: Materials are free. Delivery costs comprise teacher time.

Comparator will be treatment as usual with schools continuing with existing activities to promote student mental health and prevent violence and bullying. Process evaluation will describe this. PPIE suggests that no UK schools currently use interventions resembling those proposed.

Outcome measures

Pilot outcomes

For this pilot trial, the primary outcome is assessment of criteria for progression to phase III RCT as follows:

- randomisation occurs and 5+ schools continue;
- interventions achieve 70+% fidelity and reach;
- interventions acceptable to 70+% of students and teachers;
- student survey response rates are 80+% in 5+ schools; and
- informed by qualitative research, hypotheses developed about how contextual factors affect intervention implementation and mechanisms.

The precise metrics used to assess implementation fidelity and acceptability will be defined in phase one when intervention materials are optimised. These criteria will be shared with the study steering committee and NIHR for approval. The study steering committee will judge at the end of the study whether criteria for progression to phase III RCT have been met.

Trial outcomes to be piloted

All will be measured at 12-month follow-up (24 in phase III RCT). The co-primary outcomes for a phase III RCT (assessed for performance in the pilot) are student-reported SDQ(60) and Short Warwick Edinburgh wellbeing (SWEMWBS).(61)

Student-reported secondary outcomes at 24 months are:

- aggression (Edinburgh Study of Youth Transitions and Crime school misbehaviour subscale;(62)
- bullying victimisation and perpetration in past 2 months (Revised Olweus Bully/Victim Questionnaire).(63) and
- substance use (tobacco, alcohol and drug use assessed using existing measure(64)).

Other secondary outcomes are:

- student exclusions and attendance (routine data)
- teacher-reported perceived behaviour of students (Pupil Behaviour Questionnaire(65));
- teacher-reported self-efficacy (Teacher Sense of Efficacy scale(66)); and
- teacher-reported burnout (Maslach Burnout Inventory).(67)

Secondary outcomes will also include the Child Health Utility (CHU)9D measure(68) which will be used for cost-utility analyses (see below). The CHU-9D is a validated age-appropriate measure explicitly developed using children's input.(69)

We will also measure the following mediators at follow-up (interim follow-up in a phase III RCT): student-reported staff-student relationships, school belonging and academic commitment (Beyond Blue School Climate Questionnaire subscales);(70) student-reported academic anxiety and trust in school staff using existing measures;(43) and a validated measure of teacher empathy.(71) We will also assess an Office for National Statistics measure of life satisfaction as an exploratory outcome informed by PPIE.(72)

Assessment and follow-up

Baseline surveys will be done pre-randomisation with year-8 students aged 12-13 and teachers in June/July 2025, 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. Paper questionnaires will be completed confidentially by students in classrooms supervised by trained fieldworkers, with teachers maintaining order but unable to read responses. 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 trusted 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.(73, 74) We will survey absent students by leaving questionnaires and stamped addressed envelopes with schools, and liaising with schools to maximise returns. We will also explore the feasibility of linking student self-report data to routine school data on student SEND status to assess if we can assess subgroup effects in a phase III RCT. For teacher surveys, we will consult with teachers 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. This may involve paper-based surveys conducted in staff meetings or emailing teachers links to the survey online.

We will conduct follow-up surveys at 12 months to test their feasibility (Jun-Jul 2026) at the end of year 9. This period is sufficient to assess the feasibility of follow-up in the 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-ups at 12- and 24-months post-baseline with primary outcomes at 24 months. We would liaise with the Educational Endowment Foundation (EEF) to fund an independent evaluation of effects on GCSE attainment among our phase III trial cohort at 24 months. Survey fieldworkers and CTU staff but not students or teachers will be blind to allocation.

Process evaluation data collection

As well as assessing progression criteria and informed by existing frameworks,(75-77) we will examine: fidelity, reach and acceptability and how this varies by school, teacher and student characteristics; usual practice in control schools; potential contamination; and implementation processes and intervention mechanisms, and how these vary by context.

Intervention fidelity, reach, engagement and acceptability

Fidelity, reach (exposure and uptake), engagement and acceptability will be assessed quantitatively among staff via: teacher logbooks of student lesson attendance; survey of school leads on the introductory training; survey of classroom teachers on teacher training; automated data on online teacher training participation and fidelity; teacher logbooks of fidelity of delivery of student lessons; and observations of a randomly selected lesson per school. We will examine exposure, uptake, engagement and acceptability among students via our survey (overall and by student gender, ethnicity and family affluence, and by school-level Ofsted rating and free school meals entitlement).

Comparator and potential contamination

Data on control provision will be collected via student surveys and structured interview with one staff-member per school (drawing on the School Health Research Network Questionnaire(78)). 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.

Implementation processes/intervention mechanisms and context

Informed by May's implementation theory and realist evaluation,(77, 79) we will collect qualitative data to explore: implementation, including 'sense-making', 'commitment (i.e. engagement)', 'collective action' (i.e. uptake) and 'reflection', by teachers; perceptions of the intervention; intervention mechanisms; and how implementation and mechanisms vary between schools and students. These analyses will examine what contextual factors influence implementation and intervention mechanisms, which will allow us to draw conclusions about the potential feasibility and appropriateness of the intervention in different schools and for different staff and students. This will allow us to make empirically informed assessments of the potential scalability of the intervention. While such assessments will be limited by the size of this pilot study, they will nonetheless be useful and would inform similar and more wide-ranging assessments to be conducted should the intervention be evaluated in a phase III trial. Informed by 'dark logic' methods, we will explore whether any hypothesised mechanisms of harm appear plausible, and if so whether and how these might be mitigated.(80)

Data will be collected from intervention schools via: interview with teacher leading intervention plus one focus group with 4-8 staff (purposive by involvement, seniority, role) and two focus groups with 4-8 students per school (purposive by involvement, ethnicity,

gender) per school. Purposive sampling will be used to explore a range of perspectives and experiences according to factors likely to be associated with differences in these. It will not be feasible in schools to purposively sample by student socio-economic position but we will strive to be inclusive of a diverse range of students.

Economic evaluation data collection

The pilot RCT will examine whether it is feasible to measure costs and assess cost effectiveness using cost-consequence and cost-utility analyses within a phase III trial.(81) CHU-9D is described above. Within the pilot study, methods to measure the incremental cost of the intervention in a phase-III trial study will be developed and piloted. Within this, key interventional resources will include school staff time, training time and consumables. Cost estimates will draw on automated records of the delivery of teacher training and teacher logbooks of student attendance and fidelity of delivery of student lessons, reports from school leads assessing time spent on tasks relating to intervention and other expenses relating to the intervention. We will also assess the feasibility of data linkage to National Pupil Database and Hospital Episode Statistics databases. This could then be used in a phase III RCT to estimate costs within the trial period arising from primary and secondary outcomes.

Data management

Anonymised 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

Optimisation phase

Activities in the optimisation phase will be PPIE rather than research. Such activities will be summarised but not subject to research analysis.

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 materials have been culturally optimised to the satisfaction of the participating schools, and whether the fidelity and acceptability metrics for the pilot phase have been defined (RQ1). The optimisation 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.(82) Descriptive statistics on fidelity will draw on: survey of

school leads on the training; teacher survey; automated data on teachers online training; teacher logbooks of student lessons; and observations of a randomly selected lesson per school. Statistics on acceptability will draw on surveys of students and staff. Other analyses will address our other research questions. Descriptive summaries of baseline and follow-up data by arm will be tabulated. We will assess responses rates for our outcome and covariate measures, and where appropriate assess the reliability of scaled measures by reporting Cronbach's alpha statistics (RQ3). School recruitment will be summarised in the CONSORT diagram (RQ4).

Qualitative data will be subject to thematic content analysis involving in vivo and then axial coding with constant comparison.(83) Analyses will be informed by May's implementation theory,(77) realist approaches to evaluation(79) and dark logic methods.(80) Qualitative research in intervention schools will examine: how contextual factors including student, teacher and school characteristics influence implementation (RQ5); what mechanisms interventions are reported to triggered; how implementation and mechanisms vary across students, teachers and schools (RQ5); and what mechanisms might plausibly be triggered to generate harmful outcomes (RQ6). These analyses will examine the scaleability of the intervention and any factors limiting this. Qualitative research in control schools will describe treatment as usual and explore the potential for contamination (RQ7). 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 (RQ8).

We will pilot our outcome analyses, providing confidence intervals but not point estimates given the small sample. A future phase III RCT would undertake intention-to-treat analyses to assess intervention effects on our primary and secondary outcome measures, plus cost-utility and cost-consequence economic analyses. Additional, secondary analyses would examine: on-treatment effects according to school-level fidelity; mediation of intervention effects by our hypothesised measured (listed above); and moderation of intervention effects by school-level (free school meals rates, Ofsted rating), student-level (gender, ethnicity, socio-economic position and school engagement) and teacher-level (gender, role) characteristics. Alongside insights from the process evaluation of how context influenced implementation and mechanisms, 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 and survey fieldwork teams 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 as well as the General Data Protection Regulation 2016. Data processing will operate on the basis of the public task legal basis.(84)

Head teachers as gatekeepers will be asked for informed consent for school study participation, random allocation and intervention. In line with the law, guidance and existing practice,(85) students deemed competent by teachers to do so and teachers will be asked for informed consent for their own participation in data collection. Parents will have the right to opt their children out of data collection. For all data collection, participants (and, in the case of students, their parents too) will be given an information sheet one week before data collection and will be able to opt out of data collection should they wish. Just before data collection, participants who have not previously opted (or been opted) out will receive written information (and in the case of face-to-face surveys and interviews also an oral description

from and chance to ask questions of trained fieldworkers). 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 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. 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 duties 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 in this pilot study, 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

The Belonging intervention is a universal intervention which aims to disproportionately benefit disadvantaged and minority students, having been developed for such populations in the USA. It does by addressing individual and school influences on student sense of school belonging, which are likely to be particularly implicated in adverse outcomes among disadvantaged and minority students.(86)

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) and vary by ethnicity. Schools recruited to the pilot RCT will vary by free school meals, Ofsted rating, urban/peri-urban setting and ethnicity. The pilot RCT will focus recruitment on south-east England but within this include very different areas. A phase III RCT would be national in focus and aim to be representative in terms of school rates of free-school-meal entitlement.

In the pilot RCT, we will assess how intervention reach and acceptability vary by student gender, ethnicity, socio-economic position 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, family affluence (as a marker of socio-economic position), 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). These will focus on the feasibility and acceptability of the intervention and of evaluation methods. 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.

The Belonging intervention will be developed as a very low-cost, 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 PHR for a phase III effectiveness trial. 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. The intervention would be made freely available to schools free of charge. If effective, this should benefit student and staff mental health as well as reducing student violence and substance use. Accreditation for the intervention would then be sought from Blueprints for Positive Youth Development and Early Intervention Foundation to promote scale-up. 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 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. Independent study steering committee and data monitoring and ethics committee will be established to oversee the study. The former will include expertise on scaling up school-based interventions. These will meet three times during the study period. These committees would involve independent researchers including statisticians and PPIE representatives as discussed above. 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.
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.
Intervention fidelity is poor.	The intervention is low demand and the teacher training is supported by web-based technology to facilitate fidelity even in highly stressed schools.
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.

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 and is expert in school-based health promotion, adolescent health and evaluation methods. He will supervise the trial manager and research assistant working on the study via weekly team meetings. Miranda Perry will lead PPE. She is an ex-secondary school teacher with previous experience implementing Learning Together, and leading workshops with teachers, parents and young people. 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 RCTs. 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 Ruth Ponsford will be the trial manager. She is an experienced schools researcher and trial manager having worked on the previous Positive Choices pilot and phase III RCTs. 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.

Project timeline

Task	**Timing**																		
	2025										*2026*								
	Mar	*Apr*	*May*	*Jun*	*Jul*	*Aug*	*Sep*	*Oct*	*Nov*	*Dec*	*Jan*	*Feb*	*Mar*	*Apr*	*May*	*Jun*	*Jul*	*Aug*	*Sep*
Optimise the intervention with PPIE	X	X	X	X	X	X	X												
Recruit 6 schools for pilot RCT	X																		
Conduct baseline year-8 student & teacher surveys			X	X	X														
Randomise 4 schools to intervention and 2 to comparator					X														
Implement interventions to students & teachers in intervention schools							X	X	X	X	X	X	X	X	X	X	X		
Conduct process evaluation							X	X	X	X	X	X	X	X	X	X	X		
Conduct follow-up year-9 student & teacher surveys															X	X	X		
Analyse data										X	X	X	X	X	X	X	X	X	X
Write outputs												X	X	X	X	X	X	X	X
Disseminate findings and assess progression to phase III RCT																			X

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