Initiating change locally in bullying and aggression through the school environment (INCLUSIVE): trial protocol

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Aim

Our aim is to evaluate the effectiveness and cost-effectiveness of the INCLUSIVE intervention over three school years (two externally facilitated; one internally facilitated) using a cluster RCT design with integral process and economic evaluation to address the following research questions (RQ):

RQ1. Is the INCLUSIVE intervention implemented over three school years more effective and cost-effective than standard practice in reducing bullying and aggression among 12-15 year olds in English secondary schools?

RQ2. Is the INCLUSIVE intervention more effective than standard practice in improving students' quality of life, well-being, psychological function and attainments, and reducing school exclusion and truancy, substance use, sexual risk, NHS use, police contacts among students, and improving staff quality of life and attendance and reducing burn-out?

RQ3. What pre-hypothesised factors moderate and mediate the effectiveness of the INCLUSIVE intervention; including, do effects vary by socioeconomic status and sex?

Research objective milestones:

(i) To recruit and undertake baseline student and staff surveys in 40 schools by June 2014.
(ii) To randomly allocate schools and schedule key meetings in intervention schools by July 2014.
(iii) To deploy education facilitators, convene action groups and provide schools with data on local needs by September 2014.
(iv) To deliver restorative training and the INCLUSIVE curriculum, review school policies and plan and implement local actions as planned in the 2014/5 and 2015/6 academic years.
(v) To have completed all externally facilitated aspects of the intervention and to have assessed the fidelity and acceptability of this by July 2016.
(vi) To provide intervention schools with data on local progress and needs by Sept 2015 and 2016.
(vii) To assess processes of unfacilitated third year of intervention by July 2017.
(viii) To collect follow-up data on student and staff outcomes by July 2016 and July 2017.
(ix) To have completed all data cleaning and analysis by December 2017.
(x) To submit final report by March 2018.

Design

Cluster RCT with integral economic evaluation and process evaluation, with schools as the unit of allocation.

Study population

INCLUSIVE is a universal intervention, aimed at all 11 to 16 year olds in participating secondary schools in England. While the intervention aims to have effects on the whole school, our study population of students will be those at the end of year 7 (age 11-12 years) at baseline and be at the end of year 10 at final follow-up (age 14-15), as well as all school teaching and teaching assistant staff. All students in the school in that year and all teaching staff will be surveyed at each time-point, not only those who participated at baseline.

Inclusion/Exclusion criteria

Planned inclusion/exclusion criteria: (applied only to schools).

(i) Secondary schools within the state education system (including community, academy or free schools, and mixed or single sex) in England. We will take the widest definition of a 'state school' and will only exclude private schools, non-mainstream schools (e.g. for those with learning

disabilities) and pupil referral units. The latter two will be excluded as it is unlikely that INCLUSIVE will be appropriate for their populations.

(ii) Ofsted rating (most recent) of 'requires improvement'/'satisfactory' or better; we will exclude schools with an 'inadequate'/'poor' Ofsted rating because such schools are subject to special measures which are likely to impede INCLUSIVE delivery. To maximize generalisability we will not exclude schools by deprivation status. Note there are no inclusion/ exclusion criteria for students.

Recruitment and randomisation

For pragmatic reasons we will target the secondary schools in Greater London and the surrounding Boroughs (Surrey, Kent, Essex, Hertfordshire, Buckinghamshire, Windsor) with a maximum travel time of 1 hours, of whom the majority will be eligible for this study. Further schools can be recruited from elsewhere in south-eastern or south central England if required. To aid recruitment, we will partner with existing schools networks such as the UCL Partners Schools Network, Institute of Education Teaching Schools and schools that are part of our collaborating schools network, Challenge Partners (>180 schools nationally). We will approach approximately 250 eligible schools, initially by letter and email with a telephone follow-up by an educational facilitator, complying with good practice and research governance for undertaking studies within the education system.

Forty schools will be recruited during the study set-up phase (Months 1-5, February to June 2014). Suitable schools (see inclusion criteria below) whose head-teacher give informed written consent to participate will be allocated with a 1:1 ratio between intervention and control arms. Randomisation will be undertaken remotely by the Clinical Trials Unit (CTU) at the London School of Hygiene & Tropical Medicine (LSHTM). To promote baseline equivalence, we will stratify by key school-level determinants of violence: single sex versus mixed sex school; school level deprivation, as measured by percentage of students eligible for free school meals (low/ moderate 0-23%; high >23%); and school Best 8 value added in GCSE exams (above and below median for England of 1000). Value added (VA) scores is a school-level measure of students' attainment in public exams adjusting for their attainment on entry to the school. We use VA rather than Ofsted ratings for schools as there is better evidence for VA being associated with violence rates. Within each of these 8 strata, schools will be allocated using stratified randomisation.

Protecting against bias: (1) School level: The randomisation schedule will be drawn up once the schools have consented and after the baseline survey thus guarding against selection biases at entry of clusters to the trial. This may occur sequentially in blocks of ten schools, should there be any delays with reaching final sample size or with baseline surveys in some schools. As with most social intervention trials, schools, their students, teachers and other staff cannot be 'blinded' to allocation status. However, data-input staff will be blinded to each school's status throughout the study and analysis of follow-up quantitative data will be undertaken blind to allocation. Retention of control schools will be maximised by ensuring regular senior liaison and provision of participation incentives (£500). (2) Student level: We had very high student participation in our pilot study: 96% of students' eligible at baseline and 93% at follow-up. To minimise bias, we will use in-school, mail and telephone contacts to try to include all enrolled students absent at either baseline or follow-up questionnaires. Note we will not attempt to follow-up students who have left the school.

Intervention and comparison groups:

1. Intervention:

The intervention is intended principally to augment rather than to replace existing activities (e.g. training, curricula, etc.) in intervention schools. However, it is intended to replace existing non-restorative disciplinary school policies and practices where restorative approaches are deemed by the action group to be more appropriate.

The two-year facilitated phase provides the following **inputs**:

i) annual surveys of local needs and assets (bullying, aggression, prevalence and determinants) and progress in addressing these
ii) support from an external expert education facilitator trained in facilitating INCLUSIVE
iii) social and emotional learning curriculum resources
iv) staff training in restorative practices provided by the education facilitators and comprising a short introduction and subsequent half-day for all staff (focused on introducing them to restorative practices, such as 'circle-time', to promote positive relationships and communication, plus enhanced three-day training course in restorative practices targeting 5-10 staff at each school, including training in formal 'conferencing' to deal with more serious incidents via bringing together students, parents and/or staff.)

These inputs will enable schools during all three years to convene an **action group**, which comprises (at a minimum): six students; six staff, including at least one senior management team (SMT) member and one member of each of the teaching, pastoral and support staff. Membership from specialist health staff, such as the school nurse and/or local child and adolescent mental health services staff, is desirable but optional. The action group must meet at least six times per school year (i.e. approximately once every half-term).

The action group develops an action plan that coordinates delivery of the following intervention **outputs**:

i) Reviewing and revising *school rules and policies* relating to discipline, behaviour management and staff-student communication
ii) Implementing *restorative practices* throughout the school. Restorative practices include 'circle-time' (which brings students together with their teacher during registration periods or other lessons to maintain good relationships, or be used to deal with specific problems) and 'conferencing' (used to deal with more serious incidents and brings together relevant staff, students, parents and, where necessary, external agencies.
iii) Additional *tailored actions* to address local priorities.
iv) Delivering the six-module *social and emotional skills curriculum* for years 8-10. The curriculum targets students in years 8-10 who receive 5-10 hours teaching and learning per year on restorative practices, relationships, and social and emotional skills based on the Gatehouse Project curriculum. The curriculum is designed as a set of learning modules which schools can address using our own or existing materials if these aligned with our curriculum. Modules cover: establishing respectful relationships in the classroom and the wider school; managing emotions; understanding and building trusting relationships; exploring others' needs and avoiding conflict; and, maintaining and repairing relationships. Informed by the needs-assessment data, schools tailored the curriculum to their needs and could deliver modules either as 'stand-alone' lessons, for example within PSHE, and/or integrated into various subject lessons (e.g. English).

The intervention enables local tailoring, informed by the assessment survey and other local data sources. These locally adaptable actions will occur within a standardized overall process with various core standardized intervention elements, such as the staff training in restorative practices; review and revision of school rules and policies; and the social and emotional skills curriculum. This balance of standardisation and flexibility is a common practice in complex interventions, enabling a balance between fidelity of the core components with local adaption. This allows schools to build on their current good practice, and also encourages students and staff to develop ownership of the work, which may be a key factor in intervention effects. To support this, the facilitator works with schools to ensure all members of the action group are supported to identify and undertake locally determined actions to improve the school environment.

Internally facilitated intervention year: The third intervention year will be identical to the externally facilitated intervention described above, with the exception that there will be no provision of external

facilitation. One of the roles of the external facilitator over the two facilitated years will be to ensure the school action group and SMT develop the capacity to undertake this internal facilitation in the third year.

2. Comparator:

Schools randomized to the control group will continue with normal practice for the school in question and receive no additional input. They will be provided with £500 (to cover administrative costs and/or provide cover for staff involvement in organising data collection) and at the end of the study be offered a brief report of the survey data collected at the school because we know that schools highly value such data. Control schools are free to engage in actions to reduce bullying and aggression but the contract signed with Heads will preclude their engaging in a facilitated whole-school programme such as INCLUSIVE. We will examine control schools' policies and practices related to bullying and aggression.

Assessments

Student primary and secondary outcomes will be assessed at 36 months at the end of year 10 (age 14-15 years), with a baseline survey having been undertaken at the end of year 7 (age 11-12). Staff secondary outcomes will also be assessed at 36 months. Additional student and staff surveys will be conducted at 24 months in order to measure secondary outcomes, examine intervention process and determine intermediate outcomes to be used in mediation analysis (see below). Student surveys will be conducted in exam conditions in schools, maximizing privacy. All students in the school in that year and all teaching and teaching assistant staff will be surveyed at each time-point, not only those who participated at baseline. Paper-based questionnaires will be completed confidentially in a 45 minute class session devoted to the purpose. Field workers will supervise the students completing the questionnaire, with the teacher present (for disciplinary purposes) but unable to see the questionnaires. The field-workers will assist students with questions that they don't understand and ensure students complete as much of the questionnaire as possible. Note that students with mild learning difficulties or with limited command of written English will be supported to complete the questionnaires by fieldworkers.

We will assess the potential for measurement error and bias by asking students completing surveys whether their responses to questionnaires were completely truthful. We will ask students in intervention schools involved in qualitative interviews whether their reporting (as opposed to their experience) of bullying and aggression might have been affected by the intervention.

Outcomes

1. Primary outcomes

These will be measured at 36 months (i.e. after three intervention years) through student survey self-reports. As is conventional in trials of interventions addressing violence and aggression in schools, we will rely on self-reports from students, rather than observations or teacher reports because of respectively the impracticality and greater likelihood of information bias of the latter two. The primary outcomes measures include one measure of bullying victimization and one measure of perpetration of aggressive behaviours:

a. **Gatehouse Bullying Scale (GBS).** The GBS is a short, reliable tool to measure the occurrence of bullying victimisation in schools. This measure was designed by one of our collaborators (LB) and has been shown to be related to other measures of social attachments, school engagement, and anxiety and depressive symptoms. The scale has 12 items, and asks about being the subject of recent teasing, name calling, rumours, being left out of things and physical threats or actual violence from other students in the last 3 months. Each section asks about the recent experience of that type of bullying (yes or no), how often it occurred, and how upset the student was by each type of bullying.

b. **Edinburgh Study of Youth Transitions and Crime (ESYTC) school misbehaviour subscale**. The ESYTC measures several domains of violence and aggression at school.

2. Secondary outcomes

The GBS and ESYTC outcomes will be measured at 24 months as secondary outcomes.

In addition we will measure the following at 24 and 36 months:

(i) Student level self-report outcomes: These will be measured through student survey self-reports:

1. Paediatric quality of life inventory (PedsQL) version 4.0 will be used to assess overall quality of life. The 30-item PedsQL has been shown to be a reliable and valid measure of quality of life (QoL) in normative adolescent populations. It consists of 30 items representing five functional domains: physical, emotional, social, school and well-being, and yields a total QoL score, two summary scores for 'Physical Health' and 'Psychosocial Health' and three subscale scores for 'Emotional', 'Social', and 'School' functioning.

2. Psychological function & well-being

a. **The Strengths and Difficulties Questionnaire (SDQ)** is a brief screening instrument for detecting behavioural, emotional and peer problems and pro-social strengths in children and adolescents. It is brief, quick to complete, and validated in national UK samples.
b. **Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS)** is a seven-item scale designed to capture a broad concept of positive emotional well-being including psychological functioning, cognitive-evaluative dimensions and affective-emotional aspects, with a total 'Well-being Index' generated.
c. **The K6 screening tool for serious emotional disturbance (K6)**: The K6 is a 6 item scale that has been shown in previous research to be a strong predictor of serious mental illness related to emotional disorders in adolescents in community samples.

3. Risk behaviours

~~a.~~ a. **Substance use**. Validated age-appropriate questions taken from national surveys and/or previous trials will be used to assess smoking (smoking in previous week; ever smoked regularly), alcohol use (use in previous week; number of times really drunk; binge drinking) and illicit drug use (last month; lifetime use).

~~a.~~b. **Sexual risk behaviours:** Age of sexual debut and use of contraception at first sex will be examined using Ripple trial measures. We will consult with schools about the acceptability of asking these questions at baseline as well as at follow-up (Year 10).

4. Use of NHS services: self-report use of primary care, accident & emergency, other service in past 12 months.

5. Contact with police will be assessed using the Young People's Development Programme (YPDP) evaluation measure, which asks whether the young person has been stopped, told off, or picked up by the police in the last 12 months.

(ii) Student-level data collected from schools

1. School attendance will be measured via routine school data on each student expressed as number of half days absent; for which we will seek students' informed consent to access.

2. Educational attainment: We intend to explore students' progress between key stages 2 and 4 in English and Maths but this will require additional data collection after the end of the trial i.e. after student participants have sat GCSE examinations in 2018. This will be the subject of a Bloomsbury PhD studentship or a small grant proposal to the Educational Endowment Foundation.

(iii) Individual staff-level outcomes. We will measure the following secondary outcomes through survey self-reports from teachers and teaching assistants:

1. **Staff attendance** will be measured via routine school data on each staff-member expressed as number of half days absent; for which we will seek staff-members' informed consent to access.

2. **Staff quality of life** will be measured using the SF-12 version 2 Health Survey, a brief well-validated measure of adult health related quality of life.

3. **Staff stress and burnout** will be measured using the Maslach Burnout Inventory, an established scale which uses a three dimensional description of exhaustion, cynicism, and inefficacy.

(iv) School-level outcomes: Routinely-collected data on school rates of temporary and permanent exclusions.

Power and sample size

The average English school has approximately 190 students per year, although this varies across schools. Recent data from three large UK school cohorts suggest that intra-cluster correlation coefficients (ICC) for aggression and bullying outcomes vary between 0.01 and 0.03 (ICC). We will conservatively assume an ICC of 0.04 in this trial. A systematic review of school-based secondary preventive interventions to prevent violence reported a pooled effect size of 0.41 on measures of aggressive behaviour. Effect sizes for aggressive behaviour from similar interventions approximate 0.3 to 0.4 SDs in males.

A trial involving 20 schools per arm, with (conservatively) 100 students per school, will provide sufficient power to identify an effect size of 0.23 SD at 90% power or 0.20 SD at 80% power, both at 95% significance level. If two schools per arm (i.e. 10%) were to be lost to follow up over the course of the trial we would still have 80% power to detect an effect size of 0.23. The total student sample size will be between 4000 (assuming 100 students per school) and 6000 (assuming 150 per school). Note that as we will be surveying all young people in the relevant school year at each follow-up, this sample is likely to remain similar across the study.

Economic evaluation

The aim of the economic evaluation is to assess the costs, consequences and cost-effectiveness of the Inclusive intervention compared with standard school-based practices for managing aggression.

The primary economic evaluation will take the form of a within trial cost-consequence analysis, with a secondary analysis that will report relative cost-utility with health outcomes expressed in terms of Quality-Adjusted Life-Years (QALYs), as recommended by NICE's public health methods guidance.

This NICE guidance also recommends that the base-case cost-effectiveness estimate is presented from a public sector perspective as this allows the costs and benefits of more than one central / local government body to be taken into account. This statement is particularly pertinent to Inclusive as the costs of implementing it are likely fall on the educational sector, yet there are potential cost implications for sectors such as the NHS, the police and the judiciary through reduced anti-social behaviour. The implications for NHS resource use and policing will be identified with specific questions in the student survey and valued accordingly. The impact on staff time will be identified in the teacher survey. Costs will be collected on the delivery of the intervention as incurred during the trial.

The time horizon will capture costs and outcomes within the trial.

Changes in health-related quality-of-life (as expressed using QALYs) will be measured from the study participant's (i.e. student's) perspective.

The **Child Health Utility (CHU) 9D measure** will be used to assess health-related quality of life as part of the economic evaluation. The CHU-9 is a validated age-appropriate measure that was explicitly developed using children's input and has been suggested to be more appropriate and function better than other health utility measures for children and adolescents. Utility values will be collected using the CHU-9D questionnaire at baseline and 24 and 36 months. Student and teacher utility values will be collected (at baseline and at follow-up surveys 1 and 2) using the CHU-9D and by converting the SF-12 questionnaires respectively.

Process evaluation

The trial will incorporate an integral process evaluation. Data will be used to examine intervention implementation and receipt and hypothesise possible causal pathways, in order to facilitate interpretation of outcome data. In line with MRC guidance on complex interventions, this component of the trial will also enable refinement of the intervention logic model. Informed by existing frameworks, the process evaluation will examine the following:

Trial context: We will assess the context within the intervention and control arms, including what other relevant services and practices operate such as the nature of school discipline systems, staff training, social skills curricula and student participation in decision-making. This will draw on annual: interviews with intervention facilitators (n=5); telephone interviews with action-team members (n=2 per school) in intervention schools; interviews with SLT (n=1 per school) and other staff (n=2 per school) in intervention and control schools; and 2 focus group discussions (FGDs) with students and 1 FGD with staff in eight randomly selected intervention and control schools (purposively sampled by students participation, gender and age and staff participation and role), which will also allow us to explore mechanisms of actions.

Trial arm fidelity: We will assess the fidelity with which INCLUSIVE is delivered in each school. In addition to the above sources, we will draw on: annual structured quantitative researcher observational data of a random selection from each school of one action team meeting (n=20), staff training (n=20) and one curriculum session (n=20); structured diaries of action team meetings and staff training maintained by intervention facilitators in each school; qualitative data from action-team minutes (from 10 randomly selected schools in the full trial).

We will assess fidelity and acceptability rates for each facilitator.

Participation, reach and dose: We will assess the extent to which students and staff are involved in or in receipt of intervention processes and outputs. This will draw on quantitative data from 24 and 36 month follow-up surveys of students, staff and action group members. The last of these will also assess the extent to which members felt empowered to participate in decision making using a modified version of the Learner Empowerment Scale.

Reception and responsiveness: We will assess the *experiences* of participation in INCLUSIVE and in school environments shaped by this, to assess *acceptability and* any barriers or facilitators to this. This will draw on the annual interviews with action-team members (n=2 per school) in intervention schools; interviews with SLT (n=2 per school) and other staff (n=2 per school) in intervention and control schools; and FGDs with students in eight randomly selected intervention schools described above.

Intermediate outcomes: To assess possible intervention causal pathways and examine whether these mediate intervention effects in order to assess and refine our logic model, we will use two measures that examine students' perception of the school environment and their connection to the school:

a. **Beyond Blue School Climate Questionnaire (BBSCQ)**, which will be used to measure students' perceptions of the school climate. It consists of 28 items which produce an overall score and also assess four key domains of school climate (sub-scale): supportive teacher relationships, sense of belonging, participative school environment, and student commitment to academic values
b. **Student reports of anti-school actions** will be assessed using the ESYTC self-reported delinquency (SRD) sub-scale. Involvement with anti-school peer groups will be assessed using a single item measure previously used in the YPDP evaluation measure.

Analysis

Outcome analysis: All primary analyses will be carried out according to the principle of intention-to treat (ITT) and using multilevel modelling to take into account clustering at the school level. The primary analysis will be a repeat cross sectional analysis for two main reasons: (1) the intervention is a whole school intervention and, based on a school-level theory of change, is expected to impact on all pupils, not just on those pupils who were present at baseline; (2) the literature suggests that in cluster randomised trials, when migration into or out of the clusters is high over time, the baseline cohort may not remain representative of the cluster and therefore repeated cross-sectional analysis is preferred to minimise bias. Based on our pilot data and existing research on student mobility, we anticipate student turn-over of up to 25% in some schools over 36 months. Because of this we will use multilevel analyses that include all students at all time-points, which essentially provides a repeat cross sectional analysis with a nested longitudinal cohort.

Data will be analysed by appropriate multivariate regression models, fitting pre-hypothesised potential confounders as covariates. Note that data on ethnicity and socioeconomic status will be collected by self-report from students, using measures appropriate for adolescent self-report piloted by us in the phase II trial. Both primary outcomes will be fully analysed and reported separately, using separate multi-level models. A small number of secondary analyses based on explicit hypotheses, e.g. subgroup effects/ causal pathway analyses will be specified in advance. These will include a longitudinal analysis of pupils present at both baseline and follow up, with further analyses using individual level baseline data to explore the implications of missing individual level outcome data.

Secondary analyses will also examine moderators and mediators. We will examine whether intervention effects are moderated by individual-level gender and socio-economic status measured using the HBSC Family Affluence Scale and sex, as well as by school-level stratifying factors (single sex versus mixed sex school; school level deprivation; most recent Ofsted rating of overall school effectiveness); and facilitator, though these analyses may be underpowered. We will examine whether intervention effects are mediated by process and intermediate outcome measures. Other such analyses will be informed by hypotheses derived from analysis of qualitative data.

Economic analyses: The primary economic evaluation will be a cost-consequence analysis. We will undertake a cost-utility analysis as a secondary analysis. These analyses will be linked and use of both is consistent with NICE methods guidance for evaluating public health interventions. We propose using a multi-level modelling approach with random intercepts to estimate the mean and standard errors for both cost and effects along with the covariance matrix. From these data mean incremental net benefit and confidence intervals will then be estimated. Missing data will be handled using multiple imputation.

Process evaluation analyses: Qualitative data will be entered into the data analysis package NVivo, which will be used to manage and code data. Qualitative data from the process evaluation will be subjected to a thematic content analysis. Codes will be applied to transcripts, which identify key themes and how these inter-relate in order to develop an analytical framework. Each transcript will be coded to indicate the type of participant, school and date, allowing analytical themes to be explored in relation to different groups' experiences and to compare processes across schools. Drawing on methods associated with 'grounded theory', we will make constant comparisons and examine deviant cases to refine our analysis. Analysis will explore implementation and receipt and contextual factors affecting these, as well as potential causal pathways in order to develop hypotheses to examine in secondary moderator and

mediator analyses. Additionally, quantitative data from surveys and observations will be used in analyses of intervention fidelity and reach using simple descriptive statistics.

Ethical issues

Consent

Written consent will be obtained at school level (head-teacher) for random allocation and for intervention, and at the individual intervention facilitator, student and staff level for data collection. For students, written age-appropriate information sheets will be provided in class 1-2 weeks before the baseline survey, together with oral explanation by teachers. Written consent will be required from all participating young people, which will be collected immediately before conducting the baseline survey. Young people will also be asked to take home written information sheets for parents. Parents who do not wish their child to participate will be asked to notify this opt-out in writing using a prepared form.

Risk, burdens and benefits

Benefits: If successful, the INCLUSIVE intervention will result in the following benefits:

1. Reduction of bullying and aggression which will be of benefit to all participants, the whole school, local communities and society in general.
2. Reduction in other health-risk outcomes (e.g. substance use) and improvements in mental health, emotional well-being and quality of life.
3. Reduction in costs to society related to bullying and aggression. These include reductions in NHS costs (related to violence and mental health problems), and in social costs including costs within the justice system.
4. Benefits to school staff through increased access to restorative training and an improved school environment, which may improve staff well-being and quality of life.
5. Benefits to students who participate in the intervention, through opportunities for learning and improved self-efficacy.

Risks: There are no anticipated risks to participants or to schools. However as in all interventions, there may be unanticipated risks. Harms will be assessed through examination of outcomes at 24 and 36 months. An independent Data Monitoring Committee (DMC) will examine any potential harms at 24 months. If any major harms are detected, the DMC will inform the Trial Steering Committee (TSC) who will decide what action should be taken.

Our approach may be ineffective, and its introduction in trial schools may prevent the use of more effective techniques to reduce aggression. Although some educational interventions to raise awareness of risk behaviours during adolescence have been shown to increase participation in these behaviours, we believe this is extremely unlikely in the case of this study because as our approach is based upon what is shown to be effective in systematic reviews. Because of the above, we believe that risks are minimal and that benefits justify the risks.

Study Governance

Trial documentation: Relevant trial documentation will kept for a minimum of 15 years.

Trial registration and conduct: The pilot study was registered with controlled-trials.com (ISRCTN 88527078) and the full trial will be similarly registered. Note that as the trial is not within clinical settings nor using clinical samples nor using a medicinal product, there is no requirement to comply with the 'The Medicines for Human Use (Clinical Trials) Regulations 2004'. We will follow the MRC Guidelines on Good Clinical Practice in Clinical Trials. Note that the CI and the majority of the other investigators have been trained in Good Clinical Practice for clinical trials.

Sponsor: The UCL Institute of Child Health, the employer of the CI, will act as the sponsor of this trial.

Trial Steering Committee (TSC): The trial will be overseen by a TSC, including an independent chair, at least two other independent members, and a Patient and Public Involvement representative, and an investigator representative of each institution involved in the research. The TSC formed for the pilot trial has agreed to continue for the full trial (Chair: Prof. Rona Campbell, Bristol University; other members listed in the uploaded pilot trial report). Observers from the HTA programme will be invited to all TSC meetings. The TSC will meet 6 monthly throughout the trial. A monitoring schedule covering the roles and responsibilities of the Researcher, Project Team, Management Committee and TSC for monitoring recruitment, data quality, compliance, safety and ethics will be developed and agreed.

Data Monitoring and Ethics Committee (DMC): A DMC will be established independent of the investigators and of the TSC, but reporting to the TSC and (via the TSC) to the sponsors and the HTA programme. This will consist of an independent chair, a senior statistician and at least one other senior academic independent of the investigators. This will meet approximately yearly during the study. The DMC will monitor data for quality and completeness. Data quality, follow-up and trial monitoring will be facilitated through the development of a trial specific database, including validation, verification, monitoring and compliance reports and follow up report functionalities. The DMC will examine the results of an interim analysis at 24 months both to consider any potential harms.

Study management: RV will direct the study together with CB as co-director. The intervention and research teams will be functionally independent. The research team will be managed by RV with CB and Anne Mathiot an experienced full-time trial manager based at the UCL Institute of Child Health. CB will direct the process evaluation. An executive of RV, CB, MW and EA will meet monthly with the trial manager. The trial manager will have day to day responsibility for the conduct of the trial and the operations of the research team, and report to the study executive and ultimately to RV. The investigator group will form the Scientific Steering Committee for the study and meet four-monthly throughout the trial. Responsibility for data integrity and analysis will be held by the CTU at the LSHTM.

The intervention team will be managed by MW at the Institute of Education, together with Miranda Perry, the intervention manager who will direct day-to-day operation of the intervention and coordinate the educational facilitators. Note that MW will form part of the Scientific Steering Committee.

Timetable

Month	Milestone
Month (-4) to 0 (Pre set-up)	• Ethics authorisations obtained • Identification of potentially eligible schools and initial written approaches to 350 schools. • Identification of potential pool of approximately 80 interested schools
M1-3 (Mar-May 2014) Set-up & Recruitment	• Recruitment of 40 schools from pool of interested schools; • Recruitment of field workers. • Preparation of instruments • Recruitment of educational consultants (continues to July)
Apr-July 2014	• Baseline surveys of Year 7 groups, who will be in Year 8 for 1st intervention year • Randomisation of schools (after baseline surveys) • Timetabling of intervention and training for next school year in schools allocated to intervention
M8 (Sept 2014)	• Needs assessment data feedback to intervention schools • Beginning of 2 year facilitated intervention M8 to M 29
M17-18 (Apr-July 2015)	• Repeat needs assessment survey in intervention schools
M18 (July 2015)	• End of intervention Year 1
M20 (Sept 2015)	• Feedback of repeat needs assessment & beginning of 2nd intervention year

M29-30 (Apr-July 2016)	• Follow-up survey 1 with collection of secondary outcome data
July 2016	• End of intervention Year 2 (end of externally facilitated intervention)
M31 (August 2016)	• Interim analysis for DMC
M32 (Sep 2016)	• Start of third intervention year (internally facilitated)
M41-42 (Apr--July 2017)	• Collection of Primary Outcome and Secondary outcome data through follow-up survey 2
July 2017	• End of intervention Year 3
M43-47 (August – December 2017)	• Data cleaning and final database preparation • Analysis and report preparation
M48 (Feb 2018)	• End of project • Submission of project report

Annex 1: Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made