Pilot Cluster RCT of Project Respect: a school-based intervention to prevent dating and relationship violence and address health inequalities among young people

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Protocol

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Background

Dating violence and public health

Dating and relationship violence (DRV) is the term applied to intimate partner violence during adolescence(1, 2). The term encompasses threats, emotional abuse, controlling behaviours, physical violence, and coerced, non-consensual or abusive sexual activities perpetrated by a current or former casual or steady partner(3). Globally, 10-50% of women report violence from current or previous partners at some point in their lives(4) with prevalence highest among girls in adolescence.(5-8) Most young people perceive few peer sanctions against DRV,(9) and norms accepting of gender based violence and harassment strongly correlate with DRV perpetration and victimisation.(7, 8, 10-12) Young people who experience dating violence are more likely to be victims or perpetrators of relationship violence as adults.(13, 14) Early experience of dating violence is also associated with subsequent adverse outcomes such as: substance misuse and anti-social behaviour;(15-18) sexually transmitted infections (STIs) and teenage pregnancy;(19) eating disorders;(20), suicidal behaviours and mental health problems;(21, 22) physical injuries;(23) and low educational attainment.(24) During pregnancy, DRV correlates with poorer maternal and neonatal health outcomes(19, 25). In 2008, it was estimated that domestic violence cost the NHS £1.73bn per year with total costs to the UK of £15.73bn per year.(26)

Interventions

Recent Cochrane and Campbell reviews of DRV prevention for young people have meta-analysed effects on behavioural, attitudinal and knowledge outcomes, respectively finding overall effects on knowledge and on knowledge and attitude, but not behaviour.(27, 28) However, more promising results for behaviour are reported from randomised controlled trials (RCTs) of the Safe Dates and Shifting Boundaries interventions.(29, 30) These were included in the Campbell but excluded from the Cochrane review; exclusion of Safe Dates and Shifting Boundaries from the Cochrane review being because of incomplete reporting and recent publication respectively. The authors of the Cochrane review noted that non-inclusion of Safe Dates was a major limitation of their review. These interventions were also identified in a broader review of interventions to prevent sexual violence perpetration as the only effective interventions addressing this among young people.(31) The Safe Dates curriculum was delivered over ten sessions to eighth and ninth grade students (aged 13-15 years) in North Carolina, USA and focused on: the consequences of DRV; gender roles; conflict management skills; and student participation in drama and poster activities. A school cluster RCT(29, 32) reported significantly reduced perpetration of physical DRV and victimisation of serious physical DRV (p value < 0.05 for both) and significantly reduced perpetration and victimisation of sexual DRV (p value = 0.04, 0.01 respectively) at 4-year follow-up. The duration of these effects suggests these might be real behavioural effects rather than merely social desirability effects on reporting. The intervention was equally effective for males and females.(33) A four-arm school cluster RCT of the Shifting Boundaries interventions allocated schools to receive a 1) curriculum intervention, 2) a school environment intervention, 3) combined intervention or 4) neither intervention.(30) The curriculum comprised six sessions on the consequences of DRV, the social construction of gender roles and what constitutes healthy relationships. The environment intervention included: higher levels of staff presence in hot-spots for gender-based harassment mapped by students; posters; and increased sanctions for perpetrators. The environment and the combined interventions were effective in reducing sexual violence victimization at 6-months follow-up (respectively OR=0.662 p=0.028; OR=0.659 p=0.011). There were also reductions in sexual violence perpetration in the environment-only and combined intervention (respectively OR=0.527 p=0.002; OR=0.524 p=0.001). No such effects were reported for the curriculum-only intervention. Results show similar benefits for both sexes and for those with and without a history of DRV.(34) The Cochrane review recommended that further research on multi-component interventions in schools is a priority. The Campbell review recommended that future interventions more explicitly address skills and the role of peer norms in preventing DRV. Recent NICE guidance on domestic violence has also highlighted the lack of current evidence for interventions preventing adolescent DRV.(35)

Rationale for proposed study

There is a pressing need to prevent DRV in the UK. Recent surveys of English young people suggest victimisation prevalence of 66-75% for young women and 32-50% for young men aged 14-17 years.(36, 37) Universal, primary prevention of DRV is required since these behaviours are widespread and under-reported rendering targeting challenging.(38) Prevention during early adolescence is important because this is the time when dating behaviours begin, behavioural norms become established, and DRV starts to manifest.(39, 40) Schools are a key site to achieve this since these are settings in which young people are socialised into gender norms and in which significant amounts of gender-based harassment and DRV go unchallenged.(41, 42) Multi-component interventions for example addressing school curricula, policies and environments are required(43) because DRV arises not only from individual deficits in communication and anger management skills(44), but also from sexist gender norms and pervasive gender based harassment(23, 45-47). There is thus a pressing need for a UK RCT of a universal multi-component, school-based prevention intervention targeting early adolescents informed by existing evidence. Project Respect is a UK intervention addressing similar topics to those targeted by the effective curriculum used in the Safe Dates study and also addressing the school environment in a manner similar to the Shifting Boundaries intervention. A UK-specific intervention is needed because direct replication of a US intervention is unlikely to be effective in the UK given cultural differences.(48) We have already developed the logic model, theory of change and intervention components for Project Respect. In the proposed project, we will begin by collaboratively elaborating and optimising the intervention and producing the manual, curriculum and other intervention materials. We will then subject Project Respect to a pilot cluster RCT to assess feasibility and acceptability and optimise methods prior to a phase III RCT. This would be the first UK RCT of an intervention to prevent DRV among young people.

Benefits and risks

There are major potential public health benefits arising from the prevention of adolescent DRV as suggested above. Project Respect includes a curriculum addressing similar topics to the Safe Dates curriculum and like the Shifting Boundaries intervention also addresses environmental determinants of DRV. Neither the intervention nor the research study are likely to pose any physical or psychological risks to research participants.(49) Participants will be informed that participation is voluntary and that they may withdraw at any point. Ethical issues are addressed below. Any potential mechanisms of harmful effects of the intervention will be explored through qualitative data in this pilot RCT and in later evaluation phases. We will closely liaise with participating schools to facilitate data collection with students. We will minimise disruption for staff and ensure student privacy and confidentiality both by employing previously successful strategies, such as having the trial manager liaise directly with each participating school to identify convenient times and places for data collection, and by piloting innovative methods in this context, such as the use of computer assisted self-interview (CASI) surveys.

Research aims, research questions and objectives

Aims

I. With stakeholders, to elaborate and optimise Project Respect informed by existing research.
II. To conduct a pilot RCT (four intervention, two control schools) in southern England.

Research questions

1. Is progression to a phase III RCT justified in terms of pre-specified criteria?: randomisation occurs and four or more schools out of six accept randomization and continue within the study; the intervention is implemented with fidelity in at least three of the four intervention schools; the process evaluation indicates the intervention is acceptable to 70% or more of year 9 and 10 students and staff involved in implementation; CASI surveys of students are acceptable and achieve response rates of at least 80% in four or more schools; and methods for economic evaluation in a phase III RCT are feasible.
2. Which of two existing scales - the Safe Dates ('SD') and the short Conflict in Adolescent Dating Relationships Inventory ('CADRI') - is optimal for assessing DRV victimisation and perpetration as primary outcomes in a phase III RCT, judged in terms of completion, inter-item reliability, and fit?
3. What are likely response rates in a phase III RCT?

4. Do the estimates of prevalence and intra-cluster correlation coefficient (ICC) of DRV derived from the literature look similar to those found in the UK so that they may inform a sample size calculation for a phase III RCT?
5. Are secondary outcome and covariate measures reliable and what refinements are suggested?
6. What refinements to the intervention are suggested by the process evaluation?
7. What do qualitative data suggest about how contextual factors might influence implementation, receipt or mechanisms of action?
8. Do qualitative data suggest any potential harms and how might these be reduced?
9. What sexual health and violence related activities occur in and around control schools?

Objectives

a. To elaborate and optimise Project Respect and produce intervention materials in collaboration with the National Society for the Prevention of Cruelty to Children (NSPCC), four secondary schools, youth and policy stakeholders, and the originators of effective US programmes informing our intervention.
b. To adapt and cognitively test the 'SD' and 'CADRI' scales prior to piloting.
c. To recruit six schools, undertake baseline CASI survey of two cohorts of students at the ends of year 8 and 9 respectively plus online staff survey, and randomise four schools to receive the intervention and two to be usual-treatment controls (see Appendix 1).
d. To ensure Project Respect is implemented for students in years 9 and 10 and conduct process evaluation, plus follow-up student CASI and staff online surveys 16 months post baseline.
e. To address the above research questions to inform progression to a phase III RCT.

Research design

1) Intervention elaboration and optimisation and DRV scales cognitive testing

The core components of the intervention and the underlying theory of change have already been determined informed by existing research including on the Safe Dates and Shifting Boundaries interventions and existing systematic reviews and other evidence described above. Further work is required March-September 2017 to elaborate the intervention methods and produce materials (manual, staff training, student curriculum), optimising these for use in the UK. This process will be led by the investigators and NSPCC working in close collaboration, and with the participation of students and teachers drawn from four secondary schools (different to those to be involved in the pilot RCT) as well as the ALPHA young researchers group and policy stakeholders. This will involve a systematic process involving: review by researchers and NSPCC of existing systematic reviews and evaluation reports; elaboration of Project Respect methods and production of draft materials by NSPCC staff and the research team; consultation with stakeholders on these via two facilitated workshops and web-based consultation; and refinement of these. At the same time, we will adapt two existing DRV scales and refine the adaptations through cognitive testing, a method to improve survey questions through pre-testing to identify problems respondents encounter with the items. This is so that these may then be piloted in order to determine which is optimal for measuring DRV victimisation and perpetration as our primary outcomes in a phase III RCT. The testing will also include selected items on attitudes and norms related to gender and DRV. Cognitive testing will occur in one of the schools participating in intervention elaboration, involving eight male and eight female students. Students will complete paper questionnaires covering basic socio-demographics followed by the two DRV scales. These students will then be interviewed and asked to 'think aloud' about how they answered the questions(50) with some probing(51) about comprehension, recall, judgement and response in relation to each item.(52)

2) Pilot RCT

We will then conduct an external pilot cluster RCT (four intervention, two control schools; different to those involved in intervention elaboration and any subsequent phase III RCT), with integral process evaluation and economic evaluation feasibility study. In this phase (and the phase III RCT), the research and intervention teams will be separately managed to ensure the evaluation is independent and does not distort intervention delivery. Although in the phase III RCT the intervention will be delivered for two academic years (targeting students progressing from year 9 to year 10), in this pilot RCT the intervention will be implemented for one school year to students in years 9 and 10. One year is sufficient to assess feasibility and acceptability in order to address our research questions. Similarly, although a future phase III RCT will involve follow-up surveys at 28 months post baseline, in the pilot RCT proposed here, follow-up surveys will occur 16 months post-

baseline because this is sufficient to assess the feasibility of trial methods among a population of the same age as that in a phase III trial at 28 months. Due to the sensitive nature of the baseline and follow-up student surveys, we will use a repeat cross-sectional rather than longitudinal design. The follow-up surveys will be conducted with the same two cohorts of students who took part in the baseline survey, but surveys will not be linked at the level of the individual. This design does not require that we link respondent names to the responses they submit, therefore protecting students' anonymity.

Setting

Project Respect is intended for all secondary schools (including free schools and academies). If our phase III RCT suggests that Project Respect is effective, we will consider developing new studies aiming to adapt the intervention for pupil referral units (PRUs). There is no clear evidence that DRV among UK adolescents is associated with individual socio-economic status (SES) or school-level deprivation.(37, 53) Evaluating Project Respect in a sample of schools over-representing those in deprived areas would therefore unnecessarily undermine the generalisability of our findings.

Pilot (and subsequent phase III) trial inclusion criteria

- Secondary schools (including free schools and academies) in southern England.

Pilot (and subsequent phase III) trial exclusion criteria

- Private schools, PRUs or schools for those with learning disabilities.

Population

As with similar previous studies,(29, 30) Project Respect is a universal intervention for male and female students aged 13-15 (in years 9 and 10 in UK schools). This age group is appropriate because this is the time when dating most behaviours begin, behavioural norms become established and DRV starts to manifest.(39, 40) PPI suggests provision to year 11 students is not feasible because of GCSE preparation. In the pilot RCT, the intervention will run for one year only, targeting years 9 and 10 students, so that we may assess the intervention feasibility and acceptability rather than assess effectiveness.

Pilot trial inclusion criteria

- Students nearing the end of years 8 and 9 at baseline survey.

Pilot (and subsequent phase III) trial exclusion criteria

- No students in participating schools will be excluded from our study. Those with mild learning difficulties or poor English will be supported to complete the questionnaire by fieldworkers.

Analytic sample and proposed sample size

The pilot RCT will focus on feasibility and no power calculation for this has been performed. The analytic sample for outcome assessment in the pilot will be a minimum of 1800 students at the ends of years 8 and 9 (age 12/13 and 13/14) at baseline, with follow up at 16 months. A preliminary sample size calculation for the full RCT employing a repeat cross-sectional analysis is that for at least 80% power and 5% significance we will require 20 schools per arm to detect a relative risk (RR) reduction to 0.72 conservatively assuming: 150 students per school; drop out of two schools per arm; 80% response rates at 28 months among remaining schools; an ICC of 0.07 for our primary outcome; and prevalence of DRV of 50% among those in the control arm at 28 month follow up. Our effect size is conservative, i.e. smaller than those on DRV reported in the Safe Dates and Shifting Boundaries RCTs(17, 23, 30, 32), but of public health significance for social interventions. The prevalence of DRV used in the sample size calculation is a conservative estimate informed by recent surveys of English young people suggesting victimisation prevalence of 66-75% for young women and 32-50% for young men age 14-17 years.(36, 37) Published ICCs for measures of DRV range from <0.02 to 0.07(54-56) derived from age cohorts comparable to ours but from North American samples. Our pilot RCT will explore whether these estimates look similar to those found in this UK sample to inform a power calculation for a future proposal for a phase III RCT (see Analysis).

Recruitment and randomisation

Four schools will be involved in intervention elaboration and optimisation, purposively sampled to vary by region and deprivation (as measured by the income deprivation affecting children index, IDACI). In the subsequent pilot RCT phase, three schools in south-east England and three schools in south-west England

will be recruited (different from those participating in optimisation). These will purposively sampled to ensure variation by deprivation and school-level value-added academic attainment, as approximate indicators of school capacity to deliver Project Respect. School recruitment will proceed via letters and phone calls to schools, local authorities, academy chains and school networks. Response rates will be recorded, as will any stated reasons for non-participation. In a phase III RCT, we currently anticipate recruiting 40 schools (inclusion criteria as above; no purposive criteria). In the pilot RCT, after baseline CASI surveys with students at the end of years 8 and 9, schools will be randomly allocated 2:1 to intervention/control (1:1 in full trial) remotely by LSHTM clinical trials unit, stratified by region. The original plan was to stratify by value-added academic attainment in the pilot trial but the investigators concluded it would be more appropriate to stratify by region. Unlike a phase III RCT in which stratification is used to increase the probability that intervention and control arms are similar at baseline, in a pilot trial where the main focus is on examining feasibility the purpose of stratification is to ensure there is sufficient diversity on the factor used to stratify in the intervention arm and in the control arm so that the extent to which that factor affects feasibility can be assessed. Initial consultation with schools suggested that while there was a considerable demand for an intervention addressing dating and relationship violence in London and the south east region (and a demand which was no different among schools with high and low value added attainment), the demand appeared to be somewhat less strong in Bristol and the south west. The investigators therefore concluded that it would be more important to explore the feasibility of intervention in a diversity of schools with regard to region than with regard to value-added educational attainment. The 2:1 allocation in the pilot will enable us to pilot randomisation while ensuring sufficient diversity among four schools for piloting the intervention. In a phase III RCT, schools will be allocated 1:1 to intervention and control, stratified by sex of intake and school value-added attainment as key predictors respectively of DRV victimisation/perpetration and school capacity to implement Project Respect. Retention of control schools will be maximised via £500 payment and feedback of survey data.

Planned interventions

Intervention components

Project Respect is a manualised, multi-component school-based universal prevention intervention. It will comprise the following components: (a) training by NSPCC; for senior leadership (where appropriate including governors) and other key staff (pastoral support; personal, social and health education curriculum deliverers) to enable them to plan and deliver the intervention in their schools and review school rules and policies to help prevent and respond to gender-based harassment and DRV, and increase staff presence in 'hotspots' for these behaviours; (b) training by these trained school staff of all other school staff in safeguarding to prevent, recognise and respond to gender-based harassment and DRV; (c) written information for parents on the intervention and advice on preventing and responding to DRV; (d) making available to students the 'Circle of 6' app which helps individuals contact friends or the police if threatened by/experiencing DRV but disguised as a games app (http://www.circleof6app.com/); and (e) classroom curriculum delivered by teachers to students age 13-15 including student-led campaigns. The NSPCC will further support intervention delivery by offering weekly one-hour advice sessions to intervention schools. Intervention schools only will be able to access a website to access intervention materials. The interventions will address DRV perpetrated both by young men and young women in heterosexual or same-sex relationships. School policies and rules will be rewritten to ensure these aim to prevent and respond to DRV. Hotspots for DRV and gender-based harassment on the school site will be patrolled by staff to prevent and respond to incidents. Responses will include appropriate sanctions for perpetration, support for victims, and referral of victims or perpetrators to specialist services where necessary. We anticipate that our curriculum will comprise only six sessions in year 9 and two booster sessions in year 10 to ensure it can be implemented in busy school timetables in tutorial, PSHE or other sessions. Lessons will focus on: 1) defining healthy relationships and inter-personal boundaries; 2) challenging gender norms and mapping 'hotspots' for harassment and violence on the school site; 3) empowering students to run campaigns challenging gender-based harassment and DRV in and beyond their schools (for example, posters, social media, stalls); 4) communication and anger management skills relating to relationships and intervening as bystanders; 5) accessing local services relating to DRV; and 6) reviewing local campaigns. Learning activities will include: information provision; whole class discussions; use video vignettes to help students identify abusive

relationships; quizzes; role plays and exercises like measuring personal space; and cooperative planning and review of local campaigns. Schools that are randomly allocated to the intervention will be asked to continue with usual provision in addition to implementing the Project Respect intervention.

Theory of change (see Appendix 2)

Project Respect is underpinned by the theory of planned behaviour(57) and the social development model,(58) supported by reviews which suggest that interventions should challenge attitudes and perceived norms concerning gender stereotypes and violence, as well as support the development of skills and control over behaviour.(43) Informed by the theory of planned behaviour, Project Respect will aim to reduce DRV by challenging student attitudes and perceived social norms about gender, appropriate behaviour in relationships and violence, and promoting student sense of control over their own behaviour. A key element of our theory of change is that attitudes and norms will be challenged not only via the student curriculum but also via school-environmental actions to reduce gender-based harassment observable on the school site and increase school sanctions against gender-based harassment and DRV. Sense of control over behaviour will be promoted via the student curriculum promoting communication and anger management skills. Informed by the social development model, Project Respect will enable student participation in curriculum lessons and leadership of campaigns in order to maximise learning and increase student bonding to school and acceptance of school behavioural norms. The curriculum also aims to reduce DRV by ensuring those exposed to this are able to seek early support via promoting awareness of the Circle of 6 app and local services.

Providers and funding

In close collaboration with the research team, NSPCC will lead the intervention elaboration and optimisation, and the production of materials. In the delivery phase within the pilot RCT, NSPCC will work independently from the research team to train SLT and other key staff: in safeguarding to prevent, recognise and respond to gender-based harassment and DRV; to enable them to lead the intervention in their schools; to review school rules and policies to help prevent and respond to gender-based harassment and DRV, and increase staff presence in 'hotspots' for these behaviours. School staff will then implement the school environment and curriculum components, cascading training in safeguarding to all staff. In this feasibility study, we are seeking NIHR funding for intervention elaboration and refinement but not delivery, which will be funded by NSPCC. If found to be effective in a phase III RCT, the intervention would be scaled up by the NSPCC. Delivery costs would be met by schools, academy chains, local authorities and/or NHS commissioners as is the case with other school-based health promotion interventions.

Comparator

The comparator in this pilot and a subsequent phase III RCT would consist of schools randomly allocated to the control group, and not implementing Project Respect but continuing with any existing gender, violence or sexual health-related provision. At the request of NSPCC, we will undertake a number of additional activities: NSPCC will offer a support session to the safeguarding officers of all schools in case they experience increased numbers of students seeking support as a result of the research (though all schools will receive this support session, this will take place before the baseline surveys and therefore before randomisation); the research team will provide a short report to intervention and control schools about the prevalence of DRV; and NSPCC will brief its 'Childline' telephone helpline staff so that they are aware of the project in case the research or intervention results in students contacting them. While these activities mean that the experience of control schools will differ slightly from treatment as usual we felt this was a measured response essential to fulfill our duty of care to trial participants while not excessively distorting the nature of our comparator. The nature of the comparator will be assessed within the current pilot RCT by examining provision in and around comparator schools as well as intervention schools at baseline. It would also be examined within a phase III RCT in the integral process evaluation.

Outcome measures

Pilot RCT

In the pilot RCT, the primary outcome will be whether progression to a phase III RCT is justified in terms of the pre-specified criteria listed above. The pilot RCT will also determine which of two existing DRV scales will be used as primary outcomes measuring DRV victimisation and perpetration in a phase III trial.

Phase III RCT

In a phase III RCT, primary and secondary outcomes would be assessed via self-reports at 28 months (age 15/16 years). The twin primary outcomes would be binary measures of DRV victimisation and perpetration, measured using self-reports rather than via routine data because most episodes of DRV will not result in notifications to the school, police or NHS(27) and our intervention is likely to increase rates of such notifications with the risk of ascertainment bias. While our intervention may also result in increased self-reports, this reporting bias will be minimised by use of a validated and reliable measure comprising items focused on specific behaviours. We are currently uncertain whether the 'SD' or short 'CADRI' measure is the optimal scale to assess DRV victimisation/perpetration as primary outcomes so we will adapt and pilot these measures in the pilot RCT to determine which is most suitable. The Safe Dates measure of dating violence is based on self-reported perpetration and victimization of psychological abuse and of physical and sexual violence in the previous year. It covers all the aspects of DRV discussed above. Participants are asked "How often has anyone that you have ever been on a date with done the following things to you?" Response options range 0-3 indicating frequency. Items are summed and then recoded 0-3 indicating overall degree of abuse. Psychological abuse is assessed in terms of 14 acts (Cronbach's alpha=.91 for victimisation and .89 for perpetration(59, 60)). Physical and sexual violence are assessed in terms of 18 acts, 6 of which indicate serious physical violence and 2 indicate forced sexual acts. Cronbach's alphas for perpetration of moderate physical violence=.92, for severe physical violence=.89 and sexual violence=.86. For victimisation, Cronbach's alphas are respectively are .90, .86 and .74.(60) The Safe Dates measure is one of the most commonly used in research on adolescent dating violence (61) and correlates with poor mental health and various health risk behaviours.(62-64) Reliability has been examined in multiple studies of adolescents but not to date in the UK. We will add introductory text clarifying our interest in on/offline behaviours. Our primary outcome will examine categorical measures of DRV dating violence perpetration and victimisation while secondary outcomes will examine each subscale. The 'CADRI' measure comprises 92 items assessing DRV victimisation and perpetration over the past two months. Subscales cover emotional abuse, relational abuse, controlling behaviours, physical violence, and non-consensual sexual activities. Items are rated on a 4-point scale according to frequency, allowing generation of a binary measure of prevalence or a quantitative measure of frequency created from the summed score divided by the number of items. Research has found that DRV as measured via the 'CADRI' scale is correlated during adolescence with early sexual debut, unsafe sex, violence and suicidal ideation.(65) The 'CADRI' instrument has been used in research with young people in US and Canadian studies(66, 67) as well as Spain (68) though not the UK. However, the use of this measure within trials is problematic due to its length. A 10-item version of the 'CADRI' has been developed and piloted among school-based samples of 9-12th graders and at-risk samples in Canada. The new measure was found to be slightly less sensitive than the full questionnaire but to have good reliability, fit and convergent validity with the full measure.(69) We plan to further assess this short version. We will modify the scale by adding text clarifying to participants our interest in on- and off-line behaviours and adding two items from the original 'CADRI' to assess experience of controlling behaviours. The developers of the SD and CADRI have permitted our use and modification of these measures. We propose to use the pilot RCT to refine the two existing measures, cognitively test these to inform further refinements and then pilot the measures, assessing completion rates, inter-item reliability (using Cronbach's and ordinal alphas), and fit (using confirmatory factor analysis) to determine which one should be used to measure DRV victimisation and perpetration within a phase III RCT.

Informed by our theory of change, secondary outcomes in a phase III RCT will examine:

-DRV frequency of victimisation and perpetration (using the above measures).

-Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS). This is a 7-item scale designed to capture a broad concept of positive emotional well-being including psychological functioning, cognitive-evaluative dimensions and affective-emotional aspects.(70) Items are rated on a 5-point scale: none of the time, rarely, some of the time, often, all of the time. The responses are scored and aggregated to form a 'well-being index' with higher score representing greater well-being.(71)

-Paediatric quality of life inventory (PedsQL) version 4.0. This is used to assess overall quality of life. The 23-item PedsQL(72) has been shown to be a reliable and valid measure of quality of life in normative adolescent populations. It consists of 23 items representing five functional domains: physical, emotional, social, school and well-being, and yields a total score, two summary scores for 'physical health' and 'psychosocial health' and three subscale scores for 'emotional', 'social', and 'school' functioning.

-Sexual harassment (73).
-Strengths and Difficulties Questionnaire (SDQ). This is a brief screening instrument for detecting behavioural, emotional and peer problems and pro-social strengths in children and adolescents. It is validated in national UK samples.(74)
-Self-reported sexual health. We will examine pregnancy and unintended pregnancy (initiation of pregnancy for boys) and STIs, age of sexual debut, partner numbers, and use of contraception at first and last sex using measures from previous RCTs.(75, 76)
-Self-reported use of primary care, accident & emergency, other service in past 12 months.
-Self-reported contact with police.(77)
-School attendance and educational attainment via routine school-level data on half-days absent and GCSE performance for the year-groups in question.

Informed by our theory of change, we will also examine the following mediators:
-Social norms and gender stereotyping. We will use a modified version of a multi-item subscale developed by Foshee(23) measuring acceptance of prescribed norms (acceptance of dating violence under certain circumstances) using a 4-point Likert scale format, and adapt these items to measure beliefs about others' attitudes towards dating violence. Items are averaged to create a composite score.(23) We will use a modified version of items used by Cook-Craig et al. to measure DRV descriptive norms (how common respondents believe the behaviour is).(79) We will measure gender stereotyping using a modified version of the 16-item Attitudes Towards Women Scale, which has high reliability, and uses a 4-point Likert scale format. We will adapt these items to measure beliefs about others' attitudes towards these stereotypes.(80)
-Self-reported awareness of services, and help seeking for victims and perpetrators will be assessed by existing single item self -report measures.(23)
-Communication and anger management will be assessed by the Modified Sexual Communication Survey and SDQ respectively. MSCS measures open sexual communication with a current or potential partner.(81) The modified scale includes 21 eight-point Likert scale items examining frequency. The scale has excellent reliability.(82, 83)
-Dating violence knowledge. This will be measured via a modified version of the reliable multi-item scale involving true/false questions on definitions of abuse, resources for help, etc.(30).
-Downloading and use of the 'Circle of 6' app (http://www.circleof6app.com/) will be measured by a new single-item measure.

All these measures will be assessed for reliability in our pilot. Items with sensitive sexual content will be included in follow-up but not baseline student surveys to ensure surveys are age-appropriate.

Economic outcome measures

In this pilot project, the aims are to plan the economic evaluation that would accompany the phase III trial, identify sources of data, and how best to collect these. We will: undertake a detailed cost analysis of the intervention; collect resource use data as per our proposal and examine response rates and data quality; use the process evaluation to identify any costs to students, schools and NSPCC not included so that if necessary we can amend our list of cost components to be included in the phase III trial; use the process evaluation to consider ways of maximising responses to economic data collection; identify unit costs for the cost components; and review the existing literature again to identify any new potential sources of data to model long-term costs and outcomes. In a phase III RCT the primary economic evaluation will take the form of a within-trial cost-utility analysis, with health outcomes expressed in terms of Quality-Adjusted Life-Years (QALYs). Changes in health-related quality-of-life will be measured primarily from the study participants' perspectives with a secondary analysis examining teacher outcomes. Within the phase III RCT, the Child Health Utility (CHU) 9D measure[72] will be used to assess students' 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. For teachers, we will use the SF-12 for this purpose[68]. In the phase III RCT, student and teacher utility values will be collected (at baseline and 28-month follow-up) using the CHU-9D and by converting the SF-12 questionnaires respectively. It is anticipated that these measures would be used in a phase III RCT to measure short-term impact on health-related quality of life. These measures will be assessed for reliability in the pilot RCT. In addition, a cost consequence analysis will be presented with further outcomes. The time horizon will capture costs and outcomes within the trial. In terms

of costs, NICE's public health methods guidance recommends that the base-case cost-effectiveness estimate is presented from a public sector perspective. We will do this but given Project Respect is to be delivered by a charity, our costing perspective will also be extended to include the third i.e. voluntary sector.

Assessment and follow up

Pilot RCT

Baseline surveys will be done before randomisation with two cohorts of students, one nearing the end of year 8 (age 12/13) and one nearing the end of year 9 (age 13/14), in May-July 2017. Baseline surveys will collect data on socio-demographic variables, pre-hypothesised outcome variables and potential confounders. Where feasible, surveys will be done at the same time of day in all schools. Prior to all data collection, students will be given an information sheet at least one week in advance, and an oral description of the study prior to consent being sought with the opportunity to ask questions. We will be clear about the topics to be explored and the total anonymity of questionnaire data. Students will then be invited to assent to participate in data collection. Students will be provided with information about school and where relevant other local safeguarding officers and national helpline and other agencies for those experiencing DRV and other forms of abuse. As is conventional with UK trials in secondary schools including of sexual health and violence prevention interventions, (75, 84, 85) parents/guardians will be sent a letter and detailed information sheet at least one week prior to data collection and asked to contact the school or research team should they have questions or not wish their child to participate. We have previously used pen-and-paper questionnaires including for research on sensitive topics. However, given the particularly sensitive nature of DRV, we will pilot the use of tablet based CASI to increase student privacy and collect data of better quality. Surveys will be completed confidentially and anonymously by students with researchers present to explain data collection and support students where necessary. Teaching staff will be present but will remain at the front of the classroom, helping to maintain order but being unable to read student responses. We will question students on the acceptability of this. We will survey absent students by leaving paper questionnaires and stamped addressed envelopes with schools. We will survey students at 16 months (September-October 2018) near the beginning of years 10 and 11 (age 14/15 and 15/16) and will collect self-report data on intervention participation, outcomes and potential mediators. Fieldworkers will be blind to allocation. Based on past experience,(84) in the pilot we expect 95% baseline survey participation and 90% at follow-up. Staff will also be surveyed online at baseline and 16 months for our economic and process evaluations.

Phase III RCT

Baselines would occur before randomisation with one cohort of students as they near the end of year 8 (age 12/13). Primary and secondary outcomes would be assessed at 28 months with students at the start of year 11 (where our previous experience suggests 80% follow up is feasible).(75)

Process evaluation

Integral process evaluation informed by existing frameworks(86-88) has three purposes: first, to examine intervention feasibility, fidelity, reach and acceptability ; second, to assess provision of sexual health and violence prevention in and around control schools; and third, to explore context and potential mechanisms of action including potential unintended effects, in order to refine the intervention theory of change and methods.

Intervention feasibility, fidelity, reach and acceptability

In addition to assessing the 'progression criteria' relating to intervention feasibility and acceptability (see above), we will also examine reach and how this varies by student and school characteristics. Data will be collected via: audio-recording of all NSPCC and school-delivered training (fidelity); logbooks completed by teaching staff delivering all curriculum sessions (feasibility, fidelity, costs); structured observations of a randomly selected session per school of one curriculum lesson (fidelity); student surveys (reach, acceptability); staff survey (reach, acceptability of training and intervention overall); interviews with the two NSPCC trainers (feasibility, fidelity); interviews with four staff per intervention school purposively sampled by seniority/which intervention component involved in (acceptability, fidelity); interviews with two parents per intervention school purposively sampled by age and sex of child (acceptability); and interviews with eight

students per intervention school, purposive by year 9/10, sex and whether or not they were involved in intervention delivery (acceptability). Fidelity will be assessed quantitatively against tick-box quality metrics which will form an integral part of each intervention component. For example: each training and curriculum session will be assessed against session-specific quality metrics relating to the topics covered, the exercises used and opportunities for discussion. The precise fidelity metrics to be used cannot be finalised until the intervention is fully elaborated (which will occur in September 2017). The investigators will finalise fidelity metrics by September 2017 and ask the Study Steering Committee (SSC) to approve these prior to their use in the process evaluation. Interviews will occur in private rooms by trained researchers guided by semi-structured interview guides. Although qualitative research will not aim to explore students' personal experiences of sex, relationships or dating and relationship violence, disclosures of abuse may occur within interviews. In focus groups we would instruct all participants not to disclose any experiences of abuse since we could not guarantee that all participants would keep this information confidential, though disclosures could potentially still occur during or after the focus groups. All focus groups will be conducted by our researchers who will be trained to steer discussion away from any potential disclosures. Were any disclosures of sexual intercourse before age 13 years or other abuse to occur in qualitative research, the researcher would establish that the reported abuse met our criteria for referral and would inform the student that the researcher must report this to the school safeguarding officer. We will define *a priori* categories of harm warranting such responses with the advice of a social worker specialising in child protection (see ethics). Interviews will be audio-taped and transcribed in full. Drawing on May's theory of implementation (87) qualitative research will assess how implementation is influenced by NSPCC and school staffs': perceptions as to the intervention's potential workability and integration within the school system; possession of the required norms and relationships to underpin implementation; shared commitment to enact the complex intervention; and continuous contributions that are sustained in time and space.

Provision in control schools
We will examine sexual health provision in and around control schools to describe our comparator. Data on this will be collected via: staff and student surveys; interviews with two staff members per control school, purposive by seniority; and four students per control school, purposive by year 9/10 and sex.

Context and mechanisms of action
Informed by realist approaches(89, 90), qualitative research will also aim to explore potential intervention mechanisms and how these interact with contextual factors to enable outcomes. Analysis is described below. Qualitative research will also explore potential mechanisms of action and how these might vary with school context and student characteristics, in order to refine and optimise the intervention's theory of change and methods. We will explore mechanisms that might give rise to unintended, potentially harmful consequences. Data on context and mechanisms will be collected via: interviews with NSPCC trainers; student and staff surveys; interviews with four staff and eight students per intervention school (purposive criteria as above). As explained below, our quantitative research will pilot mediator analyses.

Data analysis
In the pilot RCT, our primary analysis will determine whether criteria for progression to a phase III RCT are met. Descriptive statistics on fidelity will draw on audio-recordings of training, logbooks of providers and structured observations of intervention activities. Acceptability will be assessed through student and staff surveys. Recruitment and response rates will be reported in a flow chart and used to refine our power calculation. Pilot RCT analyses will also assess which of our indicative primary outcomes is sufficiently reliable to use within a phase III RCT, assessing: response rates; inter-item reliability (using Cronbach's and ordinal alphas); and fit (using confirmatory factor analysis). In line with our previous INCLUSIVE pilot trial, we will prioritise completion rates and inter-item reliability when judging between measures (91). The threshold for acceptable reliability will be set at a Cronbach's alpha of 0.70 or higher. If both measures perform well on these, we will choose the short CADRI since this is the more established measure. If neither perform well, we will not progress to phase III without first identifying and piloting alternative measures. Although the pilot RCT will be too underpowered to determine an ICC and prevalence among the comparator of DRV, it will enable more qualitative assessment of whether estimates derived from North American studies look

appropriate for English schools. Data from our process evaluation will be analysed to describe violence- and sexual health-related activities in and around survey schools, contextual influences on intervention feasibility and acceptability, and potential mechanisms of benefits and unintended impacts to refine our theory of change. Qualitative data will be subject to thematic content analysis using techniques drawn from grounded theory such as in vivo/axial codes and constant comparison.(92) As well as deriving themes inductively from the data we will also use realist approaches to evaluation(90) and May's implementation theory(87) to inform analyses, identifying characteristics of the intervention, providers and settings which promote or hinder implementation or which might interact with intervention mechanisms to enable outcomes. Qualitative research will develop hypotheses which will be tested in exploratory quantitative analyses where data allow. Our economic feasibility study will pilot assessment of quality of life and assess the feasibility of methods to be used within a full RCT which as per NICE guidance would involve cost utility and wider cost consequences analyses. We will also pilot the primary intention-to-treat analyses of outcomes which will use repeat cross-sectional data [59] as would be done within a phase III RCT, as well as secondary per protocol and various moderator and mediator analyses. In a phase III RCT, moderator analysis would be conducted to examine how effects vary by student SES, sex and ethnicity, and by school IDACI and value-added academic attainment. Mediator analysis would examine whether intervention effects on mediators might explain effects on our primary outcomes using established methods.(93) All such analyses will be underpowered in this pilot RCT but will be piloted to refine methods.

Protecting against bias

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

Socioeconomic status and inequalities

Project Respect aims to prevent DRV in all state schools regardless of local deprivation. As reported above, there is no clear evidence that DRV is socially stratified. Our process evaluation will assess how implementation and intervention mechanism appears to vary by school and student characteristics. In a phase III RCT, secondary analyses would examine the extent to which intervention effects are moderated by student SES, sex and ethnicity, and school-level value-added attainment and deprivation.

Ethical issues

Ethical approval for the study will be obtained from the London School of Hygiene and Tropical Medicine Ethics Committee and the NSPCC ethics committee. All work will be carried out in accordance with guidelines laid down by the Economic and Social Research Council (ESRC), the Data Protection Act 1998, and the latest Directive on Good Clinical Practice (2005/28/EC). Any member of the research/fieldwork team visiting a school to conduct unsupervised research with a student will be required to have a full Disclosure and Barring Services (DBS) check. Informed consent procedures and the extent and limits to participant confidentiality are described above. Quantitative and qualitative data will be managed by project staff using secure data management systems and stored anonymously. Quantitative data will be managed by LSHTM, an accredited clinical trials unit (CTU). All data will be stored in password-protected folders. The names used in qualitative data will be replaced with pseudonyms in interview transcripts. In reporting the results of the qualitative research, care will be taken to use quotations which do not reveal the identity of respondents. In line with MRC guidance on personal information in medical research, we will retain all research data for 20 years after the end of the study. 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. In order to maintain the accessibility of the data the files will be refreshed annually and upgraded if required.

Prior to all data collection, students will be given an information sheet (at least one week before any fieldwork) and an oral description (immediately prior to fieldwork) of the study including the sensitivity and

potentially upsetting nature of the topic matter and in the case of student survey data the total anonymity of data, and have the chance to ask questions. Students will then be invited to assent to participate in data collection. Students will be provided with information about school and where relevant other local safeguarding support for those experiencing DRV, other abuse or neglect. As is conventional with UK trials in secondary schools including of sexual health and violence prevention interventions, (75, 84, 85) parents/guardians will be sent a detailed information sheet at least one week prior to data collection via the means of communication preferred by each school, and asked to contact the school or research team should they have questions or not wish their child to participate.

Consent materials for qualitative research will indicate anonymity will be broken if serious abuse is reported. In the case of the interviews/focus groups we will establish whether the experiences meet our criteria for breaching confidentiality and where this is the case inform the student that we must inform the school safeguarding lead. We will consult with school safeguarding officers in advance to ensure this process is in line with school policies. We will give all participants information on school and national sources of support irrespective of their answers. We will also give young people research team contact details to report any concerns relating to the research. Any case of abuse that meets the criteria for a serious adverse event (SAE) or suspected unexpected serious adverse reaction (SUSAR; defined as an unexpected SAE) will be reported to the study steering committee (which because this is a pilot not a phase III RCT will undertake data monitoring and ethics duties) and LSHTM and NSPCC ethics committees in anonymised form in real time if the event might plausibly have been caused by the intervention or research. Any other SAEs and SUSARs will be reported to these committees annually in anonymised form. Any cases meeting criteria for suspected unexpected serious adverse reactions to the intervention will be reported in anonymised form to these committees in real time. These will be categorised by type, circumstances, the extent of any possible connection with intervention or research activities and the outcome of the response.

Research governance

The principal investigator (PI) will have overall responsibility for the conduct of the study. The day-to-day management of the RCT will be coordinated by the study manager based in LSHTM. The following governance structures will be instituted: study executive group (SEG) where the PI (CB) will chair fortnightly SEG meetings with the study manager, statistician (EA), and, where appropriate, CTU and fieldwork staff; study investigators' group (SIG) which CB will also chair and including all co-investigators and members of the SEG and which will meet monthly during the early stages of the research (months 1-6), and then every 3 months thereafter; SSC which will be established and meet three times throughout the life of the project to advise on the conduct and progress of the study, and relevant practice and policy issues. Because this is a pilot not a phase III RCT the SSC will undertake data monitoring and ethics duties as described above under 'ethics'. During the optimisation phase, NSPCC staff will be invited to attend executive and investigator meetings but during the pilot RCT phase this will not be the case, in order to enable the research and interventions to proceed independently with separate internal lines of accountability. The project will employ standardised research protocols and pre-specified progression criteria, which will be agreed and monitored by the SIG and SSC. The study protocol will be publically registered online.

Consultation with public and stakeholders

From March-April 2015, we collaborated with five schools involved in the IOE/UCLPartners Schools Health and Wellbeing Research Network (co-directed by CB): Whitefield School, Park View School, Burnt Mill School, Wren Academy, Parliament Hill School and Mulberry School. Three were in principle interested in being involved in our pilot. Two schools were not because they were satisfied with their existing provision in this area. All the schools thought this was an important topic which required prevention work in schools and reported their staff lacked skills in these areas. We consulted with the ALPHA youth group on 28/3/15. Participants supported a non-targeted intervention spanning years 9 and 10 delivered by specialist plus school staff. They were worried possession of the 'circle of 6' might anger partners but were reassured that it is disguised as a game. We also consulted with Fiona Elvines (Rape Crisis South London) and Baljit Banga (Working for Women, Working Against Violence). They suggested that schools vary enormously in their attitude to prevention work; some welcoming it and others denying that their students need such work. The

key to access is identifying a member of staff with an interest in and willingness to coordinate the work. Responses also vary among parents, but with increasing recognition that this is a serious problem for which programmes are required. Students tend to be very positive. Curriculum sessions should involve a combination of single and mixed sex sessions for example to address the objectification of women and healthy relationships respectively. Schools need support to develop and revise policies on prevention and responding to incidents. Research by Christine Barter with policy stakeholders in England suggests whole-school interventions are considered the best candidates and require a school champion.(94) Awareness in schools is however low and there is a need for programmes which focus on perpetrators and not merely victims. Professionals including teachers report a lack of confidence and training in addressing the issue. While some interventions are delivered these are generally occasional and responsive rather than taking a systematic, primary preventive, universal approach. Stakeholders suggested that schools tended not to focus on the gendered dimension of DRV, and sometimes used stereotypical language in dealing with incidents. Engaging young men in interventions was considered critically important. Consultation with young people found they were supportive of more primary prevention in schools.(38)

Going forward, the intervention will be elaborated and optimised by the study team and NSPCC working with the ALPHA young researchers group and policy stakeholders including teachers as well as young people recruited via Rape and Sexual Abuse Support Centre to ensure our intervention and evaluation are sensitive to the needs and preferences of young people directly affected by DRV. Teachers and young people from the ALPHA group will also be consulted on research methods: at the beginning of the study on recruitment, assent/consent materials, refinements of DRV scales and survey methods and strategies for increasing retention; and at the end of the study on RCT/intervention refinement and knowledge transfer. We will also convene two meetings with policy stakeholders, including representatives from Association for Young People's Health, the Department for Education, the Department of Health, Public Health England, the PSHE Association and Rape and Sexual Abuse Support Centre: at the start to build support for the study and ensure it is policy-relevant; and near the end to inform preparations for the full RCT and knowledge transfer.

Expertise

Prof. Chris Bonell (LSHTM) is PI directing all aspects of the study. He is an expert in school-based RCTs, sexual health and violence prevention, and has co-directed evaluation of an intervention preventing gender-based violence in South Africa. Prof. Rona Campbell (Bristol) will co-direct the project, leading fieldwork in the south-west. She is an expert on adolescent risk and school health. Dr Christine Barter (Bristol) will advise on intervention design and measures. She has led UK and international surveys of DRV among young people. Dr Elizabeth Allen (LSHTM) will lead CTU involvement and statistical analyses. She is an expert in cluster RCTs. Prof. Diana Elbourne (LSHTM) will provide senior trials advice. Dr Adam Fletcher (Cardiff) will advise on process evaluation and oversee youth PPI. He is an expert on school health interventions. Dr Honor Young (Cardiff) is an expert on young people's sexual health research and will support the development and piloting of data collection tools and support consultation events with ALPHA. Professor Kate Hunt will advise on researching gender. Professor Steve Morris (UCL) is an expert in and will supervise the economic evaluation. G.J. Melendez-Torres (Warwick Medical School) will advise on evaluation and statistics. Peter Watt leads national services for the NSPCC. He will oversee NSPCC's involvement which will be managed by Lindsey Gullick. Dr H. Luz McNaughton Reyes (University of North Carolina) is an expert in DRV prevention among young people and led the RCT of Safe Dates program. She will advise on intervention development. Dr Bruce Taylor (University of Chicago) is an expert in DRV prevention among young people and was lead investigator on the RCT of Shifting Boundaries program. He will advise on intervention development. Neil Underwood (London Borough of Camden) is a social worker specialising in child protection who will advise us on defining specific a priori categories of serious abuse which we will require us to breach confidentiality to discuss with the young person and a specialist member of school staff what actions are required.

Expected outputs of research / impact

As well as reporting in the NIHR Public Health Research journal, we would submit two open access papers to high impact journals reporting our key findings regarding (1) implementation of Project Respect and (2) design and piloting of innovative survey methods and outcome measures. We will present our findings at two international conferences (Society of Prevention Research; International Association for Adolescent

Health) in 2019, as well as national conferences. We will disseminate the results to participating schools, to the ALPHA youth group based at DECIPHer, and to schools in the Schools in Mind and Healthy Schools London networks. We will draft an article for the Times Education Supplement about the research. The research team will also use blog-posts (such as the Conversation, The Cost of Living) and Twitter to increase public awareness of the study. Knowledge exchange is built into the proposed work from the outset via the stakeholder group. We will present emerging findings at two meetings with policy stakeholders, including policy officials and public health commissioners in the UK nations. Two policy and practice dissemination events will be held: one seminar in partnership with Public Health England and one at the Association for Young People's Health. These events will bring together academics, practitioners and policy makers. We will also present the results of the study at other national practitioner and policy conferences drawing on the capacity of our whole team. The most important scientific outputs generated by this project will be increased knowledge about the value of conducting a phase III RCT of Project Respect. This will inform the development of a subsequent proposal to NIHR. The final report will recommend: whether such an RCT should occur; how the intervention (theory of change and logic model, manual, teaching materials) should be further refined; and how the RCT design and methods (including outcome measures) should be amended as a result of the pilot. If the subsequent phase III RCT found the intervention to be effective in reducing DRV, this would be scaled up by NSPCC working collaboratively with the investigators, marketing the intervention to secondary schools, local authorities and school networks. The phase III RCT would also examine impacts on educational attainment since this is likely to be a critical factor in its potential scale-up. We also believe that our intervention has the potential to reduce gender-based harassment and DRV among students in pupil referrals units too. We have excluded these institutions from this proposal but if the results from our work in mainstream schools look promising we would intend to start consultations with a view to develop a similar intervention studies in pupil referral units.

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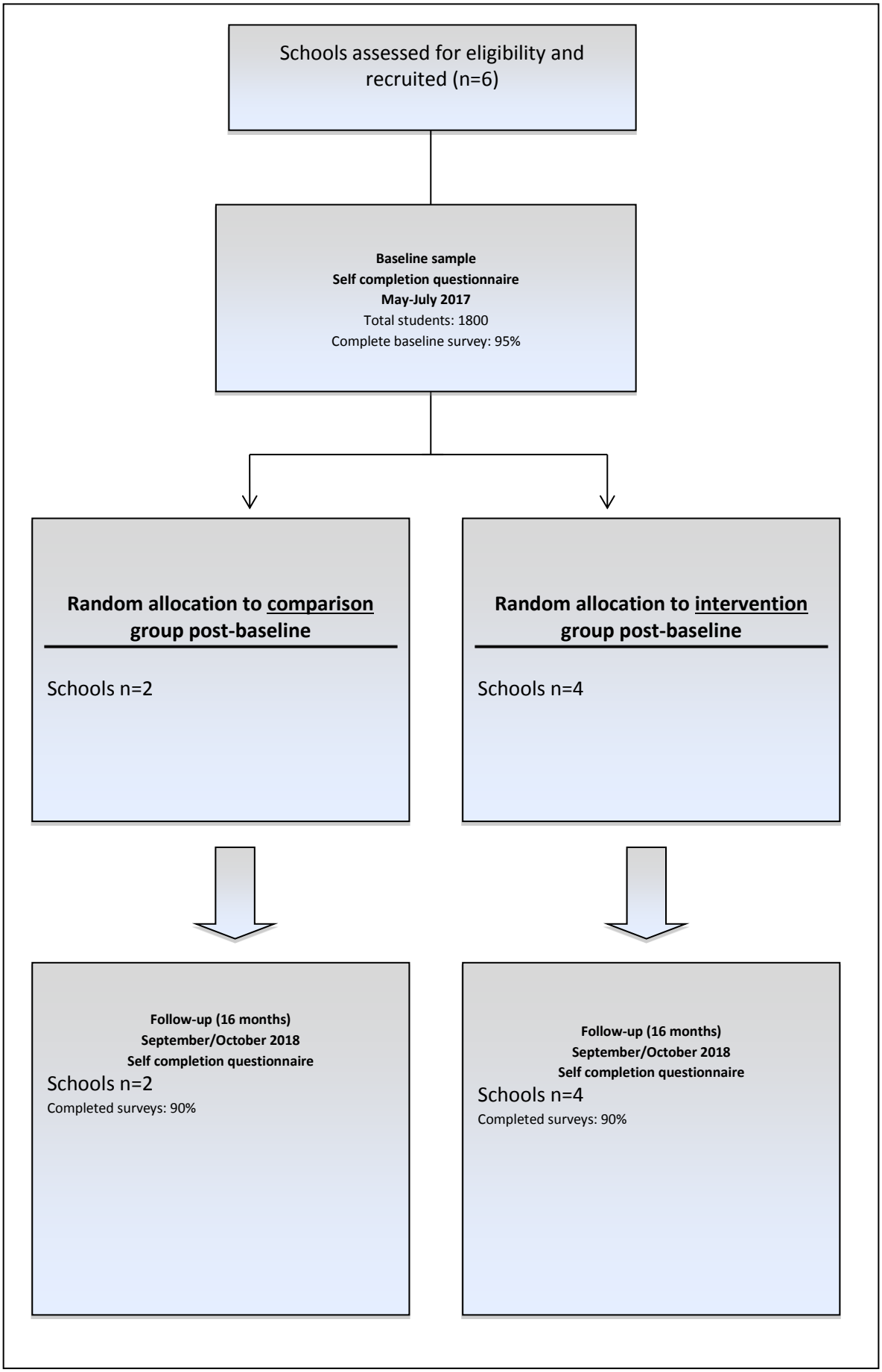
Appendix 1: Flow diagram pilot cluster randomised controlled trial of Project Respect



Appendix 2: Logic Model