Optimisation, feasibility testing and pilot randomised trial of Positive Choices: a school-based social marketing intervention to promote sexual health, prevent unintended teenage pregnancies and address health inequalities in England

Protocol

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Background

This proposal is for a study optimising, assessing the feasibility of and then pilot trialling Positive Choices, a school based social marketing intervention to promote sexual health, prevent unintended teenage pregnancies and address health inequalities.

Teenage pregnancy and sexual health

The UK still has the worst rate of teenage pregnancy in western Europe despite recent declines and the success of the teenage pregnancy strategy.[1] Even after controlling for prior disadvantage, teenage pregnancy is associated with adverse medical, social, educational and economic outcomes for both mothers[2-4] and children.[5, 6] Teenage pregnancy is subject to and contributes to maintaining health inequalities.[7] In 2006, teenage pregnancy costs the NHS £63m per year.[8] In 2009-10, £26 million was paid in benefits to teenage mothers on income support.[9] Other adverse sexual health outcomes also cost the NHS large sums. [10, 11]

Social marketing and other interventions to prevent teenage pregnancy

A recent systematic review of social marketing interventions to reduce teenage pregnancy examined studies of interventions embracing social marketing elements[12] regardless of whether these were explicitly termed 'social marketing'.[13] Heterogeneity precluded meta-analysis but narrative synthesis concluded this was a promising approach.[13] We propose to optimise with the National Children's Bureau's Sex Education Forum (NCB SEF) and other stakeholders an intervention, Positive Choices. This intervention is informed by selected components from two effective interventions included in the above review: 'Safer Choices' and the 'Children's AIDS Society (CAS) Carrera' program, plus selected elements from the 'Gatehouse Project', which though not included in the review, also embraced social marketing principles and was effective in postponing age of sexual debut.

Safer Choices is a school-based social marketing intervention involving: a school health promotion council coordinating intervention activities; a classroom-based sexual health curriculum; student-led social marketing campaigns; and information for parents. A US RCT of this intervention reported reduced unprotected last sex and reduced numbers of partners with whom unprotected sex occurred but did not measure effects on pregnancy.[14-16] The 'CAS Carrera' program is an after-school intervention providing: careers, academic, arts, sports and life-skills sessions; and sexual health services. An RCT of this intervention in New York City reported fewer pregnancies and delayed sexual debut among girls.[17] An attempted replication trial in other US locations reported no such reductions, reportedly due to poor fidelity.[18] The Gatehouse project is a school-based intervention which includes: a student needs survey; and classroom-based curriculum addressing social and emotional learning. Although primarily addressing mental health, an RCT in Australian high schools reported participants' increased age of sexual debut but did not measure impacts on teenage pregnancy.[19]

Rationale for proposed study

Our proposed optimisation, feasibility assessment and pilot RCT of Positive Choices would be the first UK study of a whole-school social marketing intervention to prevent unintended teenage pregnancy. The intervention involves multiple components. Although not aiming to replicate existing interventions, the intervention is informed by approaches and certain components used in the previous Safer Choices, [14-16] CAS Carrera [17] and Gatehouse interventions.[19]

Our study will involve three elements: intervention optimisation; assessing the feasibility of each component of the intervention by implementing, assessing and refining it in a single secondary school involved in optimisation; and undertaking a pilot RCT of the intervention across 6 schools to assess the feasibility and value of conducting a future phase III trial of the effectiveness of the intervention. Positive Choices is informed by components from the above interventions in a

systematic facilitated process described below which will be undertaken in a collaboration between researchers, NCB SEF and one secondary school.

Benefits and risks

There are major potential public health benefits arising from the prevention of teenage pregnancy and promotion of positive sexual health. Optimisation of Positive Choices intervention will be informed by existing social marketing interventions with the strongest available evidence of effectiveness. But before an expensive and lengthy phase III trial of the effectiveness of this intervention is conducted, we will conduct a formative feasibility assessment and refinement of each component in one school followed by a pilot RCT and process evaluation in 6 schools to examine the feasibility and acceptability of the intervention and trial methods, to determine progression to a phase III. Participants are unlikely to experience any physical or psychological risks, either because of the intervention or the research study. Existing reviews suggest sex education is extremely unlikely to bring about increases in sexual activity and risk taking[22]. Any potential harmful effects of the intervention will be explored in the process evaluation. Participating schools will facilitate data collection with students. We will minimise disruption for staff and students and ensure high response and retention rates by employing strategies we have previously used for collecting data in recent pilot and phase-III cluster RCTs in schools. For example, the trial manager will liaise directly with each participating school to identify convenient times and places for surveys and qualitative research. Participants will be informed that participation is voluntary and they may withdraw at any point.

Changes to the proposal from previous stages

Following comments on the outline, we now describe precisely under 'Planned interventions': which components of the Safer Choices, the CAS Carrera and Gatehouse interventions Positive Choices is informed by; a structured process by which the intervention will be optimised; and how schools may locally tailor intervention components via a systematic process informed by needs data. We also address board comments on the outline relating to intellectual property and the PI's time commitments in our letter of submission. Following reviewer and board comments on our full proposal, we are now: dropping plans for an extra-curricular activities component; much clearer that Positive Choices is informed by but does not directly replicate existing interventions; including a longer phase dedicated to optimising the intervention and conducting an initial formative feasibility assessment and refinement phase.

Research aims, research questions and objectives

Aims

A) With NCB SEF, a secondary school and other stakeholders, to optimise Positive Choices a school-based social marketing intervention to promote sexual health, prevent unintended teenage pregnancies and address health inequalities in England.

B) To conduct a formative feasibility assessment and refinement of the intervention in collaboration with the secondary school involved in optimisation.

C) To conduct a pilot RCT (4 intervention, 2 control schools) to determine the feasibility and utility of conducting a phase III trial of effectiveness and cost effectiveness.

D) To answer the following research questions:

a) Is it possible to optimise Positive Choices in collaboration with NCB SEF, a secondary school and other stakeholders?

b) Is it feasible and acceptable to implement each component of this intervention in the secondary school involved in optimisation and what refinements are suggested?

c) In the light of a pilot RCT across 6 schools, is progression to a phase III trial justified in terms of pre-specified criteria: the intervention is implemented with fidelity in ≥3 of 4 intervention schools; process evaluation indicates that the intervention is acceptable to a

majority of students and staff involved in implementation; randomisation occurs and ≥5 of 6 schools accept randomization and continue within the study; student questionnaire follow up rates are ≥80% in ≥5 of 6 schools; and linkage of self-report and routine administrative data on pregnancies is feasible.

d) Are secondary outcome and covariate measures reliable and what refinements are suggested?

e) With what rates are schools recruited to and retained in the trial?

f) What level of student reach does the intervention achieve?

g) What do qualitative data suggest in terms of intervention mechanisms and refinements to programme theory and theory of change?

h) How do contextual factors appear to influence implementation, receipt and mechanisms of action?

i) Are any potential harms suggested and how might these be reduced?

j) What sexual health related activities occur in and around control schools?

k) Are methods for economic evaluation in a phase III trial feasible?

Objectives

1. To optimise Positive Choices in collaboration with NCB SEF, the staff and students from one secondary school, and other stakeholders.
2. To assess the feasibility and acceptability of implementing each component of the intervention in the school involved in optimisation, and to make any necessary refinements in the light of this feasibility assessment.
3. To recruit 6 schools for the pilot RCT, undertake baseline surveys of students at the end of year 8 (age 12/13 years) and randomise schools.
4. To implement the intervention to students in year 9.
5. To conduct quantitative and qualitative elements of the process evaluation.
6. To undertake follow-up surveys at 12 months post baseline.
7. To link self report data to routine administrative data on teenage pregnancies 18 months post baseline.
8. To conduct data analysis addressing all of the above research questions and draft a report of the pilot evaluation.
9. To disseminate findings and determine whether progression to a phase III trial is justified.

Proposed research

Design

1) Facilitated, systematic optimisation of the Positive Choices intervention.
2) Formative feasibility assessment of intervention components in one secondary school and refinement.
3) External pilot cluster randomised controlled trial across six schools with integral process evaluation and economic evaluation feasibility study.

Intervention optimisation

Key elements of the theory of change (see 'Planned interventions' below and logic model; appendix 1) of the intervention as well as the basic outline of the core components have already been determined, informed by selected components from the Safer Choices, CAS Carrera and Gatehouse interventions. Further work is required to elaborate this theory of change and optimise the intervention for the UK, developing in detail the intervention components and intervention materials. The optimisation of the intervention will be led by the research team and staff from NCB SEF as well as the staff and students of one secondary school plus other youth and policy stakeholders. Optimisation will occur in phases:

1) Elaboration of the intervention theory of change, logic model and overall approaches to intervention (April-June 2017).

2) Development of the student needs survey, manual guiding the School Health Promotion Council, staff training package (June-August 2017)
3) Development of the student curriculum (September-December 2017)
4) Development of guidance on student-led social marketing and consultancy regarding school sexual health services. (January-March 2018).

In each case, optimisation of the above resources will occur through a systematic process as follows:

a) Review by researchers and NCB SEF staff of existing systematic reviews and the evaluations of and, where appropriate, intervention materials from the Safer Choices, CAS-Carrera and Gatehouse interventions.
b) Drafting of the above resources 1-4 by NCB SEF staff and the research team.
c) Consultation with staff and students from the secondary school, as well as the ALPHA young researchers' group and other stakeholders.
d) Refinement of these resources.

Feasibility assessment and intervention refinement

The intervention components will then be implemented and assessed for feasibility and acceptability in the school involved in optimisation. This will occur over one school year in phases:

i) Term 1 (September-December 2017): implementation of student needs survey, staff training and School Health Promotion Council.
ii) Term 2: (January-March 2018): implementation of student curriculum.
iii) Term 3 (April-July 2018): implementation of student-led social marketing and consultancy regarding school sexual health services.

Intervention components will be assessed by the research team as they are implemented in order to inform phased refinements led by NCB SEF staff as follows:

- January-March 2018: refinements of survey, materials for School Health Promotion Council and staff training);
- April-July 2018: refinement of student curriculum;
- June-August 2018: refinement of student-led social marketing and consultancy regarding school sexual health services.

Settings

Positive Choices is intended for delivery in all secondary schools (including free schools and academies) excluding pupil referral units (PRUs) or schools for those with learning disabilities (although if found to be feasible and effective in schools it may be possible to also adapt this intervention for PRUs in the future). We will collaborate with one secondary school in the optimisation and feasibility assessment phases. This school will be purposively selected based on location in south-east England, and having a higher than median local index of multiple deprivation and value-added GCSE attainment to reflect high need but high capacity to participate in optimisation and refinement.[29]

Pilot (and subsequent phase III) trial inclusion criteria

- Secondary schools (including free schools and academies) in south east England (to reduce travel time and costs).

Pilot (and subsequent phase III) trial exclusion criteria

- Private schools, pupil referral units or schools for those with learning disabilities.
- Boys' (but not girls') schools will be excluded from the pilot and full trial since our primary outcome focuses on unintended pregnancies among girls.

Study population

In a phase III trial the intervention would target students in years 9 and 10. This age-group is targeted because: proximal risk factors are manifesting,[29] prevention is not too late; and sex education is acceptable.[15, 26, 30] PPI suggests provision to year 11 students is unfeasible because of GCSE preparation. In the feasibility assessment and pilot RCT phases, the intervention will target year 9 students reflecting the truncated timescales of these phases.

Pilot (and subsequent phase III) trial inclusion criteria

- Students nearing the end of year 8 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 sample for feasibility assessment will be 180 year-9 students in one school. The analytic sample for outcome assessment in the pilot RCT will be approximately 1080 students at the end of year 8 (age 12/13) at baseline with follow up at 12 and 18 months (see appendix 2). The feasibility assessment and pilot phases will focus on various aspects of feasibility and no power calculations for these have been performed. We anticipate that in a subsequent phase III trial, follow up 1 (self report questionnaires) would occur when these students are at the end of year 10 (24 months post baseline age 14/15) and follow up 2 (routine data on births/terminations) would occur when aged 16/17 (48 months post baseline). In the phase III trial, our primary outcome will be assessed among girls only. We calculate that for 80% power and 5% significance we will require 21 schools per arm to detect a relative risk (RR) reduction of 0.5 (informed by the Carrera trial reported OR=0.5 for pregnancy) conservatively assuming: a cohort of girls of 90 per school[31]; drop out of two schools per arm; near 100% follow-up per school (using routine data[25]); an intra-cluster correlation coefficient of 0.004 for our pregnancy outcome (informed by the Ripple study[25]); and prevalence of pregnancy of 4% among those in the control arm (informed by current monitoring data[32]). A more conservative assumption of an effect size of RR=0.6 would require 30 schools retained per arm. Our pilot will provide estimates for recruitment and retention rates which will allow us to estimate more accurately the sample size required for a phase III trial.

Recruitment and randomisation

The feasibility assessment will involve one purposively sampled secondary school (see above for criteria) with no random allocation. This school will be recruited via our existing contacts to ensure the school has the capacity to participate.

In the pilot RCT phase, 6 schools across south-east England will be recruited (purposively varying by local deprivation and school level GCSE attainment). As with our previous trials, schools will be recruited to the pilot RCT by a combination of mail outs, phone calls and prior networks including the UCL Partners School Health and Wellbeing Research Network. Response rates will be recorded, as will any stated reasons for non-participation. After baseline surveys with students at the end of year 8 (approximately 180 per school), schools will be randomly allocated to intervention/control remotely by LSHTM clinical trials unit, stratified by GCSE attainment, a key predictors of pregnancy[29]. In the pilot, allocation will be 2:1 favouring the intervention (c.f. 1:1 in full trial), enabling us to pilot randomisation while minimising costs and ensuring sufficiently diversity for piloting.

In a phase III trial, schools (inclusion criteria above, no purposive criteria) will be allocated 1:1 to intervention and control, stratified by school GCSE attainment rates plus local index of multiple deprivation to maximise balance on key predictors of teenage pregnancy.[29]

Planned interventions

Intervention components

Positive Choices is a manualised social marketing intervention, delivered for one academic year to year-9 students (age 13/14 years) in the pilot trial, and for two academic years to year 9-10 students (age 13/14-14/15 years) in a future phase III trial. In the feasibility assessment phase, different intervention components will be delivered in different terms of one academic year.

The intervention is a universal intervention which has the potential for greater population-level impacts than targeted interventions[7, 29] while minimising risk of 'positive deviancy training' which can be a problem in targeted interventions which bring together at-risk individuals from different schools and neighbourhoods.[33] The intervention has the following existing evidence-

based components which are informed by selected components of the Safer Choices, CAS Carrera and Gatehouse interventions and these will be delivered in all schools:

1) A student needs survey (drawing on baseline trial survey) of year 8 students which will be used to enable each intervention component 3-6 below to be tailored to local priorities in each school.

2) A School Health Promotion Council which will comprise 6 staff/6 students and review local needs data and use this to tailor each intervention component 3-6 below, and will then coordinate delivery of the intervention.

3) A classroom curriculum which will address social/emotional skills (5 hours' class time per year) and sex education (5 hours' class time per year) delivered by school staff to increase the scalability and sustainability of the intervention informed by further consultation with schools. The curriculum will be designed as a set of learning modules. Social and emotional skills modules will 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. Sexual health modules will cover: healthy relationships; negotiation and communication skills; positive sexual health; sexual risk reduction; contraception; and local services. Informed by the needs-assessment data, School Health Promotion Councils will select: in what order to deliver modules; whether to deliver within personal, social and health education (PSHE), tutor groups or integrated into other lessons (e.g. English); and whether to use our materials or existing materials if these conform to our curriculum.

4) Student-led social marketing which will be facilitated by trained teachers and led by teams of 12-18 students per school. Teachers will actively promote recruitment among at-risk students based on the strongest evidenced risk factors for teenage pregnancy on which schools have data (free meals eligibility; persistent absenteeism; slower than expected academic progress[29]). This is not to target provision at those most at risk but rather to ensure campaigns appeal to a diversity of students including those most at risk of teenage pregnancy. When recruiting such students, teachers will be open with them about this rationale. Campaigns may use social and other media, posters and events, and will focus on healthy relationships, sexual and human rights, delayed sex, and access to local services. Student social marketers will use data from the student needs survey to segment the student population based on multiple characteristics such as existing knowledge and attitudes to sexual health as well as cultural styles (e.g. hip hop, skate) and peer group identifications (e.g. sporty boys, cool girls). The student social marketers will use such information to design social marketing campaigns which address the most important topics among the groups who need interventions most.

5) Parent information – 3 newsletters, 2 homework assignments per year addressing parent-child communication.

6) Consultancy on school sexual health services. We originally envisaged that new sexual health clinics would be implemented but initial consultation with schools indicates that almost all schools already have some form of clinic provision of variable extent and quality. Therefore, NCB SEF will provide consultancy to schools on how such services might be developed.

Intervention theory

Positive Choice's programme theory is informed by social marketing, and has been developed with experts in this field, addressing the '4Ps'[34, 35] - this will 'sell' consumers a **P**roduct *they* want (education on emotions and relationships) in an accessible **P**lace (school) at a low **P**rice (free to students), with **P**romotion to peers and parents (campaigns, parent information) [13, 35] addressing competing influences from peers, media etc. [37] Our survey component enables our School Health Promotion Councils (with student involvement) to tailor provision in each school to local consumer priorities. The intervention's theory of change has been informed by those used in the interventions informing Positive Choices. This theory of change will be further developed in the optimisation phase. We anticipate that the School Health Promotion Council, student-led social marketing and curriculum components will be elaborated, informed by 'Safer Choices' [14-16]

theory and based on models of school change,[38] social influence [39] and social cognitive theory,[40] to address the following determinants of teenage pregnancy: sexual health knowledge, self-efficacy, skills and competence; communication with parents; school wide social norms supporting positive relationships/sexual health. We anticipate that the social and emotional skills curriculum will be elaborated informed by 'Carrera', [17] and informed by the social development model,[41] promoting additional determinants of pregnancy: intentional self-regulation; positive aspirations; and school engagement.[20] Refined school sexual health services will provide advice and contraception in line with NICE guidance.[42]

Intervention providers

NCB SEF will lead intervention optimisation in collaboration with the research team. It will also train school staff to: implement School Health Promotion councils (which decide the precise form in which activities are implemented locally to meet local needs and preferences and build on existing work in each school); implement the classroom curriculum; and facilitate student-led marketing. NCB SEF will also provide consultancy to schools on refining their existing sexual health services. In each school, a 'product champion' (senior leadership team member) will oversee the School Health Promotion council, which is an approach that has been used successfully in other secondary school interventions.[43] Staff sitting on this council will include those coordinating student-led social marketing as well as, where applicable, the school nurse. Teachers of personal, social and health education at each school will deliver the curriculum and facilitate student-led social marketing. Students will sit on the School Health Promotion Council and will also lead on social marketing to their peers guided by a teacher and manual with clear milestones, including plans for 'quick wins' to build momentum and enthusiasm.[15] ETR Associates and the Children's AID Society (originators of the Safer Choices and Carrera interventions) will contribute to intervention optimisation, advising on learning from their interventions.

Intervention funding

We seek NIHR funding for intervention optimisation and refinements. Intervention delivery in the feasibility assessment and pilot RCT phases will be funded by NCB SEF who will seek new funding streams for this work, and by schools who will provide staffing for the running of School Health Councils and social marketing teams.

Comparator

The feasibility assessment will involve no comparator. In the pilot RCT phase, two schools will be randomised to the control group, and will not receive the intervention but will continue with any existing sexual health-related provision, which will be examined in our process evaluation, as will be sexual health services in the surrounding area.

Data collection

Outcome measures

Optimisation and feasibility assessment phases

Outcomes for these phases will be meeting criteria for progression to the pilot RCT comprising: materials for the training, school health promotion council, social marketing meetings, student curriculum and clinic are optimised in line with the theory of change and to the satisfaction expressed in writing of the research team, NCB SEF, the participating secondary school and the study steering committee; according to audio recordings, provider diaries and researcher observations, the training, school health promotion council, social marketing meetings, student curriculum and clinic components are implemented with 70%+ fidelity in the participating school; and interviews with students and staff conducted as part of the process evaluation indicate that the intervention is acceptable to at least 70% of students and staff involved in implementation. 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; meetings will be assessed against meeting-specific quality metrics relating to the agenda items covered, opportunities for discussion and the actions agreed; and clinics will be assessed against quality metrics concerning hours of opening, staffing and services available. The investigators will agree a set of metrics with NIHR and the SSC in the early stages of the project prior to moving to the next stage of the research.

Pilot RCT

The pilot RCT will not aim to assess intervention effects. Pilot primary outcomes will be meeting criteria for progression to phase III comprising: the intervention is implemented with fidelity in ≥3 of 4 intervention schools; process evaluation indicates that the intervention is acceptable to a majority of students and staff involved in implementation; randomisation occurs and ≥5 of 6 schools accept randomization and continue within the study; student questionnaire follow up rates are ≥80% in ≥5 of 6 schools; and linkage of self-report and routine administrative data on pregnancies is feasible. Secondary outcomes address other research questions including the feasibility of economic evaluation.

Phase III trial

In a phase III trial, we will have one primary outcome to assess the most important intended effect while reducing risk of type 1 error. This primary outcome (routine data on births and terminations) would be assessed at 48 months (age 16/17) and secondary outcomes via self reports at 24 months (age 14/15). Routine data on terminations minimises information bias and clearly indicates unintentional pregnancy. However, some unintended pregnancies will not result in termination and changes in termination rates may also reflect variations in access.[25] Therefore, our primary outcome measure will additionally encompass routine data on live births. While recognising that around half of teenage pregnancies will be to some extent intended[44] this outcome measure will nonetheless provide a better indication of the overall impact of the intervention.

We will assess secondary outcomes to examine broader intervention effects using measures drawn from the Ripple and Share trials[24, 25]:

- self-reported pregnancy and unintended pregnancy (initiation of pregnancy for boys) and sexually transmitted infections,
- age of sexual debut; number of sexual partners; use of contraception at first and last sex; non-volitional sex;
- educational attainment (which is a plausible and, for scale up, critical outcome of our intervention[45]).

(See below for economic outcomes.)

The full trial will examine how effects on the above outcomes are moderated by SES, gender, ethnicity and baseline risk to assess intervention impact on health inequalities.

Informed by our theory of change,[40, 41] we will also examine the following mediators[46] using existing measures[14, 17, 26, 47]:

- school-level social norms supportive of positive relationships and sexual health;
- individual-level sexual health knowledge and skills, contraceptive skills and access, intentional self-regulation, self-efficacy, sexual competence, communication with parents, school engagement, and career/educational aspirations.

All of the above measures will be assessed for reliability in our pilot. We will assess reliability by reporting intra-cluster correlation coefficients (ICC) for repeat measures over time and Cronbach's alpha statistics at baseline and follow-up for scaled outcomes.

Economic evaluation outcomes

The pilot RCT will examine whether it is feasible to assess cost effectiveness using a cost consequence analysis within a phase III trial. Within the pilot, study methods to measure the incremental cost of the intervention in a phase-III trial study will be developed and piloted. With use

of a broad public and third sector perspective, resources to be measured will include: resources used by NCB SEF, schools and the NHS. Within this, key interventional resources will include NCB SEF and school staff time, training events/workshops and consumables. Measures will include: standardised sessional checklists to monitor and document attendance, preparation and delivery time for key training events and School Health Promotion Councils; detailed surveys emailed to school staff charged with intervention delivery, assessing time spent on tasks relating to intervention; and all intervention staff travel and other expenses relating to the intervention charged to a specific project grant code.

The Child Health Utility (CHU) 9D measure[72] will be used to assess student's 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]. Student and teacher utility values will be collected (at baseline and at follow-up surveys at 24 and 36 months in a full RCT) 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 trial to measure short term impact on health-related quality of life.

Assessment of harms

It is unlikely that any harms will arise because of the intervention or the research. This pilot study is not powered to examine intervention effects (positive or adverse) but qualitative data will be collected as part of the process evaluation to explore any potentially harmful mechanisms.

Assessment and follow up

Feasibility assessment phase

A baseline needs survey of students in year 9 will be undertaken. Other data collected in the feasibility phase is described below under 'Process evaluation' below.

Pilot RCT

Baseline surveys will be done before randomisation as students near the end of year 8 (age 12/13) in June 2018 and will collect data on pre-hypothesised outcome variables, potential confounders and moderators, drawing on existing survey items.[48] Prior to all data collection, students will be given an information sheet and an oral description of the study, and have the chance to ask questions. Students will then be invited to assent to participate in data collection. As is conventional with UK trials in secondary schools (including of sexual health interventions),[25, 30, 49] parents/guardians will be sent a letter and detailed information sheet two weeks before data collection and asked to contact the school or research team should they not wish their child to participate in the trial. Paper questionnaires will be completed confidentially in classrooms supervised by fieldworkers, with teachers remaining at the front of the class to maintain quiet and order, but unable to see student responses. We will survey absent students by leaving questionnaires and stamped addressed envelopes with schools.

We will resurvey students at 12 months (June 2019) as students near the end of year 9 (age 13/14) and will collect self report data on experiences of the intervention, outcomes and pre-hypothesised potential mediators. Fieldworkers will be blind to allocation. Based on past experience,[61, 62] in the pilot we expect 95% baseline survey participation and 90% at follow-up.[61] In the pilot, data on terminations and births at 18 months will be obtained in collaboration with the Office of National Statistics by linking data on female trial participants via the national pupil database and other identifiers to routine ONS data on registration of births and statutory termination notifications, by staff blind to allocation. Linkage of such data has been previously conducted for observational studies[29] and initial discussion with ONS has established that data linkage is feasible despite the limited identifiers attached to termination records, and is consistent with DH guidance and data protection law. Retention of control schools will be maximised via £500 payment and feedback of survey data after trial analysis.

Full trial

Baselines would occur as in the pilot. The primary outcome would be assessed at 48-month follow-up (for which virtually 100% follow up can be achieved since this draws on linked, routine data[25]) and self-reported secondary outcomes at 24 months (where our previous experience suggests 85% follow up is feasible).

Process evaluation

Integral process evaluation informed by existing frameworks[50-52] has three purposes: first, to examine intervention feasibility, fidelity, reach and acceptability in the feasibility and pilot RCT phases; second, to assess provision in control schools and potential contamination in the pilot RCT; and third, to explore context and potential mechanisms of action in the pilot RCT phase, including potential unintended effects, in order to refine the intervention theory of change and design.

Feasibility assessment phase

This will assess the 'progression criteria' to advance to the pilot RCT phase (see above). Data will be collected via: audio-recording of NCB SEF training for school staff; surveys of school staff trained by NCB SEF; diaries (including time logbooks) of school staff implementing School Health Promotion Councils, curriculum and social marketing meetings; structured observations of two sessions of School Health Promotion Councils, curriculum lessons and social marketing meetings; and individual or group interviews with 4 NCB SEF staff and 4 schools staff (purposive by role/seniority) and 8 year-9 students (purposive by gender and SES). All collaborators and the study steering committee will express in writing whether they are satisfied with the optimised intervention.

Pilot RCT phase

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 via qualitative research as well as questionnaire survey items at follow-up. The information collected on socio-demographic, educational and neighbourhood characteristics in the student surveys will also allow us to examine reach according to these measures, and how this varies by institutional setting. We will also assess the fidelity, reach and perceived impacts of staff training activities. Data will be collected via: audio-recording of NCB SEF training for school staff; surveys of school staff trained by NCB SEF diaries (including time logbooks) of school staff implementing School Health Promotion Councils, curriculum and social marketing meetings; and structured observations of randomly selected session per school of School Health Promotion Councils, curriculum lessons and social marketing meetings.

Provision in control schools and potential contamination

We will examine sexual health provision in and around control schools in order to describe our comparator. We will examine the potential for contamination across arms to ensure this is not a threat to internal validity in a phase III trial. Data will be collected via: student surveys; interviews with 2 staff per control school (purposive by seniority) and 4 x year-9 students (purposive by gender and SES) per control school.

Context and mechanisms of action

In addition to piloting intermediate outcome variables required for mediator analyses in a subsequent phase III RCT, we will also collect rich, contextual qualitative data and analyse this in order to explore potential mechanisms of action and thus refine our theory of change. These qualitative analyses will also examine how mechanisms may vary with context, students' socio-demographic characteristics and/or other factors, in order to refine and optimise the intervention's theory of change. We will also analyse qualitative data to explore any mechanisms that might give rise to unintended, potentially harmful consequences. Data will be collected via: student surveys; and individual or group interviews with 2 trainers, 4 staff per intervention school (purposive by seniority/activity involved in), 8 x year-9 students per intervention school, (purposive by involvement, risk status and gender).

Data analysis

Feasibility assessment

Our analysis will determine whether the study should proceed to the pilot RCT phase. Descriptive statistics on fidelity will draw on audio-recordings of training, diaries of providers and structured observations of intervention activities. Analysis of acceptability will draw on interviews with staff and students. Findings will be fed back to NCB SEF staff who will be responsible for refining the intervention ready for implementation in the pilot RCT.

Pilot RCT

Our main analyses will determine whether criteria for progression to a phase III trial are met. Descriptive statistics on fidelity will draw on audio-recordings of training, diaries of providers and structured observations of intervention activities. Statistics on acceptability will draw on surveys of students and trained staff, while qualitative description will draw on interviews with staff and students. School randomisation and retention, and student follow-up will be described using a CONSORT diagram.[53] We will assess the precision of data linkage in association with ONS researchers.

Other analyses will address our other research questions. Descriptive summaries of baseline and follow-up data by arm will be tabulated. We will assess the reliability of secondary outcome measures by reporting intra-cluster correlation coefficients (ICC) for repeat measures over time and Cronbach's alpha statistics at baseline and follow-up for scaled outcomes. We will pilot intention-to-treat analyses of outcomes[53] and moderator analyses (how effects vary by SES, gender, ethnicity and baseline risk) but in this study such analyses will be underpowered. In the phase III trial the analysis of the primary outcome will include data on pregnancies and terminations at follow up only (because there will be virtually no pregnancies at baseline). Analysis of all other outcomes will be a repeat cross sectional analysis that includes data from all students at both time points 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.

Qualitative data will be subject to thematic content analysis (in vivo/axial codes; constant comparison[54]) informed by realist approaches to evaluation[55] and May's implementation theory[51] to: examine potential mechanisms of action and of harm, and how contextual factors influence implementation and mechanisms; describe relevant activities in and around intervention and control schools; and refine our programme theory and theory of change. Our economic feasibility study will pilot collection of quality of life and assess the feasibility of methods to be used within a full trial which in line with NICE guidance would involve a wider cost consequence analysis, comparing intervention costs with the full range of study outcomes.

Protecting against bias

Although the aim of this study is to optimise the intervention, assess feasibility and then pilot outcome measures and analyses, rather than estimate intervention effects, we will pilot methods aimed at minimising bias. The investigator team and the intervention delivery team will be separately managed. In the pilot RCT, outcome data will be collected and analysed blind to allocation, and we will examine effects adjusting for potential baseline confounders (age, gender, SES and ethnicity). We will aim to maximise response rates at each pilot RCT site at baseline and follow-up to minimise non-response and attrition bias, for example following up those individuals not present during survey sessions. Response rates and qualitative data will be analysed to refine data collection methods prior to a phase III trial examining effectiveness. Blinding of participants to allocation is not possible.

Socioeconomic position and inequalities

In the pilot RCT, 6 schools in south-east England will be recruited (varying by local deprivation and school level GCSE attainment). In a full trial, 42 schools (inclusion criteria above, no purposive criteria) will be allocated 1:1 to intervention and control, stratified by local index of multiple deprivation and school GCSE attainment to maximise balance on key predictors of teenage pregnancy.[29] Our process evaluation will assess how implementation and intervention mechanism appears to vary by student SES and gender. In a phase III trial, we would examine the extent to which effects are moderated by individual socio-demographic measures (gender, parental SES, ethnicity), school-level GCSE attainment and area-level deprivation.

Ethical issues

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

Head teachers as gatekeepers will be asked for informed consent for intervention and random allocation, as is standard practice in cluster randomised trials in schools. As is normal within public health and educational research in secondary schools in the UK (e.g. RIPPLE, SHARE, ASSIST trials), informed written opt-in consent will be sought from all research participants, including students, judged competent to provide this. We sought advice from Professor Richard Ashcroft, Professor of Medical Ethics at Queen Mary University London who is an expert on informed consent. He advised that young people attending secondary schools should be considered as competent agents to give consent. In all cases of data collection including surveys, interviews and focus groups, observations and audio-recordings, except where practically impossible, participants will be given an information sheet several days before data collection. Just before data collection participants will also receive an oral description of the study, and have the chance to ask questions. Participants will then be advised that participation is voluntary and they may withdraw at any point. All participants will be advised that they are free to withhold consent and this matter will not be fed back to teachers or, in the case of staff participants, their managers. Students opting not to participate in surveys will be offered alternative activities in the classroom. Those opting out of other data collection will be free to continue with their normal activities.

All participants, including students, will be informed in consent materials of the confidentiality with which the information they provide will be treated as well as the circumstances in which we would need to breach confidentiality. In collaboration with a qualified social worker specialising in child protection, we will develop a priori categories of abuse reported through the research that necessitate our breaching confidentiality to ensure individuals are offered care and protection. These criteria will be established so that we balance our ethical duty of promoting participant autonomy by respecting confidentiality and our ethical duty of promoting participant wellbeing when we determine that we need to breach confidentiality to address abuse that appears to be serious and ongoing. Where such abuse is reported through a questionnaire, we will contact the safeguarding lead in the school. Where it occurs directly to research staff we will first discuss the need for a response with the research participant prior to contacting the school safeguarding lead. The research will also involve the piloting of the attempted linkage of student survey data to administrative data on births and terminations by the Office for National Statistics. Survey participants will be informed of this process as part of consent procedures and their consent to it sought. In addition, students' parents will be contacted by letter one week prior to any specific research fieldwork informing them about this and providing them with the option of withdrawing (opting out) their child by contacting the school or the research team. As is normal within public health and educational research involving secondary school students in the UK, we will not seek opt-in consent from student participants' parents. The context is that the intervention being evaluated is a universal intervention delivered in intervention schools as part of their broad educational mission

rather than a service which parents have sought a referral into for their children. We have discussed this matter in detail with Richard Ashcroft, Professor of Medical Ethics at Queen Mary University London who advises that requiring opt-in consent from parents is redundant and paternalistic. On the advice of Professor Ashcroft, we will offer parents the right to withdraw their children from the research not because these are judged to be more competent than their children to give consent but as a courtesy.

All participants will be informed in consent materials of the confidentiality with which the information they provide will be treated as well as the circumstances in which we would need to breach confidentiality. In collaboration with Neil Underwood a qualified social worker specialising in child protection, we will develop a priori categories of abuse reported through the research that necessitate our breaching confidentiality to ensure individuals are offered care and protection. These criteria will be established so that we balance our ethical duty of promoting participant autonomy by respecting confidentiality and our ethical duty of promoting participant wellbeing when we determine that we need to breach confidentiality to address abuse that appears to be serious and ongoing. Where such abuse is reported through a questionnaire, we will contact the safeguarding lead in the school. Where it occurs directly to research staff we will first discuss the need for a response with the research participant prior to contacting the school safeguarding lead.

Qualitative research (interviews, focus groups, observations) will not ask staff or students about their experience of sex. However, if participants nonetheless describe any sexual abuse, or otherwise become upset in any way, our researchers will be trained in how to respond. In the case of focus groups our researchers will be trained to ensure that discussions do not move in the direction of personal disclosures of sexual behaviour since this is not the purpose of the groups and it would be very difficult to ensure that all focus group participants did not talk about such disclosures outside the group. Our staff will be trained to identify the potential for such disclosures, work to avoid them but then to approach participants immediately after the focus group to offer support and to assess whether any other response is needed, using the same procedures as described above.

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

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

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

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

Research governance

The principal investigator (PI) will have overall responsibility for the conduct of the study. The day-to-day management of the trial will be coordinated by the trial manager based in LSHTM. The following governance structures will be instituted:

- Trial executive group (TEG): The PI (CB) will chair weekly TEG meetings with the trial manager, statistician (EA), and, where appropriate, NCB SEF, CTU and fieldwork staff.
- Trial investigators' group (TIG): CB will also chair a TIG which will include all co-investigators and members of the TEG; the TIG will meet monthly during the early stages of the research (months 1-6), and then every 3 months thereafter.
- Study steering committee (SSC): An independent SSC will be established and meet three times throughout the life of the project to advise on the conduct and progress of the trial, and relevant practice and policy issues. Professor Angela Harden of the University of East London has agreed to chair the SSC. Because this is a pilot not a phase III RCT the SSC will undertake data monitoring and ethics duties and be informed of any serious adverse events as described under 'ethics' above.

The project will employ standardised research protocols and pre-specified progression criteria, which will be agreed and monitored by the TIG and SSC. The study protocol will be registered at www.clinicaltrials.gov.

Consultation with public and stakeholders

Consultation to date

We have collaborated with schools involved in UCLPartners Schools Health Research Network (co-directed by CB) via consultations in September-October 2014 with staff and students from 5 schools. These have informed our decisions to: focus our year 9 curriculum on social/emotional skills and our year 10 curriculum on sexual health and contraception/protection; include a focus on sexual health drop-in clinics; ensure student-led social marketing embraces social media; use interviews where appropriate in our process evaluation; and interview students as well as staff in control schools to assess usual provision.

We also consulted with 5 members of the ALPHA youth group based at the DECIPHer Centre on 29 October 2014. Participants: were enthusiastic about the intervention; supported this starting in year 9; very supportive of drop-in clinics; and felt that targeting would be problematic. Although some components are already being delivered in some schools, none use a coherent programme informed by social marketing principles.

Ongoing consultation

Positive Choices will be optimised by the research team, NCB SEF staff and staff and students from one secondary school, consulting with other stakeholders via the process described under 'Intervention optimisation' above. Policy stakeholders as well as young people from the ALPHA group will also be consulted three times during the project.

Expertise

Prof. Chris Bonell (LSHTM) is PI directing all aspects of the study. He is an expert in school-based trials and sexual health. Dr Elizabeth Allen (LSHTM) will lead CTU involvement and statistical analyses. She is an expert in cluster randomised controlled trials of sex education. Prof. Diana Elbourne (LSHTM) will provide senior trial and statistical advice. Dr Catherine Mercer (UCL) will advise on sexual health measures. She is an expert on quantitative research on sexual health. Prof. Rona Campbell (Bristol) will advise on intervention and trial design. She is an expert on adolescent risk behaviours and school health. Dr Adam Fletcher (Cardiff University) will advise on process evaluation and oversee youth PPI. He is an expert on school health interventions. Dr Honor Young (Cardiff University) will assess the reliability of outcomes, and lead youth PPI. Professor Steve Morris (University College London) is an expert in and will supervise the economic evaluation. Dr Maria Lohan (Queen's University Belfast) is an expert on young men and teenage pregnancy and will advise

on how the intervention addresses their needs. Prof. Gerard Hastings (Stirling) is the UK's prime expert in social marketing and will ensure our intervention maximally benefits from this. Alison Hadley OBE (University of Bedfordshire) will advise on policy and scale-up. She led the teenage pregnancy strategy and has vast experience across sectors. Lucy Emmerson (NCB SEF) will oversee NCB SEF's involvement. Dr Michael A. Carrera is Thomas Hunter Professor Emeritus of Health Sciences, City University of New York. He will advise on learning from the Carrera program. Dr Karin Coyle is senior research scientist at ETR Associates and will advise on learning from the Safer Choices program. Claudia Wells works at the Office for National Statistics and will oversee data linkage.

Expected output 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) process evaluation of integrated social marketing strategy and (2) student/staff experiences of the intervention. 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 Institute of Education/UCLPartners School Health and Wellbeing Research Network and Healthy Schools London network, both of which we are already heavily involved in. We will draft an article for the Times Education Supplement about the research. The research team will also use blog-posts 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 2 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.

The most important scientific outputs generated by this project will be increased knowledge about the feasibility and acceptability of delivering and trialling an intervention which uses social marketing strategies and is informed by existing effective interventions to prevent unintended teenage pregnancies. This will inform the development of a subsequent proposal to NIHR for a phase III effectiveness trial. If the subsequent phase III trial found the intervention to be effective in reducing unintended teenage pregnancies, this would be scaled up by NCB SEF working collaboratively with the investigators, marketing the intervention to secondary schools, local authorities and school networks. The phase III trial would also examine impacts on educational attainment since this is likely to be a critical factor in its potential scale-up.

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