A school-based social-marketing intervention to promote sexual health in English secondary schools: the Positive Choices pilot cluster RCT

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Declared competing interests of authors: Chris Bonell was a member of the National Institute for Health Research (NIHR) Public Health Research (PHR) programme research funding board (2013–2019). Rona Campbell is a member of the NIHR PHR programme research funding board (2018 to present). Lucy Emmerson reports funding from the London School of Hygiene & Tropical Medicine, London, during the conduct of the study. Lucy Emmerson reports that the Sex Education Forum is hosted at the charity National Children's Bureau and receives funding from a number of organisations; for example, income is generated through training contracts with local authorities, membership, and a grant programme delivered in partnership with the Anti-Bullying Alliance (also hosted at the National Children's Bureau) and funded by the Government Equalities Office. All work operates under a clear set of values and principles that are in line with evidence-based comprehensive relationships and sex education and is, therefore, compatible with our contribution to Positive Choices. Steve Morris reports being a member of the following NIHR committees: NIHR Health Services and Delivery Research (HSDR) Funding Board, 2014–19; NIHR HSDR Commissioning Board, 2014–16; NIHR HSDR Evidence Synthesis Sub-board, 2016; NIHR Health Technology Assessment (HTA) Clinical Evaluation and Trials Board (associate member), 2007–10; NIHR HTA Commissioning Board, 2009–13; NIHR PHR Funding Board, 2011–17; NIHR Programme Grants for Applied Research expert subpanel, 2015–19.

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Scientific summary

Positive Choices pilot cluster RCT

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Scientific summary

Background and rationale

The UK has the highest rate of teenage births in western Europe, despite significant declines over the last 20 years and the success of the England teenage pregnancy strategy. Teenagers are the age group at highest risk of unplanned pregnancy, with around half of conceptions in those aged < 18 years ending in abortion. After controlling for prior disadvantage, teenage parenthood is associated with adverse medical and social outcomes for mothers and children. Teenage childbearing is subject to and contributes to health inequalities. We developed a new intervention, Positive Choices, with the National Children's Bureau Sex Education Forum as intervention provider and other stakeholders. This intervention was informed by selected elements from three effective interventions: Safer Choices, the Children's AIDS Society Carrera programme and the Gatehouse Project. The intervention consisted of a student needs survey; staff training; a school health promotion council comprising staff and students to review data, identify local priorities and co-ordinate intervention; a student curriculum; student-led social-marketing campaigns; and a review of school and local sexual health services.

Aims

- In collaboration with the Sex Education Forum, one 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.
- To conduct a formative feasibility assessment and refinement of the intervention in collaboration with the secondary school involved in optimisation.
- To conduct a pilot randomised controlled trial involving four intervention and two control schools to determine the feasibility and utility of conducting a Phase III randomised controlled trial of effectiveness and cost-effectiveness.
- To answer the study's research questions.

Research questions

- Is it possible to optimise Positive Choices in collaboration with the Sex Education Forum, one secondary school and other stakeholders?
- Is it feasible and acceptable to implement each component of this intervention in the secondary school involved in optimisation, and what refinements are suggested?
- In the light of a pilot randomised controlled trial across six schools, is progression to a Phase III randomised controlled trial justified in terms of prespecified criteria: the intervention is implemented with fidelity of delivery compared with a priori standards in three or four out of four intervention schools; process evaluation indicates that the intervention is acceptable to a majority of students and staff involved in implementation; randomisation occurs, and five or six out of six schools accept randomisation and continue in the study; student questionnaire follow-up rates are ≥ 80% in five or six of six schools; and linkage of self-report and routine administrative data on pregnancies is feasible?
- Are secondary outcome and covariate measures reliable and what refinements are suggested?
- At what rates are schools recruited to and retained in the randomised controlled trial?
- What level of student reach does the intervention achieve?
- What do qualitative data suggest in terms of intervention mechanisms and refinements to programme theory and theory of change?

- How do contextual factors appear to influence implementation, receipt and mechanisms of action?
- Are any potential harms suggested and how might these be reduced?
- What sexual health-related activities occur in and around control schools?
- Are methods for economic evaluation in a Phase III randomised controlled trial feasible?

The theory of change and components of Positive Choices were developed prior to the study. The study comprised intervention optimisation and feasibility testing (April 2017–August 2018), and a pilot randomised controlled trial (May 2018–December 2019).

During optimisation, the research team collaborated with the National Children's Bureau Sex Education Forum (the intervention provider) to elaborate the intervention, and draft and refine intervention materials, informed by a review of the existing evidence, consultation with students and staff in one secondary school, and consultation with the Advice Leading to Public Health Advancement (ALPHA) young researchers' group and practitioner/policy stakeholders.

This was followed by feasibility testing in the same secondary school, which occurred component by component across one school year. Data for feasibility testing comprised audio-recording of Sex Education Forum training for school staff; surveys of school staff trained by the Sex Education Forum; logbooks completed by school staff implementing the school health promotion council, curriculum and student-led social marketing; structured observations of at least two sessions of the school health promotion council, curriculum lessons and social-marketing meetings; and individual or group interviews with three Sex Education Forum staff, five school staff and eight year 9 students.

We then conducted a pilot randomised controlled trial (four intervention and two control schools), with an integral process evaluation and economic evaluation feasibility study. State secondary schools in south-east England, excluding pupil referral units and special schools, were sent recruitment e-mails. We selected six mixed-sex schools, varying by local deprivation and school-level General Certificate of Secondary Education (GCSE) attainment. The pilot randomised controlled trial focused on feasibility and no power calculation was performed.

Baseline student surveys were conducted from May 2018 until July 2018 in classrooms using paper surveys with students nearing the end of year 8 (aged 13–14 years). Schools were then randomly allocated 2 : 1 to intervention or control arms by a clinical trials unit, stratified by GCSE attainment. We resurveyed students from June 2019 until July 2019 at the end of year 9.

The intervention is described in *Background and rationale*. It was informed by social-marketing principles, models of school change, and social influence and social cognitive theory, aiming to reduce teenage pregnancies by increasing knowledge, communication self-efficacy, sexual health skills and competence, and improving communication with parents and school-wide social norms supportive of sexual health. Schools randomly allocated to the control arm continued with usual provision.

We assessed the feasibility of measuring primary outcomes (births and abortions) via linkage to administrative data. We assessed the completion, discrimination (distinguishing sizeable subgroups of participants varying according to the measure) and reliability of self-reported secondary outcomes of pregnancy (girls) and initiation of pregnancy (boys); diagnosed sexually transmitted infections; age at sexual debut; number of sexual partners; use of contraception at first and last sex; and non-volitional sex; plus an economic outcome of Child Health Utility-9D. We also assessed various potential mediators and piloted trial analyses. Data collectors and analysts were masked to allocation.

Our process evaluation assessed intervention implementation and potential mechanisms, and control provision, drawing on data from audio-recordings of training, staff logbooks, lesson observations, surveys, and interviews with staff and students in intervention and control schools. Qualitative data were analysed using thematic content analysis. Fidelity was assessed against prespecified metrics.

The economic analyses aimed to estimate the costs of delivering the intervention; collect data on the use of services and health-related quality of life, and examine response rates and data quality; and make recommendations on the design of a future economic evaluation conducted alongside a Phase III randomised controlled trial.

The research was approved by the London School of Hygiene & Tropical Medicine ethics committee. Students/adults gave informed assent/consent to participate. Parents/carers were informed of data collection and that they could withdraw their child(ren) if they wished.

We also undertook additional public involvement meetings with the Advice Leading to Public Health Advancement and practitioner/policy stakeholder groups.

Results

The intervention was optimised to the satisfaction of the intervention and research teams, the participating school and the Study Steering Committee. The school involved in optimisation and feasibility testing experienced a poor national schools inspectorate report just prior to its involvement, which resulted in repeated changes in leadership and a refocusing on academic attainment, leading to a reduced commitment from the senior leadership team to Positive Choices. However, in feasibility testing, overall implementation met fidelity targets and acceptability of the intervention was 100%, assessed via staff and student interviews. Only the curriculum element was delivered with suboptimal fidelity, reflecting difficulties identifying staff and time for lessons. The Study Steering Committee and the National Institute for Health Research approved progression to the pilot randomised controlled trial.

In the pilot randomised controlled trial, of the 334 schools invited, 11 expressed interest and eight provided consent, of which six were recruited, with one dropping out and being replaced quickly. Baseline surveys were conducted in these six schools. Four schools were then randomised to receive the intervention and two to continue with usual activities. No schools withdrew from the study. Student response rates in the intervention and control groups were 868 (89.4%) and 298 (84.2%), respectively, at baseline, and 863 (89.0%) and 296 (82.0%), respectively, at follow-up.

In terms of intervention delivery, the target of achieving 70%+ implementation of essential elements in three schools was achieved. Training on school health promotion councils and student-led social marketing were implemented with fidelity in all four schools. The curriculum training, the school health promotion council meetings, the curriculum lessons, student-led social-marketing meetings and the sexual health services review were implemented with fidelity in three out of four schools. The second criterion was that the intervention is acceptable to a majority of students and staff involved in implementation. Of students reporting awareness of the programme, around 80% reported acceptability. Students in the intervention arm reported much more comprehensive coverage of relationships and sex education topics than those in control schools. Interviews with staff and students involved in implementation indicated predominantly positive views.

Regarding secondary outcome and covariate measures, completion rates were high for all outcomes/measures except for age at sexual debut and partner numbers (where lower completion probably reflected the use of free-text responses) and contraception at last vaginal sex (possibly because of issues with question routing). There was poor discrimination for secondary outcome measures in the sense of some measures not identifying a sizeable subgroup of participants reporting an outcome. This probably reflected the truncated period of follow-up and, therefore, the young age of participants in this pilot randomised controlled trial in comparison with any future Phase III randomised controlled trial. For mediators, response rates were high and missing data were low. Test–retest reliability was low for potential mediators, probably reflecting rapid transitions in early adolescence. Inter-item reliability was, however, generally high.

Interviews with students suggested that the curriculum and social-marketing components had brought students together, enabling them to learn together and have more open conversations about sexuality and sexual health. Staff interviews similarly suggested that the intervention could enhance staff–student relationships and increase engagement among less academic students. Staff also highlighted synergies between the intervention components. Some students saw the intervention as providing 'the basics' of knowledge, which could provide the foundation for broader transformations in attitudes and behaviours. Several students indicated that the curriculum had raised awareness of their rights within relationships, particularly their right to say 'no' to unwanted sexual activities. These insights support the existing theory of change, with its emphasis on sexual health knowledge and self-efficacy, but also suggest that the theory might be broadened to include improving relationships between and among students and staff.

Staff and student interviews suggested several factors that promoted good implementation: senior leadership team commitment to personal, social, health and economic education, and the intervention; relationships and sex education becoming statutory in English schools; personal commitment among staff responsible for implementation; and trusting relationships between staff delivering the intervention. No harms for students were apparent from student or staff accounts. The possibility of increased stress for staff who were experiencing fertility problems or who were not comfortable teaching relationships and sex education was raised in staff interviews.

In terms of the comparator, some aspects of the provision in control schools resembled that offered in Positive Choices. Teachers delivered relationships and sex education, largely in tutor time; however, in neither school did the total time devoted to relationships and sex education approach that offered in Positive Choices. There was also less staff training in control schools than in the intervention. The comprehensiveness, quality and acceptability to students of teaching appeared to differ between the two control schools. In one school, actual provision appeared to fall short of what was aimed for in terms of the topics covered and classroom approaches used, with many teachers taking a cursory approach, which was largely rated badly by students. In the other school, lessons were much more comprehensive, addressing a breadth of topics similar to those in Positive Choices, with more participative teaching methods and greater acceptability to students. Neither school had a staff/student committee that co-ordinated sexual health activities, but there was some evidence that relationships and sex education was discussed at the student council in at least one of the schools. One school used a student survey similar to that used in Positive Choices to inform relationships and sex education planning. Neither school explicitly used student-led social marketing to promote sexual health across the school, but one school did include some student-led posters and assemblies. Both control schools had little or no on-site sexual health services. Both marketed local sexual health services to students, but with variable impact. Both schools had revised sexual health provision at around the time they were recruited into the trial and allocated to the control group.

Conclusions

The progression criteria for progression to a Phase III randomised controlled trial were met. Positive Choices was well delivered, highly acceptable to staff and students, and distinctive from the provision in control schools. Students in the intervention arm reported much more comprehensive coverage of relationships and sex education topics. Now is an auspicious time for a rigorous study of the effects of such a programme, with the advent of statutory relationships and sex education in all English schools for 2020.

Further work is needed to refine Positive Choices. This includes the development of curriculum materials for year 10 students. Our pilot suggested that the intervention theory of change was appropriate, but that this might be refined to encompass enhanced relationships among and between staff and students, and increased school engagement among less academic students; these mechanisms

resonate strongly with the theory of human functioning and school organisation, which might, therefore, usefully inform the theory of change.

The pilot study found that trial methods were feasible, but suggests several ways in which they could be refined for a Phase III randomised controlled trial. Routine data on births and abortions, although feasible to collect, do not make for an appropriate primary outcome. There were no abortions among the trial cohort based on exact matching on date of birth and postcode. Prevalence of teenage pregnancy is now so low that powering a primary analysis based on births and abortions would require a very large sample size. An alternative primary outcome might be the National Survey of Sexual Attitudes and Lifestyles measure of non-competent first sex, which was recommended by our policy/practice stakeholder group. To facilitate school planning and implementation, there should be a longer lead-in time between schools finding out that they have been allocated to the intervention group and the schools being expected to start implementing the intervention. It was determined that an economic evaluation in the form of a cost–consequences analysis as described is likely to be feasible; however, further research is warranted, especially in terms of identifying the costs associated with the potential consequences of the intervention.

Trial registration

This trial is registered as ISRCTN12524938.

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