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

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Competing interests

Chris Bonell was a member of the NIHR Public Health Research programme research funding board 2013-2019. Rona Campbell is a current member of the NIHR Public Health Research programme research funding board.

Dr. Emmerson reports other from LSHTM, during the conduct of the study; and The Sex Education Forum is hosted at the charity National Children's Bureau. The Sex Education Forum receives funding from a number of organisations, for example income we generate through training contracts with Local Authorities; a grant programme delivered in partnership with the Anti-Bullying Alliance (also hosted at National Children's Bureau) and funded by Government Equalities Office, also revenue from our membership. All our work operates under a clear set of values and principles which are in line with evidence-based comprehensive Relationships and Sex Education, and are therefore compatible with our contribution to Positive Choices.

Dr. Morris reports being a member of the following NIHR committees: NIHR HS&DR Funding Board, 2014-2019; NIHR HS&DR Commissioning Board, 2014-2016; NIHR HS&DR Evidence Synthesis Sub-board, 2016; NIHR, NIHR HTA Commissioning Board, 2009-2013; NIHR Public Health Research Funding Board, 2011-2017; NIHR Programme Grants for Applied Research expert sub-panel 2015-2019

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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 at highest risk of unplanned pregnancy with around half of conceptions to under 18s ending in abortion. After controlling for prior disadvantage, teenage parenthood is associated with adverse medical and social

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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's (NCB) Sex Education Forum (SEF) as intervention provider and other stakeholders. This intervention was informed by selected elements from three effective interventions: 'Safer Choices', the 'Children's AIDS Society (CAS) Carrera' program and the 'Gatehouse Project'. The intervention consisted of: student needs survey; staff training; a school health promotion council (SHPC) comprising staff and students to review data, identify local priorities and coordinate intervention; a student curriculum; student-led social-marketing campaigns; and review of school and local sexual-health services.

Aims

A) With SEF, 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.

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 randomised controlled trial (RCT) involving four intervention and two control schools to determine the feasibility and utility of conducting a phase-III RCT of effectiveness and cost effectiveness.

D) To answer the study's research questions.

Research questions

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

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

3) In the light of a pilot RCT across six schools, is progression to a phase-III RCT justified in terms of pre-specified criteria: the intervention is implemented with fidelity of delivery compared to a priori standards in ≥three 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 of six schools accept randomisation and continue within the study; student questionnaire follow

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up rates are ≥80% in ≥five of six schools; and linkage of self-report and routine administrative data on pregnancies is feasible.

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

5) With what rates are schools recruited to and retained in the RCT?

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

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

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

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

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

11) Are methods for economic evaluation in a phase-III RCT 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 RCT (May 2018-December 2019).

During optimisation, the research team collaborated with the NCB SEF (the intervention provider) to elaborate the intervention, drafting and refining intervention materials, informed by a review of existing evidence, consultation with students and staff in one secondary schools, and consultation with the Advice Leading to Public Health Action (ALPHA) young researchers' group as well as 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 SEF training for school staff; surveys of school staff trained by SEF; log-books completed by school staff implementing the SHPC, curriculum and student-led social marketing; structured observations of at least two sessions of the SHPC, curriculum lessons and social-marketing meetings; and individual or group interviews with three SEF staff, five school staff and eight year-9 students.

We then conducted a pilot RCT (four intervention, two control schools), with integral process evaluation and economic evaluation feasibility study. State secondary schools in south-east England,

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excluding pupil referral units and special schools, were sent recruitment emails. We selected six mixed-sex schools, varying by local deprivation and school-level GCSE attainment. The pilot RCT focused on feasibility and no power calculation was performed.

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

The intervention is described above. 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 sub-groups 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 (STIs); age of 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 (CHU9D). 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 log-books; 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 pre-specified metrics. The economic analyses aimed to: estimate the costs of delivering the intervention; collect data on 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 RCT.

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

We also undertook additional public involvement meetings with the ALPHA 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 (SSC). 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 reduced senior leadership team (SLT) commitment 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 sub-optimal fidelity, reflecting difficulties identifying staff and time for lessons. The SSC and NIHR approved progression to the pilot RCT.

In the pilot RCT, of the 334 schools invited, eleven 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 intervention and control groups were 868 (89.4%) and 298 (84.2%) at baseline, and 863 (89.0%) and 296 (82.0%) at follow-up.

In terms of intervention delivery, the target of achieving 70%+ implementation of essential elements in three schools was achieved. Training on SHPCs and student-led social marketing were implemented with fidelity in all four schools. The curriculum training, the SHPC 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 RSE topics than those in control schools. Interviews with staff and students involved in implementation indicated predominantly positive views.

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Regarding secondary outcome and covariate measures, completion rates were high for all except for age of sexual debut and partner numbers (where lower completion likely reflected the use of a 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 likely reflected the truncated period of follow-up and therefore the young age of participants in this pilot RCT in comparison with any future phase-III RCT. For mediators, response rates were high and missing data low. Test/retest reliability was low for potential mediators, likely 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, 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 as promoting good implementation: SLT commitment to personal, social, health and economic education (PSHE) and the intervention; RSE becoming statutory in English schools; personal commitment among staff responsible for implementation; and trusting relationships between staff delivering the intervention. No harms on students were apparent from student or staff accounts. The possibility of increased stress for staff experiencing fertility problems or not comfortable teaching RSE were raised in staff interviews.

In terms of the comparator, some aspects of provision in control schools resembled that offered in Positive Choices. Teachers delivered RSE, largely in tutor time. However, in neither school did the total time devoted to RSE approach that offered in Positive Choices. Staff training in control schools was also less 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

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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 that in Positive Choices, with more participative teaching methods and greater acceptability to students. Neither school had a staff/student committee which coordinated sexual-health activities but there was some evidence that RSE 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 RSE 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 RCT were achieved. Positive Choices was well delivered, highly acceptable to staff and students, and distinctive from provision in control schools. Students in the intervention arm reported much more comprehensive coverage of RSE topics. Now is an auspicious time for a rigorous study of the effects of such a programme, with the advent of statutory RSE in all English schools for 2020.

Further work is needed to refine Positive Choices. These include 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 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 RCT. Routine data on births and abortions though feasible to collect does 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 Natsal measure of non-competent first sex, which was recommended by our policy/practice stakeholder group. To facilitate school planning and

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implementation, there should be a longer lead-in time between schools finding they have been allocated to the intervention group and 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.

Registration

The study protocol was publicly registered on-line:
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