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Pilot study to develop and assess the feasibility and acceptability of Positive Choices: a school-based social marketing intervention to improve sexual health and reduce unintended teenage pregnancies in England

Submission date
27/06/2017

Registration date
03/07/2017

Last Edited
05/09/2023

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims:
The UK still has the worst rate of teenage pregnancy in Western Europe despite recent declines and the success of the teenage pregnancy strategy. Even after controlling for prior disadvantage, teenage pregnancy is associated with adverse medical, social, educational and economic outcomes for both mothers and children. The aim of this study is to develop, feasibility test and pilot 'Positive Choices': a new school-based sex and relationships programme that aims to prevent unintended teenage pregnancies and improve sexual health. Researchers from the London School of Hygiene and Tropical Medicine are collaborating with the National Children's Bureau Sex Education Forum (NCB SEF) and one London secondary school to develop the intervention. Following initial feasibility testing in the school that helped to develop the intervention and refinement of the programme based on what we find out, 'Positive Choices' in a further four state secondary schools, using two others as comparison sites. This will evaluate how feasible it is to implement Positive Choices in secondary schools in England and whether staff and students like it. This study is not intended to tell if Positive Choices is effective in reducing unintended teenage pregnancies or improving sexual health, but should help us understand if it is practical and worthwhile to carry out a larger study that could help us find this out. This initial study is important because a larger study looking at effects on pregnancies and sexual health would be much long term and expensive.

Who can participate?
Secondary school students nearing the end of year eight at the start of the trial.

What does the study involve?
Positive Choices has six core elements. It involves a school needs assessment so that the programme can be tailored to each individual school, a School Health Promotion Council to involve staff and students in organising and promoting the programme in their school,

classroom education on emotions and relationships (not just the biology of sex), students running campaigns in their school highlighting the importance of making informed decisions about relationships, sex and parenthood; parent information; and a review of school sexual health services. Positive Choices is implemented and feasibility tested in the school that helped to develop it in phases across the course of one academic year and the refined in light of what we find out. In the pilot, involving six further English secondary schools, all students nearing the end of year 8 are asked to complete a questionnaire to find out about their knowledge and attitudes towards sexual health. Schools are then randomly allocated to one of two groups. Four of the schools receive the refined Positive Choices programme, while two continue with their usual sex and relationships provision. The programme is assessed through observation, staff surveys, log books and staff and student interviews and focus groups. Measures for testing how well the programme has worked are also assessed through a follow up survey students are asked to complete at the end of year-9, 12 months after the first questionnaire.

What are the possible benefits and risks of participating?
Participants may benefit from being able to make more informed decisions about relationships, sex and parenthood and are unlikely to experience any physical or psychological harm, either because of the intervention or the research study. However, all participants are offered information about sources of support. Existing reviews suggest sex education is extremely unlikely to bring about increases in sexual activity and risk taking. Positive Choices is informed by the strongest international evidence on of effective interventions.

Where is the study run from?
The study is being run by the London School of Hygiene and Tropical Medicine

When is the study starting and how long is it expected to run for?
April 2017 to December 2019

Who is funding the study?
The National Institute of Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PHR 14/184/02

Study information

Scientific Title
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

Study objectives
Research Questions:
1. Is it possible to optimise Positive Choices in collaboration with NCB SEF, a 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 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.
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 trial?
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 trial feasible?

Ethics approval required
Old ethics approval format

Ethics approval(s)

The London School of Hygiene and Tropical Medicine Ethics Committee, 21/03/2017, ref: 11927

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

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Unintended teenage pregnancy and sexual health

Interventions
This study consists of three parts.

Part 1:
This phase of the study consists of the facilitated, systematic optimisation of the Positive Choices intervention. 'Positive Choices' is a manualised social marketing intervention comprising the following components:
1. A student needs survey (drawing on baseline trial survey) of year 8 students which are 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 comprises of six staff/six students and review local needs data and will review this to tailor each intervention component 3-6 below, and then coordinate delivery of the intervention.
3. A classroom curriculum which addresss 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 is designed as a set of learning modules. Social and emotional skills modules cover: establishing respectful relationships in the classroom and the wider school; managing emotions; understanding and building trusting relationships; exploring others' needs and avoiding conflict; and, maintaining and repairing relationships. Sexual health modules 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 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 is facilitated by trained teachers and led by teams of 12-18 students per school. Campaigns may use social and other media, posters and events, and focuses on healthy relationships, sexual and human rights, delayed sex, and access to local services. Student social marketers 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 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. Our collaborators from the Sex Education Forum provides consultancy on how sexual health service provision might be developed in schools.

This study works with the National Children's Bureau Sex Education Forum (NCB SEF) and one purposively sampled London secondary school to optimise and feasibility test Positive Choices. Optimisation occurs through a systematic process as follows:
1. Review by researchers and NCB SEF staff of existing systematic reviews and the evaluations of and, where appropriate, intervention materials from related programmes with strong evidence of reducing teenage pregnancy and/or improving sexual health.
2. Drafting of intervention resources by NCB SEF staff and the research team.
3. Consultation with staff and students from the secondary school, as well as the ALPHA young researchers' group based at the DECIPHer Centre at Cardiff University and other stakeholders.
4. Refinement of intervention resources.

Part 2:
This phase of the study includes formative feasibility assessment and refinement of intervention components in one secondary school.
The intervention components is then be implemented in phases over one school year and assessed for feasibility and acceptability in the school involved in optimisation. Following this, intervention materials are refined before a pilot trial to be carried out with six secondary schools the following academic year (2018-19).

Part 3:
This phase of the study consists of the external pilot cluster randomised controlled trial across six schools with integral process evaluation and economic evaluation feasibility study. Six schools across south-east England are recruited (purposively varying by local deprivation and school level GCSE attainment). 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 are recorded, as are any stated reasons for non-participation. Baseline surveys are carried out before randomisation as students near the end of year 8 (age 12/13) in June 2018. Prior to all data collection, students are given an information sheet and an oral description of the study, and have the chance to ask questions. Students are then be invited to assent to participate in data collection. As is conventional with UK trials in secondary schools (including of sexual health interventions) parents/guardians are 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 are 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. Absent students are surveyed by leaving questionnaires and stamped addressed envelopes with schools.

After the baseline surveys with students at the end of year 8 (approximately 180 per school), schools are randomly allocated to either the intervention or the control groups remotely by LSHTM clinical trials unit, stratified by GCSE attainment, a key predictor of pregnancy. In the pilot, allocation is done 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.

Schools in the intervention arm receive the refined Positive Choices intervention over the course of one academic year. The control group continue with existing sex and relationships education programmes (usual treatment). The nature of control schools is assessed by examining provision in and around both control and intervention schools at baseline.

Students are followed up with surveys at the end of the academic year 2018/19 (12 months after baseline) when they are nearing the end of year 9. Although, the pilot's primary aim is not to assess intervention effects, but feasibility for progression to a phase III trial, outcome measures, including the linking of routine data on pregnancy and terminations to the study participants, and mediator analyses are piloted.

In phase one and two, feasibility and acceptability of the intervention is assessed using data 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 School Health Promotion Councils, curriculum lessons and social marketing meetings; and individual or group interviews with NCB SEF staff, school staff (purposive by role/seniority) and year-9 students (purposive by gender and SES). Rich, contextual qualitative data is collected and analysed in order to explore potential mechanisms of action and thus refine our theory of change. These qualitative analyses 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. Qualitative data is also analysed to explore any mechanisms that might give rise to unintended, potentially harmful consequences.

Intervention Type
Behavioural

Primary outcome measure
Feasibility testing phase:
Meeting the criteria for progression to a pilot RCT (70% fidelity and 70% acceptability in one school) measured at 12 months by a tick box fidelity assessment, observations in the school where the intervention is implemented and interviews and focus groups with students and staff.

Pilot meeting the progression criteria to a phase III trial comprising:
1. The intervention is implemented with fidelity in ≥3 of 4 intervention schools
2. Process evaluation indicates that the intervention is acceptable to a majority of students and staff involved in implementation
3. Randomisation occurs and ≥5 of 6 schools accept randomization and continue within the study
4. Student questionnaire follow up rates are ≥80% in ≥5 of 6 schools
5. Linkage of self-report and routine administrative data on pregnancies and terminations is feasible.
These are measured at 12 months by a tick box fidelity assessment, observations in schools where the intervention is implemented, interviews and focus groups with students and staff, statistical assessment of survey follow up rates; and successful testing of data linkage.

In a phase III trial:
Unintended teenage pregnancy measured by linking routine data on births and terminations at 48 months (age 16/17) and secondary outcomes via self-reports at 24months (age 14/15) to study participants.

Secondary outcome measures
1. Pregnancy (initiation of pregnancy) and unintended pregnancy is measured using self-report questionnaire measures adapted from the RIPPLE Trial at 12 months
2. Sexually transmitted infections is measured using self-report questionnaire measures adapted from Natsal3 at 12 months
3. Age of sexual debut, number of sexual partners, use of contraception at first and last sex is measured using self-report questionnaire measures adapted from the SHARE Trial and Natsal3 at 12 months
4. Non-volitional sex is measured using self-report questionnaire measures adapted from the Conflict in Adolescent Dating Relationships Inventory at 12 months
5. Educational attainment is measured using school routine administrative data at 12 months.
6. School-level social norms supportive of positive relationships and sexual health are measured using self-report questionnaire measures adapted from the Safer Choices trial at 12 months
7. Individual-level sexual health knowledge and skills and contraceptive skills and access is measured using self-report questionnaire measures adapted from the SHARE Trial at 12 months
8. Self-efficacy is measured using self-report questionnaire measures adapted from the SHARE Trial and the Sexual Communication Self-Efficacy Scale at 12 months
9. Sexual competence is measured using self-report questionnaire measures adapted from Natsal3 at 12 months
10. Communication with parents is measured using self-report questionnaire measures adapted from the RIPPLE Trial at 12 months
11. School engagement is measured using the Beyond Blue School Climate Self-Report Questionnaire at 12 months
12. Career and educational aspirations are measured using self-report questionnaire measures adapted from the RIPPLE Trial at 12 months

Overall study start date
01/04/2017

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Secondary school student nearing the end of year 8

Participant type(s)
Healthy volunteer

Age group
Child

Sex
Both

Target number of participants
180 in optimisation aged 12-13. Approx 1080 for pilot RCT aged 12-13 at baseline and 13-14 at follow up.

Total final enrolment
1159

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

Date of first enrolment
01/11/2017

Date of final enrolment
14/05/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Trials Unit at the London School of Hygiene and Tropical Medicine
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
Public Health Research Programme (project number 15/03/09)

Alternative Name(s)
NIHR Public Health Research Programme, The Public Health Research (PHR), PHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
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 process evaluation of integrated social marketing strategy and 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.

Intention to publish date
01/05/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as consent was not obtained.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/05/2018		Yes	No
Basic results		15/01/2021	15/01/2021	No	No
Other publications	co-production of interventions	17/02/2021	23/02/2021	Yes	No
Results article	results	01/01/2021	23/02/2021	Yes	No
Participant information sheet			05/09/2023	No	Yes
Results article	Criteria for progression to a phase III trial	04/03/2022	05/09/2023	Yes	No