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The Positive Choices trial of a social marketing intervention to promote sexual health and reduce health inequalities among English secondary school students

Submission date
03/09/2021

Recruitment status
No longer recruiting

Registration date
03/09/2021

Overall study status
Completed

Last Edited
10/11/2025

Condition category
Other

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

Plain English summary of protocol
Background and study aims
Many young people experience poor sexual health. Most report a lack of 'competence' at first sex defining in terms of not using contraception, feeling pressure to have sex, partners not being equally willing to have sex and not feeling it is the right time to have sex. Relationships and sex education in school classrooms can contribute to promoting sexual competence and health, but in general its impact on students' sexual health is small, inconsistent and not sustained. Education in classrooms needs to be supplemented by 'whole-school' work such as student campaigns or sexual health services. Such work can be informed by 'social marketing' techniques which harness commercial marketing to social ends. There is good evidence from other countries that such interventions work but not from the UK. This study evaluates Positive Choices, a school-based programme informed by the above evidence. The aim is to assess if the Positive Choices intervention is effective in ensuring young people are competent at first sex, alongside other benefits. Involvement from policy, practice and youth groups recommended this outcome because those who report lack of sexual competence at first sex are more likely to experience later problems such as sexually transmitted infections, unplanned pregnancy, forced sex and sexual dysfunction. Furthermore, sexual competence is relevant for young people regardless of gender and sexual orientation.

Who can participate?
Young people aged 12/13 years attending English secondary schools

What does the study involve?
Schools will be randomly allocated to either deliver the intervention or act as comparisons. The study will include involvement from the public and professionals. Positive Choices is a whole-school social marketing intervention for secondary schools aiming to promote sexual health and comprising: a school health promotion council which involves staff and students working together to coordinate intervention delivery; student surveys informing local decisions about how to deliver the intervention; classroom lessons; student-run campaigns; parent information;

and review of sexual health services to inform improvements. The researchers will assess impacts by surveying students with questionnaires at the beginning of the study and then 33 months later. Surveys will ask students about sexual knowledge and experiences. They will also evaluate whether the intervention is worth the money and whether it is delivered well.

What are the possible benefits and risks of participating?
The intervention has the potential to improve participants' sexual health and relationships. Neither the intervention nor the evaluation are likely to harm participants. The evaluation will assess any potential harms or adverse events that occur during the study.

Where is the study run from?
The London School of Hygiene and Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
August 2021 to January 2025

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

Who is the main contact?
Prof. Chris Bonell
Chris.Bonell@lshtm.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

National Institute for Health and Care Research (NIHR)
131487

Study information

Scientific Title
Phase III randomised controlled trial of Positive Choices: a whole-school social-marketing intervention to promote sexual health and reduce health inequalities

Acronym
PositiveChoices

Study objectives
The Positive Choices intervention reduces by 36% student-reported measures of non-competent first sex (primary outcome) in intention-to-treat analyses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/08/2021, LSHTM research ethics committee (London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT, UK; +44 (0)20 7636 8636; ethics@lshtm.ac.uk), ref: 26411

Primary study design
Interventional

Study design
Superiority Phase III cluster parallel-group randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Sexual health

Interventions
Positive Choices is a whole-school intervention with the following components: school health promotion council comprising staff and students to plan, launch, coordinate and oversee delivery; a student needs survey of year-8 students which provides evidence to inform local tailoring; a classroom curriculum addressing social and emotional skills and relationships and

sexual health knowledge and skills delivered by school staff; student-run social-marketing campaigns facilitated by trained teachers; parent information; and review of school and other local sexual and reproductive health services to inform improvements.

This trial will recruit 50 schools, half of whom will be randomly chosen to deliver the intervention with the others acting as
comparisons. Schools will be randomly allocated 1:1 to intervention/control as a single batch using a random number generator remotely by LSHTM clinical trials unit (CTU), stratified by school-level GCSE attainment and local index of deprivation, which are key predictors of sexual health. Schools will be given unique study numbers to preserve allocation concealment within the CTU.

The researchers will assess impacts by surveying students with questionnaires at the beginning of the trial and then 33 months later. Surveys will ask students about sexual knowledge and experiences. The researchers will also evaluate whether the intervention is worth the money and whether it is delivered well.

Intervention Type
Behavioural

Primary outcome(s)
Non-competent first sex assessed among trial participants having sex for the first time between baseline and follow-up (33 months), using the established Natsal self-report measure defined in terms of the absence at first sex of: autonomy of decision; equal willingness of partners; it being the ‘right time’; and, for those reporting heterosexual intercourse, use of effective contraception.

Key secondary outcome(s)
Current secondary outcome measures as of 06/11/2023:

1. Age at sexual debut measured using an adapted version of the RIPPLE measure of sexual debut at baseline and 33 months
2. Non-use of contraception at first and last sex among those reporting heterosexual intercourse measured using an adapted version of the RIPPLE measure of contraception use at 33 months
3. Number of sexual partners measured using an adapted RIPPLE measure of partner numbers at 33 months
4. Dating and relationship violence victimisation measured using an adapted version of the short Conflicts in Adolescent Dating Relationships Inventory at baseline and 33 months
5. Self-reported diagnoses of sexually transmitted infections measured using an adapted version of the RIPPLE measure of sexually transmitted infections at 33 months
6. Pregnancy and unintended pregnancy among girls measured using adapted versions of the RIPPLE measures of pregnancy at 33 months
7. Initiation of pregnancy among boys measured using an adapted version of the RIPPLE measures of pregnancy initiation at 33 months
8. Health-related quality of life measured using the Child Health Utility 9D measure at baseline and 33 months

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Previous secondary outcome measures:

1. Non-competent last sex measured using the Natsal measure of sexual competence at 33 months
2. Age at sexual debut measured using an adapted version of the RIPPLE measure of sexual debut at baseline and 33 months
3. Non-use of contraception at first and last sex among those reporting heterosexual intercourse measured using an adapted version of the RIPPLE measure of contraception use at 33 months
4. Number of sexual partners measured using an adapted RIPPLE measure of partner numbers at 33 months
5. Dating and relationship violence victimisation measured using an adapted version of the short Conflicts in Adolescent Dating Relationships Inventory at baseline and 33 months
6. Self-reported diagnoses of sexually transmitted infections measured using an adapted version of the RIPPLE measure of sexually transmitted infections at 33 months
7. Pregnancy and unintended pregnancy among girls measured using adapted versions of the RIPPLE measures of pregnancy at 33 months
8. Initiation of pregnancy among boys measured using an adapted version of the RIPPLE measures of pregnancy initiation at 33 months
9. Health-related quality of life measured using the Child Health Utility 9D measure at baseline and 33 months

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. Students aged 12-16 years
2. Deemed competent to consent by schools
3. Moving from year 8 into year 11 during the trial
4. In English secondary schools (including faith schools, free schools, academies and private schools) excluding pupil referral units, schools for those with special educational needs and disabilities, and schools with poor Ofsted (government school inspectorate) inspections

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 Years

Upper age limit
16 Years

Sex
All

Total final enrolment
6970

Key exclusion criteria
1. Students not deemed competent to consent by schools or students in pupil referral units
2. Schools for those with special educational needs and disabilities
3. Schools with poor Ofsted inspections

Date of first enrolment
01/09/2021

Date of final enrolment
01/03/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
London School of Hygiene and Tropical Medicine
15-17 Tavistock Place
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Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name

Public Health Research Programme

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Chris Bonell (chris.bonell@lshtm.ac.uk). Anonymised baseline and follow-up quantitative data will be available from January 2026 for 5 years for academic researchers with a peer-reviewed protocol and ethics committee approval who contact the trial team contact to analyse the data to assess intervention effects subject to the development of a data-sharing agreement between the researchers and the trial team. Consent was obtained from participants for this.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/11/2025	10/11/2025	Yes	No
Participant information sheet	Consent form		03/09/2021	No	Yes
Participant information sheet	Parents/carers		03/09/2021	No	Yes
Participant information sheet	Students		03/09/2021	No	Yes
Participant information sheet		04/07/2024	19/07/2024	No	Yes
Participant information sheet		04/07/2024	19/07/2024	No	Yes
Participant information sheet		04/07/2024	19/07/2024	No	Yes
Protocol file	version 1.0	09/07/2021	03/09/2021	No	No
Protocol file	version 2.0	15/10/2021	12/10/2021	No	No
Protocol file	Flowchart for v2		21/10/2021	No	No
Protocol file	Logic model for v2		21/10/2021	No	No
Protocol file	version 5	03/11/2023	06/11/2023	No	No
	version 6				

Protocol file	version 7	30/05/2024	19/06/2024	No	No
Protocol file			30/07/2024	No	No