


UPDATE

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The Positive Choices trial: update to study protocol for a phase-III RCT trial of a whole-school social-marketing intervention to promote sexual health and reduce health inequalities

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Abstract

Background: Positive Choices is a whole-school social-marketing intervention to promote sexual health among secondary school students. Intervention comprises the following: school health promotion council involving staff and students coordinating delivery, student survey to inform local tailoring, teacher-delivered classroom curriculum, student-run campaigns, parent information and review of sexual/reproductive health services to inform improvements. This trial builds on an optimisation/pilot-RCT study which met progression criteria, plus findings from another pilot RCT of the Project Respect school-based intervention to prevent dating and relationship violence which concluded such work should be integrated within Positive Choices. Young people carry a disproportionate burden of adverse sexual health; most do not report competence at first sex. Relationships and sex education in schools can contribute to promoting sexual health but effects are small, inconsistent and not sustained. Such work needs to be supplemented by 'whole-school' (e.g. student campaigns, sexual health services) and 'social marketing' (harnessing commercial marketing to social ends) approaches for which there is good review-level evidence but not from the UK.

Methods: We will conduct a cluster RCT across 50 schools (minimum 6440, maximum 8500 students) allocated 1:1 to intervention/control assessing outcomes at 33 months. Our primary outcome is non-competent first sex. Secondary outcomes are non-competent last sex, age at sexual debut, non-use of contraception at first and last sex among those reporting heterosexual intercourse, number of sexual partners, dating and relationship violence, sexually transmitted infections and pregnancy and unintended pregnancy for girls and initiation of pregnancy for boys. We will recruit 50 school and undertake baseline surveys by March 2022, implement the intervention over the 2022–2024 school years and conduct the economic and process evaluations by July 2024; undertake follow-up surveys by December 2024; complete analyses, all patient and policy involvement and draft the study report by March 2025 and engage in knowledge exchange from December 2024.

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Discussion: This trial is one of a growing number focused on whole-school approaches to public health in schools. The key scientific output will be evidence about the effectiveness, costs and potential scalability and transferability of Positive Choices.

Trial registration: ISRCTN No: [ISRCTN16723909](https://www.isrctn.com/ISRCTN16723909). Registered on 3 September 2021.

Keywords: Schools, Adolescents, Sexual health, Sexual competence, Pregnancy, Sexually transmitted infections, Whole-school, Cluster trials, Public health

Changes to the protocol

Changes for version 3.0

Amendment 1: Option of surveying students online at home

If schools dismiss classes and move to online learning because of COVID infections, we will offer schools the option of surveying students online at home. Schools will send students details of how to log in to surveys using laptops, phones or tablets. Surveys will include links to information boxes explaining key terms informed by the questions students have raised during classroom-based surveys. Students will be asked to skip questions they do not understand or do not wish to answer. Students will be advised to contact their school safeguarding lead for support should they feel confused or upset as a result of completing the questionnaire, with the team briefing safeguarding leads about this and liaising with them to record where this has occurred.

Amendment 2: Increase in number of lessons

We will add one additional (core) lesson for year 10 students in intervention group to ensure dating and relationship violence and sexual harassment are adequately addressed [1].

Amendment 3: Flexibility for training arrangements

We will provide training to schools more flexibly to fit with school needs. The initial training for school leads in the curriculum will remain as 7 h in total, but this will be delivered in flexible sections to fit school needs. This training will be video-recorded and made available to schools. The training which school leads cascade to other teachers involved in delivering the curriculum will involve a minimum of three hour's training but organised flexibly to fit school needs.

Changes for version 4.0: Further amendments to intervention

Amendment 4

The intervention has been modified in three ways. First, the initial start-up meeting with schools has been reduced from 2 h to half an hour. Second, the cascading of training by schools internally has been broadened to allow a range of total training duration from 1 to 3 h. Third is additional support in the form of webinars and

drop-in sessions. These changes have been made based on advice from the Sex Education Forum as the intervention lead agency. They reflect the need for support to schools to be more flexible to reflect schools' varying needs.

Trial status

Schools were recruited September–December 2021, and students are being recruited and surveyed November 2021–March 2022.

Abbreviations

DRV: Dating and relationship violence; RCT: Randomised controlled trial; RIPPLE: Randomised intervention for pupil led sex education in England

Acknowledgements

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Authors' contributions

Chris Bonell is the principal investigator and led the development of this protocol. Ruth Ponsford is the trial manager and advised on drawing on the previous pilot trial of Positive Choices to inform this protocol. Rebecca Meiksin advised on drawing on the previous pilot trial of Project Respect to inform how DRV is addressed and researched within this protocol. Elizabeth Allen is the lead statistician and advised on the sample size calculation and statistical analysis plans. GJ Melendez-Torres advised on the statistical analysis and analysis of process data. Steve Morris is the trial economist and advised on economic methods. Catherine Mercer advised on outcome measures. Rona Campbell advised on intervention refinement and process evaluation methods. Honor Young advised on quantitative methods. Maria Lohan advised on intervention elements for boys as well as trial design. Karin Coyle advised on Positive Choices being informed by the Safer Choices intervention. All co-authors contributed to drafting and approved the submitted version of this paper.

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Sponsor: London School of Hygiene and Tropical Medicine Research Governance and Integrity Office, Keppel St, London WC1E 7HT. No role in study design or conduct.

Oversight: Independent SSC and DMEC appointed by the funder with respectively oversight of trial design and conduct and data integrity, ethics and participant safety. Composition available on request.

Availability of data and materials

Data will be made available after the main trial analyses have been completed on reasonable request from researchers with ethics approval and a clear protocol.

Declarations

Ethics approval and consent to participate

Ethical approval for the study has been obtained from the LSHTM Ethics Committee (reference 26411). Any member of the research/fieldwork team working with students without supervision by school staff will be required to have a full disclosure and barring services check. All work will be carried out in accordance with guidelines laid down by the Economic and Social Research Council, the Data Protection Act 1998 and GDPR.

Head teachers as gatekeepers will be asked for informed consent for intervention and random allocation by the principal investigator. Parents will have a statutory right to withdraw their children from sex education lessons in intervention and control schools. In terms of research participation, as is normal within public health and educational research in secondary schools in the UK (e.g. RIPPLE trial), informed written opt-in consent will be sought from all research participants by trained fieldworkers, including students judged by teachers as competent to provide this. Parents will also be given the right to opt out their children if they wish. In all cases of data collection, participants (and, in the case of students, their parents also) will be given an information sheet 1 week before data collection and will be able to opt out (or, in the case of parents, can opt their children out) of this should they wish. Just before data collection, participants who have not previously opted or been opted out will receive an oral and written description of the study and the chance to ask questions of trained fieldworkers. In the eventuality of online surveys being conducted in schools not allowing face-to-face fieldwork, participants will receive the same information and have the same opportunity to ask questions of trained fieldworkers via telephone or internet technologies in real time. 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 will not be communicated to others within the school or family. Students will then be asked for their written consent to participate by the fieldworker. In the eventuality of online surveys being conducted, students will be asked to consent via preliminary pages of the online survey. Students opting not to participate in research activities will continue with normal school activities.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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