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Effects of a whole-school relationships and sexual health intervention on non-competent sexual debut: cluster-randomised trial

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ABSTRACT

Background Relationships and sex education (RSE) impacts some sexual behaviours but could be strengthened by incorporating whole-school approaches (eg, building engagement, providing contraception). These can prevent pregnancies and sexually-transmitted infections but are unevaluated in UK schools.

Methods A cluster-randomised trial of 'Positive Choices' compared it with usual practice in English secondary schools. Intervention comprised: RSE, school-health-promotion councils involving students, student-needs data to tailor provision; student-led campaigns; review of sexual-health services; and parent information. The primary outcome was prevention of non-competent sexual debut (lacking decision autonomy, judging timing as right, partners' equal willingness or contraception).

Results Of 2845 schools invited, 50 (1.76%) consented, 1 leaving post-allocation. Of 25 control and 24 intervention schools, 4 withdrew pre-endline. 6970 (77.3%) students participated at baseline and 6268 (77.9%) at 33-month endline. Fidelity of whole-school components was suboptimal. No schools achieved 'good' fidelity; two achieved 'adequate' fidelity across components. 11 achieved 'adequate fidelity on selected components' (student-needs report, school-health-promotion council meetings, lessons, parent information). Control schools delivered similar activities to intervention schools. Among 780 (12.44%) students sexually debuting between baseline and endline, non-competent debut was reported by 268 (64.42%) in the control and 240 (65.93%) in the intervention group (risk difference=0.020 (95% CI -0.05 to 0.09)). There were no effects on secondary outcomes. Incremental costs were £1337 per school (£10 per student).

Conclusion Positive Choices did not prevent non-competent sexual debut (primary outcome) or impact secondary outcomes compared with usual RSE, possibly explained by weak fidelity of whole-school elements and/or comprehensive RSE in control schools.

Trial registration number [ISRCTN16723909](https://www.isrctn.com/16723909).

INTRODUCTION

Globally, adolescent girls report later sexual debut, more contraception use and later birth of their first child than 25 years ago.¹ However, in the UK,

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Relationship and sex education (RSE) can impact some sexual behaviours but could be strengthened by incorporating whole-school approaches addressing school environments (eg, building engagement or providing contraception).

WHAT THIS STUDY ADDS

⇒ Positive Choices did not prevent non-competent sexual debut (primary outcome) or impact secondary outcomes compared with usual RSE.
⇒ This might be explained by weak fidelity of whole-school elements and/or comprehensive RSE in control schools.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Positive Choices was ineffective and should not be scaled up. Whole-school sexual health interventions are challenging to deliver in some school systems.

despite reductions in recent decades, births among women aged 15–17 remain the highest in western Europe.² Rates of sexually-transmitted infections (STIs) overall and among those aged 15–24 are increasing, and burden is greatest among the latter.³ Most adolescents do not report first sex as being 'competent' (involving: autonomy of decision, judging timing to be right, partners' equal willingness and contraception).⁴ Non-competent debut predicts human papillomavirus diagnosis and dissatisfaction and distress with one's sex life, and, among women, STI diagnosis, unplanned pregnancy and non-volitional sex.⁴ In the UK, most adolescents experiencing dating relationships report dating-and-relationship violence (DRV), and half of girls and one-tenth of boys report forced or pressured sex.⁵ Sexual harassment is experienced by around two-thirds of adolescents.⁶

From 2020, relationships-and-sex education (RSE) became statutorily required in English secondary schools, requiring schools to deliver comprehensive RSE addressing



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biological and social topics and aiming to promote healthy relationships and risk reduction. RSE can delay sexual debut, increase condom and contraception use and prevent DRV, but effects vary.^{7–10} There is less evidence that RSE alone can prevent teenage pregnancy, HIV or STIs,¹¹ outcomes influenced by broader determinants. RSE should be complemented with environmental interventions.¹² ‘Whole-school’ interventions are one means to do this, including environmental components (eg, building school engagement, student-led campaigns, contraception access). A 2019 systematic review reported these delays in sexual debut and can prevent pregnancies and STIs.¹³ Safer Choices was a US whole-school intervention comprising: school-health-promotion council involving students coordinating activities; RSE; student-led campaigns; parent information; and linkages with sexual-health services. A randomised controlled trial (RCT) reported sexually experienced students in intervention schools reported: less frequent intercourse without a condom (ratio of adjusted means=0.63, $p=0.05$); unprotected sex with fewer partners (ratio of means=0.73, $p=0.02$); and more condom (OR=1.68; $p=0.04$), and effective contraception use (OR=1.76; $p=0.05$).¹⁴ In Australia, the Gatehouse whole-school intervention comprised: student needs assessment;

student/staff decision-making group; and social and emotional learning. An RCT reported delayed sexual debut (OR=0.55, 95% CI 0.37 to 0.83).¹⁵

Whole-school sexual health interventions have not been tested in the UK. The present RCT evaluated the effects of the Positive Choices whole-school intervention with similar components to Safer Choices on non-competent sexual debut (primary outcome) and secondary outcomes using a cluster-RCT to reflect school-level intervention. A prior pilot RCT assessed feasibility.¹⁶ All progression criteria were met: the intervention was feasible, delivered with good fidelity and acceptability. Here, we report phase-III trial results addressing the following questions prioritised by stakeholders¹⁶:

1. What is the effect of the intervention in intention-to-treat analyses on student-reported non-competent first sex (primary outcome), and various secondary and intermediate outcomes?
2. Are effects moderated by student and school characteristics?
3. Are effects greater after accounting for intervention fidelity?
4. What does the intervention cost and is it cost-effective?
5. What is usual treatment in control schools?

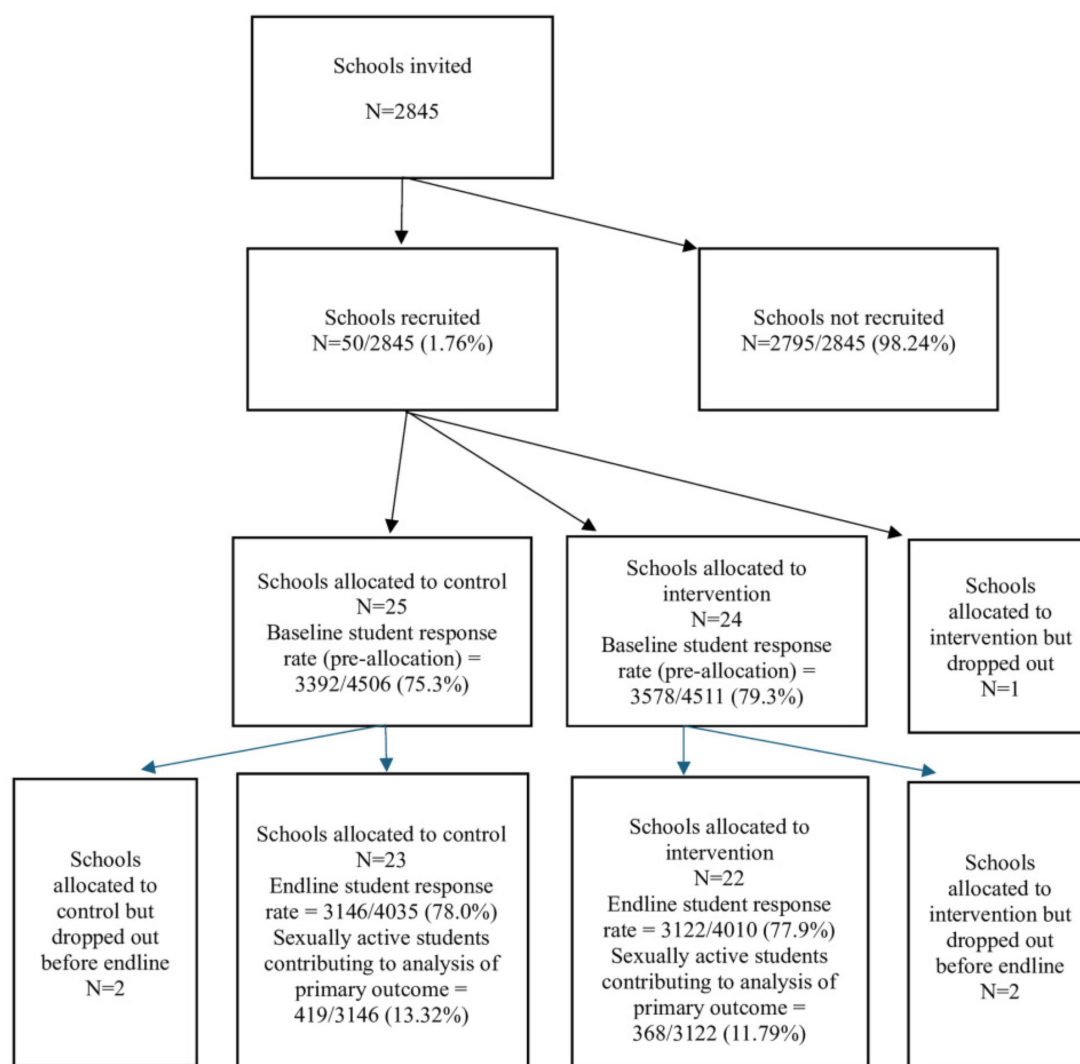


Figure 1 Recruitment and response rates.

Table 1 School and student characteristics at baseline

Characteristic		Control group N (%)	Intervention group N (%)
Schools		25	24
School sex mix*	Schools providing data	25	24
	Mixed	22 (88.0)	21 (87.5)
	Female only	3 (12.9)	1 (4.2)
	Male only	0 (0)	2 (8.3)
School type*	Schools providing data	25	24
	Voluntary-aided	4 (16.0)	0 (0)
	Voluntary-controlled	1 (4.0)	0 (0)
	Community	2 (8.0)	6 (25.0)
	Academy (converter mainstream)	10 (40.0)	10 (41.7)
	Academy (sponsor led)	5 (20.0)	4 (16.7)
	Foundation	1 (4.0)	2 (8.3)
	Free school	1 (4.0)	1 (4.2)
	Private	1 (4.0)	1 (4.2)
	Schools providing data	25	24
Faith schools*	Faith schools	3 (12.0)	3 (12.5)
	Non-faith schools	22 (88.0)	21 (87.5)
Ofsted rating*†	Schools providing data	24	23
	Outstanding	3 (12.5)	4 (17.4)
	Good	18 (75.0)	13 (56.5)
	Requires improvement	0 (0)	4 (17.4)
	Not available	3 (12.5)	2 (8.7)
	Schools providing data	23	22
Attainment 8 measure of academic achievement (SD)*†‡	Mean (SD)	47.68 (9.97)	47.50 (7.55)
	Schools providing data	24	23
Proportion of students entitled to free school meals*§	Mean (SD)	21.7 (14.1)	24.4 (14.3)
	Schools providing data	25	24
School size	Mean (SD)	1048 (475)	1096 (362)
	Schools providing data	25	24
Income Deprivation Affecting Children Index¶	Mean (SD)	0.117 (0.100)	0.136 (0.094)
	Schools providing data	25	24
Students		3392	3578
Age, mean (SD)		12.4 (0.50)	12.5 (0.50)
Sex, N (%)	Male	1366 (40.3)	1925 (53.8)
	Female	1997 (58.9)	1624 (45.4)
Gender, N (%)	Boy	1341 (39.5)	1900 (53.1)
	Girl	1787 (52.7)	1492 (41.7)
	Trans boy	33 (1.0)	20 (0.6)
	Trans girl	7 (0.2)	2 (0.1)
	Non-binary	76 (2.2)	54 (1.5)
	Other	92 (2.7)	66 (1.8)
	White	2417 (71.3)	2416 (67.5)
	Mixed/multiple ethnic groups	177 (5.2)	219 (6.1)
Ethnicity, N (%)	Asian or Asian British	221 (6.5)	237 (6.6)
	Black African, black Caribbean or black British	152 (4.5)	240 (6.7)
	Any other ethnic group	53 (1.6)	33 (0.9)
	Straight or heterosexual	2515 (74.1)	2803 (78.3)
	Gay or lesbian	109 (3.2)	74 (2.1)
Sexual orientation, N (%)	Bisexual	221 (6.5)	205 (5.7)
	Asexual	63 (1.9)	57 (1.6)
	Unsure/questioning	212 (6.3)	164 (4.6)
	Other	117 (3.4)	87 (2.4)

Continued

Table 1 Continued

Characteristic		Control group N (%)	Intervention group N (%)
Religion, N (%)	None	1781 (52.5)	1899 (53.1)
	Christian (including Protestant and Catholic)	895 (26.4)	937 (26.2)
	Jewish	16 (0.5)	5 (0.1)
	Muslim/Islam	160 (4.7)	225 (6.3)
	Hindu	49 (1.4)	41 (1.1)
	Buddhist	20 (0.6)	19 (0.5)
	Sikh	13 (0.4)	31 (0.9)
	Other religious group	39 (1.1)	29 (0.8)
	I do not know/not sure	331 (9.8)	310 (8.7)
Family structure, N (%)	Two parents	2355 (69.4)	2398 (67.0)
	Single mother	470 (13.9)	605 (16.9)
	Single father	50 (1.5)	58 (1.6)
	Reconstituted	281 (8.3)	284 (7.9)
	Other	49 (1.4)	34 (1.0)
Sexual experience, N (%)	No, never	2903 (85.6)	3092 (86.4)
	Yes, once	4 (0.1)	2 (0.1)
	Yes, more than once	2 (0.1)	9 (0.3)
Family Affluence Scale (mean, SD)		8.0 (2.13)	7.8 (2.16)
Child Health Utility (mean, SD)		0.8 (0.12)	0.8 (0.12)

*Data on school population, Ofsted ratings and school sex make up were taken from get-information-schools.service.gov.uk, accessed January 27 2022.

†Statistics for state-funded schools only.

‡Due to the COVID-19 pandemic, data from 2018 to 2019 were the latest available for Attainment 8 score and absence. These were taken from compare-school-performance.service.gov.uk/download-data, accessed on January 25 2022 (absence data) and February 27 2022 (Attainment 8 and Progress 8 scores).

§Data on free school meals for 2020–2021 were taken from <https://www.compare-school-performance.service.gov.uk/download-data>, accessed 27 January 2022.

¶Income Deprivation Affecting Children Index data were taken from <https://imd-by-postcode.opendatacommunities.org/imd/2019>, accessed 4 February 2022.

METHODS

Study design and participants

We aimed to conduct a parallel-arm, school-level cluster RCT in 50 secondary schools from 2021 to 2025 with process and economic evaluations. Eligible schools were of any type except those for students excluded from mainstream schools or with special educational needs and disabilities, or judged ‘inadequate’ by government school inspectors. We recruited across central/southern England (online supplemental materials 1) via emails to schools. We sought head teachers’ consent.

For baseline surveys before randomisation, we obtained enrolment lists of students in year 8 (aged 12–13) during the 2021/2022 school year. Students deemed competent by schools to consent were eligible. At endline, students enrolled in year 11 (aged 15/16) during the 2024/2025 school year were eligible. At baseline and endline, parents/carers were informed about the study, could ask questions or withdraw their children. We sought opt-in student consent. Students received information 1 week before surveys and could opt out. Immediately before the survey, students received verbal and written information and could ask questions before deciding whether to participate.

A protocol (online supplemental materials 2) was registered (ISRCTN16723909). For amendments to, and deviations from, this see online supplemental materials 3 and 4. An independent study steering committee and data monitoring and ethics committee oversaw the study.

Randomisation and masking

After baseline surveys, schools were randomly allocated 1:1 to intervention/control as a single batch using random-number generation by London School of Hygiene and Tropical Medicine clinical trials unit, stratified by school-level educational attainment (General Certificate of Secondary Education) and local

deprivation (Income Deprivation Affecting Children Index): predictors of sexual health.¹⁷ We informed schools of allocation in April 2022. Trial statisticians and survey fieldworkers were masked.

Intervention and comparator

Positive Choices was informed by Safer Choices and Gatehouse interventions,^{14 15} [4] comprising:

1. School-health-promotion council (SHPC) involving six staff and six students, meeting termly to plan and oversee components 3–6. SHPCs included a school senior leader plus a day-to-day lead (usually school RSE coordinator).
2. Student-needs report (drawing on baseline survey) to inform tailoring of intervention components 3–6.
3. RSE delivered by teachers (eight ‘essential’ lessons for year 9 and five for year 10 plus two ‘add-on’ lessons for year 9 and one for year 10 chosen from a menu, providing 10 hours for year 9 and 6 hours for year 10 in total (online supplemental materials 5).
4. Student-led campaigns, planned and implemented by 12–18 students per school, facilitated by trained teachers. Campaigns focused on relationships and sexual health, with at least one campaign per year.
5. Parent information: three communications and two homework assignments per year addressing parent-child communication about sexual health.
6. Review of school and local sexual health services to improve awareness or provision.

Delivery was supported by the Sex Education Forum (SEF) charity, which provided materials for all components (online supplemental materials 5).

Intervention theory of change (online supplemental materials 6) was informed by social influence¹⁸ and social cognitive¹⁹

Table 2 Primary outcome at 33-month endline: intention-to-treat analysis

Primary outcome measures	Control group N (%)	Intervention group N (%)	Adjusted* risk ratio (95% CI)	P value	Additionally adjusted† risk ratio (95% CI)	P value	Adjusted* risk difference	Additionally adjusted† risk difference	ICC (95% CI)
Non-competent sexual debut (among students reporting sexual experience)	268 (64.42)	240 (65.93)	1.034 (0.93 to 1.15)	0.538	1.025 (0.92 to 1.14)	0.649	0.020 (−0.05 to 0.09)	0.014 (−0.05 to 0.08)	0.009 (0.000 to 0.357)

* Adjusted for school-level General Certificate of Secondary Education attainment and local index of deprivation.

† Additionally adjusted for prespecified cluster level summaries of baseline student age, gender, ethnicity and family affluence scale.

theories to address: RSE knowledge, skills and communication self-efficacy; attitudes about gender and DRV; social norms about sexual health and relationships; and sexual health communication with parents. It was also informed by the social development model,²⁰ with student participation theorised to increase school engagement and aspirations. Student campaigns drew on social-marketing approaches.

Control schools continued with planned RSE/sexual-health provision.

Data collection

We conducted baseline student surveys (December 2021 to March 2022) and endline surveys around 33 months later. Students completed paper questionnaires in classrooms. Field-workers offered support. Teachers remained at classroom fronts, not viewing student responses.

We assessed fidelity of implementation against prespecified indicators based on observations, implementor logbooks and meeting minutes. We collected qualitative data to explore implementation and address gaps in quantitative data. We aimed to interview school intervention leads each year. In four case-study intervention schools selected for diversity in attainment and local deprivation, we interviewed three other staff members involved in intervention activities. We assessed provision in control schools through annual interviews with liaising staff members.

Outcomes

The primary outcome, recommended by stakeholder engagement, was prevention of non-competent sexual debut between baseline and endline (defined for heterosexual sex as penis-vaginal and for same-sex sex simply as 'sex'), assessed using the National Sexual Attitudes and Lifestyles measure defined in terms of the absence of any of: autonomy of decision; equal willingness of partners; being the 'right time'; and (for heterosexual sex) use of effective contraception.^{4 21} This predicts risk of STIs, non-volitional sex, unplanned pregnancy and sexual dysfunction⁴ and has been recommended as an impact measure by the WHO.²²

Secondary outcomes examined other potential benefits (using versions of self-report measures from a previous trial²³ except indicated): age of sexual debut among those reporting this; non-use of contraception at first and last sex (respectively among those reporting at least 1 and >1 heterosexual intercourse); number of sexual partners among those reporting this; DRV victimisation using an adapted short Conflicts in Adolescent Dating Relationships Inventory (CADRI-s) among those reporting dating in the previous year²⁴; diagnosis with common STIs among all participants; pregnancy and unintended pregnancy among girls; and causing a pregnancy among boys. Because it was apparent as we analysed the data that sexual debut in the trial was lower than expected, so that age of sexual debut would be a poor indicator of any intervention effects on delaying debut, we additionally report heterosexual and same-sex sexual debut as binary secondary outcomes (see deviations from protocol in online supplemental file 1). The economic analysis used the Child-Health-Utility (CHU)-9D measure to calculate quality-adjusted life years.²⁵ Responses were converted to utility scores using UK preference weights.²⁶

Informed by our theory of change, we undertook exploratory analyses of 'intermediate' outcomes using the following existing measures: school-level social norms supportive of healthy relationships and sexual health; attitudes towards DRV and gender roles; school engagement; aspirations; sexual health knowledge;

Table 3 Binary secondary outcomes at 33-month endpoint: intention-to-treat analysis

Secondary outcome measures	Control group N (%)	Intervention group N (%)	Adjusted* risk ratio (95% CI)	P value	Additionally adjusted† risk ratio (95% CI)	P value	Adjusted* risk difference	Additionally adjusted† risk difference
Heterosexual debut (among all participants)	386 (12.57)	345 (11.33)	0.877 (0.71 to 1.09)	0.237	0.830 (0.68 to 1.01)	0.060	-0.14 (-0.04 to 0.01)	-0.028 (-0.05 to -0.01)
Same-sex sexual debut (among all participants)	33 (1.18)	23 (0.84)	0.638 (0.41 to 1.12)	0.127	0.688 (0.39 to 1.20)	0.194	-0.004 (-0.01 to 0.00)	-0.002 (-0.01 to 0.01)
Non-use of contraception at first heterosexual intercourse (among students reporting heterosexual intercourse)	110 (28.50)	98 (29.08)	0.992 (0.79 to 1.25)	0.947	0.898 (0.70 to 1.14)	0.389	-0.006 (-0.07 to 0.06)	-0.029 (-0.10 to 0.04)
Non-use of contraception at last sex (among students reporting >1 heterosexual intercourse)	85 (29.01)	64 (22.61)	0.781 (0.58 to 1.06)	0.115	0.689 (0.51 to 0.94)	0.017	-0.068 (-0.14 to 0.01)	-0.102 (-0.18 to -0.03)
Self-reported sexually transmitted infection (among all students)	9 (0.33)	14 (0.51)	1.62 (0.66 to 3.98)	0.291	1.37 (0.56 to 3.38)	0.489	0.002 (-0.002 to 0.006)	0.001 (-0.00 to 0.01)
Pregnancy (among all femalest)	7 (0.40)	6 (0.48)	0.982 (0.33 to 2.92)	0.975	1.064 (0.31 to 3.65)	0.922	-0.000 (-0.01 to 0.01)	0.000 (-0.01 to 0.01)
Unintended pregnancy (among all females)	6 (0.34)	5 (0.40)	0.933 (0.28 to 3.10)	0.910	1.044 (0.26 to 4.15)	0.951	-0.000 (-0.01 to 0.00)	0.000 (-0.01 to 0.01)
Initiation of pregnancy (among all males ⁴)	4 (0.29)	12 (0.65)	2.310 (0.79 to 6.72)	0.124	2.01 (0.58 to 6.92)	0.270	0.004 (-0.00 to 0.01)	0.003 (-0.00 to 0.01)

*Adjusted for school-level General Certificate of Secondary Education attainment and local index of deprivation.

†Additionally adjusted for prespecified cluster level summaries of baseline student age, gender, ethnicity and family affluence scale.

#Pregnancy questions only asked of students reporting heterosexual intercourse; pregnancies assumed to be nil for other students.

sexual health and contraceptive skills; sexual communication self-efficacy; communication with parents; sexual-health services access; DRV perpetration measured using CADRI-s; and sexual harassment (online supplemental materials 7).

Serious adverse events (SAEs) were collected from school leads in both arms in December 2022 and 2023 and February 2025.

Statistical analysis

The planned sample size (50 schools, 6440–8500 students) aimed to provide 80% power with 5% significance to detect a 36% reduction in the primary outcome from 9% prevalence in the control arm to 5.8% assuming: 140 students per school; drop-out of two schools per arm; 80% student survey response at endline; and intracluster correlation coefficient (ICC) of 0.015 for our primary outcome. No ICC estimates for non-competent sexual debut were available but we expected this to resemble those for non-use of contraception at first sex (0.01).²⁷ Prevalence of the primary outcome was informed by evidence that 18% of adolescents sexually debuted between age 12–13 and 15–16,²⁸ with around half being non-competent.⁴ Our assumed effect on reducing non-competent first sex would be of policy significance according to consultation and aligns with estimates from previous trials.¹⁴

Primary analysis of outcomes was intention-to-treat using a complete-case analysis accounting for school clustering. All outcomes were analysed using generalised-estimating equations (GEEs) with an exchangeable correlation structure and sandwich estimator of variance to account for clustering, with small-sample bias-correction for the df. For binary outcomes, GEEs were fitted with a log-link to estimate risk ratios and identity link to obtain risk differences²⁹ between arms. Where low prevalence resulted in non-convergence, a hierarchical modified Poisson regression model was used to obtain risk ratios, followed by marginal standardisation to calculate risk differences. For continuous outcomes, GEEs with an identity link were used to obtain mean differences between arms. Primary analysis of all outcomes adjusted for stratification factors. Additional analysis adjusted for prespecified cluster-level baseline student age, gender, ethnicity and socioeconomic status (SES; family affluence scale).³⁰ We did not adjust for baseline sexual debut because of its very low prevalence. Age and ethnicity were imputed from endline if missing at baseline.

Secondary, complier-average causal-effect analysis (CACE) was conducted to estimate effects on the primary outcome accounting for whether their school complied with the intervention. Schools assessed to have adequately delivered the intervention on all or selected components (student-needs report, SHPC, lessons and parent information) were classified as compliers, and those assessed not to have were deemed non-compliers. We defined a generalised structural-equation model (gSEM) with arm as the main explanatory variable, and the covariates adjusted for in the main analysis, and cluster-robust SEs to adjust for clustering. In this model, the treatment effect for non-compliers was constrained to zero while the treatment effect among compliers was unconstrained. The gSEM included a latent-class model for compliers and non-compliers in the treatment group. In the latent-class model, the probability of compliance among non-compliers was fixed at zero and the probability of compliance among compliers was fixed at one.

We examined moderation of our primary outcome by student gender (boys, girls and other), ethnicity (Office for National Statistics categories), SES (at or above median family affluence vs below), sexual orientation (exclusively heterosexual, other)

Table 4 Continuous secondary outcomes (including economic utility measure) at 33-month endline: intention-to-treat analysis

Secondary outcome measures	Control group mean (SE)	Intervention group mean (SE)	Adjusted* mean difference (95% CI)	P value	Additionally adjusted† mean difference (95% CI)	P value	Adjusted* effect size	Additionally adjusted† effect size
Age at sexual debut (among students reporting sexual experience)	14.74 (0.05)	14.67 (0.04)	-0.075 (-0.20 to 0.05)	0.242	-0.066 (-0.19 to 0.06)	0.311	-0.097 (-0.25 to 0.06)	-0.084 (-0.24 to 0.07)
Number of sexual partners (among students reporting sexual experience)	1.83 (0.20)	1.79 (0.16)	-0.018 (-0.52 to 0.48)	0.944	-0.143 (-0.66 to 0.37)	0.585	-0.005 (-0.16 to 0.15)	-0.040 (-0.18 to 0.10)
Dating and relationship violence victimisation (Short Conflicts in Adolescent Dating Relationships scale) victimisation (among students reporting a serious or casual relationship in the last 12 months)	0.25 (0.01)	0.25 (0.01)	0.004 (-0.02 to 0.03)	0.789	0.001 (-0.03 to 0.03)	0.962	0.011 (-0.07 to 0.09)	0.007 (-0.07 to 0.09)
Health-related quality of life: Child Health Utility measure (CHU-9D) (among all participants)	0.82 (0.004)	0.83 (0.004)	0.010 (-0.00 to 0.02)	0.054	0.001 (-0.01 to 0.01)	0.808	0.807 (-0.00 to 0.18)	0.010 (-0.06 to 0.08)

*Adjusted for school-level General Certificate of Secondary Education attainment and local index of deprivation.

†Additionally adjusted for prespecified cluster level summaries of baseline student age, gender, ethnicity and family affluence scale.

and school academic attainment (above or at/below national median for an 'attainment 8 score' in public examinations). We examined moderation of secondary outcomes only where qualitative data suggested plausibility. Regression models with interaction were fitted. Where global Wald tests suggested evidence of moderation, effect estimates are reported for each subgroup. We also undertook exploratory analyses of intervention effects on intermediate outcomes, estimating CIs but not reporting p values. All analyses were conducted using Stata 18.0.

Process and economic analysis

Fidelity data were descriptively analysed using frequencies. Interviews were audio-recorded and transcribed. Data were coded inductively by one researcher, with further coding identifying inter-relationships between initial codes and codes organised into hierarchical themes. Memos explained these themes and were reviewed and revised into a final framework involving multiple researchers.

The economic analysis was designed to be a cost-utility analysis (primary) and cost-consequences analysis (secondary). The time horizon was the within-trial period (33 months), taking a public-and-voluntary-sector perspective. SEF and schools were asked to report resource use (staff time) associated with each intervention component (online supplemental materials 8). We applied unit costs to calculate costs of each component.³¹ For intervention schools, we applied the mean cost of each component to all schools reporting they delivered that component. For control schools, we applied the mean cost of each component to all schools reporting they delivered an activity resembling that component (acknowledging delivery may have differed). Costs were incurred in 2022–2024 and inflated to 2024 prices using the mean 2022–2024 inflation rate.³² We included costs arising from primary and secondary outcomes where these differed between arms. Costs over 33 months were discounted at an annual rate of 3.5%.³³ We calculated costs-per-student based on the numbers likely exposed to intervention within each school. We undertook cost-utility and cost-consequences analyses where outcomes differed between the intervention and control groups. To measure outcomes, we used the same modelling approach as for the main statistical analysis.

RESULTS

Of 2845 schools emailed, 50 consented, participated in baseline surveys and were allocated to intervention or comparator (figure 1). One school allocated to intervention withdrew in September 2022 due to a merger, not commencing intervention activities and with data not analysed. Recruited schools resembled other schools in the recruitment regions and other English schools (online supplemental materials 9).

Baseline surveys involved 3392 (control) and 3578 (intervention) students (response rate of 75.3% and 79.3%, respectively). Table 1 describes baseline school and student characteristics. The intervention arm included more male-only and fewer female-only schools; slightly more community (local authority) and fewer voluntary-controlled (autonomous from local authority) schools; and slightly more schools rated by government inspectors as outstanding and fewer rated as good. Intervention schools were in slightly more deprived areas, and their students were more likely to be male/boys and Muslim, and less likely to be white or sexual-and-gender-minority. Arms were well balanced on other characteristics. Two further schools dropped out of the control group and two from the intervention arm before endline surveys. Endline surveys involved 3146 (control) and

3122 (intervention) students (response rates of 78.0 and 77.9%, respectively).

Among 780 (12.44%) students sexually debuting between baseline and endline, our primary outcome of non-competent first sex was reported by 268 (64.42%) in the control group and 240 (65.93%) in the intervention group (adjusted risk ratio of 1.034 (95% CI 0.93 to 1.15; $p=0.538$)) (table 2). An additional analysis adjusting for baseline differences in school sex-entry did not change this (online supplemental materials 10).

Regarding secondary outcomes (tables 3 and 4), in primary adjusted analyses adjusting for stratifying factors, there was no evidence of intervention effects on heterosexual and same-sex debut, mean age of sexual debut, non-use of contraception at first sex or last sex, mean number of partners, DRV, STIs, pregnancies, unintended pregnancies or causing pregnancy. For non-use of contraception at last sex, the lower rate in the intervention arm was not significant in the primary analysis but was significant ($p=0.017$) in that also adjusting for student characteristics. Our economic outcome, the CHU-9D score for health-related quality of life, was 0.82 (SE=0.004) for the control group and 0.83 (SE=0.004) for the intervention group. This was of borderline statistical significance ($p=0.054$) in the analysis adjusting for stratifying variables but not in that also adjusting for student characteristics.

There was no evidence of differences by arm for most intermediate outcomes (online supplemental materials 11). Students in intervention schools had less negative attitudes towards DRV and less positive attitudes to equitable gender roles than controls. There was some evidence of moderation by gender of intervention effects on same-sex debut, STIs and age of sexual debut (online supplemental materials 12) but CIs for subgroup estimates did not suggest significant effects. There was no evidence of moderation by school characteristics.

No schools achieved our metric of overall good fidelity, defined as completion of the student-needs survey, start-up meeting and all training, termly quorate SHPC meetings, 10 year-9 and 6 year-10 lessons to all classes with 70% fidelity of content coverage, student campaigns in both years, sexual-health services review and parent information (three communications and two homework assignments); two achieved that of adequate fidelity across all components, defined as delivering the student-needs survey, any SHPC meetings, some year-9 and year-10 lessons, any student campaigns, the sexual-health services review and any parent information (online supplemental materials 13). 11 schools achieved a reduced compliance threshold of adequate fidelity on selected components (student-needs report, any SHPC meetings, some year-9 and year-10 lessons and any parent information). Fidelity varied by components. SEF-delivered training and support sessions were well delivered. 21 and 18 schools, respectively, reported delivering year-9 and year-10 lessons, with 15 delivering all core lessons in year 9 and 14 in year 10. Most logbooks reported high fidelity of lessons. All schools received a student-needs report. 13 reported SHPC meetings but none held termly, quorate meetings across both years. Most schools provided parental information, but only one implemented three communications per year and two homework assignments. Only six and four schools, respectively, implemented student campaigns and reviewed sexual-health services. CACE analysis accounting for fidelity of selected components did not suggest an effect on the primary outcome (online supplemental materials 14).

Staff reported that implementation was facilitated by the high quality of the training and materials. Many said a major draw was accessing reputable RSE when this became statutorily required.

Many prioritised the curriculum, viewing this as part of schools' 'core business', unlike the whole-school elements. Staff felt lesson topics were appropriate. School leads reported teaching was enhanced when they had a consistent team of teachers with the commitment and skills to teach RSE. Other schools relied on teachers with timetable gaps, often lacking these attributes. Whole-school elements were hindered by school leads lacking the time and authority to 'make things happen', and whole-school components not aligning with existing school priorities emphasising academic attainment.

Many control schools implemented work resembling Positive Choices components (online supplemental materials 15). Six organised staff/student groups to plan RSE/sexual-health provision. 18 consulted students to inform provision. 18 collected data on student RSE needs/preferences. All taught RSE in years 9 and 10. 19 schools leads received external training about RSE and 18 leads cascaded training to RSE teachers. Most control schools covered similar topics to Positive Choices but were less likely to teach about DRV, pregnancy choices, sexual response and pleasure. 11 schools ran student campaigns about sexual health. 22 informed parents about RSE or other aspects of sexual health. None set homework for RSE. Most advertised or provided sexual-health services and six reported recently reviewing this.

Mean intervention costs in the intervention group were £10 803 per school (online supplemental materials 7). Assuming 139 eligible students per school (6268 students in 45 schools), mean intervention costs per student were £77. For the control group, applying the mean cost of each component in intervention schools to control schools reporting they delivered an activity resembling that component, the mean costs were estimated to be £9466 (£68 per student). Based on these differences, incremental intervention costs were £1337 per school (£10 per student). We did not include cost differences arising from primary and secondary outcomes, as these did not differ between arms. Cost-utility and cost consequences analyses are not reported given the lack of difference in utility scores and other outcomes.

Schools variably responded to requests for SAE information; 106 were reported by control and 64 by intervention schools (online supplemental materials 16). None were judged by school leads to be linked to intervention or trial activities.

DISCUSSION

Summary of key findings

There was no evidence that the intervention reduced non-competent sexual debut (primary outcome) and little evidence of effects on secondary outcomes. Non-use of contraception at last sex was lower in the intervention than control group, but an effect is unlikely given there was no evidence of effects on knowledge, skills or communication self-efficacy. This contrasts with previous trials of whole-school interventions¹⁴ and the recent UK trial of the Jack RSE intervention which reported increased contraception use among sexually-active participants.³⁴ There was no evidence that the intervention was effective when accounting for intervention fidelity or subgroups. There was no evidence of effects on intermediate outcomes other than that intervention students had less progressive attitudes to DRV and gender roles. These may be false positives from multiple significance tests or might suggest some lessons evoked unintended reactions, which we will explore further in qualitative analyses.

Lack of effects may be explained by the adequate delivery of the curriculum but not whole-school elements. The adequate delivery of RSE but not whole-school elements might reflect

recruitment occurring soon after RSE became statutory, so schools were primarily seeking RSE materials. Schools might have viewed sexual health as a ‘curriculum’ rather than ‘whole-school’ issue. Although contemporaneous government guidance on RSE did briefly refer to whole-school approaches, there was no guidance on delivery. Lack of implementation of whole-school elements might also reflect the study occurring immediately after the COVID-19 pandemic when schools juggled increased student needs with reduced capacity. The lack of whole-school activities might explain the lack of effects on STIs and pregnancies, given evidence that although RSE lessons can delay debut, increase condom and contraception use, and prevent DRV,^{7–10} RSE alone is unlikely to prevent biological outcomes influenced by broader determinants.¹¹ Our lack of impact on DRV might be explained by the curriculum dedicating insufficient time to emphasising the unacceptability of this.¹⁰

Limitations

Our ability to examine effectiveness was undermined by poor fidelity of whole-school components. Our ability to detect effects on sexual behaviours was undermined by lower-than-expected sexual debut rates, which were even lower than estimates from recent surveys,³⁵ and by our sample being slightly less than that targeted. Our assessment of same-sex sexual behaviour intentionally focused on ‘sex’ rather than defining specific behaviours, given the diversity of practices this could involve. Regarding our primary outcome, the threshold for competence was high, requiring all items describing the circumstances of debut to be positive. Our assessment of the comparator did not assess ‘dose’ or fidelity of activities in control schools and was limited by staff recall. Our calculation of mean incremental costs is likely an underestimate because it assumed that control schools delivered activities resembling intervention components in an equally resource-intensive way.

Implications for research and policy

This was an ambitious study of a complex intervention conducted immediately after the pandemic when schools experienced severe challenges. As delivered, with poor fidelity of the whole-school elements, Positive Choices was not effective in terms of our primary or secondary outcomes. Our results cannot be interpreted as indicating that RSE is ineffective because we compared a whole-school intervention including comprehensive RSE to a comparator which involved comprehensive RSE. Many intervention schools relied on teachers with timetable gaps to teach RSE, with these often lacking the necessary skills and commitment. This suggests the potential of schools to promote sexual health is critically constrained by capacity and teacher expertise. This might be improved by addressing RSE in initial teacher education and continuing professional development, and inspecting schools on whether RSE is delivered by trained staff. Whole-school actions to address sexual health might be more feasible if undertaken as part of ‘health promoting schools’ interventions addressing a range of health outcomes including sexual health.

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