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Citation for final published version:

Lohan, Maria, Gillespie, Kathryn, Aventin, Aine, Gough, Aisling, Warren, Emily, Lewis, Ruth, Buckley, Kelly, McShane, Theresa, Brennan-Wilson, Aoibheann, Lagdon, Susan, Adara, Linda, McDaid, Lisa, French, Rebecca, Young, Honor, McDowell, Cliona, Logan, Daniella, Toase, Sorcha, Hunter, Rachael M, Gabrio, Andrea, Clarke, Mike, O'Hare, Liam, Bonell, Chris, Bailey, Julia V. and White, Jamie 2023. School-based relationship and sexuality education intervention engaging adolescent boys for the reductions of teenage pregnancy: the JACK cluster RCT. *Public Health Research* 11 (8) 10.3310/YWXQ8757

Publishers page: <https://doi.org/10.3310/YWXQ8757>

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Title Page

Title

JACK trial: a phase III UK-wide cluster randomised controlled trial of a school-based relationship and sexuality education intervention focusing on engaging young men in reducing adolescent pregnancy and promoting positive sexual health

Keywords

Relationship and Sexuality Education, Adolescents, Gender-transformative, engaging boys/men, sexual health, adolescent pregnancy, cluster randomised controlled trial, health economics, process evaluation

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Disclosure of interest: None declared

Scientific Abstract

Background:

The need for Relationship and Sexuality Education (RSE) to especially engage with boys and young men to reduce adolescent pregnancy is endorsed by the WHO and UNESCO. The *If I Were Jack* intervention was designed to achieve this, in order to prevent teenage pregnancy through avoidance of unprotected sex.

Objectives:

To evaluate the effects of *If I Were Jack* on the avoidance of unprotected sex and other sexual health outcomes.

Design:

A multicentre, parallel-group cluster randomised trial, incorporating a health economic analysis and process evaluation.

Setting:

Sixty six secondary-level schools across the four nations of the UK.

Participants:

Students aged 13-14 years.

Interventions: A brief, school-based, teacher delivered RSE intervention developed with substantial user co-design and of proven feasibility (*If I Were Jack*) compared with the school's usual RSE.

Main Outcome Measures:

Self-reported avoidance of unprotected sex (i.e. remaining sexual abstinent or using reliable contraception at last sex) in the 12 to 14 months after baseline data collection. Secondary outcomes included knowledge, attitudes, skills, intentions and sexual behaviours.

Results:

The analysis population is the 6556 students who completed both baseline and follow up questionnaires (79.80% of those who completed baseline questionnaires).

Primary outcome

Fewer young people in intervention schools than in control schools had unprotected sex during the 12 to 14 months follow-up [13.6% vs. 14.1%; OR 0.85 (95% CI 0.58 to 1.26), ICC = 0.12], but the difference was not statistically significant (p=0.42).

Secondary outcomes

Students in intervention schools had statistically significantly higher scores on the following outcomes: knowledge [adjusted mean difference (aMD) 0.19 (95% CI 0.017 to 0.37), p=0.032], sexual self-efficacy [aMD 0.035 (95% CI 0.006 to 0.065), p=0.018], comfort in communicating with peers, parents and professionals about avoiding pregnancy [aMD 0.13 (95% CI 0.000 to 0.26), p=0.05], and intentions to avoid unintended pregnancy [aMD 0.85 (95% CI 0.19 to 1.50), p=0.01] compared with control schools. There was no evidence of a difference in attitudes towards gender roles [aMD -0.092 (95% CI -0.39 to 0.21), p=0.55].

Among the sexually active population at 12-14 months follow-up (total: 392 students), fewer students in the intervention schools reported unprotected sex at last sex [intervention 27.5%, control 32.9%, OR 0.55 (95% CI 0.31 to 0.97) p=0.04]. There was no significant difference in the number of students who reported ever having sex.

Health Economic outcomes

The total mean incremental cost of the *If I were Jack* intervention compared to standard RSE was £2.83 (95% CI -£2.64 to £8.29) per student. Based on a 20-year time horizon, the *If I Were Jack* intervention is likely to be cost-effective based on the point estimate for the effect on unprotected sex, because it would result in fewer unintended pregnancies and sexually transmitted infections and a gain in quality-adjusted life years (QALYs), leading to a cost saving of £9.70 per young person who receives the intervention compared to standard RSE.

Limitations:

The trial is underpowered to detect some effects because four schools withdrew after randomisation and the intra-class correlation coefficient (ICC) (0.12) is much larger than the ICC used in the sample size calculation (0.01), which was based on previous research in this area.

Conclusions:

The *If I Were Jack* intervention was not found to be effective in reducing unprotected sex for students as a whole (measured as remaining sexually abstinent or reliable use of contraception). However, it was found to reduce unprotected sex amongst young people (males and females) who were sexually active. *If I Were Jack* was also effective in improving knowledge, skills and intentions to prevent unintended pregnancy across the whole population, and was found to be an acceptable, feasible and low-cost intervention. It is likely to be cost-effective in relation to healthcare costs.

Future work:

Further studies are required to assess refined versions of the intervention in other settings.

Trial registration:

ISRCTN10751359.

Funding:

National Institute for Health Research Public Health Research programme (NIHR PHR 15/181/01)

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List of abbreviations

AOUM	abstinence–only-until marriage-approach
BHSCT	Belfast Health and Social Care Trust
CCEA	Council for the Curriculum, Examinations and Assessment
CSE	comprehensive sex education
DECIPHer	Centre for Development, Evaluation, Complexity and Implementation in Public Health Improvement
DSA	deterministic sensitivity analysis
HBSC	health behaviour in school-aged children
HES	hospital episode statistics
HIV	human immunodeficiency virus
HPV	human papillomavirus
IFS	Institute for Fiscal Studies
IVD	interactive video drama
LGBTQ	lesbian, gay, bisexual, transgender, and questioning (or queer)
MB	mistimed birth
NATSAL	National Survey of Sexual Attitudes and Lifestyles
NHS	National Health Service
NI	Northern Ireland
NICE	National Institute for Health and Care Excellence
NICTU	Northern Ireland Clinical Trials Unit
NIHR	National Institute for Health Research
ONS	Office of National Statistics
PSA	probabilistic sensitivity analysis

PID	pelvic inflammatory disease
PSHEA	Personal, Social and Health Education Association
QUB	Queen’s University Belfast
QUALY	Quality adjusted life years
RCT	randomised controlled trial
RSE	relationships and sexuality education
ROI	return on investment
SHARE	sexual health and relationships education
SRHR	sexual and reproductive health and rights
SRE	sex and relationship education
STD	sexually transmitted disease
STI	sexually transmitted infections
SEN	special education needs
SAC	Stakeholder Advisory Committee
SEQ	student engagement questionnaire
TIDieR	Template for Intervention Description and Replication
TSC	Trial Steering Committee
UNCRC	United Nations Convention of the Rights of the Child
UTP	unintended teenage pregnancy
WHO	World Health Organisation
YLT	Young Life and Times
YPAG	Young Person’s Advisory Group

Plain English summary

Adolescent pregnancy is often thought to be an issue for young women alone but it is important to engage young men to tackle the problem and find solutions. The *If I Were Jack* intervention was designed to engage with young men as well as young women aged 13-14 to prevent adolescent pregnancy and promote positive sexual health, and was tailored to make it relevant to each of the four UK nations. This relationship and sexuality education intervention encourages young people to avoid unprotected sex by delaying sexual activity until they feel ready and to use reliable contraception once sexually active. It also promotes knowledge and skills for safe and pleasurable relationships. In this trial, we compared students in 33 schools randomly allocated to deliver the intervention with students in 33 schools that continued with their usual relationship and sexuality education practices. Four schools withdrew, two because of COVID-19 related school closures. This left a total of 6556 students who completed questionnaires at the start of the study and 12 to 14 months later. Responses from all these students showed that *If I Were Jack* increased knowledge and skills required for safe and pleasurable relationships, but did not have a significant effect on rates of unprotected sex. However, when we focused on sexually active students, the intervention did reduce rates of unprotected sex. We also found that *If I Were Jack* was acceptable to schools and that it is likely to provide value for money by reducing unintended pregnancies and improving sexual health.

Scientific summary

Background:

The need for Relationship and Sexuality Education (RSE) to especially engage with young men and boys to promote positive sexual health for all, and to challenge the gender inequalities that underlie young women's generally poorer sexual health outcomes (especially in relation to sexual violence, adolescent pregnancy and sexually transmitted infections) is widely endorsed by the WHO and UNESCO, amongst others.

Objectives:

The Jack Trial evaluated the effectiveness and cost-effectiveness of the *If I Were Jack* intervention, a schools-based RSE intervention, which is designed to especially engage young men as well as young women and promote joint responsibility in preventing adolescent pregnancy by avoiding unprotected sex and in promoting positive sexual health and relationships. We assessed whether there would be lower rates of self-reported unprotected sex (either by remaining sexually abstinent or using a reliable form of contraception) among students in schools allocated to use *If I Were Jack* compared to schools that continued with their usual RSE.

Design:

We undertook a multicentre, parallel-group cluster randomised trial of the *If I Were Jack* intervention with schools as the unit of randomisation. We incorporated a health economic analysis and process evaluation.

Setting:

The trial was conducted in secondary-level schools across the four nations of the UK.

Recruitment:

We sampled schools from Department of Education listed secondary schools in each nation of the UK (Northern Ireland, South Wales, Central Scotland and South-East of England), with consideration of socio-economic status of schools (based on proportion of students eligible for free school meals (FSM) as indicated by the School Meal Census). In each nation, eligible schools were stratified into two levels according to FSM (schools above and below the median % FSM for all eligible schools). Exclusion criteria were

Independent private, special, and Irish/Welsh-medium and Scottish Gaelic schools and schools with fewer than 30 pupils in the target year group. In 2018, letters of invitation were sent to sampled schools and a £1000 payment was offered as an incentive to schools who completed all data collection.

Participants:

Our study population consisted of students who were aged 13-14 years in the target year groups at baseline (year 11 in Northern Ireland, S3 in Scotland and year 10 in England and Wales) and were aged 14-15 years at follow-up (12 to 14 months later).

Allocation and concealment:

Schools were randomly allocated (1:1) using computer-generated random permuted blocks of mixed size to the intervention or control group, stratified by nation and proportion of pupils eligible for FSM. Allocation of schools was concealed from the school and the research team until after baseline data collection.

Intervention:

If I Were Jack is an evidence-based, gender-transformative and comprehensive-approach RSE intervention, developed with substantial user co-design and of proven feasibility. It is a brief intervention designed to be delivered by trained teachers during four or six consecutive RSE lessons in classroom settings (depending on normal class durations). In preparation for the trial, the intervention was optimised with a UK-wide group of young people and RSE experts to enhance the cultural salience of the intervention components across the four nations of the UK and to ensure that it reflected a comprehensive approach to RSE education.

Schools allocated to the *If I Were Jack* group were provided with

- (i) The *If I Were Jack* opening interactive video drama (IVD), a culturally sensitive (locally filmed in both NI and England) film intended to immerse adolescents in a story of a week in the life of Jack, a young man who has just been told his girlfriend is pregnant;
- (ii) Classroom materials for teachers with four detailed lesson plans with specific classroom-based and homework activities which provide students with sexual health

information and opportunities for discussion, skills practice, reflection and anticipatory thinking;

(iii) Ninety-minute face-to-face training session for teachers provided by trained facilitators;

(iv) Online materials for parents/guardians; and

(v) Information brochures and factsheets about the intervention and unintended teenage pregnancy for schools, teachers, teacher trainers, young people and parents.

Comparator:

Schools allocated to the control group were asked to continue with their existing RSE.

Primary outcome:

Self-reported avoidance of unprotected sex (i.e. remaining sexually abstinent or using reliable contraception at last sex) in the 12 to 14 months after baseline, among the students as a whole and among those who were sexually active.

Secondary outcomes:

Secondary outcomes were collected 12 to 14 months after baseline. Knowledge was measured by items selected from the Mathtech Knowledge Inventory and SKATA. Attitudes were measured by the Male Role Attitudes Scale. Skills were measured through the Comfort Communicating Scale and the Sexual Self-efficacy Scale. Intentions to avoid an unintended pregnancy was assessed using an 'Intentions to avoid a teenage pregnancy scale' developed and psychometrically tested in our feasibility trial. Behavioural outcomes included avoidance of unprotected sex at last sex, and whether or not students reported ever having sex.

Economic evaluation:

Resource use included self-reported use of sexual health related resources and use of teacher resources for delivering RSE. Costs of adolescent pregnancy and sexually transmitted infections were calculated from published sources.

Process evaluation:

The process evaluation addressed: (1) context (reasons for school participation); (2) implementation (intervention delivery and fidelity and RSE provision in control schools and potential contamination caused by any changes to provision that could be due to participation in the trial); and (3) mechanisms of impact (perceptions of effectiveness among pupils, teachers and school principals/head teachers).

Data Collection:

Baseline, paper questionnaire were completed in August to October 2018 and the 12 to 14 months follow-up paper questionnaires were completed in October 2019 to January 2020. Students completed these in lesson time in classrooms under exam-like conditions, facilitated by trained researchers with teachers present but unable to read student responses. The field workers assisted students with questions that they did not understand and supported students with mild learning difficulties or with limited command of written English to complete the questionnaires.

Analysis:

The primary effectiveness analysis was on an intention-to-treat basis, using a multi-level logistic regression model (two levels: pupils nested within schools) adjusting for the baseline outcome and stratification variables (country and schools above and below the median national percentage of FSM). Health economic analysis involved both a within trial economic analysis to assess cost per pupil of delivering the intervention and a decision-analytical model to assess cost effectiveness over a 20-year time horizon. The process evaluation used a qualitative thematic analysis.

Results:

A total of 8216 students completed the baseline questionnaire and a total of 6561 pupils completed the follow up questionnaire. Of those who completed the baseline questionnaire, 6556 students (79.80%) also completed the follow up questionnaires, and these students comprise the analysis population. One intervention school and one control school were lost to follow-up because of COVID-19 school closures and two other intervention schools withdrew from the study after baseline.

Primary outcome

Fewer students in the intervention schools than in the control schools had unprotected sex between baseline and 12 to 14 months follow-up [13.6% vs. 14.1%; OR 0.85 (95% CI 0.58 to 1.26), ICC = 0.12], but the difference was not statistically significant ($p=0.42$).

Secondary outcomes

Knowledge scores were significantly higher for the intervention group [adjusted mean difference (aMD) 0.19 (95% CI 0.017 to 0.37), $p= 0.032$]. Students in intervention schools had improved sexual self-efficacy [aMD 0.035 (95% CI 0.0059 to 0.065), $p= 0.018$], greater comfort in communicating with peers, parents and professionals about avoiding unintended pregnancy [aMD 0.13 (95 % CI -0.00015 to 0.26), $p=0.05$], and stronger intentions to avoid unintended adolescent pregnancy [aMD 0.85 (95% CI 0.19 to 1.50), $p= 0.01$] compared with students in control schools. There was no evidence of a difference in attitudes towards gender roles [aMD -0.092 (95% CI -0.39 to 0.21), $p= 0.55$].

Fewer students (both males and females) in the intervention group reported unprotected sex at last sexual intercourse [intervention 27.53%, control 32.88%, OR 0.55 (95% CI 0.31 to 0.97) $p=0.04$] compared to the control group. There was no significant difference between the intervention and control group in relation to the number of young people who reported ever having sex.

Process evaluation findings

The intervention was acceptable to schools (to teachers and students) including faith-based schools. It was feasible to implement but fidelity to implementation varied. RSE delivery was broadly comparable in intervention and control schools (apart from the *If I were Jack* intervention) and RSE delivery did not significantly change in control schools as a result of participation in the trial, although implementation varied. Teachers and students perceived the programme to have triggered realisations around relationships and sex which, combined with practical knowledge, was already creating the foundations to avoid unprotected sex and childbearing until the young person was ready.

Economic Evaluation

The total mean incremental cost of the *If I were Jack* intervention compared to standard RSE was £2.83 (95% CI -£2.64 to £8.29) per student. Based on a 20-year time horizon, *If I Were Jack* is likely to be cost-effective because it would result in fewer unintended pregnancies, sexually transmitted infections and a gain in quality-adjusted life years (QALYs) for a cost saving of £9.70 per young person who receives the intervention rather than standard RSE.

Limitations:

The trial is underpowered to detect some effects because four schools withdrew after randomisation and the intra-class correlation coefficient (ICC) (0.12) is much larger than the ICC used in the sample size calculation (0.01), which was based on previous research in this area.

Conclusions:

We present here the first randomised controlled trial, health economic and process evaluation of a schools-based Relationship and Sexuality Education intervention using a gender-transformative approach designed to especially engage young men as well as young women to promote joint responsibility in preventing adolescent pregnancy by avoiding unprotected sex and promoting positive sexual health and relationships. The Jack trial is also the first UK-wide trial of school-based RSE which has shown that it is possible to recruit and retain faith-based schools in a trial of comprehensive RSE. Although *If I Were Jack* was not found to be effective in reducing unprotected sex for the population as a whole (through remaining sexually abstinent or use of reliable contraception), it was effective in reducing unprotected sex amongst sexually active young people (males and females). *If I Were Jack* was also effective in improving knowledge, skills and intentions to prevent unintended pregnancy, but there was no significant effect on gender attitudes. The intervention was acceptable to schools and feasible to implement (although fidelity to implementation varied) and is a low-cost intervention which is likely to be cost-effective in relation to healthcare costs.

Implications for Practice:

The *Jack Trial* provides practitioners with an evidence-based example of how RSE can positively and intentionally engage with young men as part of the solution to better sexual and reproductive health for all. Given the range of positive outcomes from a brief intervention, *If I Were Jack* is available for use and could be incorporated as part of a broader programme in second-level education.

Implications for Research:

We recommend further trials to explore the fidelity, acceptability and effectiveness of the *If I Were Jack* intervention across a range of diverse contexts, including low- and middle-income settings. We have plans underway to adapt and test the intervention in South America and Southern Africa, building on our learning from the current study. We also recommend further exploration of the acceptability and feasibility of conducting RSE interventions in faith-based schools, including in non-Christian faith-based schools.

Trial registration: ISRCTN10751359.

Funding: National Institute for Health Research Public Health Research programme (NIHR PHR 15/181/01)

Chapter 1. Introduction

Structure of this report

This report presents the findings from a cluster randomised controlled trial evaluation of the *If I Were Jack* programme. This chapter provides the background for the study and a description of the programme. Patient and public involvement in the study is described in *Chapter 2*. The major focus of the PPI involvement was in relation to the optimisation of the programme which occurred within this study, prior to the trial. The methodology for the trial and process evaluation is outlined in *Chapter 3*. The results of recruitment and data collection processes are outlined in *Chapter 4*. The quantitative findings from the trial regarding the impact of the programme on student outcomes are reported in *Chapter 5* and the findings from the accompanying qualitative process study are set out in *Chapter 6*. *Chapter 7* details findings of the economic evaluation and key issues and conclusions emerging from the findings are set out in *Chapter 8*.

The public health problem addressed: reducing unintended teenage pregnancy and promoting positive sexual health

Relationship and sexuality education (RSE) for young people is a challenging, complex, controversial and critical, worldwide public health issue. High quality comprehensive RSE for young people is not only essential to achieving better health and healthcare for adolescents but is also key to ensuring women's rights, gender equality, sound demographic and economic development for future generations. As such, high quality RSE addresses three 2030 sustainable development goals to ensure quality education, gender equality and good health and wellbeing.^{1,2}

Whilst teenage pregnancy is not universally negative,¹ reducing teenage pregnancy has the potential to reduce a myriad of negative medical outcomes, such as low-birth weight and under-nutrition, as well as the negative consequences for educational, social-wellbeing of young people and their babies over the life course globally.²⁻⁶ Teenage pregnancy is widely understood as not just a cause, but also a consequence, of under-

privilege, which is why addressing teenage pregnancy through developing young people's agency to improve their own lives is so important.

The UK still has the highest rate of teenage pregnancy in Western Europe.⁷⁻⁹ This is despite the fact that conception rates for women aged under 18 have been falling, (halved in the last decade) in England and Wales, in 2018, rates were 16.8 per 1000 population.^{10,11} Approximately 25,000 teenage women become pregnant in England and Wales annually and approximately half of these end in legal abortion.¹² The teenage pregnancy rate in Scotland was 30.2 per 1,000 in 2017.¹³ In Northern Ireland (NI), abortion was illegal until October 2019^{14,15} and was only considered lawful in exceptional circumstances where the life of the pregnant woman was at immediate risk, or if there was a risk of serious injury to her physical or mental health. Reflecting the different legal framework (pre-October 2019), government targets around reducing teenage pregnancies in NI relate to births and not conceptions. In NI, the birth rate to teenage mothers per 1,000 young women aged 13-19 years was 11.3 in 2013.¹⁶ In the same year, the teenage birth rate in the most deprived areas was 23.0 per 1000, nearly six times that of the least deprived areas (3.9 per 1000).¹⁷

Preventing unintended conceptions implies preventing unprotected sex. Drawing from robust representative epidemiological data of school-aged children across the UK¹⁸ and Young Persons' Behaviour and Attitudes Survey NI,¹⁹ it is known that between 25% and 33% of 15-year-olds are having sex, with an associated rate of 2.8% reporting unprotected sex. Changing practices of unprotected sex and unintended pregnancy are complex phenomena that may not be prevented through RSE alone.²⁰⁻²⁶ However, high quality comprehensive RSE is an essential component in the process of reducing unintended pregnancy rates, as well as being a vital aspect of improving holistic sexual health and wellbeing.²⁷⁻³³ The UK governments emphasise the policy importance of the implementation of RSE in schools in decreasing under-18 conception rates and the promotion of positive sexual health among teenagers.³⁴⁻³⁶

Current status of RSE

The current status of RSE provision in schools in the UK is as follows: Educational policy, including relationship and sexuality education is devolved to the nations of the UK. Hence, the terminology to describe the education young people receive relating to sex and relationships varies in each nation as follows. Relationships and Sexuality Education (RSE) guidance in Northern Ireland is predominantly structured under the Personal Development strand of the Learning for Life and Work curriculum. In England, Sex and Relationship Education (SRE) is provided under the umbrella term Personal, Social, Health and Economic Education (PSHE). Pupils in Scotland learn about Relationships, Sexual Health and Parenthood Education (RSHP) as part of their Curriculum for Excellence framework. In Wales, Sex and Relationships Education (SRE) forms one of the six Areas of Learning Experience (AoLE). For the purposes of uniformity in this report, the appellation RSE is applied UK-wide. In England and Wales, RSE is currently undergoing significant reform. England introduced compulsory RSE in 2020, post data collection for this trial³⁷ and Wales is set do to so in 2022.³⁸ In England however, parents will still be able to opt-out their children when the topic of sex is being discussed. NI and Scotland have statutory guidance on what should be taught, although this is not compulsory, and many schools follow their own guidance or ethos concerning how the curriculum is delivered.^{39,40} Therefore, throughout the UK there is no uniform guidance for the curriculum and where guidance it exists, it is open to interpretation by schools in how it should be implemented.

The If I Were Jack programme

Brief description

If I were Jack is an evidence-based, theory-informed, user-endorsed intervention designed to especially engage with teenage boys and intended to increase both teenage boys' and girls' intentions to avoid an unplanned pregnancy and to promote positive sexual health. Additionally, it fits with a comprehensive approach to relationship and sexuality education.⁴¹ *If I were Jack* is a classroom-based RSE resource intended for use by teenagers aged 14–15 years. A specific aim of the intervention is to open up for scrutiny

the gender norms which typically situate the issue of a teenage pregnancy as a woman's problem, to also encourage males to share sexual and reproductive responsibility.

How it was developed

It has been designed, developed and piloted in Ireland, South Australia, NI and the remainder of the UK over twelve years by a team based at Queen's University Belfast (QUB) led by Professor Maria Lohan and in consultation with pupils, teachers, sex education specialists, and governments' education and health promotion departments.⁴¹ Further cultural adaptations are underway, one being led by Dr Sarah Skeen (Stellenbosch University) and Dr Áine Aventin (QUB) in South Africa and Lesotho and one being led by Professor Alejandra López Gómez (Universidad de la República), in Uruguay and Professor Hernando Muñoz Sanchez (Universidad de Antioquia) Colombia, South America.

Some key stages in the development of *If I were Jack* as used in this study are:

- **Development of an earlier version of the interactive video drama (IVD) of *If I Were Jack*, for the purposes of researching adolescent men's views on teenage pregnancy and pregnancy resolution options in schools only.**^{42,43} The *If I were Jack* IVD was directly inspired by, and closely based on, *If I were Ben* – an original IVD used by Carolyn Corkindale and team at Flinders University for the purposes of similar research.
- **Development of *If I Were Jack* RSE resource.** In response to positive feedback and demand from schools who viewed the IVD, the QUB team re-developed the IVD and developed an accompanying RSE programme (4-6 classes) for NI and Ireland (two versions) through funding from the Economic and Social Research Council of the UK (RES-189-25-0300). Intervention development occurred in close consultation with young people, teachers, RSE experts and statutory policy stakeholders in Departments of Health and Education in Ireland and NI as well close examination of the evidence on the most acceptable and effective RSE components; and in line with MRC guidelines for the development of complex interventions.⁴¹
- **Feasibility trial, process evaluation and health economic evaluation (ISRCTN99459996) of *If I were Jack* RSE resource in NI and a transferability study in England, Scotland and Wales**^{44,45} funded by the NIHR Public Health Research programme (15/181/01). The primary results of this stage were that:

- I. Recruitment of schools was successful across a broad range of school types including faith-based schools (target 25%, achieved 38%).
- II. No schools withdrew during the year-long trial and pupil retention was good (target 85%, achieved 93%).
- III. The process and transferability evaluations showed the intervention to be acceptable to schools, pupils and teachers, and that it could be feasibly implemented with some straightforward enhancements, including re-making a version of the IVD with English actors for an England/Wales audience and increasing ethnic mix of actors.
- IV. The cost of delivery per pupil was calculated to be £13.66 and behavioural changes effects showed promise.

The programme was also separately implemented and evaluated in Ireland through a qualitative mixed methods study in a maximum variation sample of schools where again the acceptability and feasibility of implementation was demonstrated.⁴⁶

- **Re-development of the parental component of the intervention:**⁴⁷ The parental component was changed from a face to face to an online component and retaining student-parent homework exercise in response to results of the feasibility trial above in a separate study funded by the Public Health Agency of Northern Ireland.
- **The Jack Trial:** Current Study to include: optimisation of intervention to update materials and make it more suitable for use in England, Scotland and Wales, and UK-wide effectiveness trial with process and health economic evaluation.⁴⁸
- **Underpinning research on parents and young people with highest needs:** Alongside the above development of the intervention and the underpinning research with young people, the lead PI has been involved in related studies researching parents' experiences of talking to their pre-adolescent and adolescent children about relationships and sexuality⁴⁹⁻⁵¹ and researching RSE needs of especially vulnerable young people groups, notably young people in care.^{52,53}

Intervention components

The Intervention components available on <https://www.ifiwerejack.com/> include:

- A culturally sensitive computerised interactive video drama (IVD) to immerse young people in a hypothetical scenario of a week in the life of Jack, a teenager who has just found out that his girlfriend is unexpectedly pregnant. The *If I Were Jack* interactive film asks pupils to put

themselves in Jack's situation and consider how they would feel and what they would do if they were Jack (The film is interactive in the sense that it requires viewers to respond about how they would think or act as the narrative develops, but the film doesn't change in response to these choices);

- Classroom materials for teachers containing detailed lesson plans with specific classroom-based and homework activities designed to build pupils' skills to a) obtain necessary information, and b) develop communication skills with peers and trusted adults. Teachers can deliver the intervention to pupils during four 50-60 minute or six 35-45-minute weekly classes;
- Ninety-minute training session for teachers implementing the intervention;
- Two short animated films to engage parents/guardians and help/encourage them to have a conversation with their teenager about avoiding unintended pregnancy; and
- Detailed information brochures, letters for schools, letters for parents about the intervention and factsheets and wallet cards about unintended teenage pregnancy in general for schools, teachers, teacher trainers, young people and parents/guardians.

The Template for Intervention Description and Replication (TIDieR) checklist⁵⁴ is used to describe the intervention in more detail and this longer description of intervention is available in *Appendix 1*.

Theory of change and how it is hypothesised to work

Presented in *Figure 1* is the theory of change Logic Model of the intervention. Described on the left is the core public health problem: the relatively high rates of teenage pregnancy as noted above. In addition, the public health need to engage young men as well as young women in addressing teenage pregnancy is stated. In brief, we hypothesise that by encouraging personal identification with the unintended teenage pregnancy (UTP) scenario in the IVD, we engage pupils in an exercise of the imagination whereby they stop and think about the consequences that an UTP might have on their current life and future goals. This identification and reflection process is reinforced by providing knowledge about the risks and consequences of UTP and ways to avoid it and offering opportunities to practice communicating about UTP with peers and parents/guardians (activities that also increase awareness of peer norms and personal and familial values

and beliefs about sexual behaviour and unintended pregnancy). We hypothesise that by targeting these psychosocial factors, as well as inviting scrutiny and critical thinking in relation to wider social norms (gender norms and class norms) we impact on teenagers' sexual behaviour via pathways through their intention to avoid UTP. The behavioural outcomes we seek to achieve are delaying sex until young people feel prepared and avoidance of unprotected sex.

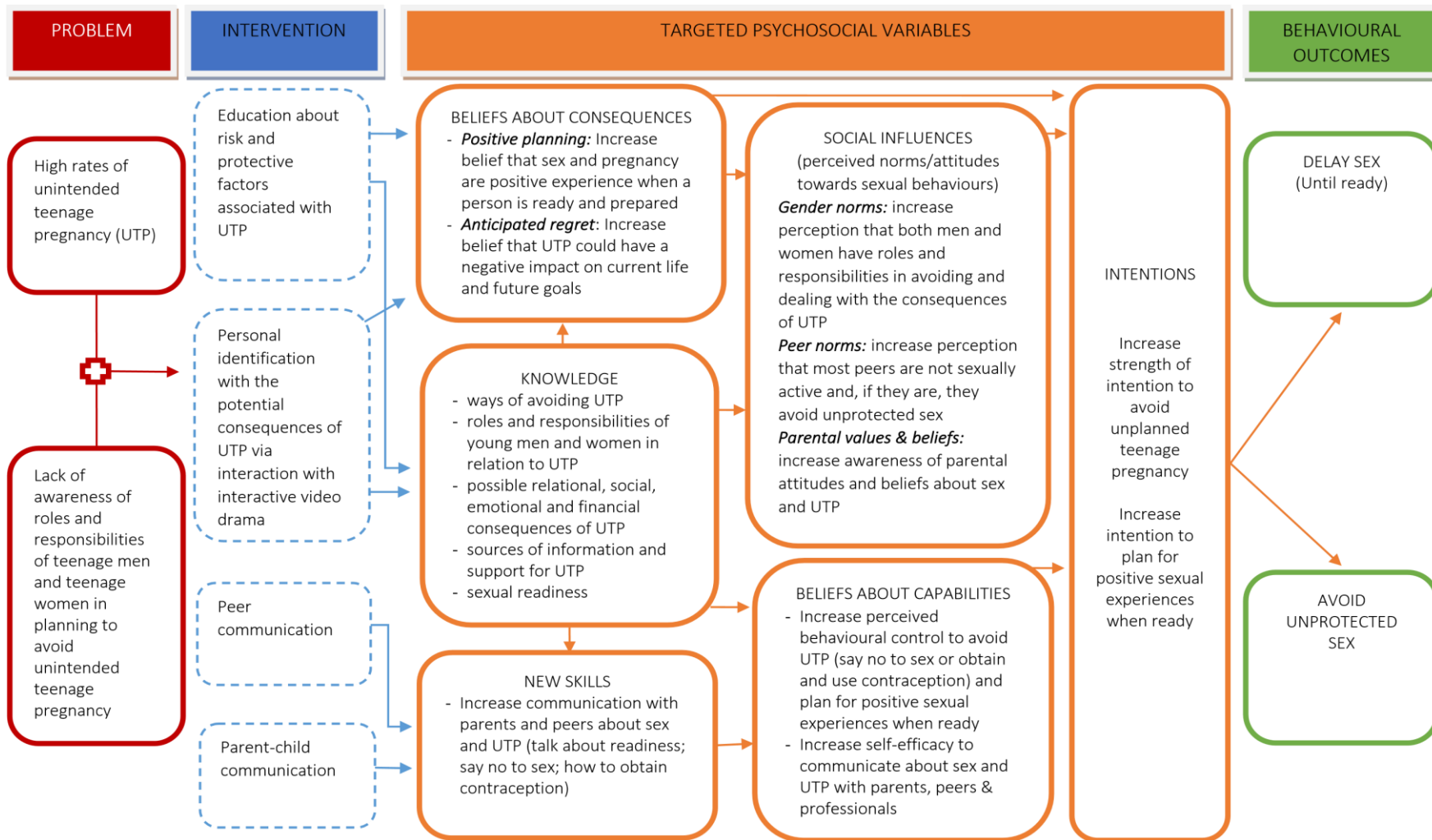


Figure 1 Theory of change Logic Model of the intervention

Evidence supporting intervention components and theory of change

The characteristics of effective RSE programmes which help to increase their impact on sexual risk-taking behaviours have been précised in a number of systematic reviews.^{25,55–62} These impactful characteristics include: the use of theoretically-based interventions targeting sexual and psycho-social mediating variables such as knowledge, attitudes, self-efficacy, intentions, perceptions of risk, and perceptions of peer norms which are linked to sexual behaviour change; the use of culturally-sensitive and gender-sensitive interventions; the use of interactive modalities which promote personal identification with the educational issues and engagement of young people; the use of skills-building components; the involvement of parents in the RSE process; and facilitating linkages with support services. The *If I were Jack* intervention represents an innovative combination of all these different elements and is therefore predicted to decrease young people’s sexual risk-taking behaviour in relation to avoiding teenage pregnancy. The evidence for each of the components is further broken down below.

Evidence supporting a theory-based approach

Providing a theoretically-informed foundation for sexual health education programmes is considered key to their effectiveness, ensuring that the most important determinants of young people’s sexual behaviour are targeted.^{28,57,59,63–65} The underpinning theoretical framework for this intervention combines the Theory of Planned Behaviour^{66,67} and gender-transformative programming.^{68,69}

The use of Theory of Planned behaviour in *If I were Jack*

The Theory of Planned Behaviour focuses largely on individual-level behavioural antecedents of a particular behaviour of an unplanned pregnancy. The *If I were Jack* intervention has been designed to increase teenagers’ intentions to avoid an unplanned pregnancy by delaying sexual intercourse until ready, or avoiding unprotected sex by use of modern contraception. With these behaviours in mind, the intervention targets six psycho-social mechanisms which research indicates are related to a reduction in risk-taking behaviour. These are: knowledge; skills; beliefs about consequences; social influences; beliefs about capabilities; and intentions^{25,70,71} (see theory of change model, *Figure 1*). Each

of the activities included in the intervention is designed to specifically target one or more of these psycho-social mechanisms, such as activities which provide pupils with educational information and opportunities for discussion, skills practice, reflection and anticipatory thinking.

Later critiques of the theory of planned behaviour bring an understanding of the broader socio-environmental factors and underlying values which influence behaviours, such as religiosity and gender ideologies associated with teenage pregnancy^{24,67} While these normative values are not addressed at a societal level in this intervention, they are addressed through young people's agency. Through intervention activities, young people are invited to think critically about social class, religious and gender norms which may influence their thoughts and behaviours on this topic—hence especially the importance of gender-transformative theory.

If I were Jack is also informed by gender-transformative programming

A gender-transformative approach was first developed by Geeta Rao Gupta⁶⁸ in the context of the HIV/AIDS epidemic, and has since gained traction as a means to improve health and wellbeing in SRHR and health and development policy more generally.^{69,72–75} The World Health Organisation (WHO) defines gender-transformative approaches as those 'that address the causes of gender-based health inequities through approaches that challenge and redress harmful and unequal gender norms, roles, and power relations that privilege men over women'.⁶⁹

Over the past decade in the RSE evidence base, the need for *gender-sensitive* interventions to address teenage pregnancy has been highlighted as a global health need by the World Health Organisation^{76–78} and recommended in systematic reviews of RSE education.^{25,79–81} By gender-sensitive, it is meant that RSE should seek optimal ways to engage both young men and young women and to address gender-norms, roles and relations that may lead to generating healthy and enjoyable relationships and positive sexual and reproductive health over the lifespan. In addition, the language of gender-transformative theory that explicitly challenges gender inequalities has been part of the WHO Guideline⁸² on preventing

adolescent pregnancy in developing countries since 2011, specifically in relation to the engagement of men and boys. More recently, the WHO⁸³ recommendations on adolescent sexual and reproductive health and rights states that ‘building equitable gender norms through comprehensive sex education can contribute to preventing gender-based violence and to promoting joint decision-making on contraception in couples’. The United Nations Population Fund also emphasises a focus on gender and empowerment outcomes consistent with a gender-transformative approach,⁸⁴ as does the most recent agenda-setting document in the field the *Guttmacher–Lancet Commission on Sexual and Reproductive Health and Rights*.⁸⁵ A further term used in the scientific literature by Haberland and Rogow is an “empowerment approach to Comprehensive Sex Education (CSE)” to refer to programs that emphasise gender/power versus those that do not. Their review states that CSE is most effective when it highlights a gender/power perspective.⁸⁶ Finally, engaging men and boys in a gender-transformative approach is also embedded in an ‘enabling environment’: An ecological framework to improve adolescent sexual and reproductive health:

‘Addressing unequal and harmful gender norms is therefore a key element of creating enabling environments. These approaches promote alternative norms and understandings of masculinity and behaviors in intimate relationships that involve mutual respect and equitable decision making, sharing responsibilities for reproductive health (e.g., condom use), and the greater involvement of men as fathers’.⁸⁷

Hence collectively across the literature with reference to a gender-sensitive, gender-transformative or empowerment approach to comprehensive sexuality education, the need to develop RSE interventions which successfully engage adolescent women and adolescent men, and which address *unequal* gender dynamics in intimate relationships has been expressed.

The *If I Were Jack* programme is designed to be both gender sensitive and gender transformative. It is gender sensitive as per the WHO definition, in that it is designed to include, and to engage young men on this topic alongside young women. It is gender transformative in that it addresses the negative gender norms and attitudes which place the

burden of responsibility with young women for preventing and dealing with the impacts of a teenage pregnancy. It encourages communication and behavioural skills among young men and young women to prevent a teenage pregnancy and to know how to seek help. *If I Were Jack* acknowledges sexual pleasure and sexual intimacy in young people's lives and asks young people to consider for themselves the balances between sexual pleasure and sexual responsibility in a gender-equitable manner. In addition, the programme seeks to address deficits in sex education for young men, particularly with respect to teenage pregnancy, identified in the scientific literature which disadvantage adolescent men as well as adolescent women.^{28,42,79,87-93}

Evidence supporting the use of culturally-relevant interventions

The resource includes an interactive computer-based modality incorporating drama and film. This is informed by research suggesting the need to engage with young people both empathetically and cognitively in order to increase the relevance of the issues being raised.^{29,56,59,63,94} The feasibility trial and process evaluation^{44,45} demonstrated that the use of locally-produced contemporary drama (in the IVD) made sex education more enjoyable and engaging for pupils. It is important to harness the potential for sex education to be enjoyed, especially by those who are less engaged in the wider school curriculum,^{30,95,96} a factor that was identified as a possible barrier to impact.²⁵ The feasibility trial^{44,45} also showed that the ability of users to identify with the key characters in the IVD, along with the overall tailored nature of the intervention in terms of linking in with local services, was central to its appeal and acceptability to pupils.

Evidence supporting the use of interactive computer-based interventions

The value of interactive-computer-based interventions has been demonstrated in systematic reviews,^{59,60,97} particularly tailored, video-based interventions for behaviour change.⁹⁸ A meta-analysis examining these reviews in relation to the theoretical mediators of safer sex⁶¹ concluded that they were successful in impacting knowledge, attitudes and self-efficacy relating to sexual health. Wearing headphones and sitting at individual computers, each participant is invited to answer questions on how he/she would feel and act as the drama unfolds.

Evidence supporting the use of skills-building components

Simply providing information does not lead to behaviour change, but rather, young people must be supported to develop their own communication skills in relation to preventing risky sexual behaviours.^{25,27–29,57,59,63,65,77,99–101} *If I Were Jack* emphasises the need for active participation and deliberation by the users so as to increase self-awareness and encourage ‘stop and think’ strategies in relationships. A further specific aim of the resource is to desensitise the discussion of sexual and reproductive topics through practicing explicit ‘verbal scripts’⁶³ for such conversations between young men and women.

Evidence supporting the involvement of parents in relationship and sexuality education

Although evidence suggests that schools are an important context for sex education,^{63,102,103} a number of systematic reviews have also shown that programmes that reach beyond the classroom can enhance effectiveness.^{25,31,104} In particular, factors such as parental monitoring and supervision, and familial communication have been associated with teenage sexual behaviours.^{105,106} Parents are often a primary source of information about sex for adolescents,¹⁰⁷ and teenagers who can recall a parent communicating with them about sex are more likely to report delaying sexual debut and increased condom and contraceptive use.^{108–110} One element of the *If I were Jack* theory of change involves increasing self-efficacy in communicating about teenage pregnancy among parents and teens. This is built into the resource in home resources to generate communication and through short animated films for parents and guardians. This component informs parents of the resources and information about communicating about teenage pregnancy, including hints and tips to do so. Learning from the feasibility trial,^{44,45} where parental attendance at information sessions was low (2.3%), the parental materials were re-developed as animated films and provided online. Recent studies^{111–113} demonstrate the potential of embracing such ‘education entertainment’ or ‘edu-tainment’ modalities as engaging adjuncts to school-based education.

Importance of comprehensive RSE despite limitations of impact on health outcomes

Above we have described the evidence for the programme characteristics of high-quality comprehensive RSE. Before we embark on describing the aims, objectives and results of this study, it is important to also sound a note of caution in terms of the limitations of comprehensive RSE alone in impacting on complex health behaviours such as preventing unprotected sex and consequently preventing teenage pregnancy and reduction in STIs. Also important, however, to the motivation of this study, is the importance of comprehensive sex education as an international human right of young people and as an expressed need by young people.

By way of definition, **comprehensive sex education (CSE)** teaches about abstinence as the best method for avoiding STDs and unintended pregnancy, but also teaches about condoms and contraception to reduce the risk of unintended pregnancy and of infection with STDs, including HIV. It also teaches interpersonal and communication skills and helps young people explore their own values, goals, and options.¹¹⁴ This can be contrasted with **the Abstinence-only-until marriage-approach (AOUM)**. The AOUM approach teaches abstinence as the only morally correct option of sexual expression for teenagers. It usually censors information about contraception and condoms for the prevention of sexually transmitted diseases (STDs) and unintended pregnancy.¹¹⁴ *If I Were Jack* is part of CSE.

First, within the UK, we acknowledge that two large cluster randomised controlled trials (RCTs) of CSE programmes did not show a significant effect on health outcomes. The SHARE (sexual health and relationships) programme trialled in Scotland did not reduce conceptions or terminations by age 20 compared with conventional provision.²⁴ The Ripple trial was a peer-led sex education programme conducted in South-East England. Final results showed the programme was not associated with change in teenage abortions but may have led to fewer teenage births.¹¹⁵

Second, overall reviews of evidence have also detailed the limitations of CSE alone in impacting on health outcomes, though they can have important impacts on knowledge,

attitudes and skills. An NIHR-funded systematic review²⁵ of the effect of interventions aiming to encourage young people to adopt safer sexual behaviour found that school-based interventions which provide information and teach young people sexual health negotiation skills can bring about improvements in behaviour-mediating outcomes such as knowledge, attitudes and self-efficacy but do not show significant results in adjusting health outcomes. The review noted that these variables are, however, no less valuable than behavioural health outcome variables because they provide young people with a solid foundation on which to make sexual decisions. Similar findings have been noted in other reviews^{116–118} and meta analyses, some of which are undertaken by organisations opposed to the implementation of comprehensive sex education^{119,120} and favouring abstinence until marriage approaches. However, the AOUM approach has not only been found to be scientifically ineffective in helping adolescents to delay intercourse, but is regarded as ethically flawed in terms of denying young people rights to information, endangering gender stereotypes and marginalizing sexual minority youth.¹²¹

Thus, despite some limitations noted in the scientific evidence for CSE alone in impacting on ultimate health outcomes, such as teenage conceptions and teenage pregnancy terminations, the United Nations¹²² and WHO concludes from the evidence that ‘CSE can help adolescents to develop knowledge and understanding; positive values, including respect for gender equality, diversity and human rights; and attitudes and skills that contribute to safe, healthy and positive relationships’.⁸³ As the NIHR review also stated, these skills are no less important and reflect a holistic approach to RSE.^{123–125}

Moreover, young people have a right to high quality comprehensive RSE. The United Nations Convention of the Rights of the Child (UNCRC)¹²⁶, Article 24 (health and health services) states:

‘Every child has the right to the best possible health. Governments must provide good quality health care... and education on health and well-being so that children can stay healthy. Richer countries must help poorer countries achieve this’.

Article 34 (sexual exploitation)¹²⁶ states:

‘Governments must protect children from all forms of sexual abuse and exploitation’.

Flowing from these fundamental rights, international human rights standards require that governments guarantee the rights of adolescents to health, life, education and non-discrimination by providing them with CSE in primary and secondary schools that is scientifically accurate and objective, and free of prejudice and discrimination.¹²⁷

The Committee on the Rights of the Child has further indicated that:

‘States parties should provide adolescents with access to sexual and reproductive information, including on family planning and contraceptives, the dangers of early pregnancy, the prevention of HIV/AIDS and the prevention and treatment of sexually transmitted diseases (STDs)’.¹²⁸

The right to sexual and reproductive health is also protected under the “right to the highest attainable standard of physical and mental health,” enshrined in Article 12 of the International Covenant on Economic, Social and Cultural Rights.¹²⁹ And finally, the right Information and education to promote sexual and reproductive health and rights is also linked in the United Nations sustainable development goals (targets 3.7 and 5.6)¹³⁰

However, few countries follow human rights standards¹³¹ for CSE curricula to be part of the mandatory school curriculum or implement and sustain large-scale CSE programmes.⁸³ Hence, the *Guttmacher–Lancet Commission on Sexual and Reproductive Health and Rights*⁸⁵ recognises the need for all countries to establish national curricula for comprehensive sexuality education based on evidence and drawing from international technical guidance such as that provided by the international policy community.¹²² Furthermore, the Commission noted that to be comprehensive, sex education must include strategies to increase gender equality and holistic health more broadly.

Finally, comprehensive RSE is also not just a right, but is a need, as expressed by young people themselves^{41,45,96,132–135} and human rights standards state the curricula should be developed with young people’s input, such as in the case of *If I Were Jack*, and described

more fully in the next chapter. With that balance of views on scientific evidence and children's rights in mind, we now describe the aims and objectives of this study.

Aims and objectives of the Jack trial

The overall aim is to carry out the first UK wide cluster randomised controlled trial of a comprehensive relationship and sexuality education intervention using a gender-transformative approach to specifically engage with young men and young women to address teenage pregnancy and promote positive sexual health.

The objectives of the study are to:

1. Assess the effectiveness of the intervention in preventing unprotected sex at 15 years of age amongst teenage boys and girls in a cluster RCT across the UK.
2. Assess the impact of the intervention on secondary outcome measures of knowledge, attitudes, skills and intentions to avoid teenage pregnancy, as well as additional behavioural outcomes of engagement in sexual intercourse, contraception use, and sexually transmitted infections (STI).
3. Examine any differential impacts for teenage boys and girls as well as for different socio-economic groups and nations of the UK.
4. Conduct an economic evaluation of the intervention compared to current practice.
5. Conduct a process evaluation examining reasons for participation and non-participation; intervention delivery and fidelity in intervention schools; RSE provision in all participating schools; and self-reported perceptions of effectiveness and moderating influences in intervention schools among a sample of pupils, teachers and school principals and parents.

The full protocol for this trial published in June 2018⁴⁸ and the protocol and any updates to the protocol (described under Methods) can be found at the [NIHR Evaluation, Trials and Studies website](#).

Chapter 2. Patient and public involvement (PPI)

Introduction

Stakeholder engagement involving policy makers and commissioners, as well as teachers, young people and parents has been central throughout this study. The purpose of engaging stakeholders was to ensure that their views and opinions were used to inform key aspects of the intervention optimisation (Stage 1 of this study), as well as study design processes, data collection procedures, and dissemination. We begin this chapter with an overview of stakeholder involvement and then move to a fuller description of the process and results of stakeholder involvement as part of Stage 1 of this study: Intervention refinement and optimisation.

Overview of purpose and mechanisms of stakeholder engagement

The purpose and mechanisms of stakeholder engagement were as follows:

Intervention refinement and optimisation

1. During the intervention refinement and optimisation phase, (Stage 1 of this Study), we convened and consulted with a **Jack Trial Stakeholders Advisory Committee (SAC)** (see *Appendix 2.1*) consisting of senior representatives from key government departments and non-government organisations involved in RSE policy making across the whole of the UK, including the Belfast Health and Social Care Trust (BHSCT), the Rainbow Project, Education Scotland, Council for the Curriculum, Examinations and Assessment (CCEA), Personal Social and Health Education Association (PSHEA), National Health Service (NHS) Glasgow and Public Health Wales, teachers and young people.
2. During the intervention refinement and optimisation phase, we also convened and consulted with a UK wide **Young Person's Advisory Group (YPAG)** (see below) on the refinement and acceptability of the intervention materials and processes.

Informing Trial Methodology

1. Throughout the study, consultations were held with the **Trial Steering Committee (TSC)** (see *Appendix 2.2*). The TSC met four times: 13 March 2017, 22 February 2018, 16 May 2019 and April 2021. The collective members of international TSC included independent public members: young people, parents, teachers and school principals; policy advisors to Public

Health England; experts in trial methodologies; and school based randomised controlled trial (RCT) experts.

2. In addition, we engaged **young people** in refinement of the trial outcome measure questionnaire. Representatives from the project YPAG, as well as young people who served on the TSC provided feedback on the questionnaire that resulted in minor changes to the wording of some questions.

Implications of interim Findings and dissemination

1. Members of the TSC, especially young person members, were consulted on the production of posters (see *Appendix 2.3*) to thank schools for their involvement and provide an interim summary of findings.
2. The 2019 SAC meeting took the form of a [“6 Nations” Relationships and Sexuality Education Symposium](#) held at Queen’s University Belfast (QUB) (through additional funding from QUB and [EuroSocial](#)). In addition to members of the SAC, international experts from Departments of Health and Education attended from across the four nations of the UK, Ireland and delegates from the Ministry for Health in Uruguay. Dr Chandra Mouli from the World Health Organisation (WHO) and Ineke van der Vlugt from Rutgers International, Netherlands also joined.





Figure 2 “6 Nations” Relationships and sexuality education symposium, 2019

The symposium involved short presentations from each nation (including interim results of the Jack Trial) and round table policy discussions on RSE & related sexual health policies.

3. The TSC met in April 2021 to consider the final findings of the study.

Stakeholder involvement in stage 1 intervention refinement and optimisation

Background and rationale

As reported in the Introduction, in 2014/15 we conducted a cluster randomised controlled feasibility trial of the *If I were Jack* intervention in eight schools in Northern Ireland (NI). In addition to the feasibility trial, and in preparation for the current UK wide trial reported here, we also conducted a transferability study in nine schools in Wales, England and Scotland. The following research questions were addressed in the transferability study:

- Was the intervention acceptable to schools and RSE curricula in other parts of the UK?
- Would students and teachers in other parts of the UK find the intervention useful?
- Could students in England, Wales or Scotland understand and relate to Jack and Emma as they appeared in the NI film?
- Were there changes they would like to see to the classroom materials and film itself?

Together, the findings of the feasibility trial and transferability study indicated that in all four UK nations, students, school staff, and RSE experts welcomed and enjoyed the intervention. However, they also made some suggestions for improvements to the film, classroom materials, teacher training and parental components in order to make the resource materials relevant for use in their nations. We therefore sought to implement

these and other changes in consultation with stakeholder groups, prior to commencing a full UK-wide trial. (Refinements to the parental components were conducted as part of a separate study in 2016, funded by the Public Health Agency for Northern Ireland.) This was achieved, as described below, during Stage 1 of the current study.

Stage 1 Aim and objectives

Aim

- To refine and optimise the *If I Were Jack* intervention for target populations in England, Scotland and Wales prior to a UK-wide RCT.

Objectives

Stage 1 of the current study involved a twelve-month (January – December 2017) intervention refinement and optimisation process. This stage had the following objectives:

1. To convene a UK-wide SAC composed of RSE specialists and statutory stakeholders and young people's advisory groups (YPAGs) in each nation to inform refinement of the intervention and continue to build implementation capacity over the longer term.
2. To produce updated and culturally-refined versions of the *If I Were Jack* interactive video drama (IVD); one for Scotland and NI using NI accents and one for Wales and England using English accents, both set in a UK urban setting and closely based on original script and storyboarding.
3. Refine classroom materials to match lesson plan outcomes to learning outcomes of RSE curricula of the four nations where relevant (Scotland and Wales) and insert local information resources.
4. Test the refined intervention in three schools based in England, Scotland, and Wales judged against 'stop/go' criteria and deliver results to the National Institute for Health Research (NIHR) before progressing to Stage two.

Methods

Intervention refinement and optimisation was achieved via an iterative process involving consultation with stakeholders, including experts and YPAG members and a pilot study in England, Scotland and Wales. *Table 1* summarises the key tasks and timeline of Stage 1.

Table 1: Intervention refinement and optimisation tasks and timeline

Intervention refinement and optimisation tasks	STAGE 1 YEAR 1 Jan – Dec 2017											
	J	F	M	A	M	J	J	A	S	O	N	D
Tendering and procurement (films)	✓	✓	✓									
Recruit YPAG and SAC			✓									
YPAG consultations				✓				✓				
Stakeholder group consultations						✓	✓	✓				
Produce refined versions of interactive films				✓	✓	✓	✓	✓	✓	✓		
Produce refined intervention materials								✓	✓	✓		
Pilot Study England, Scotland Wales											✓	✓
Further minor refinements to intervention materials												✓
Phase 1 report to NIHR												✓
Phase 2 Stop/go decision												✓

Consultation on refinements to the IVD

Our UK-wide YPAG was composed of 12 young people, aged 14-16, six male and six female, three from each of the nations, Northern Ireland (NI), Wales, Scotland and England. The young people were recruited via the project team’s network with pre-established community youth groups.

Young Person’s Advisory Group (YPAG) residential Cardiff April 2017

We held a two-day residential workshop in Cardiff in April 2017, to discuss refinements to the *If I Were Jack IVD*. Three youth workers accompanied the NI, Scottish and English young people on the journey to Cardiff. Two film producers from Morrow communications who were commissioned to produce the new IVDs, also attended the workshop. The workshop was led by experienced youth advisory group facilitators from the Centre for Development, Evaluation, Complexity and Implementation in Public Health Improvement (DECIPHer) at Cardiff University. It included six structured sessions over two days involving interactive focus groups, workshops and debates designed to promote discussion among, and feedback from the young people. The sessions addressed the following: a) identifying problems with the IVDs and film scripts and b) suggesting changes that would maximise the relevance and

acceptability of the films for young people across the UK. YPAG members met again via videoconference in August 2020 to consult on draft versions of the films.



Figure 3: Young Person's Advisory Group (YPAG) Residential Cardiff April 2017

Consultation on refinements to intervention materials

In June 2017, members of the research team engaged in a one-day workshop in London with the SAC from the four nations (see section above). This consultation focused on refinements to the non-film-based intervention inputs, activities and materials including teacher training materials, student activities and materials and proposed intervention delivery processes.

Stakeholders provided feedback, relevant to their representative nations, on the following:

- 1) Sexual health services for young people including online information and local services.
- 2) The RSE curriculum and potential positioning of the intervention within it and identification of existing similar interventions.
- 3) Delivery processes including proposed length of sessions and identification potential challenges.

- 4) Detailed comments on proposed teacher, student and parent activities.
- 5) Members of the SAC provided follow-up comments and feedback via email on the refined versions of the intervention materials during July and August 2017. Draft digital and hardcopy versions of the intervention materials were prepared in October 2017 for use during the pilot study.

Feedback from the YPAG and SAC was collated and, along with findings from the feasibility and transferability studies, informed amendments to the script and film storyboard as outlined in the results section below.

Intervention optimisation: Pilot study

In November and December 2017, the refined intervention was piloted in three schools, one each in Wales, Scotland and England. Teachers were trained to deliver the intervention by members of the research team, and students and teachers completed short surveys regarding their views on the intervention. Teachers who delivered the programme also took part in circa 30-minute semi-structured interviews with members of the research team.

Results

Intervention refinements: Films

The primary recommendations of the YPAG in relation to the IVD were: a) technology and music (e.g. add more generic background music and include texts on screen rather than on a particular phone); b) fashion (e.g. sportswear instead of jeans and updated hairstyles); c) language (e.g. use of slang and occasional swear words to make interactions more informal and realistic); d) filming locations and scenarios (e.g. pros and cons list at home not in a café) and; e) cultural representations (e.g. include more actors from ethnic minority/non-white backgrounds and to include mixed-sex friendship groups). The young people also examined the films' scripts in detail and recommended changes to the language used. A full report of the YPAG methods and outcomes is available in *Appendix 2.4*.

The team worked with the film production company (Morrow Communications) to cast and produce two versions of the film (one for Scotland and NI casting actors with NI accents and one for Wales and England casting actors with English accents). YPAG members met again via videoconference in August 2017 to consult on draft versions of the films and minor

amendments were made at this stage following their recommendations. These minor amendments related to slight changes to the questions that appear in the IVD and inserting a space between the various parents' reactions in the films. The young people were overwhelmingly positive about the revised versions.



Figure 4: If I Were Jack filming June 2017

Intervention refinements: Materials

As well as the provision of nation-specific information noted above, the SAC offered the following key recommendations on refinements to the intervention materials:

- 1) Due to the variability in relation to sexual health services, sexual health and RSE terminology and the provision of RSE across the nations, separate sets of materials would be required for each nation.
- 2) Stakeholders encouraged the use of more 'sex-positive' language in the materials e.g., changing references to 'abstinence' to 'sex when ready'.

- 3) Stakeholders encouraged the inclusion of activities and amendment of language that would make the materials more relevant to the lesbian, gay, bisexual, transgender, and questioning (or queer) communities (LGBTQ).

Pilot study results

In November and December 2017, the refined intervention was successfully piloted in three schools, one each in Wales, Scotland and England. Teachers were trained to deliver the intervention by members of the research team, and students and teachers completed short surveys regarding their views on the intervention. Teachers who delivered the programme also took part in circa 30-minute semi-structured interviews with researchers. As outlined in Table 2 below, survey findings relating to the films were used to inform the Stage 2 progression rules. Findings relating to the non-film intervention components (i.e. teacher resources and student activities) informed further minor refinements to the classroom activities and teacher training materials but were not part of the progression criteria.

Stage 2 Progression rules and pilot study findings

PROGRESSION RULES	PILOT STUDY FINDINGS			STOP/GO DECISION
	ENGLAND	SCOTLAND	WALES	
<i>At least 60% of students view the entire film</i>	93% of 43 participating students viewed the entire film.	100% of 34 participating students viewed the entire film.	100% of 56 participating students viewed the entire film.	GO
<i>At least 80% of students who view the entire film find the accents clear and understandable</i>	88% of 43 students found the accents 'clear and understandable'.	85% of 34 students found the accents 'clear and understandable'	100% of 56 students found the accents 'clear and understandable'	GO
<i>At least 80% of teachers report that they would be happy to use the If I were Jack film again</i>	100% of 2 teachers said they would use the film again.	100% of 2 teachers said they would use the film again.	100% of 2 teachers said they would use the film again.	GO

Table 2: Stage 2 Progression Rules and Pilot Study Findings

Conclusion

The involvement of stakeholders has been a key method of ensuring the quality and acceptability of the intervention and trial methods. Stakeholder voices and opinions informed intervention development and optimisation, study design processes and dissemination. The dedicated intervention refinement phase and pilot study allowed optimisation of the intervention materials prior to progressing to the Stage 2 trial. Close consultation with stakeholders throughout was key to the success of Stage 1 of the project and laid solid stakeholder-informed foundations on which to build and implement processes and procedures for Stage 2 of the study. All resulting materials were made available on the [If I Were Jack](#) website post trial.

Chapter 3. Methodology

Study design

The JACK Trial was a phase III¹³⁶ multicentre, parallel-group cluster randomised controlled trial (cRCT) with two treatment arms: the *If I Were Jack* intervention versus schools' usual RSE provision. Schools were the unit of randomisation with a 1:1 allocation. An embedded process evaluation and economic evaluation were conducted (economic evaluation methods are detailed in *Chapter 7*). The trial protocol was published.⁴⁸

Ethical approval and research governance

The trial was conducted in line with the ESRC Framework for Research Ethics and received a full ethics review by the School of Nursing and Midwifery (QUB) Research Ethics Committee in July 2017 (Ref: 11.MLohan.05.17.M6.V1), who independently assessed our compliance with the ESRC Framework. This approval covered data collection in each partner site. A trial steering group was convened to oversee the trial (see *Appendix 2.2*). QUB acted as the main sponsor of the research and ensured that governance and indemnity procedures were in place. The project was registered on the Human Subject Projects database in QUB and prospectively registered in an international register of trials ([ISRCTN99459996](https://www.isrctn.com/ISRCTN99459996)).

Participants

The study sought to recruit schools in the four nations of the UK, and to recruit teachers and pupils within these schools. Parents were also recruited but participated only in the process evaluation.

Inclusion criteria for schools

The whole of NI is included but, for reasons of practicality, convenience and cost, selected geographical restrictions for England (Greater London area), Scotland (five specified local authority areas) and Wales (South Wales) were put in place. All secondary schools with over 30 pupils in Year 11 (Northern Ireland), Year 10 (England and Wales), and S4 (Scotland) were eligible to participate. The detailed recruitment strategy can be found in *Appendix 3.2*.

Further inclusion criteria were as follows

- Schools had to be able to send e-mail or text messages containing a link to the video to parents of their pupils. Prior feasibility and transferability studies suggested that this would exclude a very small proportion of schools.
- Faith-based schools were not excluded in any UK region.

In terms of exclusion criteria,

- Independent private, special, and Irish/Welsh-medium and Scottish Gaelic schools were excluded. This exclusion criteria did not exclude schools that have an embedded Irish/Welsh medium component.
- Schools with fewer than 30 pupils in the target year group (Year 11 in NI, S3 in Scotland and Year 10 in England and Wales) were excluded.
- Schools that had already participated in the feasibility ($n = 8$ in NI), transferability (England $n = 3$, Scotland $n = 3$ and Wales $n = 3$) and pilot studies (England $n = 1$, Scotland $n = 1$ and Wales $n = 1$) involving the *If I Were Jack* intervention in preparation for Phase III study were also excluded.

Inclusion criteria for teachers

Teachers who were responsible for the delivery of RSE to pupils in year 11 in NI, S3 in Scotland and year 10 in England and Wales during the 2018/2019 academic year were eligible for the study.

Inclusion criteria for pupils

All pupils entering Year 11 in NI, S3 in Scotland and Year 10 in England and Wales (mean age 14 across all nations) in 2018/19 in eligible schools were eligible for the study. In any schools where students had mild learning difficulties or poor English, they were supported to complete the questionnaire by trained fieldworkers.

Inclusion criteria for parents

All parents in intervention schools were eligible for inclusion in the study.

Recruitment procedure

Sampling frame

A sampling frame of Department of Education listed schools for each nation of the UK and defined socio-economic status of schools (based on eligibility for free school meals (FSM) as indicated by the School Meal Census) was used. In each nation eligible schools were stratified into two levels according to FSM (schools above and below the median %FSM for all eligible schools, rank ordered randomly). In NI 14 schools were randomly selected from the above-median stratum and 10 from the below-median stratum (total 24) and in England, Scotland and Wales, eight schools were randomly selected from the above-median stratum and six from the below-median stratum (to give a total of 14). The decision to select slightly more schools from the above-median %FSM stratum was to allow for even random allocation of schools to trial groups and to reflect research which indicates that public health need for addressing adolescent unintended pregnancy is greater in areas of higher social deprivation.^{137,138}

Recruitment of schools

Main study recruitment took place over a 6-month period (February–June and to end September 2018), with a break during the summer period (July and August). Where possible, schools were approached via a relevant senior manager in the schools (e.g. senior teacher or deputy head in charge of pastoral care, identified with the help of the School Health Research Network in Wales, the School Health and Wellbeing Research Network in London, and local professional networks in Scotland and NI). In Scotland permission was obtained from each local authority (typically by approaching the Director of Education) prior to commencing recruitment. Any schools that declined to participate were replaced by a randomly selected school in the same stratum. A multifaceted approach to recruitment of school was employed and consisted of an email with attachments including:

1. Promotional leaflet (see *Appendix 3.3*);
2. Invitation letter and information sheet (see *Appendix 3.4*).

To promote school retention schools were provided with £1000 on completion of baseline and follow-up measures. Schools that decided to participate were invited to consent by

signing a Memorandum of Understanding (MoU), and were asked to nominate a main point of contact (a trial champion teacher who was typically a teacher with responsibility for RSE delivery or governance) within the school to deal with future correspondence between the research team and the school. No stopping guidelines were put in place for this study; any and all schools and students who agreed to take part were included. The full school recruitment strategy is detailed in *Appendix 3.2*.

Recruitment of teachers

Trial champion teachers then identified teachers responsible for RSE delivery to the relevant year groups during the 2018/2019 academic year, and researchers delivered an information session and provided the school letter and information sheet (see *Appendix 3.4*), memorandum of understanding (see *Appendix 3.6*) and consent form (see *Appendix 3.23.3*).

Recruitment of pupils

Schools posted to parents/guardians an information sheet and an opt-out consent form for participation in the trial research for their child (see *Appendix 3.7*) with prepaid response envelopes and a return deadline. Researchers collated a list of parents/guardians who opted their child out of participation and returned this to teachers. At least one week prior to baseline data collection, pupils attended a short information session delivered by a member of the research team, which included an animated video. Pupils were provided with pupil information sheets (see *Appendix 3.8*) and given an opportunity to ask questions prior to deciding whether to participate. Only eligible pupils whose parents/guardians did not opt-out of providing consent for them to participate attended.

Recruitment of parents

Schools texted/emailed parents of all participating pupils in intervention schools a short online survey asking for their views on the parents' videos and parent/pupil homework exercise. A maximum of two texts/emails was sent to parents (the original message and link to survey and one reminder). At the end of the survey, respondents were asked to provide their contact details if they would like to be approached to take part in a parents' focus group discussion if their school was selected as a case study school.

Informed consent

Informed consent was sought for every participant group in the trial. In the case of pupils, parents were also informed about the study by letter and offered the opportunity to withdraw their child from the study (see *Appendix 3.7*). Informed consent forms for each participant group are available in *Appendices 3.7, 3.8, 3.22 and 3.23*.

Randomisation, concealment and blinding

When recruitment quota for schools had been filled and prior to baseline data collection; schools within each nation and socio-economic stratum were randomly allocated (1:1 concealed allocation) to a trial group by an independent NI Clinical Trials Unit (NICTU) statistician. The statistician produced eight randomisation schedules (using unique identifiers for schools), one for each %FSM stratum for each nation, using random permuted blocks of mixed size, generated using nQuery Advisor 7.0. The NICTU were not involved with recruitment and released the randomisation code only when all schools were recruited and baseline data collection completed, ensuring allocation concealment.

The statistician sent teacher trainers the allocation schedule for all schools. The teacher trainers were part of the intervention delivery team, composed of appointed RSE trainers independent and external research team). School allocation was communicated to each school by the nation-specific teacher trainer following baseline data collection within the school. Research teams were unaware of school allocation until after schools were informed of their allocation (In a trial of this type it was not possible to blind participants to allocation). At randomisation, the NICTU Trial Statistician also randomly selected two intervention group schools from each nation as case study schools for the process evaluation (see process evaluation methods section).

Treatment group allocation

Intervention: The schools that were randomly allocated to the intervention group received the *If I Were Jack* programme in their respective year group.

Usual RSE provision: The remaining schools in the control group did not receive the *If I Were Jack* programme but continued with the regular RSE curriculum and usual classroom activity. Schools in the control group were placed on a waiting list to receive the programme in 2020 following completion of the final follow-up survey.

Data collection and management

Data management

A Data Management Protocol (see *Appendix 3.5*) was developed detailing the procedures to be followed in recording, storing and sharing project data. Survey data was provided to NICTU in the form of excel documents, sent by password-protected email by an external scanning company. Working files were created for each of the four locations; England, NI, Scotland and Wales. Validation checks were carried out on these datasets as per Data Management Guidelines and when complete four master datasets were created for analysis. Data sharing between sites was facilitated via a university-secure, password-protected Dropbox.

Data ownership

Queen's University Belfast, the sponsoring organisation, is the custodian of all data collected during the study. The Principal Investigator (PI), Professor Maria Lohan, controls the use, publication and copyright of the project data. Any intention to use or share project data for purposes other than those outlined in the JACK Trial Project Protocol or the JACK Trial Data Management Protocol must be approved by the PI and Trial Management Group (consisting of representatives from all partner sites).

Data retention/archiving

All data will be retained by QUB for a minimum of five years after completion of the final report (stored on a secure server, protected against unauthorised access by user authentication and a firewall). All hardcopy materials (other than pupil questionnaires) will also be stored by each partner institution for a minimum of five years after completion of the final report, in secure storage with restricted access, and accessible to the PI if needed

upon request. The data will be archived by year ten in The UK Data Archive (UKDA) located in the University of Essex.

Data collection

Baseline

At baseline (prior to commencement of intervention delivery), fieldworkers administered paper-based questionnaires to participating pupils, which they completed during the school day under exam conditions. Teachers were asked to stay at the front of the room to maintain order while also alleviating pupils' concerns that teachers could see their answers. Fieldworkers supported pupils requiring extra help and ensured questionnaires were completed confidentially.

Follow-up

Participating pupils were in the study for approximately 18 months, and completed follow-up questionnaires between 12 and 14 months post-intervention during identical procedures to those employed at baseline.

Outcomes and measures

The outcomes measured in this trial are based on the logic model (see *Figure 1, Chapter 1 Introduction*) and described in *Table 3*. A full copy of the baseline questionnaire is available in *Appendix 3.9*.

Primary outcome

The primary outcome was unprotected sex at last sexual encounter, as defined by sexual intercourse without use of contraception (barrier or hormonal), as measured by items on a paper-based questionnaire at baseline and again between 12 and 14 months later.

Analysis of the primary outcome, unprotected sex, was undertaken with the whole study analysis population and included those not yet sexually active, alongside those who were.

The Unprotected sex category combined respondents who reported no contraception or unreliable contraception at last sex. Protected sex combined all those who remained sexually abstinent and those who used reliable contraception at last sex.

Figure 5 shows how the primary outcome was determined. Three questions were used to determine if students were sexually active: 'Have you ever had sex (penis- in- vagina)?'. If they answered 'no', their response was coded '0' (no unprotected sex). If they answered 'yes', they were next directed to answer the question: 'Last time you had sex did you use contraception?' If they answered 'no' to this question, their response was coded '1'. If they answered 'yes' their response to a third question was used as a check on reliable use of barrier or hormonal contraception. If participants answered 'yes' to the question 'Last time you had sex, did you or your partner use withdrawal (pulling out before ejaculating/cuming) or natural family planning/rhythm method (only having sex at certain times of the month)?', their responses was coded '1'. If they answered, 'no', their response was coded '0'. A binary outcome was derived where a score of '0' indicated not having had unprotected sex, or never having had sex and a '1' indicated having unprotected sex.

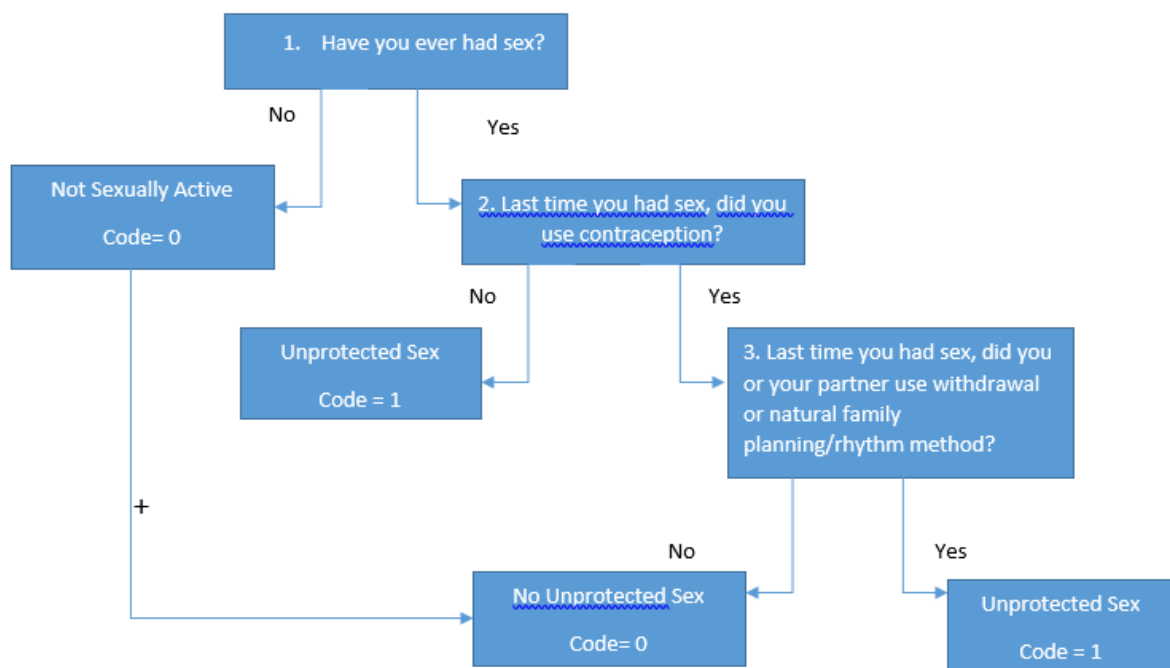


Figure 5 Flow Diagram showing how the primary outcome was assessed.

Secondary outcomes

Secondary outcomes were 12-14 month impacts on knowledge, attitudes, skills and intentions to avoiding teenage pregnancy as well as sexual behaviours. Secondary outcomes were assessed using a number of standardised measures as follows. Knowledge was

measured by items selected from the Mathtech Knowledge Inventory and SKATA.^{139,140} This measure included items relating to knowledge of safe contraceptive methods, how to access contraception, and the age of sexual consent. Attitudes were measured by the male role attitudes scale.¹⁴¹ This scale was included to examine change in gender attitude (masculinities) more generally in society and not specifically related to teenage pregnancy. Higher scores indicate endorsement of traditional male role stereotypes. Skills were measured through the comfort communicating scale¹⁴⁰ and the sexual self-efficacy scale.¹⁴² The comfort communicating scale specifically looked at communication between peers, parents and health professionals around avoiding pregnancy. The sexual self-efficacy scale measured ones perceived ability to have protected consensual sex when ready. It included items relating to communicating consent, sexual preferences and sexual readiness. Intentions to avoid an unintended pregnancy was assessed using an 'intentions to avoid a teenage pregnancy scale' (TUPS), developed and psychometrically tested in the phase II feasibility trial.¹⁴³ The TUPS measure was based on the concepts of sexual competence¹⁴⁴ to include sub scores on contraception (intentions to know about, discuss and use contraception effectively); willingness (intentions to have sex when both partners have communicated willingness and consent); readiness (intentions to weigh up when they are ready to begin a sexual relationship); norms (intentions to avoid peer pressure to have sex); and attitudes (intentions to be prepared and share responsibility for contraception with a partner). The items that make up each scale, as well as the internal validity of the scales used as part of the questionnaire are described in *Appendix 3.12*.

Secondary behavioural outcomes were assessed using the following questions:

1. Have you ever had sex with another person?
2. Have you ever had sex without using any contraception?
3. The last time you had sex, was any form of contraception used?

Subgroup Analyses

Informed by the intervention theory of change model and research design (see Figure 1, Chapter 1 Introduction), the effect of the intervention on the primary outcome for the following pre-specified sub-groups was examined: those reporting having had unprotected sex at baseline or not (as an especially high-risk group); nation (Wales, England, Scotland, NI); sex; and socioeconomic status as measured by the Family Affluence Scale. Finally, we also looked at subgroup variation by ethnic group.

Table 3: Questionnaire components and key measures

Component	Aim	Measurement
Knowledge	Increase knowledge about ways of avoiding unintended pregnancy; roles and responsibilities of young men in relation to unintended pregnancy; possible negative relational, social, emotional and financial consequences of unintended pregnancy; and sources of information and support for unintended pregnancy	Individual assessment. Selected items from the Mathtech Knowledge Inventory ^{139,140}
Communication skills	Increase skills for communicating with parents and peers about avoiding unintended pregnancy	Comfort Communicating about Pregnancy scale (parents, peers and professionals). Selected items from the Mathtech Behaviour Inventory ^{139,140}
Attitudes about unintended pregnancy	Increase anticipated regret about the consequences of unintended pregnancy on current life and future goals	Items from the Intentions to Avoid Teenage Unintended Pregnancy scale (TUPS) developed and psychometrically tested in our feasibility trial ¹⁴³
Social influences	<p>Increase awareness of peer norms, stereotypical gender norms and parental attitudes and beliefs about teenage pregnancy</p> <p>Gender norms: increase perception that both men and women have roles and responsibilities in avoiding and dealing with the consequences of unintended pregnancy</p> <p>Peer norms: increase perception that most peers are not sexually active and use contraception when they are</p>	<p>Male role gender norms: Male Role Attitudes scale¹⁴¹ and knowledge items relating to responsibility for avoiding pregnancy</p> <p>Peer norms: knowledge items about sexual behaviour/contraceptive use among peers and Sexual Socialisation instrument (Peer subscale)¹⁴⁵</p>

	Parental values and beliefs: increase awareness of parental attitudes and beliefs about unintended pregnancy	Parental values and beliefs: Sexual Socialisation instrument (Parent subscale) ¹⁴⁵
Beliefs about capabilities	Increase perceived behavioural control to avoid unintended pregnancy (say no to sex or obtain and use contraception correctly) and increase self-efficacy to communicate about avoiding unintended pregnancy with parents, peers and professionals	Sexual Self-Efficacy scale using an adapted version of the Sexual Self-Efficacy scale ^{142,146}
Intentions	Increase strength of intention to avoid UTP	TUPS ¹⁴³
Sexual behaviour	Abstinence from sexual intercourse (delay initiation of sex or return to abstinence) or avoidance of unprotected sexual intercourse (consistent correct use of contraception)	Sexual behaviour items (ever had sexual intercourse; frequency of sexual intercourse; contraception use ever/at last intercourse). Items adapted from previous sexual health surveys ^{147,148}
Pregnancy	Avoidance of unintended pregnancy	Ever pregnant

Sample size

This trial was powered to detect a 50% reduction in the incidence of unprotected sex (from an expected rate of 2.8% to 1.4%) by 15 years of age. A difference of 1.3% in unprotected sex has been shown to have a meaningful impact on pregnancy rates.^{24,149–151} The between-group difference in the incidence of unprotected sex of 1.3% (95% CI 0.5% to 2.2%) by nine months in our feasibility trial¹⁵² demonstrates that such an effect size is plausible and is consistent with effect sizes seen in the literature.¹⁴⁹ This study was designed to also take account of clustering. In the feasibility trial data, the intra-class correlation coefficient (ICC) was 0.01.¹⁴³ As pilot studies can provide imprecise estimates of ICCs,¹⁵³ we re-estimated using ICCs from three sources: (1) the Randomised Intervention of PuPil-Led sex Education (RIPPLE) cluster RCT;¹⁵¹ (2) data from the WHO Health Behaviour in School-aged Children Survey GB;¹⁸ and (3) the Young Persons' Behaviour and Attitudes Survey 2011.¹⁵⁴ The data from the WHO and Northern Ireland Statistics and Research Agency (NISRA) studies were combined. Both the RIPPLE and combined WHO and NISRA studies found an ICC of 0.004. In terms of our sample size calculation based on these data, first, based on the ICC of 0.01 (95% CI 0.01 to 0.04), and assuming 120 students per year group in school, second, a 7% rate of attrition (based on the conservative attrition rate found in the feasibility study plus two additional schools), the sample size calculation stated that a trial involving 33 schools per group would provide 80% power at a 5% significance level. The alternative ICC of 0.004 was calculated to provide 93% power.

Statistical analysis

Statistical analysis (primary and secondary outcomes)

Primary analysis (12-14 month follow-up)

The primary effectiveness analysis is on an intention-to-treat basis, using a multi-level logistic regression model (two levels: pupils nested within schools) adjusting for the baseline outcome and stratification variables.¹⁵⁵

Sub-group analysis (12-14 month follow-up)

Multi-level logistic regression was used with interaction terms (treatment group by subgroup) for each of the above pre-specified subgroups. Due to the low power and number of interactions being tested, the results of the subgroup analysis are reported using 99% confidence intervals.

Missing data

Sensitivity analyses including imputed follow up data based on the worst performing school (in relation to detected incidence of unprotected sex), and best performing school (where students did not have unprotected sex) at baseline were conducted for schools that did not collect follow up data.

The scales captured as secondary outcomes for this trial generally had two types of missing data: (1) complete missing data (i.e. because the student was not present in school when data were collected; and (2) partial missing data where the student has completed some but not all items of the questionnaire. The N is reported for each outcome in order to show the level of complete missing data for each outcome. The analysis population includes those who had both baseline and follow-up data completed. Partial missing data for the following scales: Male Role Attitudes Scale¹⁴¹; Comfort Communicating^{139,140}; and Intentions Scale¹⁴³ was dealt with by averaging the responses of the questions answered, standardized on a scale of 0 to 1 then multiplying by 100 in order to derive a score for all students who completed some of the questionnaire.

Data Linkage

This study did not undertake any data linkage with Health and Social Care or National Health Service records, given that data on conception rates are not available in NI and that data for sexual health-related services across the UK are not readily available as part of routinely collected data given patient privacy requirements.

Process evaluation methods

Aims and research design

The overall aim of the process evaluation was to understand implementation of the intervention as well as its acceptability and perceived effectiveness to pupils, teachers, parents and RSE stakeholders. The research design of the process evaluation was informed by realist approaches to the evaluation of interventions^{136,156} as well as Medical Research Council (MRC) guidance¹⁵⁷ for process evaluations to consider the context; implementation; and mechanisms of impact of interventions. Multiple methods were utilised with triangulated design.

Recruitment and sampling

Schools and participants included in the process evaluation were first recruited to the trial via methods and ethical procedures outlined above. All study schools were included in the process evaluation. In addition, more in-depth study was conducted in eight case study schools in intervention arm. These were selected as follows: at randomisation the NICTU Trial Statistician randomly selected two schools in the intervention arm from each nation to be case study schools and informed the schools.

Data collection

Table 4 outlines total data collection and the purpose of each item of data collection. Below are further details on each of these data collection items.

Table 4: Process Evaluation Data collection and purpose

Data source	Key focus area/purpose
All schools	
School Background Questionnaire	School structure, socio-demographic profiling, and experience of unintended teen pregnancy
RSE Questionnaire	Extant RSE provision
Fieldworker Perception Form	What worked well and what did not in relation to data collection; any other relevant observations
Intervention schools	
Parent/guardian online survey	Engagement with and opinion of the parent/guardian animations and homework session; whether their child discussed programme with them
Parent/guardian data analytics	Website viewing statistics of the parental component for the implementation period obtained using Google Analytics
Teacher Implementation Log	Recorded activities delivered in each lesson to assess each school's fidelity to programme guidance
Semi-structured trial champion/principal/head teacher interviews	Perceived barriers and facilitators of successful implementation and engagement with different components of the intervention
Student Engagement Questionnaire	Programme delivery, parental participation, quality of teaching and perceptions of their engagement in the programme
Case study schools (in addition to data collection outlined above in intervention schools)	
Lesson observations (Lead Fieldworker Observation Form)	Measuring teacher fidelity to implementation protocol and pupil engagement
Teacher focus groups	Perceived barriers and facilitators of successful implementation and engagement with different components of the intervention
Pupil focus groups	Perceived barriers and facilitators of successful implementation and engagement with different components of the intervention
Parent focus groups	Assess parental engagement and evaluation of the intervention
Education/policy specialists	
Education/policy specialist interviews	Current context of RSE policy and practices and perceptions of how this might influence programme uptake; acceptability of intervention and future implementation potential
Teacher trainers	
Audio/video-recordings of teacher training	Check fidelity of teacher training in randomly selected intervention schools
Teacher trainer telephone interviews	Issues relating to delivery of training on school-by-school basis; perceptions on quality of training materials and how training was received by teachers

Data Collection, Location and Purpose

All study schools

School background and existing RSE provision: Prior to intervention implementation, both intervention and control schools completed a school background questionnaire to gain an understanding of the broader school context (see *Appendix 3.14*). Intervention and control schools also completed a questionnaire about their extant RSE provision (see *Appendix 3.13*).

Intervention schools

Teacher training: fidelity of delivery and evaluation: All intervention schools received a teacher training session. Teacher trainers were asked to audio-record a random sample of four sessions (six in Northern Ireland). The research team used an online random number generator to select sessions and informed trainers. Teacher training satisfaction surveys (see *Appendix 3.22.3*) and sealable envelopes were distributed to all teachers by the trainer at the end of sessions. Teachers were not asked to record their name on these surveys.

Teacher fidelity of delivery: Teacher implementation logs were delivered to teachers during teacher training. These were designed to be filled out by each teacher at the end of each session or at the end of the programme (see *Appendix 3.15*).

Intervention school trial champion interviews: In intervention schools, researchers conducted audio-recorded interviews on an encrypted device with trial champion teachers or a teacher nominated by the trial champion teacher. Interviews were conducted during or at the end of the school day, by researchers from each nation, in school facilities or by telephone.

Intervention school pupils: Student Engagement Questionnaires (SEQ) (see *Appendix 3.17*) were distributed by teachers to all intervention school pupils after programme implementation and returned to researchers.

Intervention school parents: A link and invitation to complete a short online survey was texted or emailed by schools to the primary parent/carer contact of all participating students (n=approximately 4097 potential parents). Information sheets and parent factsheets were available in English, Polish, Urdu, Punjabi, Arabic, Bengali and Mandarin. Parents who completed the survey were entered into a prize draw for £500. Trial champion teacher inquiries led to doubts that the link had been sent by some schools, but this remained difficult to confirm. Google Analytics provided website-viewing statistics of the parental component for the implementation period.

Intervention case study schools

Case study school teachers: Focus group interviews were conducted by researchers with the school trial champion teacher and teachers who had delivered the programme, sometimes also including Year Heads or Heads of Pastoral Care (see *Appendix 3.16*).

Case study school pupils: Teachers who delivered the intervention invited pupils to volunteer to participate in focus-group interviews, one per case-study school, through the use of an information and consent form (see *Appendix 3.23.1*). Teachers were encouraged to include diversity in terms of sex, academic and behavioural records and socio-demographic background (topic guide available in *Appendix 3.16*).

Case study school parents: Parents' views were sought in semi-structured interviews. Parents were recruited via school requests for volunteers from case study schools and respondents to the online survey.

Case study school observational analysis: Researchers conducted classroom observations on between two and eight *If I Were Jack* lessons in each case study school. Researchers liaised with trial champion teachers to determine the school's chosen programme delivery route, to ensure observation of as many different programme exercises as possible, by a variety of teachers.

External participants: teacher trainers and policy specialists

Teacher trainers: Researchers conducted short telephone interviews (see *Appendix 3.22.4*) with one teacher trainer per nation.

Policy specialists: Policy specialists involved in the development of RSE policies or curricula in each of the four nations were identified by the research team and approached via email or phone call, providing an information and consent form (see *Appendix 3.23.4*). Researchers conducted audio-recorded interviews largely by telephone (topic guide available in *Appendix 3.16*).

Data analysis

All audio files were transferred securely to QUB and transcribed verbatim (interviews and focus groups) or typed up by researchers (observational field notes and other secondary source data). Data were organised using NVivo 12 software and analysed systematically and thematically based on the six steps proposed by Braun and Clarke¹⁵⁸ to enable identification and analysis of patterns within the data by moving iteratively between theoretical understandings and the new data.

Methodological rigour was ensured by establishing credibility, transferability, dependability and confirmability using techniques suggested by Lincoln and Guba.¹⁵⁹ These inductively and deductively derived codes were first compiled as a code book and then applied to the data. These codes as applied to the data were discussed with the researchers from each of the four nations to check validity of emerging themes and bring out some of the complexity in the data. All transcripts were independently coded by two members of the research team (10% coded by seven members). Meaningful quotes from participants were extracted to support and exemplify identified themes/sub-themes. The data was analysed to form overarching themes emerging from each of the participant groups outlined above and also across these groups, but at all cases paying attention to deviant data. Open-ended questions from the SEQ and parent survey were transferred to NVivo 12 and thematically coded as per other qualitative data.

Implementation fidelity data were entered into excel files in each site and transferred to QUB for summary descriptions. Data from the parents' survey and student engagement questionnaire were imported to Excel and SPSS and tabulated as summary statistics. Descriptive data analysis was conducted to identify general patterns in the data.

Figure 6 Data collection timeline



Deviations and rationale

The protocol for this evaluation was published in June 2018 and since amended in August 2019. It is available at: [NIHR Evaluation, Trials and Studies website](#). The original aims and objectives of the evaluation have not been altered and the overall approach to the research design in relation to the cluster randomised trial, the process evaluation and the cost effectiveness evaluation have also remained unchanged. A small number of minor deviations to the original Protocol published in June 2018 have been made and these are detailed below.

Minor changes to recruitment timing

The published protocol stated that the school recruitment period would run from February to June 2018. However, in order to recruit the full number of schools, this was extended slightly, and school recruitment took place over a six-month period (February–June and to end September 2018), with a break during the summer period (July and August).

Minor changes to intervention implementation

Our published protocol stated that:

As part of intervention implementation there will be a standardised 60 min training session for RSE teachers implementing the intervention. The training session will adhere to a predefined teacher-trainer protocol and will be delivered in schools by **nation-specific established statutory and non-statutory RSE co-ordinators who normally provide RSE teacher training in schools.**

We encountered difficulties in using RSE coordinators who normally provide RSE in schools in Scotland and England. In Scotland, Education Scotland was unable to provide us with this teacher trainer resource. In England the non-statutory facilitator did not complete training in two of the six schools in the intervention arm. To address both these issues, the project team appointed external teacher trainers. These teacher trainers were trained in the same way as all other teacher trainers as per protocol. The fidelity of the teacher training offered by the

replacement teacher trainers was also assessed along with all other teacher trainers as part of trial methodology.

Minor changes to data collection

There was a change in timing in the collection of Teacher Implementation Logs and Teacher Resource Use Questionnaires. These data were planned for collection following implementation. However, teacher time and workload made it difficult to accommodate this. As a compromise, and to avoid the risk of retrieving no data, flexibility on timing of receipt was introduced and it was agreed that at a minimum, a single Implementation Log/Teacher Resource Use Questionnaire would be completed on behalf of a given school.

Additionally, it was not possible to arrange and collect focus group data from parents as specified in the original protocol. Parental engagement limited opportunity to conduct focus groups, thus individual face-to-face and telephone interviews were held in place of these.

Minor additions to data collection

In addition to the published aims, a Student Engagement Questionnaire (SEQ) was also added post-protocol to the process evaluation in all intervention schools (Appendix 3.17). The SEQ was distributed by teachers to pupil participants in the intervention arm in 32 schools (n=3179 pupils) across the four nations of the UK upon completion of the intervention. The SEQ included questions on pupil demographics and implementation factors (delivery length/mode, parental participation, and teaching quality) and included a six-item student engagement questionnaire (which showed good reliability and validity with a Cronbach's alpha = 0.85). It also included three open-ended JSEQ questions which asked pupils their opinions on the IVD, as well as their most and least favourite programme activities, and reasons.

Minor additions to secondary outcomes

In the protocol we include an examination of secondary behavioural outcomes but these are not clearly specified. At the point of the statistical analysis plan, prior to study analysis, we

specified the following secondary behavioural outcomes as relevant to trial analysis: 1) Have you ever had sex with another person? 2) Have you ever had sex without using any contraception? 3) The last time you had sex, was any form of contraception used?

Minor changes to analysis plan/analysis principles

Analysis of individual level socio-economic analysis was stated in published protocol as being measured by 'highest qualification level of parents'. However, this was as a drafting error. It was not intended to use this measure for two reasons. First, it was found to be unreliable in the feasibility trial owing to a large amount of missing data. Second, it was predicted to be unreliable due to the non-standardisation of educational terms for highest school qualification (e.g. A-levels and Scottish Highers). This was replaced with the Family Affluence scale¹⁶⁰ (number of family holidays during the past 12 months, family computer(s), ownership of a family car, and ownership of a dishwasher). The data was analysed in terms of three tertiles, low, medium and high. Other measures also included were pupils' highest educational aspirations, and age expected to leave school).

The first stage in mediation analyses required investigating the effect of the intervention on each of the five measured mediators (i.e. knowledge, attitudes, sexual self-efficacy, intentions, and behaviour). This was shown in the secondary outcomes analyses where the intervention was shown to have a significant effect on one or more mediator (i.e. intentions, knowledge and sexual self-efficacy and behaviour). The second stage of mediation analyses is only conducted if both the intervention has been shown to effect one or more of the mediators (first stage of mediation analyses) *and* the intervention has been shown to effect the primary outcome. As the intervention did not prove effectiveness on the primary outcome (i.e. having had unprotected sex), the statistical analysis team deemed it was not appropriate to explore whether mediators explain the effect of the intervention on the primary outcome.

Chapter 4. Results 1: Recruitment and data collection results

Aims

The purpose of this chapter is to report the recruitment and data collection achieved in the cluster-RCT and the process evaluation. We also report attrition at cluster and individual level, and reasons for withdrawal.

School recruitment

A total of 803 schools was initially identified from educational authority records in each of the four nations as being eligible for participation based on inclusion criteria. These criteria were schools in defined geographic areas as set out in recruitment protocol, see *Chapter 3 Methodology*. Exclusion criteria were schools that were independent private, special and Irish/Welsh-medium and Scottish Gaelic schools (but not those with an embedded Irish/Welsh-medium component), and schools with < 30 pupils per year group (year 11 in NI, S3 in Scotland and year 10 in England and Wales). Schools involved in previous studies involving the *If I Were Jack* intervention (n=15) were also not eligible to participate in the current study. Eligible schools were stratified by socio-economic status based on eligibility for free school meals (FSM), resulting in two lists identifying schools above and below the nation-level median percentage of pupils eligible for FSM. These lists were then sent to NICTU and shuffled randomly before schools were approached (See *Appendix 3.2* for Recruitment protocol). From these, 263 schools were contacted (172 above the FSM stratum and 91 below) and 66 were recruited, giving an overall recruitment rate of 25%. Rates of recruitment by nation were: 29% Northern Ireland, 11% England, 60% Scotland and 40% Wales. Reasons for recruitment and failure to recruit are discussed in process evaluation results (see *Chapter 7*).

Pupil Recruitment

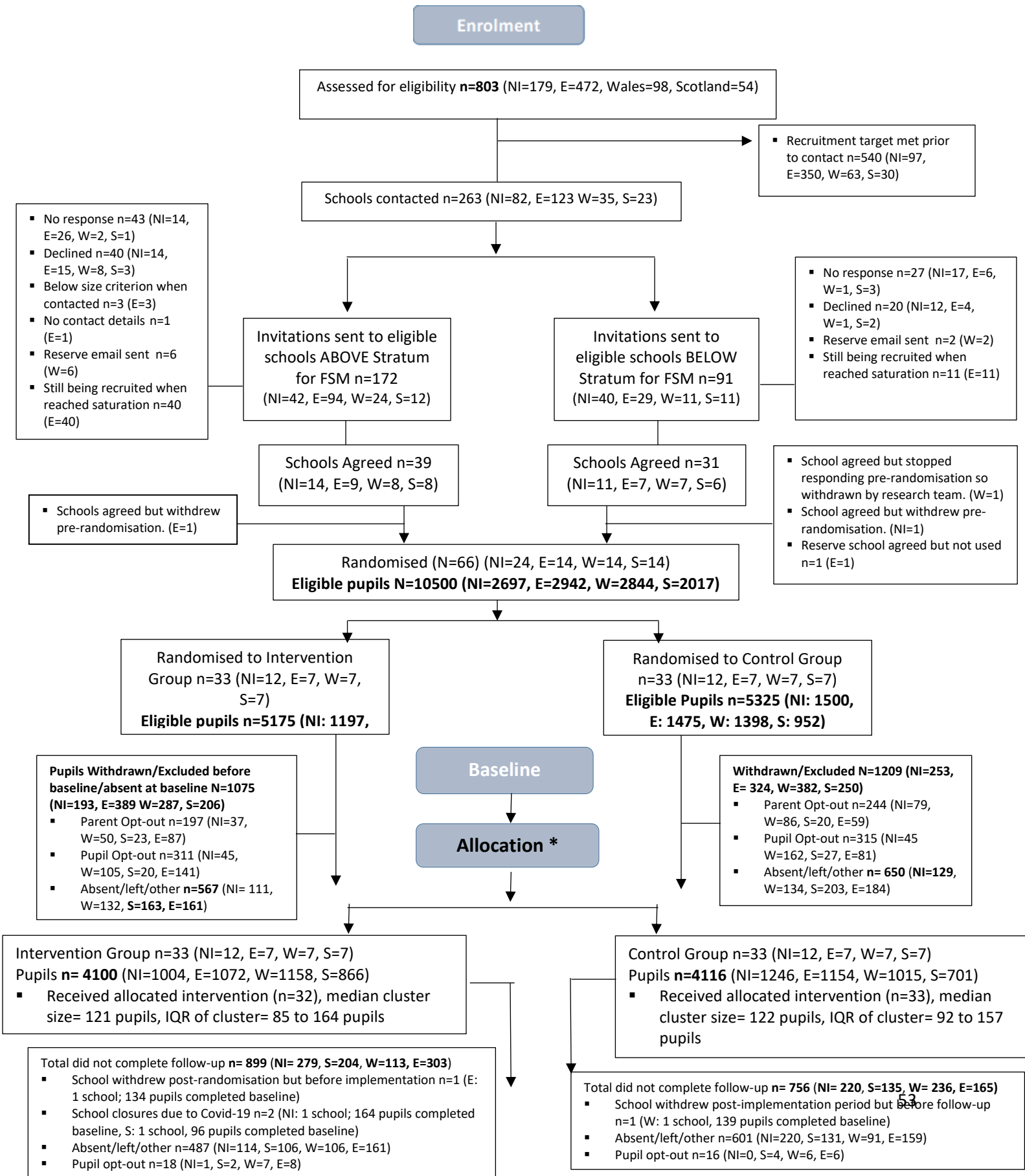
All pupils from the target year group in recruited schools were eligible to participate in the trial. The 66 schools recruited to the trial included a total of 10,500 eligible pupils. Of these, a total of 8,216 (78.3% eligible pupils) consented to participate in the trial.

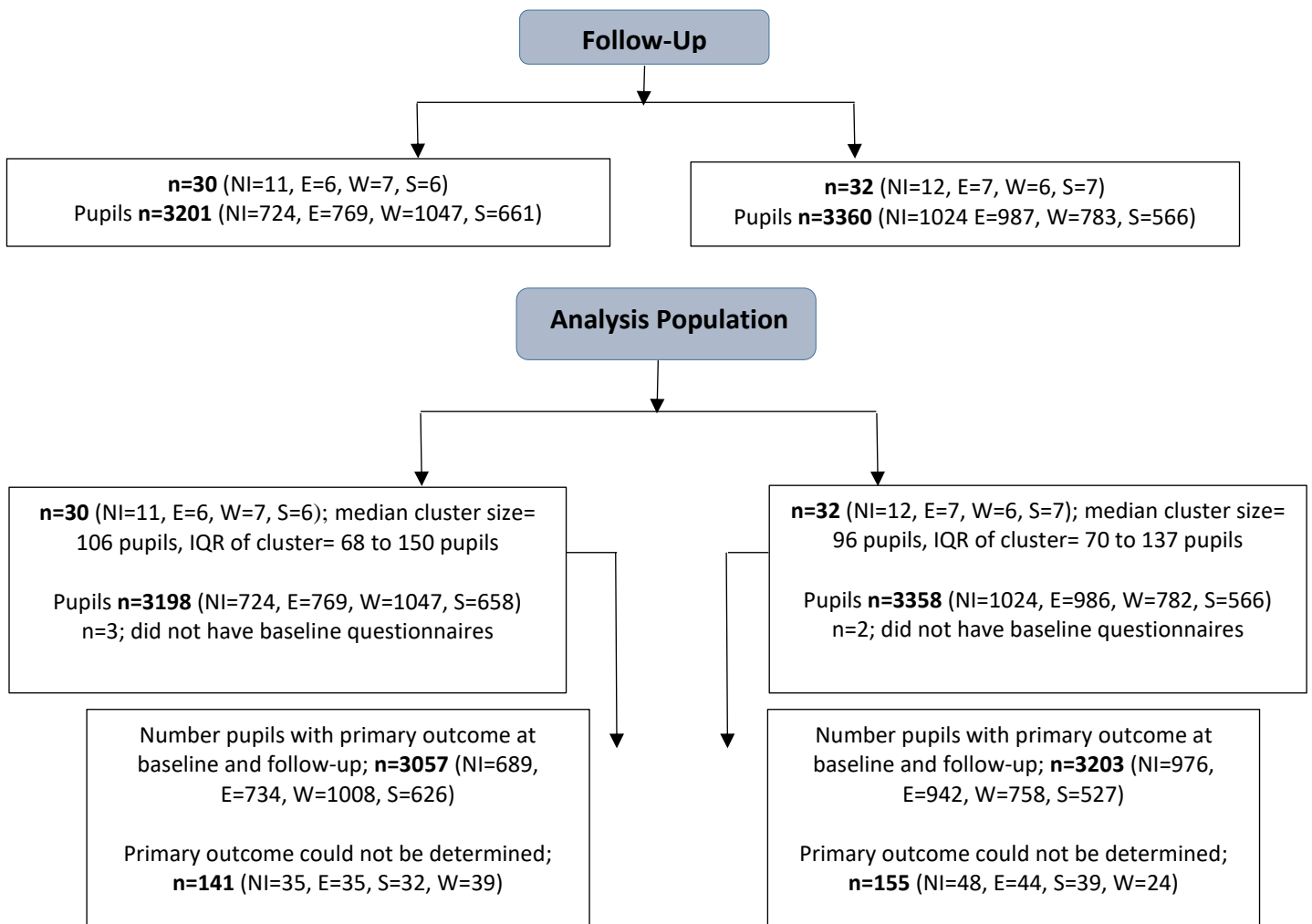
Flow of participants in the trial

CONSORT diagram

In total, 66 schools (n=8,216 pupils) were recruited to the Jack Trial, with 33 (n=4100 pupils) allocated to the intervention arm and 33 (n=4116 pupils) allocated to the usual RSE practice control group. The CONSORT flow diagram is shown in [Figure 7](#), summarising school eligibility, number approached, recruitment and randomisation, and retention through the trial, along with median cluster size. [Figure 7](#) additionally reports the numbers of schools who declined to participate prior to randomisation and withdrew following randomisation (n=1) or were lost to follow-up (n=3). It also reports numbers of pupils who opted out of participation within schools and those lost to follow up. Losses to follow up at the school and pupil level are discussed further below.

Figure 7 CONSORT Extension for Cluster Trials 2012 Flow Diagram (nation breakdown included)





*Sites were allocated to intervention or control post baseline data collection.

Losses to follow-up

School-level attrition from trial

- Retention at school level was generally strong. However, four recruited schools (533 pupils; 6.5% of pupils enrolled in the trial) who completed baseline surveys were lost to follow-up (three in the intervention and one in the control arm). The first school withdrew prior to implementation (Intervention arm, England, 134 pupils (1.6%), all girls, in above median FSM stratum (34% of pupils in receipt of FSM) and non-faith based). Withdrawal reasons were teachers' reluctance to engage with teacher training and additional commitments associated with being 'a case study school' involving observations and interviews.
- The second school withdrew after implementation of intervention but before follow-up surveys were conducted (control arm, Wales, 139 pupils (1.7%), co-educational, in above median FSM stratum (28.6% pupils in receipt of FSM), non-faith-based). Withdrawal reasons cited were 'due to other commitments with year 11 at this time'.
- The final two schools withdrew owing to the Covid-19 pandemic lockdown measures. The UK lockdown (from March 2020) led to school closures, making it impossible to visit and collect survey data from two schools. Both schools were in the intervention and had implemented the programme. One school was in NI (164 pupils (2.0%), co-ed, in above FSM stratum (20% of pupils in receipt of FSM), faith-based); the other school was in Scotland (96 pupils (1.2%), co-ed, in the below FSM stratum (6% of pupils in receipt of FSM; non faith-based).

Pupil-level attrition from trial

441 pupils (4.2% of eligible pupils) were opted out of participation in the research by parents before baseline data collection. A total of 8,216 pupils (n=4,100 intervention; 4,116 control) completed baseline and 6,561 (n=3,201 intervention; n=3,360 control) completed follow-up. Therefore, 1,655 pupils (20.1% of pupils enrolled in the trial) were lost to follow up at this stage. The primary reason accounting for the 20.1% loss to follow up from baseline to follow-up was pupil absence or pupils having left the school (n= 1088; 65.7% of losses to follow up). The

remaining losses to follow up were due to school withdrawal (n= 273; 16.5%), school closures due to the Covid-19 pandemic (n= 260; 15.7%), and pupil opt out (n= 34; 2.1%).

Risk of bias

Losses to follow up

Losses to follow up were assessed to determine any potential risk of bias. Specifically, we queried whether there were more losses to follow up in certain types of schools based on location, eligibility for free school meals and whether or not the school was faith based. We also assessed whether there were differences in losses to follow up between the two trial arms.

The rate of loss to follow up was lowest in Wales (15.8%) and similar across the other three nations (approx. 22%). There was very little difference in loss to follow up in relation to the proportion of pupils eligible for FSM in schools (below the nation-level median = 20.3%; above 20.1%) and loss to follow up for faith based and non-faith based schools was almost identical (approx. 37%). There was only a small difference in relation to parent opt-out (at the point of recruitment) for faith based (13.2%) and non-faith based schools (10.7%). Differences in losses to follow up for the intervention (n=899, 21.9%) and control groups (n= 756; 18.4%) were also small.

Baseline comparability

Participant Characteristics

A summary of demographic characteristics and descriptive statistics of the randomised groups is presented in Table 5. The characteristics of the two groups were very similar in terms of sex, sexual identity, ethnicity, socioeconomic status, and educational aspirations. There was a slightly higher number of pupils who reported having no religion or who identified as not at all religious in the intervention group, and a higher number of pupils who identified as Catholic in the control group.

Table 5 Baseline comparability of randomised groups

Characteristic	Intervention	Control	Total
Sex			
<i>Male, n (%)</i>	1980 (48.3%)	2121 (51.5%)	4101 (49.9%)
<i>Female, n (%)</i>	2120 (51.7%)	1994 (48.5%)	4114 (50.1%)
Sexual Identity			
Heterosexual/Straight, <i>n (%)</i>	3652 (90.1%)	3722 (91.5%)	7374 (90.8%)
Gay/Homosexual/Bisexual, <i>n (%)</i>	219 (5.4%)	175 (4.3%)	394 (4.8%)
Not Sure/Prefer not to say/Other, <i>n (%)</i>	183 (4.5%)	173 (4.2%)	356 (4.4%)
Ethnicity			
<i>White, n (%)</i>	3114 (76.5%)	3079 (75.5%)	6193 (76.0%)
<i>Asian, Asian British/Irish, n (%)</i>	475 (11.7%)	326 (8.0%)	801 (9.8%)
<i>Black African, Black Caribbean, Black British/Irish, n (%)</i>	255 (6.3%)	369 (9.0%)	624 (7.7%)
<i>Mixed/Multiple ethnic backgrounds, n (%)</i>	155 (3.8%)	180 (4.4%)	335 (4.1%)
<i>Other, n (%)</i>	71 (1.7%)	126 (3.1%)	197 (2.4%)
Religion			
<i>No Religion, n (%)</i>	1643 (41.0%)	1327 (33.0%)	2970 (37.0%)
<i>Catholic, n (%)</i>	743 (18.5%)	1074 (26.7%)	1817 (22.6%)
<i>Protestant, n (%)</i>	997 (24.9%)	1089 (27.1%)	2086 (26.0%)
<i>Buddhist, n (%)</i>	11 (0.3%)	20 (0.5%)	31 (0.4%)
<i>Jewish, n (%)</i>	13 (0.3%)	6 (0.2%)	19 (0.2%)
<i>Muslim, n (%)</i>	417 (10.4%)	362 (9.0%)	779 (9.7%)
<i>Sikh, n (%)</i>	25 (0.6%)	32 (0.8%)	57 (0.7%)

<i>Other, n (%)</i>	162 (4.0%)	108 (2.7%)	270 (3.4%)
Religiosity			
<i>Very Religious, n (%)</i>	260 (6.4%)	324 (8.0%)	584 (7.2%)
<i>Fairly Religious, n (%)</i>	1053 (25.9%)	1175 (28.8%)	2228 (27.3%)
<i>Not Very Religious, n (%)</i>	1043 (25.6%)	1140 (28.0%)	2183 (26.8%)
<i>Not at all Religious, n (%)</i>	1717 (42.2%)	1439 (35.3%)	3156 (38.7%)
Socioeconomic Status			
<u>Cluster Level</u>			
<i>Schools Above FSM Median, n (%)</i>	20 (60.6%)	19 (57.6%)	39 (59.1%)
<i>Schools Below FSM Median, n (%)</i>	13 (39.4%)	14 (42.4%)	27 (40.9%)
<u>Individual Level</u>			
<i>Family Affluence Scale, M(SD)</i>	6.1 (1.9)	6.1 (1.9)	
<i>Low tertile, n (%)</i>	1495 (36.7%)	1445 (35.3%)	2940 (36.0%)
<i>Medium tertile, n (%)</i>	1617 (39.7%)	1656 (40.5%)	3273 (40.1%)
<i>High tertile, n (%)</i>	963 (23.6%)	988 (24.2%)	1951 (23.9%)
Educational Aspirations			
<u>Expected age leaving school</u>			
<i>16 years old, n (%)</i>	756 (18.5%)	702 (17.2%)	1458 (17.9%)
<i>18 years old, n (%)</i>	2372 (58.2%)	2474 (60.5%)	4846 (59.3%)
<i>I don't know yet, n (%)</i>	949 (23.3%)	914 (22.4%)	1863 (22.8%)
<u>Aspiration on leaving school</u>			
<i>Getting or trying to get a job, n (%)</i>	811 (20.4%)	829 (20.7%)	1640 (20.5%)

<i>Be in a job training scheme or apprenticeship, n (%)</i>	330 (8.3%)	383 (9.6%)	713 (8.9%)
<i>Be at university, n (%)</i>	1893 (47.6%)	2022 (50.5%)	3915 (49.0%)
<i>Be at a further education college (studying for a trade/ job), n (%)</i>	784 (19.7%)	623 (15.6%)	1407 (17.6%)
<i>Be a full-time mum or a dad, n (%)</i>	15 (0.4%)	11 (0.3%)	26 (0.3%)
<i>Other, n (%)</i>	147 (3.7%)	139 (3.5%)	286 (3.6%)
Total N at Baseline	4100	4116	8216

School characteristics

The 66 schools recruited to join the trial had diverse contextual characteristics, an overview of which is presented in Table 6. Schools that later withdrew are identified in the table. In summary, of the 66 schools recruited to the trial, 59 schools were co-educational schools, and seven were single-sex schools (four all girls and three all boys). Six of the single-sex schools were retained in the trial with a loss of one of the all-girls school due to pandemic measures. Fifteen of the 66 schools were faith based, 13 of which were Catholic denomination. Two faith based schools – one Protestant, one Catholic one, was lost to follow-up. Of the 66 schools, 39 schools were in the above FSM stratum and 27 schools were below. The range in the number of pupils eligible for FSM in schools was as low as 2% in lowest school and 52% in highest school.

Table 6 Characteristics of participating schools (*† show where numbers later affected by attrition)

Region	Schools per trial allocation (n=)	Single sex/mixed sex schools (n=)	Faith-based schools (n=)	Range of % pupils eligible for free school meals (%)
Northern Ireland	Intervention: 12 (including 1 school †)	Co-ed: 9 (including 1 school†) All boys: 1 All girls: 2	7 (7 Catholic) (including 1 School†)	7-52%

	Control: 12	Co-ed: 11	5 (5 Catholic)	7-44%
		All boys: 1		
England	Intervention: 7*	Co-ed: 4	0	2-38%
		All boys: 1		
		All girls: 2*		
	Control: 7	Co-ed: 7	2 (1 Catholic; 1 Protestant)	3-26%
Scotland	Intervention: 7†	Co-ed: 7†	0	7-28%
	Control: 7	Co-ed: 7	0	5-32%
Wales	Intervention: 7	Co-ed: 7	0	9-44%
	Control: 7*	Co-ed: 7*	1 (1 Protestant)	8-32%
Intervention total	Intervention: 33*	Co-ed: 27*	7* (7* Catholic)	2-52%
		All boys: 2		
		All girls: 4*		
Control Total	Control: 33*	Co-ed: 32*	8 (6 Catholic; 2 Protestant)	3-44%
		All boys: 1		
Sample Total	Schools: 66* (including 4 schools who withdrew)	Co-ed: 59*†	15*† (13 Catholic; 2 Protestant)	3-52%
		All boys: 3		
		All girls: 4*		

*School later withdrew from trial prior to follow-up data collection

†Unable to complete follow-up data collection due to school closures (Covid-19)

Process evaluation

In this section we report the data collection achieved in the process evaluation, and outline the removal of process evaluation data collected from schools who withdrew from the trial.

Data collection achieved

Published aims of the process evaluation are detailed in *Chapter 6* with targets for triangulated data collection including questionnaires, interviews, and focus group interviews, detailed in Table 7.

Table 7 Data collected, intended totals, and reasons for missing data

Who completed	Data source	Data collected*†	Intended total*	Reason for missing data
All schools	School Background Questionnaire	58 schools	62 schools	Schools unable to return before closure due to Covid-19
	RSE Questionnaire (Baseline)	55 schools	62 schools	Schools unable to return before closure due to Covid-19
Intervention schools	Parent/guardian online survey	134	N/A	N/A
	Teacher Implementation Log	29 intervention schools	30 intervention schools	One school (S12S) was unable to return these prior to closure due to Covid-19
	Trial champion/principle/head teacher interviews	30 intervention schools	30 intervention schools	N/A
Case study (CS) schools	Observations	8 CS schools	8 CS schools	N/A
	Teacher focus groups	8 CS schools	8 CS schools	N/A
	Pupil focus groups	8 CS schools	8 CS schools	N/A
	Parent focus groups	6 (5 interviews in CS schools plus interviews in 1 non-CS study school)	8 CS schools	Recruitment of parents for focus groups was challenging and not possible in all CS schools despite repeated efforts from trial team. Alternative interviews were conducted in non-CS school with strong relationship with parents

Fieldworkers	Fieldworker perception form	Baseline: 66 schools Follow-up: 60 schools	Baseline: 66 schools Follow-up: 62 schools	In 2 schools (S20S and S15NI) fieldworkers did not return perception forms at follow-up
Education/policy specialists	Education/policy specialist interviews	11	4-8	N/A

*Excluding withdrawn schools

†Figure shows total of schools returning questionnaires/logs as this corresponds to the intended total, and does not include additional questionnaires/logs where more than one was returned by a school

In addition to the published aims, a Student Engagement Questionnaire (SEQ) was also added post-protocol in all intervention schools (see *Appendix 3.17*). See *Chapter 3 Methods* for discussion of changes to protocol. Pupils completed a total of 3179 SEQs. One school (S12S) was unable to return these prior to closure due to Covid-19.

Table 8 Summary table of process evaluation participants

Participant type	Data source	Study group	Participants (n=)
Schools	All school data	Intervention	30
	All school data	Control	32
Parents	Online Survey	Intervention	134 (2 male)
	Individual semi-structured interviews	Intervention - case study (and some additional interviews in schools with strong relationships with parents)	10 (1 male)
	Web Analytics (unique visits to parent resources section of website)	Intervention	1123

Students	Student Engagement Questionnaire	Intervention	3179 (47% male)
	Focus groups (case study schools)	Intervention - case study	8 groups, n=58
Teachers	Focus groups (case study schools)	Intervention - case study	8 groups, n=31
	Semi-structured interviews with trial champions/principals/head teachers	Intervention	Individual interviews: 29 (n=29)
			Paired interviews: 5 (n=10)
			Total teacher participants: n=39
	Teacher Implementation Log	Intervention	128
	RSE Questionnaire	Intervention	29
	RSE Questionnaire	Control	26
School Background Questionnaire	Intervention	29	
School Background Questionnaire	Control	30	
Observations: students/ teachers	Classroom observations (case study schools)	Intervention – case study	35 observations in 8 schools
RSE policy experts	Semi-structured interviews	N/A	11

Trial and Process Evaluation Missing data owing to Covid-19 measures

Data collection of certain process evaluation data sources was also impacted by school closures resulting from Covid-19 and as such led to further missing data.

Table X. Data missing as a result of Covid-19 school closures

Data source	Number schools unable to return data due to Covid-19
Trial follow-up survey	2 (2 intervention schools)
School Background Questionnaire	4 (2 intervention schools, 2 control schools)
RSE Questionnaire	7 (1 intervention school, 6 control schools)
Teacher Implementation Log	1 intervention school
Student Engagement Questionnaire	1 intervention school

Chapter 5. Results 2: Trial results

Baseline Data

The values for the primary outcome and secondary outcomes at baseline are summarised in Table 9. There were no notable differences between the intervention and control groups in relation to the primary or secondary outcomes at baseline. There were also no differences between the two groups in relation to missing data at baseline.

Table 9 Primary and secondary outcomes at baseline by trial arm

	Intervention (n=4100)		Control (n=4116)	
Primary Outcome	n (%)		n (%)	
Unprotected Sex				
Yes	154 (3.86%)		180 (4.51%)	
No	3836 (96.14%)		3808 (95.49%)	
Secondary Outcomes	n	mean (SD)	n	mean (SD)
Knowledge				
Knowledge Score	4100	4.13 (1.92)	4116	4.19 (1.90)
Attitudes				
Male Roles Attitudes Score	3871	17.78 (4.19)	3879	18.13 (4.22)
Skills				
Comfort Communicating	3958	7.78 (1.85)	3944	7.93 (1.83)
Sexual Self-Efficacy Score	3958	3.17 (0.47)	3945	3.19 (0.47)
Intentions to Avoid a Teenage Pregnancy				
Intentions total score	3974	49.01 (9.11)	3981	49.42 (8.65)
Intentions contraception subscale score	3935	19.82 (4.09)	3946	20.05 (3.96)
Intentions willingness subscale score	3957	12.93 (2.13)	3972	12.96 (2.10)
Intentions time subscale score	3912	4.20 (0.81)	3939	4.20 (0.82)
Intentions readiness subscale score	3914	8.69 (1.64)	3934	8.76 (1.60)
Intentions norms subscale score	3921	21.25 (3.80)	3946	21.33 (3.73)
Intentions attitudes subscale score	3904	11.72 (2.45)	3936	11.79 (2.45)
Secondary Outcomes – Behavioural	n (%)		n (%)	
Ever had sex with another person	234 (5.85%)		251 (6.28%)	
Ever had sex without using any contraception	101 (45.09%)		108 (43.72%)	
Last time had sex, no form of contraception used	69 (34.67%)		75 (35.55%)	

% based on number of students who answered the question

Primary outcome

The primary and secondary outcomes are summarised in Table 10.

The primary outcome, unprotected sex, includes the whole study population (n=6,556) and included those not yet sexually active. Fewer young people in intervention schools than among control schools had unprotected sex at 12-14 month follow-up [13.57% vs. 14.07%; OR 0.85 (95% CI 0.58 to 1.26), ICC = 0.12], but the difference was not statistically significant (p=0.42).

Secondary outcomes

Students in the intervention schools had higher knowledge scores on avoiding unintended teenage pregnancy [mean difference 0.19 (95% CI 0.017 to 0.37), p= 0.032]. There was no effect of the intervention on the perceived gender roles of males and females [mean difference -0.092 (95% CI -0.39 to 0.21), p= 0.55]. Students in the intervention schools had improved sexual self-efficacy [mean difference 0.035 (95% CI 0.0059 to 0.065), p= 0.018] and reported greater comfort in communicating with peers, parents and professionals about avoiding pregnancy [comfort communicating scale: mean difference 0.13 (95 % CI -0.00015 to 0.26), p=0.05]. Students in intervention schools also had stronger intentions to avoid unintended teenage pregnancy [mean difference 0.85 (95% CI 0.19 to 1.50), p= 0.01]. Intentions to avoid unintended pregnancy included sub scores on contraception, willingness, timeliness, readiness, norms, and attitudes. While the results indicate no effect of the intervention on the intentions sub-scales of willingness [mean difference 0.042 (95% CI -0.091 to 0.18), p=0.53], timeliness [mean difference -0.021 (95% CI -0.073 to 0.032), p=0.44], or readiness [mean difference 0.097 (95% CI -0.013 to 0.21), p=0.084], students in the intervention schools had stronger intentions to use effective contraception [contraception sub-scale: mean difference 0.48 (95% CI 0.17 to 0.80), p=0.002], avoid peer pressure to have a sexual relationship [norms sub-scale: mean difference 0.29 (95% CI 0.010 to 0.57), p=0.042], and not to have sex until ready and be prepared and to share responsibility for contraception with a partner [attitudes sub-scale: mean difference 0.35 (95% CI 0.16 to 0.53), p<0.001].

There were no differences between the intervention and control groups at 12-14 month follow-up in relation to the number of students who reported ever having sex with another person [intervention 21.90%, control 22.25%, OR 0.85 (95% CI 0.58 to 1.24), p=0.39], or ever having sex

without contraception (intervention 42.57%, control 44.38%, OR 0.66 (95% CI 0.40 to 1.09), $p=0.10$). However, more students in the control arm reported no use of contraception at last sex than in the intervention arm at follow-up [intervention 27.53%, control 32.88%, OR 0.55 (95% CI 0.31 to 0.97) $p=0.04$].

Table 10 Primary and secondary outcomes at 12-14 month follow-up by trial arm

	Intervention (n= 3,198)		Control (n=3,358)			
Primary Outcome	n (%)		n (%)		Adjusted OR ^a (95% CI), p value	ICC
Unprotected Sex						
Yes	425 (13.57%)		463 (14.07%)		0.85 (0.58, 1.26), p=0.42	0.12
No	2707 (86.43%)		2827 (85.93%)			
Secondary Outcomes	n	Mean change from baseline (SD)	n	Mean change from baseline (SD)	Mean difference ^a (95% CI), p value	ICC
Knowledge						
Knowledge Score	3198	1.09 (1.92)	3358	0.87 (1.90)	0.19 (0.017 0.37), p= 0.032	0.023
Attitudes						
Male Roles Attitudes Score	2999	-0.35 (4.16)	3146	-0.26 (4.07)	-0.092 (-0.39, 0.21), p= 0.55	0.010
Skills						
Comfort Communicating	3053	0.50 (1.92)	3186	0.37 (1.98)	0.13 (-0.00015, 0.26), p=0.05	0.007
Sexual Self-Efficacy Score	3063	0.13 (0.45)	3202	0.09 (0.48)	0.035 (0.0059, 0.065), p= 0.02	0.005
Intentions to Avoid a Teenage Pregnancy						
Intentions total score	3075	2.49 (8.80)	3228	1.72 (8.75)	0.85 (0.19, 1.50), p= 0.01	0.011
Intentions contraception subscale score	3043	0.61 (2.69)	3190	0.27 (2.66)	0.48 (0.17, 0.80), p= 0.002	0.011
Intentions willingness subscale score	3061	0.36 (2.15)	3215	0.33 (2.23)	0.042 (-0.091, 0.18), p=0.53	0.004
Intentions time subscale score	3021	0.036 (0.95)	3184	0.055 (0.97)	-0.021 (-0.073, 0.032), p=0.44	0.002
Intentions readiness subscale score	3023	0.24 (1.75)	3180	0.14 (1.72)	0.097 (-0.013, 0.21), p=0.084	0.005
Intentions norms subscale score	3034	0.79 (3.97)	3193	0.54 (3.96)	0.29 (0.010, 0.57), p= 0.042	0.009
Intentions attitudes subscale score	3020	0.61 (2.69)	3179	0.27 (2.66)	0.35 (0.16, 0.53), p< 0.001	0.008
Secondary Outcomes – Behavioural	n (%)		n (%)		Adjusted OR ^a (95% CI), p value	ICC
Ever had sex with another person	688 (21.90%)		733 (22.25%)		0.85 (0.58, 1.24), p=0.39	0.122

<i>Ever had sex without using any contraception</i>	292 (42.57%)	324 (44.38%)	0.66 (0.40, 1.09), p=0.10	0.008
<i>Last time had sex, no form of contraception used</i>	174 (27.53%)	218 (32.88%)	0.55 (0.31, 0.97), p=0.04	0.000

^a Adjusted for baseline value, nation and above or below FSM median; % based on number of students who answered the question

Subgroup Analysis

Exploratory, post-hoc subgroup analysis was conducted to look specifically at the effect of the intervention for those who were sexually active at baseline (average age 14). Among those sexually active at baseline, fewer students in intervention schools had unprotected sex at 12-14 month follow-up, compared with those in the control schools (49.38% vs. 60.92%, p for interaction = 0.06). The confidence intervals (CIs) in the adjusted analysis indicate benefit for nearly all who were sexually active at baseline [OR 0.56 (99% CI 0.29 to 1.09)]. Narrowing this down to look at the subgroup who had unprotected sex at baseline, the results also favour the intervention but are not statistically significant [OR 0.64 (99% CI 0.28 to 1.46), $p=0.27$].

Other subgroup analyses focused on socio-demographic characteristics and their effect on the primary outcome results. In relation to nation, there was evidence that the intervention decreased the rate of unprotected sex in NI, Scotland and England. The p -value for the test for interaction ($p=0.05$) indicates evidence of a difference in the effectiveness of the intervention between nations. The confidence intervals in the adjusted analysis indicate benefit for nearly all participants in England [OR 0.46 (99% CI 0.18 to 1.13)]. In Wales, the direction of the effect of the intervention differed from that of the other nations but the confidence intervals were especially wide and indicate no significant difference between the intervention and control groups in Wales [OR 1.68 (99% CI 0.72 to 3.91)].

There were no differential effects of the intervention on the primary outcome according to participant socioeconomic status, as measured by the Family Affluence Scale ($p=0.60$), participant sex ($p=0.81$) or ethnicity ($p=0.16$).

Table 11 Subgroup analyses by sexually active at baseline, having had unprotected sex at baseline, nation, family affluence scale, sex, and ethnicity for the primary outcome (unprotected sex) at 12-14 month follow-up

	Intervention	Control	Adjusted OR (99% CI)	Interaction p-value ^a
Subgroup	n (%)	n (%)		
Sexually Active at Baseline^b				
Yes	80 (49.38%)	106 (60.92%)	0.56 (0.29, 1.09)	0.06
No	330 (11.4%)	332 (11.0%)	0.89 (0.53, 1.51)	
Having had unprotected sex at baseline				
Yes	65 (60.75%)	82 (66.13%)	0.64 (0.28, 1.46)	0.27
No	344 (11.66%)	353 (11.46%)	0.87 (0.52, 1.47)	
Nation^c				
Northern Ireland	113 (15.94%)	174 (17.40%)	0.78 (0.41, 1.51)	0.05
Scotland	96 (14.95%)	108 (19.67%)	0.76 (0.45, 1.28)	
England	28 (3.74%)	87 (9.01%)	0.46 (0.18, 1.13)	
Wales	188 (18.22%)	94 (12.13%)	1.68 (0.72, 3.91)	
Family Affluence Scale				
Low tertile	143 (12.6%)	140 (12.6%)	0.83 (0.46, 1.47)	0.60
Medium tertile	149 (12.1%)	181 (13.6%)	0.80 (0.46, 1.41)	
High tertile	132 (17.4%)	140 (16.8%)	0.97 (0.52, 1.81)	
Sex^c				
Male	219 (14.38%)	250 (14.65%)	0.84 (0.49, 1.42)	0.81
Female	206 (12.80%)	213 (13.46%)	0.87 (0.49, 1.56)	
Ethnicity				
White ^e	394 (16.34%)	408 (16.78%)	0.86 (0.58, 1.27)	0.16
Asian	8 (2.13%)	5 (1.78%)	1.43 (0.31, 6.55)	
Black	12 (6.82%)	16 (5.16%)	1.69 (0.55, 5.21)	
Other ^f	8 (5.33%)	30 (12.10%)	0.43 (0.11, 1.65)	

^a Interaction p-value is from a global test for interaction;

^b Adjusted for primary outcome at baseline, nation and above or below FSM median; ^c Adjusted for primary outcome at baseline & above/below FSM median; ^d Adjusted for primary outcome at baseline & nation ^e includes white English/Irish/Northern Irish/ Scottish/Welsh/British and any other white background; ^f Includes mixed/multiple ethnic background and Other

Sensitivity analyses and missing data

Standardised scores were calculated for the Male Role Attitudes Scale, Comfort

Communicating Scale, and Intentions (including sub-scales) in order to deal with partial

missing data where students responded to some but not all questions (see *Chapter 4*). The

results of the secondary analyses (based on the standardised scores) for these scales

suggest that the intervention was effective in increasing adolescents' intentions to say no to

sex until ready [mean difference 1.26 (95% CI 0.026 to 2.49), $p=0.045$], which was not observed in the main analysis reported above. The results for the other scales yielded similar results reported in the main analysis.

Follow-up data was not available for four schools (3 intervention; 1 control – see *Chapter 4*). The sensitivity analyses made different assumptions on the best and worst case scenarios. The best-case scenario assumes that none of the students in the intervention schools had unprotected sex but 13% of students in control schools did. The worst-case scenario assumes that none of the students in the control school had unprotected sex but 13% of students in the intervention schools did. The rate of 13% was based on the school with highest rate of unprotected sex at baseline.

The results of the sensitivity analysis are presented in Table 12. In the best-case scenario, fewer students in the intervention school reporting unprotected sex at 12-14 month follow up than those in control schools [12.05% vs 14.53%, OR 0.59 (95% CI 0.34 to 1.03), $p=0.06$]. In the adjusted worst-case scenario, a slightly higher number of students in the intervention schools had unprotected sex than those in control schools [14.92% vs 13.49%, OR 1.39 (95% CI 0.71 to 2.71), $p=0.34$].

Table 12 Sensitivity analysis

	Intervention	Control	Adjusted OR (95% CI) ^a , p -value	ICC
Primary Outcome				
Best Case				
Yes, n (%)	425 (12.05%)	481 (14.53%)	0.59 (0.34, 1.03), $p=0.06$	0.21
No, n (%)	3103 (88.0%)	2829 (85.5%)		
Worst Case				
Yes, n (%)	475 (14.92%)	463 (13.49%)	1.39 (0.71, 2.71), $p=0.34$	0.31
No, n (%)	2709 (85.08%)	2968 (86.51%)		

^a Adjusted for primary outcome at baseline, nation and above or below median FSM

Serious Adverse events

This was a low risk study, therefore, no data monitoring was required. No adverse events were observed or reported.

Chapter 6. Results: Process evaluation

Aims

The published aims⁴⁸ of the process evaluation were informed by realist approaches to the evaluation of interventions^{136,156} as well as Medical Research Council (MRC) guidance¹⁵⁷ for process evaluations to consider the context, implementation and mechanisms of impact of interventions. Our aims were to:

Context

1. Examine reasons for school participation and non-participation to inform risk of bias in the trial as well as long-term sustainability of implementation of the intervention.

Implementation

2. Examine intervention delivery and fidelity in the context of overall RSE provision in intervention schools.
3. Assess RSE provision in control schools and potential contamination caused by any changes to provision that could be due to participation in the trial.

Mechanisms of impact

4. Explore self-reported perceptions of effectiveness and moderating influences in intervention schools among a sample of students, teachers and school principals/head teachers and parents.

Below we address each of these aims in turn detailing the data sources used to address each section, namely: context, implementation and mechanisms of impact.

Context

Reasons for participation

As described in *Chapter 3*, a total of 258 eligible secondary schools across the UK were randomly selected and approached to participate in the study. Of schools retained in the trial (62 of 66), the majority of schools (n=56) provided for students in co-educational settings. The all boys schools were situated in Northern Ireland (n=2) and England (n=1) and the all girls schools in Northern Ireland (n=2) and England (n=1). The majority of the 14 faith-based schools were situated in Northern Ireland (n=11). Scotland reported no faith-based schools in

their sample and England and Wales had two and one respectively. All these schools were Christian denominations. The widely utilised student socio-economic indicator of percentage of students in a school entitled to free school meals (%FSM), was applied in this study. The percentage of children eligible for free school meals in the included schools ranged from as low as 2% to as high as 52%. The median was 22.29%.

Data sources for this section were:

1. Researchers notes of telephone calls or written correspondence with schools
2. Interviews (n=29 individual interviews and n=5 paired interviews) with school Trial Champions and school principals/head teachers (total n=39 participants)
3. School Background Questionnaires (n=59) with school Trial Champions and school principals/head teachers
4. Interviews with policy and education specialists (n=11)

A Summary of main reasons for participation and non-participation in the trial

<u>Main reasons given for participation</u>	<u>Main reasons given for not participating</u>
Quality novel resource	Research saturation or other commitments
Need to address RSE/holistic	RSE provision already in place
Education	Too busy to commit to surveys and/or this RSE
Gap in male focus	Programme delivery
Teacher training	Non-alignment with school ethos
Financial incentive	

Table 13 Reasons given for participation and non-participation in the trial

Participant type (participant type code)	Example participant number (participant number code)	Example school number, nation (school ID code)	Example ID code
School (S)	N/A	15, England (15E)	S15E
Teacher (T)	1 (01)	11, Northern Ireland (11NI)	T0111NI
Parent (P)	1 (01)	12, Wales (12W)	P0112W
Student (PU)	1 (01)	12, Scotland (12S)	PU0112S
Student - Student Engagement Questionnaire (SEQ)	1 (01)	11, England (11E)	SEQ0111E
Policy specialist (PS)	1 (01)	No school number, Northern Ireland (NI)	PS01NI
Researcher observation (RO)	N/A	23, England (23E)	RO23E

Table 14 Participant ID explanation

Quality, novel resource supportive of teacher skill development

Head teachers and trial champions, across all nations and school contexts, identified the lack of resources as the principal barrier to quality provision of RSE. Universally, schools talked about cuts to their budgets which meant they were less able to afford to bring in external experts to teach this subject. As a result, teachers often felt that they were left to their own devices to ‘cobble something together’ (T0119E) in terms of developing their own RSE provision:

‘[Teachers] create their own resources by taking bits from everywhere e.g. YouTube videos etc. They find they need to tailor resources to their students’ needs and to strike the right tone. A lot of the downloadable resources and lesson plans from the internet or organisations are poor quality.’ (T0122W)

The *If I Were Jack* resource was reported as addressing teachers’ needs to have a current, relevant and high-quality programme to support teacher skill development.

‘With the level that our boys are at, you need to be giving them something that isn’t just sort of pulled together off the internet or someone’s sat there and gone, “Oh, could you just put something together for this?” ... To have something [If I Were Jack] that was so structured and had really, really clear, obvious outcomes, and actually had sort of different levels to it where you could push the levels of discussion, I think was really important because you could easily, with this subject, just cover the bare minimum and actually not really get them thinking a lot.’ (T0119E)

Schools welcomed a place on the Jack trial because they viewed the programme as a novel and tested resource that would provide students with valuable information about sexual health:

‘We like to try the sort of new cutting-edge ways of delivering different parts of our curriculum. It fits in really well.’ (T0123W)

If I Were Jack was received as a high quality, 'off the shelf' resource making it particularly attractive to teachers due to the inclusion of full lesson plans, classroom activities and comprehensive, step by step instructions for delivery:

'The lessons were provided, the focus was there, the learning intentions were there.'
(T0117NI)

'Seeing something that was ready made that we could use was great ... yeah, brilliant!'
(T0116W)

Other reasons given by teachers as motivators to take part included their overall impressions of the resource's 'novel use of interactive video drama' and the programme's flexible delivery options meaning it would fit with their timetables: 'a nice enough short programme that doesn't totally disrupt your teaching of your curriculum'. (T0113NI)

'It looked like a no-brainer, as far as we were concerned ... It's a great resource, it really is, and we are always looking for good resources.' (T0119E)

Recognising the need to address RSE in school/holistic education

There were three layers to the acceptance by schools of the need and desire to address/improve, RSE provision. First, was a growing push by educational authorities of the need to address RSE, exemplified by changes in legislation to mandatory RSE provision in schools in England in 2020 and, concurrently, schools' own recognition of this need. Second, but equally important, was a desire by schools to meet the more holistic pastoral support needs of students within education, especially among socially deprived communities. Third, some schools recognised the specific need to address prevention of teenage pregnancy and closely related sexual health and well-being matters.

The changing RSE legislative landscape was highlighted particularly in schools in England.

'Well, it's because it's statutory, isn't it, as of this September? So, I know that that was something that was important, the fact that we're going to have to be doing it.'
(T0119E)

However, the pressure from educational authorities to improve was also evident across the UK.

'One of our targets this year was to renovate our [RSE] resources, and that's one of the areas, the kind of teenage pregnancy and parenthood thing, that we felt we weren't hitting the right note with it, so we thought it was a perfect time to try something new.'
(T0111S)

School staff also earnestly conveyed to researchers addressing RSE was important to them because a holistic approach to education was their overarching educational goal.

'We are fairly, yeah, bohemian for a grammar school,..., some of the other grammar schools, certainly in this area, push, we regard push their kids too far to get better grades and to the detriment of their all-round health. Whereas, we certainly don't do that.' (T0119E)

The importance of a holistic approach to education was especially emphasised in schools in areas of high social deprivation where holistic education was regarded as essential to supporting students' broader social and emotional needs. Concerns over poor student mental health and wellbeing were expressed including the need for formal support in schools for students in the context of deprived local communities affected by unemployment, crime and high rates of substance use, alcoholism and domestic violence.

'It's a really, really, really high area for social deprivation, and we're surrounded by, you know, quite difficult housing estates. ... So, parents are facing a lot of financial challenges. We've got parents with all kinds of mental health issues and drug issues and alcohol issues, and our kids come in from a background of that, some of them.'
(T0115NI)

Addressing RSE was seen as an essential part of this holistic approach to education

'I think, because educating them in lots of different ways. We do lots around, em, consent, healthy relationships, what healthy sexual relationships look like, em, about coercive control in relationships. So, I think this was just another part of that, for us, em. And then it comes back to our positive relationship ... So, that is the reason that we wanted to be involved in it, from a, "this is how it can change your future".'
(T0122W)

This need for a holistic approach incorporating comprehensive sex education was also recognised by several Catholic schools recruited to the trial in Northern Ireland especially.

'We are a Catholic grammar school and we're very aware of the Catholic Church's teachings with regard to sexuality and sexual relationships. Yet, at the same time, we're very aware ... we have a duty of care to our young people and that is our priority ... Our approach to reflect how society is changing, and we're very willing to do that, you know ... under the umbrella of the Catholic ethos of strong morals and values.'
(T0127NI)

Furthermore, for some schools, albeit fewer, the issue of adolescent pregnancy was thought to be especially relevant and schools again emphasised providing education on safe sex was part of their role in educating young people.

'We had about five girls, all within the same year group, at various stages, had become pregnant ... and we just felt that maybe we needed to re-visit, eh, around the areas of safe sex. ... So, it came at a good time for us, whenever we heard about this pilot programme.' (T0120NI)

'We have a duty, if they are not being supported at home, to prevent this from happening. We have a duty, as educators, in terms of pastoral care, to try and

intervene and to try and give the children, you know, the information, the education to try and prevent this from happening.' (T0220NI)

Addressing the gap in male focus

Teachers in several schools commented that they were drawn to participation in the trial by the gender element of the resource. Several teachers and school principals noted boys' roles and responsibilities were being neglected, especially in relation to teenage pregnancy, and the resource was regarded as filling a gap in provision in RSE.

'Even the title, "Jack", and the emphasis on the boy, and not just the girl, in the pregnancy, was really, em, good, and that was new because I think any of the programmes I've looked at in the past, it was generally looking from the focus of the female in the relationship, on how her life was changing, whereas I think we got a very good balance here, and I think that brought it really well up-to-date.' (T0124NI)

'Certainly, this is the first time that we have covered anything from Jack, the male perspective, and that actually, that was really good.' (T0121S)

Teachers understood and liked that the programme was also challenging harmful masculinities that impact on boys and girls.

'It's looking at it from a boy's point of view. ... Lots of our children, the boys have got quite a dominant ... em, I'm going to say controlling sort of opinion, you know, that they've been brought up in an environment where the man has been in control, you know, and it's hard to break that mould because, and the women ... some of the girls, in some relationships we deal with, they're quite happy with that, you know, and you have to say, "Well, that is not [a healthy relationship]".' (T0119W)

Teachers in both co-educational and single sex schools felt the resource would strike a positive note in terms of focusing on young men's viewpoints:

'We thought it was important. We really liked the idea that the focus of the project is from a boy's perspective, and ... certainly, from teaching in an all-boys' school, that was a real big draw for me, getting involved in the project.' (T0112NI)

Overall, the resource's gender focus was viewed as especially novel and a common reason offered by teachers for joining the trial. Students' perspectives on this are discussed further below.

Teacher training and support

The offer of teacher training in the resource was a further hook to becoming involved. The demand for teacher training arose from the perceived lack of teacher training in RSE, a near universally-expressed view in interviews with teachers and policy specialists.

'I didn't feel terribly comfortable beforehand teaching it [RSE]. This is not my subject area. It's not anything that I have any great experience in and I did need to be shown how to teach this to students or talk to students about it.' (T0129NI)

Hence the opportunity to have teacher training as part of the Jack Trial was regarded as useful not only for this resource but as a way to help some schools develop or model further RSE teacher training.

'I think, with [RSE], becoming statutory, sort of following that sort of framework [in the Jack Trial] with training the staff beforehand, understanding what they need to do and what could be expected. It's definitely a framework that we would use so we can implement it across the other relationship and sex education stuff for the other things that we'll be teaching in future.' (T0112E)

Financial incentive

Teachers were asked during interviews if the £1000 incentive offered to schools for taking part in the study influenced their decision to join. The majority stressed that they would have joined the trial without it due to their positive appraisal of *If I Were Jack* as a quality and much needed resource:

'No, the money never came into it. For us, it was what can we do to best equip our children to make the right choices in what they're doing, and ... going back to contraception, STIs, em, positive, healthy relationships, and try and get them to understand that, if they are going to enter into a relationship like that, then contraception is the responsibility of both people, not just one.' (T0122W)

'It's £1000. Just a nice bonus. If it wasn't there, we still would have done it because ... It's about the topic and what the students would get out of it and, ultimately, what we would get out of it with being given quality resources.' (T0117NI)

However, a minority did acknowledge it was a motivating factor particularly against a backdrop of increasing challenges related to managing a school budget.

'You will take any extra funding you can get.' (T0123W)

The financial incentive worked in terms of Trial Champion teachers recruiting senior management to come on board to join the trial.

'[The money] didn't impact me ... because I wanted to do it and I liked the whole look of it. But ... it was a good thing to get then senior management to jump on-board with it. That was a good ... flag to wave and say, "look". So, that was a good thing just to make sure that the whole school jumped on-board, yeah.' (T0134NI)

Equally, internally in schools it worked for school management to bring teachers on board with them—as a means of both acknowledging their workload and as an opportunity to finance additional support for their departments.

'I possibly would [have joined without the money], but it definitely was something that was [useful] because I was able to offer those teachers – you know, if I hadn't had it ... I might have panicked about giving those teachers extra work, and, definitely, they

might be more likely to turn round and say, “No ... I just can’t do it”, and I would have listened to them, you know.’ (T0115NI)

‘It certainly gives us the option of buying in a whole load of other resources ... that’s massive for us.’ (T0111S)

Overall, although teachers in several schools reported they would have joined the study without the offer of the incentive, many commented that it was a welcome bonus, particularly in terms of alleviation of tight budgets. It was also cited by teachers as a powerful, domino-style recruitment aid for persuading colleagues or senior management to join.

Reasons for non-participation

Of the 258 schools approached with information and offers to participate in the trial, 192 were not recruited. Of these, the majority of schools (n=119) did not respond to any communication attempts from researchers. The rest of the schools (n=73) declined to take part. The main reasons in the order of importance for refusal to participate – drawn from researchers notes on correspondence with schools were

- Research saturation or other commitments
- RSE provision already in place
- Too busy to commit to surveys and/or programme delivery
- Non-alignment with school religious ethos – in some faith-based schools only

As these were brief notes from telephone conversations, we do not have extensive data to offer on these reasons.

Implementation fidelity

This section reports on intervention implementation fidelity to cover all aspects of implementation as follows:

1. Implementation of Teacher Training – assessed through a random selection of audio-recordings of the teacher training
2. Implementation in the classroom – both in terms of the structure of the programme and content – assessed through 35 observations in classrooms in eight case study schools; 128

teacher implementation logs and 29 individual interviews, five paired interviews (n=10 participants), and eight focus group interviews (n=31 participants) with teachers and eight focus group interviews with students (n=58) in case study schools.

3. Implementation of parental component – assessed through an online survey with parents (n=134 returned) and a student engagement questionnaire (n=3179).

Fidelity of implementation of teacher training delivery

In all intervention schools, teacher trainers delivered training to teachers prior to programme implementation (n=13 teacher trainers: one in Scotland, two in NI, two in England, and nine in Wales). Training in Wales was delivered by the Healthy Schools coordinators (Public Health Wales staff). All teacher trainers were trained in a face-to-face two-hour session with the Jack Trial team prior to delivering teacher training. This included the provision of the teacher Classroom Activity manual.

Fidelity to the teacher training protocol was assessed in 50% of the schools across the four sites through 16 audio recordings (including one video recording) made by trainers. As described in *Chapter 4*, a fidelity checklist was used to assess fidelity of teacher training. Each session was scored out of a possible maximum of 49 points and structured under nine sections to cover all aspects of the programme. Percentage scores were graded as <50% = low; 50-70% = medium; and >70% = high.

Table 15: Percentage of fidelity to teacher training protocol

Site	Number of trainers	Number of schools audio assessed	Avg % Fidelity	Fidelity Grading
				<50% = Low 50-70% = Medium >70% = High
NI	2	6 (inc. one video)	100%	High
Eng	2	4	61%	Medium
Scot	1	4	99%	High
Wales	9	2	71%	High
TOTAL UK	14	16	83%	High

Trainers in NI (100%), Scotland (99%), and Wales (71%) demonstrated ‘high’ fidelity. Only England demonstrated ‘medium’ fidelity (61%). Here, the contracted teacher trainer had

delivered training in four out of six schools before researchers identified issues with low fidelity (average 26%). A replacement trainer completed training in two remaining schools, with consequent audio recording assessed as 'high', increasing the overall grading to 'medium'.

Some teachers who received 'low' fidelity training reported that certain activities were not covered, and that they felt unprepared when they encountered exercises seen as more challenging to deliver. These teachers still described the training as 'good', but felt it had focused on factors such as accessing materials, 'rather than ... the real content that you need them to understand and this is how to deliver it and this is how to talk about it' (T0123E). Conversely, teachers trained by the replacement trainer suggested a more positive experience, and awareness of the importance of fidelity.

'It was a forum to ask questions as well, and by making you go through it page by page, bit by bit by bit, it did make you really read it properly.' (T0215E)

Teacher perceptions of the training were generally positive. For some, the comprehensiveness of the training was a considerable advantage that meant that, 'We all left very clear as to what we had to do' (T0320NI). For others, clarity over the research and the programme's origin and objectives appeared to strengthen engagement.

'It was good to put a face behind training because sometimes whenever you go to training, or, sure, whenever you get a programme, you know, you don't know who has made the programme or what the purpose of the programme was. Well, at least we, you know, could say that this was research.' (T0125NI)

In summary, fidelity of teacher training though varied by nation was generally high, with a minority of schools receiving training which did not adhere closely to the protocol.

Fidelity of implementation in the classroom

Approximately 168 teachers delivered the resource in the 30 intervention schools that completed the trial across the UK (*Table 16*).

Table 16: Number (^aApprox.) of teachers who implemented the If I Were Jack resource

Nation	NI	Eng	Scot	Wales	Total UK
No. teachers	36	46	31	55	168

(^aApprox.)

Delivery-time models

The intervention was programmed to include four delivery time models (See Options A-D, *Table 17*) to reflect the different way classes are organised and the different ways in which RSE is typically structured across the four nations of the UK.

Table 17: Delivery options chosen by intervention schools

Intervention	Option A (50-60 min. lessons x 4)	Option B (35-45 min. lessons x 6)	Option C (2 half- days)	Option D (1 full day)	Combination
Schools (N=30)					
NI (n=11)	4	2	0	0	5
England (n=6)	3	2	1	0	0
Scotland (n=6)	2	2	0	0	2
Wales (n=7)	5	0	0	2	0
Total (N=32)	14	6	1	2	7

Most popular was Option A. Almost half of the schools delivered over four 50-60 minute lessons. Six schools chose Option B (six 35-45 minute lessons). All Scottish schools had 50-minute lesson periods, and those choosing Option B reported doing six (and sometimes more) 50-minute lessons. Combinations of options (seven schools) could vary between classes in the same school, and were generally due to unforeseen difficulties, rather than by design. Six schools reported disjointed implementation and delayed completion. Most delays were a few weeks. However, one teacher in a school in Wales reported taking five months to complete due to a series of mitigating events in the school. Reasons given for

delays in all nations included: inspections, conflicting curriculum priorities, staff illness or bereavement and temporary closure.

Delivery of classroom intervention activities

Teachers reported delivering an average of 83% of Intervention activities across all sites (*Table 18*). Teachers in NI reported the highest delivery rate (88%), followed by Wales (85%), England (80%) and Scotland (78%). Most activities were delivered at least 80% of the time. The IVD had the highest delivery rate (99%) and the parent survey the lowest (38%) (see further below). Wallet cards, which signposted students to sources of information and support, had the next poorest delivery rate (75%).

Overall data shown in the tables suggest that while certain activities were not delivered to high fidelity, overall fidelity of delivery of classroom materials was high. However, it must be emphasised that fidelity of implementation in the classroom is based on teacher self-report (in interviews and Implementation Logs). Additionally, not all teachers who delivered all or part of the programme returned an Implementation Log. We know of at least one incidence of a teacher who attended teacher training and who was meant to deliver the programme choosing not to deliver this to their class, and then not returning an Implementation log. Information from the Trial Champion at this school allowed this to be taken into account and added to fidelity figures. However, it is possible that teachers in other schools similarly chose not to deliver part of or all of the programme to their classes, and that their disengagement, for whatever reason, with the programme and/or the research may have also led to them not returning an Implementation Log. Consequently, the Teacher Implementation Logs should be understood to represent a picture of teachers who may have been most engaged with the programme and research.

Table 18: Percentage of activities delivered by nation (teacher reported)

Resource Activity	Nation				^a Total UK
	NI	Eng	Scot	Wales	
Activity 1 – Intro (Not asked for in TIL)	---	---	---	---	---
Activity 2 - Ground rules	93%	88%	91%	100%	94%
Activity 3 – IVD	98%	100%	100%	100%	99%
Activity 4 – Pause, fast-forward, rewind	98%	88%	88%	89%	91%
Activity 5 – What about Emma?	95%	88%	72%	92%	87%
Activity 6 – If I had to look after a baby	88%	94%	75%	94%	87%
Activity 7 – Fact or Fiction?	88%	88%	75%	89%	85%
Activity 8 - Jack Wallet Card	84%	65%	53%	86%	75%
Activity 9 – Jack Forum Dilemmas	86%	82%	72%	92%	83%
Activity 10 – Online Scavenger Hunt	84%	59%	91%	94%	85%
Activity 11 – Homework Parent Survey	40%	53%	34%	33%	38%
Activity 12 – Staying Safe Scenarios	98%	76%	94%	92%	92%
Activity 13 – Controversial Statements	95%	82%	84%	89%	89%
Activity 14 – My Plan	95%	71%	91%	50%	78%
TOTAL ACTIVITIES DELIVERED	88%	80%	78%	85%	83%

^a Average by nation and total percentages in this table calculated from individual class completion logs

Table 19: Implementation fidelity by school

School ID	Classes for which a TIL was returned ^a (n=)	Maximum total activities (classes delivering x 13 activities) n=	Activities completed (n=)	% activities completed	Fidelity rating (high/medium/low)
S12NI	5	65	42	65%	Medium
S13NI	5	65	58	89%	High
S15NI	2	26	25	96%	High
S17NI	4	52	50	96%	High
S20NI	3	39	34	87%	High
S24NI	7	91	81	89%	High
S25NI	2	26	26	100%	High
S27NI	5	65	64	98%	High
S29NI	4	52	45	87%	High
S32NI	1	13	10	77%	High
S34NI	5	65	56	86%	High
S11S	5	65	62	95%	High
S12S ^b					
S18S	10	130	87	67%	Medium
S19S	4	52	43	83%	High
S21S	7	91	79	87%	High
S24S	6	78	55	71%	Medium
S12W	8	104	91	88%	High
S14W	3	39	32	82%	High
S16W	5	65	51	78%	High
S17W	8	104	83	80%	High
S19W	6	78	71	91%	High
S22W	2	26	21	81%	High
S23W	4	52	47	90%	High
S11E	3	39	29	74%	Medium
S12E	7	91	79	87%	High
S15E	4	52	48	92%	High
S19E	1	13	3	23%	Low
S20E	1	13	11	85%	High
S23E	1	13	6	46%	Low

^a Classes for which teacher returned TIL or for which there was sufficient information to ascertain which activities were delivered (for example, if a Trial Champion reported that one teacher who was meant to deliver the programme did not deliver any of it, this was counted as a returned TIL with a score of zero on all activities).

^b Did not return Teacher Implementation Log

Reasons for deviations from intervention delivery fidelity

The primary reasons reported by teachers for deviations in intervention delivery fidelity were insufficient time, perceived clash with school ethos and inadequate computer facilities. Implementation fidelity was also more generally impacted by teacher creativity – teachers changing/adapting materials to the perceived needs of students. Each of these points will be briefly elaborated with data below.

Despite frequent reporting by teachers of the usefulness of the Classroom Activity manual for timing activities, teachers also frequently reported that delivering all activities within timeframes was challenging. Time spent ‘settling students’ (T0216W), dealing with behavioural issues, and delivering lessons to mixed abilities could mean rushing activities to cover material within time slots, while some activities would ‘overlap’ (T0312S) into succeeding lessons.

One teacher explained her decision to deviate from prescribed timings to suit the needs of her students:

‘I couldn’t have followed [the protocol] bit by bit. There was just no chance ... We had open discussions, and then, once they started talking ... they couldn’t stop. So I deviated a wee bit ... to suit their special needs, to include them all.’ (T0329NI)

The issue of special education needs (SEN) students struggling to understand material was commonly reported to be a main reason for classes ending before all activities could be completed as time was spent on more simplified explanations of the tasks and materials to students with mixed abilities. Having classroom assistants present was reported by teachers as greatly assisting delivery. In two schools, teachers delivering to classes with students with significant additional learning needs reported adding extra lessons as several students needed more time to digest content and key messages. However, most who reported partial completion were unable to provide more classes and subsequently left activities unfinished or left them out altogether.

A perceived clash of the programme with the school ethos also impacted on implementation in schools who had volunteered for the trial. In one faith-based (Protestant) school, the teacher did not deliver the programme to his class within that school. The trial champion cited non-alignment of messages with this teacher's moral values as the main factor. More commonly a perceived clash with school ethos impacted the delivery of a single component, namely the wallet cards with signposting to local/national external sexual and reproductive health services. In response to PPI involvement and especially the voice of schools during the optimisation phase, two versions of the wallet cards were available—one which gave a wide variety of voluntary and statutory services and one which was restricted to statutory services only, such as NHS choices.

Despite this choice, one trial champion in a faith based school indicated that apprehension around parental reaction had prompted his decision not to issue wallet cards of either description at all, stating that school staff felt unable to endorse all website content.

'Can we stand by everything that was on all the websites? And the answer was we couldn't be sure that everything on there was something we could say, and so it was to keep parents happier, to avoid issues with that down the line.' (T0129NI)

In another school, four out of seven teachers who delivered the programme reported distributing wallet cards, while the remaining three in the same school did not, stating that this was due to material not fitting with the school ethos, highlighting there were at times disjointed approaches to RSE within individual schools.

Finally, the issue of deficits in school's ICT suites also impacted delivery, especially the online scavenger hunt. In one school, a researcher observing the online scavenger hunt lesson commented on how a combination of poor behaviour, an unprepared teacher and disruption due to computer issues impacted on the delivery of the lesson:

'The classroom was so loud and chaotic, I looked around and couldn't see a single student doing any work. The teacher was half-yelling/half-begging the students to

log in and those who did couldn't progress because they didn't know what to do and other students had no initiative or were totally unwilling to listen.' (RO23E)

Teachers reported adding in additional content, motivated by teachers' intentions to improve absorption of key messages for students. Mostly teachers reported making changes to make the material more attuned for students with special education needs (SEN). For example, one teacher reported a small change to the open-ended closing scene of the IVD—designed to encourage students to think through how it could end—in order to reassure a student with special educational needs.

'Especially with the autistic children, they need to have an ending ... For one of mine in particular, that was a very big struggle for him. He needed that closure. So, in the end, I just whispered an ending.' (T0429NI)

Others reported delivering paper-based activities verbally or in smaller chunks for mixed ability classes to increase absorption of knowledge and key messages.

'For children with special educational needs, they [worksheets] were very bulky at times ... Too much on a page and you lost them and they couldn't follow where you were. So, we didn't use the worksheets as much as we could have because they just couldn't do it. They preferred to [do it] verbally, which is very typical of a lot of our special needs.' (T0329NI)

A small number of teachers reported adding websites not on the recommended list, feeling that these provided additional sources of information and support that students could avail of, particularly from relevant local services. Students in one school, where STIs amongst students were a concern for staff, reported being shown images of STI-infected genitals. However, this was not part of the intervention programme nor recorded in this school's teacher implementation logs.

Researcher observations also attest to widespread use of teacher independence and creativity in using the intervention. Some of these were reported as enhancing discussion in

the classroom—for example, in relation to popular Activity 6 ‘If I had to look after a baby’, some teachers spoke of their own experiences, such as the added stresses of twins or a colicky baby, or shared versus single parenthood, to emphasise messages and enhance relationships with students. However, some of this teacher independence was also noted as having a negative effect on students’ ability to consider and discuss. For example, one teacher insisted that a consensus should be formed among the students when discussing issues.

‘The teacher insisted that pupils working in groups should all come up with the same answer and she did not want different ones. In this respect discussion was not encouraged and personal opinion not validated.’ (RO29NI)

In two observations, researchers observed teachers walking around the classroom and reading students’ responses over their shoulders, and/or collecting and commenting on these.

Summary

Overall, in relation to classroom implementation fidelity, data drawn from teacher self-reports (interviews and implementation logs) suggests relatively high fidelity to protocol. However, classroom observations in eight of the 30 schools suggests that fidelity was lower. Hence, we acknowledge the strengths and limitations of capturing implementation of fidelity through these methods and our overall understanding of this. Reasons for deviation in delivering classroom components were: insufficient time, perceived clash with school ethos and inadequate computer facilities. Implementation fidelity was also more generally impacted by teacher creativity.

Fidelity of implementation of parental component

The parental component of the intervention was composed of two parts:

1. A URL link texted/emailed by the school to parents bringing them to a website with online animated films and material for parents/guardian on the topic and information for parents to tell them the intervention was happening in schools and opportunities for parents to participate with their child in the intervention.

2. A homework activity brought home by the student to do with a parent/guardian/trusted adult. This activity was designed from the outset as an optional activity in response to feedback from schools in our prior research.⁴⁴

Overall, implementation of both these components was low.

Implementation fidelity for digital parental materials

The total potential parents/guardians that could have been reached was *circa* 4097. Website analytics indicated 1123 unique visits to ‘parent resources’ webpages during implementation, signifying around 27% of parents visited these on one occasion or more. Analytics showed that when visiting the website, 380 (9%) viewed the shorter animated film, 288 (7%) the longer animation, and 658 (16%) the interactive film excerpt.

As noted in *Chapter 4*, an online survey to obtain feedback on the parental component was texted or emailed by schools to a primary parent/carer contact of participating students (n= approximately 4097) and 3% of these were returned (n=134, 2 male). One reason for the low response rate may be accounted for by failure of some schools to send this out (50% of intervention schools were able to confirm they sent the text). Survey findings (*Table 20*), indicated that, of 134 respondents, 50% had watched the short animated ‘hook’ feature, 45% the longer animated instructional feature, and 42% the interactive film excerpt. While 4% of respondents said they did not watch the films because they were not interested; most said they did not know about them (68%), forgot (14%), or did not have time (11%).

Table 20: Parent responses to the online survey (n=134, 3% response rate)

SURVEY ITEM	YES % (n)	NO % (n)	NOT SURE % (n)
Parent watched shorter animated film for parents	50% (67)	50% (67)	-
Parent watched longer animated film for parents	45% (60)	55% (74)	-
Parent watched <i>If I Were Jack</i> interactive film excerpt	42% (56)	58% (78)	-
Parent completed homework exercise with their child	34% (46)	55% (73)	11% (15)

Implementation fidelity for the parent-student homework communication exercise

The above online digital materials were intended to prepare parents for an optional parent-student communication exercise assigned by teachers. This involved students completing a 'survey' worksheet by asking a parent/carer or trusted adult to watch or read the script of the interactive film excerpt and then answer three questions about what they would think and do if they were Jack or Emma's parent/carer. Teachers were instructed to assign the homework exercise to students, informing them that, while they recommended they complete the exercise, it was not compulsory.

Across the four sites, an implementation rate of 38% was reported in teacher implementation logs for the homework exercise, ranging from 33% in Wales, to 53% in England. A similar figure of 34% of parent survey respondents said they had completed the exercise with their child (*Table 20*). However, the student engagement questionnaire responses (n=3179) revealed that only 13% of students (n=403) said they had completed the task with their parents. Student-reported implementation varied by nation, with 17% in NI, 11% in England and Wales, and 10% in Scotland. Differences in completion rates by sex of student was evident with an independent t-test showing significantly more females reporting completion than males $t(2955)=2.5, p=0.011$.

Explanations for low Implementation of parental component

Explanations for the low implementation of this component were sought out in interviews with teachers, parents and students and RSE experts. Teachers indicated that non-completion of the exercise was mostly due to student refusal and/or reluctance at school or teacher level. Some schools and teachers decided to omit the activity from the outset to avoid parent controversy, while some said they did not set it because of student discomfort.

'We're facing ... the sort of post-Birmingham backlash. So, a number of our Muslim parents are writing me letters and are wanting their children withdrawn from RSE.'
(T0115E)

'I think the majority of parents aren't comfortable talking about these things, you know, with their kids, and when you speak to the kids, they say there is no way they would discuss this with their parents.' (T0111S)

Parents also reported reluctance to engage in the homework activity because of the awkwardness of speaking to their children about sex, including fears about appropriateness, religious and cultural barriers, and own lack of knowledge.

'A girl I know, she's Christian, and I said my daughter was doing the [JACK] trial and she nearly didn't speak to me for a week! ... She doesn't think it is appropriate that a 15-year-old should know all about those different things.' (P0129NI)

'And a lot of the time, the parents have had bad experiences of education, so the kids are actually more educated than the parents and [kids] don't feel comfortable in talking about it because they feel that they've got to explain things to their parents.' (T0314W)

One RSE expert noted the difficulties engaging parents in general, particularly when parents have not been encouraged to begin having conversations regarding relationships and sexuality with their children during the early years:

'Trying to involve parents in these kinds of subjects and activities ... I've found it difficult, on a number of levels. My opinion would be to get in early.' (PS02W)

Last and not least, turning to students, the vast majority of students said that it felt uncomfortable or 'awkward' to raise these issues with parents, suggesting that it was better to allow these conversations to occur naturally.

'Like if I get homework, I do it obviously, but then, "Go home and talk to your parents about it", and I was just a bit, yeah, "I'm not doing that". I can't go up to my mum and just mention it at the dinner table!' (Female, PU0112S)

In interviews, parents shared some suggestions for improving fidelity, such as compulsory homework exercises and more regular school contact with parents about RSE: ‘A wee overview, you know, just like through email, because then you can say, “Oh, you had this today - tell me about that”’ (P0434NI). RSE policy experts and teachers also noted that if RSE teacher training and support for teachers could be improved, the resulting rise in confidence would have a knock-on effect in terms of engaging parents.

‘[Teachers might think] “I don’t feel comfortable with dealing with it, I haven’t had the training”. ... They don’t want to open a can of worms, they’re afraid ... they won’t get the backing from their own management. Or ... parents might complain.’
(PS03NI)

Summary

In summary, fidelity for the parental components of the programme was lower than for other programme elements and reported completion levels varied across participant types. Parents, students, teachers, and RSE experts reported multiple obstacles to parental component fidelity. However, a level of parental engagement with parental components is clear, and it is likely that targeted materials increased engagement.

RSE provision in control schools

As outlined in *Chapter 1*, heterogeneity in RSE provision across UK schools is high. This section addresses the question of what was the RSE provision in control schools and a summary of changes to provision as a result of agreement to take part in the Jack Trial. Data for this section is drawn from RSE Control School Questionnaires (completed by n=26 out of n=32 control schools). In addition, we add a brief comparative analysis of RSE provision in control and intervention schools (the latter prior to intervention of *if I Were Jack*) based on identical RSE provision and identical analyses.

Assessment of provision in control schools

RSE Control School Questionnaires were analysed to determine approach to RSE and identify any reported changes to provision which could have been due to participation in the trial. Responses were analysed using an assessment tool (see *Appendix 4.5*), informed by the Whole School RSE Audit tool developed by the National Children's Bureau for the Sex Education Forum (2020). Criteria were organised into three categories: RSE quality; RSE quantity; and RSE governance and broader pastoral care. Examples of quality criteria included teacher training and confidence to deliver RSE. Examples of quantity criteria included time being clearly allocated for RSE. Examples of criteria relating to RSE governance and broader pastoral care included the presence of a written RSE policy or ethos. Schools received ratings for each of these categories and for their RSE provision overall. The 'quality' category was judged to be the most crucial and was consequently double-weighted within the overall score.

Table 21: RSE provision in control schools (n=26)

ID	Quality ^a		Quantity		RSE governance and pastoral context		Overall ^a	
	% score	Rating	% score	Rating	% score	Rating	% score	Rating
S11NI	30%	Low	63%	Medium	50%	Medium	38%	Low
S16NI	37%	Low	38%	Low	29%	Low	35%	Low
S18NI	37%	Low	63%	Medium	38%	Low	39%	Low
S19NI	83%	High	75%	High	67%	Medium	78%	High
S21NI	80%	High	75%	High	71%	Medium	77%	High
S22NI	20%	Low	0%	Low	13%	Low	16%	Low
S26NI	53%	Medium	75%	High	21%	Low	47%	Low
S28NI	57%	Medium	75%	High	38%	Low	53%	Medium
S30NI	53%	Medium	75%	High	63%	Medium	58%	Medium
S33NI	20%	Low	0%	Low	17%	Low	17%	Low
S35NI	30%	Low	13%	Low	8%	Low	23%	Low
S14S	27%	Low	38%	Low	33%	Low	29%	Low
S16S	62%	Medium	75%	High	64%	Medium	63%	Medium
S17S	77%	High	63%	Medium	71%	Medium	74%	Medium
S23S	54%	Medium	75%	High	41%	Low	52%	Medium
S11W	38%	Low	50%	Medium	23%	Low	35%	Low
S15W	93%	High	75%	High	96%	High	92%	High
S13W	40%	Low	13%	Low	25%	Low	34%	Low
S24W	70%	Medium	63%	Medium	63%	Medium	67%	Medium
S13E	40%	Low	25%	Low	29%	Low	36%	Low
S14E	43%	Low	75%	High	21%	Low	40%	Low
S17E	67%	Medium	50%	Medium	29%	Low	55%	Medium
S18E	62%	Medium	50%	Medium	64%	Medium	61%	Medium
S21E	40%	Low	25%	Low	42%	Low	39%	Low
S22E	42%	Low	50%	Medium	18%	Low	37%	Low
S25E	42%	Low	38%	Low	32%	Low	39%	Low

^a Quality was considered the most important category and so this was double weighted in the overall score

The majority of control schools (n=15/26) received 'low' ratings for their overall RSE provision, with eight receiving 'medium' ratings, and only three receiving 'high' ratings. Schools tended to score highest for RSE quantity, with nine schools receiving 'high' quantity ratings and eight receiving 'medium' quantity ratings. Schools scored lowest overall on RSE governance and broader pastoral care, for which only one school received a 'high' rating, and eight 'medium'. While a majority of control schools (n=17/26) reported having a written RSE policy or ethos, this was only one of the criteria used to assess this aspect. Finally, in relation to quality, only four schools received 'high' quality ratings and eight 'medium'.

More generally apart from this scoring of school RSE provision, further insights were obtained regarding the delivery of RSE in control schools. First, control schools, in common with intervention schools reported using a variety of delivery mechanisms for RSE, including through timetabled PSHE or Personal Development (PD) or through other curriculum subjects, most commonly science and religion. Some schools used drop down days, targeted talks, and health and wellbeing weeks to cover RSE. Nineteen schools of 32 control schools reported that external agencies such as specialist organisations, health or education authorities, and police services were involved. Some reported working 'in tandem' (T0115W) with these, while others reported that their RSE was 'led by external providers' (T0113W). However, every control school reported that teachers delivered at least some RSE, often 'form teachers', PD or PSHE teachers, or teachers of other subjects, such as science or religion. Only in four schools, school nurse involvement in delivery was noted. Fifteen reported that staff who delivered RSE had received some training. However, just as in the majority of intervention schools, responses suggested that this was rarely sufficient, with even teachers who had received training describing lack of confidence, and stating that 'teachers don't feel equipped with the correct language' (T0118S). One school described lack of training as 'a big area of weakness' (T0123S).

Changes to provision and potential contamination

No schools reported changes to RSE provision as a result of participation in the trial. However, five of the control schools described ongoing attempts to develop and update provision, with some describing previous resources as 'outdated' (T0117S). More broadly, most schools reported at least some recent changes in their approach to RSE. In general,

there was an increased awareness in schools due to changes in society. There was ‘slightly more opportunity for debate. ... Children are much freer to talk now’ (T0128NI). There was also increased awareness owing to external (State) guidance (T0116S, T0114E), namely the PSHE review in Scotland (2019) and the introduction of statutory RSE in England (2020).

Comparison of Control and Intervention Schools

A further interesting question is to look at overall differences in RSE provision between control and intervention schools—prior to the implementation of *If I Were Jack* in the intervention schools. Analysis to address this question was conducted using the same RSE provision questionnaire and analysis based on tool as reported above (National Children's Bureau for the Sex Education Forum (2020) for control schools. The results shown in *Table 22* show that schools in both the control and intervention arms were broadly comparable/equal in terms of the distribution of schools categorised as having high, medium, or low provision of RSE, outside of *If I were Jack*.

Table 22: The quality of RSE provision in Intervention and Control schools excluding provision of If I Were Jack

RSE in School Context	Number in Intervention Schools	Number in Control Schools
High provision	3	3
Medium provision	7	8
Low provision	19	15
Not available	5	6
Total	32	32

Summary

In summary, RSE provision in control schools was regarded as low to medium when judged against a tool designed to capture best practice. No schools reported changes to provision as a result of participation in the trial, but five schools reported updating their provision and most control schools made small ongoing changes to the provision of RSE. The quality of RSE provision in control and intervention schools overall (outside the provision of *If I were Jack*)

was broadly comparable with the majority of schools in both arms rated as low to medium provision.

Mechanisms of impact

In this section, we refer to the underpinning theory of change of the intervention based on social cognitive theory (theory of planned behaviour) along with gender transformative theory (which challenges gender inequalities) as discussed in *Chapter 1*. Based on the logic model, we focus in on the end users' self-perceptions of effectiveness in relation to some of the key active programming mechanisms of *If I Were Jack*. These are:

- Engaging boys and gender transformation
- Knowledge acquisition
- Enhanced communication skills
- Intentions for behaviour change in relation to avoiding unprotected sex (delaying sexual intercourse/practicing safe sex)

By breaking it down in this way we offer a better sense of *what* was perceived to have worked best *for whom* as well as an overall sense of perceived effectiveness.

The data for this section is drawn from:

- Teacher and trial champion interviews (n=29 individual interviews and n=5 paired interviews, total n=39 participants)
- Teacher focus groups (eight groups, n=31)
- Student focus groups (eight groups, n=58)
- Student Engagement Questionnaires (n=3179)

Engaging males and gender transformation

For both students and teachers, the programme's gendered focus was considered a key strength. However, it was also regarded for some as creating a tension between male and female perspectives. While for some this was negative, for the most part this tension was regarded as positive and the active spark for critical thinking on gendered roles in preventing unintended pregnancy and promoting positive sexual health. Below we firstly examine data on the aspect of engaging males and secondly the data on gender transformation.

Engaging males

Students, both male and female, reported that the programme had engaged boys and encouraged consideration of male perspectives.

'... the boy as well because they have to go through and tell everybody that obviously they're going to be a dad.' (Female, PU0112S)

'F: I think it should be on both sides, like, you know, I think, em, it is good to focus on their [boys'] side as well.'

M: It's not just one person's, it's both responsibilities on things.' (Female, PU0116W and Male PU0216W)

'... it's both the people who are responsible really.' (Male, PU0123E)

Teachers sometimes reported being 'pleasantly surprised' at this perceived uncharacteristic engagement from male students (T0212S). Teachers stating that this '[opened] up so many conversations and it, from a unique angle, I think it just really gets them thinking' (T0116W). Teachers reported that this encouraged female students to consider male classmates' views, and the 'emotional impact [of UTP] on the boy as well as the girl' (T0221S). This aspect was also noted by students and perceived as generating empathy with how others (both male and female) may experience an unintended pregnancy

'It showed that men can be scared too.' (Female, SEQ8019W)

'If you were in that position and you were a boy, you wouldn't know all like your girlfriend would be thinking, and that would definitely help.' (Female, PU0129NI)

'It was good that Jack put, em, like Emma first, instead of putting himself first, thought about her and like what she's going to do with the baby.' (Male, PU0229NI)

However, there was also a sense from some of the students and teachers that the programme at times overshadowed female perspectives. Some female students felt that

insufficient detail had been provided on female perspectives; ‘we didn’t really hear much from her [Emma], like what she was going through’ (Female, PU0212S). Some reported struggling to engage with the programme for this reason; ‘like, I’m not a man ... I ain’t going to get a girl pregnant anytime soon’ (Female, PU0316W).

Others described how initial scepticism from girls (‘What’s the point in this then, Sir? ... It’s all about the boy’s point of view’ T0222W) had led to useful discussion, and later, a sense of the programme’s relevance for female perspectives; ‘there was sort of like a turning point for them and then “oh, right, actually, this is to do with us [girls] as well”’ (T0222W).

Gender transformation

Next, we consider if this perceived enhanced engagement and empathy of males was also regarded as a trigger to challenge gender stereotypes and gender inequalities.

Teachers observed that the concept of shared responsibility with regard to timing of pregnancy and parenting, vocally supported by girls, had ‘sparked the debate’ (T0320NI) which caused male students to reconsider their perspectives:

‘That was definitely a key message that was delivered, that it’s everybody’s role, it’s everybody’s responsibility.’ (T0220NI)

‘[At first] it was all on the girl. But then they found out ... that it’s actually two-way – there’s consequences and there’s responsibilities that come from my actions ... you could see them saying, “Oh my god, ah, I have to do this!”.’ (T0323E)

‘It was very much like, not making it too in your face but, if you’re in a relationship, this is an issue, an issue that you have to face together.’ (T0412S)

Increased awareness of concept of shared responsibility for preventing unintended pregnancy was confirmed by male students.

'M: It's good. They need to know that they have, they have some responsibility like ... they can't just run away, run away from it, you know what I mean?' (Male, PU0120NI)

More broadly, students stated the programme provoked them to challenge gender stereotypes in relation to readiness for sex and roles and responsibilities for preventing pregnancy. For example, one group recalled the challenging of gender stereotypes during a discussion on readiness for sex.

'F: Boys, like always seem ready, but like, if it is your first time, like you're obviously going to be like scared.

M (1): That's a bit sexist.

M (2): Aye, but then girls sort of have the stereotype that boys are always comfortable and then the girls sort of, when they feel ready, they think it's just going to happen because they think, oh, the boys are ready to do it, but the boys mightn't feel comfortable. ... The boys go through the same thought process of all of it and they still need to think more about it as well.' (Female, PU0220NI, Male, PU0120NI, and Male, PU0320NI)

Students stated that it also challenged stereotypes in relation to females carrying condoms

'There was one about, em, was it "Is it slutty that a girl is carrying a condom?" ... I brought up the point that she just maybe doesn't want to become pregnant and that's just a safety precaution—that's not anything strange. That's literally just - that's being sensible if the male is an idiot.' (Male, PU0416W)

Teachers also thought messages went beyond stereotypes around practicing safe sex to gender equality and responsibility for parenting more broadly.

'Some of the boys, who are a bit blasé and bombastic even about it, if they're like that in front of their friends, I'm certain that some of them would have gone away and started to think about things in a slightly different way, you know, and even if it's

just planted a seed of “Oh, I need to think about women differently” or “Oh, I need to think about this situation differently”.’ (T0316W)

However, both teachers and students also highlighted limitations to the ability of a programme such as this in significantly challenging gender stereotypes. This was for a mix of reasons:

- 1) Some students felt that in order for the programme to have been effective, a certain level of receptiveness to its messages had to pre-exist.

‘Anybody who was going to leave the kid or was just going to leave her to her own devices, I don’t think that changed their minds on that.’ (Male, PU0216W)

- 2) Some male and female students felt males are males, and they are not going to ‘change’ in response to a programme like this.

‘Let’s be honest, boys just want to have a sex with a girl don’t they? ... Some of them might think differently after using the programme. But some of them won’t care.’ (Male, PU0114W)

- 3) Some thought the programme activities might act to even embed stereotypes either because of the way they were framed or because of a lack of sufficient time, student, or indeed teacher confidence, to challenge these in discussion.

‘Some people put really stupid things for their answers, and then there was no sort of like, “Oh no, you [shouldn’t be] doing that”, it was just moving straight on, and if they actually believed that, then there was nothing to sort of tell them, no, you don’t want to be doing that, you want to be doing something else.’ (Male, PU0416W)

The teachers, despite agreeing that the controversial statements exercise was one of the strongest exercises, suggested that completing this activity earlier in the programme would

allow such messages to be addressed and learning to be ‘threaded through’ the rest of the lessons (T0323E).

In summary, the gender focus of the programme was regarded as a key strength by both teachers and students for generating engagement, ‘sparking the debate’ and as a ‘unique angle’ to both question and understand gendered perspectives. It created a learning opportunity for male and female students to challenge unequal gender relations in relation to sexual freedoms and reproductive responsibility and gender equality more broadly. Limitations of this approach though was the potential to de-emphasise female perspectives and overshadow these through male perspectives. Furthermore, other limitations in the programme were its smallness in the face of societal gender norms and the lack of time within the programme activities to sufficiently disrupt gender norms and practices.

Knowledge acquisition

Students and teachers perceived the programme to have increased students’ factual knowledge and practical skills in gaining knowledge, addressed misconceptions, and improved understanding of the impact and options available following unintended pregnancy, as well as personal risk.

New knowledge and practical skills for acquiring knowledge

Students described how activities had led to gaining new information. Areas of reported increases in knowledge included contraception and condoms (Female, SEQ3615E; Male, SEQ0116W), and ‘different characteristics about teenage pregnancy and sex’ (Male, PU0320NI).

Some recounted how the programme had challenged myths they had previously believed.

‘F: I definitely believed that [you can’t get pregnant the first time you have sex].

F: Yeah, as in you don’t really get any free trial [laughing].’ (Female, PU0529NI; Female, PU0129NI)

However, not all agreed, with one all-boys' group describing finding some misconceptions addressed by the programme as 'kind of ridiculous, like you wouldn't really believe them' (Male, PU0419E).

Teachers commonly perceived that the programme had been, 'an eye-opener' (T0119W). Additionally, teachers perceived the programme to have addressed 'myths' (T0216W) on subjects such as the fallibility of the withdrawal method; 'A lot of the boys said, "But it's okay if you withdraw". No. You know, and I think they were like, "What, it's not?"' (T0119W).

However, teachers also noted that not all students might have agreed, especially they thought this was truer for males than females who often regard themselves as more informed. Teachers discussed how some male students 'literally convinced themselves' that they had already known information before the programme, but disputed this; 'The boys certainly had that attitude that, "Well, you didn't teach us anything that we didn't know". I doubt that's true' (T0219E).

Students considered lessons containing practical information impactful as this could be used to protect themselves and make informed choices. They described how learning, 'where we could get help and where we could go for contraception and other things' was 'very helpful' (Female, SEQ9217W). Others reported that they 'never knew you could just show up to the sex clinic place', particularly without parental consent (Male, PU0312S).

This was confirmed by teachers who reported noticing students 'lift their heads' (T0420NI) to take in information, such as types of contraception and how to obtain it. Such elements were perceived by teachers to have been particularly impactful for students; 'Mine were like "We didn't know a lot of that"' (T0319E). Another echoed the sentiment that the programme had left a lasting practical impact on students; 'They definitely left, to me, knowing they had a lot more information to make responsible decisions with regard to sex' (T0420NI).

Students reported that activities incorporating finding answers online had provided them with skills to seek information independently 'ourselves' (Female, SEQ6927NI), and 'gave us information whilst teaching us how to find more in the future' (Male, SEQ7019E). Reported barriers included navigation issues and 'blocked' sites (Female, SEQ0927NI), limited website utility, and getting 'side-tracked' by other content (Male, PU0216W).

Teachers felt it been particularly effective in signposting students to resources where they could access reliable information independently rather than relying on friends; 'It was very much a wee bit of independent research and ... any questions were answered' (T0117NI). Another noted that while it was impossible to know if students had done further research, they had accepted programme wallet cards; 'there wasn't too many left on the floor, which is always a good sign [laughing]!' (T0112NI).

Unintended pregnancy: options, impact, and personal risk

The programme was perceived by students to have effectively communicated information about 'where to get help if I needed it' (Female, SEQ0727NI), and options available to a young person facing unintended pregnancy. Some males reported learning that they could speak to a crisis pregnancy counsellor, 'just showing that that was like an option that you could have ... it was quite useful to know that you could go and do that' (Male, PU0219E).

Some students reported struggling to relate to IVD characters, seeing them as too 'robotic' (Male, PU0416W), or insufficiently distressed; 'She didn't seem [that stressed]. Like, if that was me personally, I would be like, this is the end of the world' (Female, PU0223E).

However, generally the participatory and character-focused nature of the programme was seen to have been effective in helping young people understand the realities of unintended teenage pregnancy. Students felt messages had encouraged 'mature' engagement with the topic (Female, PU0129NI), and sympathetic engagement with the characters' challenging experiences, showing, 'what people actually go through, like people who are like getting beat up inside, you know, about having a baby' (Male, PU0329NI).

Reflecting this, one teacher reported that the programme had been ‘genuinely relevant’ to her students’ lives, and its recognition of them as potentially sexually active had been key to ensuring engagement.

‘They saw it as something that really, really spoke to them. I also wonder if maybe we’re guilty sometimes of infantilising them a little bit, and because we treated them with a mature topic, in a mature way, they responded.’ (T0112S)

In terms of drawbacks of the programme in this regard, apart from the aforementioned perceived implausibility of some of the myths challenged, generic limitations of internet searches, perhaps more significantly across a number of focus groups students perceived more attention was required on lesbian, gay, bisexual, transgender and questioning (LGBTQ) issues. One student who identified themselves as gay described the programme as ‘really focusing on straight people’ (gender not recorded, PU0121S), Teachers were encouraged to acknowledge this limitation from the very outset of the programme, but nonetheless it was important to the students to also express this.

Some students expressed negative views on the programme, perceiving it to be ‘extremely centred around straight people, heteronormativity, and very uncomfortable’ (gender missing, SEQ0711E). Others felt that the programme was not relevant to them, and that there was already sufficient information on the issue of unintended teenage pregnancy.

‘It’s stereotypical and doesn’t inform us on anything but heterosexual sex ... there is enough info on teen pregnancy.’ (Female, SEQ9418S)

However, there were also examples of LGBTQ students reporting enjoying the programme or feeling that it was covered important issues, despite the perceived reduced relevancy of the issue of pregnancy. One student expressed very positive perceptions on the IVD and found activities involving internet research and information on STIs ‘very good [and] useful to me’, but reported reduced personal relevancy over the focus on pregnancy ‘I’m gay so I don’t think I’d really ever be affected directly by something like that’ (Male, SEQ10819E).

In summary, teachers and students mostly reported that gaining knowledge, and gaining skills to acquire knowledge in relation to relationships and sexuality and the relevant ways the knowledge was presented was a key mechanism of the programme's effectiveness. A key limitation of this relevance however was in relation to the heteronormative focus of the intervention and, to a lesser extent, the focus on teenage pregnancy in limiting opportunities for all students to benefit.

Communication and skills

Students and teachers often reported perceiving the programme to have improved students' ability to communicate on the subject. Sharing of perspectives and consideration of IVD characters' experiences were perceived to have increased empathy.

Empathy and opportunities for practising communication

First and foremost, the programme seemed to have provided an opportunity for the students to think through the situation themselves and communicate with others in their classroom setting, including among those who might normally be hesitant to communicate. Students reported finding it useful to see the thought processes the main character went through before discussing his situation with others.

'His thought process and how he kind of talked things out and how he communicated with others to try and solve the issue that he had, and it was kind of like a first-hand thing because ... he's literally saying his thoughts out-loud, and it's like as if you're thinking with him and making the decisions with him.' (Male, PU0119E)

'They kind of got interactive ... after the video, they were more confident.' (Female, PU0429NI)

'Especially hearing other people say their opinion, it made them like, "oh, I'll just say mine".' (Female, PU0129NI)

Teachers agreed that the approach had facilitated shared reflection on issues.

'It really got them communicating and talking about things and seeing things.'
(T0314W)

'At the beginning ... just the word "sex" sort of makes everybody laugh, and by the end of it, they were having really positive conversations.' (T0319E)

Nonetheless, some students reported some challenges to engaging different groups of students in discussion, owing to 'general disruption' (Male, PU0320NI) and phone use.

Second, both teachers and students reported that the programme developed the young people's communication skills in listening, challenging and widening perspectives.

'It did get people thinking ... like some people were saying that some girls do wear certain clothes and then other people kind of gave them more of a different perspective and then they kind of like changed their mind and stuff. It was good.'
(Female, PU0529NI)

'Where we have got a range of different races and cultures and faiths, it worked really nicely ... with our British values as well in order to be able to, you know, take on board what people say and ... be respectful to other people's viewpoints.' (T0112E).

Finally, in this regard, enhanced sense of communication skills from the programme was perceived by students and teachers to equip students with a greater ability to communicate about personal issues and wellbeing more generally. Teachers highlighted the importance of the programme in creating open environments for discussing concerns in school settings, focusing on wider cultural change and teacher approachability: 'we create a culture of we're prepared to discuss things' (T0111S). Others agreed that the programme had highlighted the importance of communication more widely for students around sex, pregnancy, and other risks; '[opening] their mind to the fact that they have to have discussions, regardless of whether it was just one night or whatever' (T0321S).

'M: There's people have brought things up to me that I never would have ... There was a conversation I had today with a young man that would not have thought.

F: Yeah. I find mine don't whisper anymore, you know, about what they did on the weekend ... I think they feel a lot more comfortable to come and say, "This has happened, you know – what can [I] do?"' (T0129NI; T0229NI)

'Even though we finished it ... five weeks ago, the kids are still talking about "If I were Jack".' (T0312S)

Students also acknowledged they had a stronger sense of their own ability to communicate on sexuality.

'M: They've got experience and now they know about this stuff ... they can talk about it. ...

F: I think, after, they'll be more responsible about like having sex and everything and being more careful about the whole thing.' (Male, PU0120NI; Female, PU0420NI)

However, indications of barriers to ongoing communication were also present in the data. Some male students still agreed that young men were less likely to talk about it than young women putting this down at times to 'immaturity' (Male, PU0329NI). Another group reported that discouragement from discussion after primary school RSE had continued to influence them; 'we were told like not to talk about it outside of class and stuff like that ... I think it just kind of carried on' (Female, PU0221S).

In summary, a key strength of the programme was teacher and student perceptions that it had raised their ability to communicate on relationships and sexuality both within the classroom and beyond it with enduring effects. Participants reported that it raised their competence to listen, appreciate other perspectives and challenge ideas. However, the potential for this impact to last beyond the support of the intervention or to override gendered stereotypes/behaviour was also questioned.

Perceived effectiveness in terms of intentions for behaviour change

Teachers were hesitant to draw conclusions on whether behavioural changes had occurred as a result of the programme so soon after implementation, it was 'early days' (T0123W). Others anticipated that behavioural change would be a slow process; 'not something like flicking on a switch. It's going to take time for that to seep in' (T0124NI). In addition, some students were sceptical about the likelihood that the programme would effect behavioural change; 'no boy or girl will listen to that or change what they will do' (Female, SEQ12818S). However, more commonly students and teachers perceived the programme to have triggered realisations surrounding risk which combined with practical knowledge, was already creating the foundations to delay sex and childbearing until they were ready and to avoid unprotected sex.

Delaying sex

A number of students and teachers focused on how the programme had highlighted the importance of feeling personally ready for sex.

'It taught me that I should be careful when having sex and have it when you're ready.' (SEQ16812E, female)

'It was well explained why it's better not to have sex until you feel ready.'
(SEQ5717NI, male)

'I think, in every lesson, there was an opportunity for me to say that, "remember this is meant to be a positive experience".' (T0420NI)

Students and teachers considered programme statistics useful to challenging peer norms that underage sex (lower than 16 years of age) was widespread.

'Lower, far lower than we thought.' (Male, PU0120NI)

'To know that it's not [more people] ... that's good, because a lot of people feel under pressure.' (Female, PU0429NI)

Students and teachers described especial pressure on males to have sex, 'like a lad thing' (Female, PU0429NI). A male student reported how the programme had encouraged him to rethink beliefs drawn from claims of his vocal peers.

'I hear loads of stories ... and you're like, "oh, that's loads", but then if you round, like see how many of my friends around me haven't lost it, so.' (Male, PU0229NI)

Some students and teachers considered females more likely to experience pressure to have sex from male partners and that female empowerment to delay sex would be enhanced as a result of the programme. Teachers observed that the confidence of girls to decline unwanted sex had been strengthened by the knowledge that their male classmates had also received this information, and they no longer 'felt they were the only one saying no' (T0320NI). This teacher observation was also acknowledged by a male student in a focus group.

'More guys are thinking about [sex] way more than girls, so if they think, "oh, fine, I'll just wait until my girlfriend's ready", then it might be better for both of us in the long-term.' (Male, PU0229NI)

Safer sex

The most common theme here was a greater sense among students, and confirmed by teachers, that the students had an opportunity to take in the messages in a way that made sense to them plan their behaviour and plan to have safe sex. There was a strong sense across the data with students and teachers that the resource was perceived as effective in this regard.

'It gives you a chance to discuss what you, how you would respond in that situation.' (Male, PU0120NI)

F: 'I think people will actually think about what they're doing instead of just, it's just a thing that happens in life. I think they will actually think, "oh, if I do this, it will be – "'
M: 'Then my life might be ruined or' (Female, PU0212S; Male, PU0312S)

M: 'I think, overall, it was good ... and it was helpful as well.'

M: 'What to do if you're planning on doing it ...'

F: 'Protection.'

[Laughter] (Male, PU0312S; Male, PU0412S; Female, PU0112S)

'Made me think deeply on pregnancy and the choices I make in the future.' (Female, SEQ3220E)

Others added that information on STIs as well as pregnancy had helped them consider how to stay safe as they, '[didn't] want to catch something' (Male, PU0329NI).

While some teachers reported that some male students initially distanced themselves from the suggestion that such strategies were relevant to them, after targeted explanations, teachers observed them to be more open to learning.

'They did understand, "if I'm prepared for this and if I'm clued-in, I'll make a better decision, you know, or things maybe will go, will go more positively".' (T0420NI)

Many teachers reported that the 'baby's vs Saturday schedule task' was particularly helping in reinforcing the message that delaying childbirth until one was ready. Teachers offered as evidence of effect their observations of students after class visiting recommended websites on their phones noting practical information and suggested that this indicated intentions to make use of these resources, as well as using school resources. One teacher observed more use of school-based resources.

F:'One boy was like, "Do you know you can get free condoms from this place?" ... But they weren't doing it in a way that it was like hilariously funny. They were actually quite interested ...'

M: 'I saw a couple of them taking a picture of it as well ... and you know that that's serious then.' (T0412S; T0212S)

Another teacher also speculated about wider impacts; 'We have had, sort of on the back of this, a lot of boys going to see her [the school Health and Wellbeing Lead]' as well as having, 'sparked more awareness, definitely' of sexual health and wellbeing as an issue within the wider school environment (T0117W).

In summary, participants perceived the programme to have triggered realisations around relationships and sex which combined with practical knowledge, was already creating the foundations to avoid unprotected sex and delay sex and childbearing until they were ready. Teachers and students reported that students were actively seeking out information to help them to be informed and had greater confidence to think about relationships and sex. However, despite these benefits teachers and students also recognised that behaviour change is generally the product of cumulative actions, rather than the outcome of a single programme, and that time would tell.

Summary and conclusion

This chapter was structured to answer focussed questions of the process evaluation as defined in our study protocol.⁴⁸

First, we asked the question why schools chose to participate or decline to participate in the trial. The data demonstrated the primary reasons for participation was an acknowledgement by schools that *If I were Jack* was a high quality, novel resource; a recognised need by schools to address RSE/holistic pastoral education; recognition that there was a gap in current materials in relation to engaging males, the opportunity for teacher training which could have wider benefits for future RSE programmes and the financial incentive. The main reasons for not participating were: research saturation or other commitments; a perception that there was adequate RSE provision already in place; the additional time commitment required by the trial to co-operate with the research components and/or programme delivery.

Second, we asked whether the intervention was delivered with fidelity. The data demonstrated that the teacher training and classroom activities were generally delivered with high to medium fidelity with some exceptions; while the parental component, an optional element, was delivered with low fidelity. We noted, however, the potential for a high risk of bias in measuring implementation fidelity of the classroom based activities on teacher self-reports in implementation logs, some of which was picked up through data triangulation with classroom observations, student focus groups and student-engagement questionnaire. Gathering data through implementation logs was problematic.

Relatedly, we sought understanding for the reasons for high and low implementation, especially of classroom activities and the parental component. High fidelity to classroom implementation was enhanced by teacher training and the manualised and user-friendly nature of the programme – following years of prior optimisation with teachers. The primary reasons reported by teachers for deviations in intervention delivery fidelity were insufficient time, perceived clash with school ethos and inadequate computer facilities. Implementation fidelity was also more generally impacted by teacher creativity – teachers changing/adapting materials to the perceived needs of students, including students with special education needs. Low fidelity to implementation of the parental component was explained by parents in terms of not receiving the material, and embarrassment or fear of raising this with their child. Teachers reported barriers to implementation due to student refusal and/or reluctance at school or teacher level to engage with parents on these issues. Students said it would be embarrassing and awkward. A proposed solution to mitigating these barriers was normalising these conversations between parents and school at an earlier stage in education, with continuity on the topic throughout all stages—in other words avoiding the ‘big talk’ with schools and parents at age 11/12.

Third, we asked about the nature of RSE delivered in control schools and whether or not this had changed owing to participation in the trial—as a marker of risk of bias. Judged against assessment criteria informed by a best practice tool of RSE implementation in the UK (Sex Education Forum, 2020), most control schools (n=15) received ‘low’ ratings for their overall RSE provision, with eight receiving ‘medium’ ratings, and only three receiving ‘high’ ratings.

There was no indication that the direction of RSE had substantially changed as result of participation in the trial. There was also broad comparability in the quality of RSE provision in both control and intervention arms – outside of the provision of *If I Were Jack*. On the whole, the quality of RSE provision in both arms was rated as low to medium.

Fourth, we asked about the perceptions of effectiveness of the intervention, from the perspectives of both teachers and students, especially probing key theory-driven programming mechanisms as depicted in the intervention logic model. The data demonstrated that the gender focus of the intervention, the engagement of males and the generation of empathy and understanding of both male and female perspectives was a key strength of the programme: ‘It really got them communicating and talking about things and seeing things’ (T0314W). Potential limitations to effectiveness relating to this mechanism was a perception that the programme could overshadow female perspectives and an acknowledgment that a short programme may be insufficient to challenge deeply-embedded gendered ideas around sexuality.

The data demonstrated that the intervention was an opportunity to gain new knowledge on sex and relationships as well as acquiring skills of where and how to find information and support. According to teachers it ‘lifted heads’ and was an ‘eye opener’. Students reported that learning where they could get ‘contraception and other things’ was ‘very helpful’ as well as learning ‘where you could get help if you need it’ and for males especially, ‘it was quite useful to know that you could go and do that’. A key limitation in the programme to generating knowledge acquisition was its strong heteronormative bias and focus on teenage pregnancy, though some LGBTQ students thought the programme was nonetheless relevant.

Data confirming teacher and student perceptions that the programme provided an opportunity to learn and practice communication skills was especially evident. Teachers and students both noted increased confidence of students to communicate with peers about sex and relationships. According to one teacher ‘we treated them with a mature topic, in a mature way, [and] they responded’ (T0112S). The interactive video seemed to be an especially important trigger for generating communication skills on relationships and

sexuality in the classroom. This was because the IVD was regarded as centring the importance of young people's thoughts and ideas; thereby laying the groundwork and confidence-building for young people in the classroom to pick up and continue the conversation. There was a stronger sense that these communication skills would endure—though limitations to this were also noted.

Finally, the perceived impact of effecting behavioural change especially in terms of delaying sex until one is ready and practising safe sex was considered. Teachers and students tended not to 'over-promise' the programme's potential impact on behaviours – 'it's like early days'. However, there was ample data to suggest the programme provided an opportunity to think about and plan sexual behaviours in ways that were positive and healthy, both in terms of the messages that teachers conveyed: 'I think, in every lesson, there was an opportunity for me to say that, "remember this is meant to be a positive experience"' (T0420NI), and the messages that students recounted for themselves: 'More guys are thinking about [sex] way more than girls, so if they think, "oh, fine, I'll just wait until my girlfriend's ready", then it might be better for both of us in the long-term' (Male, PU0229NI).

In the final discussion chapter, the process evaluation data, the trial data and health economics data will be considered in the round to draw together the final conclusions of the study.

Chapter 7. Results: Economic evaluation

Aim

The aim of the economic evaluation was to describe the costs and consequences of implementing *If I were Jack* in UK schools to provide information to decision makers on the implications of rolling out the intervention further. Two analyses were conducted:

- 1) *Within-trial economic analysis*. The aim of this analysis was to calculate the cost of teacher time to deliver *If I Were Jack* compared to current Relationships and Sex Education (RSE) provision (and hence the opportunity cost) based on teacher completed resource use questionnaires. Descriptive statistics for sexual health related health care resource use and costs and inputs to the model based on participant completed data were also calculated.
- 2) *Decision analytic model*. The aim of this analysis was to report the long term cost-effectiveness of *If I Were Jack* based on a decision model with input data collected from the trial in addition to relevant data from the published literature.

Methods

Within-trial analysis

For the within-trial economic evaluation, the main outcomes were the students' health care resource use related to STI services used in the last six months at baseline and since baseline (covering approximately the last 12 months) at follow-up and teacher resource use in delivery of the intervention.

- The student health care resource use data included: number of visits at sexual health clinics; number of school nurse appointments; number of GP and GP nurse visits; number of free condoms received and number of condoms bought; number of emergency contraception pills purchased and other contraception methods accessed; number of pregnancy and STI tests obtained.
- The teacher resource use questionnaire included: time spent on lesson and photocopy preparation; time and type of other inputs used (e.g. discussion and/or equipment); lesson delivery time.

Costs of If I Were Jack intervention

The cost of *If I Were Jack* was based on the opportunity cost of teachers delivering the intervention and the cost of adapting the intervention for different groups. The first was calculated from the time spent preparing and delivering the intervention multiplied by the average hourly wage of a secondary school teacher as reported by the Office of National Statistics (ONS).¹⁶¹ This was divided by the number of students in each school randomised to the intervention arm to calculate the total opportunity cost per student.

It is possible though that this time could have been spent delivering other RSE activities, whose effectiveness make up the control group. A questionnaire was circulated to control schools to collect information on the resources required to deliver standard RSE. Costs were calculated using a similar methodology to costing the *If I Were Jack* intervention.

The *If I Were Jack* resources were adapted for the four different nations to make them more culturally relevant (i.e. the original resource was re-filmed and updated for NI and Scotland and remade with English actors for England and Wales). We included the cost of adapting the *If I Were Jack* resources given that it is likely that these resources will need to be updated over time to reduce the risk of them appearing dated. Based on the finances from the trial we report the total cost of updating the materials as well as an upper and lower estimate of the cost per student to update the materials, with the upper estimate being the greatest possible cost per student to update the materials if only the same number of students as those randomised to the intervention accessed it, and the lower estimate being the lowest possible cost per student if all of the students aged 14 in the respective country accessed the intervention.

Sexual health related service resource use and costs

Descriptive statistics for the percentage of students and mean number of contacts for self-reported health service use were reported for students in the control and intervention arm. Resource use for each student was multiplied by unit costs from published sources (see Table 23). Both unadjusted and adjusted mean cost per student at follow-up were reported for the control and intervention groups, the latter obtained after adjusting for baseline resource use and stratification variables using clustering as a random effect. 95% CIs were calculated based on bootstrapped bias corrected methods.

Table 23: Unit costs sexual health resource use

Resource	Cost(£)	Reference
Sexual health consultation in clinic	£120	PSSRU ¹⁶²
Sexual health advice from school nurse	£11	PSSRU ¹⁶²
Sexual health advice from GP	£34	PSSRU ¹⁶²
Sexual health advice from GP nurse	£12	NICE ¹⁶³
Condom (assumed three condoms per pack)	£2	Boots ¹⁶⁴
Other contraception (average cost of different contraceptives indicated by the students in the trial)	£7.16	Boots ¹⁶⁴
Pregnancy test	£4	Boots ¹⁶⁴
STI test	£16.50	NICE ¹⁶³
Emergency contraception	£30	Boots ¹⁶⁴

Missing data

We assumed that data were missing at random (MAR). In line with published guidance on handling missing data in randomised controlled trials¹⁶⁵ and specifically in cost-effectiveness analysis alongside a randomised controlled trial¹⁶⁶ our main analysis was a complete case analysis. A sensitivity analysis using multiple imputation by chained equation (MICE) was conducted to test the robustness of the MAR assumption.¹⁶⁷ The MICE approach included a multilevel imputation method to account for clustering. Age and sex were included in the model as predictors of missingness in addition to the stratification variables and baseline costs. Estimates were derived using 20 imputations and 95% CI were calculated based on bootstrapped bias corrected methods over a total of 10000 iterations for each imputed dataset.

Cost-consequences and decision model inputs

For consequences and relevant inputs to the decision model we reported instances of unprotected sex (i.e. no contraceptive use at last sex), ever had sex, pregnancy tests, contraception use, STIs and testing for STIs. Unadjusted and adjusted (adjusting for stratification variables and baseline) odds ratios were reported for the intervention compared to control for unprotected sex, ever had sex, pregnancy tests, and testing for STIs.

Further sub-group analyses for contraception type and specific STIs were not possible due to small patient numbers.

Long term decision model

We designed a behaviour change-based decision model⁶⁷ aimed at assessing the long term cost-effectiveness of the *If I Were Jack* versus RSE. The model was populated using evidence collected from the trial and published literature on different types of outcomes which are directly and indirectly related to pregnancies and STIs among young people. Where no trial data were available, assumptions were made from pre-existing data and expert input. The model had a 20 year time horizon and calculated the expected costs and consequences for a hypothetical cohort of patients with similar characteristics to those enrolled in the trial. Both deterministic and probabilistic sensitivity analysis were conducted to assess the robustness of the results to alternative modelling assumptions. The long-term decision analysis model was conducted in R version 4.0.3.

Design

A conceptual model developed to evaluate the long term cost-effectiveness of the intervention, which incorporated theories of behaviour change is illustrated in *Figure 9*. Reading from left to right, we started with the target population (young people aged <16) who engaged with the *If I were Jack* intervention and experience an increase in the levels of the cognitive outcomes in topics related to sexual health (knowledge, attitude and skills). We hypothesised a change in the behaviour outcomes with an increase in the number of people who delayed vaginal sexual intercourse (abstinence), an increase in the instances of protected sex for those sexually active, and a decrease in the instances of unprotected sex. This, in turn, lead to a decrease in the number of unintended pregnancies and STIs in the target population.

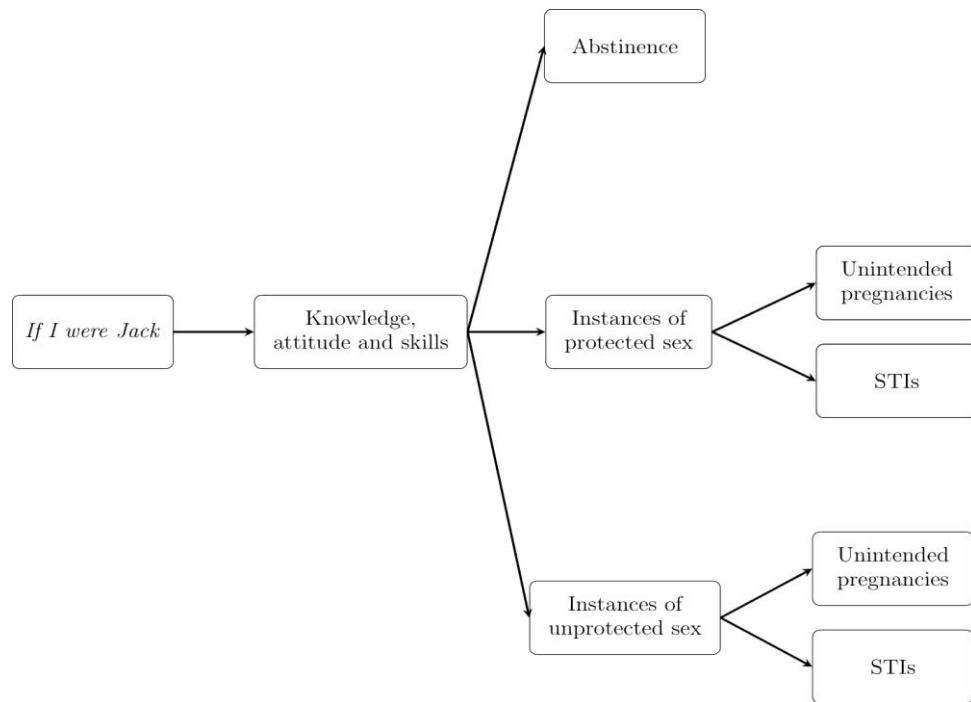


Figure 8. Health economic conceptual model of the *If I Were Jack* intervention

Population. The target population were young people in post-primary schools in the UK under 16 years of age within the general population. An intervention that encourages the use of contraceptives is unlikely to prevent young people who hoped to become pregnant from endeavouring to become pregnant. The model therefore assumes that the intervention is aimed at teenagers who want to prevent pregnancy.

Outcomes. The outcomes were reported in terms of the output of a cost-benefit or return on investment (ROI) analysis, whereby both costs and benefits are measured in monetary units. The “benefits” were the cost savings that result from averted pregnancies. The “cost” was the total amount of public money currently being spent for preventing pregnancies and STIs among young people.

Perspective. The analysis took a public sector perspective which included costs incurred by the public sector. The analysis was presented with and without the inclusion of government-funded Benefits. We reported aggregated costs by public sector (education, health-care, welfare)

Modelling the health consequences of behavioural change

An extensive literature search and consultation with experts was conducted to identify quantitative evidence about the different elements (cognitive, behavioural and biological) of the theory of change behaviour that could be used to inform the final structure of the model for the target population. However, since no evidence was found about how variations in the cognitive outcomes could be converted into changes in the behavioural and biological outcomes, the structure of the model shown in Figure 8 was modified and focussed on how changes in behavioural outcomes were translated into changes in biological outcomes. Specifically, the updated model assumed that the behavioural change targeted by the intervention will result in a delay in sexual debut and/or increase of contraception use. The analysis focussed on how any changes in these behavioural outcomes affected the number of pregnancies and cases of STIs.

Modelling the number of pregnancies

To estimate the number of pregnancies averted, we used a mathematical model to define how different types of contraceptive methods were translated into cases of pregnancy.

$$Y = N_f(g_{con}K_{con} + g_{pil}K_{pil} + g_{eme}K_{eme} + g_{inj}K_{inj} + g_{dia}K_{dia} + g_{imp}K_{imp} + g_{iud}K_{iud} + g_{wit}K_{wit} + g_{noc}L).$$

The total number of pregnancies (Y) depended on the number of sexually active females in each arm of the study (N_f), the probability of becoming pregnant within one year without contraception (L), the percentage of students using condoms (g_{con}), pill/patch/ring (g_{pil}), emergency pill (g_{eme}), injection (g_{inj}), diaphragm/cap/spermicide (g_{dia}), implant (g_{imp}), intrauterine device (g_{iud}), withdrawal (g_{wit}) or no contraception (g_{noc}), and the contraceptive failure rates for each contraceptive class (K_{con} , K_{pil} , K_{eme} , K_{inj} , K_{dia} , K_{imp} , K_{iud} , K_{wit}). Evidence on the failure rates was taken from the return-on-investment analysis of improving access to contraception in the UK.¹⁶⁸ The failure rate was defined as the percentage of women experiencing unintended pregnancy within one year of typical use of that contraceptive method. The rates of contraception use were taken from responses to the follow-up questionnaire in the *If I were Jack* trial. The impact that social disadvantage may have on the number of unplanned pregnancies was accounted for based on evidence from the third National Survey of Sexual Attitudes and Lifestyles¹⁶⁹ and the proportion of pupils receiving

free school meals collected from the trial.¹⁷⁰ Sensitivity analysis was conducted to assess the impact that variations in the area-level deprivation effect and failure rates of the contraceptive methods may have on the final results.

The proportion of sexually active males and females aged less than 16-years old was estimated using the answers to the Health Behaviour in School-Aged Children (HBSC) surveys for England¹⁷¹, Wales¹⁷² and Scotland¹⁷³ and the Young Life and Times¹⁷⁴ survey for Northern Ireland. We took this frequency to be an approximation of the proportion of sexually active females and males in the target population in each country. We used National Office of Statistics (NOS) data about the population estimates of females and number of births by age in 2017 in England, Wales, Scotland and Northern Ireland to obtain the total number of sexually active females in the target population in each country.^{175–178} We then combined these data with the evidence from the answers to the NATSAL-3 survey to obtain estimates of the number of sexually active females in three different age groups: 11-13, 14 and 15 years.

There were no directly measured data for the probability of becoming pregnant within one year without contraceptive use in the UK. For the US, evidence from the published literature was available to first calculate the one-month pregnancy probability and convert this into a one-year probability.¹⁷⁹ This evidence was adapted in the literature using data from about the HBSC surveys for England, Wales and Scotland and the 2011 YLT survey for Northern Ireland. We used the available evidence on the conceptions and population of females, baseline condom use and annual condom failure rate to derive an estimate of L for each country in the UK among the young people aged less than 16-years old.^{171–177,180} We included in the model different types of outcomes associated with the number of pregnancies averted using the structure shown in *Figure 9*.

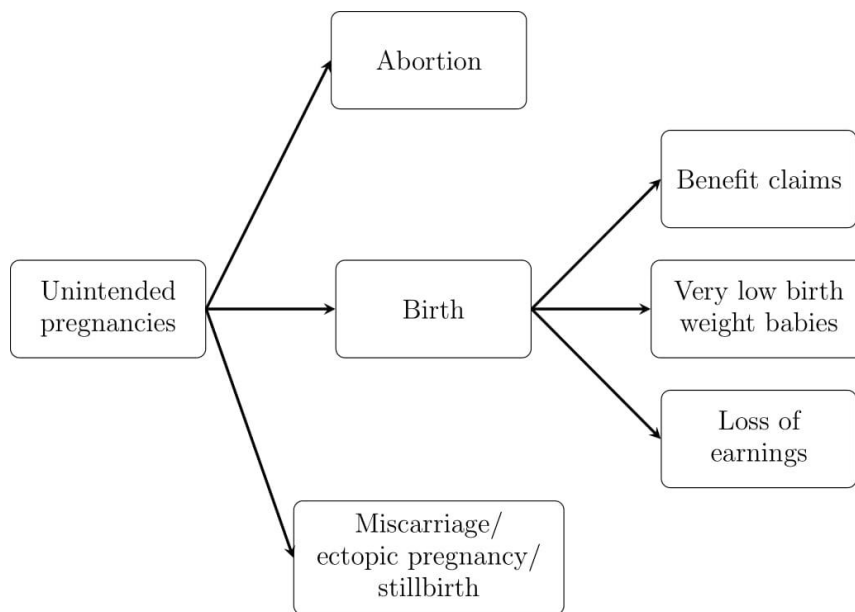


Figure 9. Model structure for the outcome associated with the number of pregnancies averted

The probability of becoming pregnant in the target population was expressed, following conception, in terms of the probability of females giving birth, terminating the pregnancy, miscarrying, having an ectopic pregnancy or a stillbirth. The probability of birth, abortion, miscarriage/ectopic pregnancy/stillbirth was based upon national government statistics for England, Wales and Scotland.^{173–178} For Northern Ireland, the model uses the information about the number of abortions in England and Wales for Northern Ireland residents.¹⁸¹ The probability of miscarriage/ectopic pregnancy/stillbirth is reported by Hospital Episode Statistics (HES) data collected by the Information Centre for Health and Social Care.¹⁸²

Modelling the number of STIs

The number of infections of each type of STI for each individual were modelled using a discrete event simulation approach based on an individual (or agent) multi-STI model.¹⁸³ The model estimated the number of STI cases averted for HIV and also for chlamydia, gonorrhoea and genital warts, according to the risk of infection as shown above and the proportion of sexually active individuals who received the intervention.

Sexual Behaviour

Evidence about the frequency of vaginal sexual intercourse, number of sexual partners and proportions of sexually active teenagers using condoms for vaginal sexual intercourse were taken from the trial. Evidence about the effectiveness of condoms for protecting against STI

infections and reducing heterosexual HIV transmission was estimated based on evidence from the literature.^{184–192} For genital warts, we used to the evidence from a longitudinal study on young people,¹⁹³ while a Cochrane systematic review estimated the reduction in HIV incidence due to condom use.¹⁹⁴

Benefit and cost outcomes

Monetising quality of life and other non-cost benefits

Utility scores were not assigned to teenage conceptions due to lack of evidence from the literature, difficulty in reaching a consensus around the valuation of pregnancies carried to term and those that are not, and the fact that it is not by any means certain that pregnancy as a health state generally diminishes health related quality of life.^{195,196} However, the model can explore the cost-effectiveness of reduced young people conceptions based on willingness to pay criteria. The utilities associated with various STI outcomes were estimated using the evidence from the published literature.^{197–199} We used these values to assign the utility weights to each type of STI considered, which were then used to calculate the quality adjusted life years (QALYs) gained from the reduction in cases of chlamydia, gonorrhoea, genital warts and HIV. The QALYs gained from reduction in each STI was calculated by multiplying the cases averted by $(1 - \text{utility for STI})$ multiplied by $(1 - \text{proportion treated for STI})$.

Costs

The costs incorporated within the health economic model included:

- The costs from the trial for the intervention and control group
- Contraception methods and maternity costs
- Abortion and Miscarriage costs
- Costs for the treatment of very low birth weight babies
- Costs for the testing and treatment of STIs and their health consequences
- Government-funded Benefits
- Medium and long-term loss of earnings due to teenage pregnancy

The costs associated with the resource use collected in the trial are described in section 2 above. The average costs of birth, abortion and miscarriage/ectopic pregnancy/stillbirth were taken from the NHS reference costs.²⁰⁰ The cost of pre-school and primary school education for children was also considered in the analysis, under the assumption that the government would maintain funding at current levels.²⁰¹ While we recognise there are variations in school age start and costs across the four nations, the figure for England was used. The mean per pupil funding was taken from the analysis of the Institute for Fiscal Studies (IFS), with preschool costs only incurred at age 3 and 4, while primary school costs were incurred from age 5.²⁰² The cost of treatment of STIs was based upon the health economic model developed for the NICE Sex and Relationship Education (SRE) public health guidance.¹⁸⁰ Treatment for chlamydia and gonorrhoea was assumed to require one dose of Azithromycin and a GP consultation, whilst treatment for genital warts was assumed to require one dose of imiquimod and a GP consultation. An average cost of HIV treatment per year was estimated based upon the sum of the average cost of care for HIV patients and the average cost of drug treatment. The costs of Benefit payments were also included within the model as they were costs incurred by the public sector, which represent real resource savings if the child that might otherwise eventuate had not been conceived. Evidence on different types of Benefit payments (Child Benefits, Child Tax Credits, Income Support and Housing Benefits) for the target population was taken from published sources, such as the Teenage Pregnancy Strategy report²⁰³ and governmental sources.^{204,205}

Finally, when calculating the number of pregnancies and births averted through the use of contraception, it is generally not correct to assume that all of these births, if avoided today, would not have occurred later as a planned birth.¹⁸⁰ Evidence from the USA National Survey of Family Growth suggests that 60% of unplanned births are mistimed, whereas 40% of births would have otherwise never occurred.²⁰⁶ The full direct and indirect costs of birth can only be considered for those 40% of unplanned births that would have not occurred later. For the remaining 60% of births which are mistimed, the cost averted by contraception was the cost of incurring expenditure at an earlier point than otherwise would have occurred later. We calculated the cost of a mistimed birth (MB) as

$$MB = B - \frac{B}{(1 + r)^d}$$

where B is the cost of a birth, r the discount rate and d is the number of years by which the birth would have been delayed (taken as 2 years in the literature²⁰⁷). Given that the proportion of mistimed births was based on US data, we varied this in sensitivity analysis to assess its impact on the results.

Sensitivity analysis

A number of deterministic (DSA) and probabilistic (PSA) sensitivity analyses were undertaken to assess the impact on the results of key parameters and assumptions in the model. Under each scenario, each parameter was varied either separately in a deterministic way (DSA) or simultaneously using probability distributions (PSA) over a large number of iterations of the model.

Cost-effectiveness analysis

We calculated the mean incremental total cost of *If I were Jack* compared to standard RSE practice for (i) cost per pregnancy averted; (ii) cost per STI averted; (iii) cost per QALY gained over a 20 year time under a healthcare (excluding government-funded Benefits) and public sector perspective (including government-funded Benefits).

All benefits and costs after 12 months were discounted at an annual rate of 3.5% in line with NICE guidance to capture time preferences for costs and benefits.²⁰⁸ All costs are reported in 2019/2020 British Pounds.

Results

The cost of training and teacher time delivering *If I Were Jack*

The cost of *If I Were Jack* was based on the opportunity cost of teachers delivering the intervention. The data were collected via questionnaires from a total of 96 teachers across 30 intervention schools. Estimates for the lesson duration were obtained by taking the average time required for each type of lesson: type A (50-60 min), type B (6 35-45 min), type C (drop-down day/two half days). Estimates for the overall time spent and associated cost were then derived by summing up the estimates computed for each lesson type and

dividing by the total number of students in the *If I Were Jack* group (Table 24). For comparison standard RSE costs £4.42 per student (see Appendix 5, Table 15).

Table 24. Teachers' resource use and costs for preparing and delivering the If I were Jack intervention. Summary statistics are reported in terms of number and proportion of observations, means and standard deviations.

Resource use	N (%)	Time (min) – mean (sd)	Costs (£) – mean (sd)
Lesson preparation	87 (0.91)	109 (84)	£44 (£34)
Photocopy preparation	63 (0.66)	36 (51)	£35 (£82)
Other input (e.g. discussion)	63 (0.66)	78 (114)	£31 (£45)
Other input (e.g. equipment)	50 (0.52)	-	£77 (£74)
Overall preparation	92 (0.96)	187 (172)	£139 (£133)
Lesson delivery	94 (0.98)	262 (89)	£104 (£36)
Total	94 (0.98)	438 (229)	£240 (£153)
Treatment cost per student	-	-	£5.48

Completion of the health-care resource use questionnaires

Out of the 8216 students enrolled in the trial (4100 in the RSE group and 4116 in the Jack group), a total of 7734 (94%) and 6561 (80%) students completed health resource used questions at baseline and follow-up, respectively. Overall, a total of 6519 (79%) students provided complete responses, with a slightly higher completion rate in the intervention arm (jack) (81%) compared to the control group (Standard RSE) (77%).

Sexual health resource use and costs

Each type of sexual health resource use was summarised in terms of number and proportion of observations, means and standard deviations (see Table 25). Given the large number of

students who did not use any resource, summary statistics related to the resource use questionnaire data were reported for students that used the resource only. Cost data were summarised in terms of means and standard deviations for all students since the average costs in the economic evaluation should be calculated based on all participants (see Table 26). The mean adjusted difference of *If I were Jack* minus standard RSE for healthcare resource use costs only is -£2.33 (95% CI -£6.73 to £2.07) per student, adjusting for stratification variables (proportion of free school meals and country) using a random intercept model to account for clustering (students within schools).

Table 25. Number of students with percentage that used each type of resource and mean (sd) resource use for those that used the resource

Resource	Baseline		Follow-up	
	Standard RSE N=4100	Jack N=4116	Standard RSE N=3178	Jack N=3341
Sexual health clinic				
n (%)	58 (0.014)	57 (0.014)	150 (0.047)	113 (0.034)
Mean (sd)	1.67 (1.05)	1 (2.53)	2.11 (1.70)	1 (1.82)
School nurse				
n (%)	256 (0.062)	271 (0.066)	105 (0.033)	131 (0.039)
Mean (sd)	1.57 (1.05)	1.61 (0.93)	1.8 (1.24)	1.63 (1.06)
GP				
n (%)	62 (0.015)	81 (0.020)	138 (0.043)	141 (0.042)
Mean (sd)	1.53 (0.95)	1.81 (1.64)	1.67 (1.34)	1.38 (0.80)
GP nurse				
n (%)	40 (0.010)	41 (0.010)	55 (0.017)	79 (0.024)
Mean (sd)	1.25 (0.54)	1.80 (1.71)	1.64 (1.22)	1.71 (2.05)
Free condoms				
n (%)	256 (0.062)	395 (0.096)	434 (0.137)	427 (0.128)
Mean (sd)	2.56 (4.67)	1 (5.31)	2.93 (3.96)	1 (4.67)
Bought condoms				
n (%)	103 (0.025)	155 (0.038)	299 (0.094)	395 (0.103)

Mean (sd)	4.17 (7.24)	3.92 (7.87)	3.35 (4.81)	3.38 (4.80)
Other contraception				
n (%)	53 (0.013)	75 (0.018)	214 (0.067)	218 (0.065)
Mean (sd)	1.77 (1.92)	1.75 (1.44)	2.03 (2.13)	2.12 (2.28)
Pregnancy test				
n (%)	33 (0.008)	50 (0.012)	85 (0.027)	87 (0.026)
Mean (sd)	1.67 (1.08)	1.30 (0.84)	1.48 (0.87)	2.05 (3.14)
STI test				
n (%)	23 (0.006)	33 (0.008)	50 (0.015)	55 (0.016)
Mean (sd)	1.52 (0.99)	2.55 (3.09)	1.50 (0.84)	2.22 (3.60)
Emergency contraception				
n (%)	18 (0.004)	25 (0.006)	78 (0.025)	96 (0.029)
Mean (sd)	2.17 (2.96)	1.76 (2.24)	1.31 (0.84)	1.98 (2.35)

Table 26. Sexual health care resource use: observed cost means and standard deviations (£) per participant for all students.

Resource	Baseline				Follow-up		
	Standard RSE		Jack	Standard RSE		Jack	
	Mean(sd)		Mean(sd)	Mean(sd)		Mean(sd)	
Sexual health clinic	2.992 (28.708)		4.030 (49.163)	12.352 (70.706)		8.764 (61.427)	
School nurse	1.146 (5.225)		1.240 (5.264)	0.681 (4.404)		0.734 (4.260)	
GP	0.832 (7.692)		1.284 (11.884)	2.552 (15.207)		2.054 (11.135)	
GP nurse	0.154 (1.649)		0.228 (3.033)	0.353 (3.256)		0.505 (4.987)	
Free condoms	0.336 (2.704)		0.665 (3.914)	0.833 (3.616)		0.869 (4.063)	
Bought condoms	0.219 (2.692)		0.310 (3.474)	0.657 (3.607)		0.725 (3.774)	
Other contraception	0.173 (2.163)		0.241 (2.228)	1.019 (5.485)		1.035 (5.726)	
Pregnancy test	0.056 (0.725)		0.066 (0.695)	0.164 (1.130)		0.221 (2.443)	
STI test	0.148 (2.284)		0.354 (6.001)	0.403 (3.587)		0.623 (9.029)	
Emergency contraception	0.299 (7.320)		0.338 (6.744)	0.997 (7.360)		1.765 (15.742)	
Total costs	Mean(sd)	95%CI	Mean(sd)	95%CI	Mean(sd)	95%CI	Mean(sd)
	5.485 (33.979)	(4.303;6.667)	7.403 (59.531)	(5.384;9.422)	18.329 (78.078)	(15.614;21.045)	14.090 (63.544)

Within-trial total costs

For each student, the total costs were computed as the sum of the costs of delivering the *If I were Jack* intervention, obtained from the teacher completed resource use questionnaires, and the costs of the health care resource use, obtained from the student completed questionnaires. The total mean incremental cost of the Jack intervention compared to standard RSE was £2.83 (95% CI -£2.64 to £8.29) per student. The adjusted mean total cost per student at follow-up obtained from the complete cases was £22.59 (95% CI £16.27 to £28.88) for the Jack intervention and £19.78 (95% CI £13.59 to £25.96) for standard RSE. The adjusted analysis controlled for baseline total costs and stratification variables (proportion of FSM and nation) using a random intercept model to account for clustering (students within schools). 95% CIs were calculated based on bootstrapped bias corrected methods over a total of 10000 iterations.

For the MICE sensitivity analysis with 20 imputed datasets, the total mean incremental cost per student of *If I were Jack* compared to standard RSE was £1.81 (95% CI -£7.67 to £4.04).

We also included information on the cost of adapting the intervention to different groups, or updating it over time. The direct costs of making an adapted version for England/Wales with new video production was £35,000 to include all interactive video production and production of adapted online resource materials. Divided by the number of young people randomised to the intervention in England (n=1071) and Wales (n=1160) the cost per student was £15.69, which represents the upper estimate of the cost per student to adapt the intervention. If the intervention were rolled out to all young people 14 years of age in England (664,025 in 2020) and Wales (35,967 in 2020) the cost per student would be £0.05. The direct costs of making changes to the online resource materials for Scotland was £1000 or £1.15 per student if divided by the number of students randomised to the intervention in Scotland (n=866) or £0.02 per student if rolled out to all students aged 14 in Scotland (57,487 in 2020).

Consequences and decision model inputs

The comparative results between the two trial arms in terms of unadjusted odds ratio at each time point and adjusted odds ratios at follow-up are reported in Table 27. Separate odds ratios between the arms are reported by time point (baseline and follow-up) for key

outcome variables including ever had unprotected sex, ever had sex, having a pregnancy or STI test; all adjusted odds ratios were computed after controlling for the corresponding baseline outcome values and stratification factors.

Summary statistics for different types of consequences (by type of contraception and STI) at follow-up are reported in Table 28. Total number of cases and proportions for each type of contraception method (pill, condom, emergency pill, injection, implant, IUD, Diaphragm/cap/spermicide, other, none) and STI (chlamydia, genital warts, herpes, gonorrhoea, pubic lice, trichomonas, syphilis, HIV, hepatitis, PID, other) are separately reported for the standard RSE and Jack group as well as for all individuals in the study.

Table 27. Summary statistics for a selected number of consequences based on the complete cases for the comparison between the Jack and standard RSE and group.

Consequences	<u>Baseline</u> N=7734 OR (95%CI)	<u>Follow-up</u> N=6561 OR (95%CI)	<u>Adjusted</u> N=6519 OR (95%CI)
Ever had unprotected sex	0.849 (0.682;1.106)	0.959 (0.832;1.105)	0.845 (0.625;1.142)
Ever had sex	0.926 (0.771;1.113)	0.980 (0.871;1.103)	0.839 (0.622;1.131)
Testing for pregnancy	1.519 (0.976;2.362)	0.975 (0.719;1.319)	0.952 (0.629;1.440)
Testing for STI	1.431 (0.839;2.442)	1.046 (0.711;1.540)	0.960 (0.619;1.488)

Table 28. Summary statistics for consequences at follow-up in the standard RSE and Jack group for students defined as ever having sex.

Consequences – n (%)	Standard RSE N=688	Jack N=733	All N=1472
Type of contraception			
Pill	188 (0.273)	193 (0.263)	381 (0.268)
Condom	380 (0.552)	402 (0.548)	782 (0.550)
Emergency pill	34 (0.049)	21 (0.029)	55 (0.039)
Injection	32 (0.047)	11 (0.015)	43 (0.030)
Implant	57 (0.083)	39 (0.053)	96 (0.068)
IUD	6 (0.009)	4 (0.005)	10 (0.007)
Diaphragm/cap/spermicide	1 (0.001)	1 (0.001)	2 (0.001)
Other	6 (0.009)	4 (0.005)	10 (0.007)
None	126 (0.183)	164 (0.224)	290 (0.204)
Type of STI			
Chlamydia	3 (0.004)	11 (0.015)	14 (0.010)
Genital warts	3 (0.004)	5 (0.007)	8 (0.006)
Herpes	2 (0.003)	7 (0.010)	9 (0.006)
Gonorrhoea	5 (0.007)	7 (0.010)	12 (0.008)
Pubic lice	2 (0.003)	7 (0.010)	9 (0.006)
Trichomonas	2 (0.003)	5 (0.007)	7 (0.005)
Syphilis	4 (0.006)	7 (0.010)	11 (0.008)
HIV	3 (0.004)	7 (0.010)	10 (0.007)
Hepatitis	2 (0.003)	6 (0.008)	8 (0.006)
PID	2 (0.003)	5 (0.007)	7 (0.006)
Other	2 (0.003)	4 (0.005)	6 (0.004)

Long term decision model

Over 20 years, per 100,000 young people receiving *If I were Jack*, compared to standard RSE *Jack* resulted in 379 fewer unintended pregnancies, 680 fewer STIs, 10 additional QALYs and at a cost saving of £969,876 (excluding government-funded benefits), or a cost saving of £9.70 per young person who received *Jack* (see Table 29). Table 30 reports the overall and treatment specific base-case discounted (at 3.5%) cost estimates from the model disaggregated into the different cost components, and Figure 10 shows the total number of unintended pregnancies, split between number of abortions, miscarriage and births, and the total number of STIs, by STI type. The majority of cost savings, excluding benefits, were due to costs associated with birth avoided. This is as a result of the reduction in unintended pregnancies.

The largest gap was observed in the number of unintended pregnancies that resulted in abortions (1447 for RSE vs 1229 in *Jack*), followed by births (644 in RSE vs 559 in *Jack*) and miscarriages (272 in RSE vs 220 in *Jack*). Similar trends were observed for most types of STIs, with the number of chlamydia cases being associated with the largest discrepancy between the two interventions (1090 in RSE vs 635 in *Jack*), followed by genital warts (363 in RSE vs 227 in *Jack*). Relatively small differences were observed in the cases of gonorrhoea (165 in RSE and 153 in *Jack*) and PID (females only) (94 in RSE and 80 in *Jack*), while no substantial difference was observed in the number of HIV (for both groups around 1).

When nation-specific values were included in the model, including country specific effects from the trial, the largest cost savings and greatest benefits were seen in England (see Table 11 in Appendix 5).

Table 29. Base-case analysis results from the decision model associated with unintended pregnancies, STIs, QALYs loss and total costs, either including or excluding state benefits.

Results	Standard RSE	Jack	Averted outcomes/ Incremental costs
Unintended pregnancies	2,531	2,152	379
STIs	1,853	1,173	680
Discounted			
QALYs loss	28	18	10
Total costs (without Benefits)	£20,405,365	£19,435,489	-£969,876
Total costs (with Benefits)	£191,402,794	£166,076,717	-£25,326,077

Table 30. Cost components of the base-case analysis from the decision model (discounted)

Cost components	Standard RSE	Jack	Incremental
Discounted			
Contraception costs	£4,832,457	£5,982,093	£1,145,703
Pregnancy costs	£600,064	£596,131	-£3,933
Abortion costs	£987,846	£842,759	-£145,087
Miscarriage/EP/Stillbirth costs	£99,396	£81,888	-£17,507
STI treatment	£215,744	£133,738	-£82,005
Birth costs	£13,669,857	£11,794,945	-£1,874,912
State Benefits	£170,997,429	£146,641,228	-£24,356,201

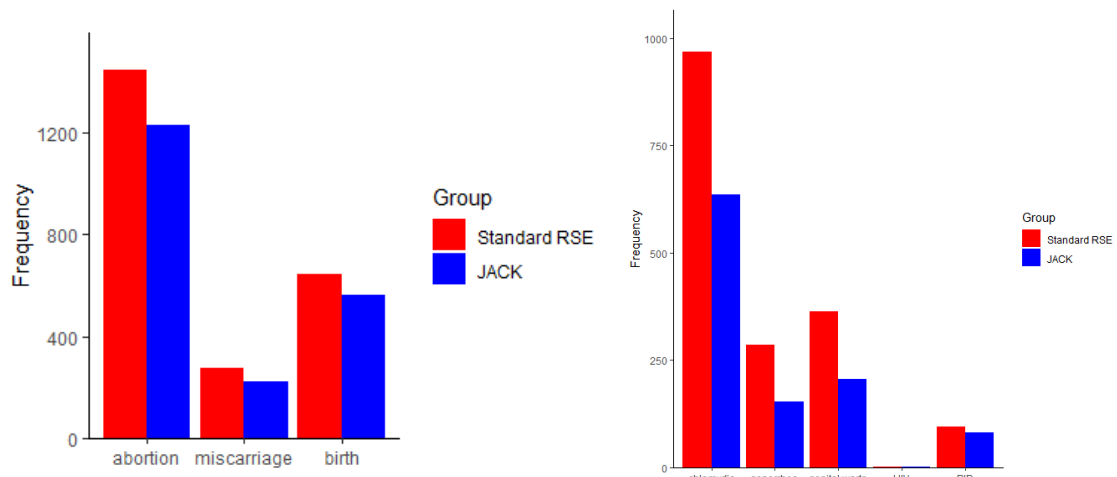


Figure 10. Total number of teenage (<16 years) unintended pregnancies and STIs per 100,000 young people over a time horizon of 20 years for standard RSE compared to the Jack intervention.

Deterministic sensitivity analysis

The results of the one- and two-way sensitivity analyses testing low and high extremes in values for failure rates (the probability of an unintended pregnancy) for condoms and withdrawal, STI prevalence and transmission rates are reported in Appendix 5 in Table A12-14. In all scenarios the *If I were Jack* intervention exceeded standard RSE in that it resulted in better outcomes for a lower cost, except under the extreme scenario where the failure rate of condoms was halved (from 18% in basecase to 9%), with a total number of 178 averted pregnancies (compared to the 379 in the basecase) and an incremental total cost of £1,082,947 (excluding Benefits). Detailed information about the results of the model under a selection of scenarios explored in deterministic sensitivity analysis is provided in Appendix Table A12 and Table A13 (one-way SA) and in Table A14 (two-way SA).

Probabilistic sensitivity analysis

Table 31 and Table 32 show the results from the probabilistic sensitivity analysis (PSA) in which the model parameters were randomly varied by drawing their values from associated probability distributions (see Appendix Table A11 for detailed information about the choice of the distributions and parameter variations). In Table 31, 95% bootstrapped confidence

intervals for the total number of unintended pregnancies, STIs and QALYs and associated costs (either excluding or including government-funded benefits) by treatment arm are reported alongside estimates obtained in the basecase analysis. In addition, 95% bootstrapped confidence intervals obtained under PSA for the averted results for each type of outcome and incremental costs between the two arms are reported and compared with corresponding basecase estimates. In Table 32, total cost results obtained under PSA reported by type of cost component, namely the costs related to contraception, pregnancy, abortion, miscarriage/EP/stillbirth costs, STI treatment, birth and government-funded benefits.

Table 31. Estimates (from basecase) and 95% bootstrapped confidence intervals (from the probabilistic sensitivity analysis) based on 1000 iterations, including the number of outcomes (unintended pregnancies, STIs or QALYs) and total costs associated with each group as well as the averted outcome and incremental cost results between the Jack and standard RSE intervention. Costs were calculated either excluding (without) or including (with) government-funded benefits.

Outcome	n - 95% CI		Total Costs (without benefits) – 95% CI		Total costs (with benefits) – 95% CI	
	RSE	Jack	RSE	Jack	RSE	Jack
Unintended pregnancies	2,531 (2,461; 3,100)	2,152 (2,078; 2,716)	£20,405, 365 (£18,388, ,500; £23,940, 455)	£19,435, 489 (£16,096, ,453; £21,6307 77)	£191,402,794 (£140,341,098;£21 2,374,70)	£166,076,171 (£134,636,171;£17 0,417,28)
STIs	1,853 (1,106; 3,400)	1,173 (412;2, 467)				
QALYs loss	28 (19;45)	18 (14;30)				
Averted outcomes/Incremental costs						
Unintended pregnancies	379 (231;477)		-£969,876 (-£1,556,062;- £446,575)		-£25,326,077 (-47,708,462;- £5,704,927)	
STIs	680 (189;1,467)					
QALYs	10 (5;16)					

Table 32. Cost estimates (from basecase) and 95% bootstrapped CI (from the PSA) based on 1000 iterations) from the decision model disaggregated into seven components: contraception, pregnancy, abortion, miscarriage/ectopic pregnancy/stillbirth, STI treatment, birth, government-funded benefits. For each component, discounted cost estimates associated with standard RSE, Jack and the incremental results are displayed.

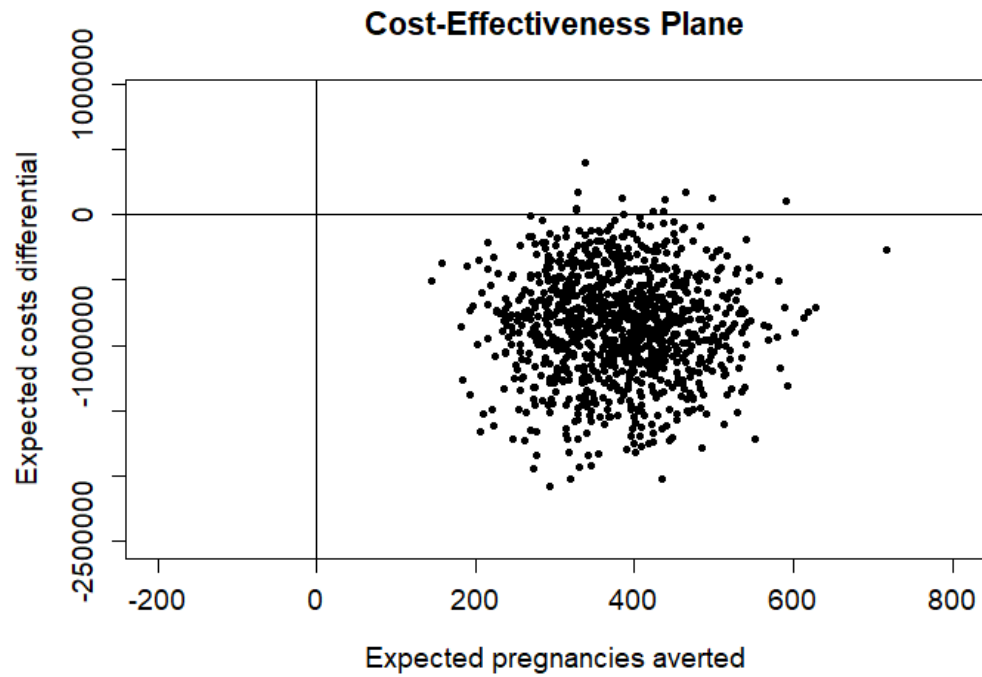
* These costs were calculated by adding up the costs associated with the application and obtainment of government-funded benefits for young mothers as well as state costs aimed at supporting the growth of their children. These costs included: costs for child healthcare, costs of child school education, costs of child benefit, costs of child tax credit, costs of housing benefits, costs of income support.

Cost components	<u>Standard RSE</u>	<u>Jack</u>	<u>Incremental</u>
	Estimate (95%CI)	Estimate (95%CI)	Estimate (95%CI)
Discounted			
Contraception costs	£4,832,457 (£4,645,046; £5,045,220)	£5,982,093 (5,791,743;6,190,293)	£1,145,703 (1,126,841;1,216,578)
Pregnancy costs	£600,064 (506,366;716,344)	£596,131 (480,238;703,678)	-£3,933 (-50,181;42,480)
Abortion costs	£987,846 (825,467;1,139,093)	£842,759 (747,888;947,512)	-£145,087 (-214,646;-60,854)
Miscarriage/EP/Stillbirth costs	£99,396 (73,811;141,232)	£81,888 (54,695;104,823)	-£17,507 (-36,428;-2,020)
STI treatment	£215,744 (94,881;639,241)	£ 133,738 (94,172;447,911)	-£82,005 (-192,179;-408)
Birth costs	£13,885,602 (11,576,613;16,041,941)	£11,928,685 (9,454,455;13,888,264)	-£1,956,917 (-3,299,170;-413,975)
Government-funded benefits*	£170,997,429 (156,208,678;183,834,114)	£146,641,228 (140,286,029;153,431,931)	-£24,356,201 (-32,711,305;-15,922,648)

Incremental results obtained from the PSA, quantifying the impact of sampling uncertainty on basecase estimates, are graphically summarised in Figure 11 using separate cost-effectiveness planes for each type of averted outcome: pregnancies averted, STIs averted and

QALYs gained. The majority of iterations (97.5% for pregnancies, 96.6% for STIs and 95.7% for QALYs) were located in the South-East quadrant as the *If I Were Jack* intervention resulted in better outcomes for a lower cost.

PSA: Cost-Effectiveness Planes



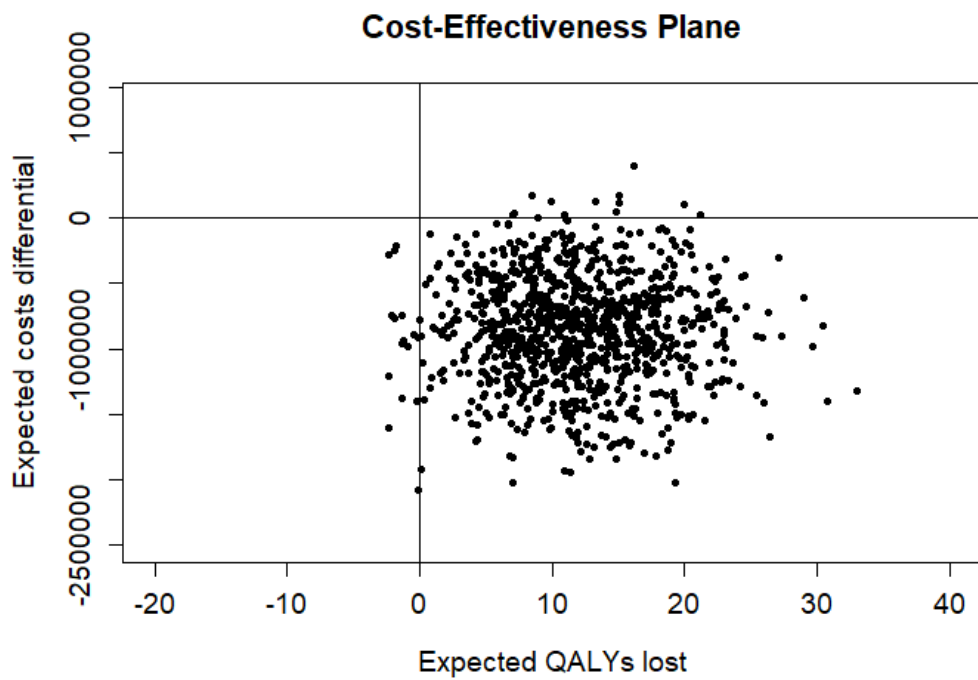
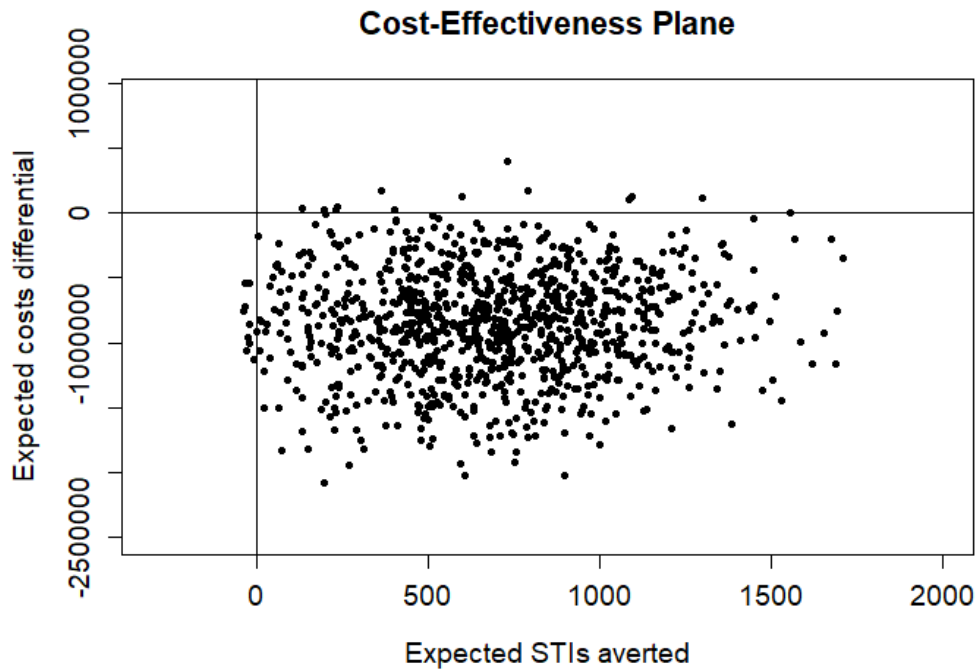


Figure 11. Cost effectiveness planes for the expected number of averted outcomes (unintended pregnancies, STIs and QALY losses) and the total costs increment (without state benefits) between the two intervention groups. Estimates are obtained based on a total of 1000 iterations for the PSA.

Chapter 8. Discussion

Primary and secondary results

The results of the primary analysis found fewer young people in the intervention arm had unprotected sex at follow up than those in the control arm, either because they remained sexually abstinent or used reliable contraception at last sex, but the difference was not statistically significant.

The *If I Were Jack* intervention led to significant improvements in a number of important secondary outcomes relating to our theory of change, notably, knowledge, sexual self-efficacy and communication skills, intentions to avoid an unintended pregnancy, and sexual behaviours in relation to use of reliable contraception among those who were sexually active. There were no significant improvements in attitudes towards gender roles.

Significant improvements in knowledge included improved knowledge of reliable contraceptive methods, how to access contraception, and the legal age of consent. In relation to skills, students in intervention schools reported significant gains in sexual self-efficacy to communicate with partners about consent for sexual intercourse, sexual preferences and sexual readiness. Students also reported greater comfort communicating with peers, parents and professionals about avoiding unintended pregnancy. Students in intervention schools had stronger intentions to avoid unintended teenage pregnancy. While the results indicate no effect of the intervention on the sub-scales of intentions to communicate willingness, timeliness or readiness, students in the intervention schools had significantly stronger intentions to use reliable contraception, avoid peer pressure to have sexual intercourse, not to have sex until ready, and be prepared to share responsibility for contraception with a partner. Analysis of secondary behavioural outcomes showed that there was no significant difference between the intervention and control group in relation to the number of young people who reported sexual abstinence (ever having sex). However, the *If I Were Jack* intervention was effective in reducing rates of unprotected sex through improvements in reliable use of contraception at last sex.

Post hoc exploratory subgroup analysis also suggest the intervention was effective on the primary outcome of reduction of unprotected sex for those who were sexually active at baseline. Additional planned socio-demographic subgroup analysis showed no significant differences between males and females in relation to the primary outcome. There were also no significant differences in relation to ethnicity, nation of the UK where delivery took place, or socio-economic status, as measured by the family affluence scale.

Intervention cost and cost effectiveness

The costs for *If I Were Jack* fall within the 'very low cost' category (<£80 per student per year) for school-based interventions according to the Education Endowment Foundation guidance.²⁰⁹ Taking account of staff time for training, lesson planning and delivery, in addition to health resource use, the cost of *If I Were Jack* was less than £3 more per student compared with standard RSE delivery.

The health economic analysis showed *If I Were Jack* is likely to be cost effective projected over a 20 year time-horizon. Those in the intervention arm were more likely to use reliable forms of contraception at last sex. This observed difference showed that the *If I Were Jack* intervention is likely to be cost-effective as it would result in 379 (95% CI 231 to 477) fewer unintended pregnancies, 680 (95% CI 189 to 1647) fewer STIs, and 10 (95% CI 5 to 16) QALYs gained per 100,000 young people for a cost saving of £9.70 (95% CI £4.47 to £15.56) per young person that receives the *If I Were Jack* intervention compared to standard RSE, with the majority of the costs savings related to health care. Approximately 96% of iterations are in the south-east quadrant of the cost-effectiveness plane, in that *If I Were Jack* results in better outcomes for a lower cost.

Process evaluation

The following questions were addressed: reasons for school participation; intervention delivery and fidelity in the context of overall RSE provision in intervention schools; RSE provision in control schools and potential contamination caused by any changes to provision that could be due to participation in the trial; and perceptions of effectiveness, especially

relating to perceptions of the mechanisms of effectiveness at play in the intervention among students, teachers and school principals/head teachers.

Reasons for Participation: Primary reasons for participation in the trial were an acknowledgement by schools that *If I Were Jack* was a high quality, novel resource; a recognised need by schools to address RSE/holistic pastoral education; recognition that there was a gap in current materials in relation to engaging males; the opportunity for teacher training which could have wider benefits for future RSE programmes; and lastly, the financial incentive. The main reasons for not participating were: research saturation or other commitments; a perception that there was adequate RSE provision already in place; the additional time commitment required by the trial to co-operate with the research components and/or programme delivery.

RSE provision in control schools: The quality of RSE provision in both control and intervention arms, prior to the provision of *If I Were Jack*, was similar. On the whole, the quality of RSE provision in both arms was rated as low to medium when judged against assessment criteria of a best practice tool of RSE implementation in the UK (Sex Education Forum, 2020).²¹⁰ The comparability of low to medium provision in the intervention and control arms was consistent across all four nations, despite the fact the statutory requirements for RSE vary across the nations. There was no indication that the direction of RSE had substantially changed in the control schools as result of participation in the trial.

Intervention delivery and fidelity: The teacher training and classroom activities were generally delivered with medium to high fidelity but the parental component, an optional element, was rarely delivered. The primary reasons reported by teachers for intervention delivery fidelity was the manualised programme, the downloadable classroom materials coupled with some flexibility in how it could be delivered. The primary reasons reported by teachers for deviations in intervention delivery fidelity were insufficient time, perceived clash with school ethos, and inadequate computer facilities. Parents reported not receiving the materials, and embarrassment or fear of having conversations about sex with their child.

Teachers also noted student refusal and/or reluctance at school or teacher level to engage with parents on RSE. Students who did not participate in parental element said it would be embarrassing and awkward.

Perceptions of effectiveness/mechanisms of effectiveness: Students and teachers thought the intervention was an opportunity to gain new knowledge on sex and relationships as well as acquiring skills of where and how to find information and support. According to teachers it 'lifted heads' and was an 'eye opener'. Students reported that learning where they could get 'contraception and other things' was 'very helpful' as well as learning 'where you could get help if you need it' and for males knowing how to access support was largely received as 'new information' for them. Teachers and students both noted increased confidence of students to communicate with peers about sex and relationships. The culturally specific interactive video seemed to be an especially enjoyable and important trigger for generating communication skills on relationships and sexuality in the classroom. It appeared to lay the groundwork and confidence-building for young people in the classroom to pick up and continue the conversation. The gender focus of the intervention, the engagement of males and the generation of empathy and understanding of both male and female perspectives was regarded as a key strength of the programme. Potential limitations relating to this mechanism was a perception that the programme could overshadow female perspectives and an acknowledgment that a short programme may be insufficient to challenge deeply-embedded gendered ideas around sexuality. A further limitation was the heteronormative bias of the intervention in focussing on adolescent pregnancy.

Interpretation of the study findings in light of previous research

Overall, the results relating to the primary and secondary outcomes are consistent with two systematic reviews of systematic reviews of school-based RSE in high income-countries.^{211,212} These reviews of reviews indicate that overall school-based RSE interventions demonstrate effectiveness in enhancing knowledge, skills and intentions, but do not demonstrate efficacy in relation to biological outcomes such as reducing adolescent pregnancy and HIV, or behavioural outcomes such as reduction in unprotected sex. While emphasising the importance of the psychosocial outcomes, these reviews also suggest that

the absence of a clear pattern of effectiveness in relation to biological and behavioural outcomes is because rates of engagement in sexual intercourse and rates of HIV, and pregnancy are low among adolescents under 16 years in high-income countries. Denford et al. suggest that interventions could nevertheless be generating positive changes in sexual behaviours that are not yet manifest. The positive effects observed for the psychosocial secondary outcomes in our study (i.e. knowledge, sexual self-efficacy, communication, and intentions to avoid unintended pregnancy) support this argument as these outcomes relate to mechanisms that research^{28,56–61,63,94} shows are linked to a reduction in risk taking behaviour once young people are sexually active. Furthermore, we found evidence that positive behavioural change to avoid unprotected sex was manifest among those who were sexually active (at baseline) or became sexually active (at follow-up). This finding in the present study is important as previous high quality systematic reviews report few schools-based interventions in high-income countries are effective in increasing contraceptive use or condom use at last sexual intercourse among young people who are sexually active and none of the previous UK based randomised trials of RSE interventions have demonstrated effectiveness on this outcome.^{31,213} A US-based study demonstrated the effectiveness of an after-schools based intervention (CAS-Carrera)⁷⁰ in reducing unprotected sex at last sex among those that were sexually active. However, this study found significant effects for females only, while our study found that the intervention was equally effective for males and females who were sexually active, suggesting the importance of male engagement.

The lack of an overall intervention effect on the primary outcome is in contrast to Haberland et al.'s⁸⁶ systematic review which reported that HIV and sexuality programs that addressed gender or power were more effective than programs that did not. It is clear from the qualitative data that the gender focus of the *If I Were Jack* intervention was explicit to participants. Specifically, the process evaluation results provide evidence that the gendered focus on generating critical gender awareness and male responsibility as being one of the most innovative, stimulating and enjoyable elements of the intervention. Despite this, we did not find evidence that the intervention had any impact of student's attitudes towards gender roles, which was unexpected. It is possible that the Male Role Attitudes measure¹⁴¹ used to assess attitudes towards gender roles was too broad and focused on concepts not specifically targeted by the intervention. We make this suggestion because

significant positive changes in the intervention arm were identified in relation to intentions to share responsibility (among males and females) to use contraception to prevent unintended pregnancy. Also, the broader field of research on interventions engaging men and boys in sexual and reproductive health has reported significant changes in attitudes to gender roles⁷⁵ when measured by the now more widely used gender equitable men's scale²¹⁴ which includes items specifically related to sexual and reproductive health.

Our finding of significant improvements in young people's sexual self-efficacy, which includes self-efficacy to communicate consent for sexual intercourse, sexual preferences and sexual readiness, (subjective perception of when one is ready to become sexually active) with an intimate partner addresses a neglected research gap on young people's sexual desire and preferences as part of healthy relationships in RSE.²¹² While RSE specialists have called for the inclusion of a discourse of pleasure to enhance a more holistic view sexual well-being and other aspects of positive sexuality,^{215,216} the inclusion of the measurement of these outcomes are 'conspicuous by their absence' in randomised trials of sex education.²¹²

The process evaluation provided valuable insights on what RSE is wanted and what is needed and implementable in the classroom, including in faith-based schools in the UK. The *Jack trial* confirms that young people want comprehensive, positive, inclusive and skills-based learning to enhance their ability to develop healthy positive relationships throughout their lives, delivered using interactive, participatory, learner-centred or critical thinking approaches.^{212,217–222} The results also confirm teachers' need for high quality, evidence-informed RSE resource materials with manualised programming that are implementable in the classroom and are designed to enable participatory and critical learning.^{222–225} Adding to this, *both* student and teacher perspectives emphasise the need to enhance teacher training and the skill set of teachers in delivering schools-based RSE.

Strengths and limitations of the study

We undertook a well-conducted, large, cluster RCT of an intervention developed with very substantial user co-design and of proven feasibility. During this study, and prior to trial commencement, we undertook a further optimisation of the intervention to especially enhance its cultural salience across the four nations of the UK through PPI. We brought together a young people's advisory group (YPAG) from the four nations of the UK in a weekend residential event to advise on all aspects of the production of two new interactive video dramas, one using actors from NI (for use in NI and Scotland) and one using actors from Great Britain (for use in England and Wales). Further consultation on all aspects of the intervention, and key aspects of study design were continued with the YPAG and a RSE expert stakeholders group, again from across all of the UK, as well as PPI membership of TSG throughout the trial. RSE experts feedback suggested that the opportunity to learn from other RSE experts across the whole of the UK, as well as invited international experts from WHO and Rutgers, Netherlands, was a key dividend of their partnership on this trial. (See [“6 Nations” Relationships and Sexuality Education Symposium](#)).

The trial was undertaken in a group of schools that are ethnically, culturally, and socio-economically diverse. Uniquely, in a trial of an RSE intervention, we included schools in the four nations of the UK and included schools that are faith-based (though all Christian) as well as those that are not. It is also one of the few trials which has disaggregated the results by sex¹⁴⁹ and included an analysis of how the intervention might promote more equitable gender relationships.

Participating schools were representative of the 263 schools initially approached and only four schools were lost to follow-up, two of which were a result of school closures during the Covid-19 pandemic lockdown measures. Our follow-up was lengthy to allow time both for intervention effects to develop, and capturing the largest number of students before school leaving age of 16 years. While a longer follow-up period would have afforded a greater possibility of capturing intervention effects, especially once students reach the legal age of sexual consent (16 years in the UK), it is very difficult to collect data once students leave school. (In the UK, students may leave school at age 16 or continue until age 18 years). The follow-up period of 12-14 months also allowed for investigation of persistence of intervention effects after the end of the facilitated intervention. Student participation was

high and parental withdrawal of students was low. Our outcome research team and intervention team remained independent throughout the trial and blinding of lead researchers was maintained. Outcomes were assessed using age-appropriate validated instruments. Although self-report outcomes can be open to recall bias, baseline data were collected before randomisation, instruments were used with standardised recall periods, and actions at the school level are very unlikely to have biased reporting between intervention and control arms. While some studies, such as 'the Gatehouse project'²²⁶ have included age of sexual debut as a secondary outcome, owing to concerns expressed by the reviewing research ethics committee relating to responsibilities to report sexual intercourse under the age of 13 years in the UK, age of sexual debut was not included.

Our data are subject to a number of limitations. Our trial was carried out in a randomly selected sample of the whole of Northern Ireland, the South of Wales, urban and peri-urban areas of the South-East of England and the midlands region of Scotland only. Our process evaluation did not identify any factors that might suggest that implementation or effects would be different in schools in other areas, given the level of diversity included, but we do not claim that the findings are generalised to all parts of the UK.

The intra-class correlation coefficient (ICC) in the current study was much larger (0.12) than expected (0.01), based on our feasibility study⁴⁴ and previous research in this area.^{138,151} The sample size was also reduced as a result of losses to follow up, including the loss of two schools due to Covid-19 related closures. Therefore, the study may have been underpowered. While missing data can introduce bias, our data were analysed using an intention-to-treat approach and sensitivity analyses to account for missing data led to little or no change in our conclusions. Missing data is likely due to the sensitivity of doing sex research among any population, but especially among young people who are not yet at the legal age of sexual consent.

The large number of secondary outcomes investigated necessitated multiple statistical testing. However, to mitigate this, we tested only pre-specified secondary outcomes, and subgroup analyses (which were reported using 99% confidence intervals). The subgroup analyses were likely to have been underpowered. Although providing the most useful data

for the majority of outcomes, student self-report is not without limitations. Specifically, it is not feasible to validate young people's self-report of sexual activity with an objective measure, and self-reports therefore offer the best method of assessing sexual activity.²²⁷ However, as is standard in measures of sexual activity, we provided definitions for sexual activities and terminology to aid comprehension, and student questionnaires were administered under exam conditions to enhance confidentiality of responses.¹⁴⁹ All the secondary outcomes were based on validated measures.

Our process evaluation was both broad in collecting data from all schools and deep in exploring some processes in randomly selected case study intervention schools in each of the four nations alongside a student engagement questionnaire in all intervention schools. Although response rates for process data collection were generally high, there were two areas of data collection, the teacher implementation logs capturing delivery of implementation, and surveys of parents, which had lower response rates. In relation to teacher implementation logs, our triangulated data collection approach (of interviews with students, teachers and trial champions) meant that we were still able to assess acceptability and fidelity of the intervention in most schools.

The economic evaluation also had some limitations. The costs and outcomes associated with school-based public health interventions fall across multiple government bodies.²²⁸ Outcomes such as QALYs, which are generally recommended for economic evaluations of health care interventions in the UK, may not be the most relevant outcome of interest when the costs fall on the education sector. To address this limitation, we reported on a range of different outcomes in our analysis. Costs are reported separately to allow different decision makers to determine the relative cost-effectiveness of the intervention on health education, and social welfare. We have included government-funded benefits, sometimes referred to as "transfer costs", as although they are complex to include and it is generally recommended that they be excluded from economic evaluations as they are cost neutral to society,²²⁹ they are a key component of the cost of unintended pregnancies and have been included in previous¹⁶⁸ return on investment analyses of contraception effectiveness. They are also likely to be of interest to some decision makers who might consider keeping government-funded benefits to a minimum, an important political outcome. Finally, a key

outcome that we are interested in, unintended pregnancy, is a rare outcome in the target age group, with costs that occur over a longer time horizon. To address this, we used decision modelling to extrapolate the hypothesised impact of reducing instances of unprotected sex on unintended pregnancies. One of the shortcomings of this approach is that the model was based on a range of assumptions. However, we attempted to address this by subjecting the model to a range of probabilistic and deterministic sensitivity tests.

Conclusion

The need for RSE to engage with young men to promote positive sexual health for all and challenge the gender inequalities that underlie young women's generally poorer sexual health outcomes (especially in relation to sexual violence, adolescent pregnancy, and STIs) is widely endorsed by the WHO⁸³ and UNESCO³³ amongst others.^{75,84,230} The *Jack* trial is the first randomised trial, health economic and process evaluation of a schools-based RSE intervention using a gender-transformative approach to especially engage young men, as well as young women, and promote joint responsibility in preventing teenage pregnancy (by delaying sex until ready or through use of effective contraceptives) and promoting positive sexual health and relationships. The *Jack* trial is also the first UK-wide trial of school-based RSE in which it was demonstrated that it was possible to recruit and retain faith-based schools in a trial of a comprehensive RSE. Although the intervention did not reduce the rate of unprotected sex overall, positive effects were observed in the sexually active population at follow-up and especially among those for whom sexual debut was early (sexually active at baseline, median age 14 years). These results are particularly promising as they indicate that this relatively low dose intervention is most effective for groups at higher risk of unintended pregnancy owing to earlier sexual debut and is likely to reflect the particular relevance of contraceptive use in those who already were, or became sexually active by the 12-14 month follow-up. Furthermore, *If I Were Jack* was effective in equipping young people (whether sexually active or not) with the knowledge and skills required for safe and pleasurable relationships now and in the future.

The health economic analysis showed that based on a 20 year time horizon, the *If I Were Jack* intervention is likely to be cost-effective as it would result in fewer unintended

pregnancies, STIs and a QALY gain for a cost saving of £9.70 per young person that receives the *If I Were Jack* intervention compared to standard RSE, with the majority of the costs savings related to health care. It is a low dose low-cost intervention with the cost per student falling well below the Educational Endowment Fund threshold for 'very low cost' interventions. The school-based method of delivery in *If I Were Jack* provides a universal and efficient way of promoting sexual health and pregnancy prevention owing to the potential population-level reach, and school delivery providing as a sustainable platform for delivery.

Implications for practice

2020 marked the 25th anniversary of the Cairo International Conference on Population and Development (ICPD) and Beijing Platform for Action Women's Rights which fundamentally shifted thinking on sexual and reproductive health towards the need to address gender inequalities that disproportionately affect girls and women's sexual and reproductive health. Equally, it drew attention to the need to engage men and boys in addressing gender inequalities and to engage with men and boys as reproductive agents in their own right. However, the lack of intentional male engagement along with a focus on addressing gender inequalities within RSE, a key starting place in achieving these aims, has been highlighted as an important gap by UNESCO²³¹ the WHO,²³² UNFPA,⁸⁴ the European Society of Experts on Sex Education in their International Guidance on Sexuality Education²¹⁶ and again noted in the latest systematic review of reviews of RSE programme evaluations.²¹²

Closer to home in 2021, a governmental agency (Office for Standards in Education, Children's Services and Skills; Ofsted) inspection of schools in England²³³ illuminated the gendered nature of deficits in sexual and reproductive health. The report found that 60% of young women in schools experienced contact forms of sexual harassment compared to 25% of males. In relation to non-contact forms of sexual harassment, such as unwanted or inappropriate sexual comments, the report found that 90% of young women in schools experienced this compared to 75% of males.

The Ofsted report recommends comprehensive RSE as a fundamental building block to addressing this problem in schools and specifically recommends improved teacher training in RSE. However, an important lesson from the *Jack Trial* to add to this recommendation,

and which builds upon decades of practitioner learning encompassed in the ICPD conference and Beijing Platform for Women's Rights resolutions is that RSE programming should not be gender neutral and assume it will equally engage with males as well as females, or gender blind in relation to addressing gender inequalities.

The problems highlighted by the Ofsted report illuminate the urgent need to address problematic masculinities in school cultures in high-income countries such as the UK. To be successful in doing so, RSE should intentionally and positively engage with young men as well as young women in addressing gender inequalities in sexual and reproductive health. As one young female pupil in the Ofsted report was quoted as saying: 'it shouldn't be our responsibility to educate boys' (page 17).

The *Jack Trial* provides practitioners and programmers with an acceptable, feasible and cost-effective gender-transformative programme. This programme invites young people to engage in young men's perspectives while equally inviting young people to challenge the unequal gender norms associated with male sexual desire and female reproductive responsibility. It encourages communication and behavioural skills among young men and young women to prevent a teenage pregnancy and to know how to seek help. *If I Were Jack* acknowledges sexual pleasure and sexual intimacy in young people's lives and asks young people to consider for themselves the balances between sexual pleasure and sexual responsibility in a gender-equitable manner. In addition, the programme seeks to address deficits in sex education for young men, particularly with respect to teenage pregnancy, identified in the scientific literature which disadvantage adolescent men, as well as adolescent women.^{28,42,46,79,87-92}

If I were Jack is, however, a *brief intervention* of low dose not designed to address all RSE needs. While this study has demonstrated the added value of even such a brief intervention - in terms of increased knowledge and skills among young people for healthy and positive intimate relationships as well as a reduction of unprotected sex among young people who are already sexually active - perhaps the greater added value is the rigorous testing of intentional male engagement and gender-transformative components which could be incorporated more broadly into RSE programming. Recognising that access to RSE is a human right under United Nations Rights of the Child¹²⁶ and optimally delivered as other subjects, over the whole school year across all year groups, in an age appropriate

manner,^{216,230–232} arguably the added value to advancing RSE practice in this trial is in demonstrating how and why male engagement and gender-transformative programming is important.

We recognise too, however, that more work could be done to enhance the gender-transformative components of the *If I Were Jack* intervention. Notably, the intervention could also be enhanced through components which challenge hegemonic heterosexuality to more holistically address gender inequalities as part of RSE and provide a broader range of knowledge, skills and access to services. Nonetheless, this study will provide an important reference point for practitioners to incorporate intentional engagement of young men and gender-transformative components in RSE.

Implications for research

While our study included schools with diverse socioeconomic characteristics, the study was conducted within the context of a high-income country and is not necessarily generalizable outside of this context. We have plans underway to develop and trial adaptations of the *If I Were Jack* intervention in South America and Southern Africa, taking learning from the current study into account. We would also recommend that the feasibility and effectiveness of gender transformative interventions should be explored further in trials across a range of diverse contexts, and in particular, low- and middle-income countries (LMICs). In addition, given the promising results of this brief, gender-transformative intervention, designed to especially engage with males, we would recommend research which could test the integration of the intervention components – or similar components - as part of broader comprehensive RSE curricula.

Although our study shows that it is feasible to recruit and maintain faith-based schools to an RSE intervention, all of the faith-based schools in the current study were of Christian denomination which limits the generalisability of the study to non-Christian faith-based schools. Therefore, we would also recommend that future studies seek to recruit a diverse range of faith-based schools alongside non-faith-based schools (where applicable) in order to better understand the feasibility, acceptability, and effectiveness of school-based RSE

interventions in faith based schools. We suggest (depending on context and prevalence of faith based schools within each context), that this can be best achieved through active engagement with faith based schools during the design or adaptation of the intervention to achieve early dialogue on acceptability.

We did not undertake any data linkage as part of the current study which means it is not possible to assess the longer-term impacts of the *If I Were Jack* intervention on the study outcomes, or in relation rates of unintended pregnancies, as such data is not routinely collected in Northern Ireland. We would recommend that future studies explore the feasibility of anonymous data linkage with routine data (if available) in order to explore the longer term effects of interventions.

As highlighted by Oringanje et al. (2016), and as evidenced in the literature, there is a lot of variation in the way some behavioural outcomes related to sexual activity are reported in RSE intervention studies. This can make it difficult to estimate intra-class correlation coefficients (ICC), and thus the required sample size for cluster RCTs in this area. The ICC in this study was much larger (0.12) than expected (0.01), despite the estimates being based on our own feasibility study²⁷ and previous research in this area.^{28,29} In addition, few RCTs of RSE interventions pre-specify primary and secondary outcomes opening the door to the possibility of outcome switching, hampering the quality of sample size calculations and study interpretation in the field. We have highlighted this with the hope of informing other researchers in planning and designing future studies.

The use of teacher implementation logs to capture teachers' implementation of the programme was not as successful as we had hoped in the current study. Given the importance of implementation data to the process evaluation, we would recommend that there should be a distinct financial incentive (for example £100 voucher) built into trials for collecting this information from individual teachers in each school. This would offset the low response rate by individual teachers and the disproportionate effort by research team in trying to collect these.

The low parental participation observed in our study is a common finding in the experimental research literature on RSE.¹⁴⁹ However, the results of the process evaluation suggest that a significant proportion of parents may not have received programme materials from their child's school which makes it difficult to draw definite conclusions about parental engagement in the current study. We recommend that future studies include training for teachers and school staff in relation to building confidence to engage with parents around RSE. Future studies might also consider closer liaison with schools to ensure information is communicated to parents to invite their participation in the research. Although the use of digital media to engage parents in this study did increase participation when compared with our earlier feasibility trial⁴⁸ there is a need to further explore opportunities and mechanisms to improve parental engagement in RSE.

Further work is required to evaluate the suitability of different health economic outcomes for inclusion in economic evaluations of sexual health interventions aimed at young people. Extrapolating outcomes over longer-time horizons will capture a wider range of cost and outcomes, but is subject to a wide range of uncertainty.

Acknowledgements

We are indebted to the pupils, teachers and school principals/head teachers from schools in Northern Ireland, England, Scotland and Wales who participated in the study, giving so generously of their time and sharing their experiences with us. There was a designated 'trial champion' teacher in each school with whom the research team closely liaised and who gave invaluable support to the trial study team. Included in our thanks to participants are the Relationships and Sexuality Education (RSE) experts from the four nations of the UK who contributed important insight into RSE provision and future directions. We are also grateful to the administrative and support staff in all the schools who provided valuable support to facilitate the research.

We would like to acknowledge the advice and support received from the Chair of the Trial Steering Committee, Prof Vivien Coates (Florence Nightingale Foundation Chair in Nursing, University of Ulster) along with all the members of Trial Steering committee. The scientific members were Dr Cary Roseth (Michigan State University), Alison Hadley OBE (University of Bedfordshire) and Prof Michelle McKinley and Prof Sarah Miller (Queen's University Belfast). The educational professional members were, Dr Darrin Barr (School Principal), Maire Thompson (School Principal) and Grace McCarthy (Teacher) who guided us with their advice. The pupil representatives were Dylan O'Neill (Parent), Iman Zatari (Pupil) and Kian Wilson (Pupil). All provided valuable assistance to us throughout the study.

We are also very grateful to those involved in the new production of the *If I Were Jack* interactive video drama for this study. Thanks to the producers and directors at Morrow Communications and to the whole cast and crew. In addition, our appreciation goes to Peter Gee of Cardiff University (Lead, the ALPHA young people's research advisory group) who facilitated a two-day residential consultation with young people to advise on all aspects of the production and to the 12 young people involved from each of the nations of the UK.

We also express sincere gratitude to the members of the Trial Stakeholder Advisory Committee who provided valuable advice on comprehensive relationship and sexuality education across the whole of the UK. The membership was Joanna Brown (Belfast Health and Social Care Trust), Kathryn Gilbert (The Council for the Curriculum, Examinations & Assessment), Dr Louise Herron and Barbara Porter (The Public Health Agency), Michael

McCarten (The Rainbow Project), Dr Julie Bishop (Public Health Wales), Wendy Ostler (Healthy Schools Wales), Elaine McCormack (National Health Service Greater Glasgow and Clyde), Suzanne Hargreaves (Education Scotland), Felicity Sung (The Scottish Government), Christina McMellon (City of Edinburgh Council), Alison Hadley, OBE (University of Bedfordshire), Jonny Hunt (Going Off the Rails, England), Lisa Hallgarten (Sex Education Forum, London), Dr Amy Booth (Barnsley Council, England) and Jonathan Baggaley (Personal, Social, Health and Economic Association, England).

In addition, we would like to express our appreciation in thanking a number of people who helped towards the successful completion of the study. Dr Eimear Ruane-McAteer, Dr Kim Appleton, Dr Florian Tomini, Dr Michelle Templeton, Dr Rhonda Curran, and Jaele Rollins were involved for a period of the study and made valuable contributions to it. Dr Lisa Maguire and Professor Adam Fletcher contributed to early stage proposal development. Mr Paul Doherty was the Northern Ireland Clinical Trials Unit manager for the study.

Finally, we would like to thank the Ethics Committee at the School of Nursing and Midwifery, Queen's University Belfast, chaired by Dr Oliver Perra, to whom we are grateful for guiding the study's ethical approval process.

Ethical approval

Ethical approval for the study was granted by the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast in July 2017 (Reference number 11.MLohan.05.17.M6.V1).

This trial was registered with the ISRCTN (reference number 99459996).

Funding

This study was funded by the National Institute of Health Research Public Health Research programme (NIHR PHR 15/181/01).

The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Public Health Research Programme, NIHR, NHS or the Department of Health.

Queen's University Belfast agreed to act as sponsor for the research.

Contribution of authors

Maria Lohan (Professor of Social Science and Health) was the Chief Investigator. She conceptualised the study, led design of the study, the research and writing of the manuscript. She conducted the trial's progress review, including staff and resources and ensured that the trial was administered in a financially responsible manner.

Kathryn Gillespie (Research fellow) was the lead researcher on the process evaluation data analysis and write-up. She contributed to data collection and to trial data interpretation and write-up.

Emily Warren, Ruth Lewis, Theresa McShane, Kelly Buckley and Linda Adara, (Research Fellows) led school recruitment and study data collection and contributed to process evaluation study design and data analysis and writing of the manuscript.

Áine Aventin (Lecturer, Sexual and Reproductive Health) (co-investigator) was trial manager (year 1) and had day-to-day responsibility for the conduct of the trial and the operations of the research team in year 1. She also contributed to conceptualisation and design of the study, optimisation of the intervention, process evaluation data analysis and writing of the manuscript.

Aisling Gough (Research Fellow) and **Susan Lagdon** (Lecturer, Psychology (Mental Health)) were trial managers during years 3 and 4 and year 2, respectively. During this time they had day-to-day responsibility for the conduct of the trial and the operations of the research team. They contributed to data collection and writing of the manuscript.

Aoibheann Brennan-Wilson (Research Fellow) was closely involved in interpretation of the trial data and the writing of the manuscript.

Lisa McDaid (Professor of Social Science and Health) (co-investigator) contributed to the conceptualisation and design of the study, led the Scotland study team, contributed to trial and process evaluation data interpretation and to writing of the manuscript.

Rebecca French (Associate Professor of Sexual and Reproductive Health Research) (co-investigator) contributed to the conceptualisation and design of the study, led the England study team, contributed to trial and process evaluation data interpretation, and writing of the manuscript.

Honor Young (Senior Lecturer) (co-investigator) contributed to the conceptualisation and design of the study, led the Wales study team, contributed to the intervention optimisation, trial and process evaluation data interpretation, and writing of the manuscript.

Clíona McDowell (Head of Statistics, Northern Ireland Clinical Trials Unit) (co-investigator) led on the design of the statistical analysis plan and statistical analysis and contributed to the writing of the manuscript.

Danielle Logan (Biostatistician) and **Sorcha Toase** (Biostatistician) contributed to statistical analysis and to writing of the manuscript..

Rachael Maree Hunter (Associate Professor - Health Economics, Head of the Health Economics Analysis and Research Methods Team, Priment Clinical Trials Unit, UCL) (co-investigator) and **Andrea Gabrio** (Assistant Professor in Statistics) designed and conducted the health economic analysis.

Mike Clarke (Professor and Director of Northern Ireland Clinical Trials Unit) (co-investigator) contributed to the conceptualisation and design of the study, trial data interpretation and contributed to the writing of the manuscript.

Liam O'Hare (Principal Research Fellow) (co-investigator) contributed to conceptualisation and design of the study, to the trial and process evaluation data interpretation and contributed to the writing of the manuscript.

Chris Bonell (Professor, Public Health Sociology) (co-investigator) contributed to the conceptualisation and design of the study, trial data interpretation and contributed to the writing of the manuscript.

Julia Bailey (Associate Professor in Primary Care) (co-investigator) contributed to the conceptualisation and design of the study, intervention optimisation and to the writing of the manuscript.

James White (Reader in Population Health) (co-investigator) contributed to the conceptualisation and design of the study, development of sample size calculation and recruitment strategy, statistical analysis plan, trial data interpretation and writing of the manuscript.

All co-authors (except Aishling Gough who was unavailable) approved final manuscript.

The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the Department of Health.

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Appendices