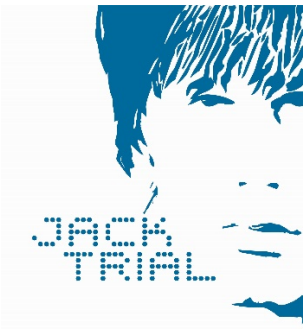
The JACK Trial

A multi-site cluster randomised trial of an interactive film-based intervention to reduce teenage pregnancy and promote positive sexual health



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Chief Investigator: Professor Maria Lohan

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PROJECT PROTOCOL

The JACK Trial: A multi-site cluster randomised trial of an interactive film-based intervention to reduce teenage pregnancy and promote positive sexual health

1. Overview

The JACK Trial has a two-stage design lasting 48 months in total. Stage One, 12 months in duration, involves refinement of an interactive film-based relationship and sexuality education intervention called *If I Were Jack* and pilot testing against progression rules to Stage Two. Stage Two is a 36-month Phase III Cluster Randomised Controlled Trial in 66 schools across the UK with embedded process and health economic evaluations. The study aims to determine the effectiveness of the *If I Were Jack* intervention in reducing the incidence of unprotected sex in boys and girls by age 15. It will incorporate a cost-consequences analysis of the intervention and a decision model of long-term costs and consequences as a result of behaviour change. It will also involve a process evaluation using a mixed-methods triangulated design to assess fidelity to implementation protocol and determine the contextual factors associated with participation and effectiveness.

2. Background

2.1 Existing Research

The UK has the highest rate of teenage pregnancy in Western Europe [1]. While conception rates for girls aged under 18 have halved since 1998 in England and Wales, and now stand at 22 per 1000 population [2] it remains that just under 26,000 teenage women became pregnant in England and Wales in 2014 and approximately half of these ended in legal abortion [3]. The conception rate for Scotland was 37.7 per 1000 in 2013 (last available data) [4]. In Northern Ireland (NI), abortion is illegal and is only considered lawful in exceptional circumstances where the life of the pregnant woman is at immediate risk or if there is a risk of serious injury to her physical or mental health. Reflecting this different legal framework, 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.[5] 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) [6].

Although the life course for teenage parents is not universally negative [7], the social disadvantage and exclusion that are linked to teenage pregnancy are considered problematic [8]. Unintended teenage pregnancy can lead to considerable adverse health problems for teenagers and their infants as well as generating enormous emotional, social and economic costs for teenagers, their families and society [9,10]. While unintended teenage pregnancy is a complex phenomenon that cannot be prevented through RSE alone [11–17], high quality 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 [18–22]. The UK governments all emphasise the policy importance of decreasing under-18 conception rates and increasing sexual health precaution behaviours in teenagers via the implementation of RSE in schools as a key objective in current sexual health policies [23–25]. Drawing from robust representative epidemiological data of school-aged children across the UK (the WHO Health Behaviour in School-aged Children Survey GB, 2014) [26] and Young Persons' Behaviour and

Attitudes Survey NI (2013) [27] , it is known that between 25% and 33% of 15-year-olds are having sex. Looking more closely at the rates of unprotected sex for this age group reported in these surveys, we can determine a rate of 2.8% reporting unprotected sex (overall in England, Wales, Scotland and NI) (Sample n= 7904 and n reporting unprotected sex =224).

A number of systematic reviews have identified the characteristics of effective RSE programmes which help increase their impact on sexual risk-taking behaviours [16,28–34]. These 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-specific 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 of these different elements and is therefore predicted to decrease young people's sexual risk-taking behaviour in relation to avoiding teenage pregnancy, as discussed in more detail in the evidence below.

Evidence supporting a theory-based approach

Providing a theoretically informed foundation for sexual health education programmes is considered key to effectiveness because it ensures that the most important determinants of young people's sexual behaviour are targeted [19,30,32,35–37]. The underpinning theoretical framework for this intervention combines the well-established Theory of Planned Behaviour [38] and recent updates to this theory [39] which focus on the individual behavioural antecedents of an unplanned pregnancy along with an understanding of the broader socio-environmental factors (such as socio-economic status (SES)) and underlying values (such as religiosity and gender ideologies) associated with the occurrence of teenage pregnancy [15]. The *If I were Jack* intervention has been designed to increase teenagers' intentions to avoid an unplanned pregnancy by abstaining from sexual intercourse or consistently using contraception. In order to achieve this impact, the intervention targets six psycho-social mechanisms which research indicates are related to a reduction in risk-taking behaviour: knowledge, skills, beliefs about consequences, social influences, beliefs about capabilities, and intentions [16,40,41] (see theory of change model in Appendix 1). The intervention components include eleven different activities which provide pupils with educational information and opportunities for discussion, skills practice, reflection and anticipatory thinking [42]. Each of the activities included in the intervention is designed to specifically target one or more of these psycho-social mechanisms. The intervention components also include explicit reference to the impact of socio-economic status, religion and gender norms on sexual behaviour, inviting participants to think through how underlying social influences, such as social class and gender norms of sexual behaviour, can also be challenged through individual agency.

Evidence supporting the use of culturally relevant and gender-specific interventions

Teenage boys have been neglected in relation to RSE, particularly with respect to teenage pregnancy [19,43–48]. The lack of targeted resources for teenage boys in relation to unintended pregnancy is prioritised in recent European and global health policy papers [49,50] and identified in systematic reviews commissioned by the US-based National Campaign to Prevent Teen Pregnancy [46,51], and the NIHR [16]. The *If I were Jack* intervention is aimed at teenage boys and girls but it explicitly draws attention to the role of teenage boys in preventing an unintended pregnancy in their lives. A specific aim of the *If I*

were Jack resource is to open up for scrutiny the gender norms which typically situate the issue of a teenage pregnancy as a woman's problem – by filming the Lesson 1 interactive video drama (IVD) from the perspective of a 16-year-old-boy. Nonetheless, care has also been given to not exclude teenage girls' perspectives. While both girls and boys are invited to imagine they were Jack, the interactive film also contains three questions which focus on how Emma, the female character, might be feeling.

In relation to cultural relevance, we incorporate the medium of drama and film in an interactive computer-based modality. In so doing, we are 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 [20,29,32,35,52]. The feasibility study [53] demonstrated that the use of locally produced contemporary drama (in the IVD) made sex education more enjoyable and engaging for pupils. As Ingham and Hirst [21] have noted, 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, a factor that was identified as a possible barrier to impact [16]. The feasibility study also showed that the ability of users to identify with the key characters in the IVD, and the overall tailored nature of the intervention in terms of linking in with local services, was central to its appeal and acceptability to pupils. Added to this, teachers stated they were more willing to implement the intervention because it was clearly linked to statutory curriculum goals for NI. The transferability study demonstrated that while pupils in Scotland were happy with a NI accent, and preferred it to a Scottish accent of a different cultural group, pupils in England and Wales struggled with the NI accent of the characters. Based on this feedback and the appeal of locally produced drama, we will make two new versions of the IVD to allow for cultural adaptation to England and Wales along with an overall updating of the IVDs for all. We will also culturally adapt the intervention materials to link with local services and statutory requirements of RSE in each of the countries, where relevant.

Evidence supporting the use of interactive computer-based interventions

Recent systematic reviews have shown the value of interactive-computer-based interventions [32,33,54] and a meta-analysis examining these reviews in relation to the theoretical mediators of safer sex [34] concluded that they were successful in impacting knowledge, attitudes and self-efficacy relating to sexual health. The IVD invites both teenage boys and girls to imagine being Jack *and* being in the situation of a teenage boy whose girlfriend has just discovered she is unintentionally pregnant. Wearing head phones and sitting at individual computers, each participant must answer questions on how he/she would act as the drama unfolds. When we used an earlier version of this IVD as part of a collaborative research study on teenage men's attitudes and decision making in relation to a teenage pregnancy, 85% of a sample of male pupils in Ireland (N= 360) and 72% in Australia (N= 386) agreed or strongly agreed with the statement that it 'helped me understand the effect an unplanned pregnancy would have on a guy like me'. Seventy nine percent of users in Ireland and 69% in Australia agreed or strongly agreed that the IVD 'made me realise that I should never get myself in that situation' [55]. Pupils who used the intervention during the feasibility study indicated that they found the IVD engaging. Teachers commented that even pupils with challenging behaviours appeared genuinely interested in Jack's story.

Evidence supporting the use of skills-building components

Reviews and trials of health promotion and educational interventions show that simply providing information does not lead to behaviour change and that instead it is necessary to support young

people to develop their own communication skills in relation to preventing risky sexual behaviours [16,18–20,30,32,35,37,56,57]. The *If I were Jack* intervention 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 desensitize the discussion of sexual and reproductive topics through practicing explicit 'verbal scripts' [35] for such conversations between young men and women. A recent NIHR-funded systematic review [16] 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. The review noted that these variables are no less valuable than behavioural variables because they provide young people with a solid foundation on which to make sexual decisions.

Evidence supporting the involvement of parents in relationship and sexuality education

Although evidence suggests that schools are an important context for sex education [35,58,59] recent systematic reviews have also shown that programmes that reach beyond the classroom can enhance effectiveness [16,22,60]. In particular, factors such as parental monitoring and supervision, and familial communication have been associated with teenage sexual behaviours [61,62]. 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 [63–65]. 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 two ways. First, the resource includes a homework task and materials to generate the communication from the child's perspective. Second, it includes education and guidance in the form of two short animated films for parents and guardians to inform them of the resource being used in the classroom and the homework activity, information about the importance of communicating with their child about teenage pregnancy and sexual health, and hints and tips for doing so. The parental videos will also be shared with children in the classroom to increase empathy with parents by raising scenarios of "If I were Jack's parent". These on-line video materials for parents will replace the earlier planned teacher-facilitated face-to-face information and discussion session because parental attendance at these sessions was very low (2.3%) in the feasibility trial. Recent studies [66–68] demonstrate the potential of embracing such 'education entertainment' modalities as engaging adjuncts to school-based education. This refinement has been funded by the Health and Social Care Research and Development Office (HSC R&D) of NI. It was completed in 2016 and will be tested in Stage one of the current study through analysis of online viewing statistics and an online survey with parents to inquire into their views about the perceived usefulness of the delivery method and content. However, we regard this parental component as a bonus of the intervention design, rather than as something that is integral to it and it is not core to the intervention effects for pupils. The logic model of our intervention is based on the teacher delivered classroom components to pupils (Appendix 1), rather than parental engagement. Therefore, the intervention will prove its effectiveness on the basis of what is delivered to pupils directly through classroom activities (regardless of whether parents chose to find out more by watching the videos). Based on our research to-date, and extensive consultations with school principals, teachers and pupils, and the results of a parental survey in the feasibility study, engagement of parents is likely to improve when we deliver through a more favourable medium directly to them via electronic devices. However, engagement is still unlikely to be high and so it would not be wise to plan core delivery of our intervention (which is designed for pupils) through parents. Thus, although we regard this parental component as good

practice, it is not a requisite of intervention success, and, therefore, not included in 'stop/go' criteria of stage one to stage two (see below).

2.2 Rationale for the Current Study

The proposed study is justified on the following grounds:

i. *The public health concern of teenage pregnancy and the potential reach of targeted school-based interventions to provide young people with a solid foundation on which to make sexual decisions*.

Teenage pregnancy is both an outcome of, and a contributor to, inequalities in health [8], and the costs of teenage pregnancy to the exchequer are high. Each teenage pregnancy is estimated to cost £20,000 on the basis that a teenage pregnancy effectively withdraws the mother from the labour market for at least eighteen months and accounting for unemployment benefits and administration, plus tax revenue foregone [24]. Educating to achieve a reduction of unprotected sex has other sexual health benefits also. The aggregate projected spend for 2013-2020 for treating both unintended pregnancy and STIs across the UK is estimated to be between £84.4 billion and £127 billion. This is based on a projected spend of £11.4 billion of National Health Service (NHS) costs as a result of unintended pregnancy and STI costs, and between £73 billion and £115.3 billion of wider public sector costs [69]. Targeting teenagers is especially efficient since they are the group at highest risk of unprotected sex [70,71] . This low–cost (£13.66 per pupil, including teacher training), theory informed and user endorsed intervention, if found to be effective, could be rolled out universally to pupils attending schools across the UK. For example, in NI, the intervention could be delivered to nearly 25,000 pupils in the target year group, and in Scotland, to approximately 290,000 pupils. This is consistent with the evidence that universal interventions are necessary to achieve population-level reductions in teenage pregnancies [72–75].

ii. The need to develop and evaluate age and gender-specific RSE resources

The need for gender-sensitive interventions to address teenage pregnancy has been highlighted as a global health need by the World Health Organisation [49,56] and recommended in systematic reviews of RSE education [16,46,51,76]. In the UK in 2013, Ofsted [82] reported that 40% of schools were failing to provide high quality age appropriate RSE in part because of a lack of tailored resources. We aim to initiate a process of robust scientific evaluation which will ultimately produce generalisable findings especially relating to gender-specific interventions. The intervention we propose is gender-inclusive in terms of intent and impact and it can be used in mixed sex classrooms, but is gender-specific in that it specifically targets the inclusion of young men by developing the IVD from a young man's point of view.

iii. The strengths of the If I were Jack intervention

The *If I were Jack* intervention is grounded in our earlier empirical research on young men's attitudes to unintended teenage pregnancy [43,55,77], was developed in consultation with key health and education experts, pupils and teachers, and is informed by the best available evidence regarding the development of classroom-based RSE interventions. It is predicted to impact on a number of behavioural and psycho-social mediating variables which research suggests decrease sexual risk-taking behaviour. It uses an innovative combination of intervention components which address deficits in existing RSE interventions and aim to maximise potential impact. The evidence for each of

these components has been presented above. In addition, we have taken steps to optimise fidelity to implementation protocol, a factor which has been implicated in failure to demonstrate impact in previous UK-based programmes [17,78]. For example, in the SHARE study, issues with fidelity to the implementation protocol related to time constraints and the low priority given to delivering the overall programme in some schools [78]. We therefore believe that although *If I were Jack* is shorter than previous UK based programmes, this is perhaps one of its strengths, because it demands less time of the already busy RSE teacher. Furthermore, we have developed and refined the intervention in close consultation with teachers and pupils and findings from the feasibility trial have indicated that its content, components and implementation process are acceptable and feasible. Also, the intervention includes focused face-to-face training for RSE teachers which emphasises the importance of fidelity to protocol. We believe that these factors will enhance implementation.

iv. The educational and policy demands for such an intervention

The House of Commons Education Committee inquiry into RSE in schools (2015) [79] concluded that urgent attention should be given to providing young people with high quality RSE and the right to information to keep them healthy and safe. The Scottish Government recently published its first Pregnancy and Parenthood in Young People Strategy in which high quality Relationships, Sexual Health and Parenthood (RSHP) education is recognised as a key intervention and fundamental to respecting and fulfilling the human rights of young people in Scotland [25]. Letters of support for this study from across the health and educational sector of the UK confirm the need and demonstrate support for this study, including in NI, the Chief Medical Officer, the Public Health Agency NI, the Department of Health, Social Services and Public Safety and the Council for Curriculum Education and Assessment, Public Health Wales, The Scottish Government, Education Scotland and Brook England (a leading sexual health charity for young people). Several of the above stakeholder organisations are also offering in-kind contribution in terms of membership of a study stakeholders group along with co-funding from HSC R&D Office NI to refine the parental component. The extent of the stakeholder investment in this project attests to the widely held need to evaluate evidence-based, theory-informed RSE resources which clearly target teenage boys as well as girls in relation to unintended pregnancy and improving sexual health and well-being.

v. The collaborative approach between the research, policy and practice communities

We believe the research and policy community will benefit because the proposed research process provides a model for an inclusive, collaborative approach to the development of research-based resources that has already proven transferable to other areas of policy and curriculum, e.g., other spin-out programmes such as, If I were Nick, a smoking cessation programme (www.men.quitnow.ca/tactics/nick).

vi. The capability of the research team to deliver high quality research to research deadlines

It is the combination of experience and knowledge of the team of investigators that is crucial to making this project a success. The team includes experts in the fields of gender and sexual health and schools-based research along with the NI Hub for Trials Methodology Research and the NI Clinical Trials Unit, and research team members with extensive expertise in process evaluation and psychometric measurement. During the course of the feasibility study and transferability study, we have demonstrated that we can deliver high quality research to deadline while working around the constraints imposed by school calendars.

3. Research Objectives

The aim of this study is to determine the effectiveness and cost effectiveness of the *If I Were Jack* intervention in reducing rates of unprotected sex among teenagers under 16 years of age and to better understand the contextual conditions of effectiveness through a process evaluation. The study is split into two stages. **Stage One** involves development and testing of intervention refinements. These refinements will be assessed against progression ('stop/go') criteria before progressing to Stage Two. **Stage Two** is a cluster RCT in 66 post-primary schools across the UK with embedded process and health economic evaluations.

The objectives of **Stage One** are to:

1. Convene, a) a UK-wide Stakeholders Group composed of RSE specialists, statutory stakeholders and b) young people's advisory groups (YPAGs) to inform refinement of intervention and continue to build implementation capacity over the longer term.
2. Produce updated and culturally refined versions of the *If I Were Jack* interactive film, 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 countries where relevant (Scotland and Wales) and inserting 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 NIHR before progressing to Stage two.

The objectives of **Stage Two** 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 countries 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 and potential contamination 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.

4. The Intervention

If I were Jack is an evidence-based, theory-informed, user-endorsed intervention designed to meet the much neglected pregnancy education needs of teenage boys and intended to increase both teenage boys' and girls' intentions to avoid an unplanned pregnancy [42]. It has been designed, developed and piloted in NI, Ireland and South Australia over six years in consultation with pupils, teachers, sex education specialists, and education and health promotion departments [42]. For the purposes of the trial, the intervention materials and interactive film are available online on a password protected website and in-person teacher training will be provided (see below 'Implementation'). Post-trial, the online resource will be transferred to a recognised provider of RSE education in each of the four countries. In NI, this will be the Public Health Agency. In Scotland, this will be Education Scotland. In England this will be the PSHE Association, and in Wales, this will be Public Health Wales. The JACK Feasibility Trial [80] determined that the cost of delivery of the intervention per pupil, including teacher training, is £13.66 per pupil. Further details on the *If I were Jack* resource, including excerpts from the film are available from: www.qub.ac.uk/IfIWereJack.

4.1 Intervention components

- The *If I Were Jack* interactive film which asks pupils to put themselves in Jack's situation and consider how they would feel and what they would do if they were Jack[1];
- Classroom materials for teachers containing four 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;
- Sixty-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 and factsheets about the intervention and unintended teenage pregnancy in general for schools, teachers, teacher trainers, young people and parents/guardians.

4.2 Experimental Intervention

The intervention is a classroom-based RSE resource designed to improve teenage boys' as well as girls' sexual health precaution behaviours. The resource, entitled *If I were Jack* is based around a computerised IVD which tells the story of Jack; a teenager who has just found out that his girlfriend is unexpectedly pregnant. It includes classroom materials for teachers containing detailed lesson plans and resources for young people including a factsheet and worksheets for classroom activities and homework tasks. Teachers can deliver the intervention to pupils during four 50-60 minute or six 35-45 minute weekly lessons but the objective of most of the activities is generating pupil agency and enhanced peer communication to raise intentions to avoid an unintended pregnancy.

4.3 Comparator Intervention

The control group will not receive the *If I were Jack* intervention and will continue with normal RSE practice.

[1] The film allows for different response choices but the film doesn't change in response to these choices.

4.4 Setting

The *If I were Jack* intervention will be delivered to pupils in the 33 schools in the intervention group by RSE teachers as part of Key Stage 4 Personal Social and Health Education (PSHE) curriculum (NI, Wales and England), and in Scotland, as part of *Curriculum for Excellence* Relationships, Sexual Health and Parenthood education.

4.5 Implementation

Implementation will be preceded by teacher training in the intervention schools. Teachers will take part in a 90-minute training session which will detail the components of the intervention and its delivery and highlighting the research procedures. The training will take place on a one-to-one or group basis in the participating schools (as requested by the school). Sessions will be arranged at times that are suitable for teachers. The training session for teachers follows the teacher-trainer protocol which is part of the intervention and includes information about the resource and how it should be delivered. The training will be delivered by RSE co-ordinators in each of the countries: the RSE co-ordinator for NI employed by Queens University Belfast; in Scotland, this will be MRC/CSO Social and Public Health Sciences Unit; in Wales, this will be the Healthy School Coordinators (Public Health Wales); and in England this will be an independent sexual health youth worker and RSE coordinator. Teacher trainers will be asked to audio-record a random sample of 4 training sessions (6 for Northern Ireland). Trial Coordinators will make a random selection of which sessions these will be and inform the teacher trainer during the teacher training session. At the beginning of a session that is to be audio-recorded, the Trial Coordinators will distribute information sheets and consent forms to the teachers in relation to the audio-recording. If any one teacher declines to consent to the session being recorded, the trainer will not record the session and the Trial Coordinator will pick another session to be recorded. Teacher training satisfaction surveys will be delivered to teachers by the trainer at the end of all training sessions (not just the 4 audio-recorded sessions). These will be collected by the trainer and returned to the Trial Coordinator, along with information sheets and consent forms collected at the same time.

A dedicated website for the intervention has been developed, with the primary intention of providing summary information to potential users. A password protected version of the film and associated materials is available on the website (www.qub.ac.uk/IfIWereJack). Teachers will also be provided with hard copies of the film and resource materials during the training session. Participating schools will cover the costs of printing/photocopying paper materials for classroom use. The feasibility study demonstrated that this is not problematic for teachers.

The parental component of the intervention will be delivered through two short online animated films. The links for these videos will be texted and/or emailed by participating schools (with one additional reminder) to all parents/guardians of the intervention year group on school communication lists. To enhance universal parent/guardian access to the parental materials, parents will also be posted a copy of the *If I Were Jack* parents/guardian factsheet (available in English, Polish, Punjabi, Arabic, Mandarin, Bengali and Urdu).

5. Methods

5.1 Research Design

The proposed study has a two stage design and lasts 48 months in total. Stage One involves intervention refinement and pilot testing in three schools against progression rules to Stage two (see progression rules below). Stage two is a Phase III effectiveness study using a cluster RCT with embedded process and health economic evaluations. The study will assess the effectiveness of the intervention in reducing unprotected sex for teenage boys and girls. It will include a cost-consequences analysis of the intervention and a decision model of long term costs and consequences as a result of behaviour change. It will also include a process evaluation using a mixed-methods triangulated design to assess fidelity to implementation protocol and determine the contextual factors associated with participation and effectiveness. See project flowchart in Appendix 2.

5.2 Criteria for Progression to Stage Two

We will progress to Stage Two of this trial if the Stage One findings indicate the following:

- At least 60% of children in three pilot schools (England, Scotland and Wales) view the entire interactive film, and at least 80% of those report that they find the accents used clear and understandable.
- At least 80% of the staff in the three pilot schools report that they would be happy to implement the *If I were Jack* programme in its amended format.

5.3 Stopping Rules/Discontinuation Criteria

Our preliminary investigations have indicated positive responses from teachers and pupils who have used the intervention. Thus, we do not anticipate harm and believe there is a low risk of having to stop the study. However, we will continue to monitor for harm largely through process evaluation data using a protocol for adverse events and serious adverse events details of which can be found in the projects data collection protocol. In addition, we will also examine data at the end of the trial in this regard.

5.4 Study Population

Target Population

The target population is teenagers in post-primary schools in the UK, in the year group in which the mean age is 14 years at the time of the intervention. In NI this will be Year 11 pupils, in Scotland S3 pupils and in Wales and England it will be Year 10. The pilot schools sampling and eligibility will replicate that in the full trial.

Within schools, the study will be conducted with all classes in the selected year group. This group of teenagers will be targeted for a number of reasons. First, proximal risk factors of teenage pregnancy are manifesting [15,75] prevention is not too late, sex education is acceptable in society and education [15,30,36] and there is an identified deficit of resources for this age group in relation to teenage pregnancy [81,82]. Second, our feasibility study has indicated that there is greater opportunity for implementation of the intervention during a year where there are no statutory examinations. Third, this population has been chosen to facilitate a 12-14-month follow-up of pupils (post-intervention) before some pupils will exit formal education following first major statutory exams or reaching the age of 16 years.

Inclusion & Exclusion Criteria

Effectiveness trial: All post-primary schools in NI with more than 30 pupils in the targeted intervention year will be eligible to participate, excluding those that took part in the Jack feasibility study. In Scotland all secondary schools with over 30 pupils in the targeted intervention year in five local authorities in mainland Scotland (North Ayrshire; North Lanarkshire; Perth & Kinross; South Ayrshire; Stirling) will be eligible to participate. In Wales, all secondary schools in South Wales with over 30 pupils in year 10 will be eligible to participate (Blaenau Gwent County Borough Council; Bridgend County Borough Council; Caerphilly County Borough Council; City and County of Swansea; City of Cardiff Council; Merthyr Tydfil County Borough Council; Neath Port Talbot County Borough Council; Newport City Council; Rhondda Cynon Taf County Borough Council; Torfaen County Borough Council; Vale of Glamorgan Council; Monmouthshire Council). Similarly, in England all secondary schools with over 30 pupils in year 10 within the Greater London area will be eligible to participate (Barking and Dagenham; Barnet; Bexley; Brent; Bromley; Camden; Croydon; Ealing; Enfield; Greenwich; Hackney; Hammersmith and Fulham; Haringey; Harrow; Havering; Hillingdon; Hounslow; Islington; Kingston upon Thames; Lambeth; Lewisham; Merton; Newham; Redbridge; Richmond upon Thames; Royal Borough of Kensington and Chelsea; Southwark; Sutton; Tower Hamlets; Waltham Forest; Wandsworth; Westminster). The geographic inclusion criterion is included to reduce travel time and costs. A further inclusion criterion will be that schools must be able to send e-mail or text messages containing a link to the video to parents of their pupils. Our feasibility and transferability studies show that this will exclude a very small proportion of schools. Faith-based schools will not be excluded.

Independent private, special, and Irish/Welsh-medium and Scottish Gaelic schools (but not excluding schools that have an embedded Irish/Welsh-medium component) will be excluded. Schools with less than 30 pupils in the target year group (Year 11 in NI, S3 in Scotland and Year 10 in England and Wales) will be excluded. Schools that have 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 will also be excluded.

All pupils who are entering Year 11 in NI, S3 in Scotland and Year 10 in England and Wales (mean age 14 across all countries) in 2018/19 in eligible schools will be eligible for the study. Those with mild learning difficulties or poor English will be supported to complete the questionnaire by fieldworkers. To maximise follow-up we will return to schools to survey pupils who were absent.
Process evaluation with teacher trainers, school staff, pupils and parents: School principals, Heads of Year and teachers who deliver the intervention and agree to participate in the research will be included in the proposed process evaluation. Teacher trainers will also be asked to participate in a short telephone interview. Additionally, all parents/guardians of participating pupils in intervention schools will be asked to complete an online parents' survey giving their views of the intervention. Participation by parents who are unable to communicate in English but speak Polish, Urdu, Punjabi, Arabic, Bengali or Mandarin will be facilitated by providing a translation of the information sheets and parent factsheets. Using the bespoke teacher questionnaire method established in the feasibility study we will collect costs of delivery of the intervention. Focus group discussions with pupils and observations of a sample of intervention lessons will also be used.
Case study schools: Participating intervention schools will be randomly rank ordered in each country and two case study schools from each country will be randomly selected by NICTU to participate in the process evaluation. Should a school refuse participation; a further random selection will be made.

Observations: Country-specific trial co-ordinators will conduct structured observations of one randomly selected lesson in four class groups in receipt of the intervention in the eight case study schools. Observations will be focused primarily on measuring teacher fidelity to implementation protocol and pupil engagement.
Focus groups: Trial co-ordinators will conduct three 60-minute focus group discussions in each of the eight case study schools. One group will be composed of all teachers who delivered the intervention. The second group will include a maximum of six English-speaking pupils who received the intervention. Teachers who delivered the intervention will ask for a mixture of male and female pupil volunteers and pass details of those pupils to the trial co-ordinator. In the event that more pupils volunteer than are needed (per school), a random selection will be made. The third group will be a maximum of six English-speaking parents/guardians (of children who received the intervention). Discussions will focus on perceived barriers and facilitators of successful implementation and engagement with different components of the intervention. Acknowledging the difficulty in recruiting parents in a school based trial; if insufficient numbers are recruited for a focus group discussion, interviews/paired interviews will be conducted.
Individual Interviews: semi-structured interviews with teacher-trainers and education/policy specialists in each of the four countries will take place. Teacher trainer interviews will focus on two main areas relating to the Jack teacher-trainer experience - issues relating to delivery of training to individual schools on a school-by-school basis; and at a broader level, regarding delivery of the training more generally. Interviews with education/ policy specialists will focus on the current context of RSE policy and perceptions of how this might influence the uptake and implementation of the Jack intervention.

5.5 Recruitment, Randomisation and Retention

The study will take place in 66 post-primary schools in the UK, with 24 in NI and 14 in each of the other three countries. We will develop a sampling frame based on UK country and socio-economic status (based on eligibility for free school meals (FSM) as indicated by the School Meal Census). In each country eligible schools will be 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 will be randomly selected from the above-median stratum and 10 from the below-median stratum (total 24) and in England, Scotland and Wales 8 schools will be randomly selected from the above-median stratum and 6 from the below-median stratum (to give a total of 14). The decision to select slightly more schools from the above-median %FSM stratum allows even random allocation of schools to trial groups and reflects research which indicates that teenage pregnancy and unprotected sex is more acute in more deprived areas [8, 26].

In Scotland we will obtain permission from each local authority (typically by approaching the Director of Education) prior to commencing recruitment. Where possible, schools will be 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). Any schools that decline to participate will be replaced by a randomly selected school in the same stratum. We will also reserve the alternative recruitment option of advertising the project to school representatives at events such as RSE training days and head-teacher events and stratifying and randomly selecting from a list of interested schools.

Randomisation will be carried out independently by the NI Clinical Trials Unit. Prior to baseline data collection, schools within each country and socio-economic stratum will be randomly allocated (1:1 concealed allocation) to a trial group. School allocation will be communicated to each school by the country specific teacher trainer following baseline data collection within the school.

We will offer an incentive of £1000 to retain all intervention and control schools. The control group will also be offered continued use of the JACK Resource, following completion of final follow-up survey. These schools will be asked not to use the resource with pupils involved in the Jack Trial in the event that long term follow-up of participants is conducted in future studies. Additionally, all schools will be offered feedback in the form of a 'needs assessment' detailing anonymised school level statistics on issues such as prevalence of unprotected sex and alcohol and drug use which they might use to lobby for funding to address such issues. We will determine resistance to assignment to the control group by recording refusal to participate or difficulties with retention at follow-up in the control group.

Protection against bias: The investigator team and the intervention delivery team will be separately managed. Outcome data will be collected blind to allocation, fieldworkers will not be informed of the allocation. We will aim to maximise response rates at each site at baseline and follow-up to minimise non-response and attrition bias, for example by following up those individuals not present during survey sessions if there's more than 20% student absenteeism on day of data collection. In order to prevent possible contamination, participants in the control group will not be told the name of the intervention. Blinding of participants to allocation is not possible.

5.6 Sample Size

The study will be powered to detect a 50% reduction in the incidence of unprotected sex (from expected rate of 2.8% to 1.4%[2]) by 15 years of age. A difference of 1.4% in unprotected sex has been shown to have a meaningful impact on pregnancy rates [15,71,83,84]. The between-group difference in the incidence of unprotected sex of 1.3% (95% CI 0.5 to 2.2%) by 9 months in our feasibility trial demonstrates that such an effect size is plausible and is consistent with effect sizes seen in the literature [71]. The study will take account of clustering. In the feasibility data the ICC was 0.01. As pilot studies can provide imprecise estimates of ICCs [85], we re-estimated using ICCs from three sources, the RIPPLE cRCT [84], data from the WHO Health Behaviour in School-aged Children Survey GB, 2014) [26] and 2013 Young Persons' Behaviour and Attitudes Survey NI, NISRA, (2013) [27]. The data from the WHO and NISRA studies were combined. The RIPPLE and combined WHO and NISRA studies found an ICC of 0.004. Assuming 120 students per school[3], an ICC of 0.01 and 7% rate of attrition (plus 2 additional schools to be conservative), a trial involving 33 schools per group will provide 80% power at a 5% significance level. The power would rise to 93% if the ICC is 0.004.

[2] Drawing from robust representative epidemiological data of school-aged children across the UK (the WHO Health Behaviour in School-aged Children Survey GB, 2014) [26] and Young Persons' Behaviour and Attitudes Survey NI (2013) [27], it is known that between 25% and 33% of 15 year olds are having sex. Looking more closely in these surveys at the rates of unprotected sex for this age group, we can determine a rate of 2.8% reporting unprotected sex (overall in England, Wales, Scotland and NI) (Sample n= 7904, and n=224 reporting unprotected sex).

[3] This is based on the average year size across the four countries of the UK drawn from statutory statistics for each country.

5.7 Stage One Intervention Refinements

Production of two updated IVDs: We will produce two updated versions of the original *If I were Jack* IVD, one for use in England and Wales, using actors with English accents and one for use in NI and Scotland, using actors with NI accents. Both will be closely based on the original film script and storyboarding and set in an urban environment which reflects a typical UK city. The rationale for this refinement is based on findings from the transferability study of the original IVD in Scotland, England and Wales to (a) develop a more culturally appropriate version of the IVD for England and Wales, and (b) an overall update of the IVD to modernise it from the previous version made in 2009. Making use of this opportunity to make a modernised version means the IVD will be directly comparable across all four countries.

Pre-production of IVDs: This will involve consultations with Young People's Advisory Groups (YPAGs) available to the study team in each of the UK countries during full and half-day workshops to further advise on any necessary changes to script. The YPAGs will be attended by the project manager and convened using each research sites extant networks of YPAGs. There will be two "script-reading" workshops. The first will bring all partners (YPAGs and Research Fellows) from Belfast, Glasgow, London and Cardiff together for a script-review workshop to take place in Cardiff. At this workshop the YPAGs will work on the original IVD film script which may also have modifications suggested by the film production team. The YPAG groups will include participants from minority ethnic backgrounds where feasible. A second workshop will be held in each site through video conference to provide feedback on the revised film script based on the young people's feedback. The final scripts will then be delivered to the film company who will manage casting, filming and final packaging of the films as IVD applications. Final versions will also be shown to YPAGs.

Refinements to classroom materials: The site research teams will propose changes to be made to the classroom materials/lesson plans on the basis of the transferability study which involved consultations with teachers and RSE experts in each of the sites. These changes will then be reviewed by the collective RSE stakeholders group (one meeting in Belfast linked by video conference as necessary) before being sent for typographic production (integration with original production of classroom materials).

Refinements to Parental Component: The parental component has been changed from face-to-face teacher-led information session to two short animated films using supporting funding separate from this study.

5.8 Data Collection Methods

Methods for Testing Intervention Refinements

The intervention will be piloted in two class groups in one school in England, Scotland and Wales with a clear focus on the interactive video drama. We will conduct qualitative interviews with teachers involved in the delivery of the intervention, in the pilot schools, especially examining any problems with acceptability and fidelity to implementation protocol. In addition, we will analyse online viewing statistics of parental videos and conduct a survey with parents inquiring into their views on content and delivery, but, as noted earlier, this latter research will not be included in 'stop/go' criteria.

Stage Two Methods for Main Trial

Participating pupils will be in the study for approximately 18 months and asked to complete a questionnaire during one lesson at baseline and again between 12 and 14 months later. Paper based questionnaires will be used as the feasibility study suggested electronic data collection was not feasible due to reliability issues and that the majority of schools preferred to use paper based questionnaires. A fieldworker will administer baseline questionnaires to pupils prior to intervention assisted by a teacher who will remain in the classroom/assembly hall to maintain order and will help to ensure questionnaires are completed confidentially. Additional fieldworkers will be on hand to provide support to pupils who require extra help. If student absenteeism is 20% or more, a repeat information session and baseline data collection session will be facilitated in agreement with the school to accommodate any pupils who are absent from the initial session. In the unlikely event that absenteeism remains in excess of 20% in a school, the research team, in agreement with the school, will return a third time to facilitate an additional information session and baseline data collection. If absenteeism is less than 20% and the school requests opportunity for absentee students to complete a questionnaire, questionnaires and instructions will be left for absent pupils to complete. Researchers will then follow this up with individual teachers. Identical procedures will be applied at follow-up. Data will be entered using optical recognition software by a scanning company and quality checked by the Clinical Trials Unit (NICTU) (See Appendix 2 Project Flowchart).

Methods for Process Evaluation

Informed by realist approaches to the evaluation of interventions [87,88] the process evaluation has four aims. First, we examine reasons for participation and non-participation to inform risk of bias in the trial as well as longer term sustainability of implementation of the intervention. Second, we examine intervention delivery and fidelity in the context of overall RSE provision in intervention schools. Third, we assess provision in control schools and potential contamination. Fourth, we explore self-reported perceptions of effectiveness and moderating influences in intervention schools among a sample of pupils, teachers and school principals and parents. Utilising a mixed-methods triangulated design it will involve semi-structured interviews with teacher trainers, teachers, focus group discussions with pupils, observations of a sample of lessons and a survey of parents with potential follow-up focus groups should we experience low engagement with the parental component or if parents indicate a desire to engage in such discussions. Methods for each of these aims is as follows:

<u>February – June 2018</u>

In the process of recruiting schools, researchers will record any communication (by telephone, in person or in writing) which indicates the school's reasons for participation or non-participation in the study.

<u>August – October 2018</u>

All schools:

- At baseline data collection fieldworkers will complete 'fieldworker perception forms' after each visit to a school (notes on school context any challenges/problems etc.).
- Fieldworkers will submit observation forms to Trial Co-ordinators. Trial Co-ordinators will review observations forms similar to a thematic analysis format, providing a short summary paragraph on each

school. This will be followed by a final summary paragraph reporting on overall data collection. This will be approx. 3 pages max

- Principals/Vice-Principals/Designated Trial Champions will be asked to complete a questionnaire asking for background information on the school (e.g. management structure, number of pupils, holidays/closures over the coming year etc.).

Intervention schools:

- RSE leads will be asked to complete a questionnaire about current RSE provision in the school.

November 2018 – April 2019

Intervention schools:

- Parents of all participating pupils in intervention schools will be texted or emailed a link to a short online survey asking for their views on the parents' videos and parent/pupil homework exercise. They will also be instructed that they can request a hard copy of the questionnaire from the school office. At the end of the survey, respondents will be 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 is selected as a case study school. Where possible, parents who have opted-out their children from the research component of the Trial will not receive this texted or emailed link. A maximum of two texts/emails will be sent to parents (the original message and link to survey and one reminder).
- Teachers in all intervention schools will be asked to record 'implementation logs' to detail what activities were completed or not completed during each lesson, and perceptions of pupil engagement with each activity.
- We will conduct case studies in eight randomly selected intervention schools. Data will be gathered via observation and focus group discussions with teachers, pupils and parents.

  Observations: Research fellows and/or Fieldworkers will conduct structured observations of one randomly selected lesson in a maximum of four class groups in the relevant year for each of the eight schools. Observations will be focused primarily on measuring teacher fidelity to implementation protocol, enthusiasm and control of the class, and pupil engagement.
- Student Engagement Questionnaire: Teachers are asked to distribute these as part of the resource at the end of the final lesson and return them to Trial Champion to give to Trial Co-ordinator.
- *Focus Groups:* Research fellows will conduct three 90-minute focus group discussions in each of the 8 schools. One group will be composed of all teachers who delivered the intervention, one group a maximum of 6 pupils (boys and girls) who received the intervention, and one group a maximum of 8 parents. Discussions will focus on perceived barriers and facilitators of successful implementation and engagement with the different components of the intervention. Teachers will be advised to approach a diversity of students and parents to participate in focus group discussions as to ensure a range of views are captured during interviews.

January - March 2019

Interviews with education/policy specialists

- Trial Co-ordinators will conduct telephone or face-to-face interviews with one or two education/policy specialists in each of the four countries. Interviews will focus on the current context of RSE policy and perceptions of how this might influence the uptake and implementation of the Jack intervention.

- The sample of education/policy specialists will be achieved initially via the projects Advisory Committees. Future focus groups may also be held with these health and education policy experts starting with a presentation with the projects preliminary findings, followed up with a focus group discussion in order to gather collective and rich insights, interpretations, and advice on broader implementation.

Intervention schools:

- 15-30 minute telephone interviews will be conducted with principals or trial champions in the non-case study intervention schools to determine any barriers or facilitators of engagement with the intervention.

Teacher-Trainer Interviews:

These four interviews will be completed via telephone by the Northern Ireland Trial Co-ordinator and will focus on two main areas relating to the Jack teacher-trainer experience - issues relating to delivery of training to individual schools on a school-by-school basis; and at a broader level, regarding delivery of the training more generally.

January – March 2020

All schools:

- *At foll*ow-up data collection, fieldworkers will complete 'fieldworker perception forms' after each visit to a school.

Control schools:

- RSE leads will be asked to complete a questionnaire about current RSE provision in the school.
- Follow-up interviews with school will be conducted if necessary (e.g. to clarify RSE provision or discuss any impacts on data collection).

Intervention schools:

5.9 Compliance Issues

Based on the feasibility and transferability studies, we do not anticipate any problems with compliance in participating schools in the intervention group. There was no loss to follow-up in schools during our Phase II feasibility study in intervention or control schools. To enhance compliance, we will offer £1000 to schools at end of data collection, as our research suggests this would be a significant incentive to remain in the study [80].

5.10 Outcome Measures

In this trial, a reduction in unintended teenage pregnancy rates would be the ideal primary outcome measure. However, the sample size would need to be very large in order to detect change in relation to this. We will therefore use a surrogate measure associated with unintended pregnancy: having had unprotected sex (calculated at 12-14 month follow-up). Unprotected sex during teenage years is well established as the main proximate behavioural determinant of teenage pregnancy and is a commonly measured behavioural outcome in studies examining the impact of RSE interventions on teenage pregnancy [11,3,15,71,89,90]. Studies indicate that, although other behavioural determinants (such as frequency of sexual intercourse and number of sexual partners) are important, avoidance of

unprotected sex via consistent use of contraception is central in explaining variation in levels of teenage pregnancy [19,83].

Secondary outcomes informed by our theory of change (see Appendix 1) include knowledge, attitudes, skills and intentions relating to avoiding teenage pregnancy. These short-term impacts are hypothesized to lead to increased intention to avoid teenage pregnancy. As part of the feasibility trial, data were collected using a number of standardized measures chosen because the constructs they measure map closely to the theoretical framework underpinning the intervention. Overall, the reliability and completion rates of the measures were satisfactory. The male role attitudes, sexual socialisation peer scale, sexual self-efficacy scale and intentions to avoid an unintended pregnancy all had high internal consistency (Cronbach's alpha in excess of 0.7), family connectedness, comfort communicating about pregnancy, comfort communicating about contraception, total sexual socialisation and the parent sexual socialisation scales had satisfactory internal consistency (Cronbach's alpha: 0.5-0.7). Our knowledge questions also worked well, showing good variability except for one item which will be deleted in this future trial. In addition, to assist with the economic evaluation, additional secondary outcomes are frequency of engagement in sexual intercourse, contraception use, and diagnosis of STIs. This was shown to be feasible in the feasibility study (see below for rates of return for questionnaires in feasibility study). Finally, we will collect important individual level demographic and socio-economic characteristics of sample to deepen understandings of how these factors moderate effectiveness.

Assessment will take place at baseline with follow-up at 12-14 months later. The 12-14-month follow-up allows maximum possibility for observation of behavioural impacts by accounting for the fact that most teenagers do not have sexual intercourse before they are 16 [26,27] and also that it is the latest time we can do so before participants have the option to leave formal education or change schools.

The feasibility study also demonstrated that the survey instruments can be delivered to time in the recruited schools and that matching questionnaires across the data points was unproblematic using barcodes on questionnaires and envelopes. The instruments showed high acceptability with the majority of participants stating that they felt comfortable in answering most of the questions in this questionnaire (80%, n=608). Ninety three percent (93%) of the pupils completed primary outcome at follow-up two.

5.11 Data Analysis

Statistical Analysis

A detailed statistical analysis plan will be written prior to analysis. The reporting and presentation of findings will be in accordance with the CONSORT guidelines for cluster RCTs [91]. All analyses will take account of clustering by school using robust standard errors, and intervention and control groups will be compared at baseline via frequencies/descriptive statistics (percentage, mean or median as appropriate) in relation to gender, ethnicity, SES (perceived family financial status, measures of family affluence (number of family holidays during the past 12 months, family computer(s), ownership of a family car, and ownership of a dishwasher), pupils' highest educational aspirations, and age expected to leave school), primary and secondary outcomes.

Primary analysis (12-14 month follow-up): The primary effectiveness analysis will be 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 [92]. Sensitivity analyses, making different assumptions on the best and worst case scenarios, as well as imputation models of missingness will be conducted to investigate the potential impact of missing data.
Secondary analysis (12-14 month follow-up): Although the trial is not powered to detect the influence of mediating and moderating variables, we will examine the following outcomes informed by our theory of change model (See Appendix 1): i) interaction terms will be used to investigate possible differences in the effect of the intervention on the primary outcome by whether pupils at baseline reported having had unprotected sex or not, country (Wales, England, Scotland, NI), gender, socio-economic group (see earlier section 5.5) and ethnicity); ii) a mediational analysis, using an analytic framework recommended for RCTs [93], will be used to explore whether the effect of the intervention on the primary outcome is mediated by individual-level sexual health knowledge & sexual competence, perceived behavioural control, intentions to avoid an unintended pregnancy, communication with parents, and gender ideologies. In these secondary analyses, p-values will be interpreted with caution due to the low power and number of interactions being tested (e.g. we will use Bonferroni corrected p-values).

Process Evaluation

All audio files will be securely transferred to QUB and transcribed verbatim (in the case of interviews) or typed up in detail by trial co-ordinators (in the case of observational field notes and other secondary source data). These data will be organised using NVivo software and analysed systematically and thematically based on the six steps proposed by Braun and Clarke (2006) to enable identification and analysis of patterns (or 'themes') within the data by moving iteratively between theoretical understandings and the new data. These inductively and deductively derived codes will be first compiled as a code book and then applied to the data which will then be analysed to form overarching themes emerging from each of the participant groups outlined above. It is envisaged that the data will be analysed first by participant group (e.g. teachers, pupil's parents) across all sites, while a subsequent analysis will look for overarching themes running across the participant groups.

The qualitative software 'NVivo 10' will be used to organise the data, and we will ensure methodological rigour by establishing credibility, transferability, dependability and confirmability using techniques suggested by Lincoln and Guba (1985). In addition, following Hyde et al. (2005), specific attention will be given to analysing the group dynamics of the focus groups as part of the overall interpretive process. In schools in the control group, special attention will be given to the specifics of analysing interview data. It is likely that this number of interviews (specified above and in Appendix 1) will be sufficient to ensure no new themes are emerging. If, however, further themes are emerging at this stage, further interviews will be conducted as necessary. See Appendix 1: Flow Chart of 'Integration of Process Evaluation with Experimental Design Methods to achieve Research Objectives'.

Those conducting focus groups and interviews will also provide a summary overview of how these went, remarking on group dynamics, any reflections etc.

QUB will lead on data analysis (trial co-ordinator and project manager) based on the transcribed data from all sites. However, other Trial co-ordinators will also become involved in data analysis, by contributing to the development of the code book (of inductively and deductively derived codes) by

applying these codes to the country site data and by assisting in developing the thematic analysis of the overall data.

Where trial co-ordinators from other sites become involved in data analysis of process evaluation data, they will also have opportunities for co-authorship of presentations and publications relating to the UK wide process evaluation.

Economic Evaluation

The groundwork for an economic evaluation has been laid by the feasibility trial. The objectives of the economic component were to:

- identify the costs of delivering *If I were Jack*; and
- develop a framework for assessing cost effectiveness in a future trial.

This was achieved by:

1. Identification of the relevant resources used in the set up and delivery of *If I were Jack* and their associated costs was completed using a micro-costing approach, from a public sector decision maker perspective. Relevant costs were identified, measured and valued in monetary units using the 2013/2014 price year, guided by a recognised practical guide to costing behavioural interventions [97]. The mean cost per pupil for delivery of the intervention (including training of teachers) was calculated as £13.66.
2. Identification of parameters for a future cost-effectiveness decision model that incorporates theories of behaviour change. The structure of the model is illustrated in Appendix 4. Reading from left to right, we start with a cohort (or defined population) who would engage with the intervention. This would then lead to an increased level of awareness in that population and, we hypothesise, to subsequent changes in sexual behaviour which would then have implications for future pregnancy rates, other health events and life opportunities. Such a framework requires estimates of the baseline levels of occurrence of such events, how these levels will be changed by engaging in the intervention and the magnitudes of costs and benefits associated with such events. In the effectiveness trial, this framework will be populated with data from future primary research, policy documents and published literature.

The aim of the economic evaluation in the trial is to describe the costs and consequences of implementing *If I were Jack* in UK schools so as to provide information to decision makers on the implications of rolling out the video intervention further. This will include the duration of time taken up by *If I were Jack* in school from the perspective of the teacher and impact on time spent on other important curricula activities compared to time spent on standard RSE. The aim of this will be to provide a measure of the opportunity cost to schools of implementing *If I were Jack* compared to current RSE in control schools. The structure of the evaluation will follow NICE guidance for evaluating public health interventions [98] and recent guidance published by Tudor Edwards et al. [99] on economic evaluations in public health. Costs will include the cost of implementing the intervention in schools including any training involved and the cost of current RSE in the control schools. We will also collect information on health care cost information in the intervention and control arms including the costs of sexual health related primary care attendances, costs of any STIs and cost of unintended pregnancies, although numbers of these are likely to be small. The cost of adapting *If I were Jack* to different groups will also be reported given that others may want to also adapt the intervention before rolling it out. Mean cost per pupil will be reported alongside consequences including use of

contraception, STIs and unintended pregnancies collected using questionnaires administered to pupils at baseline and follow-up. Although 12-14 month recall is significant, pupils are likely to be able to recall high impact events that occurred during this period. The follow-up time is also important to fit within the school year timetable. Costs will also be reported by country given the different sexual health services provided and hence differential implications for health service costs by country.

Given that STIs and unintended pregnancies are likely to be rare but potentially high impact events in this group, the long terms costs and consequences will be modelled as part of the decision model described above in point 2 and shown in Appendix 4. In addition to collecting information as part of the trial we will look to systematic reviews in the literature of evidence of the impact of digital interventions on sexual health behaviour in this population group, for example the review recently undertaken and published by Bailey et al. [54]. We will review the literature for any gaps in evidence identified. We will undertake one way, two way and probabilistic sensitivity analyses of the results. Cost effectiveness acceptability curves and cost-effectiveness planes will be reported. The model will have a 20-year time horizon and discounting of future costs and benefits will comply with NICE guidance for evaluating public health interventions [98].

5.12 Ethical Arrangements

The study will comply with the ESRC Framework for Research Ethics and will receive a full ethics review by the School of Nursing and Midwifery (QUB) Research Ethics Committee, who will independently assess our compliance with the ESRC Framework. This approval will cover data collection in each partner site. A trial steering group will oversee the trial. QUB will act as the main sponsor of the research and ensure that governance and indemnity procedures are in place. The project will be registered on the Human Subject Projects database in QUB and prospectively registered in an international register of trials.

6. Project Timetable & Milestones

• DATE	MILESTONE	
Jan 2017 – Jan 2018	**Project set up:** Staff recruitment; ethics applications; tendering & procurement; register trial; prepare & submit study protocol for publication **Stage 1:** Intervention refinement & piloting; stage 1 report to NIHR & stage 2 stop/go decision	
Feb – Jun 2018	**Stage 2 start** Recruitment; parental consent	
	RESEARCH (both groups treated identically unless otherwise indicated)	INTERVENTION
Aug- Nov2018	**Baseline data collection (pupils)** Randomisation & allocation notification **Process Evaluation**: fieldworker perception forms	**Process evaluation: all intervention schools** Principal and teacher questionnaires (RSE provision)
Oct 2018– Jan 2019		Teacher Training
Feb -June 2018	Questionnaire scanning (13 weeks) Data checking & cleaning (13 weeks)	
June – Aug 2019	Statistical Analysis (baseline descriptive statistics)	
Nov 2018– March 2019		**Implementation** (4- 6 weeks)
Nov 2018 – Apr 2019		**Process evaluation: 8 case studies** Classroom observations

		Interviews/focus groups (pupils, principals, teachers, parents) **Process evaluation: all intervention schools** Implementation logs (pupils) Parent questionnaire
Apr – Jun 2019	**Process evaluation:** Interviews education/policy specialists	Process evaluation data analysis
Jul – Dec 2019	**Dissemination:** methodology publications	
Jan – Mar 2020	**Follow-up data collection (pupils)** **Process Evaluation**: fieldworker perception forms **Process evaluation: (control schools)** Principal and teacher questionnaires (RSE provision) & follow-up interviews if necessary	**Process evaluation: All intervention schools** Telephone interviews principals/trial champion teachers (perceived barriers and facilitators of engagement with intervention)
Apr- Jul 2020	Questionnaire scanning (7 weeks) Data checking & cleaning (12 weeks)	
Apr – Aug 2020	Process evaluation data analysis	
Aug –Oct 2020	Statistical analysis (final statistical report)	
Aug –Dec 2020	Write-up and dissemination	

7. Risks and benefits to participating in the research

Research Participation: In terms of participating in the trial, there is very little risk to participants as it involves completing repeat questionnaires in their classroom/assembly hall settings by trained and disclosed researchers. The questions being asked are well-established and the feasibility study demonstrated a high level of satisfaction among pupils with the research processes. Nonetheless, the research may be distressing to those pupils who may already have experienced an unintended pregnancy or unintended sexual contact. Researchers will leave a bookmark with each pupil advising them of how to contact ChildLine. Researchers will also identify a contact within each school in advance of data collection who may be approached by pupils who may need further support on foot of participating in the research. Thus, participating in the research may lead to pupils receiving support when they otherwise may not have been identified as needing such support. In relation to pupils' and parents' focus group discussions on the topic of the intervention, there is an additional risk that these discussions may touch on areas of a sensitive nature. The trained researchers will remain alert to any discomfort, taking appropriate steps to change the direction of discussion and avoid concentration on individuals' personal experiences. A protocol will be developed in case pupils disclose information that would raise any safety concerns, so it is clear to researchers on the ground what action would need to be taken. Additional anticipated benefits of participation for young people is that the research team will prepare engaging audio-visual information to explain the research and consent process in ways which are designed to engage and educate pupils in trial research. This learning opportunity will be enhanced for pupils participating in the Young People Advisory Groups.

Intervention participation: The risks of intervention participation are similar to those described for research participation. The materials may lead to distress and so the support structures described above are an important part of conducting the research sensitively and ethically in schools. A further potential harm is the time lost to other RSE materials that could be used. However, based on pupil and teacher enthusiasm for the resource materials in the feasibility study, we believe the potential benefits of using *If I were Jack* in the classroom is worth this risk.

8. Socioeconomic Position and Inequalities

Research suggests that interventions targeting only schools in disadvantaged areas are insufficient for achieving population level reductions in teenage pregnancy [69–72]. However, the feasibility trial demonstrated that interest in participation was strongest among schools in areas of high socio-economic deprivation, suggesting we are well placed to capture schools where the need for intervention is greatest [69]. Within schools the proposed trial will increase participation by pupils who may otherwise be socially excluded by including an audio-track on the IVD so the questions may also be read aloud to individual pupils. Fieldworkers will also be present during the administration of questionnaires. Pupils with poor literacy skills will be aided in completing the questionnaires both by the practice of reading each question aloud and also, where necessary, by direct support from the fieldworker. A record will be kept of all instances where such individual assistance was required. Our feasibility study indicates this provision requires 1.5 additional fieldworkers per site over and above the one fieldworker needed per classroom. We will also endeavour to recruit some fieldworkers from ethnic minority backgrounds which may help to provide additional assistance to participants from minority ethnic backgrounds who may have poorer literacy skills. Prior consultation with teachers will help us plan this appropriately. Addressing teenage boy's RSE is an important mechanism for promoting positive development and improving the lives of all young adults; especially those suffering

the effects of various types of disadvantage [44–47]. This proposed trial will seek explicitly to explore whether there is a differential impact of the intervention according to gender, ethnicity and the socio-economic status of the children's family background (see secondary analysis under section 5.11). We will also collect information on deprivation at school level and individual level, using data on free school meals. Finally, the intervention has been designed to be sufficiently flexible so as not to exclude faith based schools, such as Roman Catholic schools. This has special significance in NI where approximately 51% of children are educated in Roman Catholic-managed schools. The intervention is non-directive in terms of pregnancy resolution options and is flexible enough to be taught within the framework of a school's ethos and personal development/RSE policy. The feasibility study was the first sexual health intervention trial in the UK to include and successfully recruit faith-based schools.

9. Project Management and Oversight

Research Management

The research team is an established partnership between Queen's University Belfast (QUB), University of Glasgow, London School of Hygiene and Tropical Medicine, Cardiff University, University College London and NICTU. QUB will act as sponsor for the research. The partnership was established early on during the Feasibility Trial when we collectively funded a 'Transferability Study' of the intervention to lay groundwork for a UK-wide trial.

The research team will meet every 6 weeks (by tele-conference for GB partners with bi-annually in person meetings in London) for the duration of the study. The meetings, chaired by Lohan, will involve the production and pre-circulation of progress reports. The expert advice and support of all team members will be coordinated through these team meetings, where clear activities and tasks will be agreed and monitored. Each research site has a nominated site lead (Aventin, Young, McDaid & French) and reports using the template provided for a site task sheet will be presented at each meeting.

Day-to-day project management of the trial will be by the project manager. They will be closely supported by the Trial Manager and Research Fellows, and have weekly supervisory meetings with Lohan and Clarke. McDowell will assume responsibility for NICTU involvement and provide monthly reports, and be responsible to Lohan.

Research Team Expertise

The study team represent a range of academic disciplines and offer the following domains of expertise:

- Adolescent sexual health and well-being (Lohan, McDaid, Young, Bonell, French, Bailey, Aventin)
- Young people's health behaviours (McDaid, Fletcher, Young, Bailey, White)
- Gender-sensitive health interventions (Lohan, McDaid, Bailey, Aventin)
- School based research (Lohan, Aventin, Fletcher, White, Bonell, Maguire, O'Hare)
- Running cluster randomised control trials (Clarke, Maguire, Lohan, Bonell, White, Fletcher)

- Statistical analysis for cluster randomised control trials (McDowell, White, O'Hare, Maguire)
- Health economics especially in sexual health (Hunter + PDRA)
- Collecting and analysing qualitative data (Lohan, Aventin, McDaid)
- Dissemination (All) and creative knowledge translation and public engagement (Lohan, Clarke, O' Hare)

Partner Collaboration

A UK wide study stakeholders' group will be set up to continue the partnership approach of this study (see below). We have obtained Letters of Support outlining financial and in-kind commitment in support of this proposed study in NI from the Department of Health, Social Services and Public Safety, the Public Health Agency, the Belfast Health and Social Care Trust, and the Council for the Curriculum, Examinations and Assessment. In Scotland, we have obtained letters of support from NHSGGC, Education Scotland and the Scottish Government. In Wales and England, we have obtained letters of support from Public Health Wales and Brook. Collaborating partners, BHSCT (NI), NHS GGC (Scot), Brook (Eng) and Public Health Wales have all agreed to provide teacher training to intervention schools.

Public Involvement and project oversight

The study thus far has been informed by extensive patient and public involvement from the outset. It has been designed, developed and piloted in Ireland, NI and South Australia involving over ten years of research with pupils, teachers, sex education specialists, and education and health promotion departments. These collaborations have influenced the current proposal by allowing different perspectives to inform the design and optimal conditions of implementation.

1) Trial Steering Committee: composed of trials experts, school principal, teacher, parent and pupils, provided independent expert advice on the intervention itself as well as refining research methods for delivery in schools. The committee will meet twice a year for the duration of the study.
2) Stakeholders Group: composed of a UK-wide group of RSE specialists and senior representatives from key statutory organisations and government departments helped to refine the intervention and this application by ensuring the research outcomes were important public concerns and the methods proposed are acceptable and sensitive to all study participants. The group will meet twice a year for the duration of the study.

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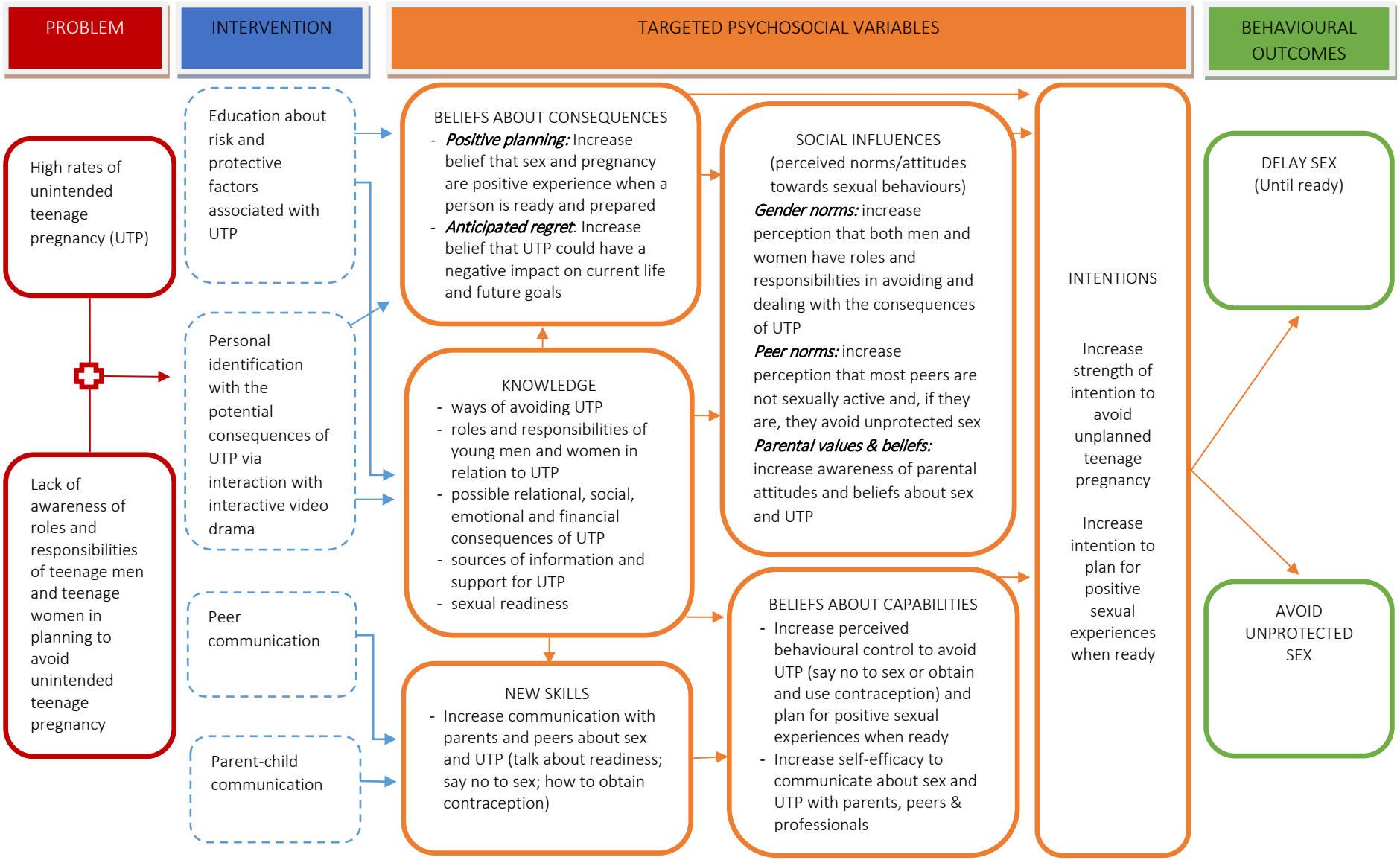
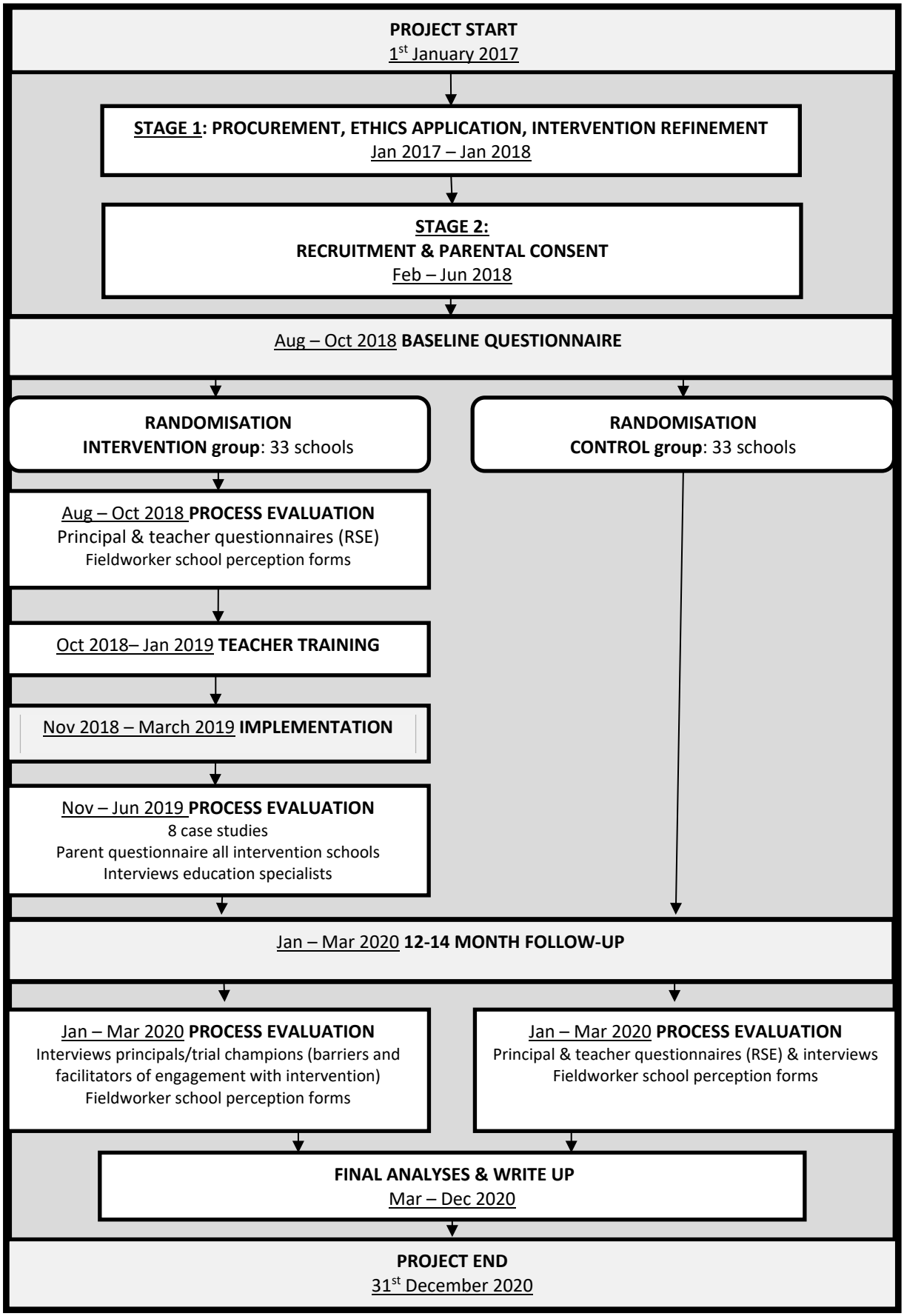
IF I WERE JACK THEORY OF CHANGE MODEL

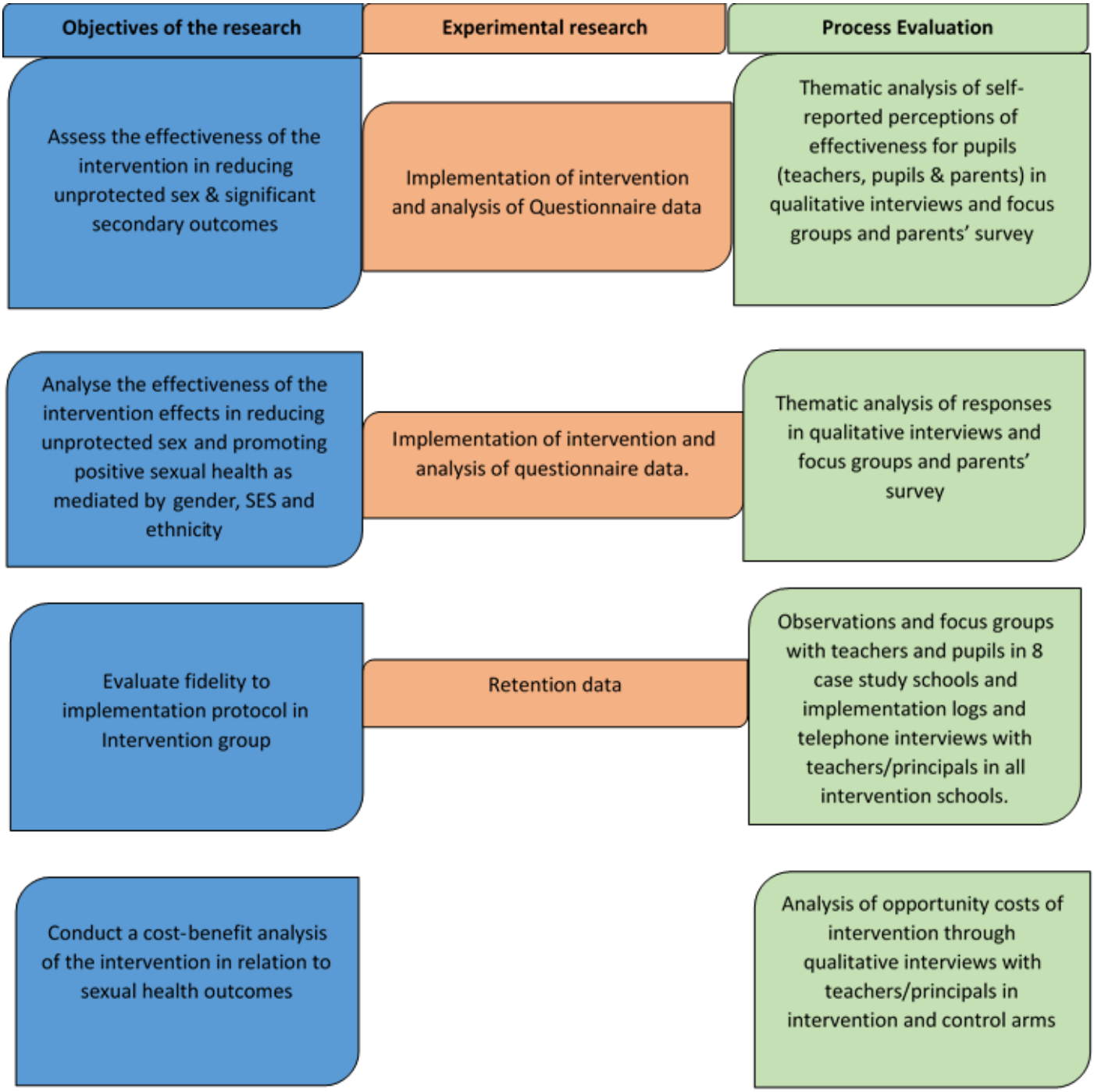

PROBLEM
INTERVENTION
TARGETED PSYCHOSOCIAL VARIABLES
BEHAVIOURAL OUTCOMES
High rates of unintended teenage pregnancy (UTP)
Lack of awareness of roles and responsibilities of teenage men and teenage women in planning to avoid unintended teenage pregnancy
Education about risk and protective factors associated with UTP
Personal identification with the potential consequences of UTP via interaction with interactive video drama
Peer communication
Parent-child communication
BELIEFS ABOUT CONSEQUENCES
- Positive planning: Increase belief that sex and pregnancy are positive experience when a person is ready and prepared
- Anticipated regret: Increase belief that UTP could have a negative impact on current life and future goals
KNOWLEDGE
- ways of avoiding UTP
- roles and responsibilities of young men and women in relation to UTP
- possible relational, social, emotional and financial consequences of UTP
- sources of information and support for UTP
- sexual readiness
NEW SKILLS
- Increase communication with parents and peers about sex and UTP (talk about readiness; say no to sex; how to obtain contraception)
SOCIAL INFLUENCES (perceived norms/attitudes towards sexual behaviours)
Gender norms: increase perception that both men and women have roles and responsibilities in avoiding and dealing with the consequences of UTP
Peer norms: increase perception that most peers are not sexually active and, if they are, they avoid unprotected sex
Parental values & beliefs: increase awareness of parental attitudes and beliefs about sex and UTP
BELIEFS ABOUT CAPABILITIES
- Increase perceived behavioural control to avoid UTP (say no to sex or obtain and use contraception) and plan for positive sexual experiences when ready
- Increase self-efficacy to communicate about sex and UTP with parents, peers & professionals
INTENTIONS
Increase strength of intention to avoid unplanned teenage pregnancy
Increase intention to plan for positive sexual experiences when ready
DELAY SEX (Until ready)
AVOID UNPROTECTED SEX

Appendix 2: Jack Phase III Project Flowchart

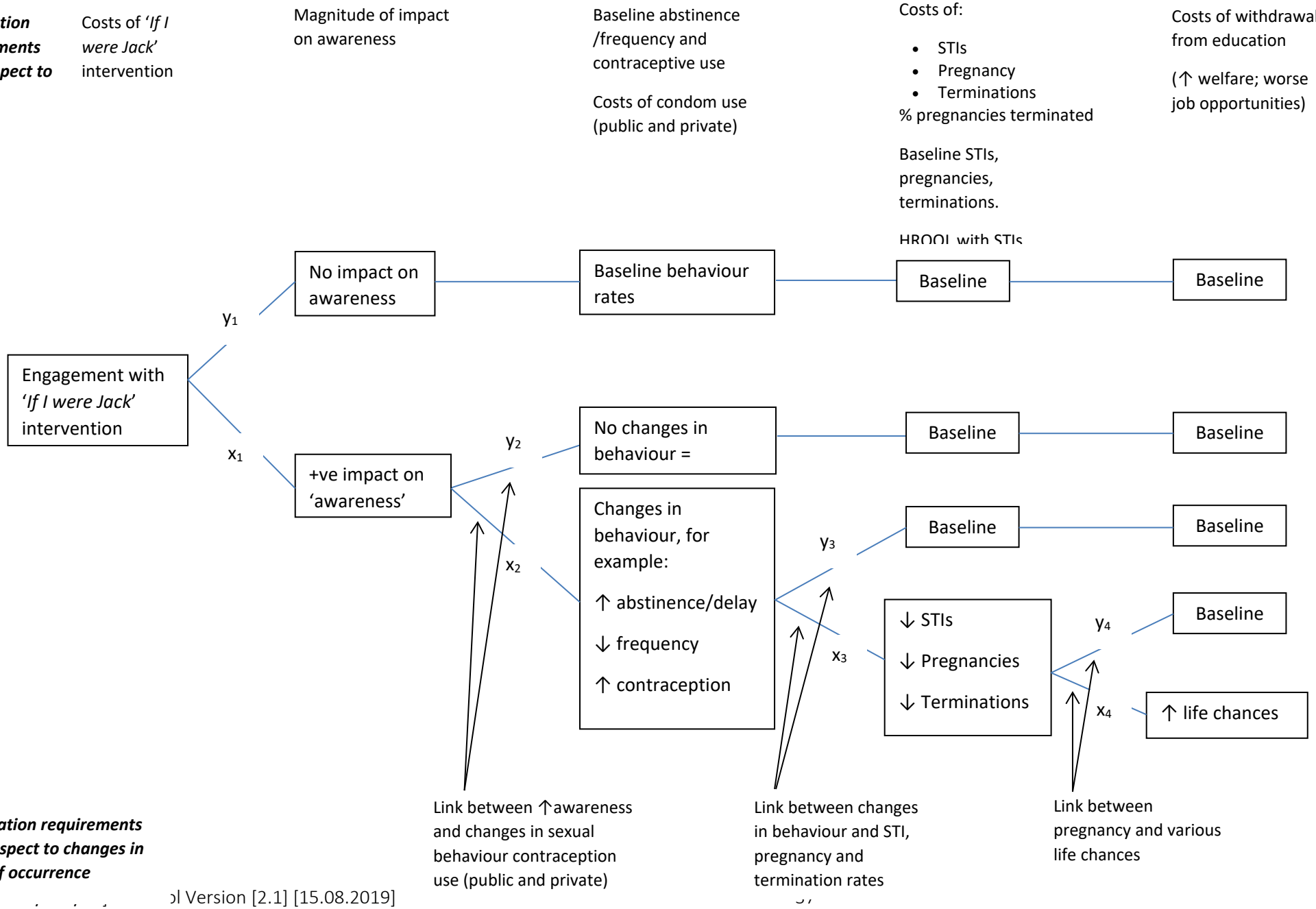


Appendix 3: Integration of Process Evaluation with Experimental Design Methods

to achieve Research Objectives



Appendix 4: Current and future impacts of *'If I were Jack'* on costs and benefits



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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.

Version Control Table

Date	Version	Change	Changed by
28.11.2016	1.0	Original document	N/A
18.02.2019	2.0	V1.0	N/A
15.08.2019	2.1	2.0	N/A