Increasing boys' and girls' intentions to avoid teenage pregnancy: a cluster randomised controlled feasibility trial of an interactive video drama-based intervention in post-primary schools in Northern Ireland

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## **Scientific summary**

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# **Scientific summary**

#### Background

The *If I Were Jack* intervention aims to increase the intention of both boys and girls to avoid unintended teenage pregnancy (UTP) and addresses gender inequalities in Relationship and Sexuality Education (RSE) provision by explicitly focusing on young men and teenage pregnancy. The need for gender-sensitive interventions to address teenage pregnancy has been highlighted as a global health need by the World Health Organization and recommended in systematic reviews. The intervention has been designed specifically for use across the range of schools in Northern Ireland (NI), but it is based on international research regarding effective RSE interventions.

Teenage pregnancy remains a worldwide public health concern. The UK has the highest rate of adolescent pregnancy in Western Europe. Although rates of teenage pregnancy have been gradually falling across the UK since 2002, the birth rate for girls aged under 20 years in England and Wales remains high at 37.4 per 1000 in 2014. In real terms, just under 26,000 women under the age of 20 years became pregnant in England and Wales in 2014 and approximately half of these pregnancies ended in legal abortion, reflecting the potentially unintended or unwanted nature of these conceptions. The conception rate for Scotland was 37.7 per 1000 in 2013 (last available data). In NI, abortion is illegal and is considered lawful only in exceptional circumstances in which 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 1000 of the female population aged 13–19 years in 2014 was 10.3 per 1000 young women (a total of 839 births). The rate for young women in the most deprived areas was nearly 30 per 1000.

Although the life course for teenage parents is not universally negative, the social disadvantage and exclusion that are linked to teenage pregnancy are considered problematic. UTP can lead to considerable adverse health problems for teenagers and their infants, as well as generate enormous emotional, social and economic costs for adolescents, their families and society. Although UTP is a complex phenomenon that cannot be prevented through RSE alone, 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 well-being. Reflecting the importance of RSE, the governments of NI, England and Scotland all emphasise the policy importance of the reduction of teenage pregnancy rates via the implementation of RSE in schools as a key objective in current sexual health policies.

The UK government and the devolved parliaments and assemblies all emphasise the policy importance of decreasing conception rates in those aged under 18 years and increasing sexual health precaution behaviours in teenagers via the implementation of RSE in schools as a key objective in current sexual health policies. Drawing from robust representative epidemiological data of school-aged children across the UK [Inchley J, Currie D, Young T, Samdal O, Torsheim T, Augustson L, *et al.*, editors. *Growing Up Unequal: Gender And Socioeconomic Differences in Young People's heAlth and Well-Being. Health Behaviour in School-aged Children (HBSC) Study: International Report from the 2013/2014 Survey.* Copenhagen: World Health Organization; 2016, and Northern Ireland Statistics & Research Agency; 2011], 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).

### **Objectives**

The study aimed to determine the value and feasibility of conducting a Phase III effectiveness trial of the *If I Were Jack* RSE intervention in post-primary schools in NI. Secondary objectives of the study were to (1) assess the acceptability of the intervention to schools (principals and RSE teachers), male and female pupils (Year 11, aged 14–15 years) and parents; (2) identify optimal delivery structures and systems for the delivery of the resource in the classroom; (3) establish intervention participation rates and reach, including equality of engagement across schools of different socioeconomic and religious types; (4) assess trial recruitment and retention rates; (5) ascertain variation in normal RSE practice across the participating schools; (6) develop and refine survey instruments for use in a Phase III trial; (7) assess differences in outcomes for male and female pupils; (8) identify potential effect sizes that might be detected in an effectiveness trial and estimate appropriate sample size for that trial; and (9) identify the costs of delivering *If I Were Jack* and pilot the methods for economic analysis/cost-effectiveness in a Phase III trial.

### **Methods**

#### The intervention

The If I Were Jack intervention is a classroom-based RSE resource intended for use by teenagers aged 14–15 years, based around a core component – a culturally sensitive 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 unintentionally pregnant. Additional components based around the IVD include classroom materials for teachers containing four detailed lesson plans with specific classroom-based and homework activities, which include group discussions, role-plays, worksheets and a parent-pupil exercise, a comprehensive training session for teachers/RSE facilitators, an information and discussion session for parents/guardians and detailed information brochures and factsheets about the intervention and UTP in general for schools, teachers, teacher trainers, young people and parents/guardians. The intervention is designed to be delivered by teachers over 4 weeks and aims to increase teenagers' intentions to avoid UTP by delaying sexual intercourse or consistently using contraception in sexual relationships and addresses gender inequalities in RSE by explicitly focusing on young men. To achieve this impact it uses an innovative combination of intervention components to (1) address identified deficits in existing RSE interventions; (2) develop a case scenario of an unintended pregnancy from a teenage male's point of view; (3) target a number of behavioural and sexual psychosocial variables that are key to decreasing sexual risk-taking behaviour (namely knowledge, attitudes, perceptions of risk, self-efficacy in communication, skills, beliefs about consequences, other sociocultural influences such as peer norms, gender norms and parental values and beliefs, beliefs about capabilities, and intention to avoid sexual risk-taking behaviour in order to help boys, as well as girls, build skills to avoid UTP); (4) provides comprehensive training and information about teenage pregnancy for teachers/RSE facilitators; and (5) incorporate communication about UTP within the classroom as well as with parents/guardians.

The development of the intervention was informed by baseline data on adolescent men's attitudes to UTP and the best available evidence regarding the components of effective RSE interventions. It was designed to fit with the RSE curriculum by a team of researchers working with experts from the Department of Health, Social Services and Public Safety, the Public Health Agency (PHA) of NI, and the Council for the Curriculum, Examinations and Assessment, as well as teacher trainers, teachers, parents and young people. Although produced in NI, the intervention would have strong cultural resonance for the UK as a whole. Further details on the *If I Were Jack* resource, including excerpts from the IVD and feedback from end users regarding the acceptability of the IVD, are available from: www.qub.ac.uk/IfIWereJack. Control schools will continue with their normal RSE practice.

#### Study design

A Phase II cluster randomised feasibility trial, with schools as the unit of randomisation, with embedded process and economic evaluations to determine recruitment, participation and retention rates; quality of

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implementation; acceptability and feasibility of the intervention and trial procedures; and cost. The study also piloted the feasibility and acceptability of collecting demographic information and other sexual-psychosocial data (via a questionnaire) relating to measuring the proposed primary and secondary outcomes in a future larger Phase III trial. Each participating pupil was enrolled in the study for approximately 9 months and was asked to complete a questionnaire three times, at baseline and 5 and 9 months later. The process evaluation included semistructured interviews and focus group discussions with a sample of pupils, teachers, and parents guardians regarding the acceptability and feasibility of the questionnaire, the intervention, and participation in the trial and also included observations of a sample of lessons and parent information sessions.

#### Study outcomes

Surrogate measures (alternatives to the use of UTP) used to create the composite primary outcome were abstinence from sexual intercourse (delay initiation of sex or return to abstinence) or avoidance of unprotected sexual intercourse (consistent correct use of contraception that does not include withdrawal or natural family planning). Secondary outcomes were drawn from the theoretical framework underpinning the intervention (theory of planned behaviour). The first of these was Knowledge to determine if pupils had increased knowledge about UTP. The second was Attitudes, in order to determine if pupils had increased awareness that men and women have roles and responsibilities in avoiding UTP, hold less stereotypical gender-related attitudes and have increased perception that most peers are not sexually active and use contraception when they are, and have increased perception. The third secondary outcome was Skills, in order to determine if pupils had increased self-efficacy to communicate about UTP and increased self-efficacy to avoid UTP. The final outcome was Intentions, in order to determine if pupils had higher anticipated regret about UTP and increased strengths of intention to avoid UTP.

#### Criteria for progression to main trial

The following issues were identified for consideration when using the results of the feasibility trial to decide whether or not to develop a protocol for a future Phase III effectiveness trial:

- The intervention is acceptable to schools (school principals and RSE teachers), pupils and parents/ guardians; can be feasibly implemented by teachers in schools in NI; and any indications of necessary further development do not exceed the PHA's contribution of £20,000. If there is a consensus among school teachers that the *If I Were Jack* intervention would be of little value to other schools or if fundamental logistical problems in its delivery become evident and cannot be rectified, we would not proceed to trial.
- Recruitment, participation and retention rates are likely to be adequate for a main trial. We would expect high rates of recruitment, participation and retention. However, if we do not recruit at least 25% of schools approached we shall not proceed to trial. In addition, if we experience > 25% of parents withdrawing their children from the study or > 25% of pupils refusing to participate we shall not proceed to trial. Finally, in relation to retention, if < 85% of pupils complete the primary outcome measure at follow-up, we would not proceed to trial.</li>
- Potential effect sizes indicate an achievable sample size.
- The survey instruments can be feasibly delivered and show acceptable reliability and validity.
- An economic evaluation can be feasibly conducted as part of the main trial.

## Results

The intervention proved acceptable to schools, pupils and parents/guardians, as evidenced through positive process evaluation. One minor refinement in relation to the parental component was required, namely the replacement of the teacher led face-to-face information session for parents/guardians by online videos designed to deliver the information to parents/guardians into their home. Recruitment of schools was successful (target 25%, achieved 38%). Withdrawal from the study was also low (10%); no schools

withdrew, parental withdrawal of consent accounted for 6.8% of loss (n = 70) and pupil opt-out for 3.2% (n = 32). Pupil retention was successful (target 85%, achieved 93%).

The between-group difference in incidence of unprotected sex of 1.3% (95% confidence interval 0.5% to 2.2%) and intraclass correlation coefficient of 0.01, by 9 months' follow-up in the feasibility trial, demonstrated an effect size consistent with those reported to have had a meaningful impact on UTP rates (resulting in an achievable sample size estimate of 66 schools for a future Phase III effectiveness trial).

Survey instruments showed high acceptability and reliability of measures. The Male Role Attitudes scale, Sexual Socialisation Peer scale, Sexual Self-Efficacy scale and Intentions to Avoid an UTP scale all had high internal consistency (Cronbach's alpha in excess of 0.7), and Family Connectedness, Comfort Communicating about Pregnancy, Comfort Communicating about Contraception, Sexual Socialisation Total and the Sexual Socialisation Parent scales had satisfactory internal consistency (Cronbach's alpha: 0.5–0.7). The knowledge questions also worked well, showing good variability, except for one item, which will be deleted for a future Phase III effectiveness trial. 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 (93%) of the pupils completed primary outcome at follow-up 2. Minor necessary changes to the questionnaire and classroom materials that became evident through process evaluation will also be addressed.

An economic evaluation at Phase III is feasible because during the feasibility study it was possible to (1) identify costs of delivering *If I Were Jack* (mean cost per pupil, including training of teachers, was calculated as £13.66); and (2) develop a framework for assessing cost-effectiveness. Additional secondary outcome measures including frequency of sexual intercourse, contraception use and diagnosis of sexually transmitted infections that will assist with economic evaluation at Phase III were shown to be feasible to collect during this Phase II feasibility study.

## Conclusions

Trial methods were appropriate, and recruitment and retention of schools and pupils was satisfactory, successfully demonstrating all criteria for progression to a future Phase III effectiveness trial.

#### **Trial registration**

This trial is registered as ISRCTN99459996.

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