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The 'If I Were Jack' feasibility trial

Submission date
28/11/2014

Recruitment status
No longer recruiting

Registration date
19/12/2014

Overall study status
Completed

Last Edited
20/07/2018

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There is increasing concern about high rates of teenage pregnancy in Northern Ireland (NI). This study will test a Relationship and Sexuality Education (RSE) resource which is designed to tackle this by strengthening young people's intention to avoid a teenage pregnancy. Parents, teachers, researchers and others who work with young people are recognising that targeting teenage men is an important but neglected part of addressing unintended teenage pregnancy. This study will fill this gap. This research will test the acceptability and practicality of using and evaluating a unique and scientifically informed educational resource on the topic of teenage men and unintended pregnancy in post-primary schools in NI. The proposed study will examine the value and practical issues surrounding the conduct of a definitive trial which would find out whether or not this intervention can improve young people's sexual health knowledge and behaviours over the medium and longer term. Thus, this study is the first step in a two-stage evaluation.

Who can participate?
All post-primary schools in Northern Ireland with more than 30 Year 11 pupils will be eligible to participate, with the exception of Special Schools, Hospital Schools, Independent Schools and Junior high schools. All pupils who are entering Year 11 in 2013/14 in eligible schools will be eligible for the study. School principals, Heads of Year 11 and teachers who deliver the intervention and agree to participate in the research will be included in the proposed process evaluation. Additionally, all parents of participating pupils will be asked to complete a questionnaire giving their views of the intervention and a sample of those who attend parents' /guardians' information evenings will be invited to participate in a focus group discussion about the intervention.

What does the study involve?
The key aim of this educational resource is to help boys and girls consider the consequences of an unintended pregnancy and to develop communication strategies for future or present relationships which will help them avoid an unintended pregnancy. The learning resource includes an interactive video drama which 'brings to life' a scenario of an unintended pregnancy from a teenage man's perspective and invites boys and girls to reflect on the possibility of such a situation in their lives. Each participant sits in front of a computer watching the story unfold and is prompted to answer questions about how they would think and feel in the situation in the video. The film is made using local actors and local settings to help young people in NI identify with the lead character and the situation. This resource is accompanied by a 4-week lesson plan,

which invites young people to consider the issues more deeply and to develop communication skills with their peers and parents in relation to avoiding an unintended pregnancy. The study involves a pilot trial and interviews with those who are delivering and receiving the intervention to gain their feedback. For the purposes of the trial, we will compare the results of implementing the intervention in five schools with what happens in two comparable schools where normal practice will continue. We will also conduct a process evaluation, interviewing school principals and teachers and conducting focus groups with a selection of parents and pupils to gather their opinions on whether the intervention is appropriate and useful. We will also collect information on the costs of running the project. The data will be analysed in preparation for a large-scale evaluation of the resource, to determine if it is effective in increasing young people's intention to avoid an unintended pregnancy and cost-effective as a public health intervention.

What are the possible benefits and risks of participating?
It is anticipated that taking part in the research will provide participants with the opportunity to be involved with an innovative RSE resource that is designed to decrease unintended teenage pregnancy. The findings of this research will be widely shared and should help to inform future policy and practice regarding pregnancy education for young people. There are no anticipated risks associated with taking part. Participants in the control group are not at any educational disadvantage as the study will be an add-on to the existing relationship and sexuality education (RSE) curriculum that all children in Northern Ireland receive.

Where is the study run from?
Queen's University Belfast (UK)

When is the study starting and how long is it expected to run for?
May 2014 to April 2016

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02092480

Protocol serial number
NIHR PHR 12/153/26 Lohan

Study information

Scientific Title
Increasing boys’ and girls’ intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

Study objectives
This feasibility study will:
1. Assess the acceptability of the intervention to schools (principals and RSE teachers), pupils and parents
2. Identify optimal structures and systems for the delivery of the intervention in the classroom
3. Establish intervention participation rates and reach, including equality of engagement across schools of different socio-economic 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
9. Identify the costs of delivering 'If I Were Jack' and pilot the methods for economic analysis in a phase III trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
School of Nursing and Midwifery Ethics Committee, Queen's University Belfast, 08/04/2014, application no: 14.02.02.V2 If I Were Jack

Study design
Phase II feasibility study with an embedded process evaluation

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Unintended teenage pregnancy

Interventions
The proposed study is a phase II feasibility study with an embedded process evaluation, 20 months in duration. It will assess the feasibility and acceptability of the intervention and trial methods, and provide estimates for a phase III cluster randomised trial, including potential effect sizes and recruitment, retention and participation rates, so that the feasibility and optimal design of a full-scale trial can be ascertained. The study will include an analysis of the costs of delivering the intervention and a process evaluation using a mixed-methods triangulated design to determine the acceptability of the intervention and research measures to participants and to establish fidelity to implementation protocol. It will also assess variation in normal practice of RSE in relation to teenage pregnancy.

Intervention: educational
The 'If I Were Jack' intervention is a classroom-based RSE resource designed to be delivered by teachers over 4 weeks, which also involves parents in the RSE process. It is composed of the following components:
1. The 'If I Were Jack' interactive video drama (IVD) which asks pupils to put themselves in Jack’s shoes and consider how they would feel and what they would do if they were Jack
2. 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
3. 60-minute training session for teachers wishing to implement the intervention
4. 60-minute information and discussion session for parents/guardians delivered by RSE teachers
5. Detailed information brochures and factsheets about the intervention and unintended teenage pregnancy in general for schools, teachers, teacher trainers, young people and parents

Study arm(s):
Intervention arm: after baseline data collection, four schools will be randomly assigned to the intervention arm. RSE teachers will deliver the intervention to all participating Year 11 pupils during four weekly lessons of the ‘Learning for Life and Work’ strand of the Key Stage 4 curriculum.

Control arm: after baseline data collection, three schools will be randomly assigned to the control arm. Participating pupils will not receive the 'If I Were Jack' intervention and will continue with normal RSE practice.

Intervention Type
Behavioural

Primary outcome(s)
1. Quality of intervention implementation and recruitment, participation and retention rates
2. Assessing fidelity to implementation protocol and differences in recruitment, participation and retention rates among those in intervention and comparison arms

Key secondary outcome(s))
1. Acceptability of the intervention to schools (principals and RSE teachers), pupils and parents
2. Acceptability of feasibility trial methods to participants
3. Variation in normal RSE practice across participating schools
4. Reliability and validity of survey instruments
5. Differences in outcomes for male and female pupils
6. Estimates of potential effect sizes for a full trial
7. Estimate of appropriate sample size for a full trial
8. Costs of delivering the intervention.

Other outcome measures:
9. Feasibility and acceptability of collecting demographic data and data relating to the proposed primary and secondary outcomes of a future phase III trial, i.e. sexual behavior data including engagement in sexual intercourse, contraception use, and diagnosis of STIs
10. Data regarding knowledge, attitudes, skills and intentions relating to avoiding teenage pregnancy
11. Assessing completion of the survey instruments at baseline and 5- and 9-month follow-up and participants' perceptions of the acceptability of the instruments and feasibility of delivering them in classroom settings

Completion date
30/04/2016

Eligibility

Key inclusion criteria
Feasibility trial: All post-primary schools in Northern Ireland with more than 30 Year 11 pupils will be eligible to participate, with the exception of Special Schools, Hospital Schools, Independent Schools and Junior high schools. All pupils who are entering Year 11 in 2013/14 in eligible schools will be eligible for the study.

Process evaluation with staff and parents: School principals, Heads of Year 11 and teachers who deliver the intervention and agree to participate in the research will be included in the proposed process evaluation. Additionally, all parents of participating pupils will be asked to complete a questionnaire giving their views of the intervention and a sample of those who attend parents' /guardians' information evenings will be invited to participate in a focus group discussion on the acceptability and feasibility of the intervention. Parents who are unable to communicate in English will be facilitated by university translation services.

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
Feasibility trial: Special Schools, Hospital Schools, Independent Schools and Junior high schools will be excluded from the sampling frame. Pupils who refuse to participate or pupils whose parents refuse to allow them to participate will be excluded. The principal analyses will be intention-to-treat but pupils who are absent at baseline and/or follow-up and fail to fill out a questionnaire on their return to school will be excluded from on-treatment analyses.

Process evaluation with staff and parents: Those who decline to participate will be excluded.

Date of first enrolment
01/11/2014

Date of final enrolment
20/12/2014

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Queen's University Belfast
School of Nursing and Midwifery
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Sponsor information

Organisation
Queen's University Belfast (UK)

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Government

Funder Name
Public Health Research Programme

Alternative Name(s)
NIHR Public Health Research Programme, The Public Health Research (PHR), PHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/07/2016		Yes	No
Results article	results	01/11/2018		Yes	No
Protocol article	protocol	01/01/2014		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes