The JACK Trial: Evaluation of an interactive filmbased intervention to reduce teenage pregnancy and promote positive sexual health

Submission date	Recruitment status	[X] Prospectively registered		
21/11/2016	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/11/2016	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
28/09/2023	Pregnancy and Childbirth			

Plain English summary of protocol

Background and study aims

The UK has the highest rate of teenage pregnancy in Western Europe, but too little is known about how to reduce this and there are large gaps in areas of research that might help. For example, policy makers and teachers alike recognise that targeting teenage boys is an important part of reducing rates of teenage pregnancy that has been largely neglected up to now. This still will address this gap by testing one of the few programmes available internationally which explicitly targets boys (as well as girls) to raise their awareness and improve their communication skills in order to avoid teenage pregnancies. It's about helping teenage boys to become part of the solution to avoiding teenage pregnancy. If I were Jack is a unique programme which was developed collaboratively with scientific experts, government bodies, relationship & sexuality education experts, pupils and teachers over several years in Northern Ireland. One of its unique characteristics is that it starts off with an interactive film which brings to life a week in the life of Jack, a young man whose girlfriend has just told him she is pregnant. The interactive drama invites each of the viewers, to 'be jack', to imagine how they would react and to make some decisions. We have already shown that the film drama and four-week programme helps to make the message real for boys and girls and helps them to think for themselves about how to avoid an unintended pregnancy, but we need to find out if this leads to changes in behaviour that might prevent teenage pregnancies. The aim of this study is to investigate whether the 'If I were Jack' programme will succeed in preventing unintended teenage pregnancies.

Who can participate?

Schools in Northern Ireland, Scotland, Wales and England and pupils who are entering Year 11 in NI, S3 in Scotland and Year 10 in England and Wales (about 14 years old).

What does the study involve?

Participating schools are randomly allocated to one of two groups. Pupils attending schools in the first group receive the If I Were Jack programme during four 30-40 minute school lessons over a period of four weeks. Pupils attending schools in the second group continue with normal school relationship and sex education throughout the study. At the start of the study and then

again 12-14 monhts later, pupils complete a 30-minute questionnaire. A sample of pupils, parents and teachers (approximately 50 of each) from eight randomly selected 'case study' schools are asked to take part in separate focus group discussions with a researcher regarding their views of the programme and its delivery. A sample of teachers in all participating schools also complete surveys regarding current relationship and sex education practice and parents of pupils who receive the programme are asked to complete a short online survey regarding their perceptions of the programme.

What are the possible benefits and risks of participating?

Participants may benefit from receiving support when they otherwise may not have been identified as needing such support. There is very little risk to participants as it involves completing repeat questionnaires in their classroom 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. In relation to pupils' focus group discussions on the topic of the programme, there is an additional risk that these discussions may touch on areas of a sensitive nature.

Where is the study run from?

The study is run from Queen's University Belfast, University of Glasgow, Cardiff University and London School of Hygiene and Tropical Medicine and takes place in 66 schools in the UK.

When is the study starting and how long is it expected to run for? November 2016 to December 2020

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

Who is the main contact?

1. Dr Aine Aventin
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2. Professor Maria Lohan
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Study website

http://www.qub.ac.uk/lflWereJack

Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers NIHR PHR 15/181/01

Study information

Scientific Title

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

Acronym

JACK Trial

Study objectives

At follow-up, fewer boys and girls in the intervention group will have had unprotected sexual intercourse than boys and girls in the control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Committee of the School of Nursing & Midwifery (SREC), Queen's University Belfast, 01/07/2017, ref: 11.MLohan.05.17.M6.V1

Study design

Phase III cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Unintended teenage pregnancy

Interventions

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 by avoiding unprotected sexual intercourse.

Participating schools will be randomly allocated to a trial group (experimental or control), stratified by UK country and socioeconomic group (% Eligibility Free School Meals).

Intervention group: Participants receive the If I were Jack intervention. This consists of 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 by avoiding unprotected sexual intercourse. The intervention is a classroom-based RSE resource designed to improve teenage boys' as well as girls' sexual health precaution behaviours. (I think you could remove this sentence given the addition of previous). It consists of the following components:

- 1. The If I Were Jack interactive film 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 designed to build pupils' skills to a) obtain necessary information, and b) develop communication skills with peers and trusted adults
- 3. Sixty-minute training session for teachers implementing the intervention
- 4. Two short animated films to engage parents/guardians and help/encourage them to have a conversation with their teenager about avoiding unintended pregnancy
- 5. Detailed information brochures and factsheets about the intervention and unintended teenage pregnancy in general for schools, teachers, teacher trainers, young people and parents /guardians

Teachers will deliver the intervention to pupils during four 30-40 minute weekly lessons but the object of most of the activities is generating pupil agency and enhanced peer communication to raise intentions to avoid an unintended pregnancy.

Comparator group: Participants do not receive the If I were Jack intervention and will continue with normal RSE practice.

Follow up for all participants takes place at 12-14 months past baseline and involves completing the same questionnaire as at baseline during one 30-minute session.

Intervention Type

Behavioural

Primary outcome measure

Avoidance of unprotected sex by age 15 is measured using a composite of individual responses to the questions 'Have you ever had sex without using contraception?' and 'The last time you had sex did you use contraception?' at baseline and 12-14 months later.

Secondary outcome measures

Secondary outcomes are measured at baseline and 12-14 months later:

- 1. Knowledge is measured by total score on items selected from the Mathtech Knowledge Inventory and SKATA
- 2. Comfort Communicating about sex and pregnancy are measured using scores on the Comfort Communicating about Avoiding Unintended Teenage Pregnancy Scale (to parents, peers and professionals) which was adapted items from the Mathtech Behaviour Inventory
- 3. Intentions to avoid unintended pregnancy is measured using scores on the Intentions to Avoid Unintended Pregnancy Scale
- 4. Social influences are measured using scores on the Male Role Attitudes Scale and Sexual

Socialisation Instrument (peer and parents sub-scales)

5. Beliefs about capabilities are measured with scores on an adapted version of the Sexual Self-Efficacy Scale

Overall study start date

01/11/2016

Completion date

31/12/2020

Eligibility

Key inclusion criteria

School inclusion criteria:

- 1. All post-primary schools in Northern Ireland with more than 30 pupils in the targeted intervention year
- 2. In Scotland all secondary schools with over 30 pupils in the targeted intervention year in the six Local Authority areas covered by NHS Greater Glasgow and Clyde (NHSGGC) Health Board
- 3. In Wales, all secondary schools in South and mid-Wales with over 30 pupils in year 10
- 4. In England all secondary schools with over 30 pupils in year 10 within one hour train time from central London
- 5. All schools must be able to send e-mail or text messages containing a link to the video to parents of their pupils.

Pupil inclusion criteria:

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 2017/18 in eligible schools.

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

13 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

66 schools, with approximately 120 pupils per school. Total approximately 7920 pupils.

Total final enrolment

8220

Key exclusion criteria

School exclusion critera:

Schools with less than 30 pupils in specified year group.

Pupil exclusion criteria:

- 1. Pupils who decline to participate
- 2. Pupils whose parents have returned opt out forms to the researchers

Date of first enrolment

01/02/2018

Date of final enrolment

30/06/2018

Locations

Countries of recruitment

England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre Queen's University Belfast

University Road Belfast United Kingdom BT7 1NN

Study participating centre University of Glasgow

Glasgow United Kingdom G12 8QQ

Study participating centre Cardiff University

Cardiff United Kingdom CF10 3AT

Study participating centre London School of Hygiene and Tropical Medicine

Keppel Street London United Kingdom WC1E 7HT

Sponsor information

Organisation

Queen's Univeristy Belfast

Sponsor details

63 University Road Belfast Northern Ireland United Kingdom BT7 1NN

Sponsor type

University/education

Website

www.qub.ac.uk

ROR

https://ror.org/00hswnk62

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

30/09/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the study contact. At the end of the study, all data will be stored for a minimum of 5 years and a maximum of 10 years in Queen's University Belfast (stored on a secure server, protected against unauthorised access by user authentication and a firewall). All data will be archived by year 10 in The UK Data Archive (UKDA) located in the University of Essex.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2017		Yes	No
<u>Protocol article</u>	protocol	28/07/2018	23/10/2019	Yes	No
Results article	results	27/08/2020	02/09/2020	Yes	No
Results article Results article		01/07/2022 01/09/2023	25/08/2022 28/09/2023	Yes Yes	No No