# Pilot evaluation to assess the feasibility and acceptability of Project Respect: a school-based intervention to prevent dating and relationship violence among young people

| Submission date                     | Recruitment status No longer recruiting | [X] Prospectively registered   |  |  |
|-------------------------------------|---|--------------------------------|--|--|
| 06/06/2017                          |   | [X] Protocol                   |  |  |
| <b>Registration date</b> 08/06/2017 | Overall study status Completed          | Statistical analysis plan      |  |  |
|                                     |   | [X] Results                    |  |  |
| Last Edited                         | Condition category                      | [] Individual participant data |  |  |
| 11/07/2023                          | Other                                   |                                |  |  |

## Plain English summary of protocol

Background and study aims

Dating and relationship violence refers to violence within or following a dating or longer-term sexual or romantic relationship. It includes threats, emotional and relational abuse, controlling behaviours, physical violence and non-consensual sexual activities. 'Project Respect' is a new programme that will be piloted in English secondary schools that aims to prevent dating and relationship violence among young people. In order to run a larger study to assess whether Project Respect works in reducing dating and relationship violence, a smaller study is needed to assess whether the intervention and research methods are practically possible. This study looks to pilot the programme and receive feedback on how feasible the programme is. It will not be able to tell whether the programme has reduced dating and relationship violence, but it will tell whether the programme is possible to deliver in schools, and whether students and staff like it. It is necessary to know whether it would be feasible and worthwhile doing a larger study which could tell us whether the programme reduced dating and relationship violence. This is important because a study looking at impacts on dating and relationship violence would be longer and more expensive, and we don't want to waste time and money doing it if the intervention doesn't seem promising or if it seems to have the potential to do more harm than good. The aim of this study is to assess whether the Project Respect programme and its research methods are practically possible to deliver in schools and whether students and staff like it in order to see if it is worthwhile doing a larger study.

## Who can participate?

Secondary school students nearing the end of years 8 and 9 and teaching/school leadership staff.

## What does the study involve?

Participants undertake questionnaire surveys to find out about each school's students before the programme. Schools are then randomly allocated to one of two groups. Those in the first group receive the Project Respect programme. This involves a classroom curriculum for students aged 13-15 which aims to challenge attitudes about gender and violence, develop

communication and anger management skills, and empower students to run campaigns challenging gender based harassment and dating and relationship violence in and beyond their schools. Students also receive the "Circle of 6" app which helps individuals contact friends or the police if threatened by or experiencing dating and relationship violence. Training is provided for school/non-teaching staff in safeguarding to prevent, recognise and respond to gender based harassment and dating and relationship violence. Senior leadership and other key staff also receive training to enable them to review school rules and policies to help prevent and respond to gender-based harassment and dating and relationship violence. Staff presence at 'hotspots' for these behaviours is increased. Parents also receive written information. Those in the second group continue with their usual programming. Delivery of the programme is assessed through staff and student interviews to find out what they think of the intervention, as well as observing one curriculum session per school.

What are the possible benefits and risks of participating?

Participants may benefit from the prevention of adolescent dating and relationship violence. Project Respect is informed by the strongest international evidence of effective interventions. There are no anticipated risks. However all participants are offered information about sources of support.

Where is the study run from?

This study is being run by the London School of Hygiene and Tropical Medicine (UK) and the University of Bristol (UK) and takes place in six state schools in the UK.

When is the study starting and how long is it expected to run for? March 2017 to December 2019

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

Who is the main contact? Professor Chris Bonell chris.bonell@lshtm.ac.uk

# Contact information

Type(s)

Scientific

### Contact name

**Prof Chris Bonell** 

#### Contact details

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# Additional identifiers

## **EudraCT/CTIS** number

Nil known

#### IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

National Institute for Health Research Public Health Research Programme project number 15/03/09

# Study information

## Scientific Title

Pilot RCT of Project Respect: a school-based intervention to prevent dating and relationship violence and address health inequalities among young people

## **Acronym**

N/A

## Study objectives

Research questions:

- 1. Is progression to a phase III RCT justified in terms of pre-specified criteria?: randomisation occurs and four or more schools out of six accept randomization and continue within the study; the intervention is implemented with fidelity in at least three of the four intervention schools; the process evaluation indicates the intervention is acceptable to 70% or more of year 9 and 10 students and staff involved in implementation; CASI surveys of students are acceptable and achieve response rates of at least 80% in four or more schools; and methods for economic evaluation in a phase III RCT are feasible.
- 2. Which of two existing scales, the Safe Dates ('SD') and the short Conflict in Adolescent Dating Relationships Inventory ('CADRI'), is optimal for assessing DRV victimisation and perpetration as primary outcomes in a phase III RCT, judged in terms of completion, inter-item reliability, and fit? 3. What are likely response rates in a phase III RCT?
- 4. Do the estimates of prevalence and intra-cluster correlation coefficient (ICC) of DRV derived from the literature look similar to those found in the UK so that they may inform a sample size calculation for a phase III RCT?
- 5. Are secondary outcome and covariate measures reliable and what refinements are suggested?
- 6. What refinements to the intervention are suggested by the process evaluation?
- 7. What do qualitative data suggest about how contextual factors might influence implementation, receipt or mechanisms of action?
- 8. Do qualitative data suggest any potential harms and how might these be reduced?
- 9. What sexual health and violence related activities occur in and around control schools?

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

- 1. London School of Hygiene and Tropical Medicine Research Ethics Committee, 25/01/2017, ref: 11986
- 2. National Society for the Prevention of Cruelty to Children Research Ethics Committee, 05/06/2017, ref: R/17/97

## Study design

Pilot 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

See trial outputs table

## Health condition(s) or problem(s) studied

Dating and relationship violence

## **Interventions**

Participating students undergo baseline surveys at the end of years 8 and 9 (students age 12-15 years) to collect data on socio-demographic variables, pre-hypothesised outcome variables and potential confounders. Prior to all data collection, students are given an information sheet at least one week in advance, and an oral description of the study prior to consent being sought with the opportunity to ask questions. Topics to be explored and the total anonymity of questionnaire data is clearly stated. Students are then invited to assent to participate in data collection. Students are provided with information about school and where relevant other local safeguarding officers and national helpline and other agencies for those experiencing dating and relationship violence and other forms of abuse. As is conventional with UK trials in secondary schools including of sexual health and violence prevention interventions, parents /quardians are sent a letter and detailed information sheet at least one week prior to data collection and asked to contact the school or research team should they have questions or not wish their child to participate. Surveys are completed confidentially and anonymously by students with researchers present to explain data collection and support students where necessary. Teaching staff are present but remain at the front of the classroom, helping to maintain order but being unable to read student responses.

After the baseline surveys, schools are randomly allocated (2:1) to either the intervention arm or the control arm remotely by the London School of Hygiene and Tropical Medicine clinical trials unit, stratified by region (south-east and south-west England). The 2:1 allocation in the pilot enables randomisation while ensuring sufficient diversity among four schools for piloting the intervention.

## Intervention Arm:

Schools in the intervention arm receive the Project Respect programme. Project Respect is a school-based universal prevention intervention. It comprises the following components: training for school senior leadership (where appropriate including governors) and other key staff (pastoral support; personal, social and health education curriculum deliverers) to enable them to plan and deliver the intervention in their schools and review school rules and policies to help prevent and respond to gender-based harassment and dating and relationship violence, and increase staff presence in 'hotspots' for these behaviours; training of all other school staff in safeguarding to prevent, recognise and respond to gender-based harassment and dating and relationship violence; written information for parents on the intervention and advice on preventing and responding to dating and relationship violence; making available to students the 'Circle of 6' app which helps individuals contact friends or the police if threatened by /experiencing dating and relationship violence; and classroom curriculum delivered by teachers to students age 13-15 including student-led campaigns. School policies and rules are rewritten to ensure these aim to prevent and respond to dating and relationship violence. Hotspots for dating and relationship violence and gender-based harassment on the school site are patrolled by staff to prevent and respond to incidents. Responses include appropriate sanctions for perpetration, support for victims, and referral of victims or perpetrators to specialist services where necessary. The curriculum comprises of six sessions in secondary school year 9 (students age 13/14 years) and two booster sessions in year 10 (students age 14/15 years).

## Lessons focus on:

- 1. Defining healthy relationships and inter-personal boundaries
- 2. Challenging gender norms and mapping 'hotspots' for harassment and violence on the school site
- 3. Empowering students to run campaigns challenging gender-based harassment and dating and relationship violence in and beyond their schools (for example, posters, social media, stalls)
- 4. Communication and anger management skills relating to relationships and intervening as bystanders
- 5. Accessing local services relating to dating and relationship violence
- 6. Reviewing local campaigns.

Learning activities include: information provision, whole class discussions, using video vignettes to help students identify abusive relationships, quizzes, role plays and exercises like measuring personal space, and cooperative planning and review of local campaigns.

## Control group:

The control arm consist of schools randomly allocated to the control group, and not implementing Project Respect but continuing with any existing gender, violence or sexual health-related provision. The nature of the control schools are assessed within the current pilot RCT by examining provision in and around control schools as well as intervention schools at baseline.

Students are followed up with surveys to assess the acceptability of the programme. Absent students are surveyed by leaving paper questionnaires and stamped addressed envelopes with schools. These surveys take place 16 months from the start of the programme (September-October 2018) near the beginning of years 10 and 11 (age 14/15 and 15/16) to collect self-report data on intervention participation, outcomes and potential mediators. Staff are also surveyed online at baseline and 16 months for our economic and process evaluations.

## Intervention Type

Behavioural

## Primary outcome measure

Dating and relationship violence (DRV) victimisation and perpetration as measured by self-reports using the short Conflict in Adolescent Dating Relationship Inventory and the Safe Dates questionnaire measures at 16 months.

## Secondary outcome measures

Current version as of 12/04/2018:

- 1. Frequency of dating and relationship violence (DRV) victimisation and perpetration as measured by self-reports using the short Conflict in Adolescent Dating Relationship Inventory and the Safe Dates questionnaire measures at 16 months
- 2. Positive emotional well-being including psychological functioning, cognitive-evaluative dimensions and affective-emotional aspects as measured using self report questionnaire Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS) at 16 months
- 3. Quality of life is measured using the self report questionnaire paediatric quality of life inventory (PedsQL) at 16 months
- 4. Sexual harassment is measured using the self report Hostile Hallways questionnaire measure at 16 months
- 5. Behavioural, emotional and peer problems and prosocial strengths are measured using the self report Strengths and Difficulties Questionnaire (SDQ) at 16 months
- 6. Pregnancy and unintended pregnancy (initiation of pregnancy for boys) is measured using adapted Ripple and Share trial self report questionnaire measures at 16 months
- 7. Sexually transmitted infections are measured using adapted Ripple and Share trial self report questionnaire measures at 16 months
- 8. Age of sexual debut is measured using adapted Ripple and Share trial self report questionnaire measures at 16 months
- 9. Sexual partner numbers is measured using adapted Ripple and Share trial self report questionnaire measures at 16 months
- 10. Use of contraception at first and last sex is measured using adapted Ripple and Share trial self report questionnaire measures at 16 months
- 11. Use of primary care, accident & emergency, is measured using the YPDP self report questionnaire measure at 16 months
- 12. Contact with the police is measured using the YPDP self report questionnaire measure at 16 months
- 13. School attendance and educational attainment is measured using school routine administrative data at 16 months

## Original version:

- 1. Frequency of dating and relationship violence (DRV) victimisation and perpetration as measured by self-reports using the short Conflict in Adolescent Dating Relationship Inventory and the Safe Dates questionnaire measures at 16 months
- 2. Positive emotional well-being including psychological functioning, cognitive-evaluative dimensions and affective-emotional aspects as measured using self report questionnaire Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS) at 16 months
- 3. Quality of life is measured using the self report questionnaire paediatric quality of life inventory (PedsQL) at 16 months
- 4. Sexual harassment is measured using the self report Hostile Hallways questionnaire measure at 16 months
- 5. Behavioural, emotional and peer problems and prosocial strengths are measured using the self report Strengths and Difficulties Questionnaire (SDQ) at 16 months
- 6. Pregnancy and unintended pregnancy (initiation of pregnancy for boys) is measured using adapted Ripple and Share trial self report questionnaire measures at 16 months
- 7. Sexually transmitted infections are measured using adapted Ripple and Share trial self report

questionnaire measures at 16 months

- 8. Age of sexual debut is measured using adapted Ripple and Share trial self report questionnaire measures at 16 months
- 9. Sexual partner numbers is measured using adapted Ripple and Share trial self report questionnaire measures at 16 months
- 10. Use of contraception at first and last sex is measured using adapted Ripple and Share trial self report questionnaire measures at 16 months
- 11. Non-volitional sex is measured using adapted Ripple and Share trial self report questionnaire measures at 16 months
- 12. Use of primary care, accident & emergency, is measured using the YPDP self report questionnaire measure at 16 months
- 13. Contact with the police is measured using the YPDP self report questionnaire measure at 16 months
- 14. School attendance and educational attainment is measured using school routine administrative data at 16 months

## Overall study start date

01/03/2017

## Completion date

31/12/2019

# Eligibility

## Key inclusion criteria

- 1. Secondary school students nearing the end of years 8 and 9
- 2. Teaching and leadership staff

# Participant type(s)

Healthy volunteer

# Age group

Child

# Lower age limit

13 Years

## Upper age limit

15 Years

## Sex

Both

# Target number of participants

The pilot RCT will focus on feasibility and no power calculation for this has been performed. The analytic sample for outcome assessment in the pilot will be a minimum of 1800 students at the ends of years 8 and 9 (age 12/13 and 13/14) at baseline with follow up at 16 months.

## Total final enrolment

1426

## Key exclusion criteria

No students in participating schools who are competent to give informed consent to participate will be excluded from our study, those with mild learning difficulties or poor English will be supported to complete the questionnaire by fieldworkers.

# Date of first enrolment

12/06/2017

## Date of final enrolment

15/07/2017

# Locations

## Countries of recruitment

England

**United Kingdom** 

Study participating centre London School of Hygiene and Tropical Medicine United Kingdom WC1H 9SH

Study participating centre University of Bristol United Kingdom BS8 2PS

# Sponsor information

## Organisation

London School of Hygiene and Tropical Medicine

## Sponsor details

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# Sponsor type

University/education

## Website

www.lshtm.ac.uk

## **ROR**

https://ror.org/00a0jsq62

# Funder(s)

## Funder type

Government

## **Funder Name**

National Institute for Health Research Public Health Research Programme

# **Results and Publications**

## Publication and dissemination plan

As well as reporting in the NIHR Public Health Research journal, we would submit two open access papers to high impact journals reporting our key findings regarding (1) implementation of Project Respect and (2) design and piloting of innovative survey methods and outcome measures. All these will be submitted for publication in early 2019.

# Intention to publish date

01/03/2020

# Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from chris.bonell@lshtm.ac.uk

# IPD sharing plan summary

Available on request

# Study outputs

| Output type        | Details                        | Date<br>created | Date<br>added  | Peer<br>reviewed? | Patient-<br>facing? |
|--------------------|--------------------------------|-----------------|----------------|-------------------|---------------------|
| Protocol article   | protocol                       | 22/01/2019      |                | Yes               | No                  |
| Basic results      |                                | 15/05/2019      | 16/05<br>/2019 | No                | No                  |
| Results article    | results                        | 01/11/2020      | 04/09<br>/2020 | Yes               | No                  |
| Other publications | co-production of interventions | 17/02/2021      | 23/02<br>/2021 | Yes               | No                  |
| Results article    | results                        | 01/03/2020      | 23/02<br>/2021 | Yes               | No                  |

| Results article               |   | 04/03/2022 07/2      | 7/03<br>2022 | Yes | No  |
|-------------------------------|---|----------------------|--------------|-----|-----|
| Participant information sheet | Consent form for student interviews         | 11                   | 1/07<br>2023 | No  | Yes |
| Participant information sheet | Information Sheet for Parents<br>/Guardians | 1 <sup>-</sup><br>/2 | 1/07<br>2023 | No  | Yes |
| Participant information sheet | Information sheet for student interviews    |                      | 1/07<br>2023 | No  | Yes |