

# SaFE: a sexual health and healthy relationships intervention for further education

<b>Submission date</b> 27/01/2020	<b>Recruitment status</b> Suspended	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/03/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/01/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Dating and relationship violence (DRV) is common among young people in the UK. DRV includes threats, emotional abuse, controlling behaviour, physical violence and forced sexual activity. About half of young people in Further Education (FE) report DRV. Young people in the UK have poor sexual health including the highest rates of teenage pregnancy in Western Europe and high rates of sexually transmitted infections (STIs). Improving sexual health and reducing DRV in young people is a UK public health priority. The FE sector (including colleges and 6th forms) is growing and most students are aged 16-24. It is suited for public health interventions to improve sexual health and reduce DRV, but few exist to date.

The aim of the study is to refine and test 'SaFE,' an intervention for FE settings to improve sexual health and reduce DRV and sexual harassment among young people.

### Who can participate?

All state-funded further education settings including community colleges and 6th forms attached to secondary schools will be eligible to participate, including private and Welsh medium schools.

### What does the study involve?

SaFE intervention: 1) offering free onsite sexual health (e.g. condoms, STI tests and pregnancy tests) and relationship services; 2) publicising these services and; 3) training FE staff how to promote sexual health and recognize and respond to DRV and sexual harassment.

The researchers will survey students in six FE settings then randomly decide four settings to receive SaFE and two to act as comparisons. In sites delivering SaFE the researchers will interview staff and students to find out what they think of it, and observe the delivery of the intervention. Students in all sites will be surveyed again 12 months later. This will tell the researchers whether a much larger study to test the effectiveness of SaFE is worthwhile.

Patient and public involvement (PPI): This study builds on 15 months of work with over 2000 students and 200 staff from six FE settings, 12 sexual health staff and an advisory group of 16-21 year olds (ALPHA) to explore which components should be combined into an intervention. The researchers discussed the findings, intervention and methods for this project with 30

stakeholders at a consultation event. ALPHA are also in support of this proposal. PPI will continue in the proposed study by asking FE staff, students, parents and stakeholders to help refine the intervention materials. The Study Steering Committee will include FE staff, students, a parent and independent sexual health specialists.

What are the possible benefits and risks of participating?

Benefits of participation include: access to enhanced, onsite sexual health and relationship support services; increased awareness of indicators of dating and relationship violence among individual students and college settings; an opportunity to shape institutional practice through raising awareness of key issues; long-term improvements in sexual health and in support provision within FE settings.

There are no adverse events or serious adverse events expected to be related specifically to the trial interventions.

The researchers do not expect participants to experience any no adverse events or serious adverse events as a result of their participation in the trial. However, due to the sensitive nature of the trial topic and intervention, the researchers understand that participants may express their emotional or psychological distress related to their experiences and/or beliefs about sexual health and historical experiences, including Dating and Relationship Violence. The researchers have designed the intervention to be delivered in a supportive and non-judgmental manner by expert clinical teams who already provide similar services with the participant group. All on-site services will be provided by trained clinical teams who are leading providers of youth-focused sexual health and relationship services. These delivery staff are trained on how to deal with and support participants who express distress and advise participants on where to find additional support should they require more specific advice for their concerns. Delivery teams will also adhere to their existing Local Health Board/CCG practices on safeguarding and reporting of disclosures during service provision.

Where is the study run from?

1. DECIPHER, School of Social Sciences, Cardiff University (UK)
2. Cardiff University Centre for Trials Research (UK)

When is the study starting and how long is it expected to run for?

January 2020 to March 2023

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Honor Young  
youngh6@cardiff.ac.uk

## Contact information

**Type(s)**

Public

**Contact name**

Dr Honor Young

**Contact details**

1-3 Museum Place  
Cardiff  
United Kingdom  
CF10 3NB  
+44 (0)29 2087 9609  
youngh6@cardiff.ac.uk

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

270379

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

17/149/12, IRAS 270379

## Study information

### Scientific Title

A pilot randomised trial of SaFE: a sexual health and healthy relationships intervention for Further Education.

### Acronym

SaFE

### Study objectives

It is feasible and acceptable to deliver on-site sexual health and relationship services within FE /6th Form settings.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 23/10/2019, School of Social Sciences Research Ethics Committee of Cardiff University (Glamorgan Building, King Edwards VII Avenue, Cardiff, CF10 3WT, UK; +44 (0)2920 875179; no email provided), ref: SREC/3397

### Study design

Pilot 2-arm cluster randomized trial with an embedded process evaluation

### 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 contact details to request a participant information sheet

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

Sexual health

### **Interventions**

Randomisation will occur after all settings have completed baseline data collection.

Clusters (settings) will be randomised to receive either the SaFE intervention or usual practice. Following baseline surveys (Sep/Oct 2020), the trial statistician will randomly allocate settings into 2 arms using a 2:1 ratio: SaFE delivered in 4 settings, and usual practice in 2. The allocation will be stratified by country and type of setting. Recruitment will take place between January and July 2020.

The components of SaFE include:

1. Onsite access to sexual health and relationship services (DRV prevention) available for 2 hours on 2 days a week, delivered by NHS sexual health service providers in each region.
2. Publicity of onsite sexual health and relationship services.
3. FE staff training on how to promote sexual health, and recognize, prevent and respond to DRV and sexual harassment.

Control sites will receive usual practice for their site, which may include on-site access to free condoms and referrals to external support services in the community.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

1. Unprotected intercourse at last intercourse measured using validated questions from the SHARE questionnaires within the SaFE Student Survey, at baseline and 12-months post-baseline
2. Self-report experience of DRV victimisation in the last 12 months measured using sCADRI within the SaFE Student Survey, at baseline and 12-months post-baseline

### **Secondary outcome measures**

1. STI and pregnancy prevention methods used at last intercourse measured using the SaFE Student Survey at baseline and 12-month follow up
2. Use of emergency contraception at last intercourse measured using the SaFE Student Survey at baseline and 12-month follow up STI testing and diagnosis in the last 12 months measured using the SaFE Student Survey at baseline and 12-month follow up Self-reported pregnancy and unintended pregnancy (initiation of pregnancy for men) within the last 12 months measured using the SaFE Student Survey at baseline and 12-month follow up

3. Sexual regret at last intercourse using measures from the Avon Longitudinal Study of Parents and Children (ALSPAC), measured within the SaFE Student Survey at baseline and 12-month follow up
4. Sexual harassment taking place at FE settings in the last 12 months using measures taken from the School Health Research Network survey and Hostile Hallways survey, measured within the SaFE Student Survey at baseline and 12-month follow up
5. Non-volitional sex in the last 12 months using measures from the National Survey of Sexual Attitudes and Lifestyles (NATSAL), measured within the SaFE Student Survey at baseline and 12-month follow up
6. DRV perpetration in the last 12 months using the sCADRI as described above, within the SaFE Student Survey, at baseline and 12-months post-baseline
7. Health related quality of life, measured using the EQ-5D-5L scale, within the SaFE Student Survey, at baseline and 12-months post-baseline
8. Self-reported awareness of services, and help seeking for victims and perpetrators, measured using the SaFE Student Survey, at baseline and 12 months post-baseline

**Overall study start date**

18/06/2019

**Completion date**

31/03/2023

## Eligibility

**Key inclusion criteria**

1. All state-funded FE settings including community colleges and 6th forms attached to secondary schools will be eligible to participate, including private and Welsh medium schools
2. All students aged 16 and older enrolled at participating FE settings

**Participant type(s)**

Learner/student

**Age group**

Mixed

**Lower age limit**

16 Years

**Sex**

Both

**Target number of participants**

6 schools, 1,000 students

**Key exclusion criteria**

1. Schools/colleges for those with learning disabilities
2. Settings with extended existing onsite service provision (e.g. STI testing)

**Date of first enrolment**

06/01/2020

**Date of final enrolment**

01/09/2021

## Locations

**Countries of recruitment**

United Kingdom

Wales

**Study participating centre****Cardiff University**

Centre for Trials Research

College of Biomedical & Life Sciences, 7th Floor

Neuadd Meirionnydd

Heath Park

Cardiff

United Kingdom

CF14 4YS

## Sponsor information

**Organisation**

Cardiff University

**Sponsor details**

Research Governance

McKenzie House, 7th Floor

30-36 Newport Road

Cardiff

Cardiff

Wales

United Kingdom

CF24 0DE

+44 (0)2920879277

resgov@cardiff.ac.uk

**Sponsor type**

University/education

**Website**

<https://www.cardiff.ac.uk/>

**ROR**

<https://ror.org/03kk7td41>

# 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

The researchers will make results available via: summary reports to participating FE settings; the NIHR Public Health Research journal; two academic papers; practitioner and policy conferences; two policy stakeholder meetings (one England, one Wales); an article for the Times Education Supplement; DECIPHer and Centre for Trials Research Twitter, blogs and infographics. A publication policy will be drafted and approved by the Trial Management Group. It will state principles for publication, describe a process for developing output, contain a map of intended outputs and specify a timeline for delivery. The publication policy will respect the rights of all contributors to be adequately represented in outputs (e.g. authorship and acknowledgments) and the trial to be appropriately acknowledged. Authorship of parallel studies initiated outside of the TMG will be according to the individuals involved in the project but must acknowledge the contribution of the TMG and the Trial Coordination Centre.

## Intention to publish date

01/04/2023

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. All data requests should be submitted to the corresponding author for consideration and requests will then be reviewed by the Lead Investigator and the Cardiff University Centre for Trials Research. Access to anonymised data may be granted following this review. Data sharing will be restricted to deidentified participant

data and coding, which will be shared as an SPSS file.

No data sharing requests will be considered prior to publication of the study final report by the funders, NIHR, or more than twenty years after the study completion date (defined as end of funded period). For qualitative data generated by the research, this is not considered suitable for sharing beyond that contained within study publications and the final report to funders. Further information can be obtained from the corresponding author.

A separate study protocol document will be published in advance of the final report, subject to funder approval. The study statistical analysis plan will be published with the final approved protocol and following review by the Trial Steering Committee.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		20/12/2024	20/01/2025	Yes	No