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

Submission date
27/01/2020

Recruitment status
Suspended

Registration date
04/03/2020

Overall study status
Completed

Last Edited
20/01/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Public

Contact name
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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
270379

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)

Prevention

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Sex
All

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

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

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?
Results article		20/12/2024	20/01/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes