Optimisation, feasibility testing and a pilot randomised trial of SaFE: a sexual health and healthy relationships intervention for Further Education.

VERSION 1.7: 26.11.19

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The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the relevant trial regulations, GCP guidelines, and CTR's SOPs.
I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor. I also confirm that I will make the findings of the trial publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies from the trial as planned in this protocol will be explained.

Director:		
Name	**Signature**	**Date**
Chief Investigator:		
Name: Honor Young	**Signature:**	**Date: 28.8.19**

General Information This protocol describes the SaFE optimisation, feasibility test and randomised control trial, and provides information about the procedures for entering participants into the trial. The protocol should not be used as a guide, or as an aide-memoire for the treatment of other participants. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the trial. Problems relating to the trial should be referred, in the first instance, to CTR.

This study/project is funded by the National Institute for Health Research (NIHR) Public Health Research Programme (Project reference: 17/149/12). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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The SaFE trial is being run in partnership with the Centre for Trials Research (CTR), Cardiff University, a Clinical Research Collaboration (UKCRC) registered trials unit.

This protocol has been developed by the SaFE Trial Management Group (TMG).
For **all queries** please contact the SaFE team through the main trial email address. Any queries will be directed through the SaFE Study Manager to either the Chief Investigator or a Co-Investigators

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Glossary of abbreviations

AE	Adverse Event
ALPHA	Advice Leading to Public Health Advancement
CF	Consent Form
CI	Chief Investigator
CTR	Centre for Trials Research
CTU	Clinical Trials Unit
DRV	Dating and relationship violence
FE	Further Education
GCP	Good Clinical Practice
GP	General Practitioner
HE	Health Economics
HTA	Health Technology Assessment
IC	Informed consent
MRC	Medical Research Council
NCT	National Clinical Trial
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NIMP	Non-Investigational Medicinal Product
NLI	No Local Investigator
NPSA	National Participant Safety Agency
NRR	National Research Register
PCT	Primary Care Trust
PI	Principal Investigator
PIAG	Participant Information Advisory Group
PIC	Participant Identification Centre
PIS	Participant Information Sheet
QA	Quality Assurance
QALY	Quality-adjusted Life Years
QC	Quality control
QL (QoL)	Quality of Life
R&D	Research and Development
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

1. Amendment History

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

Amendment No. *(specify substantial/non-substantial)*	**Protocol version no.**	**Date issued**	**Summary of changes made since previous version**
1	1.8	27/01/20	University sponsorship confirmation added.

2. Synopsis

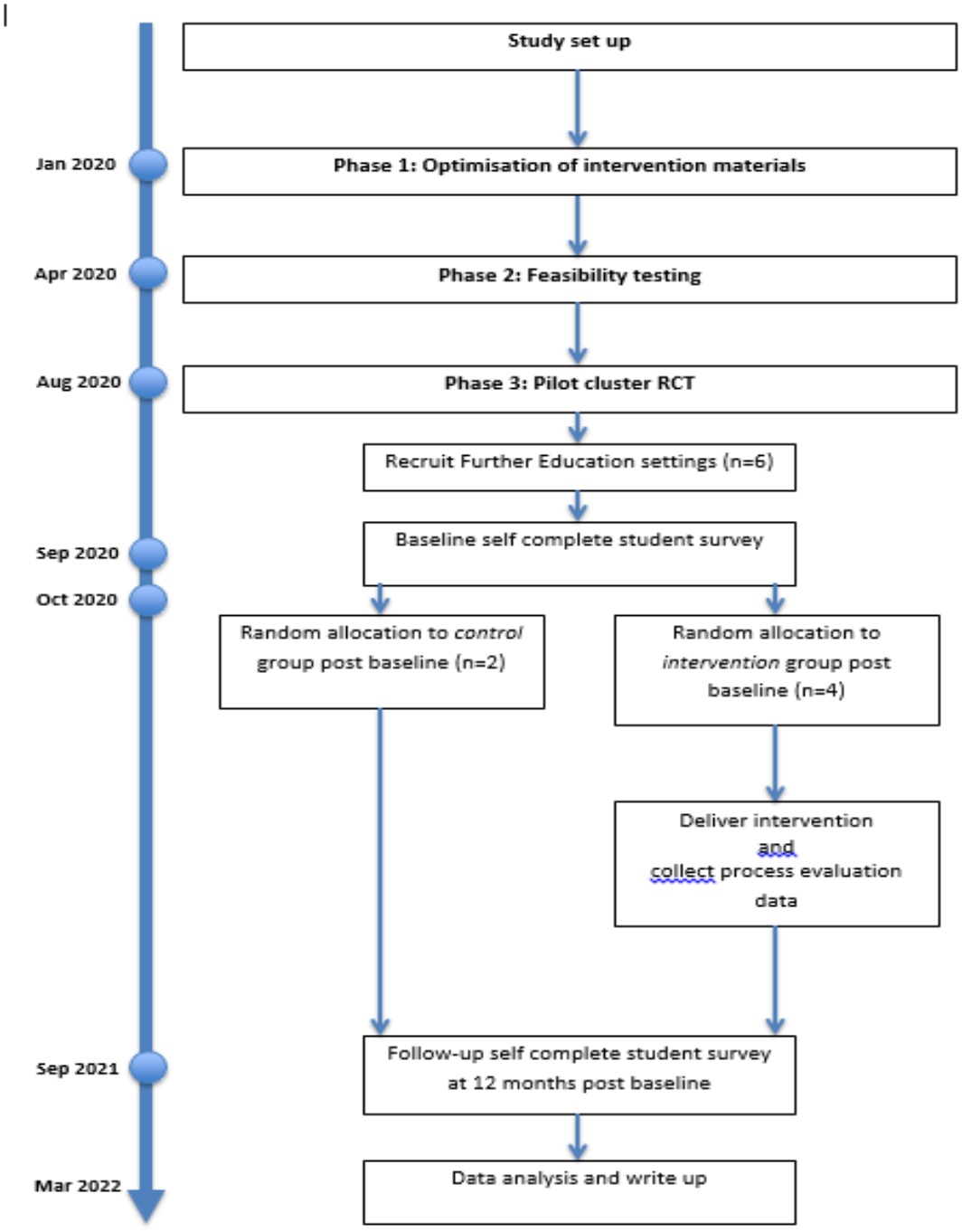
Short title	Optimisation, feasibility testing and a pilot randomised trial of SaFE: a sexual health and healthy relationships intervention for Further Education.
Acronym	SaFE
Internal ref. no.	
Development phase	(Phase II)
Funder and ref.	NIHR PHR 17/149/12
Trial design	Optimisation, feasibility testing and pilot RCT
Trial participants	Students attending FE settings.
Planned number of sites	Feasibility study: Two FE settings (one in England, one in Wales) Pilot trial: Six FE settings (3 settings from each country (England, Wales); comprising both 6th forms and FE colleges)
Inclusion criteria	Settings: Feasibility testing: One college and one 6th form will be recruited for feasibility testing. FE settings will be purposively sampled based on location in South Wales and Bristol/South Gloucester/Somerset. Pilot cRCT: 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. Students: All students aged 16 and older enrolled at participating FE settings.
Exclusion criteria	Settings: Feasibility testing: Sites used in the MRC PHIND funded SaFE project or optimisation phase (Phase 1) as well as those with current onsite sexual health provision (e.g. STI testing) will not be eligible to take part (estimated at 15.1% by Public Health England in 2015/16. National data not available for Wales). Schools for those with learning disabilities will be excluded. Pilot cRCT: Schools for those with learning disabilities will be excluded. For this study, settings with existing onsite service provision (e.g. STI testing) will also be excluded from the sampling frame. Students: FE students aged 15 and younger will be excluded.
Treatment duration	10 months
Follow-up duration	The baseline survey will occur in Sep/Oct 2020 and follow up 12 months post baseline (Sep/Oct 2021)
Planned trial period	Study will commence 1st January 2020 to 3th September 2022 (33 months)
Primary objective	To assess the feasibility and acceptability of delivering the SaFE intervention to determine whether to proceed to a full-scale RCT.

Secondary objectives	1. Is it feasible and acceptable to implement the intervention in two FE settings (one college and one 6th form); what refinements are required? 2. Are outcome measures reliable and how might they need to be refined? 3. Can a sufficient number of FE settings be recruited, randomly allocated and retained? 4. What proportion of FE students approached are recruited and retained? 5. What reach does the intervention achieve among students? 6. What are the consenting and governance requirements of data providers to link to routine sexual health data? 7. What proportion of FE students provide consent for linkage to routine sexual health data? 8. What do qualitative data suggest in terms of intervention mechanisms and refinements to programme theory? 9. How do contextual factors influence implementation, receipt and mechanisms of action? 10. Are there potential harms associated with the intervention; how might these be reduced? 11. What preventative sexual health, DRV and sexual harassment activities occur in and around control settings? 12. What methods are required and feasible to record delivery costs and potential impacts in an economic evaluation in a Phase III trial? 13. Following a pilot cRCT, is a Phase III cRCT justified in relation to our progression criteria?
Primary outcomes	Stage 1 (optimisation) outcome: an intervention that in the opinion of the research team, stakeholder advisory group and TSC is consistent with the theory of change. Stage 2 (feasibility testing) outcome: an intervention that has been prototyped and refined to improve acceptability and fidelity of implementation. Stage 3 (pilot cRCT): The primary outcome will be whether progression to a Phase III RCT is justified in terms of pre-specified progression criteria.
Intervention	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. *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.

3. Trial summary & schema

3.1 Trial flow chart

Figure 1: SaFE Intervention flow chart



3.2 Trial lay summary

Background: 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 the highest rates of teenage pregnancy in Western Europe and poor sexual health including 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.

Aim: To refine and test 'SaFE,' an intervention for FE settings to improve sexual health and reduce DRV and sexual harassment among young people.

Method: This project builds on our previously funded study where FE students, FE staff and sexual health charity staff said that they want onsite sexual health services and staff safeguarding training about sexual health and relationships, but they are not currently available. The SaFE intervention addresses these gaps by: 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. We plan to test whether SaFE improves sexual health and reduces DRV and sexual harassment, but first we need to find out whether the intervention and research methods are practical and acceptable. First, we will work with FE students, FE staff, parents, policy makers, subject experts (including third-sector) and a youth advisory group to adapt existing publicity and staff training materials for use in FE. Second, we will test and refine SaFE in two FE settings. Third, we will conduct a larger pilot of SaFE: we 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 we will interview staff and students to find out what they think of it, and we will observe the delivery of the intervention. We will survey students in all sites again 12 months later. This will tell us whether a much larger study to test the effectiveness of SaFE is worthwhile. This is important as we do not want to waste public resources if such a study is not promising.

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. We 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.

Dissemination: We will make our 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.

4. Background

According to the World Health Organisation (WHO), sexual health includes positive, pleasurable, respectful and safe sexual relationships and experiences free of coercion, discrimination and violence.[1] However, many young people's experiences fall short of this.[2] Globally, 10-50% of women report violence with a current or previous partner,[3] with prevalence highest among girls in adolescence.[4-7] In the UK, 50% of young people attending further education (FE) report experience of dating or relationship violence (DRV); among 16-19 year olds 46%-50% report controlling behaviours and 27%-32% threatening behaviours.[8]1 The median age for most recent occurrence of non-volitional sex (sex against one's will; NVS) is 18 among men and 16 among women.[9] Most young people perceive few peer sanctions against DRV,[10] and at an individual level, norms accepting of gender-based violence and harassment strongly correlate with DRV perpetration and victimisation.[6,7,11-13] Sexual harassment includes behaviours ranging from sexual comments, jokes and bullying to physical behaviour, sexual coercion and online harassment.[14] In 2017 in the UK, 64% of girls aged 13-21 reported sexual harassment at school or college in the past year; with 39% having their bra strap pulled by a boy and 27% having their skirts pulled up within the last week.[15]

Sexual health outcomes among young people in the UK also remain poor. The UK still has the highest rate of under-18 births in western Europe, and the third National Survey of Sexual Attitudes and Lifestyles (Natsal-3) in 2013 found 21% of all unplanned pregnancies occur among 16-18 year-olds.[16,17] In 2017, young people aged 15-25 accounted for 63% of chlamydia cases, 46% of genital warts, 40% of genital herpes and 37% of gonorrhoea diagnoses [18] and in 2016, 11% of new HIV diagnoses were to people under 25.[19] DRV and poor sexual health can have harms to mental and long-term reproductive health.[20-22]

Sexually transmitted infections (STIs), unplanned pregnancies and DRV impose significant costs on the NHS and public sectors.[23,24] The projected spend of unintended pregnancies and STIs across the UK between 2013-2020 is estimated to be £84.4-127bn.[25] This is based on a projected £11.4bn of NHS costs due to unintended pregnancy and STIs and £73-115.3bn of wider public sector costs.[25] For example, in 2009-10 £26m was paid to teenage mothers on income support.[26] The estimated cost of domestic violence and abuse in 2008 in the UK was £15.7bn.[24]

Reducing STIs and unplanned pregnancies in young people are public health policy priorities for UK governments[27-30] and NICE.[31,32] UK governments [33,34,14] and the WHO [35] have also requested new comprehensive DRV, sexual harassment and NVS interventions for young people, and NICE guidance on domestic violence highlights the lack of evidence for interventions preventing adolescent DRV.[36] Universal and primary prevention of DRV, sexual ill-health, STIs and unplanned pregnancies are essential to reduce inequalities in these domains;[20-22] moreover, under-reporting of these behaviours renders targeting challenging.[37]

In England, young people must now stay in education or training until aged 18. There are 1.2 million 16-18-year olds across all social groups studying in FE settings.[38] The rapid expansion of the FE sector (which includes 6th forms and community colleges) means FE may be the only universal

[1] DRV defined here encompasses the UK government term 'domestic violence or abuse' for psychological, sexual, emotional violence or abuse to someone aged 16 years or older. This is because the term DRV is more frequently used in the literature for young people aged 16-24 who comprise the largest age group in FE.

setting for delivering public health interventions to this age group. However, FE settings have a transient student population, and sites vary considerably in size, as well as range of programmes and services offered. This poses a considerably different challenge to intervention delivery and evaluation than in schools.

4.1 Existing research

Systematic reviews suggest that comprehensive interventions addressing sexual health knowledge, contraception availability and broader youth development are most effective at improving sexual health outcomes and preventing teenage conceptions.[39-41] Cochrane and Campbell reviews recommend prioritizing research on multi-component interventions in schools. They suggest interventions should attempt to improve skills (e.g. conflict management) and shift peer norms against DRV, and provide adolescents with school-based health services with a range of contraceptive choices as well as involving young people in the design of services.[42-44].

In preparation for this application, we systematically reviewed evaluations of sexual health interventions in FE settings, including systematic reviews of evaluations. After a broad and sensitive systematic search of CINAHL, Embase, ERIC, MEDLINE, PsycINFO and Sociological Abstracts in November 2017 (see Box 1), we undertook duplicate selection of abstracts (n=1,724) and full-texts (n=553). We did not find any rigorous evaluations of sexual health promotion or DRV prevention programmes in FE contexts, nor in analogous settings in high-income countries (e.g. community colleges in the United States, technical and further education in Australia).[45] While some sexual health research in the UK has included FE students ('POPI' randomised controlled trial (RCT) of chlamydia screening)[46] and while we were able to identify one cluster RCT (cRCT) currently in progress ('Test n Treat' pilot study of chlamydia/gonorrhoea testing and treatment[47]), our findings indicate that the evidence for intervention in FE settings is virtually non-existent.

Box 1. MEDLINE search strategy

(((community or junior or two-year or 2-year or technical or city or associate* or commuter*) adj college*) or TAFE* or "college of FE" or "colleges of FE" or (college* adj2 "further education")).ab,ti.
AND (psychosexual or sex* or hiv* or violenc* or abus* or rape*).ab,ti,sh.

4.2 Results from our MRC PHIND Phase I intervention development study

In response to these gaps, we have undertaken 15 months of preparatory research with FE students, FE staff, sexual health charities, public health practitioners and commissioners, funded by the Medical Research Council (MRC). This involved extensive work with over 2000 students and 200 staff from six FE settings and other stakeholders in England and Wales. In partnership with these stakeholders, we identified two intervention components that were perceived to be important and appropriate gaps in current FE provision that should be taken forward for optimisation and piloting.

In the MRC PHIND Scheme Phase I intervention development 'SaFE Project' [MR/M026272/1],[48] informed by evidence of effective interventions delivered elsewhere, we used a mixed method multi-case study to explore the feasibility of four candidate intervention components: 1) Student-led action groups to restructure FE environments to reduce sexual risk behaviours;[49,50] 2) Accessible onsite sexual health and relationship services to increase sexual health and relationships knowledge, skills and safer sexual practices;[32,51,52] 3) Training staff to recognise and respond to DRV, promote appropriate messages and support young people to form healthy relationships; [39,53] and

4) Sex and relationships education (SRE) to increase sexual health knowledge and reduce risk-taking behaviour.[54,55]

Table 1 shows that onsite access to sexual health services and staff training in safeguarding about sexual health and relationships were important, appropriate gaps in current FE provision. Staff, students and health professionals noted that interventions addressing these issues would be welcomed. The other components were not acceptable: students reported being too busy to take part in action groups and did not expect them to be effective. Staff felt students would be embarrassed, that they required more incentives and that they lacked institutional support. Both staff and students felt that SRE delivered in FE was too late in young people's lives.[48] The intervention development process is described in the paper in press attached, and the findings are summarised below.

Table 1. Results summary from Stages 1, 2 & 3 of the Phase I SaFE intervention development project.[51]

Component	**Stage 1 Interviews/focus groups**		**Stage 2 E-survey**		**Stage 3: Stakeholder consultation**
	Students (24 focus groups, n=74 male, n=60 female)	*Staff (10 staff focus groups n=44; 11 manager & 12 charity staff interviews)*	*Students (n = 2105)*	*Staff (n = 168)*	*Educators, health & government professionals & practitioners (n=30) & youth advisory group*
1) Student-led sexual health action groups	-Largely negative -Students too busy -Students do not expect groups to be effective	-Barriers; student embarrassment, engagement, motivation and cohort transience -Poor incentives -Limited funding and support	Low enthusiasm from students and staff meant that this component was not taken forward to stage 2 and was therefore not discussed at stage 3		
2) Onsite access to sexual health services	-Largely positive -Wanted free contraception, STI/pregnancy testing & advice -Accessible but discreet location -Knowledgeable, trustworthy, non-judgemental staff -Drop in service several times a week at varied times	-Largely positive - Offer a range of contraception and testing services, and advice, support and emotional care -Support to publicise services -Sustainability for onsite services (financial and staff support)	-46-77% did not know services their setting provided -88% of sexually active students had never attended onsite services but 44% would -46-65% wanted advice, support, contraception or pregnancy/STI	-35% did not know if sexual health and advice services were available for their students.	-Deliver contraception, testing, advice and support by trained youth friendly, non-stigmatising professionals -Services open at least twice a week in accessible but discreet locations. -Well publicised to

	-Well publicised via staff and digital media		tests -41-48% wanted services after FE or at lunchtime		increase student and staff awareness -Digital messages with information and signposting
3) Staff training in safe-guarding about sexual health and relation-ships	-Largely positive -Students wanted staff to identify and respond appropriately -Students wanted staff to distinguish 'banter' -Students wanted all staff to be trained so that they can approach any member	-Staff need support and training to respond to safeguarding issues on these topics -Staff wanted preventative action -All colleagues to be trained -Concerns about engagement in training and implementation of safeguarding	-44% agreed that staff took appropriate action to stop students calling each other offensive names -36-38% would speak to staff about DRV if it was happening to someone in or outside FE	-83-90% were confident intervening with sexual harassment; explicit images or pornography -47% received sex and relationships safeguarding training; 67% wanted training -75% wanted compulsory training, -83-90% wanted DRV and sexual harassment training	- Staff training needs to be delivered to all FE staff. - Face-to-face training that covers topics such as recognising signs of DRV and gender-based violence, how to take appropriate action when faced with students presenting with these issues, and how to signpost students to appropriate services.
4) Sex and Relation-ship Education (SRE)	-SRE in FE was too late -Students wanted a wider range of SRE, not just focussing on STIs and contraception -Students anticipated lack of engagement in SRE lessons	-SRE should be delivered earlier -Staff lacked knowledge, training and credibility to deliver SRE -Barriers; varied student knowledge and experience, student engagement and timetabling	-20-35% felt FE taught them about safer sex, healthy relationships, sexually offensive language, safety online dating, sexual consent or DRV -54-60% wanted lessons on these topics		SRE delivered at FE level was generally considered too late for young people and was therefore not discussed at stage 3

4.3 Rationale for current study

The proposed study will be the first UK study of a DRV prevention and sexual health intervention in FE settings (including sixth forms and community colleges). In our MRC PHIND funded SaFE project we developed the logic model, theory of change and intervention components. Following MRC guidance for the evaluation of complex interventions,[56] the proposed study builds on this Phase I intervention development study and will optimize the manuals, training and materials for the two acceptable intervention components (onsite sexual health and relationship services and FE staff training), and prototype the intervention, before conducting a pilot cRCT to examine implementation and the acceptability of trial methods.

5. Study aim, objectives and outcome measures

5.1 Primary aim:

To assess the feasibility and acceptability of delivering the SaFE intervention to determine whether to proceed to a full-scale RCT.

5.2 Study objectives

- To consider feasibility and acceptability of intervention implementation in two FE settings (one college and one 6th form) and to identify required refinements.
- To test reliability of outcome measures reliable and identify necessary refinements
- To recruit, randomly allocate and retain a sufficient number of FE settings.
- To identify the proportion of FE students approached within the stated data collection periods that are recruited and retained.
- To explore intervention reach among students.
- To identify the consenting and governance requirements of data providers to link to routine sexual health data.
- To identify the proportion of FE students providing consent for linkage to routine sexual health data.
- To consider intervention mechanisms and refinements to programme theory through qualitative data.
- To consider contextual factors influencing implementation, receipt and mechanisms of action.
- To identify potential harms associated with the intervention and means of reducing these.
- To identify preventative sexual health, DRV and sexual harassment activities occurring in and around control settings.
- To identify methods to record delivery costs and potential impacts in an economic evaluation in a Phase III trial.
- To assess whether. following a pilot cRCT, a Phase III cRCT is justified in relation to our progression criteria.

5.3 Progression criteria

The primary outcome of the pilot cRCT will be whether progression to a Phase III RCT is justified in terms of pre-specified progression criteria:

1 The intervention is implemented with fidelity in at least 3 of 4 intervention settings
2 The process evaluation indicates the intervention is acceptable to students, FE staff and public health commissioners (measured by qualitative interview, routine monitoring data on attendance and survey data).
3 At least 5 of the 6 FE settings are retained throughout the study
4 Using a traffic light system; at least 60% of students approached complete the student questionnaire at baseline and follow-up to progress (green); Amber indicates a response rates of between 50-60% = progress amending the data collection protocols; Red indicates a response rates of less than 50% = do not progress.

5.4 Pilot primary outcomes measures

In the pilot cRCT, we will examine the indicative proposed primary outcomes of a future Phase III trial:

- Unprotected intercourse at last intercourse measured using validated questions from the SHARE questionnaires.[64] Unprotected intercourse will be defined as vaginal or anal (not oral) intercourse that involves no reliable method of STI and/or pregnancy prevention (i.e., reliable meaning STI prevention (e.g. condoms) and pregnancy prevention (e.g. condoms or other contraceptives if involving a woman)).
- Self-report experience of DRV victimisation in the last 12 months (measured at baseline and 12-month follow up) using sCADRI.[65] Self-report has been used because most episodes of DRV will not result in notification to the school, police or NHS,[66] and our intervention is likely to increase rates of such notifications with the risk of ascertainment bias. While the intervention may result in increased self-report, measurement error will be minimised by using validated and reliable measures, comprising items focussed on specific behaviours. The 'CADRI' comprises 92 items assessing DRV victimisation (and perpetration) over the past two months.[67] Subscales cover emotional abuse, relational abuse, controlling behaviours, physical violence, and non-consensual sexual activities. Research has found that DRV measured using 'CADRI' is correlated during adolescence with early sexual debut, unsafe sex, violence and suicidal ideation.[68] The 'CADRI' has been used in research with young people in US and Canadian studies.[69,70] However, due to problems with its use in trials due to its length, a 10-item version of 'CADRI' (sCADRI) has been developed and piloted among school-based samples of 9-12th graders and at-risk samples in Canada.[65] It is also being piloted for use in UK samples of young people aged up to 16 in our NIHR PHR funded pilot trial of Project Respect.[71] This new measure was found to be slightly less sensitive than the full questionnaire but to have good reliability, fit and convergent validity with the full measure.[65] We plan to use this short version, adapting it for measurement of DRV in the last 12 months and adding items from the original 'CADRI' to assess experience of controlling behaviours.

5.5 Pilot secondary outcomes measures

Informed by our logic model, the indicative secondary outcomes in a Phase III RCT will be;

- STI and pregnancy prevention methods used at last intercourse (measuring use of condoms or hormonal contraceptives at first sexual intercourse is not appropriate given higher rates of sexual debut in FE than school based samples);[64,72]
- Use of emergency contraception at last intercourse;[64,72]
- STI testing and diagnosis in the last 12 months;[64,72]
- Self-reported pregnancy and unintended pregnancy (initiation of pregnancy for men) in the last 12 months;[64,72]

- Sexual regret at last intercourse using measures from the Avon Longitudinal Study of Parents and Children (ALSPAC);[73]
- Sexual harassment taking place at FE settings in the last 12 months using measures taken from the School Health Research Network survey [74] and Hostile Hallways survey;[75]
- Non-volitional sex in the last 12 months using measures from the National Survey of Sexual Attitudes and Lifestyles (NATSAL);[76]
- DRV perpetration in the last 12 months using the sCADRI [65] as described above;
- EQ-5D-5L to measure health-related quality of life and;
- Self-reported awareness of services, and help seeking for victims and perpetrators will be assessed by existing measures.[77]

We will assess the feasibility of data linkage comprising of three parts; 1) We will consult with data providers to understand their requirements for data linkage, associated costs, data transfer/storage requirements, fair processing (including participant facing materials; consent material, information sheet), timescales for data release and available data. Sexual Health Clinic, GP and Department of Health data relating to identification and treatment of STIs, pregnancy, abortion and emergency contraception prescriptions will be considered. Sensitive sexual health information has previously been successfully linked (e.g. data on abortions).[78] The logistics of linking, transferring and data storage will also form this feasibility assessment, including governance requirements of multiple data providers. This will identify the practical and associated costs for future data linkage in a phase III trial. 2) We will ask participants to provide their identifiers (name, DOB, postcode) and explore consent rates to data linkage to routinely collected sexual health data, as well as exploring consent rates by age, sex and socioeconomic status (SES) and outcomes to quantify any selection bias. To calculate SES we will request student postcodes to derive an area-level measure of deprivation, household status and employment status (where relevant). Separate information and consent materials will be developed in line with data provider requirements and participants will be able to decline data linkage whilst continuing with the study. Data will not be accessed in the pilot cRCT as there would be too few outcomes (e.g. abortions) with the expected sample size. However, understanding the acceptability of linking to routine data will inform the requirements for any future trial. 3) We also propose to ask participants to provide their identifiers and consent to enable their data to be linked at the two time points. Participants will be asked to opt-into the longitudinal sample and provide identifiers and consent at the end of the questionnaire. The rates of consent and the proportion of students retained from baseline to follow-up will inform whether we would conduct an exploratory longitudinal analysis in a phase III trial.

6. Study design

6.1 Design

Intervention optimisation, feasibility testing and a pilot cRCT with integrated process and economic evaluations (MRC complex intervention phase II study).

Stage 1: Optimisation of training and publicity materials and an intervention manual for the SaFE intervention;
Stage 2: Feasibility testing in two FE settings followed by a period of refinement of the interventions;
Stage 3: 2-arm pilot trial with cluster randomisation (at the level of FE setting) in 6 FE settings in England and Wales with an embedded process evaluation.

6.2 Risk assessment

A Trial Risk Assessment has been completed by the SaFE Study Manager to identify the potential hazards associated with the trial and to assess the likelihood of those hazards occurring and resulting in harm. A copy of the trial risk assessment may be requested from the SaFE Study Manager.

Risks: Some individuals might find aspects of intervention content or research upsetting if they, or a significant other, have experienced a problem relating to DRV, a pregnancy, or their sexual health. The trial manager will work with FE settings to ensure a system is in place to provide appropriate support in such circumstances. Research participants will be informed that participation is voluntary and that they may withdraw at any point. All students will be signposted to support services, including college safeguarding leads. We will minimise disruption for staff and ensure student privacy and confidentiality by employing previously successful strategies used in the SaFE intervention development study.[48] As with any health intervention, there is a risk of widening health inequalities if the students that are exposed to the intervention are at a lower risk of DRV or poor sexual health. In the pilot cRCT, we will be underpowered to test for differences in the effectiveness of SaFE by socioeconomic inequalities at the student and FE-level, but will describe FE and student recruitment according to inequalities. Any potential for unintended harmful or iatrogenic effects due to the intervention itself will also be explored via the collection and analysis of qualitative data.

7. FE setting and participant selection

FE settings and participants are eligible for the trial if they meet all of the following inclusion criteria and none of the exclusion criteria. All queries about school eligibility should be directed to the SaFE Study Manager before randomisation.

7.1 Setting inclusion and recruitment

Phase 1: Intervention optimisation: Optimisation of intervention materials (manual, staff training and publicity materials) for use in FE settings with stakeholders, FE students, staff and ALPHA youth group. Recruitment of the participating FE setting will commence prior to study commencement and the site will be purposively sampled based on location in South Wales; sites used in the MRC PHIND funded SaFE project will be excluded. A sample of staff and students with capacity to participate will then be recruited for group interviews. Students under age 16 will be excluded.

Phase 2: Intervention feasibility testing: One college and one 6th form will be recruited for feasibility testing (n=1 college in England, n=1 6th form Wales). FE settings will be purposively sampled based on location in South Wales and Bristol/South Gloucester/North Somerset. No random allocation will occur. Sites used in the MRC PHIND funded SaFE project or optimisation phase (Phase 1) as well as those with current onsite sexual health provision (e.g. STI testing) will not be eligible to take part. We will incentivise FE setting retention by making a payment of £250 at the end of the feasibility testing.

Phase 3: Pilot cRCT: 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. Inclusion criteria: All students aged 16 and older enrolled at participating FE settings.

Exclusion criteria: No FE students aged 16 and older will be excluded. Fieldworkers will support participation for those with learning difficulties or poor English. Schools for those with learning disabilities will be excluded. For this study, settings with existing onsite service provision (e.g. STI testing) will also be excluded from the sampling frame.

Study population: SaFE is designed to be a universal intervention for all students attending FE settings. The majority of FE students are aged 16-24. We will incentivise FE setting retention by making a payment of £500 at the end of the study. In Wales, two colleges and one 6th form will be recruited, and in England two 6th forms and one college will be recruited.

	England	**Wales**
Feasibility testing	FE college (n = 1)	6th form (n=1)
Pilot cRCT	FE college (n = 1) 6th form (n=2)	6th form (n=1) FE college (n=2)

Eligible settings will be approached via a relevant senior manager (e.g. deputy head, head of pastoral care), identified with the help of the School Health Research Network (for 6th forms in Wales), and Public Health leads and service providers in local authorities in England, and invited to participate. Schools will be emailed of posted a project information sheet, reply enveloped and form indicating if they wish to participate. If necessary, non-responders will be followed up with a reminder and then by a phone call by the Safe Study manager. All interested settings will be visited by the SaFE Study manager and a contact from the intervention delivery team to discuss the trial in more detail and agree a research contract including signing a memorandum of understanding (MoU) describing the roles, responsibilities, timeline of intervention delivery, and assessments before taking part in the study. The MoU will be signed by a member of the senior leadership team, ideally the headteacher/ FE manager, with an additional contact teacher/lead also listed. Any settings that decline before randomisation will be replaced by another setting from the same stratum and geographical area.

7.2 Randomisation

No randomisation will occur during Phase 1 or 2. In the pilot trial, 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.

7.3 Student recruitment rates

All students aged 16 or over at participating sites will be eligible to take part. We will use a repeated cross-sectional design in the pilot cRCT for three reasons: 1) the intervention aims to operate at the FE level and is expected to impact on all students, not just on those who were present at baseline; 2) the NIHR PHR funded Filter study found that, in FE settings, high turnover of students, irregular days of student attendance and lack of accurate student enrolment data, prevent the creation of an accurate sampling frame;[58] 3) in cRCTs, when migration into or out of the clusters is high over time, the baseline cohort may not remain representative of the cluster and therefore repeated cross-sectional analysis is preferred to minimise bias. This approach has been used in previous school based cRCTs.[59] The sampling frame will be defined as the number of students approached during data collection time periods. Response rates will be calculated as number of completed questionnaires.

8 Consent and retention

8.1 Informed consent

FE settings: The member of senior management will be asked to sign a formal commitment for their setting to take part in the study. The agreement will describe the roles and responsibilities of the school and the research team during the research period at the site.

Teachers, parents and intervention delivery staff: The SaFE Study manager or one of the trained fieldworkers will provide all adult participants with written information on the study, explain the aims of the study, and be asked to give informed consent prior to participation in the research. They will be assured that if they decide not to participate their decision will be handled confidentially. Written informed consent detailing the right to withdraw will be collected for all participants.

Student consent: Prior to all data collection, students will be given an information sheet and a verbal description of the study. This will include the sensitivity and potentially upsetting nature of the topic. Participants will have the chance to ask questions and the right to withdraw from participation at any time. Students will then be invited to consent to participate in data collection. Participants will be aged 16 or over and based on FE setting guidance, deemed as having capacity to provide informed consent.[86] Where required by 6th forms, as is often conventional in secondary school-based UK RCTs of sexual health and violence interventions, for young people aged under 18 years, parents/guardians will be sent a letter and detailed information sheet via the means of communication preferred by each school, and asked to contact the school or research team should they have questions or do not wish their child to participate in data collection (i.e. opt out). Note that this 'opt-out' consent is acknowledged standard practice for school-based studies in the UK, used by members of our investigator team in sexual health school-based interventions in England (e.g. Pupil-led sex education in England (RIPPLE study), and across the UK (e.g. The JACK Trial (held in 66 secondary schools across the UK)).

8.2 Registration

Participants' personal details will be collected on paper and stored electronically. This information will be stored separately from questionnaire data. All data will be handled according to the principles of the General Data Protection Regulation (GDPR) 2016 and the Data Protection Act 2018. Further details can be found later in the protocol.

8.3 Non-registration

Personal details of schools not selected for recruitment, or students in participating sites who decline to consent, will not be retained. For any sites requesting an opt-out process of parental approval, details of parents who decline to consent will be retained only until after completion of data analysis to ensure that their child is not included.

9. Withdrawal and loss to follow-up

9.1 Withdrawal

FE settings and participants will have the right to withdraw consent for participation in any aspect of the SaFE study at any time. Participants' care from health services will not be affected at any time by declining to participate or withdrawing from the study. If a participant initially consents but subsequently withdraws from the study, a clear distinction will be made as to what aspect of the study the participant is withdrawing from. Whilst it is possible to withdraw any data collected as part of the research, given that this is a college level intervention, it is not possible for participants to withdraw from receiving aspects of the intervention (e.g. publicity of on-site services) as this would require no contact with the college environment. In all instances, schools and participants who consent and subsequently withdraw should complete a withdrawal form or the withdrawal form should be completed on the participant's behalf by the SaFE Study Manager based on information provided by the participant. Any queries relating to potential withdrawal of a school or participant should be forwarded to the Trial Manager immediately, as should any completed withdrawal forms.

9.2 Loss to follow-up

The outcome measurements will be assessed at two time-points, however no longitudinal data will be collected. A repeat cross-sectional method will be employed. Baseline measures will be assessed prior to randomisation of FE settings into the two trial arms (control and intervention conditions). A second set of measurements will take place 12-months post baseline. While there is no longitudinal data collection, FE settings, whether intervention or control will be incentivised to remain in the trial by offering a payment of £500 at the end of trial.

We will assess the feasibility of data linkage. We will ask participants to provide their identifiers and consent to enable their data to be linked at the two time points. Participants will be asked to opt-into the longitudinal sample and provide identifiers and consent at the end of the questionnaire. The rates of consent and the proportion of students retained from baseline to follow-up will inform whether we would conduct an exploratory longitudinal analysis in a phase III trial. No longitudinal data collection will occur, only rates of consent to link.

10. Trial Intervention

10.1 The 'SaFE' intervention

Planned intervention: The planned intervention involves three components detailed below. The logic model for the SaFE intervention developed in the MRC funded project with staff, student and sexual health charity stakeholders.

The components of SaFE include:
Onsite access to sexual health and relationship services available for 2 hours on 2 days a week. As recommended by NICE [32] the intervention will provide free, confidential access to non-judgmental, professional advice, support and signposting, condoms, and pregnancy, chlamydia and gonorrhea tests. These will be available for at least 2 hours on 2 days a week. FE settings will be supported to optimise the location and time of access of services, where possible, with student input.

Publicity of onsite sexual health and relationship services. Texts, emails, websites, social media, posters and events will i) publicise onsite services and ii) give information and educational resources about, and signpost to, local sexual health, relationship, DRV and sexual harassment services.

FE staff training on how to promote sexual health, and recognize, prevent and respond to DRV and sexual harassment. One day, face-to-face training will train all full-time staff how to promote sexual health, recognize and respond to DRV and sexual harassment, and signpost students to (onsite) sexual health and relationship services. Training will help staff identify hotspots where DRV and harassment occur onsite. Training will also include knowledge about appropriate sanctions for perpetration, and support or referral of victims or perpetrators to specialist services. Staff training to support engagement with contraceptive information and services is recommended by NICE.[32]

SaFE will combine standardised inputs, processes and outputs with flexibility to allow local adaptation to support universal adoption, institutional ownership and the implementation of multiple activities.[60] This approach will be used to increase saturation of the intervention and to facilitate FE-wide change.

Intervention theory: The provision and promotion (via staff and publicity materials) of regular onsite sexual health services will create an FE environment where positive sexual health and relationships are normalized. The aim is to increase students' access to services; knowledge about sexual health, relationships and services and; self-efficacy, confidence and skills about these topics. Social marketing principles will address the "4Ps" selling consumers (students) a Product they want (sexual health and relationship services) in an accessible Place (their FE setting) at low Price (free) with Promotion (via staff and publicity materials).[61] In line with the Social Learning Model [62], staff training to recognize, prevent and respond to DRV and sexual harassment will challenge negative attitudes and social norms about DRV and sexual harassment in FE to create safer, more respectful FE settings. Increasing staff and FE wide sanctions and promoting appropriate behaviours will shift norms about the acceptability and tolerance of these acts. Onsite services will also support students' development of skills and behavioural control.

Intervention delivery: Current providers of sexual health services in England and Wales will deliver both staff training and onsite sexual health and relationship services. In each setting, a nominated intervention champion will oversee intervention activities; coordinating onsite services, publicity and

staff training, and implementation. This is an approach which has been used to improve implementation successfully in secondary school interventions.[63]

Intervention funding: In Wales, funding is provided for intervention delivery by Health and Care Research Wales. In England, funding will come from Public Health England.

10.2 Compliance

We will incentivise FE setting retention by making a payment of £250 at the end of the feasibility study and £500 at the end of the pilot cRCT study.

11. Trial procedures

Phase 1) Intervention optimisation (Jan–Apr20): Work is required to optimize existing intervention materials in the public domain and elsewhere for use within FE settings (manual, staff training and publicity materials). The researchers will lead this process, working in close collaboration with the stakeholder advisory group, FE students, FE staff and the ALPHA young people's advisory group. Our stakeholder advisory group will reconvene those involved with the MRC funded SaFE project or staff from similar organisations (including public health and third sector subject experts; service commissioners; College advisory groups; student representatives from FE and FE-supporting organisations; a representative from an LGBTQ+ charity). Recruitment of stakeholders will commence prior to study set up. We will review, adapt and refine existing intervention materials to draft FE staff training and publicity materials. We will then hold consultations on the draft materials using three facilitated focus groups; one with the stakeholder advisory group, one with FE students and one with FE staff. Following the process used in a previous NIHR funded optimisation study [57] we will then refine our materials based on stakeholders' views and prototype the materials with a smaller subset of the stakeholder advisory group (including intervention delivery team). The ALPHA group will then review the final intervention materials. The end result will be refined training materials and a manual for FE staff to safeguard students against DRV and sexual harassment, as well as promotional materials for onsite services.

Phase 2) Intervention feasibility testing (Apr–Aug20): The intervention components will be implemented and assessed for feasibility and acceptability in two FE settings; one 6th form and one college (one in England and one in Wales). Recruitment of these FE settings will take place during Phase 1 (or prior to study set-up subject to ethical approval). Staff will be trained, publicity materials will be implemented, and onsite services established and delivered. A process evaluation will be undertaken to examine implementation of each intervention component and inform refinements to the materials where required. Structured observations of staff training (n=1 per setting), focus groups with students (n=2 per setting) and telephone interviews with trained FE staff (n=4 per setting) and onsite sexual health service staff (n=1 per setting) will examine intervention acceptability, delivery and institutional, or student-level barriers to implementation. Logbooks for onsite sexual health service staff will examine what services were provided. Logbooks for teachers will examine time and resources spent implementing the intervention. If required, refinements will be made based on feedback.

Phase 3) Pilot cRCT (Aug20- March22): A pilot cRCT will be conducted in 4 intervention and 2 control settings with integrated process and economic evaluations. Clusters will be randomised to receive either the SaFE intervention or usual practice. Outcomes will be assessed before randomisation and

12 months later. The pilot cRCT will be conducted in Bristol/South Gloucester/North Somerset and South Wales (see inclusion/exclusion criteria above). FE settings will be invited to participate, and all interested will be visited to discuss the study in more detail and agree a research contract. Six FE settings will then be sampled from those wishing to take part so the sample contains: 3 settings from each country (England, Wales); 3 settings of each type (6th form, FE college). Allocation: See section 7.2.

12. Safety reporting

12.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant or clinical trial participant administered a medicinal product and which are not necessarily caused by or related to that product
Serious Adverse Event (SAE)	Any adverse event that - • Results in death • Is life-threatening* • Required hospitalisation or prolongation of existing hospitalisation** • Results in persistent or significant disability or incapacity • Consists of a congenital anomaly or birth defect • Other medically important condition***

***Note:** The term 'life-threatening' in the definition of serious refers to an event in which the trial participant was at risk of death at the time of the event or it is suspected that used or continued used of the product would result in the subjects death; it does not refer to an event which hypothetically might have caused death if it were more severe.

**** Note:** Hospitalisation is defined as an inpatient admission, regardless of the length of stay, even if the hospitalisation is a precautionary measure for continued observation. Pre-planned hospitalisation e.g. for pre-existing conditions which have not worsened, or elective procedures, does not constitute an SAE.

***** Note:** other events that may not result in death, are not life-threatening, or do not require hospitalisation, may be considered as an SAE when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

12.2 SAE Reporting requirements

The Principal Investigator is responsible for ensuring that all site staff involved in this trial are familiar with the content of this section. We did not encounter any problems with the MRC PHIND funded SaFE study's focus groups, interviews or questionnaires; we did not have any AEs or SAEs in the study. There are no AE's/SAE's expected to be related specifically to the trial interventions. We do not expect participants to experience any AEs/SAEs as a result of their participation in the trial. As this trial is low risk, the collection of SAEs would provide little benefit and increase

unnecessary burden to participants taking part. Therefore, there will be no formal process in place to collect AEs or SAEs for this trial. However, due to the sensitive nature of the trial topic and intervention, we understand that participants may express their emotional or psychological distress related to their experiences and/or beliefs about sexual health and historical experiences, including DRV. We 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.

12.3 Trial Specific Safeguarding requirements

We will take the steps outlined in the Cardiff University Safeguarding Policy to reduce the likelihood of any adverse events arising from the intervention or research. All intervention materials will be based on existing materials and will be approved by the stakeholder advisory group and TSC prior to use. Research and intervention activities will be delivered adhering to the ethical considerations. This pilot is not powered to test for intervention effects (positive or adverse), but qualitative data will be collected as part of the process evaluation to explore potentially harmful mechanisms.

The SaFE Study Manager will ensure that all fieldworkers are aware of the Cardiff University Safeguarding Policy as well as the Lone Worker Policy. On site at schools and FE colleges, the study will adhere to existing Safeguarding policies and procedures in, which will be identified by the SaFE Study Manager in advance of data collection. All participants will be advised that information they provide will be confidential unless they disclose something during data collection which suggests that they are at serious and immediate risk of harm, at which time study safeguarding processes will be implemented, including incident recording and escalation to the school/college Safeguarding Lead. For the purposes of this trial the following events will be considered as safeguarding issues that must be captured and reported to the SaFE Study Manager as soon as possible:

- Incidences of sexual abuse involving immediate risk of harm;
- Grooming.
- Engagement in sexual practices in exchange for reparation (under age-18)

For the purposes of this trial the following events will not require reporting as safeguarding issues:

- Any planned treatments received by participants at the start of the trial.

12.4 Safeguarding Reporting procedures

Should participants disclose any of the above issues to the service providers, this will be dealt with according to the Safeguarding Policies of that service provider. This process will be agreed with the school or FE setting in advance of intervention delivery.

For disclosures made to research staff these must be escalated to the Safe Study Manager as soon as possible after disclosure. The SaFE Study Manager will then take action in line with Cardiff University Safeguarding Policy, including completion of an incident record stating: date of disclosure; what was disclosed (reason for breach of confidentiality); actions taken (e.g. escalation to college safeguarding lead. A separate form must be used to report each event, irrespective of whether or not the events had the same date of onset. The participant will be identified only by their participant identifying number, partial date of birth (mm/yy) and initials. The participant's name should not be used on any correspondence. Further advice will be sought from the University Principle and Lead Safeguarding Officers if required.

13. Statistical considerations

13.1 Randomisation

Details of the randomisation will be specified in a separate randomisation plan.

13.2 Blinding

In the pilot cRCT all parties will be blind to allocation during the baseline data collection. It is not possible for study participants (students), teachers, trial managers, the intervention delivery team or researchers involved in the process evaluation to be blind to intervention status. However, fieldworkers at outcome data collections will remain blind to intervention status as will the statistician analysing the primary and secondary outcome data and the health economists undertaking the economic analysis. If school/college allocation becomes apparent during interactions with schools we will record this.

13.3 Sample size

No formal power calculation has been performed for this pilot trial as our primary aim is to evaluate feasibility and acceptability. See Section 8.2 for full details of sampling.

13.4 Missing, unused & spurious data

Details will be provided in the statistical analysis plan (SAP).

13.5 Procedures for reporting deviation(s) from the original SAP

These will be submitted as substantial amendments where applicable and recorded in subsequent versions of the protocol and SAP.

13.6 Termination of the trial

No formal interim analysis allowing for early termination is planned.

13.7 Inclusion in analysis

All randomised FE settings and consented students will be included in the descriptive analysis of the pilot cRCT. Details on will be provided in the SAP.

14. Analysis

14.1 Main analysis

The primary analysis of the pilot cRCT will determine whether the pre-specified progression criteria to a full-scale phase III trial are met. The analyses will be primarily descriptive, providing a realistic estimate of recruitment, response and retention rates. All outcomes related to feasibility will be reported as point estimates with 95% confidence intervals. Recruitment, randomisation and retention of FE settings as well as student recruitment, response, follow-up and consent to routine data linkage will be summarised in a CONSORT flow diagram. We will tabulate demographic characteristics of students within settings by study arm (intervention or control) and assessment time point (baseline or follow-up) using descriptive statistics: means and standard deviations (or medians and interquartile ranges, as appropriate) for continuous outcomes, and frequencies and percentages for discrete outcomes. Student recruitment, response, follow-up and consent to data linkage will also be tabulated by student-level socioeconomic disadvantage. We will examine the rates of completion and discrimination (i.e. variability of responses, floor/ceiling effects) of primary and secondary outcome measures for use in a full-scale phase III trial. We will assess the internal consistency of the scaled outcomes by reporting Cronbach's alpha statistics at baseline and follow-up. Analysis will be performed in R, SAS or Stata. Full details of the analysis will be specified in the SAP.

14.2 Qualitative analysis

Qualitative data collected through semi-structured interviews and focus groups will be audio-recorded, transcribed, and coded. Field notes from observations and free text entries in logbooks will be coded using a similar system. An inductive approach will be used to analyse the data, drawing on grounded theory techniques including the constant comparison approach to identify constructs and themes which will influence the emerging theory. In addition to inductive findings elicited via thematic analysis, the qualitative coding will use deductive a priori starting codes which reflect concepts in the research questions and used as a framework to organise and initiate qualitative analysis. Analysis will also be guided by the realist approach,[80] identifying how contextual characteristics interact with mechanisms of action configurations to impact outcomes. We will also use the interviews and focus groups to explore how contextual factors (e.g. population, setting, wider environment characteristics) may have affected implementation of the intervention. We will also explore how contextual factors interact with proposed mechanisms of action to shape implementation and affect outcomes.

The qualitative research will aim to explore intervention mechanisms and how these interact with context, for example FE context and student characteristics, to lead to outcomes. Informed by realist approaches [80,81] we will consider potential mechanisms of action for the intervention, and how these interact with contextual factors, leading to intended and unintended effects. We will develop context-mechanism-outcome (CMO) configurations around key elements of the intervention and use these to develop topic guides for interviews and focus groups. Interviews and focus groups will therefore be theory-driven yet will retain sufficient flexibility to respond to emergent findings. Qualitative data on context, mechanisms and factors influencing implementation will be collected via: telephone interviews with trainers; student surveys; telephone interviews with trained staff and focus groups with students. For example, we will test hypotheses relating to the impact of teacher workload on the fidelity of delivery of staff training and subsequent use of training.

14.3 Cost effectiveness analysis

The pilot cRCT will examine whether it is feasible to assess cost effectiveness within a Phase III trial and provide information to inform its design. Our plan for this will proceed in five parts. We will cost the intervention, using logbooks and records of intervention delivery, collected at both feasibility and pilot cRCT stages, to measure resource use. This will include asking staff to record the time spent being trained along with their salary spine points to estimate costs. These would be combined with unit costs assembled from standard sources (such as NHS reference costs [82] and the Personal Social Services Research Unit Compendium [83]) to estimate the cost of the intervention. Second, we will refine and test a resource use questionnaire for this setting, drawing on those used in similar school-based sexual health intervention trials. This will capture resource use of health and social services to better understand cost differences that might accrue to broader health and social services.

The resource use questionnaire will be administered at baseline and follow-up in the pilot cRCT. We will assess the completeness and distribution (e.g. floor and ceiling effects) of responses and carry out a descriptive comparison of responses between arms, to assess the acceptability of the questionnaire and its likely ability to capture the impact of the intervention on the use of relevant services. Third, we will explore the appropriateness and feasibility of capturing the benefits of the intervention using the EQ-5D-5L measure. We will use published tariffs from the UK population to estimate health-related quality of life from EQ-5D-5L. We will use differences between intervention and control schools to consider the feasibility and relevance of the EQ-5D-5L in determining potential impacts of the intervention in the FE setting. Fourth, we will undertake a qualitatively-led valuation and costing exercise as part of our process evaluation to identify potential benefits and cost domains that are not captured adequately by the EQ-5D-5L or by the resource use questionnaire. Fifth, we will examine whether linkage to routine data could provide long-term health and social services data.

We will determine whether an economic evaluation will be feasible based on a) the completeness and distributional characteristics of data obtained through direct costing and questionnaire use, b) the resource use questionnaire, and c) the identifying relevant cost and benefit domains through process evaluation. We will determine, based on EQ-5D-5L responses, whether a cost-utility analysis would be feasible or, if not, what the appropriate measure of effectiveness would be for a cost-effectiveness analysis. We will also determine whether there are important consequences of the intervention which would not be captured using the instruments described above, such that an additional valuation exercise (e.g. a discrete choice experiment) would be appropriate for the main trial. If so, the qualitative work we will carry out will inform the choice of attributes to be included in such a valuation exercise. It will also inform development of the final version of the resource use questionnaire to be used in the main trial. We will use the process evaluation during the pilot cRCT to give an indicative estimate of an appropriate time horizon to be used in a Phase III trial.

15. Data Management

Quantitative and qualitative data will be managed by project staff using secure data management systems and stored anonymously using participant identification numbers. Quantitative data will be managed by the Centre for Trials Research (CTR) at Cardiff University, a fully accredited registered clinical trials unit (CTU). Completed questionnaires will be transported or couriered to CTR by Trial Manager(s). All data will be stored in password-protected folders with user access restricted to those on the project.

Qualitative data will be managed by the SaFE Study Manager. Data will be stored securely in paper and/or electronic format, as appropriate. Data stored in paper format will be held securely at CU, in a locked room, in a locked cupboard or cabinet. Electronic data will be held securely in folders on CU servers and be accessed via username and password with access restricted to members of the research team. Digital recordings of interviews and focus groups will be stored securely, and will be held separately from transcripts and information on participant identities. Audio of interviews will be transferred securely and professionally transcribed, with transcripts then anonymised and entered into password-protected university files.
Identifiable data (paper-based and electronic) will be stored separately from non-identifiable source data. Access to identifiable data will be restricted to certain members of the research team. Those researchers with access to identifiable data will be responsible for anonymising the data before sharing with other members of the research team.

15.1 Data collection

Optimisation and feasibility testing phase: Facilitated focus groups will be used in the optimisation phase to consult with the stakeholder advisory group, FE students, FE staff and the ALPHA group to gain feedback on the intervention materials. Structured observations, interviews, focus groups and logbooks will be used in the feasibility testing phase to examine the feasibility, acceptability and fidelity of the intervention.

Assessments in pilot cRCT: The proposed outcome measurements will be assessed at two time points. Baseline measures will be assessed prior to randomisation into the two study arms. A second set of measurements will take place 12 months post baseline. Informed by protocols refined in the MRC-funded SaFE and NIHR-funded Filter study, data collections will take place during 3-hour sessions across three days at each FE site. Students will be provided with information sheets and consent forms and once informed consent has been gained, a paper copy of the questionnaire. In the MRC PHIND study, the majority (58%) of questionnaires were completed electronically.[48] However, participants reported a preference for completing questionnaires using pen and paper. To maximise participation, those completing the questionnaire will be offered entry into a prize draw to win an iPad. The baseline survey will occur in Sep/Oct 2020 and follow up 12 months post baseline (Sep/Oct 2021). Trained fieldworkers will attend social areas and lessons and invite students to complete questionnaires.

16. Protocol/GCP non-compliance

The CI will report any non-compliance to the trial protocol or the conditions and principles of Good Clinical Practice to the CTR in writing as soon as they become aware of it.

17. End of Trial definition

The end of the trial will be considered as the date on which the last participant has completed their follow-up assessment or qualitative component. The sponsor will notify the main REC of the end of the trial within 90 days of its completion or within 15 days if the trial is terminated early.

18. Archiving

The TMF containing essential documents will be archived at an approved external storage facility for a minimum of 15 years. The CTR will archive the TMF on behalf of the Sponsor. Essential documents pertaining to the trial shall not be destroyed without permission from the Sponsor. Archiving and access to archive will be managed in accordance with the Standard Operating Procedures of the CTR.

19. Regulatory Considerations

19.1 Ethical and governance approval

Ethical approval for the study will be obtained from Cardiff University School of Social Sciences Research Ethics Committee. All work will comply with the Economic and Social Research Council (ESRC) ethics framework, the General Data Protection Regulation 2016 and the Data Protection Act 2018, the Common Law Duty of Confidentiality and the latest Directive on Good Clinical Practice. Materials developed to facilitate linkage to routine data will also be in line with data provider requirements. All researchers/ fieldworkers visiting FE settings will have a full Disclosure and Barring Services (DBS) check and will undergo training to establish safeguarding practices. Researchers will work within lone worker protocols outlined by Cardiff University. After any distressing episode of fieldwork, researchers will undertake a de-briefing session with the PI and other appropriate team members, and directed to Cardiff University counselling services.

19.2 Data Protection

The CTR will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained. Data will be stored in a secure manner and will be registered in accordance with the General Data Protection Regulation 2016 and the Data Protection Act 2018. The data custodian and the translational sample custodian for this trial is Cardiff University.

19.3 Indemnity

The Chief Investigator, local Investigators and coordinating centre do not hold insurance against claims for compensation for injury caused by participation in a trial and they cannot offer any indemnity.

19.4 Trial sponsorship

Cardiff University will act as Sponsor for trial. Delegated responsibilities will be assigned to the sites taking part in this trial.

19.5 Funding

The trial is funded by the National Institute for Health Research Public Health Research Programme. The grant reference is 17/149/12.

20. Trial management

20.1 TMG (Trial Management Group)

The TMG will consist of the Chief Investigator (chair), co-applicants, the SaFE Senior Trial Manager, SaFE Study Manager, Data Manager, and Trial Administrator. The role of the TMG will be to assist in the trial set up by providing specialist advice, input to and comments on the trial procedures and documents (information sheets, protocol etc). They will also advise on the promotion and the running of the trial and deal with any issues that arise. The group will meet, either face-to-face or using audio-conferencing facilities, These will meet monthly during the early stages of the research (months 1-6), then every 3 months thereafter. TMG members will be required to sign up to the remit and conditions as set out in the TMG Charter.

20.2 TSC (Trial Steering Committee)

The TSC will meet three times during the lifetime of the study. The TSC will include an academic specialising in feasibility / pilot trials, an academic specialising in sexual health / dating violence, a member of FE staff, an FE student and/or student representative, and independent sexual health and relationship specialists. One academic member will chair the group. TSC members will be required to sign up to the remit and conditions as set out in the TSC Charter.

20.3 Project team

This group will consist of the chief investigator, SaFE Study Manager and where appropriate CTU and fieldwork staff who will meet weekly to discuss the day to day issues that arise from the trial.

20.4 DMC (Data Monitoring Committee)

Given the low risk nature of the study, and the fact that there are no interim data collections scheduled, we will ask the TSC to act as DMC.

21. Quality Control and Assurance

The trial may be inspected and audited by Cardiff University under their remit as Sponsor.

22. Publication policy

A publication policy will be drafted and approved by the TMG. 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.

23. Milestones

Pre study set-up (August 2019 to January 2020)

- Recruit trial managers and administration staff;
- Commence development of study measures and materials;
- Obtain ethical approval;
- Commence recruitment of settings for optimisation and feasibility phases
- Reconvene stakeholders established in MRC PHIND SaFE study as well as additional members

Phase 1) Intervention optimisation (January–April 2020) project starts;

- Review, adapt and refine existing literature and intervention materials in the public domain and elsewhere, and produce draft FE staff training and publicity materials
- Facilitated focus groups with the stakeholder advisory group, FE students and FE staff
- Refine materials based on consultation
- Prototype materials with a subset of the stakeholder advisory group and review final materials with ALPHA youth group
- Optimised staff training materials and promotional materials approved for feasibility testing by researchers, stakeholder advisory group and TSC
- Train intervention trainers

Phase 2) Intervention feasibility testing (April–August 2020)

- Train teachers using the newly optimised materials
- Implement staff training and publicity materials in two FE settings and deliver onsite services
- Observe staff training, conduct student focus groups and interviews with trained FE staff
- Refine the intervention based on feedback
- Develop data linkage information and consent materials with input from data providers
- Recruit FE settings and fieldworkers for pilot cRCT

- Prepare baseline survey

Phase 3) Pilot cluster RCT (August 2020- March 2022)

- Collect baseline data (September/October 2020)
- Randomise FE settings (post baseline survey completion) (October 2020)
- Train teachers (including observations of training)
- Intervention delivery
- Input, clean and analyse baseline questionnaire data
- Conduct and analyse process evaluation
- Collect follow up data (Sep/Oct 2021)
- Input, clean and analyse follow-up questionnaire data
- Write up report to funder and disseminate findings

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25. Appendices