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Synopsis

A Sexual health and healthy relationships intervention for Further Education (SaFE): a synopsis of results from a pilot cluster randomised controlled trial including an assessment of the feasibility of record linkage and a health economic analysis

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Abstract

Background: Poor sexual health, dating and relationship violence and sexual harassment pose significant public health concerns, especially for young people. There is potential for short- and long-term adverse medical, social, educational and economic outcomes.

Objective: To optimise the intervention materials and examine the acceptability of implementing, trialling and estimating the cost of the Sexual health and healthy relationships for Further Education (SaFE) intervention, including an assessment of the feasibility of record linkage and a health economic analysis.

Design and methods: Optimisation of intervention materials followed by two-arm repeated cross-sectional pilot cluster randomised controlled trial of the SaFE intervention compared to usual practice, including a process evaluation and a health economic assessment.

Setting and participants: Optimisation took place using an iterative process with a series of key stakeholders. The pilot cluster randomised controlled trial took place in eight Further Education settings in South Wales and the West of England, United Kingdom. Participants included Further Education students and staff, and sexual health nurses.

Intervention: The SaFE intervention had three components: (1) onsite access to sexual health and relationship services provided by sexual health nurses available for 2 hours, 2 days per week; (2) publicity about these services; and (3) Further Education staff training on how to promote sexual health, and recognise, prevent and respond to dating and relationship violence and sexual harassment.

Main outcome measures: The primary outcome was feasibility, assessing whether the study met progression criteria relating to: (1) Further Education setting and student recruitment; (2) the acceptability of the intervention; and (3) qualitative data and documentary evidence from students, staff and sexual health nurses on acceptability, fidelity of implementation and receipt. We also assessed the completeness of primary, secondary and intermediate outcome measures and estimated cost of the intervention.

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Results: Three of the four progression criteria were met. Eight Further Education settings were recruited, randomised and retained. Of students approached, 60.7% (1124/1852) at baseline and 51.9% (1139/2193) at 12-month follow-up completed the questionnaire (target 60%). Over 80% of onsite sexual health services were attended by a nurse; onsite publicity about sexual health services was observed at all intervention settings; and 137 staff were trained. The SaFE intervention was viewed positively by students, staff and nurses but needed more time to embed. The prevalence of self-reported unprotected sex at last intercourse was 15.5% at baseline and 18.7% at follow-up. There was evidence of floor effects in the measure of dating and relationship violence victimisation in the last 12 months. We found low rates of missing data for almost all variables with no discernible differences across arms. Around a quarter of participants at baseline and follow-up said they were not at all, or not very comfortable providing consent to link to their routine health records. The estimated cost per Further Education setting was £38,363.09.
Limitations: Coronavirus disease discovered in 2019 pandemic restrictions at Further Education settings meant the intervention was not implemented for as long as planned (up to 23 weeks vs. 39 weeks).
Conclusions: Overall the SaFE intervention was implemented and well received by students, staff and nurses.
Future work: If strategies to boost student recruitment to the survey can be identified and implemented, progression to a Phase III effectiveness trial of the SaFE intervention is warranted.
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Introduction

Rationale for research and background

Sexual health includes positive, pleasurable, respectful and safe sexual relationships and experiences free of coercion, discrimination and violence.[1] However, the UK still has one of the highest rates of under-18 births in western Europe[2] with 53.3% of conceptions in 2021 leading to termination of pregnancy.[3] Sexually transmitted infections (STIs) in England and Wales are currently at a 10 year high, with young people aged 15–24 accounting for 65% of chlamydia cases, 21% of genital warts, 45% of genital herpes, 57% of gonorrhoea diagnoses and 7% of new HIV diagnoses[4,5] In the UK, 50% of young people attending Further Education (FE) report experience of dating and relationship violence (DRV); among 16- to 19-year-olds 46–50% report controlling behaviours and 27–32% threatening behaviours.[6] The median age for most recent occurrence of non-volitional sex is 18 among men and 16 among women.[7]

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.[8] Cochrane and Campbell reviews recommend prioritising research on multicomponent interventions in schools.[9–11] FE settings provide a universal setting for scalable delivery of interventions to improve sexual health and prevent DRV in young people. However, FE settings have a transient and diverse student population, and sites vary considerably in size, as well as in the range of programmes and services offered. This poses a considerably different challenge to intervention delivery and evaluation than in UK primary or secondary schools.

In response to this gap, we conducted a Phase I intervention development study funded by the Medical Research Council Public Health Intervention Development (MRC PHIND) scheme [MR/M026272/1].[12] This project identified four candidate intervention components which could promote sexual health and healthy relationships among young people in FE. The study found broad support from stakeholders and young people for two of the four candidate intervention components: onsite sexual health and relationship services and FE staff training to prevent and intervene to stop DRV. The study developed an intervention logic model and theory of change, as well as the intervention components for a sexual health and healthy relationships interventions for FE settings (including sixth forms and community colleges) (SaFE).[12]

In this paper, we describe the next two phases of research on SaFE. In Phase I, we optimised the intervention materials with key stakeholders to support onsite sexual health services and staff training. In Phase II, we conducted a pilot cluster randomised controlled trial (cRCT) to determine if progression to a full-scale evaluation of the intervention was warranted. The results of the pilot trial are summarised in full elsewhere.[13] Here, we provide a synopsis of the optimisation and pilot trial phases along with a more detailed assessment of the acceptability of linking to routinely collected data to assess health outcomes and a health economic evaluation.

Objectives

The study had two objectives:

1. To convene a network of stakeholders to optimise the intervention materials.
2. To conduct a pilot cRCT in eight FE settings to determine whether a Phase III cRCT assessing effectiveness and cost-effectiveness should be conducted.

Design and setting

Figure 1 shows the study flow diagram.

Our protocol and a description of the results from the pilot cRCT have been published elsewhere.[13] Following the MRC PHIND scheme intervention development 'SaFE Project' [MR/M026272/1], further work was required to optimise existing intervention materials in the public domain and elsewhere for use within FE settings. Optimisation of intervention materials (manual, staff training and publicity materials) for use in FE settings included a series of focus groups and consultation exercises with key health and education stakeholders, FE students and staff from one FE college and the patient and public involvement (PPI) Advice Leading to Public Health Advancement (ALPHA) youth group based at Centre for the Development, Evaluation, Complexity and Implementation in Public Health Improvement (DECIPHer). In Phase II, a pilot cRCT was conducted in South Wales and the South West of England. Eight FE settings were sampled: four settings from each country (England, Wales) and four settings of each type (sixth form, FE college). All state-funded FE settings including community colleges and sixth forms attached to secondary schools were eligible to participate, including private and Welsh medium schools. Sites used in the MRC PHIND-funded SaFE development project, as well as those with current onsite sexual health provision other than condom provision (e.g. STI testing) were not eligible to take part. Eligible settings were approached and invited to participate via a relevant senior manager (e.g. deputy head, head of pastoral care), identified with the help of the School Health Research Network (for sixth forms in Wales) and public health leads and service providers in local authorities in England. FE settings were e-mailed or posted a project information sheet, reply envelope and form indicating their wish to participate. They were followed up by phone call. All interested settings were visited by the SaFE trial manager and a contact from the intervention delivery team to discuss the trial in more detail and agree a research contract describing the roles, responsibilities, timeline of intervention delivery and assessments before taking part. To speed up FE recruitment during the COVID-19 pandemic, we oversampled FE settings e-mailing 55 sites. Of those 55, we met with 17 who were interested in taking part, equating to a response rate of 30.9%. As we only needed eight, we recruited these on a first-come-first-served basis; 8/55 sites equates to a recruitment rate of 14.5%, which is most likely a conservative estimate.

Students aged 16 years or above were eligible to receive services or complete the student survey. Clusters (settings) were randomised to receive either the SaFE intervention or continue with usual practice (i.e. provide condoms, educational lessons).

Data collection process

Optimisation of intervention materials

We conducted a multistage engagement process between May and November 2021 to optimise intervention materials (staff training and publicity materials) for use in FE settings. In stage 1, together with two practitioners and subject experts in sexual health and domestic violence training and delivery, we undertook a desk review of relevant literature and improved and updated existing materials to deliver training in FE. These were collated and adapted into a slideshow presentation. This slide deck and posters were then shared with the Trial Management Group (TMG) of the pilot cRCT for feedback. The TMG consisted of 13 academics with expertise in sexual and public health, sociology, intervention development, and quantitative and qualitative methods. In stage 2, we facilitated (1) two focus groups; one with FE staff and one with FE students, and (2) a consultation session with a group of key stakeholders in the field (e.g. members from Local Authority public health teams in England and Wales, Public Health Wales, LGBTQ+ and other young people's charities) to review and feedback on the intervention materials. In stage 3, we consulted the Trial Steering Committee (TSC) of the pilot cRCT through e-mail feedback. The TSC consisted of seven delegates including academics, FE staff, students and third sector representatives who were established to provide independent oversight of the study process. In stage 4, we conducted a trial run of the training with a group of staff from one FE college. In stage 5, the TMG conducted a final review of the materials. In stage 6, members of the young people's PPI advisory group, ALPHA, gave online feedback on the posters.

Pilot cluster randomised controlled trial

In the pilot cRCT, two sets of measurements were taken; at baseline (September/October 2021) and 12 months post baseline (September/October 2022). Data collection took place onsite at the college with surveys conducted online using students' personal mobile phones or paper

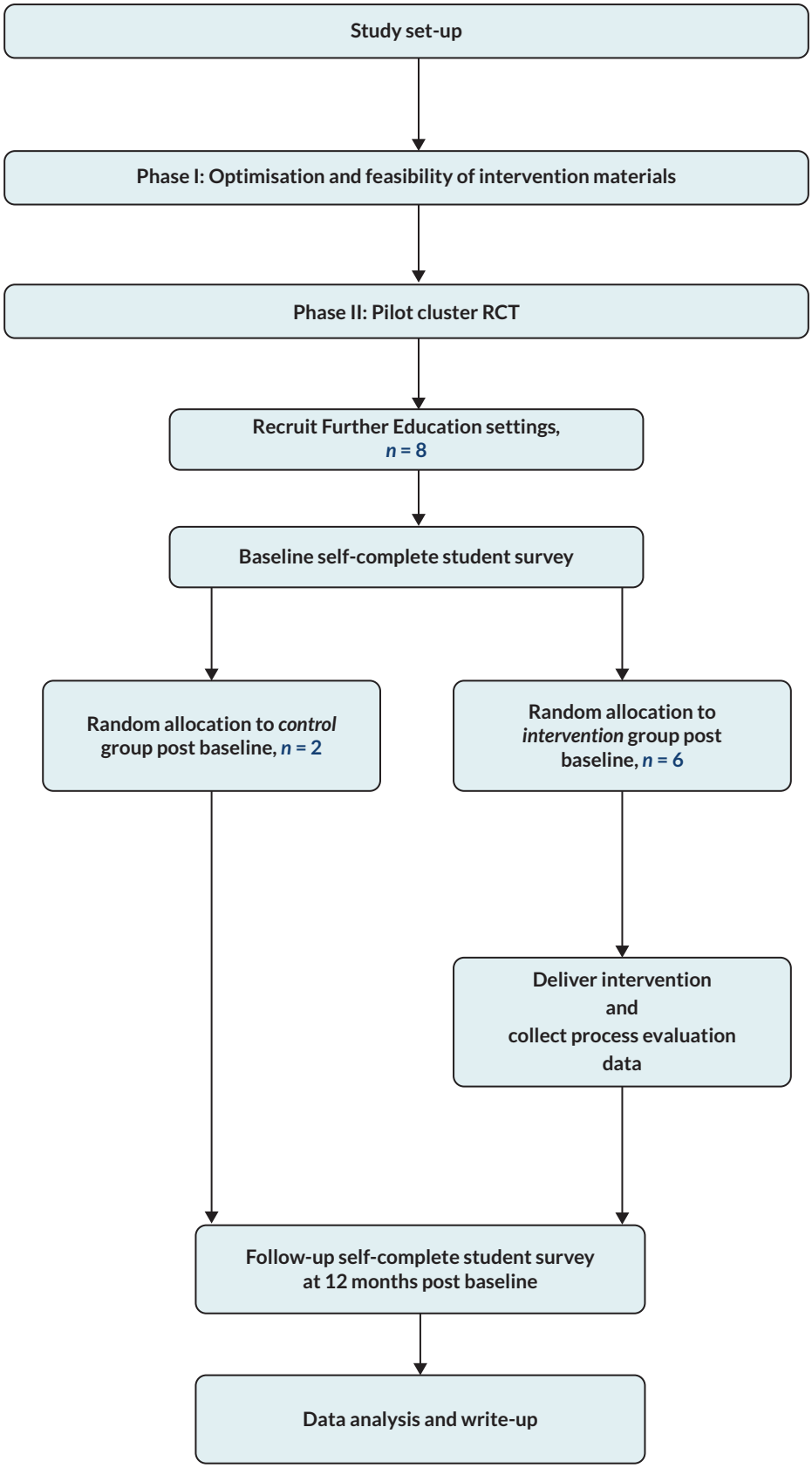

FIGURE 1 Study flow diagram.

questionnaires then entered online by a research staff member. Structured observations of staff training (n = 1 per setting), focus groups with students (up to n = 2 per setting) and telephone interviews with trained FE staff (up to n = 4 per setting) and onsite sexual health service staff (n = 1 per setting) examined intervention acceptability, delivery and institutional- or student-level barriers to implementation. Logbooks for onsite sexual health service staff examined what services were provided and post-consultation surveys examined service user experience. Logbooks for FE staff examined time and resources spent implementing the intervention. All participants provided informed consent. Full details of the pilot trial methods are detailed elsewhere.[13]

Ethics and consent

Students were provided with information sheets and consent forms, and, following informed consent, the questionnaire. In the pilot cRCT, students completing the questionnaire were offered entry into a prize draw to win an iPad. Trained fieldworkers attended social areas and lessons to invite students to participate. Ethical approval was obtained from Cardiff University School of Social Sciences Research Ethics Committee (Reference: SREC/3397) and NHS Ethics (Reference: 20/WA/0090).

Intervention

The intervention is described in accordance with the Template for Intervention Description and Replication guidelines.[14]

Name and brief description

Figure 2 shows the logic model for the SaFE intervention. SaFE aims to promote sexual health, and prevent and manage DRV and sexual harassment in FE settings.

Why: rationale of essential intervention elements?

The provision and promotion (via staff and publicity materials) of regular, free onsite sexual health and relationship services aimed to create a FE environment where positive sexual health and relationships were normalised. The aim was 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 were used to 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).[6,15] In line with the social learning model,[14] staff training aimed to provide skills to recognise, prevent and respond to DRV and sexual harassment, to challenge negative attitudes and social norms about DRV and sexual harassment in order to create safer and more respectful settings. Increasing staff and FE wide awareness and promoting appropriate behaviours attempted to shift norms about the acceptability and tolerance of these acts. Onsite services supported students' skill development and behavioural control.

What: a description of intervention materials

The SaFE intervention has three components:

1. *Onsite access to sexual health and relationship services available for 2 hours on 2 days per week.* Services provided free, confidential access to non-judgmental, professional advice, support and signposting, condoms, pregnancy, and STI (at minimum chlamydia and gonorrhoea) tests.
2. *Publicity of onsite sexual health and relationship services*. Texts, e-mails, websites, social media, posters and events: (1) publicised onsite services and (2) gave information and educational resources about, and signposted to, local sexual health, relationship, DRV and sexual harassment support services.
3. *FE staff training on how to promote sexual health, and recognise, prevent and respond to DRV and sexual harassment*. Online training was provided to FE staff on how to promote sexual health, recognise and respond to DRV and sexual harassment, and signpost students to (onsite) sexual health and relationship services. Training sought to help staff identify hotspots where DRV and harassment occur onsite. Training also included knowledge about how to manage sexual harassment at educational settings and support or refer victims or perpetrators to specialist services.

The SaFE intervention combined standardised inputs, processes and outputs but had flexibility to allow local adaptation to support universal adoption, institutional ownership and the implementation of multiple activities.[16]

Who delivers the intervention?

Further Education staff training on DRV prevention and management was provided by a specialist practitioner with expertise in sexual health, domestic violence and safeguarding. Onsite sexual health and relationship services were provided by sexual health nurses. Onsite sexual health and relationship service publicity was coordinated by a nominated intervention champion, usually a member of the safeguarding or well-being team, in each FE setting.

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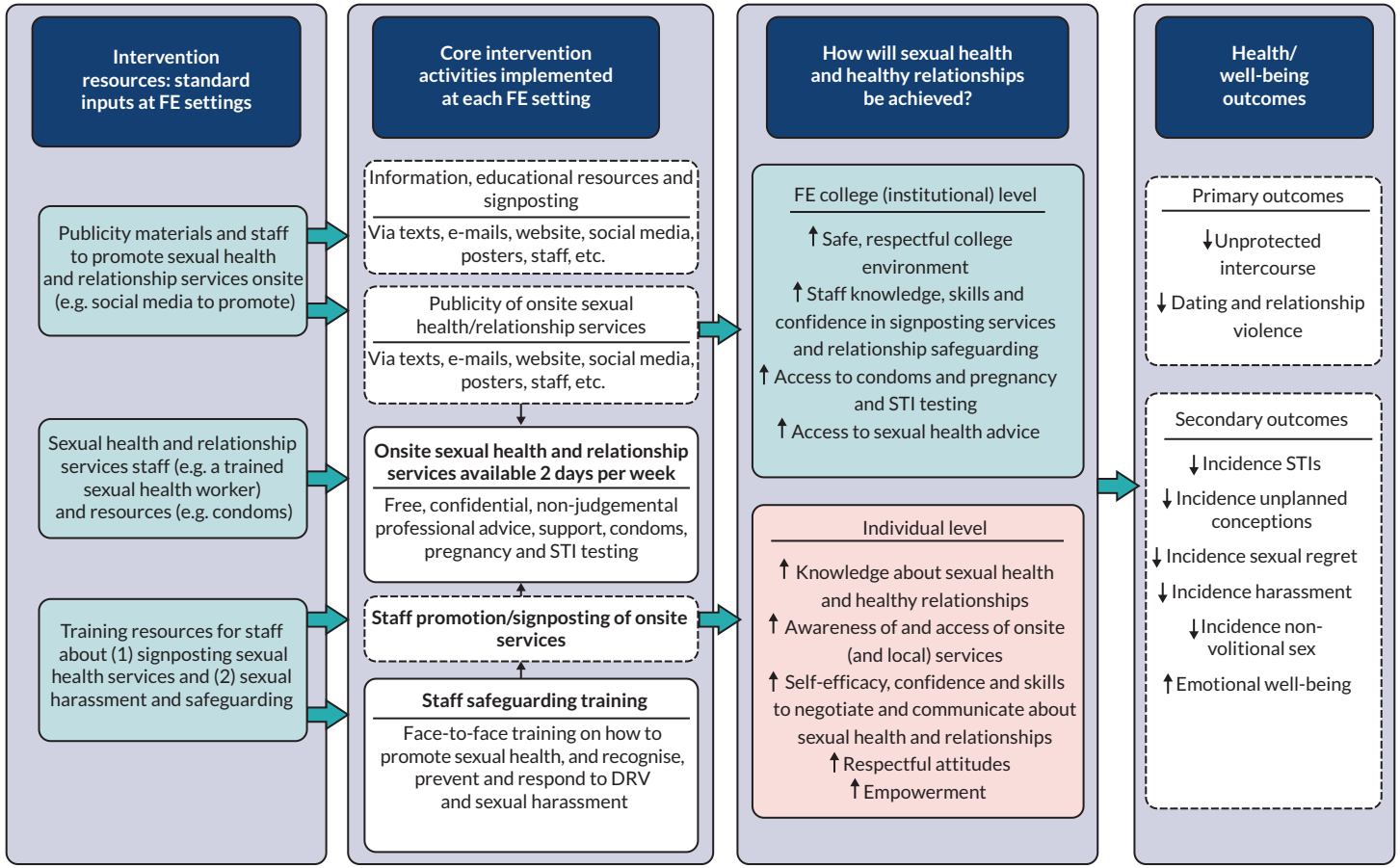

FIGURE 2 Sexual health and healthy relationships intervention for Further Education logic model. This figure has been reproduced with permission from Williams-Thomas *et al.*[13] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

How: modes of delivery of the intervention?

At least one (online or in person) staff training session was provided to each intervention setting. Nurses attended FE settings to provide onsite sexual health and relationship services. Publicity materials were developed by the research team and provided to intervention sites. In some cases, FE settings modified or developed their own posters and social media posts to publicise the services.

Where: locations where the intervention has occurred?

Further Education settings in South Wales and the South West of England, UK.

Tailoring of the intervention

Further Education staff training was interactive so staff could ask questions. Nurses provided onsite services where possible. In some cases, when they could not provide the service onsite (e.g. contraceptive pill/pre-exposure prophylaxis), they arranged the appointment with another provider. Some FE settings modified or created their own materials publicising onsite sexual health services.

Randomisation

Following baseline surveys (September/October 2021), FE settings were randomly allocated to one of two arms: SaFE and usual practice. Allocation was conducted by the trial statistician using a 3 : 1 ratio: SaFE delivered in six settings, and usual practice in two. The randomisation was stratified to ensure that three out of four settings in each country (England and Wales) and three out of four settings of each type (sixth form and FE college) would receive the SaFE intervention.

Outcomes

The outcomes in Phase I were the optimised staff training and publicity materials. In Phase II, the primary outcome of the pilot cRCT was whether progression to a Phase III cRCT was justified when judged against a set of progression criteria (*Table 1*). We also examined the acceptability of indicative proposed primary outcomes of a future Phase III trial: unprotected sex at last intercourse measured using validated questions from the SHARE questionnaires[17] and self-reported experience of DRV victimisation in the last 12 months measured using the short Conflict in Adolescent Dating Relationships Inventory (sCADRI).[18]

Feasibility of data linkage

We wanted to determine if routinely collected sexual health data were available and accessible that could be used in a full-scale evaluation. We consulted 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, general practice (GP) and Department of Health data relating to identification and treatment of STIs, pregnancy, abortion and emergency contraception prescriptions were considered. Sensitive sexual health

TABLE 1 Summary of results against the progression criteria

Progression criterion	Red	Amber	Green	Actual
1. At least seven of the eight FE settings are retained throughout the study.	< 7		≥ 7	8
2. Percentage of students approached that complete a questionnaire at baseline and follow-up.	< 50%	50–59.9%	≥ 60%	56.3%
3. The intervention is implemented with fidelity in at least five of six intervention settings.	< 5		≥ 5	6
a. Percentage of sessions for onsite sexual health service a nurse attended a FE setting	< 50%	50–79.9%	≥ 80%	82.1%
b. Number of intervention settings with onsite publicity of services	< 5	5	6	6
c. Number of intervention settings where at least five members of staff attended training sessions	< 6		6	6 (137 staff trained across sites)
4. Intervention is acceptable to students, FE staff and public health commissioners.	Low	Medium	High	High

Source
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information has previously been successfully linked (e.g. data on abortions).[19] Assessment of the feasibility of linking, transferring and storing data was also conducted, including governance requirements of multiple data providers. This identified the feasibility and associated costs for future data linkage in a Phase III trial.

We asked survey participants questions about their awareness of the possibility of researchers accessing their health data, how comfortable they would be allowing researchers to access their health data, and whether it would impact their willingness to take part in a larger trial of SaFE. We examined consent rates and outcomes by age, gender, whether participants reported living with an adult in paid employment to quantify any selection bias. Participants were able to decline completion of the data linkage questions while continuing with the study. Data were not accessed in the pilot cRCT as the sample size would not have been sufficient for some key outcomes (e.g. abortion).

Costs of the intervention and requirements for a health economic evaluation

We costed the intervention using logbooks of staff time and records of services provided by onsite sexual health and relationship services. We asked staff to record the time spent being trained along with their job title to estimate costs. These were combined with unit costs assembled from standard sources (such as NHS reference costs[20] and the Personal Social Services Research Unit Compendium[21]) to estimate the cost of the intervention. We then explored the appropriateness of capturing the benefits of the intervention using the EQ-5D-5L measure. We used published tariffs from the UK population to estimate health-related quality of life from EQ-5D-5L.

Statistical analysis

Statistical analyses were largely descriptive providing estimates of recruitment, response and retention rates. In the main results paper,[13] we presented the percentages of missing values and distributions of all categorical and continuous variables. We also presented the rates of completion and discrimination of proposed Phase III primary and secondary outcome measures and the internal consistency of the scaled outcomes using Cronbach's alpha at baseline and follow-up. Analyses were performed in Stata version 17 (StataCorp LP, College Station, TX, USA).

Qualitative data collection and analysis

All interview recordings were fully transcribed. Two members of the research team analysed the data using inductive and deductive thematic analysis. To increase consistency in the coding, a coding scheme was developed by two researchers, using two interviews from each population group (FE staff, FE students, nurses); these were selected at random. Each coding scheme included both a priori codes and in vivo codes. The coding scheme evolved during analysis, with the new codes discussed and confirmed by the team, before being applied to previously coded data. Disagreements between researchers were resolved through discussion. NVivo version 12 (QSR International, Warrington, UK) supported data analysis and storage. The language and terminology reported in the results reflects that used by participants. The terms 'learner' and 'student' are used interchangeably throughout the manuscript.

Results summary

Objective 1: to convene a network of stakeholders to optimise the intervention materials

Table 2 summarises the optimisation process. It details the feedback and changes made for each stage and intervention component. During stage 1, a desktop review of existing staff training materials on sexual health promotion and DRV prevention either publicly available or used by a local authority public health team was conducted. A slide deck and series of posters (designed to advertise the onsite sexual health and relationships services) were collated. These intervention materials were shared with the TMG who provided feedback. Overall, this involved streamlining content to ensure relevant and up-to-date material, reduce the length of the slide deck and reduce use of theoretical content in favour of case studies, scenarios and practical guidance with interactive elements. A supplementary pack of frequently asked questions (FAQs) and definitions was also proposed. Feedback indicated that consistency was needed in the presentation of slides and posters to enhance coherence and intervention identity.

From the focus groups undertaken in stage 2, two key themes emerged based on student and staff feedback: these related to content and delivery. Participants felt overall that the content was mostly comprehensive but made suggestions relating to the clarity of definitions, age groups, legality of sexual behaviours and consent, as well as safeguarding and help-seeking. With regard to the visual design, participants discussed the importance of bright, engaging, eye-catching material in the form of posters and digital resources to try to create a culture of consent and safety for students.

TABLE 2 Summary of the findings and changes made in each stage

Activity	Intervention component	Summary of suggestions + changes made
Stage 1 Desktop review, consultation with TMG (internal review)	FE staff training on how to promote sexual health, and recognise, prevent, and respond to DRV and sexual harassment	• Ensure intervention materials are clear and backed by referenced facts (e.g. prevalence rates of STIs/unprotected sex) • Emphasise practical, user-focused guidance • Ensure training challenges staff pre-existing knowledge and assumptions about learner behaviour, especially regarding women and multiple partners • Improve signposting for relevant school/college policies and referral options • Shift focus from existing content on Gillick competence to broader risky behaviours, including violence and coercion • Prioritise sexual harassment by removing outdated references and adding interactive case studies • Add sections on image sharing/sexting, digital abuse, cultural obstacles, and sexual harassment and pornography *Changes made* • The 2 slide decks of 59 and 36 slides were consolidated into 93 slides, and streamlined, typographical errors corrected, section breaks removed • Updates included adding content on image sharing/sexting and expanding content on digital abuse and cultural obstacles, along with a new section title for sexual harassment and pornography
	Publicity of onsite sexual health and relationship services	• Posters had typographical errors *Changes made.* • Typographical errors corrected
Stage 2 (1) Focus group FE staff; (2) consultation with stakeholders	FE staff training on how to promote sexual health, and recognise, prevent and respond to DRV and sexual harassment	1. Content a. Comprehensiveness and structure • Cover essential topics such as risky sexual behaviour, consent, recognising unhealthy relationships, pornography, and harassment, with special attention to the nuances of age, legal implications and personal readiness • Emphasise the legal boundaries related to consent, particularly image-sharing laws and the risks of coercion, ensuring learners understand both the legal and personal dimensions • Educate staff on safeguarding principles, including recognising exploitation and abuse. Include detailed reporting procedures and encourage educators to guide students on when and where to seek help • Ensure staff training covers how to approach sensitive topics with non-native English speakers and students with special needs, fostering an inclusive approach for diverse backgrounds and abilities b. Visual design • Design visually appealing materials, using bright colours and impactful messaging. Posters should emphasise accessibility, privacy (non-college staff), and free services • Utilise digital screens, QR codes, and push notifications on familiar platforms (e.g. Microsoft Teams) to make resources easily accessible • Provide clear pathways to external support websites and services, empowering students to access relevant information outside of college settings 2. Delivery theme a. Preferred training formats • Use activities such as case studies, group discussions, and practical examples to foster engagement and understanding, moving beyond traditional PowerPoint presentations • Ensure a mix of theoretical knowledge and real-world scenarios to keep training relevant, particularly for sensitive topics like consent and peer pressure • Recognise time limitations by designing concise yet effective half-day sessions that maximise engagement and cover essential training points b. Opportunities for practical application and skill-building • Use realistic examples and case studies to help educators relate to students' actual experiences, such as online exploitation and consent issues • Train staff to be non-judgemental and mindful of their biases when discussing sensitive topics, creating a supportive environment for students • Emphasise understanding students' social realities, allowing educators to better respond to learners' needs with empathy and situational awareness • Guide staff on using sensitive, positive terminology to avoid stigmatisation, fostering a safe and supportive learning environment for all students

continued

TABLE 2 Summary of the findings and changes made in each stage (*continued*)

Activity	Intervention component	Summary of suggestions + changes made
		Changes made • Reduced overall number of slides from 93 to 66; reducing the number of slides on participant introductions, risky sexual behaviour, and various consent and DRV topics, with content moved to supplementary materials 1. Reducing text-heavy content • Simplified content on DRV and coercive control and removed slides on gaslighting and problem extent • Adjusted training to fit a 2-hour slot, removing plans for breaks and extended activities • Supplementary materials were expanded to include extra content on risky sexual behaviour, details on Fraser guidelines, and information on support services 2. Stakeholder feedback • Revise the title 'Risky Sexual Behaviour' to avoid negative connotations and make it more inclusive • Use sensitive language, recognising that some may engage in early sexual activity due to abuse and other uncontrollable factors • Incorporate diverse perspectives on topics like 'multiple sexual partners', 'sexual health', and 'sexuality', and allow room for personal experiences. Trainers should be prepared to handle sensitive issues. • Allow trainers flexibility to focus on three key topics per session for more detailed discussions within the limited time • Include diverse imagery, representing different ethnicities and relationships, and address issues related to religion and LGBTQ+ experiences • Provide additional context for the video explaining consent using a 'cup of tea' analogy (the 'Consent and Tea' video), especially for younger audiences, and introduce consent and legality topics earlier in the session • Include a 'localised signposting' slide at the end of each section to guide individuals to appropriate support services • Clarify staff roles and responsibilities, and provide clear guidelines for handling disclosures, especially in cases of abuse • Emphasise confidentiality but also explain the duty of care and the importance of safeguarding, with specific red flags to look out for • Address abuse more inclusively, acknowledging the experiences of men and LGBTQ+ individuals, and mention issues like fetishisation of people from Black Asian and Minority Ethnic groups and LGBTQ+ people • Summarise key responsibilities at the end of the session and provide contact details for local services and follow-up support • Produce bilingual posters in Wales, with English and Welsh, and include the local, relevant service logos • Add a 'rainbow' logo to show LGBTQ+ support and inclusivity • Address privacy issues related to visibility at session rooms, consulting sexual health charities for solutions • Add a helpline number for alternative service access • Share support service details widely through social media, college screens, MS Teams and newsletters • Evaluate sexual health training and consider further training focused on resource signposting *Changes made* • The title 'Risky Sexual Behaviour' was revised to avoid negative connotations and make it more inclusive • Sensitive language was used to acknowledge the impact of abuse on early sexual activity • Trainers were given flexibility to focus on three key topics per session for in-depth discussion • Diverse imagery was included, reflecting various ethnicities, relationships and addressing LGBTQ+ issues • The 'Consent and Tea' video was contextualised for younger audiences, with consent and legality introduced earlier • Localised signposting slides were added to direct individuals to support services • Staff roles and responsibilities were clarified, emphasising confidentiality, safeguarding and handling disclosures • Posters updated with expert feedback, bilingual in Wales with relevant logos • Added LGBTQ+ 'rainbow' logo and privacy concerns addressed • Included helpline number for alternative access • Shared support service info widely and evaluated training for further improvements

TABLE 2 Summary of the findings and changes made in each stage (*continued*)

Activity	Intervention component	Summary of suggestions + changes made
	Publicity of onsite sexual health and relationship services	• Use bright, eye-catching posters to highlight that the service is free and run by external staff • Use digital images on announcement screens and platforms like MS Teams, along with QR codes, as many college teams prefer screens over posters • Incorporate push notifications via the college app and specify that the service is for over 16-year-olds *Changes made* • Developed bright, eye-catching posters to show that the service is free and run by external staff while utilising digital images and QR codes on announcement screens and Teams • Incorporated push notifications via the college app to specify that the service is for over 16-year-olds
Stage 3 Consultation with TSC	FE staff training on how to promote sexual health, and recognise, prevent and respond to DRV and sexual harassment	• The intervention materials were considered informative • The TSC emphasised the need for trainers to be able to manage participant disclosures like sexual harassment *Changes made* • The slide title was changed, and an introduction was added before covering risky sexual behaviour. The section order was also adjusted to address sex and sexualisation before definitions of risky sexual behaviour • Signposting content was moved to supplementary materials and included as slides at the end, with a reminder to check local policies and procedures
Stage 4 Trial run with FE staff	FE staff training on how to promote sexual health, and recognise, prevent and respond to DRV and sexual harassment	• Training was disrupted by staff concerns over a perception of unaddressed previous feedback • Streamline content into one slide deck to eliminate repetition • Accommodate different learning styles by adding visual material, using online platforms for engagement, incorporating task-based exercises, leveraging trainer experience and including case studies • Acknowledge that some participants found the training redundant due to prior experience in pastoral care and safeguarding *Changes made* • All the definitions were combined and added to the supplementary section: gender, sex, sexuality, sexual health, sexual activity, sexualisation, sexual rights and risk when leaving an abusive relationship • The revised approach includes more visual material, online engagement, task-based exercises, trainer experience and case studies to accommodate diverse learning styles
Stage 5 Final review by TMG	FE staff training on how to promote sexual health, and recognise, prevent, and respond to DRV and sexual harassment	• Merge slides and combine aims to highlight trainer's experience with case studies at the beginning of each section • Add engaging multimedia content, including consent animations and fact/myth videos, along with relevant case studies • Remove signposting and support sections, move that content to supplementary materials and include slides on onsite sexual health and relationship services *Changes made* • Intervention materials were made more cohesive and structured by adding more visual content, changing the wording (pornography to pornographic content), and starting each section with a case study, or lived experience from the trainer • Included detailed information on onsite sexual health services
Stage 6 ALPHA Young people's PPI stakeholder group feedback	Publicity of onsite sexual health and relationship services	• Posters were bold and concise but needed contact details and consistent formatting for clarity • Some messages, such as those on pornography and abusive relationships, required clearer communication and additional context • Varying colours and using more relevant imagery would enhance message distinction and audience engagement. • Key terms should be emphasised, and calls to action made more direct to improve accessibility to support *Changes made* • Contact details were added, and formatting was standardised for clearer communication • Messaging on sensitive topics like pornography and abusive relationships was clarified, with additional context provided • Colours, imagery and key terms were adjusted to improve message distinction, engagement, and accessibility to support

For the delivery of the training, participants felt that interactive methods and activities were vital for maintaining FE staff interest and engagement, as well as balancing theoretical knowledge and practical examples. There was a preference for real-world examples, especially to illustrate complex concepts such as consent and peer pressure. Given the demands on FE staff, delivering training in a time-sensitive and efficient way was deemed essential. Participants felt that digital engagement across the college site (i.e. to publicise the onsite sexual health and relationship services) was key to promoting student engagement. Finally, in relation to delivery, engaging and relatable material was considered crucial to the staff training element of the intervention, including case studies and practical examples which could help FE staff to recognise their potential pre-existing biases. Participants reported that staff training also needed to recognise FE staff's differential willingness to engage with sexual health topics when dealing with students.

Stakeholder feedback as part of stage 2 indicated the need for sensitive language throughout the presentation slides as well as ensuring diversity (in terms of gender, sexual identity, ethnicity and so on.) in examples across the slide deck. Stakeholder feedback incorporated suggestions about how to improve the inclusivity of the training both in terms of content and presentation. The stakeholders reported that local signposting was important at each college as well as staff expectations for safeguarding and managing disclosures. Stakeholders also discussed the promotion of off-campus or remote support should students require it.

The TSC reviewed the intervention materials in stage 3. Overall, the group suggested some minor changes to the ordering of the content to enhance the flow of material, as well as signposting to support services and ensuring the readiness of trained staff to handle disclosures (i.e. safeguarding procedures).

Stage 4 consisted of a trial run of the intervention delivery. FE staff involved in the trial run requested a more streamlined presentation with the use of more interactive materials (e.g. including delivery staff's real-life experiences along with examples and scenarios). Visual materials were also preferred. Staff supported the removal of definitions into supplementary materials, although they recognised that while many of them had prior experience and training in the areas of domestic violence and safeguarding, other FE staff would not have similar background knowledge and expertise.

A final review by the TMG was conducted in stage 5. The group recommended further condensing of the slides and the introduction of more animations as well as case study examples from the trainer's lived experience. Case studies and examples were moved to the start of each substantive focus topic to act as an anchor for the session. Further content was moved to the supplementary materials and replaced with more specific college-level and local resources as well as signposting to these.

The final review of the student facing materials was conducted by the ALPHA PPI youth group in stage 6. They emphasised the importance of consistency in formatting as well as the need for clarity in the messaging. The group suggested the incorporation of various colour schemes to promote distinction between the messages as well as the removal of overly medical content in favour of promoting the 'free', 'confidential' and 'external' nature of the services. A full report of the optimisation phase of the research is provided elsewhere.[22]

Objective 2: to conduct a pilot cRCT in eight FE settings to determine whether a Phase III cRCT assessing effectiveness and cost-effectiveness should be conducted

Table 1 summarises the results of the pilot cRCT against the progression criteria. Three of the four progression criteria were rated green and were therefore met. For the criterion relating to the percentage of students approached who complete a questionnaire, 56.3% of students approached provided data. The green threshold for this criterion was 60%.

1. At least seven of the eight FE settings are retained throughout the study.

All eight FE settings were retained throughout the study.

2. Percentage of students approached that complete a questionnaire at baseline and follow-up.

Figure 3 shows the CONSORT flow diagram. The mean percentage of students approached who completed a questionnaire at baseline and follow-up was 56.3% (the threshold for this criterion being rated green was 60%). At baseline, of the 1852 students approached, 1124 (60.7%) completed the questionnaire. At follow-up, of the 2193 students approached 1139 (51.9%) completed the questionnaire. Of the baseline participants, 13.3% [95% confidence interval (CI), 11.4% to 15.5%] were resampled at follow-up.

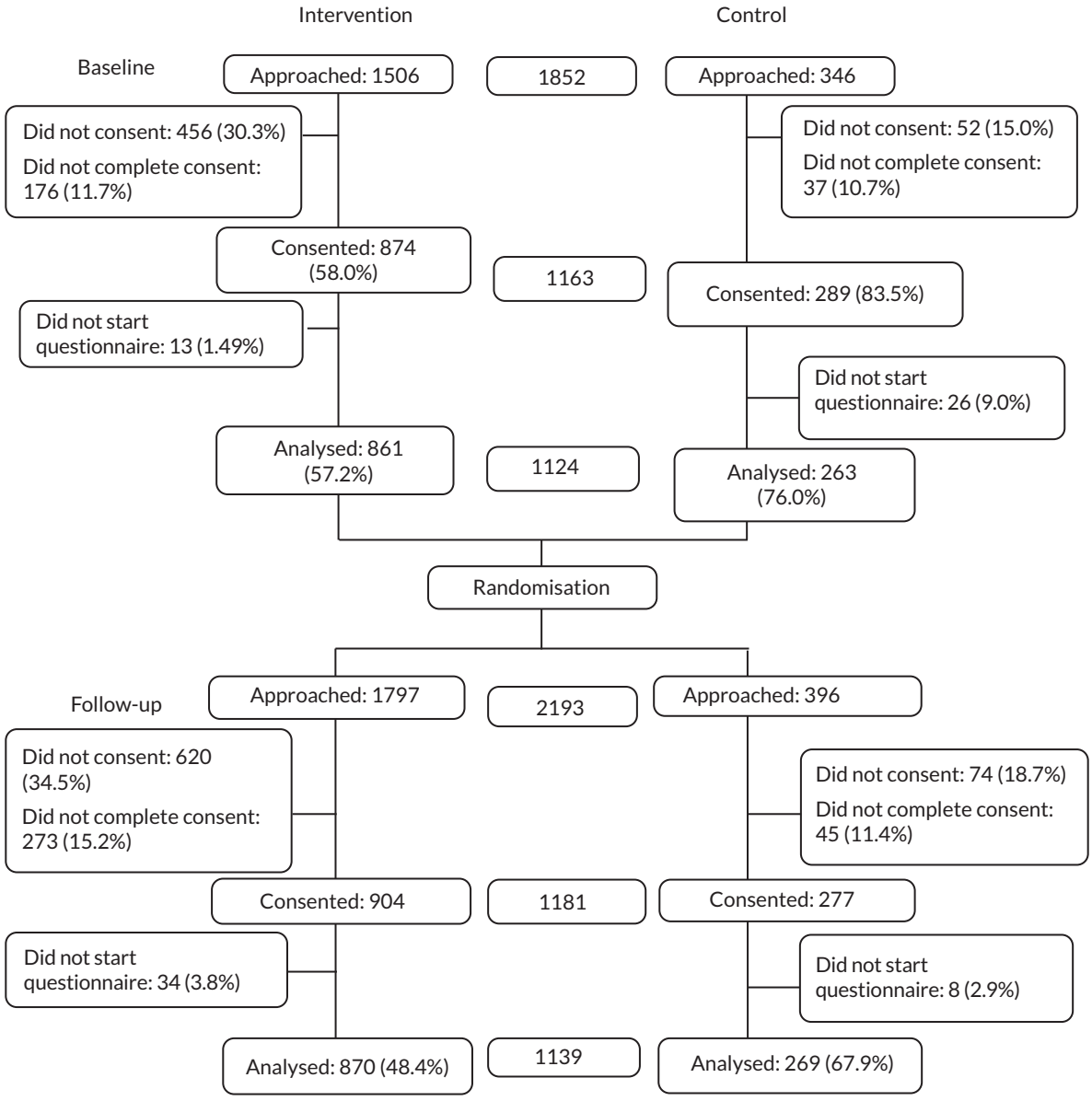

FIGURE 3 CONSORT flow diagram. Reproduced with permission from Williams-Thomas et al.[13] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

3. The intervention is implemented with fidelity in at least five of six intervention settings.

The intervention was delivered with fidelity in all six settings.

a. Percentage of onsite sexual health services sessions attended by a nurse.

Of the possible onsite sexual health service sessions delivered at FE settings during the intervention period, *n* = 192/234 (82.1%) were attended by a nurse. The most common reason for students' attendance was to get condoms (38.0%), followed by advice (15.8%), pregnancy tests (15.8%) and STI tests (14.3%). Other reasons for attendance included STI treatment (4.8%), blood tests (4.8%), contraceptive implants (3.2%) and undisclosed safeguarding incidents unrelated to the intervention (3.2%).

b. Number of settings with onsite publicity of services.

Observations conducted by the research team found onsite publicity of onsite sexual health and relationships services in all six intervention sites. All site observations were completed during the last month of the intervention period (June/July 22).

c. Number of settings where at least five members of staff attended training sessions.

At least five members of staff attended training in all six intervention sites. In total, 137 staff were trained across the six intervention sites.

4. The process evaluation indicates the intervention is acceptable to students, FE staff and public health commissioners (measured by qualitative interviews, routine monitoring data on attendance and survey data).

Four overarching themes were identified, each with a set of related subthemes: (1) staff training; (2) reach and engagement; (3) acceptability, implementation, and potential improvements to SaFE intervention and (4) school/college provision of help for sexual health and DRV. Themes are organised by stakeholders to ensure representation from all members.

Students

Students liked that sexual health and relationship provision was onsite but the location of the service within the setting was a barrier because of concerns about being seen attending the service.

> *I think it's good that it's here, but I think it's difficult because obviously people can see you in that room.*
>
> *FE setting 1 (England), student focus group*

Such feedback led the sexual health service to be moved to a more discreet, and preferred location in one intervention site, and the addition of a location in another intervention site (i.e. different rooms on different service days).

Further Education staff

Staff felt that training increased their confidence in responding to students if relevant issues were raised.

> *I think it's increased staff awareness when pupils are having conversations in class about relationships, etc. I think staff feel more confident that they can sort of challenge, you know, stereotypes, talk to pupils, you know, if, if you're in that position, perhaps you need to […]*
>
> *FE setting 2 (Wales), site lead interview*

Staff attending training were mostly well-being staff or personal tutors who were most experienced dealing with DRV or sexual harassment. They were keen to engage a wider variety of FE colleagues.

> *More training slots to cover, to cover more staff… It's only just starting to embed.*
>
> *FE setting 1 (Wales), site lead interview*

Attendees reflected that the training topics covering healthy relationships and pornography were valuable. They incorporated aspects into their teaching and disseminated the knowledge to students.

> *Uh, the healthy relationships one absolutely. Um, I also took a lot of that information and put it into my, uh, lesson when I taught about healthy and unhealthy relationships. Um, the pornography one was also quite interesting as well, um, I didn't really create, like, a lesson on, uh, pornography, but I definitely did incorporate some of the, uh, issues into, uh, consent, uh, uh, my lesson consent, yeah, and of course consent was pretty useful as well.*
>
> *FE setting 3 (England), staff*

Staff thought the onsite sexual health services would have had more attendance and reach if they had been delivered for longer and normalised as part of the well-being services within the setting.

> *But I think that potentially, the difference was just time. People just needed to get to know [Nurse] and the word get out. And you know, we often find them, that you can do some good marketing materials and put up posters and plasmas and whatever you want. But actually, it's, it's about that personal relationship. And one student going back and talking to their mate and saying, 'ah, do you know what, I spoke to this really nice person'.*
>
> *FE setting 3 (England), site lead interview*

Staff particularly valued having a sexual health nurse onsite to support students who had become pregnant.

> *And it's been a godsend, particularly with the couple of pregnancies that we've had, that they happen to have come to us on the day that the sexual health clinic was there.*
>
> *FE setting 1 (Wales), site lead interview*

Regarding onsite sexual health and relationship service publicity, staff thought that posters were important to engage students, noting the service was provided by a nurse and not FE staff.

> *I think obviously, the posters really highlight the service that was in place, and obviously, the specialist and provision provided by the school nurse. I think having*

> *that, rather than just teachers….So, I think having that external person, makes the students feel a bit more comfortable in disclosing some of the issues potentially, just because they don't want to necessarily disclose it to somebody they have to see every day. So, I think you should have an external person.*
>
> *FE setting 2 (England), site lead interview*

Nurses

Nurses also noted how finding an accessible but private room was important. However, too much privacy presented a barrier whereby students would not know if staff were available.

> *Yeah. And then when we, when they had a meeting and we and I mentioned about the room just not, not being really feasible, not in the right place.*
> *Um, and then I think the following, they moved [Nurse1] and [Nurse1] had seen like four or five that day.*
>
> *Wales, nurse interview*

Nurses felt that COVID-19 pandemic restrictions had acted as a barrier to the services embedding and that they needed longer to embed.

> *So I think, do you know, I just think it wasn't enough time, I think we came in at the wrong time for a start… So I think there was still the restrictions and everything, so I think we've sort of had that barrier from the start, because COVID wasn't over.*
>
> *Wales, nurse interview*

Nurses also reported needing more time to build trust with students. The pandemic restrictions reduced their ability to see students and they also pointed out that students having a positive experience could lead to an increase in subsequent service use.

> *[L]ike, and then I, you know, I seen one patient, then he brought his friend and, do you know, so it was, it, it, it, at the clinic I would just say it takes time to kick off.*
>
> *Wales, nurse interview*

Public health commissioners

The displacement of services from the NHS to FE settings was deemed a positive way to enhance service uptake among young people who may not otherwise be able to access services. It also provided a subsequent gateway into community services. Improving FE staff skills on how to promote sexual health and prevent DRV was also considered a positive feature of SaFE that could increase the reach of services.

> *I think it also matches priorities, really, um, the idea of developing the skills in that setting and making it relevant to, to that school and, and the children and young people, um, you know, in that, that school or college. So yeah, this, you know, it seems really promising and exciting.*
>
> *Wales, public health commissioner*

Routine monitoring exit checklist data

Exit checklists were optional for students leaving the sexual health nurses room after using the onsite sexual health and relationship service. They were completed in four of the six intervention sites. A total of 18 checklists were completed across the four intervention sites; 100% of those who completed the checklist reported that they 'got what they needed from their visit' and 77.8% indicated that they would use the service again if they needed to.

Outcome data

Survey responses indicated low rates of missing data for almost all outcome variables, with no discernible differences across arms. The highest rate of missing data on other items was 14.8%, to a question on whether participants had ever used a sexual health service in the intervention group at baseline. The prevalence of unprotected sex at last intercourse was 15.5% at baseline and 18.7% at the 12-month follow-up (see *Report Supplementary Material 1*, *Table S1*). There was evidence of floor effects with DRV victimisation in the last 12 months. The scale had a minimum score of 10.0. At baseline, the median score was 11.0 [interquartile range (IQR), 10.0–13.0] and at the 12-month follow-up of 10.0 (IQR, 10.0–13.0) (see *Report Supplementary Material 1*, *Table S2*).

Feasibility of data linkage

Several relevant trial outcomes are documented in routine records: STI testing and treatment, pregnancy, abortion and emergency contraception. Across the UK, these services are available through GPs, sexual health clinics and pharmacies. For a Phase III trial of SaFE, we would need to link information from these services to trial data at an individual level. The data sets would also need to be collated at a national level to ensure any events, at any location, were identified and linked for each consenting participant. *Table 3* outlines what is known to be currently available nationally across the UK and linkable at an individual level.

Wales has national resources that provide good coverage for pregnancy, termination and identification/treatment

TABLE 3 Outcomes of interest available through routine administrative sources and linkable at individual level

Settings	Wales	England	Scotland	Northern Ireland
Identification and treatment of STIs				
Sexual Health Clinics	☑ Public Health Wales	☑ UK Health Services Agency [UKHSA]	☒ Not available – UKHSA data on devolved nations is not well populated	☒ Not available – UKHSA data on devolved nations are not well populated
Primary Care	☑ SAIL Databank – Welsh Longitudinal General Practice data set – Welsh Primary Care prescription codes	☑ NHS England – Medicines Dispensed in Primary Care (NHSBSA)	☑ Research Data Scotland Prescription data set	☒ Not available
Abortions and termination of pregnancy				
Department of Health and Social Care	☑ Department of Health and Social Care, Abortion statistics data set	☑ Department of Health and Social Care, Abortion statistics data set	☒ Not available	☒ Not available
Sexual Health Clinics	☑ Public Health Wales	☒ Not available	☒ Not available	☒ Not available
Primary Care	☑ Primary care records will be available with these events recorded, but the information is unavailable to request due to SAIL's small number policy	☒ Not available	☒ Not available	☒ Not available
Pregnancy				
Sexual Health Clinics	☑ Public Health Wales	☒ Not available	☒ Not available	☒ Not available
Hospital records	☑ Maternity Indicator data set (MIDS), SAIL Databank	☑ Maternity Services Data Set, NHS England	☑ SMR02: Maternity Inpatient and Day Case data set, Public Health Scotland	☒ Not available
Emergency contraception prescriptions				
Sexual Health Clinics	☑ Public Health Wales	☒ Not available	☒ Not available	☒ Not available
Primary Care	☑ Primary Care prescription codes, SAIL Databank	☑ Medicines Dispensed in Primary Care (NHSBSA) – NHS England	☑ Prescription data, Research Data Scotland	☒ Not available
Pharmacies	☒ Not available	☒ Not available	☒ Not available	☒ Not available

of STIs. However, without pharmacy data, information on emergency prescriptions is limited to individuals presenting at sexual health clinics or primary care. England has some national data but is limited by primary care data being unavailable. Under the Abortion Act 1967, medical practitioners are legally required to notify the Chief Medical Officer of every abortion performed in England and Wales and, therefore, data for this outcome would have 100% coverage.[23] Scotland and Northern Ireland have different processes for notifying and collating these data, with no information available on access for research. Pregnancy (specifically pregnancy outcome) is well documented and available to link across Wales, England and Scotland. The Honest Broker Service provides access to de-identified health data (e.g. maternity data, prescriptions, hospital admissions) from Health and Social Care in Northern Ireland.[24] However, it is not currently possible to link research data to these data sets and follow-up trial participants using routine data.

Governance requirements

Governance considerations for individual level linkage of trial data to routine data across the UK nations are similar, with the key difference when using an opt-out model for linkage. England and Wales rely on Section 251 support from the Confidentiality Advisory Group to allow linkage to health data without consent (i.e. via an opt-out model). This means that a full return of data for all participants is possible. In Scotland, this approval comes from the Public Benefit and Privacy Panel for Health and Social Care.[25] The trial could provide the option for participants not to consent to linkage while continuing

with the trial, or for linkage to be part of the consent (i.e. a requirement to take part in the trial). Ethical approval from the Health Research Authority would cover all four UK nations and therefore consent and participant facing materials could be developed and used across the UK referencing all data providers. All data would be combined in one trusted research environment (TRE) for analysis. Many of the data providers mentioned above rely on the use of TREs. Swansea University and the SAIL Databank host UK Secure Research Platforms which are currently acceptable to most data providers. The Office for National Statistics also offers a Secure Research Service.

Linkage

Trial participants would need to provide their NHS number, first and last name, date of birth, sex at birth and postcode to enable linkage. Although it is possible to link without NHS number, this directly matches to records. Postcode and name need to match the GP data as that is where demographic data are held and linked.

Acceptability of consenting to linkage

In the protocol we indicated that we would ask for consent to linkage to routine health data sources; however, within the TMG and TSC, it was agreed it would be unethical to ask for consent with no plans to link data. It would also not be a cost-effective use of staff or ethical review panel time. Instead, we adopted a brief feasibility questionnaire, adapted from a previous feasibility trial also exploring acceptability of routine data linkage.[26] The three questions included at baseline and follow-up were:

- Were you aware that researchers are able to request access to health data?
- In a future study, if we were to access your health data to look at, how comfortable would you be?
- If we had asked you to consent to us accessing your routinely collected health data in the current SaFE research study, would it have affected your decision to take part in SaFE?

At both time points, over half of participants reported being aware that their research data could be linked to their health records and a third said no (the remaining were missing) (*Table 4*). At baseline 25.2% and at follow-up 27.2% reported they were either not at all comfortable, or not very comfortable, and 34.8% at baseline and 37.2% at follow-up said they were quite comfortable, or very comfortable providing consent to link to their records. Although this is not the same as asking participants to provide consent, under a third of participants said they were definitely less likely or slightly less likely to not consent to the trial if their data were linked to routine data sources. If a Phase III trial relied on routine data for the primary outcome, these results suggest the sample size calculation would require additional inflation to account for non-consent as participants may not be comfortable with linking their data to the trial. This may add costs which may impact the efficiency and value for money of the work. There were no discernible differences in participants' responses by age, gender or whether they lived with an adult in paid employment (see *Report Supplementary Material 1*, *Tables S3–S5*).

Feasibility of longitudinal follow-up

Of the students who completed a baseline survey, 150 were available for survey at follow-up, comprising a longitudinal sample (150/1124, 13.3%). Of those who were available for survey at baseline and follow-up, 134/1124 (11.9%) had data that could be linked across the two time points. The low percentage of participants available at both time points indicates that a longitudinal design is not feasible, and a repeated cross-section is the most appropriate design.

Costs of the intervention and requirements for a health economic evaluation

The SaFE intervention includes three components with resource use implications:

1. FE staff training on how to promote sexual health and recognise, prevent and respond to DRV and sexual harassment.

Delivery of staff training involved 8 hours of staff trainer time (5 hours for preparation, 2 hours for delivery and 1 hour for follow-up) per session. This was costed at £60 per hour for the pilot cRCT, giving a total of £480 per session. Where training was delivered online, there were no additional costs associated with delivery (e.g. travel). This is combined with attendee time to calculate the total cost per trained member of staff. Based on a minimum of one training session per site, the cost per trained staff member will depend on the number of attendees. This varied from 6 to 62 attendees across the 6 sites. Assuming the median attendance of 20, the cost per attendee is therefore £480/20 = £24. Using the National Education Union pay scales for supply teachers' daily cost of £211.96, working 7.5 hours per day, we can assume staff time is valued at £28.26 per hour.[27] This implies the total cost per member of staff trained is £28.26 × 2 hours attendance + £24 = £80.52. Therefore, the total cost per site is £480 + £56.52 × 20 = £1610.40.

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TABLE 4 Participants' awareness and views about the access and linking to routinely collected health data

	Sample at baseline						12-month follow-up					
	Overall (*N* = 1124)		Control (*N* = 263)		Intervention (*N* = 861)		Overall (*N* = 1139)		Control (*N* = 269)		Intervention (*N* = 870)	
Variables	***n***	**%**	***n***	**%**	***n***	**%**	***N***	**%**	***n***	**%**	***n***	**%**
Were you aware that researchers are able to request access to health data?												
Yes	573	51.0	143	54.4	430	49.9	590	51.8	145	53.9	445	51.1
No	374	33.3	86	32.7	288	33.4	346	30.4	75	27.9	271	31.1
Missing	177	15.7	34	12.9	143	16.6	203	17.8	49	18.2	154	17.7
In a future study, if we were to access your health data to look at, how comfortable would you be?												
Not at all comfortable	128	11.4	39	14.8	89	10.3	113	9.9	30	11.2	83	9.5
Not very comfortable	140	12.5	31	11.8	109	12.7	103	9.0	28	10.4	75	8.6
No preference	391	34.8	115	43.7	276	32.1	404	35.5	98	36.4	306	35.2
Quite comfortable	167	14.9	27	10.3	140	16.3	163	14.3	34	12.6	129	14.8
Very comfortable	116	10.3	17	6.5	99	11.5	147	12.9	29	10.8	118	13.6
Missing	182	16.2	34	12.9	148	17.2	209	18.3	50	18.6	159	18.3
If we had asked you to consent to us accessing your routinely collected health data in the current SaFE research study, would it have affected your decision to take part in SaFE?												
Definitely less likely to take part	142	12.6	45	17.1	97	11.3	132	11.6	41	15.2	91	10.5
Slightly less likely to take part	184	16.4	53	20.2	131	15.2	151	13.3	30	11.2	121	13.9
No difference	530	47.2	115	43.7	415	48.2	572	50.2	132	49.1	440	50.6
Slightly more likely to take part	37	3.3	10	3.8	27	3.1	35	3.1	10	3.7	25	2.9
Definitely more likely to take part	44	3.9	4	1.5	40	4.6	33	2.9	5	1.9	28	3.2
Missing	187	16.6	36	13.7	151	17.5	216	19.0	51	19.0	165	19.0

2. Onsite access to sexual health and relationship services available for 2 hours on 2 days a week.
3. Publicity of onsite sexual health and relationship services.

The intervention allows for nurse-led onsite services to be delivered for 4 hours per week during term time. Over a 39-week academic year, assuming services are provided by a band five nurse with unit cost £52 per hour,[28] this would cost £8112. Assuming a travel cost of £877.50, based on study records, the total annual cost of a fully staffed service would be £8989.50. In practice, it was found that mean nurse attendance across the study was 192 out of 234 theoretical maximal planned sessions (82.1%) (staff attendance was influenced by sickness periods, often related to COVID-19). If this attendance rate was typical, assuming a pro-rata reduction, the total annual cost per site would fall to £7380.38.

As well as providing advice, onsite services are also expected to provide condoms, pregnancy testing, and STI tests. *Table 5* shows the number and estimated cost of onsite sexual health services provided. Students use of sexual health services, including STI testing, by trial arm were measured at baseline and follow-up and are reported elsewhere.[13] The consumable costs related to this provision are expected to be £29914.52 per year, the bulk of which (£27,300 or 91.3%) relate to STI lab tests. As well as nurse-led onsite services, the intervention might be expected to increase time spent by teaching staff on supporting students with sexual health and relationship issues. FE staff were asked to complete logbooks to detail incidents where they dealt with student issues relevant to the staff training. Overall, logbooks were poorly completed by staff (n = 13 out of 137 trained members of FE staff completed logbooks detailing 13 different incidents). Logbook data suggest that time spent per episode of care varied from 5 to 60 minutes. Assuming FE staff time is valued at £28.26 per hour, this would imply a cost per episode of care of £2.36–28.26.

This is estimated to have costed £350 per site which is just under 1% of the total site SaFE costs. The estimated cost of delivering the SaFE intervention was approximately £38363.09 per FE setting. This comprises £1610.40 (4.4%) for staff training and £36752.69 (95.6%) for onsite sexual health and relationship services (excluding time spent supporting students). We did not know the total number of students onsite at any one time, so it is not possible to calculate an exact cost per student. Assuming a sixth form may have around 150 students, the cost per sixth form would equate to £259.37 per student. A community college may have 2000 students which would reduce the cost to £19.45 per student.

Table 6 summarises the EQ-5D-5L data by trial arm and overall. At baseline, 17.0% and at the 12-month follow-up 20.5% responses were missing, with slightly more missing data in the intervention than control arm. There was some evidence of ceiling effects, with the median EQ-5D-5L score at baseline of 0.89 (IQR, 0.79–0.99) and at the 12-month follow-up of 0.89 (0.80–0.99).

Changes to the protocol

The original study protocol had three phases. After the Phase I optimisation study we planned to deliver the intervention in two FE settings and collect qualitative data on its acceptability. These data would then have informed any amendments to the staff training, onsite sexual health services and publicity materials. Phase III would then have been a pilot cRCT involving four intervention and two control FE settings. The study was paused for 1 year after beginning Phase I because FE settings closed due to the COVID-19 pandemic. We consulted with our TMG

TABLE 5 Estimated cost of provisions for onsite sexual health services

Item	Number	Unit	Per unit price (£)	Total (£)	Notes
Standard condoms	14	Boxes	14.98	209.72	288 standard condoms per box
Latex free condoms	4	Boxes	38.50	154.00	144 latex free condoms per box
Pregnancy tests	78	Tests	18.60	1450.80	2 test per week, 39 term weeks
STI tests	8	Boxes	100.00	800.00	20 tests per week, 39 term weeks
STI lab testing	780	Tests	35.00	27,300.00	20 tests per week, 39 term weeks

TABLE 6 EuroQol Group Health and Wellbeing Scale: EQ-5D-5L

	Sample at baseline						12-month follow-up					
	Overall (*N* = 1124)		Control (*N* = 263)		Intervention (*N* = 861)		Overall (*N* = 1139)		Control (*N* = 269)		Intervention (*N* = 870)	
Variables	***n***	**%**	***n***	**%**	***N***	**%**	***n***	**%**	***n***	**%**	***n***	**%**
Mobility												
I have no problems walking about	908	80.8	218	82.9	690	80.1	887	77.9	216	80.3	671	77.1
I have slight problems walking about	57	5.1	16	6.1	41	4.8	61	5.4	14	5.2	47	5.4
I have moderate problems walking about	12	1.1	0	0.0	12	1.4	10	0.9	1	0.4	9	1.0
I have severe problems walking about	5	0.4	1	0.4	4	0.5	6	0.5	0	0.0	6	0.7
I am unable to walk about	1	0.1	1	0.4	0	0.0	3	0.3	0	0.0	3	0.3
Missing	141	12.5	27	10.3	114	13.2	172	15.1	38	14.1	134	15.4
Self-care												
I have no problems washing or dressing myself	943	83.9	229	87.1	714	82.9	922	80.9	223	82.9	699	80.3
I have slight problems washing or dressing myself	26	2.3	5	1.9	21	2.4	30	2.6	5	1.9	25	2.9
I have moderate problems washing or dressing myself	8	0.7	0	0.0	8	0.9	14	1.2	3	1.1	11	1.3
I have severe problems washing or dressing myself	1	0.1	0	0.0	1	0.1	1	0.1	0	0.0	1	0.1
I am unable to wash or dress myself	0	0.0	0	0.0	0	0.0	2	0.2	0	0.0	2	0.2
Missing	146	13.0	29	11.0	117	13.6	170	14.9	38	14.1	132	15.2
Usual activities (e.g. work, study, housework, family or leisure activities)												
I have no problems doing my usual activities	846	75.3	211	80.2	635	73.8	815	71.6	204	75.8	611	70.2
I have slight problems doing my usual activities	81	7.2	15	5.7	66	7.7	109	9.6	20	7.4	89	10.2
I have moderate problems doing my usual activities	39	3.5	6	2.3	33	3.8	27	2.4	4	1.5	23	2.6
I have severe problems doing my usual activities	8	0.7	1	0.4	7	0.8	10	0.9	1	0.4	9	1.0
I am unable to do my usual activities	2	0.2	1	0.4	1	0.1	3	0.3	0	0.0	3	0.3
Missing	148	13.2	29	11.0	119	13.8	175	15.4	40	14.9	135	15.5
Pain/discomfort												
I have no pain or discomfort	721	64.1	173	65.8	548	63.6	696	61.1	174	64.7	522	60.0
I have slight pain or discomfort	195	17.3	54	20.5	141	16.4	194	17.0	40	14.9	154	17.7
I have moderate pain or discomfort	40	3.6	6	2.3	34	3.9	57	5.0	12	4.5	45	5.2

TABLE 6 EuroQol Group Health and Wellbeing Scale: EQ-5D-5L (*continued*)

	Sample at baseline						12-month follow-up					
	Overall (*N* = 1124)		Control (*N* = 263)		Intervention (*N* = 861)		Overall (*N* = 1139)		Control (*N* = 269)		Intervention (*N* = 870)	
Variables	***n***	**%**	***n***	**%**	***N***	**%**	***n***	**%**	***n***	**%**	***n***	**%**
I have severe pain or discomfort	8	0.7	0	0.0	8	0.9	10	0.9	2	0.7	8	0.9
I have extreme pain or discomfort	7	0.6	1	0.4	6	0.7	5	0.4	1	0.4	4	0.5
Missing	153	13.6	29	11.0	124	14.4	177	15.5	40	14.9	137	15.7
Anxiety/depression												
I am not anxious or depressed	395	35.1	109	41.4	286	33.2	401	35.2	103	38.3	298	34.3
I am slightly anxious or depressed	257	22.9	60	22.8	197	22.9	268	23.5	64	23.8	204	23.4
I am moderately anxious or depressed	208	18.5	38	14.4	170	19.7	209	18.3	44	16.4	165	19.0
I am severely anxious or depressed	77	6.9	17	6.5	60	7.0	57	5.0	13	4.8	44	5.1
I am extremely anxious or depressed	33	2.9	9	3.4	24	2.8	30	2.6	5	1.9	25	2.9
Missing	154	13.7	30	11.4	124	14.4	174	15.3	40	14.9	134	15.4
EQ-5D score												
Median (IQR)	0.89 (0.79–0.99)		0.89 (0.79–0.99)		0.89 (0.79–0.99)		0.89(0.80–0.99)		0.89(0.80–0.99)		0.89 (0.79–0.99)	
Mean (SD)	0.85 (0.15)		0.87 (0.13)		0.85 (0.16)		0.86 (0.15)		0.87 (0.13)		0.85 (0.16)	
Min, Max	−0.09, 0.99		0.30, 0.99		−0.09, 0.99		−0.22, 0.99		0.11, 0.99		−0.22, 0.99	
Missing, *n* (%)	190 (17.0)		38 (14.4)		152 (17.7)		233 (20.5)		47 (17.5)		186 (21.4)	
EQ-5D VAS score (worst = 0, best = 100)												
Median (IQR)	78 (60–90)		76 (57.5–90.5)		79 (61–90)		80 (65–90)		80.5 (61–92)		79 (65–90)	
Mean (SD)	72.6 (22.2)		72.6 (22.2)		72.6 (22.2)		74.5 (21.7)		75.6 (21.9)		74.2 (21.9)	
Min, Max	0, 100		9, 100		0, 100		0, 100		0, 100		0, 100	
Missing, *n* (%)	171 (15.2)		31 (11.8)		140 (16.3)		199 (17.5)		47 (17.5)		152 (17.5)	

and TSC and a decision was taken to continue Phase I, optimising the intervention resources, remove Phase II of the proposed project, and instead conduct a larger pilot cRCT with eight settings: six intervention and two usual practice settings. Sexual health services have been delivered within FE settings (albeit sporadically across the sector), and FE staff training on safeguarding, among other topics, has similarly been delivered across institutions. Therefore, the pilot of the intervention materials and methods was deemed the most important focus.

Discussion

Principal findings

The multi-stage optimisation process aimed to refine the intervention materials for the sexual health and DRV intervention within FE settings. The optimisation process focused specifically on the FE staff training materials and publicity materials to advertise the onsite sexual health services. Six stages of review and refinement were undertaken with a range of

stakeholders resulting in key changes to the content and delivery methods of the intervention materials. This resulted in a set of staff training and publicity materials being produced that were acceptable and consistent with the theory of change as agreed by the research team, TSC, stakeholder advisory group, along with FE students, staff and young people.

Three out of the four progression criteria in the pilot cRCT were met. The only criterion not met was the one relating to student recruitment whereby 60% of students approached to participate should have agreed to do so; in our case, 56.3% of students approached agreed to take part. The process evaluation indicated that the SaFE intervention was acceptable to students, staff and the intervention delivery team. It was feasible to conduct a cRCT of the SaFE intervention in both sixth form and FE colleges. Qualitative findings indicate that the intervention needed longer to embed within the FE settings. Qualitative and statistical evidence suggests that there should be a follow-on full-scale cRCT of SaFE.

Contribution to existing knowledge

There is currently a lack of evidence of existing interventions to address poor sexual health and DRVs in FE settings. This study has tested the acceptability and feasibility of the intervention, as well as piloting the trial design. The results suggest that the SaFE intervention, comprising the publicity and provision of onsite sexual health and relationship services, alongside staff training to recognise and respond to dating violence and sexual harassment, shows promise for evaluation in a full-scale randomised controlled trial.

Young people account for a disproportionate amount of STIs, unplanned pregnancies, and varying forms of violence within relationships compared to older populations,[2,4–6] with potential for short- and long-term adverse medical, social, educational and economic outcomes.[29,30] However, while there are some sexual health and healthy relationships interventions targeting young people aged 15–24 years old, very few have provided an onsite sexual health and relationship service in FE settings. Similarly, there are currently no rigorous evaluations of interventions which also provide training to FE staff on DRV prevention and management. SaFE addresses this gap in provision to deliver a novel intervention package which combines both provision of an onsite sexual health and relationship service, with publicity of this service, together with FE staff training to recognise, prevent, and manage DRV and sexual harassment.

The prevalence of reported unprotected sex at last intercourse, and DRV in the trial supports existing literature indicating the extent of young people's experiences of these public health issues. This trial found that overall between 15.7% (baseline) and 18.7% (follow-up) of participants who have had sex in their life reported using no contraception at last sex (see *Report Supplementary Material 1*, *Table S1*). Welsh data from the Health Behaviour in School-aged Children (HBSC) survey indicates that 38% of 15-year-old boys and girls in Wales, and 22% of 15-year-old boys and 32% of girls in England, did not use either a condom or contraceptive pill at last intercourse (although they may have used other pregnancy prevention methods).[31] The trial also found that 50.9% (baseline) and 52.4% (follow-up) of students reported not using condoms at last sex (see *Report Supplementary Material 1*, Table S1). These figures are similar to findings from HBSC which indicate that 39% of 15-year-old boys and 53% of 15-year-old girls in England, and 49% of boys and 56% of girls in Wales reported that they did not use a condom at last intercourse.[31] In relation to DRV, the trial found that while figures vary from physical abuse (9.8% baseline, 10.2% follow-up), to sexual abuse (12.2% baseline, 9.8% follow-up), to verbal and emotional abuse (40.1% baseline, 39.8% follow-up), overall 45.9% (baseline) and 46.0% (follow-up) of students reported some form of DRV (see *Report Supplementary Material 1*, *Table S2*). This is similar to figures from our developmental work which found that 55.1% of boys and 53.5% of girls aged 16–19 in FE reported experiencing some form of DRV. Similarly, nationally representative data from 11- to 16-year-olds in Wales indicates that 28.1% of boys and 40.7% of girls report emotional dating violence victimisation, and 20.3% of boys and 15.6% of girls report physical victimisation.[6]

The process evaluation indicated that the SaFE intervention was acceptable to FE students, staff and nurses, and both wanted and needed by these key stakeholders. Students reported wanting onsite sexual health and relationship services but that they had to be discreet. Nurses described students visiting the onsite service after their peers had reported they had had a positive experience. As the intervention was only in place for 23 instead of 39 weeks (due to the implications of COVID-19 restrictions at the time), this inhibited the diffusion of positive messages about onsite services which may have meant uptake was not at the level it could have been. These findings replicate those from the 'Test n Treat' feasibility trial which offered free onsite rapid chlamydia/gonorrhoea tests at six technical colleges in London, UK.[32] In both studies, students valued the accessibility of onsite services, but reported barriers relating to embarrassment and fear of

stigma if they were to be seen accessing sexual health services. There is a paradoxical challenge of identifying rooms which are visible but also discreet which needs to be carefully considered when sexual health services are provided in any FE setting.

The students' responses relating to the acceptability of linking trial data to routine (sexual health) data were mixed. At both time points, over 50% of participants reported being aware that their research data could be linked to their health records and a third said they were unaware (the remaining were missing). Around a quarter of participants at both baseline and follow-up reported that they were not happy to provide consent to link to their routine health records. The percentage of missing responses to this question was 16.2% and 18.3%, respectively. If we were to assume that those who were not happy to provide consent or had missing responses to the question would not provide consent, around 40% of participants would not consent to data linkage. Just under a third of participants indicated that they were definitely less likely or slightly less likely to consent to the trial if their research data were linked to routine data sources. Compared to existing research using these questions, a higher proportion of respondents in the current trial reported being aware that their research data could be linked to their health records (< 40% compared to > 50%, respectively).[25] Similarly, smaller proportions reported that they would be 'not at all comfortable' or 'not very comfortable' to provide consent to link their trial data to routinely collected data. Similar proportions reported being less likely to participate in the research if their data were linked to routine sources.[26] Our findings indicate mixed views towards the acceptability of consenting and linking participants' trial and routinely collected data for outcome data. It is clear though that asking for consent from this population to link to routine data could reduce participation rates resulting in a smaller sample size for the overall analysis. With consequent reductions in statistical power, this needs to be considered carefully when powering a full-scale Phase III trial.

In a future trial, for the health economic analyses, the staff training may best be captured in terms of cost per member of staff trained. This requires consideration of the theoretical maximum and likely attendance per training session. The mode of delivery also needs to be considered, and the additional costs of face-to-face versus online delivery estimated. Potentially, the training could result in an increase in staff engagement with students requiring support. This may be an important mechanism through which the intervention creates value, but it also has resource use implications that need to be captured. The provision of onsite services was a significant component of the overall cost of the SaFE intervention. For future research, data will need to be collected on who provides this service and how many hours are provided. In particular, STI testing is a major cost driver. It would be important to capture how much testing is provided, and whether this is additional testing, or a (partial) relocation of testing that would have occurred elsewhere. Consideration should also be given to the use of a cost-effectiveness rather than cost–utility framework for the primary analysis and the use of decision-analytic modelling to extrapolate health benefits beyond the follow-up period. With an intervention like SaFE, the main health benefits may be long-term and missed by the trial follow-up which would focus on the primary outcome. However, the primary outcome may be a mediator for longer-term gains. By calculating the cost per unit improvement in the primary outcome, we can use literature-based modelling to extrapolate long-term cost-per-quality-adjusted life-year (QALY).

A repeat cross-sectional design was chosen as our previous work in FE settings found the high turnover of students, irregular days of student attendance and lack of accurate student enrolment data, and made following the same students up 12 months later unlikely. In support of this assumption, only 13.3% (95% CI, 11.4% to 15.5%) of students recruited at baseline also completed a follow-up questionnaire. These figures are lower than findings from our existing research in FE, which indicated that 36.5% of baseline respondents (17.4% of potentially eligible students at baseline) also completed a follow-up survey.[33]

Strengths and weakness of the study

Existing interventions in education settings have targeted sexual health and healthy relationships among young people aged 15–24 years old[8,32,34–36] but there are very few that have provided onsite sexual health and relationship services. Similarly, there is no evidence of rigorous evaluations of interventions which also provide training to FE staff on DRV and sexual harassment prevention and management. A strength of the SaFE intervention is that it addresses the current gap in provision to deliver a combination of onsite sexual health and relationship services, and publicity of this service, with FE staff training to recognise, prevent and manage DRV, and reduce sexual harassment. The pilot cRCT used mixed methods to systematically address uncertainties in the acceptability of the intervention and trial design. The involvement of FE staff, students and nurses in the assessment of feasibility enabled an in-depth exploration of their experiences and views of the intervention.

This synopsis should be referenced as follows:
Young H, Williams-Thomas R, Aslam RW, Townson J, Lewis R, Copeland L, *et al*. A Sexual health and healthy relationships intervention for Further Education (SaFE): a synopsis of results from a pilot cluster randomised controlled trial including an assessment of the feasibility of record linkage and a health economic analysis. *Public Health Res* 2026;**14**(6):1–32. https://doi.org/10.3310/GJHY3724

In terms of weaknesses, the timing of the research meant that the study had to be put on hold for a period during the COVID-19 pandemic. Despite restarting the study in January 2021, there was significant uncertainty about the conduct of education settings-based research during this time, and the delivery of (onsite) sexual health and relationship services. While the research team, schools and service delivery providers demonstrated excellent collaborative efforts during this challenging time, the study was inevitably impacted by higher-than-average staff and student sickness rates across both FE and service delivery teams, as well as impacts on student and staff attendance, and movement at FE sites. Similarly, COVID-19 pandemic restrictions at FE settings meant the intervention was not implemented for as long as planned (up to 23 weeks vs. 39 weeks). We believe that in combination, this has adversely impacted the provision of the sexual health service, uptake of the service, as well as engagement of students with the completion of the baseline and follow-up surveys.

The study did not meet the 'green' threshold for one feasibility progression criterion, namely that 60% of students approached to participate would agree to do so. Averaged across baseline and 12-month follow-up, 56.3% of students approached agreed to take part. While it is possible that the uncertainties surrounding COVID and social/physical distancing may have impacted students' engagement with the survey, and fewer students had returned to campus during these times, overall higher response rates were identified at baseline (60.7%; 1124/1852 students) compared to the 12-month follow-up (51.9%; 1139/2193 students). In order to move to a full-scale trial, the study team needs to work closely with young people to develop data collection methods, increase the number of fieldworkers attending data collection sessions at colleges, and increase the number of follow-up data collections to increase student response rates.

Replicating findings from previous research, completion of the staff logbooks was very low across intervention sites.[33,34] This is likely because of competing demands and priorities on staff time. However, it is possible that in the case of the SaFE intervention, this was compounded by the additional administrative burdens placed on FE staff during the COVID-19 pandemic. More work needs to be done with FE staff to understand demands on their time and to explore how to encourage and incentivise completion of logbooks.

Finally, methodologically, qualitative interviews with FE students were undertaken with self-selecting samples. Students were often invited to take part through FE staff; therefore, sample bias may be introduced by means of which students were recruited, and their views may not represent those of the wider student population.

Take-home message

There should be a follow-on full-scale cRCT of the SaFE intervention. Three of the four progression criteria were met. Following the identification of strategies to boost student recruitment to the survey, progression to a Phase III effectiveness trial of SaFE is warranted. For this trial we propose a two-arm (SaFE vs. usual practice) repeated cross-sectional cRCT (randomisation at the FE setting level) with integrated economic and process evaluations. Based on the findings from the pilot cRCT, we will not ask for consent to link to routine data as our results indicate this could reduce the number of people agreeing to participate and only add outcome data for a smaller (and likely underpowered) subgroup analysis. The primary outcome will be either unprotected sex at last intercourse or DRV, or both as (co)primary outcomes. This choice may be informed by the availability of alternative measures of DRV that do not have the floor effects we found in the sCADRI. The secondary outcome measures used in the pilot cRCT all showed promise for use in the full-scale trial.[13]

Individual training and capacity-strengthening activities

The intervention provided training to FE staff on DRV recognition, prevention and management which was identified throughout our development work as a current gap in provision for FE staff and students.[12] A strength of the SaFE study is therefore the increased opportunity for staff training and capacity building for dealing with DRV and sexual harassment. The process evaluation indicated that some FE staff used the onsite sexual health nurses for support and advice in safeguarding issues, and in many cases referred students to these services. As sexual health and relationship services were provided onsite, this may have reduced the burden on sexual health clinics located at other community settings.

Institutional capacity strengthening

The SaFE project has fostered institutional capacity building by initiating and strengthening new and existing collaborative working relationships with NHS and allied health professionals (e.g. those involved in the provision of the onsite sexual health and relationship service, as well the staff training). The project has also successfully engaged and retained FE institutions which have typically been left out of academic research, especially relating to the delivery of sexual health and DRV interventions. Finally, the project has provided invaluable career development and capacity building opportunities for early

career researchers, including the PI, with mentoring from experienced senior staff.

Patient and public involvement

This study builds on 15 months of previously published work with over 2000 students and 200 staff from 6 FE settings, 12 sexual health staff and a PPI advisory group of 16- to 21-year-olds (ALPHA) to explore which components should be combined into an intervention.[12] We discussed the findings, intervention and methods for this project with 30 stakeholders at a consultation event. Following the completion of this development work, and in the development of this pilot cRCT, we consulted with representatives from Public Health Wales and Public Health England with commissioning responsibilities, including public and sexual health services, from the Local Council, and Clinical Commissioning Group. We also consulted the ALPHA young people's PPI group at DECIPHer. All of these were overwhelmingly in support of the proposal.

Throughout the study, PPI has been a focal point. A stakeholder advisory group was established. This included reconvening members from the original MRC PHIND-funded SaFE project along with the recruitment of other relevant stakeholders (e.g. members from Local Authority public health teams in England and Wales, Public Health Wales, LGBTQ+ and other young people's charities). During the optimisation phase, feedback was gained on the draft materials from the stakeholder advisory group (n = 1 consultation group), FE staff (n = 1 focus group) and FE students (n = 1 focus group). We then refined the materials based on stakeholders' views (along with the TMG and TSC) and prototyped the materials. The ALPHA young people's PPI group then reviewed the final intervention materials. The process evaluation explored the experience of study participants (trainer delivering staff training, onsite sexual health and relationship service providers, and FE staff and students).

We will consult with relevant PPI stakeholders to support the dissemination of our findings. We have shared the findings with our TSC, and via e-mail with our stakeholder advisory group. We will coproduce an accessible summary and infographics of the study findings with the stakeholder advisory group, and disseminate the results to participating FE settings, ALPHA PPI youth group and the School Health Research Network (via newsletter and a webinar for staff). We will use blogs and the social media accounts of DECIPHer and the Centre for Trials Research (CTR) to increase public awareness of the study findings. We will encourage our stakeholder advisory group, TMG and TSC to support the dissemination of results among their networks. Findings will be presented at a policy and professional practice online event; this event will bring together academics, practitioners and policy-makers to discuss the findings and next steps of the SaFE project. We will present the results at academic meetings along with national practitioner and policy events drawing on the capacity of our team.

Equality, diversity and inclusion

Dating and relationship violence, sexual harassment and gender-based violence (GBV) are rarely considered as joint constructs despite longitudinal evidence demonstrating that experience of DRV predicts young people's later GBV victimisation and that they share common risk factors.[30] They are public health issues with inequality generating long-term impacts on health. While boys and girls both experience major burdens of emotional and physical DRV, the impacts are disproportionately reported by girls. While it is well understood that sexual and gender minority adolescents experience higher levels of GBV in terms of homophobic, transphobic bullying and sexual harassment,[37,38] girls also experience higher rates of physical and sexual DRV.[6] Importantly, a key source of these inequalities is the shared impact of educational context, including prevalence and response to DRV and GBV, both of which point to the importance of education-based interventions.[39] In order to ensure the study was inclusive and that we were able to explore differential experience by diverse socio-demographic groups, questions were included on the survey relating to gender and sexual identities to assess if the diversity seen in study participants was representative of the wider population of young people. Those involved in the qualitative focus groups were purposively recruited to represent diverse gender and sexual identities.

Impact and learning

The current study is a pilot cRCT of the SaFE intervention. The primary outcome was therefore not to explore effectiveness, but instead to examine the acceptability of the SaFE intervention and trial methods assessed using progression criteria. The thresholds for progression were met for three of the four criteria. Our view is that the study should progress to a full-scale cRCT. Thus, the long-term impact of the study ultimately will be dependent on whether the full-scale cRCT is funded. If it is funded and the SaFE intervention found to be effective, the scalable nature of the intervention has the potential to reduce unprotected sex and/or DRV in young people which has considerable costs to the health and welfare system of the UK. If funded and ineffective, this information will have important implications on informing how not to intervene and suggest alternative interventions are pursued.

This synopsis should be referenced as follows:
Young H, Williams-Thomas R, Aslam RW, Townson J, Lewis R, Copeland L, *et al*. A Sexual health and healthy relationships intervention for Further Education (SaFE): a synopsis of results from a pilot cluster randomised controlled trial including an assessment of the feasibility of record linkage and a health economic analysis. *Public Health Res* 2026;**14**(6):1–32. https://doi.org/10.3310/GJHY3724

The current pilot cRCT has provided key learning to support further research in the field. It has identified how the provision and publicity of free, onsite sexual health services for 2 hours on 2 days a week by a sexual health professional was acceptable to students, FE staff and sexual health nurses, and both wanted and needed by these key stakeholders. However, there are challenges related to finding an onsite location which is both private enough to promote anonymity as well as accessible enough so that students can access it easily. The service also needs long enough to embed within the FE setting.

This pilot cRCT indicated that asking for consent to link trial data to routinely collected health data could reduce participation rates. This indicated that requesting these permissions may result in a smaller sample size for the overall analysis. Similarly, the pilot cRCT indicated that a repeat cross-sectional design is optimal given that only a small proportion of students were recruited to the survey at both baseline and follow-up. The findings support existing evidence from FE settings which have a high turnover of students, irregular days of student attendance and lack of accurate student enrolment data. The intervention also aims to operate at the FE level and is expected to impact all students, not just those present at baseline.

One of the strengths of the current study was the collaborative partnership between the service delivery and research teams, including those delivering the staff training and those delivering the sexual health and relationship services in England and Wales. Fostering these working relationships was an important aspect of the study, which was instrumental to the successful delivery of the intervention. For future research, it is necessary to recognise and account for the time and effort that is required to successfully establish, build and maintain these professional working relationships.

As well as reporting in the NIHR *Public Health Research* journal, we will submit two open access papers for publication; one reporting on the pilot trial results and another on the optimisation of the intervention. We will consult with relevant PPI stakeholders to support the dissemination of our findings. We have shared our findings with our TSC, and via e-mail with our stakeholder advisory group. We will coproduce an accessible summary and infographics of the study findings with the stakeholder advisory group, and disseminate the results to participating FE settings, ALPHA PPI youth group and the School Health Research Network (via newsletter and a webinar for staff). We will use blogs and the social media accounts of DECIPHer and the CTR to increase public awareness of the study results. We will encourage our stakeholder advisory groups, TMG and TSC, to support the dissemination of findings among their networks. Findings will be presented at a policy and professional practice online event; this event will bring together academics, practitioners and policy-makers to discuss the findings and next steps of the SaFE project. We will present the results at academic meetings along with national practitioner and policy events drawing on the capacity of our team.

Implications for decision-makers

The current study comprised an optimisation phase followed by a pilot cRCT of the SaFE intervention. The primary outcome was not to explore effectiveness but feasibility. Therefore, caution should be exercised before making suggestions about the implications for policy, practice or local service delivery. Three of the four progression criteria were met. The only criterion not met was the one relating to student recruitment whereby 60% of students approached to participate should have agreed to do so; in our case, 56.3% of students approached agreed to take part. In order to move to a full-scale trial, the study team needs to work on enhancing recruitment processes to encourage student participation in the SaFE survey. A full-scale trial is also required to establish the economic impacts of the intervention and whether its provision is cost-effective.

Research recommendations

Following from the pilot cRCT, we make four key research recommendations. These are:

1. *A full-scale Phase III definitive trial of the SaFE intervention is warranted*. The results from the pilot cRCT are promising; they suggest that the intervention is acceptable to a wide variety of stakeholders and the findings have provided key insights into appropriate methods for a full-scale trial.
2. *Greater evaluation of onsite sexual health and relationships services is needed.* Provision of onsite sexual health and relationships services is variable across England and Wales, with some FE settings providing a range of services, and others with no provision at all.[32] It is also the case that while a FE college may provide a service for a time-limited period, funding cuts and staffing issues mean that services are stopped, leaving students having to source alternative services. There is limited rigorous evaluation of the provision of onsite sexual health services.
3. *More research and intervention on young people's experiences of DRV and sexual harassment*. The current pilot cRCT supports existing literature indicating the extent of young people's experiences of these salient public health issues.[4–6] Young people's experiences both in terms of victimisation and perpetration of DRV and sexual harassment are continually evolving.

Their interactions are ever changing, through emerging technological advances on social media, and changing social and cultural norms and expectations. More research is required to measure the extent of these issues with young people and determine how best to intervene to improve them.

4. *More research is needed within FE settings*. In the UK, FE settings comprise sixth form (often attached to secondary schools) and FE colleges where people undertake education and training after secondary education but not as part of higher/university education. In England, young people must now stay in education or training until aged 18, and the same is recommended in Wales. Therefore, FE provides a scalable setting for delivering interventions to prevent DRV and improve sexual health. However, FE settings have a transient student population, and sites vary considerably in size as well as range of programmes and services offered. Despite the rapid expansion of the FE sector,[40] FE settings are typically overlooked in academic research. More research is needed in this sector, which poses a considerably different challenge to intervention delivery and evaluation compared to schools.

Conclusions

Sexual health includes positive, pleasurable, respectful and safe sexual relationships and experiences free of coercion, discrimination and violence.[1] Poor sexual health, DRV and sexual harassment pose significant public health concerns. With more young people now staying in education or training until they are 18, this means that FE may be the only near-universal setting for delivering public health interventions to this age group. This pilot cRCT used a two-arm repeated cross-sectional design to compare the SaFE intervention to usual practice, including a process evaluation and economic assessment. Three of our four progression criteria were met. Providing that improvements can be made to recruit participants to take part in the questionnaire, progression to a Phase III definitive trial is warranted. This study would seek to establish whether the SaFE intervention is effective and cost-effective and have an embedded process evaluation. The trial will focus on unprotected sex at last intercourse, DRV or both as a (co)primary outcomes with a repeat cross-sectional design. We will not try to collect longitudinal data or ask for consent for data linkage to routinely collected data. While each intervention component was considered acceptable by each of the different stakeholders involved, work needs to be done when establishing the study to ensure that the location of onsite services meets the needs of students (i.e. in a private but accessible location).

Additional information

CRediT contribution statement

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

Ethical approval was obtained from the Cardiff University School of Social Sciences Research Ethics Committee (Reference: SREC/3397) on 23 October 2019 and NHS Ethics on 9 April 2020 (Reference: 20/WA/0090). The study registration is ISRCTN54793810.

Information governance statement

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Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/GJHY3724.

Primary conflicts of interest: James White serves on steering committees for the National Institute for Health and Care Research (NIHR) and the Scottish Government. Ruth Lewis is a member of the TSCs for the More RESPECT RCT (NIHR133865) and the Wrapped RCT (NIHR157903) and is also a member of the Sexual Health and Blood Borne Virus National Monitoring, Assurance and Research Group within the Scottish Health Protection Network. She additionally serves as coChair of the Scottish Interdisciplinary Research Group. Rachel Brown is a member of the advisory board for the Think Quit smoking cessation study, funded by Health and Care Research Wales, and serves on the Steering Committee for the Looking Forward Project, funded by NIHR. GJ Melendez-Torres is an NIHR senior investigator. We endeavour to obtain ICMJE disclosure of interests forms for all named authors. In this case, we have been unable to obtain these forms for every author. Please contact the corresponding author if you have any queries.

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This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Publications

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List of supplementary material

Report Supplementary Material 1

Supplementary material can be found on the NIHR Journals Library article page (https://doi.org/10.3310/GJHY3724).

Supplementary material has been provided by the authors to support the article and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

The supplementary materials (which include but are not limited to related publications, patient information leaflets and questionnaires) are provided to support and contextualise the publication. Every effort has been made to obtain the necessary permissions for reproduction, to credit original sources appropriately, and to respect copyright requirements. However, despite our diligence, we acknowledge the possibility of unintentional omissions or errors and we welcome notifications of any concerns regarding copyright or permissions.

List of abbreviations

ALPHA	Advice Leading to Public Health Advancement
cRCT	cluster randomised controlled trial
CTR	Centre for Trials Research
DRV	dating and relationship violence
FE	Further Education
GBV	gender-based violence
GP	general practice
IQR	interquartile range
PPI	patient and public involvement
QALY	quality-adjusted life-year
SCADRI	short Conflict in Adolescent Dating Relationships Inventory
STI	sexually transmitted infection
TMG	Trial Management Group
TSC	Trial Steering Committee

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