The FRANK friends study: protocol for a multicentre cluster randomised controlled trial to evaluate the effectiveness and cost-effectiveness of a school-based peer-led drug prevention intervention

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Abstract

Introduction Illicit drug use in UK adolescents is amongst the highest in Europe. Drug use increases the risk of poor physical and mental health. Several systematic reviews report that few school-based interventions have a beneficial effects on drug use after 12 months. This study aims to test the effectiveness and cost-effectiveness of a school-based peer-led intervention to prevent illicit drug use in UK year 9 students (aged 13 to 14).

Methods and analysis This study is a two-arm, parallel group, multicentre cluster randomised controlled trial with embedded process and economic evaluations. FRANK friends is a school-based peer-led intervention. It is based on an effective school-based peer-led smoking prevention intervention (ASSIST) which has been adapted to deliver information from the UKs national drug education website Talk to FRANK (www.talktofrank.com). Schools in the control group will not receive the intervention but will continue with any health education provided. Participants will not be blinded to allocation. Schools are the unit of randomisation stratified by geographical area (the West of England, South Wales) and students' entitlement to free school meals as a measure of socioeconomic status. We aim to recruit 40 schools (24 in Wales, 16 in England) comprising 7,242 students. A questionnaire will be administered at baseline and at 24 months post randomisation. The primary outcome will be use of any illicit drug, assessed by self-report questionnaire, at the 24-month assessment. Secondary outcomes include the use of specific drugs, the frequency of specific drug use, screening positive for cannabis dependency, any and weekly tobacco smoking, alcohol consumption, and health related quality of life.

Ethics and dissemination Ethical approval was granted by Cardiff University's School for Social Sciences Ethics Committee. Results will be published in peer-reviewed journals and disseminated to stakeholders. Funding is from the National Institute for Health Research.

Trial registration number ISRCTN72047541

Strengths and limitations of this study:

- The study evaluates a school-based peer-led drug prevention intervention adapted from an effective smoking prevention intervention (ASSIST) to deliver information from the UKs national drug education website 'Talk to FRANK' (www.talktofrank.com).
- FRANK friends was co-produced and prototyped with students, teachers, parents, public health practitioners and commissioners.
- The embedded process and economic evaluations will test the hypothesized mechanisms of impact, reach, fidelity of delivery, sustainability and cost-effectiveness.
- Due to the nature of the intervention and setting—within schools—participating schools and students cannot be blinded to allocation.
- A biological measure of illicit drug use was not possible across the wide range of possible illicit substances.

Key words: Illicit Drugs, prevention, adolescent, randomized controlled trial

Introduction

Illicit drug use in UK adolescents is among the highest in Europe.[1,2] Despite significant declines since the 1990s, the 2018 Smoking Drinking and Drug Use (SDDU) survey reports the lifetime prevalence of drug use in 15 year olds in England is 38%, [3] up from 24% in 2014.[4] There is some uncertainty about whether the increase in England between 2014 and 2018 reflects a real population level change,[5] but across surveys drug use increases rapidly between 11-15 years of age. In the 2018 SDDU, lifetime prevalence at 11, 13 and 15 years of age was 9%, 20% and 38% respectively. [3] Of those who have used in the last year at age 15, 41% solely used cannabis but 20% used ≥2 drugs including one class A drug comprising amphetamines (if prepared for injection), ecstasy, cocaine, crack, heroin, LSD, magic mushrooms and methadone.

Drug use increases the risk of poor physical and mental health. Around 10% of cannabis users will become dependent upon it,[6] and regular users have poorer verbal learning, memory, and attention,[7] respiratory functioning [8], and are more likely to have a psychotic experience compared with never users.[9] Administration in placebo controlled randomised controlled trials (RCTs) of delta-9-tetrahydrocannabinol (THC), the main active compound in cannabis, can induce short-lived transient psychotic-like experiences,[10] and epidemiological studies suggest that cannabis use is associated with an increased risk of schizophrenia.[11] Although less prevalent in adolescence, amphetamine use has also been linked to drug dependency and poor mental health in later adult life. [12] In the UK, 75% of 11-18 years olds receiving specialist drug treatment, primarily do so for cannabis use with a median age at first treatment of 16 years.[13] The annual economic costs of illicit drug use to the NHS have been estimated to be £488 million.[14]

Several school-based interventions have focused on preventing student drug use. Three systematic reviews have found these interventions are associated with modest

improvements in knowledge about drugs, but few impact on drug use after 12 months.[15, 16, 17] The latest Cochrane systematic review of universal school-based interventions to prevent illicit drug use (comprising 51 RCTs, 2 in the UK) found those that attempted to increase social competences (i.e. teaching self-management, social skills, problem-solving) and those based on social influence theories (i.e. correcting overestimates of drug prevalence) had the largest effects on drug use.[15] Another review of school-based drug prevention interventions found peer-led interventions were moderately more effective than adult-led.[18] Small protective effects on cannabis use were found in a review of 3 RCTs evaluating peer-led school-based drug prevention interventions with at least a 12 month follow-up, suggesting peer-led approaches may be promising.[17] Since publication of these reviews, an RCT of the Climate Schools intervention in Australia showed it improved drugs knowledge but the trial did not assess illicit drug use. [19] These systematic reviews also highlight methodological weaknesses in the existing evidence base including: small sample sizes, potential contamination,[20] inadequate reporting of randomisation,[15] a failure to account for clustering, [14, 17] a lack of registered protocols, and independent evaluation.[21]

In response to these gaps, we conducted a pilot study to develop and prototype FRANK friends, a school-based peer-led intervention to prevent illicit drug use in UK year 9 students (aged 13 to 14).[22] FRANK friends is based on diffusion of innovations theory, [23] and aims to recruit influential students to spread information on illicit drug through conversations with their friends. It is adapted from an effective school-based peer-led smoking prevention intervention (ASSIST) [24] to deliver information from the UKs national drug education website 'Talk to FRANK'(www.talktofrank.com). This informal delivery of through friendship groups differs from other peer-led drug prevention interventions which use peers to formally deliver drug education sessions in the classroom.[25, 26] In the pilot study we used the activities in the ASSIST intervention manual and 'Talk to FRANK'

website to co-produce and prototype the intervention with students, teachers, parents, public health practitioners and commissioners.[22]

The primary aim of this study is to evaluate the effectiveness and cost-effectiveness of the FRANK friends intervention to prevent and reduce illicit drug use compared to usual practice at a 24-month follow-up. The secondary aims are to evaluate effects on specific drugs (as well as over different time frames), screening positive for cannabis dependence, any and weekly smoking, the frequency of alcohol consumption and health related quality of life. This aim will be met using a cluster RCT with embedded process and economic evaluations.

METHODS AND ANALYSIS

Described according to the Standard Protocol Items: Recommendations for Interventional Trials guidelines (http://www.spirit-statement.org/protocol-version/; see online checklist).[27]

Trial design and study setting

A parallel-group, multicentre, two-arm, cluster RCT, with process and economic evaluations. Clusters (schools) will be randomised to receive either the 10-week FRANK friends intervention in addition to usual practice or usual practice alone (Figure 1). The trial is being be conducted in 40 schools across two geographical areas (the West of England and South Wales) to explore the generalisability of the findings.

Public involvement

Public involvement in the design of the FRANK friends intervention has been extensive. Students, teachers, parents, drug agency workers and public health practitioners were involved in the development and prototyping of FRANK friends. This included focus groups (n=11), post intervention delivery surveys (n=81), observations of intervention delivery (n=225), interviews (n=142), consultations (n=26), and co-production meetings. The results of this process have been reported elsewhere. [28] The trial design has been informed by the views of a Drug Treatment and Recovery team in Public Health England, a Director of Public Health in local government, a Director of Health Improvement in the NHS, a drug prevention charity, and an independent Trial Steering Committee (TSC).

Eligibility criteria

All state secondary schools are eligible to participate with the exception of fee-paying schools, special schools (e.g. for those with learning disabilities), pupil referral units (PRUs) and those that received the FRANK friends intervention in the pilot study (Wales n=3). Schools will also not be eligible if they: are likely to be closed or merged with another school during the trial period, have less than 60 students in Year 9 (following the exclusion criteria applied in the ASSIST RCT),[24] and are not within a 90-minute travel time by car from the two coordinating centres: the University of Bristol and the Centre for Trials Research based at Cardiff University. Eligible students are those in UK Year 9 (13-14 years) at baseline in eligible schools.

Sample size

The latest population-level study on the prevalence of illicit drug use, the 2018 SDDU survey, indicates that the lifetime prevalence of drug use at the 24-month follow-up (among 15-year olds) is likely to be 38%.[3] This is a 14 percentage point increase from the 2014 SDDU survey.[4] In the pilot cluster RCT the intracluster correlation (ICC) for the comparison between FRANK friends and usual practice was 0.003 at the 18-month follow-up.[28] Assuming an average of 185 students per school, an ICC of 0.01 (to be conservative), and a coefficient of variation of 0.30, if we use the 2018 prevalence of 38% and a 30% rate of student drop out, a trial involving 38 schools (6,872 students) would provide 90% power at a 5% significance level (Table 1, row 1). To allow for one school dropout per arm, we propose to recruit 40 schools (20 schools per arm, with 7,242 students in total; row 2). If we observe a larger ICC of 0.015 then we would require 40 schools, with a dropout rate of 13.7% observed in the pilot (row 3). If prevalence was 31% (midway between that found in the 2014 and 2016/2018 SDDU rates), we will have 90% power with 38 schools (6,938 students) (row 4). If we observed the 2014 SDDU prevalence rate of 24% and allow for a 13.7% student dropout, we will have 90% power (row 5). Applying the parameters from the pilot cRCT, a trial involving 40 schools would also provide 81% power to detect a difference of 4.9% (19.0% vs 14.1%) in the secondary outcome of any drug use in the past month at 15-years of age.

Recruitment and retention

In each geographical area, eligible secondary schools will be stratified into above and below the median percentage (country-specific) of students eligible for free school meals (FSM). Forty schools will be recruited. In England and Wales, schools will be approached initially by email then recruited by phone or face to face meeting from above and below the FSM

medians. School recruitment started in May 2019 and is ongoing at the time of submission (10th January 2020). Schools will be asked to sign a memorandum of understanding outlining the process and timelines of the research and intervention delivery.In order to support retention of schools, lists of students will be requested from schools at the 24-month follow-up to track if students move to another school. All schools are also offered a payment of £1,000 at the end of the trial upon completion of data collections.

Recruitment of students

Recruited schools will email or post information sheets to parents/caregivers, asking them to return a form to opt their child out of participation if they do not want them to take part. Parents/ caregivers wishing to withdraw will be advised that opt-out consent forms should be returned by a date no later than 2 weeks prior to commencement of baseline data collection. Trial managers within each centre will collate a list of parents/ caregivers who have opted their child out of participation. Student information sheets will be provided to schools to distribute to students one week before the baseline data collection. Participants will be provided details of who to contact if they require further information or support on their or others drug use. Students with special educational needs and will be supported where possible. Multiple absentee sessions will be carried out to minimise attrition. All schools will be incentivised to remain in the trial by offering a payment of £1000 at the end of the trial.

Randomisation

Randomisation will be coordinated centrally by the Centre for Trials Research, a UK Clinical Research Collaboration registered Clinical Trials Unit. Clusters (schools) will be randomised in a 1:1 ratio to receive either the 10-week FRANK friends intervention or usual practice.

Within each geographical area, schools will be organised into the two FSM strata. An independent statistician will randomly allocate schools within each stratum to one of two arms using random block allocations. Schools will be informed of their allocation after baseline data have been collected.

Blinding

All parties will be blind to allocation during the baseline data collection. After baseline data collection, students, teachers, trial managers, the intervention delivery team (trainers) and researchers involved in the process evaluation will not be blind to intervention status. Fieldworkers at outcome data collections will remain blind to intervention status as will the statistician and health economists.

Intervention

The intervention is described in accordance with the Template for Intervention Description and Replication (TIDieR) guidelines.[29]

Name and brief description

FRANK friends is a peer-led drug prevention intervention to prevent drug use in UK year 9 secondary school students (aged 13-14). Based on diffusion of innovations theory,[23] FRANK friends aims to diffuse information from www.talktofrank.com via secondary school students' social networks in UK Year 9.

Why, rationale of essential elements

Table 2 provides detail on the intervention processes. These processes aim to enhance the spread and sustain norms of avoiding and reducing drug use amongst peer supporters' friendship groups in school. Figure 2 shows a logic model describing the hypothesised mechanisms of action that underpin FRANK friends. These processes are intended to act on hypothesised risk factors for drug use, or encourage help seeking, and operate at the school, peer and individual level. These include recalibrating norms on the prevalence of drug use, communication on drugs, reducing drug offers, improving knowledge, and increasing intentions to seek help.

What, a description of materials

Table 2 provides a description of the materials used in the FRANK friends intervention.

Who delivers the intervention?

External specialist trainers deliver the intervention. In England, FRANK friends will be delivered by health promotion specialists with expertise in working in schools and in the NHS. In Wales, the intervention will be delivered by staff who work in school-based smoking prevention.

How, modes of delivery?

The five components of the FRANK friends intervention are delivered as follows. Peer nominations are provided by students on a questionnaire at school. Peer supporter recruitment occurs face to face with nominated students in a single 30-minute session. The two-day offsite training occurs in local training venues and students are provided with transport to get to and from the venue (if not in walking distance). Information on communication skills and illicit drugs is provided using participatory learning activities such as role plays, student-led

research, small group work and discussion, and games. The four follow-up visits by trainers occur in school premises and include reviewing peer supporters' diaries, revisiting content by watching videos, and extracting information from www.talktofrank.com. At the end of the 10-week intervention period, peer supporters are presented with a certificate in school.

Where, locations where intervention has occurred

The intervention has been delivered in schools in South Wales as part of the pilot study. [28]

Outcomes

The outcome measures were used in the pilot study and all had low levels of missing data. [28]

Primary outcome

The primary outcome will be use of any illicit drug, assessed by self-report questionnaire, at a 24-month assessment. This is measured by asking students if they have ever tried: cannabis, cannabidiol products, nitrous oxide, poppers, glues, gases or aerosols, cocaine, amphetamines or methamphetamine, synthetic drugs which mimic amphetamines or methamphetamine, ecstasy, steroids, mephedrone, synthetic cannabinoids, synthetic drugs which mimic ecstasy, other novel psychoactive substances (NPS), mephedrone, crack, heroin, ketamine, tranquilisers, methadone, Ritalin, LSD, hallucinogenic mushrooms and prescription opioids. Street and common brand names (for NPS) will be provided for all. An open response category will be provided that will be categorised.

Secondary outcomes

Secondary outcomes will be assessed at baseline and the 24-month follow-up. These include:

- Use of any illicit drug over the over the past 12 months, month and week*:* assessed by asking whether any of the drugs students indicate they have tried were used within each time frame.
- Any use, past 12-months, month and weekly use of specific drugs: assessed by asking whether each drug was used within each time frame.
- Screening positive for cannabis dependence*:* assessed using the six item Cannabis Abuse Screen Test validated in adolescents.[30]
- Any smoking and weekly smoking*:* assessed using questions used in the ASSIST trial.[24] Weekly smoking defined as usually smoking ≥ one cigarette a week.
- The frequency of alcohol consumption in the in the past 12 months, month and week.
- Health related quality of life assessed using The Child Health Utility 9D (CHU9D) index. [31]

Data collection

Students will be in UK Year 9 (aged 13-14 years) at baseline (Year 11 at follow-up aged 15-16 years) and complete paper self-report questionnaires under 'exam conditions' in a classroom or school hall. School staff will be asked to be present but not help students to ensure anonymity. Fieldworkers will be on hand to provide support to students who require help.

Process evaluation

Informed by the Medical Research Council's guidance, [32] an embedded process evaluation will be conducted. The process evaluation will explore the following issues:

- Fidelity during the training and intervention delivery. Drawing on Caroll et al's multicomponent model for measuring fidelity,[33] and tools developed in the pilot, [22] adherence to the intervention manual will be examined, as well as the extent to which training is standardised, and variations in quality of delivery across different schools and geographical areas.
- Intervention reach and reception. The proportion of students who report a conversation about drug related harms or harm minimisation in each arm will be compared. The receipt of the intervention and extent to which key intervention messages are evident with students who are and are not peer supporters will be examined.
- Contamination. Schools' activities related to drug use will be audited and interviews conducted with school staff to examine any changes to usual practice that might result due to participation in the trial.
- Acceptability of the intervention to students who are and are not peer supporters, staff within schools including members of the senior management team, and the intervention delivery team.
- Mechanisms of action, specifically whether the intervention worked as hypothesised in the logic model (see figure 2) and whether this varied between the two geographical areas and schools.

Table 3 summarises the data to be collected and issues addressed. In-depth qualitative data will be collected from four 'case study schools' which receive the intervention (two from each geographical area: the West of England and South Wales) in which more extensive evaluation will be undertaken.

Economic evaluation

The economic analysis will consist of a cost consequences analysis (CCA) based on results within the duration of the trial and a cost effectiveness analysis where between group differences in the trial are extrapolated to the longer term. The costs of FRANK friends and usual practice arm of standard drug education will be estimated using information on all staff training (e.g. number, duration and salary grade), including the training of trainers, any expenses incurred by trainers, trainees and schools (e.g. teaching time to arrange intervention delivery, travel and venue hire).

- Within Trial Analysis: Within the trial, an estimate of the incremental net costs of FRANK friends (compared to the usual practice arm) will be completed according to the difference in outcome measures at the 24-month follow-up. We will estimate the incremental cost for primary and secondary outcomes. In the CCA, results will be presented in terms of health care, criminal justice costs and academic achievement. [34] Health related quality of life will be assessed using the CHU9D [31] to calculate Quality Adjusted Life Years (QALYs). QALYs will be estimated using the area under the curve method.[35] As the staff training peer supporters will be recruited from the NHS in Wales and specialist external trainers in England a sub-group analysis by geographical area to explore the economic impact of different models of delivery will be completed.
- Long term analysis: The health gains and cost savings associated with FRANK friends may occur beyond the time horizon of the trial leading to an underestimate of cost-effectiveness. Existing health economic models will be identified that link the outcomes in the trial to longer term costs and quality of life to extrapolate effects of the intervention beyond the trial period. In the absence of an appropriate health economic model, guidelines for best practice in economics modelling will be constructed. [36] Analyses where productivity losses are included/excluded to assess

the impact on decision making will be conducted. Costs and effects will be discounted at the prevailing recommended rate (currently 3.5% per annum on both costs and effects). Probabilistic sensitivity analysis will be conducted to investigate the impact of uncertain parameters including the discount rate for public health interventions.

Statistical methods

The reporting of findings will be in accordance with the CONSORT guidelines for cluster RCTs [37] and SPIRIT recommendations for reporting trials of interventions.[38] All analyses will be intention to treat (i.e. students will be analysed in the groups to which they were randomised, regardless of adherence to the intervention) and missing outcome data will not be replaced. Between-group comparisons will be presented with two-sided 95% confidence intervals wherever possible. As the trial includes a reasonable number of clusters (schools), the analysis will be based on the individual student, allowing for clustering between students within school using robust standard errors. All analyses will control for baseline outcomes (if applicable), school level stratification variables (proportion of children eligible for FSM: geographical area-specific median, geographical area) and student characteristics (age, gender, parental employment status).

Primary outcome: Multilevel logistic regression models will be used to compare the lifetime use of illicit drugs at 24 months by arm, and results presented as odds ratios (OR) and 95% CIs. Intra-cluster correlations (ICCs) alongside 95% CIs will also be reported.

Secondary outcomes: Multilevel linear (continuous outcomes) and logistic (binary outcomes) regression models will be used to compare secondary outcomes.

Sub-group analyses: These will investigate the effect of the intervention on the frequency of any and specific drug use in a sub-group who report ever having used drugs at baseline. To examine the effect of the intervention on inequalities intervention effects in the following sub-groups: 1) school-level FSM entitlement above versus below geographical area level median), 2) student-level FSM eligible versus not eligible, 3) parental employment status, and 4) gender. We will also estimate intervention effects in the following sub-groups to examine the impact of context and the hypothesised mechanisms of action: 5) geographical area, 6) peer supporter status, and 7) having had an opportunity to use drugs. Interactions between the trial arm and these variables will be modelled. We will also estimate the proportion of drug use which is recanted (where baseline lifetime drug users respond they have never used at follow-up) as a measure of reliability. The results of these exploratory analyses will be presented using CIs.

Missing data: Baseline characteristics of students who have complete primary outcome data and those who do not will be compared. Multiple imputation will be performed to assess the impact of missing outcome data using Multivariate Imputation by Chained Equations (MICE) implemented using the ICE routine in Stata. Imputation models will be run separately within each arm and include outcomes, intervention arm, stratifying variables and a main school effect to allow for clustering, as well as any appropriate baseline covariates. The main analyses will be repeated on the imputed datasets. Another sensitivity analysis will be conducted assuming all those lost to follow-up have used drugs.

Process outcomes: Multilevel linear and logistic regression models will be used to compare the hypothesised mediators of change outlined in our logic model (see figure 2 intermediary outcomes column) at the 24-month follow-up. For the primary outcome, an interaction term

will be fitted between allocation and ever having visited www.talktofrank.com, the perceived prevalence of drug use in the year group (anyone has used vs. no-one), having a conversation with school friends about drugs (ever vs. never), and ever receiving a drug offer.

Qualitative analysis

Qualitative data will be analysed using an approach which allows for both a deductive and inductive coding.[39] Data will be initially coded using an a priori coding scheme aligned with the process evaluation objectives as a means of organising the data for subsequent interpretation. Any unexpected themes emerging from the data which do not fit the coding scheme will also be coded. A thematic content analysis of the qualitative data will be undertaken, in which emergent themes will be identified and organised into an analytic framework. Transcripts of focus groups and interviews will be entered into the software package NVivo, which will be used as a data management tool, permitting quick access to data that falls within each theme.

ETHICS AND DISSEMINATION

Ethical approval was granted by the School for Social Sciences Ethics Committee at Cardiff University prior to commencement (Reference: SREC/3342). All substantial amendments to the original protocol have obtained further approval from this ethics committee. The trial protocol has been subject to four amendments so far, including changes to the sub-group analysis and sample size calculation. The study presented describes the current approved protocol at the time of submission: version 1.4, 10th January 2020. An example of a participant consent used has been uploaded as a supplementary file as per the requirements of item 32 of the SPIRIT checklist.

Safety and monitoring

The FRANK friends intervention is low risk and no adverse events were encountered in the pilot study. If the research team finds that a student writes something on their questionnaire indicating they are at risk of serious physical or emotional harm the Chief Investigator or Trial Managers will be informed and they will contact the Child Protection Officer at the school to report the concern.

An independent TSC oversees all aspects of the study design, delivery, and analysis. The steering committee meets every 12 months and includes independent external members including: a statistician, consultant psychiatrist in addition, consultant in public health, an expert in the prevention of substance misuse, and a teacher. This is a low-risk study and no interim analyses are planned so the TSC have agreed to fulfil the role of Data Monitoring Committee

Dissemination of results

The study team are committed to the full disclosure of the results of the trial. The study is due to end in June 2022. Findings will be reported in the Public Health Research journal on the NIHR Journals Library as well as leading scientific journals and conferences. We will ensure all papers are available in open-access form. Links to all papers will be posted on the project website and team members will share via social media such as Twitter. We will also send copies of our lay summaries and an infographic describing our results to all participating schools, public health commissioners, and local education officials. We will make data available to the scientific community with as few restrictions as possible.

DISCUSSION

The latest data indicates that lifetime prevalence of illicit drug use in 11-15 year olds in the UK increased between 2014 and 2018.[3] Although most young people who use drugs will not become dependent upon them, there are currently no methods for accurately identifying accurately those who will become dependent upon drugs out of those who experiment with them. Given the high costs of drug treatment, a universal approach to drug prevention may be the most cost-effective method of reducing drug-related harms. Unfortunately, systematic reviews of school-based drug prevention intervention find they are associated with modest improvements in knowledge about drugs, but few impact on drug use after 12 months.[15, 16, 17] FRANK friends is a school-based peer-led intervention that has been shown to be acceptable to students, teachers, parents and health professionals. [28] The limitations of the study are that the nature of the intervention means participating schools and students cannot be blinded to allocation. The wide and changing nature of illicit drugs in circulation also means we are using a self-report rather than a biological measure of drug use. If FRANK friends proves to be effective, the population-wide reach of schools-based interventions suggests it could have an important impact on reducing drug related harms in the UK.

Contributors JW and LM conceived of the study and led study design. JW and LMc drafted this manuscript. All authors made substantive contributions to the development of the protocol, critically reviewed and gave final approval to the manuscript. JH is responsible for management of the process evaluation supported by RC, SM, CB, KS and SB. LM, RC, MH, CB contributed to the design of study. LMc, KM, SB, HB, AD and JT are responsible for the management of the trial. RCJ, JW, LM led the sample size calculation and statistical analysis plan. SP and HW developed the economic evaluation.

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Competing interests LM, RC and JW are scientific advisers to Evidence to Impact http://evidencetoimpact.com/, a not-for-profit organisation that licenses ASSIST. All other authors declare no competing interests.

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Data sharing statement: Following completion of the study data will be made available upon reasonable request and funder approval.

Table 1. Sample size calculations (number of schools) to detect a difference in lifetime illicit drug use at 15 years of age [a]

Row	Power	Effect size [a]	Student dropout	ICC	N school (per arm)	N students
1	**90**	**38.0[b] vs 30.0%**	**30.0%**	**0.01**	**38 (19)**	**6,872**
2	90	38.0[b] vs 30.0%	30.0%	0.01	**40 (20)[c]**	7,242
3	90	38.0[b] vs 30.0%	**13.7%**	**0.015**	40 (20)	7,289
4	90	**31.0** vs 23.9%	20.0%	0.01	38 (19)	6,938
5	90	**24.0[d]** vs 18.1%	13.7%	0.01	40 (20)	7,289

[a] Based on odds ratio of 0.70 from FRANK friends vs. usual practice in pilot cRCT [28] and MacArthur meta-analysis of peer-led drug prevention interventions. [17] [b] Smoking drinking and drug use study among young people in England: lifetime illicit drug use prevalence age 15 in 2018.[3] [c] Allowing for one school dropping out per arm; [d] Smoking drinking and drug use study among young people in England: lifetime illicit drug use prevalence age 15 in 2014. [4][28][27][27][26][25]

Table 2. Components of the FRANK friends intervention

Component	**Intervention processes**
Nomination of peer supporters	Students in UK year 9 are asked to identify influential peers using three questions, "Who do you respect in year 9 at your school?", "Who are good leaders in sports or other groups activities in year 9 at your school?", and "Who do you look up to in year 9 at your school?" The Year 9 students receiving the most peer nominations are invited to a recruitment meeting to ensure a minimum of 17.5% of the year group are recruited as peer supporters.
Recruitment of peer supporters	A meeting is held with nominees to explain the role of a peer supporter and answer questions. Parental consent is sought for participation in the training course.
Training of peer supporters	A 2-day training course is held out of school, facilitated by an intervention delivery team. External trainers provide information on the effects and risks associated with specific drugs, minimising potential harms, and the law from 'Talk to FRANK'. Peer supporters

	practise communication skills including, listening, negotiation, how to talk with their peer group about drugs, and how to access www.talktofrank.com by computer or smartphone. Methods used to achieve these aims include participatory learning activities such as role plays, student-led research, small group work and discussion, and games.
Intervention period	Peer supporters are asked to have informal conversations with their peers on drugs, when travelling to and from school, in breaks, at lunchtime, and after school in their free time, and log a record of these conversations in a pro-forma diary. Over the 10-week period four follow-up school visits are made by intervention delivery staff to meet with peer supporters to provide support, trouble shooting, and monitor peer supporters' diaries.
Acknowledgment of peer supporters' contribution	At the end of the intervention peer supporters receive a certificate.

Table 3. Summary of the process evaluation

Data source, method, sampling and timescale	Key areas covered	Issues addressed
Structured observation of training of trainers and peer supporters training (2 observations of training of trainers, 6 observations of peer supporter training (mix of the full 2 days and 4 follow-ups)).	Trainees' responses, adherence to manual.	Intervention fidelity, acceptability
10 interviews with peer supporters (or pairs of peer supporters) and 6 interviews with trainers in each case study school, ~ 1 month of being trained with 5 occurring ~ 1 month of end of 10-week intervention delivery. [a]	Trainees' experience of the training, contextual barriers and facilitators, impact on them and others.	Acceptability, mechanisms of change, reach, fidelity, sustainability
6 focus groups, with a random sample of nonpeer supporter students in each case study school ~1 month after 10-week intervention period.	Awareness of and exposure to the intervention, perception of intervention, impact on them and wider	Reach, acceptability, fidelity, mechanisms of

	school life.	change.
Intervention delivery staff (trainers) and peer supporter training evaluation forms. Attendance registers of training and follow-up sessions to examine proportion of peer supporters who attend all sessions. All intervention schools.	Trainees' response, adherence to intervention, receipt of training.	Intervention fidelity, acceptability
Questionnaire at 24-month follow-up to students in all schools.	Exposure to the intervention, whether students report a conversation about harms\ harm minimisation.	Intervention reach, acceptability, mechanisms of change, contamination.
Audit of school policies and procedures at baseline and the 24-month follow-up. All schools.	Relevant drug prevention policies or practices for dealing with drug use.	Contamination, mechanisms of change, sustainability.
Interviews with member of senior management team (SMT) in all four case study schools ~6 months of end of 10-week intervention period. [a]	Awareness of and experience to the intervention, perception of intervention.	Intervention sustainability, acceptability, mechanism of change.
School records of student attendance in all schools at 24-month follow-up.	Whether any students moved from intervention to control schools.	Contamination.

[a] Or until data saturation is reached.

Figure titles

Figure 1. Flow diagram of components of The FRANK friends Study

Figure 2. The FRANK friends logic model

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