

Adapting and piloting the ASSIST model of informal peer-led intervention delivery to the Talk to Frank drug prevention programme in UK secondary schools (ASSIST+Frank)

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Registration date 05/11/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/01/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Reducing youth drug use is a public health priority. There is no way of identifying people who are likely to graduate from experimenting with drugs to long-term drug use. A universal approach to drug prevention is most appropriate. ASSIST is an effective, informal peer-led intervention for smoking prevention used in many UK secondary schools. Talk to Frank is the UK national drug education service. Of the three clinical studies using peer support to prevent illicit drug use, there were low levels of intervention implementation in one, and a potentially harmful effect whereby drug use increased for high risk groups in another. These studies suggest that while peer-led drug prevention interventions are promising, modifying components may be necessary to improve peer support for drug prevention with young people.

Who can participate?

Year 9 pupils (aged 13-14) in UK state secondary schools, teachers and parents from participating schools, and intervention delivery staff.

What does the study involve?

We will adapt an effective peer-led smoking prevention intervention (called ASSIST) which is already delivered in Year 8 in many UK secondary schools. Peer supporters from ASSIST will be approached in Year 9 to continue and extend their role to cover drug use prevention, receiving further training, information and resources provided by Talk to Frank, the UK national drug education service. We will pilot ASSIST+Frank in one school. We will also develop a standalone drug prevention version of ASSIST called Frank friends which will be piloted in Year 9 in one school. Following these initial tests, we will make any necessary revisions, and conduct a clinical study with three schools receiving ASSIST+Frank, three Frank friends in Year 9, three schools just receiving just ASSIST in Year 8, and three schools acting as a control group. We will assess illicit drug use at the start of the study and after 18 months, and interview students, school and intervention delivery staff to explore the acceptability, likely mechanisms of change and effectiveness of ASSIST+Frank.

What are the possible benefits and risks of participating?

Schools participating in the evaluation will provide access to students to collect data. There will be a very limited degree of disruption to the school and students education to organise data collection. We will work with schools to identify appropriate methods of minimising disruption. Another potential risk is that some people might find aspects of intervention content or research data collection upsetting if they, or a significant other, have experienced a problem in relation to drug use. The study manager will work with schools to ensure a system is in place to enable appropriate support to be provided in such circumstances. There are major potential public health benefits for students, schools and wider society. If ASSIST+Frank is found to be cost-effective, the intervention will be readily implementable as an add-on to the existing ASSIST intervention.

Where is the study run from?

Participating schools will be based in South Wales, UK.

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

The study started in March 2014 and will run for 31 months.

Who is funding the study?

National Institute for Health Research (NIHR) (UK).

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

12/3060/03

Study information

Scientific Title

Adapting and piloting the ASSIST model of informal peer-led intervention delivery to the Talk to Frank drug prevention programme in UK secondary schools (ASSIST+Frank): intervention development and a pilot trial

Acronym

ASSIST+Frank

Study objectives

This study does not have a defined hypothesis/hypotheses.

The primary aim of this study is to assess the feasibility and acceptability of delivering the ASSIST+Frank adjunct and Frank friends interventions to determine whether to proceed to a full-scale RCT.

Our objectives are to:

1. Assess and refine the ASSIST logic model so that it is applicable to drug prevention
2. Assess the acceptability of the intervention and evaluation to ASSIST+Frank and Frank friends trainers, students, parents, and school staff
3. Explore the barriers and facilitators of implementing the interventions
4. Explore the fidelity of intervention delivery by ASSIST+Frank and Frank friends trainers and peer supporters
5. Explore whether the proposed outcome measures are suitable for assessing illicit drug use (primary outcome) and the secondary outcomes of interest
6. Assess trial recruitment and retention rates
7. Identify potential effect sizes that are likely to be detected as part of a definitive trial and an appropriate sample size
8. Record the delivery costs and to pilot methods for assessing cost effectiveness
9. Identify the structures, resources and partnerships necessary for a definitive trial to take place.

Ethics approval required

Old ethics approval format

Ethics approval(s)

School of Social Sciences Ethics Committee, 09/09/2013, ref: SREC/1103

Study design

Intervention development followed by a four-arm pilot cluster randomized trial (at the level of school) with an embedded process evaluation

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request an information sheet

Health condition(s) or problem(s) studied

Illicit drug use

Interventions

ASSIST is an informal peer-led smoking prevention intervention to diffuse and sustain non-smoking norms via secondary school students social networks in Year 8 (aged 12-13).

ASSIST has five stages:

1. Nomination of peer supporters: Students aged 12-13 years (UK year 8) are asked to identify influential peers using three questions, Who do you respect in year 8 at your school?, Who are good leaders in sports or other groups activities in year 8 at your school?, and Who do you look up to in year 8 at your school? The 17.5% of year 8 pupils receiving the most peer nominations are invited to a recruitment meeting.
2. Recruitment of peer supporters: A meeting is held with nominees to explain the role of a peer supporter and answer questions. Trainers make it clear that students who smoke can only be peer supporters if they commit to trying to stop smoking.
3. Training of peer supporters: The aims of the training are to: provide information about the risks of smoking and the benefits of remaining smoke-free; develop communication skills including listening, cooperation and negotiation, and conflict resolution; enhance students confidence, empathy, assertiveness, attitudes to risk-taking, and exploration of personal values and to role play having informal conversations about smoking with their peers. Training takes place at a venue outside school over 2 days by a team of external trainers experienced in youth work and health promotion.
4. Intervention period: 10-week peer-led intervention where supporters have informal conversations with their peers on smoking 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. Four follow-up school visits by trainers to meet with peer supporters and provide them with additional support and training and to review progress with the informal conversations.
5. Acknowledgment of peer supporters contribution: All peer supporters are presented with a certificate; those who hand in their diary are also presented with a gift certificate.

ASSIST+Frank

The intervention manual for ASSIST+Frank has yet to be developed and will undergo extensive piloting. There may therefore be revisions to the outline below. At present it is anticipated that ASSIST+Frank will have four stages:

1. Re-engagement of ASSIST peer supporters: ASSIST year 8 peer supporters will be invited in year 9 to continue and extend their role. Trainers will make it clear that students who take drugs can only be peer supporters if they commit to reduce and try to stop taking any drugs (in line with the ASSIST model).
2. Training of peer supporters: ASSIST+Frank peer supporters will revisit key exercises on communication skills including listening, negotiation, and ways of giving information; new sessions will focus on: the effects and risks associated with specific drugs and minimising potential harms; how to talk with their peer group about drugs including aspects of confidentiality and the law; how to access the Talk to Frank website (www.talktoFrank.com), by smartphone, or by text; and time will be devoted to answering questions. Training will be one full day on drug education and practicing conversations and be delivered by the PHW ASSIST team who are experienced in youth work and health promotion.
3. Intervention period: Peer supporters will be asked to have conversations with their peers on the risks of different drugs and log these interactions over 10 weeks. One follow-up visit will be made by two ASSIST+Frank trainers with further contact via by a preferred method (email, text and/or Facebook) when Talk to Frank is updated.
4. Acknowledgment of peer supporters contribution: At the end of the intervention, supporters would receive a certificate with an additional gift voucher for those who handed in their diary.

Frank friends

The intervention manual for Frank friends has yet to be developed and will undergo extensive piloting. At present it is anticipated that Frank friends will have five stages:

1. Nomination of peer supporters: Students aged 13/14 years (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 group activities in year 9 at your school?, and Who do you look up to in year 9 at your school? The 17.5% of year 9 pupils receiving the most peer nominations are invited to a recruitment meeting.
2. Recruitment of peer supporters: A meeting is held with nominees to explain the role of a peer supporter and answer questions. Trainers make it clear that students who take drugs could only be peer supporters if they commit to reduce and try to stop taking any drugs.
3. Training of peer supporters: The aims of the training are to: provide information about the effects and risks associated with specific drugs and minimising potential harms; including the legal consequences; develop communication skills including listening, cooperation and negotiation, and conflict resolution; enhance students confidence, empathy, assertiveness, attitudes to risk-taking, and exploration of personal values. The trainers will also discuss tobacco and alcohol use within this context. Training will be over 2 days on drug education and practising peer supporter skills by the PHW ASSIST team, who are experienced in youth work and health promotion.
4. Intervention period: 10-week peer-led intervention where supporters have informal conversations with their peers on the harms associated with different 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. Four follow-up school visits by trainers to meet with peer supporters.

5. Acknowledgment of peer supporters contribution: All peer supporters are presented with a certificate; those who hand in their diary are also presented with a gift certificate.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The progression criteria on which the decision to proceed to a definitive trial are our primary outcomes. These are:

Acceptability and feasibility of the interventions to school and intervention delivery staff

1. Was it feasible to implement the ASSIST+Frank intervention in (at least) two out of three intervention schools? This will be assessed according to whether: a) 75%+ of year 8 ASSIST peer supporters are recruited and re-trained as ASSIST+Frank peer supporters in year 9; b) 75%+ of year 9 students nominated are recruited and trained as Frank friends peer supporters and, c) PHW staff delivered the additional ASSIST+Frank training in full in all three intervention schools. This will be assessed via interviews and focus groups with peer supporters and PHW staff, as well as observations of peer supporter training.

2. Was it feasible to implement the Frank friends intervention in (at least) two out of three intervention schools? This will be assessed according to whether: a) PHW staff delivered the Frank friends training in full in all three schools. This will be assessed via interviews and focus groups with peer supporters and PHW staff, as well as observations of peer supporter training.

Acceptability of the intervention to peer supporters and fidelity

3. Was the intervention acceptable to students trained as ASSIST+Frank peer supporters? This will be assessed according to whether: a) 75%+ of ASSIST+Frank peer supporters report having at least one or more informal conversations with their peers at school about drug-related risks /harms; and b) 75%+ of ASSIST+Frank peer supporters report at least one contact with PHW staff, either via a follow-up visit and/or contact via email, text or Facebook. This will be assessed via interviews and focus groups with peer supporters and PHW staff, and analysis of documentary evidence (e.g. PHW log of attendance at follow-ups, etc.).

4. Was the intervention acceptable to students trained as Frank friends peer supporters? This will be assessed according to whether: a) 75%+ of Frank friends peer supporters report having at least one or more informal conversations with their peers at school about drug-related risks /harms; and b) 75%+ of Frank friends peer supporters report ongoing contact with PHW staff throughout the year via a follow-up visit. This will be assessed via interviews and focus groups with peer supporters and PHW staff, and analysis of documentary evidence (e.g. PHW log of attendance at follow-ups, etc.).

Acceptability of the intervention to school staff and parents

5. Was the ASSIST+Frank intervention acceptable to the majority of school senior management teams (SMT), other school staff, and parents? This will be assessed via interviews with SMT and focus groups with school staff and parents.

6. Was the Frank friends intervention acceptable to the majority of school senior management teams (SMT), other school staff, and parents? This will be assessed via interviews with SMT and focus groups with school staff and parents.

Acceptability of the trial design and assessment methods

7. Were the trial design and methods acceptable and feasible? This will be assessed according to whether: a) randomization occurred as planned and was acceptable to SMTs; b) a minimum of five out of six intervention schools and two out of three schools from the comparison arms participate up in the 18-month follow-up? and, c) the student survey response rates are acceptable at baseline (80%+) and follow-up (75%+).

Secondary outcome measures

Incidence of any illicit drug use assessed by self-report questionnaire 18 months after randomisation. Use of cannabis, cocaine, amphetamines, crack, ecstasy, aerosols, gas, glue, solvents, poppers, nitrus oxide, sedatives or sleeping pills, LSD, magic mushrooms, ketamine, steroids, methadone, other prescription drugs, and opioids. Questions will assess use: ever (lifetime prevalence), over the past 12 months, past 30 days and past week; Age of first experimentation with any drug; Cannabis use: age of first use; frequency of use; symptoms after use (e.g. anxiety, relaxation, paranoia); method of use (by itself, mixed with tobacco); cannabis dependence: Cannabis Abuse Screen Test (CAST); Tobacco use: lifetime use; current use; use in past 12 months, past 30 days and past week; frequency of use; (taken from ASSIST trial and Health Survey for England); Heaviness of Smoking Index; Fagerstrom test of nicotine dependence.

Overall study start date

01/03/2014

Completion date

30/09/2016

Eligibility

Key inclusion criteria

Schools will be eligible for inclusion if they are among the state secondary schools identified by Welsh Government and Public Health Wales as receiving ASSIST in the 2014-2015 academic year. Students in Year 8 in these schools in 2014-2015 will be eligible participants in baseline and follow-up data collections (baseline conducted in Year 8; 18-month follow-up Year 9)

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

1632 students to complete a questionnaire; 55 interviews with teachers, peer supporters, students and parents; four focus groups with students and peer supporters; two structured observations

Key exclusion criteria

Students who refuse their consent, or whose parents/carers refuse consent

Date of first enrolment

01/03/2014

Date of final enrolment

30/09/2016

Locations**Countries of recruitment**

United Kingdom

Wales

Study participating centre

South East Wales Trials Unit (SEWTU)

Cardiff

United Kingdom

CF14 4YS

Sponsor information**Organisation**

Cardiff University (UK)

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ROR

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Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Public Health Research Programme (PHR)
(ref: 12/3060/03)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results of assessing the acceptability of implementing and trialling two school-based peer-led drug prevention interventions.	01/10/2017	25/01/2019	Yes	No
Results article	results of the development of a framework for the co-production and prototyping of public health interventions.	01/12/2017	25/01/2019	Yes	No