

The FRANK friends study: a multicentre cluster randomised controlled trial evaluating a school-based drug prevention intervention

Submission date 25/06/2019	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/08/2019	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/05/2022	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Current plain English summary as of 09/01/2020:

Background and study aims

The latest UK data indicate that 37% of 15 year olds have ever tried an illicit drug. There are short-term as well as long-term effects on health arising from illicit drug use amongst young people. Schools provide a systematic and efficient way of reaching a large number of people every year. Studies evaluating school-based drug prevention interventions have found few prevent or reduce student drug use, with only a handful taking place in the UK. In response, an effective school-based peer-led smoking prevention intervention (ASSIST) that has been delivered to around 120,000 UK students was adapted to deliver information from the UK national drug education website: www.talktofrank.com. In interviews and focus groups in the pilot study of this intervention, students, teachers, and parents, all thought the intervention was acceptable, easy to deliver and could have promising effects on drug use. The pilot study was too small to evaluate whether FRANK friends could prevent drug use, so the researchers are now conducting a larger trial to evaluate effects on illicit drug use will be conducted. This trial will introduce and evaluate FRANK Friends (the "intervention") which is a school-based peer-led drug prevention intervention.

Who can participate?

Students in UK Year 9 (aged 13-14)

What does the study involve?

In each school, students in UK year 9 (aged 13-14) will be asked to nominate fellow students who they think are influential. Students in receipt of the top 17.5% of nominations are asked to become peer supporters. Those who agree receive 2-days training out of school on the effects and risks associated with specific drugs, minimising potential harms, and the law using material taken from www.talktofrank.com. Peer supporters practise communication skills including, listening, negotiation, and how to talk with their peer group about drugs. They are then asked to have conversations about the harms of drug use with their peers over a 10-week period and record them in a diary. During these 10-weeks peer supporters receive four follow-up visits from trainers at school to provide support.

There will be 40 schools in the trial and they will be randomly split into two groups, 20 schools will receive the intervention and 20 will form a comparison group, and will continue with usual practice, the trial will include about 7242 students.

Before the intervention is delivered, questionnaire data will be collected from all students in year 9. In these questionnaires the use of drugs ever, in the past year, and in the past month will be measured as well as lifetime and weekly smoking, and quality of life. These things will be measured again 24 months after the intervention is delivered. The researchers will be looking to see if there are positive changes in student drug use, and whether these changes are greater within schools that received the intervention compared to schools that did not. Interviews with peer supporters, other students and trainers will also be conducted and training sessions will be observed to explore what happened during the training, how people feel about the intervention, and in what ways it has been useful. Finally, the cost of the intervention will be calculated, and weighed up against any benefits in terms of student drug use, to see if it provides good value for money.

What are the possible benefits and risks of participating?

If effective, the FRANK friends intervention will prevent drug use onset by the age of 15 and reduce the frequency of drug use amongst students. These effects could lead to improvements in health including reducing the risk of drug dependence, poor lung function, and symptoms of psychosis, and involvement in the criminal justice system. There may be additional benefits for peer supporters. In the pilot study, teachers and parents reported that peer supporters improved their communication skills, became more confident and more involved with school activities (e.g. school councils). Potential risks of the intervention to participants are minimal. Some individuals might find aspects of intervention content or research upsetting if they, or a significant other, have experienced a problem in relation to drug use. Trial managers will work with schools to ensure a system is in place to enable appropriate support to be provided in such circumstances. Any potential for harmful effects due to the intervention itself will be explored via the collection and analysis of qualitative data to explore unintended consequences.

Where is the study run from?

1. Cardiff University (UK)
2. University of Bristol (UK)

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

March 2019 to April 2022

Who is funding the study?

1. Public Health Research Programme
2. Public Health Wales
3. NIHR Clinical Research Network (CRN): West of England
4. South Gloucestershire Council
5. Bath & North East Somerset Council

Who is the main contact?

Dr James White
whitej11@cf.ac.uk

Previous plain English summary:

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3. NIHR Clinical Research Network (CRN): West of England
4. South Gloucestershire Council
5. Bath & North East Somerset Council

Who is the main contact?

Dr James White
whitej11@cf.ac.uk

Study website

<https://www.frankfriendsstudy.com>

Contact information

Type(s)

Public

Contact name

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ORCID ID

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Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

CTR internal ref: 739

Study information

Scientific Title

A multicentre cluster randomised controlled trial to evaluate the effectiveness and cost-effectiveness of a school-based peer-led drug prevention intervention

Acronym

FRANK friends

Study objectives

Primary objective: To investigate whether the FRANK Friends intervention prevents the use of any illicit drug compared to usual practice at the 24-month follow-up.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 11/06/2019, Cardiff University, School of Social Sciences Research Ethics Committee (Glamorgan Building, King Edwards VII Avenue, Cardiff, CF10 3WT, Wales, UK; Tel: +44(0)29 2087 5179), ref: SREC/3342

2. Amendment approved 10/12/2019, Cardiff University, School of Social Sciences Research Ethics Committee (Glamorgan Building, King Edwards VII Avenue, Cardiff, CF10 3WT, Wales, UK; Tel: +44(0)29 2087 5179), ref: SREC/3342 (added 09/01/2020).

Study design

Parallel-group multicentre two-arm cluster RCT with process and economic evaluations

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Prevention of illicit drugs

Interventions

Current interventions as of 09/01/2020:

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Previous interventions:

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Intervention Type

Behavioural

Primary outcome measure

Lifetime illicit drug use is assessed using a self-report questionnaire at baseline and a 24-month follow-up

Secondary outcome measures

1. The use of any illicit drug over the past 12 months, past month and week assessed using self-report questionnaires at baseline and a 24-month follow-up
2. The use of specific illicit drugs over the past 12 months, past month and week assessed using self-report questionnaires at baseline and a 24-month follow-up
3. The frequency of use of any illicit drug over the past 12 months, past month and week assessed using self-report questionnaires at baseline and a 24-month follow-up
4. The frequency of use of specific illicit drugs over the past 12 months, past month and week assessed using self-report questionnaires at baseline and a 24-month follow-up.
5. Cannabis dependency assessed using the Cannabis Abuse Screen Test (CAST) at baseline and a 24-month follow-up
6. Smoking (lifetime and weekly smoking status) assessed using a self-report questionnaire at

baseline and a 24-month follow-up (weekly smoking defined as usually smoking \geq one cigarette a week)

7. The frequency of alcohol consumption (past 12 months, month and week) assessed using a self-report questionnaire at baseline and a 24-month follow-up

8. Alcohol use disorder defined as consuming \geq 3 whole alcoholic drinks in the past year using a self-report on the frequency of alcohol consumption at baseline and a 24-month follow-up

9. Health-related quality of life assessed using the Child Health Utility 9D using a self-report questionnaire at baseline and a 24-month follow-up

Overall study start date

01/03/2019

Completion date

30/06/2022

Eligibility

Key inclusion criteria

Students in UK Year 9 (aged 13-14)

Participant type(s)

Other

Age group

Child

Lower age limit

13 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

7242

Total final enrolment

6754

Key exclusion criteria

1. Fee-paying schools
2. Special schools (e.g. for those with learning disabilities)
3. Pupil referral units
4. Schools with less than 60 students in Year 9
5. Schools likely to be closed or merged during the trial
6. Those that received the FRANK friends intervention in the pilot

Date of first enrolment

01/09/2019

Date of final enrolment

01/03/2020

Locations

Countries of recruitment

England

United Kingdom

Wales

Study participating centre

South Wales

Centre for Trials Research (CTR)

Cardiff University

4th Floor

Neuadd Meirionnydd

Heath Park

Cardiff

United Kingdom

CF14 4YS

Study participating centre

West of England

Population Health Sciences

Bristol Medical School

University of Bristol

Canynges Hall (room 4.09)

39 Whatley Road

Bristol

United Kingdom

BS8 2PS

Sponsor information

Organisation

Cardiff University

Sponsor details

Research and Innovation Services

McKenzie House

7th Floor
30-36 Newport Road
Cardiff
Wales
United Kingdom
CF24 0DE
+44 (0)29 20875834
resgov@cardiff.ac.uk

Sponsor type

University/education

Website

<https://www.cardiff.ac.uk/>

ROR

<https://ror.org/03kk7td41>

Funder(s)

Funder type

Government

Funder Name

Public Health Research Programme

Alternative Name(s)

NIHR Public Health Research Programme, PHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Public Health Wales

Alternative Name(s)

Iechyd Cyhoeddus Cymru, Public Health Wales NHS Trust, PHW

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Funder Name

NIHR Clinical Research Network (CRN): West of England

Funder Name

South Gloucestershire Council

Funder Name

Bath & North East Somerset Council

Results and Publications

Publication and dissemination plan

Exact details of the publication policy are still being developed. However, broadly the researchers plan on publishing the protocol paper in a peer review journal once they are into recruitment (Summer/Autumn 2019), the main trial results and process evaluation in high impact journals at the end of the trial (post 30/06/2022).

Findings will be presented to people who are involved in drug prevention in the UK (e.g. parents, public health teams, teachers, charities (e.g. Off the Record, Bristol Drugs Project) policy-makers) as well as at scientific conferences. If effective, avenues for delivering the intervention to other schools across the UK will be explored.

Intention to publish date

30/06/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr James White (whitej11@cf.ac.uk).

IPD sharing plan summary

Available on request