Adapting 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, refinement and a pilot cluster randomised controlled trial

White J [1, 2]*, Hawkins J [3], Madden K [1], Grant A[1], Er V [4], Angel L[1], Pickles T[1], Kelson M [1], Fletcher A[3], Murphy S[3], Midgley L[3], Eccles G[3], Cox G[5], Hollingworth W[4], Campbell R[4], Hickman M[4], Bonell C [6], Moore L [7]

*Corresponding author (Dr James White, whitej11@cf.ac.uk; 029 20687054)

[1] Centre for Trials Research, College of Biomedical & Lifesciences, Cardiff University, UK
[2] DECIPHer, College of Biomedical & Lifesciences, Cardiff University, UK
[3] DECIPHer, School of Social Sciences, Cardiff University, UK
[4] DECIPHer, School of Social and Community Medicine, University of Bristol, Bristol, UK
[5] Public Health Wales, Oldway Centre, Swansea, UK
[6] Department of Social and Environmental Health Research, London School of Hygiene and Tropical Medicine, UK
[7] MRC/CSO Social and Public Health Sciences Unit, Glasgow University, Glasgow, UK

Important

A 'first look' scientific summary is created from the original author-supplied summary once the normal NIHR Journals Library peer and editorial review processes are complete. The summary has undergone full peer and editorial review as documented at NIHR Journals Library website and may undergo rewrite during the publication process. The order of authors was correct at editorial sign-off stage.

A final version (which has undergone a rigorous copy-edit and proofreading) will publish as part of a fuller account of the research in a forthcoming issue of the Public Health Research journal.

Any queries about this 'first look' version of the scientific summary should be addressed to the NIHR Journals Library Editorial Office – journals.library@nihr.ac.uk

The research reported in this 'first look' scientific summary was funded by the PHR programme as project number 12/3060/03. For more information visit https://www.journalslibrary.nihr.ac.uk/programmes/phr/12306003/#/

The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PHR editors have tried to ensure the accuracy of the authors' work and would like to thank the reviewers for their constructive comments however; they do not accept liability for damages or losses arising from material published in this scientific summary.

This 'first look' scientific summary presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the PHR programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the PHR programme or the Department of Health.

Scientific summary

Background

In the latest Global Burden of Disease Study, drug use disorders were ranked 14th in the causes of disability-adjusted life-years (DALYs) in 10-14 year olds, the 5th leading cause in 15-19 year olds, and 2nd in 20-24 year olds. In the UK, the lifetime prevalence of illicit drug use increases sharply between 11 to 15 year olds from 6 to 24%, and the most commonly used drugs are cannabis, glues gasses and aerosols (GGA). The harms of cannabis to health include an increased risk of dependency, psychotic experiences, poor memory, and inhalation of GGAs increases the risk for sudden sniffing death. Other harms of possession of a controlled drug include a criminal caution or conviction, restricted opportunities for employment and school exclusion.

Systematic reviews of peer-led drug prevention interventions have found there is currently insufficient evidence to recommend their use in a school setting. An informal peer-led intervention, ASSIST has been shown to be effective in preventing smoking in school-aged children. In ASSIST, influential UK Year 8 (12-13 years) students are trained to disseminate non-smoking norms through conversations with school friends. Influential students are identified in ASSIST through a process of nomination by their peers. The 17.5% of students who receive the most nominations are invited to training. We proposed adapting ASSIST to develop two peer-led drug prevention interventions to deliver information on illicit drug use from the UK national drug education website: www.talktofrank.com.

Objectives

The objectives were to:

1. refine the ASSIST logic model to drug prevention and develop the +FRANK and FRANK friends interventions;

2. test the feasibility of +FRANK and FRANK friends in one school each and,
    a. assess the acceptability of the intervention to trainers, students, parents, and school staff and explore the barriers and facilitators to implementation;
    b. explore the fidelity of intervention delivery by + FRANK and FRANK friends trainers and peer supporters;
    c. refine the interventions;
3. conduct a pilot cRCT of +FRANK and FRANK friends to:
    a) assess the feasibility and acceptability of the refined interventions to trainers, students, parents, and school staff;
    b) assess the fidelity of intervention delivery by trainers;
    c) compare the feasibility and acceptability of +FRANK and FRANK friends;
    d) assess trial recruitment and retention rates;
    e) pilot outcome measures;
    f) record the delivery costs and to pilot methods for assessing cost effectiveness;
4. determine the design, structures, resources and partnerships necessary for a full-scale trial to take place.

Methods

Design and setting

In stage one, we reviewed the evidence on the prevalence of drug use in the UK, ASSIST intervention materials, and consulted with stakeholders (young people, teachers, parents, drug agency staff, health professionals, ASSIST trainers) to develop +FRANK and FRANK friends. Stage two comprised delivering these interventions in one school each; interviewing peer supporters, teachers, observing delivery and making changes to address issues with implementation. Stage three was a four-arm parallel cluster randomised controlled external pilot trial with young people in UK Year 9 (13-14 years) in 12 schools across South Wales.

Three schools were allocated to receive ASSIST to investigate any potential indirect effects of a smoking prevention intervention on drug use. An integrated process evaluation examined the context, delivery and receipt of the interventions. An assessment of intervention costs was undertaken.

School recruitment

Schools were those eligible for ASSIST, delivered by Public Health Wales (PHW), in 2014-2015. As part of the Welsh Government's Tobacco Control Plan PHW was funded to deliver ASSIST to 50 schools a year. The Welsh Government provided PHW with a list of 160 out of a possible 220 schools eligible for ASSIST which they informed PHW were selected on the basis of having a high percentage of children in receipt of free school meals and schools were in relatively deprived areas according to the Welsh Index of Multiple Deprivation. The Welsh Government did not provide the exact cut-points applied on FSM or the WIMD to exclude schools. From this list PHW recruited schools from the counties of Cardiff, Newport, Torfaen, Blaenau Gwent, Rhondda Cynon Taf, Merthyr Tydfil, and Caerphilly inviting those which had not had ASSIST in the past two years first. Out of the 72 schools in these counties, 40 had not received ASSIST in the last two years and formed our sampling frame. Schools were sent a project information sheet, reply envelope and form indicating that they should contact PHW or KM if they wished to take part.

Participant recruitment

Parents/guardians were informed by letter to contact the school if they did not wish their child to participate in the trial. Parents who did not want their child to participate were able to opt their child out of data collections. All participants were informed of their right to withdraw from the study and asked to provide written consent.

Data collection process

The consent procedure and questionnaires were completed via self-report questionnaires in school halls or classrooms under exam conditions. All data were collected by field workers. A baseline survey of students took place between 17th September and the 20th October 2014. A follow-up survey took place 18 months later between 22nd March and 5th May 2016. Schools were paid £300 for staff cover for the data collections after the 18-month follow-up.

Randomisation

Schools were randomly allocated to one of four arms: ASSIST+FRANK, FRANK friends, ASSIST, and usual practice. Allocation was conducted by the study statistician, blind to the identity of schools, and optimally allocated by the median percentage of students in receipt of free school meals (below/ above median) and median school size (below/ above median).

Outcomes

The outcomes in stage one were draft intervention logic models, manuals and resources for +FRANK and FRANK friends. In stage two, after delivery of each intervention in one school, the outcomes were a list of refinements to the intervention resources. In stage three, the external pilot cRCT, outcomes were operationalised as progression criteria.

In the pilot cRCT the progression criteria were: (1) 75%+ of year 8 ASSIST peer supporters are recruited and re-trained as ASSIST+FRANK peer supporters in year 9; (2) PHW staff delivered the additional ASSIST+FRANK training in full in all 3 intervention schools; (3) 75%+ of ASSIST+FRANK peer supporters report having at least 1 or more informal conversations with their peers at school about drug-related risks/harms; (4) 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 or text; (5) randomisation occurred as planned and was acceptable to school SMTs; (6) a minimum of 5 out of 6 intervention schools and 2 out of 3 schools from the comparison arms participate in the 18 month follow-up; and, (7) the

student survey response rates were acceptable at baseline (80%+) and follow-up (75%+). The same progression criteria were applied to FRANK friends, except criteria one only applied to recruitment of peer supporters.

The indicative primary outcome for use in a (potential) future trial of effectiveness was lifetime drug use. Students were asked to report their use of ten illicit drugs across the lifespan. Indicative secondary outcomes were the lifetime use of tobacco and alcohol, as well as dependency on cannabis and tobacco, and the frequency of heavy episodic alcohol use.

Statistical analysis

Statistical analyses were largely descriptive. We presented the percentage of missing values and distribution of all categorical and continuous variables. Exploratory effectiveness analysis using multilevel regression models adjusting for minimisation variables was conducted. All analyses used intention-to-treat populations.

Assessment of costs

The cost of +FRANK and FRANK friends was estimated using information from PHW on basic salary, national insurance and superannuation for +FRANK and FRANK friends trainers. All expenses incurred during the intervention were documented.

Process evaluation

The process evaluation examined the feasibility and acceptability of the two interventions from the perspectives of peer supporters, school teachers, intervention delivery staff, parents, and a public health commissioner. Two members of the research team observed delivery of all intervention activities, across all sites to examine fidelity of delivery.

Qualitative data collection and analysis

All interview recordings were fully transcribed. A framework analysis was employed to examine data against the research objectives and progression criteria, while maintaining flexibility to incorporate emergent themes.

Results

Objective 1: refine the ASSIST logic model to drug prevention and develop the +FRANK and FRANK friends interventions

The study developed two peer-led drug prevention interventions. The process took 18 months and comprised 42 activities, including consultations with stakeholders, experts and ASSIST delivery staff. The population-based prevalence studies showed that the prevalence of lifetime drug use more than doubled between 13 (11%) and 15 years of age (24%); and only cannabis and glues, gases and aerosols (GGA) had a prevalence of over 1%. This led us to target delivery to UK Year 9 (13-14 years) and focus content on cannabis and GGA.

This evidence and the ASSIST intervention materials were used to co-produce +FRANK and FRANK friends with stakeholders. +FRANK was designed as an adjunct to follow on from ASSIST (which is delivered in UK Year 8) with five stages: reengage Year 8 ASSIST peer supporters in Year 9 to continue and extend their role; recruitment; one-day off-site training on the effects and risks of drugs, minimising harms and the law from Talk to FRANK (www.talktofrank.com); 10-week intervention period where supporters have informal conversations with their peers, supported by two face to face and two electronic follow-up sessions with trainers; and an acknowledgement of peer supporters.

FRANK friends is a standalone informal peer-led intervention to prevent drug use in UK year 9 secondary school children. It has the format to +FRANK apart from three features. In FRANK friends Year 9 students nominate influential students in their year. The 17.5% of students with the most nominations were invited to a recruitment meeting. Second, the off-

site training occurs over two days, with additional communication skills training. Third, there are four face-to-face follow-up visits. This design replicates that used in ASSIST.

Objective two: test the feasibility +FRANK and FRANK friends in one school each

In the feasibility testing of +FRANK, we carried out seven structured observations, collected 34 evaluation forms and conducted 13 interviews with peer supporters and trainers. Twelve of the 14 peer supporters attended follow-ups one and four which were delivered in-person. Only one peer supporter completed the e-follow-up sessions. Across the 15 activities, five were delivered in full, eight had minor deviations and two were not delivered at all.

In FRANK friends, we carried out 15 structured observations, collected evaluation forms of the training from 47 peer supporters and trainers, and conducted 13 interviews with peer supporters, trainers, teachers (including school SMT), and held five focus groups with 14 peer supporters. Between 16 and 21 of the 26 trained peer supporters attended each of the four follow-up sessions. Across the 25 activities, 13 were delivered in full, nine had minor deviations and three were not delivered at all. Interviews with trainers found that some activities were too long, others too short, and the sequencing of activities could be improved.

In +FRANK, we made the following refinements: remove electronic follow-ups and remove the final follow-up. We replaced these with three face to face follow-ups. For both interventions we made slight changes in the content and sequencing of training activities and the instruction manual.

Objective three: conduct a pilot cRCT of +FRANK and FRANK friends

In the stage three external pilot cRCT, all progression criteria for +FRANK and FRANK friends were met.

Feasibility and acceptability of the interventions to trainers, students, parents, and school staff

The process evaluation involved 66 interviews. Independent structured observations of the delivery of all intervention activities were made by two members of the research team.

In the +FRANK arm, 92% of peer supporters were recruited and retrained, and 92% of peer supporters reported at least one conversation and all reported a contact with intervention delivery staff. In the FRANK friends arm, 82% of peer supporters were trained and 94% of peer supporters reported at least one conversation and all reported a contact with intervention delivery staff.

The qualitative analysis suggested that the interventions were acceptable to students, teachers and parents.

Assess the fidelity of delivery of the interventions by trainers

All intervention +FRANK and FRANK friends (100%) intervention activities were delivered as intended.

Compare the feasibility and acceptability of +FRANK and FRANK friends

The process evaluation indicated that the hypothesised intervention logic may not hold as well for +FRANK as FRANK friends. In the three +FRANK schools, students completed the peer nomination process in Year 8 and Year 9. Around a third of +FRANK peer supporters were not nominated as the most influential by their peers in Year 9. This meant that other students who were perceived to be influential in Year 9 were not trained to be peer supporters. Trainers also reported feeling rushed to deliver content in +FRANK as it took place over one day, whereas FRANK friends took place over two days.

Assess trial recruitment and retention rates

The 12 schools recruited were randomised and retained at the 18-month follow-up. Ninety three percent of eligible students were recruited at baseline and retained at the 18-month follow-up.

Survey

We found low rates of missing data for almost all variables. The highest rate of incomplete data (23%) was on the Cannabis Abuse Screen Test (CAST), a measure of cannabis dependency at baseline. There was also some evidence at baseline of floor effects with medians on the Heaviness of Smoking Index (HSI) of 0 and Fagerström Test for Nicotine Dependence (FTND) of 0.5. At follow-up, the median scores on the FTND was 2.0 and HSI was 0.0.

The prevalence of lifetime drug use at baseline was 4.1%. The most commonly used drugs were cannabis (2.4%) and glues, gases and aerosols (GGA) (2%). At the 18-month follow-up, the prevalence of lifetime drug use was 11.6%. The most common drugs were cannabis (8.0%), glues, gases and aerosols (4.0%), legal highs (1.7%) and cocaine (1%). The intraclass correlation coefficients (ICCs) for lifetime drug use at follow-up for the comparison between usual practice with +FRANK was very small ($<1 \times 10^{-8}$) and FRANK friends was 0.003..

The odds of lifetime drug use at the 18-month follow-up was lower in the +FRANK arm (12.4% vs. 13.4%, OR = 0.96, 95% CI 0.58 to 1.59) and FRANK friends arm (9.3% vs. 13.4%, OR = 0.70, 95% CI 0.39 to 1.24) than in the usual practice arm. The overall direction of effects across the hypothesized intermediary and outcome variables indicated a positive, though non-significant, effect for FRANK friends and a mixed pattern for +FRANK.

Delivery costs and pilot methods for assessing cost effectiveness

The estimated cost per school was £3,041 (£20.69 per student) for FRANK friends and £1,942 (£13.87 per student) for +FRANK.

Objective four: determine the design, structures, resources and partnerships necessary for a full-scale trial to take place

For the definitive trial, we propose a two-arm (FRANK friends vs usual practice), cRCT (randomisation at school level), with integrated economic and process evaluations. The primary outcome will be lifetime illicit drug use. The secondary outcome measures will be all those used in the 18-month follow-up in the external pilot cRCT, except for the FTND and HSI.

Conclusions

The +FRANK and FRANK friends peer-led drug prevention interventions were acceptable to peer supporters, teachers and parents. It was feasible to conduct a cRCT of these interventions in the school setting with young people age 13-14 years. The process evaluation indicated that FRANK friends was preferred over +FRANK. Qualitative and statistical evidence suggests there should be a follow-on full-scale cluster RCT of FRANK friends.

Trial registration

The trial is registered as ISRCTN14415936.

Funding

Funding for this study was provided by the Public Health Research programme of the National Institute for Health Research. The work was undertaken with the support of The Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPHer), a UKCRC Public Health Research Centre of Excellence. Joint funding (MR/KO232331/1) from the British Heart Foundation, Cancer Research UK, Economic and Social Research Council, Medical Research Council, the Welsh Government and the Wellcome Trust, under the auspices of the UK Clinical Research Collaboration, is gratefully acknowledged.