

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

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Scientific summary

ASSIST + FRANK: intervention development, refinement and pilot RCT

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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- to 14-year-olds, fifth in 15- to 19-year-olds and second in 20- to 24-year-olds. In the UK, the lifetime prevalence of illicit drug use increases sharply between 11 and 15 years of age, from 6% to 24%, with the most commonly used drugs being cannabis, glues, gasses and aerosols (GGAs). The harms of cannabis to health include an increased risk of dependency, psychotic experiences and poor memory, and the inhalation of GGAs increases the risk of 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 that 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 the ASSIST intervention, influential UK Year 8 (aged 12–13 years) students are trained to disseminate non-smoking norms through conversations with school friends. Influential students are identified 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 the ASSIST intervention to develop two peer-led drug prevention interventions to deliver information on illicit drug use from the UK national drug education website [see www.talktofrank.com (accessed 29 August 2017)].

Objectives

The objectives of this study were to:

1. refine the ASSIST logic model to drug prevention and develop the ASSIST + FRANK (+FRANK) and FRANK friends interventions
2. test the feasibility of the +FRANK and FRANK friends interventions in one school each and
 - i. assess the acceptability of the intervention to trainers, students, parents and school staff and explore the barriers to and facilitators of implementation
 - ii. explore the fidelity of intervention delivery by +FRANK and FRANK friends trainers and peer supporters
 - iii. refine the interventions
3. conduct a pilot cluster randomised controlled trial (cRCT) of the +FRANK and FRANK friends interventions to
 - i. assess the feasibility and acceptability of the refined interventions to trainers, students, parents and school staff
 - ii. assess the fidelity of intervention delivery by trainers
 - iii. compare the feasibility and acceptability of the interventions
 - iv. assess trial recruitment and retention rates
 - v. pilot outcome measures
 - vi. record the delivery costs and 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 1 we reviewed the evidence on the prevalence of drug use in the UK and ASSIST intervention materials and consulted with stakeholders {young people, teachers [school management team (SMT) and other roles], parents, ASSIST trainers, drug agency staff and a public health committee} to develop +FRANK and FRANK friends. Stage 2 consisted of delivering these interventions in one school each; interviewing peer supporters and teachers, observing delivery and making changes to address issues with implementation. Stage 3 involved a four-arm parallel external pilot cRCT with young people in Year 9 (aged 13–14 years) in 12 schools across South Wales. Three schools were allocated to receive the ASSIST intervention 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 also undertaken.

School recruitment

Schools were those eligible to receive the ASSIST intervention, delivered by Public Health Wales (PHW), in 2014–15. As part of the Welsh Government's Tobacco Control Action Plan, PHW was funded to deliver the ASSIST intervention to 50 schools a year. The Welsh Government provided PHW with a list of 160 out of a possible 220 schools eligible for the ASSIST intervention, which they informed PHW were selected on the basis of having a high percentage of children in receipt of free school meals (FSMs). Schools were in relatively deprived areas according to the Welsh Index of Multiple Deprivation (WIMD). The Welsh Government did not provide the exact cut-off points applied for FSMs 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 that had not received the ASSIST intervention in the past 2 years first. Of the 72 schools in these counties, 40 had not received the ASSIST intervention in the last 2 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 collection. All participants were informed of their right to withdraw from the study and were asked to provide written consent.

Data collection process

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

Randomisation

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

Outcomes

The outcomes in stage 1 were the draft intervention logic models, manuals and resources for +FRANK and FRANK friends. In stage 2, after delivery of the interventions in one school each, the outcomes were a list of refinements to the intervention resources. In stage 3, the external pilot cRCT, outcomes were operationalised as progression criteria.

In the pilot cRCT the progression criteria were (1) $\geq 75\%$ of Year 8 ASSIST peer supporters are recruited and retrained as +FRANK peer supporters in Year 9; (2) PHW staff deliver the additional +FRANK training in full in all three intervention schools; (3) $\geq 75\%$ of +FRANK peer supporters report having at least one or more informal conversations with their peers at school about drug-related risks/harms; (4) $\geq 75\%$ of +FRANK peer supporters report at least one contact with PHW staff, either during a follow-up visit or by e-mail or text; (5) randomisation occurs as planned and is acceptable to school management teams (SMTs); (6) a minimum of five out of six intervention schools and two out of three schools from the comparison arms participate in the 18-month follow-up; and (7) the student survey response rates are acceptable at baseline ($\geq 80\%$) and follow-up ($\geq 75\%$). The same progression criteria were applied to FRANK friends, except criterion 1 applied only to the recruitment of peer supporters.

The indicative primary outcome for use in a (potential) future trial of intervention effectiveness was lifetime drug use. Students were asked to report their use of 10 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 percentages of missing values and distributions 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 costs of +FRANK and FRANK friends were estimated using information from PHW on the 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 the 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

Two peer-led drug prevention interventions were developed. The process took 18 months and included 42 activities, including consultations with stakeholders, experts and ASSIST delivery staff. The evidence review of population-based prevalence studies showed that the prevalence of lifetime drug use more than doubled between 13 (11%) and 15 (24%) years of age and that only cannabis and GGAs had a prevalence of $> 1\%$. This led us to target delivery to UK Year 9 students (age 13–14 years) and focus the intervention content on cannabis and GGAs.

This evidence and the ASSIST intervention materials were used to coproduce +FRANK and FRANK friends with stakeholders. +FRANK was designed as an adjunct to follow on from ASSIST (which is delivered in UK Year 8) in five stages: re-engage Year 8 ASSIST peer supporters in Year 9 to continue and extend their

role; recruitment; 1 day of off-site training on the effects and risks of drugs, minimising harms and the law using information from the UK national drug education website, Talk to FRANK; a 10-week intervention period in which 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 same format as +FRANK except for three features. First, in the FRANK friends intervention Year 9 students nominate influential students in their year and the 17.5% of students with the most nominations are invited to a recruitment meeting. Second, the off-site training occurs over 2 days, with additional communication skills training. Third, there are four face-to-face follow-up visits. This design replicates that used in the ASSIST intervention.

Objective 2: test the feasibility of the +FRANK and FRANK friends interventions 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 1 and 4, which were delivered in person. Only one peer supporter completed the electronic follow-up sessions. Across the 15 activities, five were delivered in full, eight had minor deviations and two were not delivered at all.

In the feasibility testing of FRANK friends, we carried out 15 structured observations, collected evaluation forms of the training from 47 peer supporters and trainers, conducted 13 interviews with peer supporters, trainers and teachers (including SMTs), 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 and others were too short and that the sequencing of activities could be improved.

We made the following refinements to the +FRANK intervention: the electronic follow-up sessions and the final face-to-face follow-up were removed, leaving three face-to-face follow-up sessions. For both interventions we made slight changes to the content and sequencing of the training activities and the instruction manual.

Objective 3: conduct a pilot cluster randomised controlled trial of the +FRANK and FRANK friends interventions

In the external pilot cRCT, all progression criteria for the +FRANK and FRANK friends interventions 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.

Assessment of the fidelity of delivery of the interventions by trainers

All +FRANK and FRANK friends intervention activities were delivered as intended.

Comparison of the feasibility and acceptability of the +FRANK and FRANK friends interventions

The process evaluation indicated that the hypothesised intervention logic may not hold as well for the +FRANK intervention as for the FRANK friends intervention. In the three +FRANK schools, students completed the peer nomination process in Year 8 and Year 9. Around one-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 the content in the +FRANK intervention as training took place over 1 day, whereas training for the FRANK friends intervention took place over 2 days.

Assessment of trial recruitment and retention rates

The 12 schools recruited were randomised and were retained at the 18-month follow-up. In total, 93% of eligible students were recruited at baseline and were 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 for the Cannabis Abuse Screening Test (CAST), a measure of cannabis dependency at baseline. There was also some evidence at baseline of floor effects, with medians of 0.0 on the Heaviness of Smoking Index (HSI) and 0.5 on the Fagerström Test for Nicotine Dependence (FTND). At follow-up, median scores were 2.0 on the FTND and 0.0 on the HSI.

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

Compared with the usual practice arm, the odds of lifetime drug use at the 18-month follow-up were lower in the +FRANK arm [12.4% vs. 13.4%; odds ratio (OR) 0.96, 95% confidence interval (CI) 0.58 to 1.59] and the FRANK friends arm (9.3% vs. 13.4%; OR 0.70, 95% CI 0.39 to 1.24). The overall direction of effects across the hypothesised intermediary and outcome variables indicated a positive, although 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 £3041 (£20.69 per student) for the FRANK friends intervention and £1942 (£13.87 per student) for the +FRANK intervention.

Objective 4: 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 the 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 the FRANK friends intervention was preferred over the +FRANK intervention. Qualitative and statistical evidence suggests there should be a follow-on full-scale cRCT of FRANK friends.

Trial registration

This trial is registered as ISRCTN14415936.

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