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SOFTPEERS-feasibility: peer-to-peer prevention program of binge-drinking in adolescents. A pilot experimental study.

Submission date
13/02/2025

Recruitment status
No longer recruiting

Registration date
08/08/2025

Overall study status
Completed

Last Edited
08/08/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
After tobacco, alcohol consumption is the second leading cause of avoidable death. In the early 2000s, a new mode of alcohol consumption has become particularly worrying, as it becomes a normative rite of passage for adolescents and emerging adults: binge drinking i.e., drinking 5 or more glasses of alcohol on one occasion. In France, adolescence remains a pivotal period for alcohol experimentation, with a beginning in the early years of middle school, and use increasing during the school years, particularly from junior high to high school.
The SOFTPEERS theory-based and peer-delivered program aiming to prevent binge drinking among high-school students was developed in 2017 by Epidaure, the prevention department of the Montpellier Cancer Institute, in partnership with Paul-Valéry Montpellier 3 University.
The SOFTPEERS intervention is divided into two main phases. In phase 1 of the program, a session delivered by educational staff aims to increase students' autonomous forms of motivation to prevent alcohol consumption. Then, in phase 2, peer educators are accompanied by a professional health educator during six guidance sessions to create binge-drinking prevention actions based on theoretical concepts (i.e., attitudes, subjective norms, perceived control). Finally, the peer educators disseminate their preventive actions to their high school peers (peer-to-peer).
The aims of this study are to find out whether the SOFTPEERS program is acceptable, easily implemented and adapted to high school students and reduces the prevalence of binge drinking.

Who can participate?
Secondary school students (aged 15-18 years) from 8 high schools in the Montpellier Academy (5 departments). All students in 10th and 11th grade from the recruited high schools are eligible to participate.

What does the study involve?
High schools are randomly allocated to either a group receiving the SOFTPEERS program or a control group (no intervention). The main outcome is binge drinking within the last 30 days, self-reported by a questionnaire completed in class before and after the intervention, i.e. 5 to 6 months later. Individual interviews and focus groups are conducted with the various actors

involved in the intervention: peer educators, secondary school pupils receiving the intervention, school nurses, teachers, prevention staff, educational headmaster and members of the project team.

What are the possible benefits and risks of participating?
The expected impacts are to develop a theoretically anchored public health program in high school, targeting binge drinking, that is acceptable, easily implemented and adapted to students' social backgrounds. The benefits for participants are also the improvement of psychosocial skills (i.e. psychosocial variables influencing behaviour targeted by the model).

Where is the study run from?
1. Epidaure Institute of Cancer - Montpellier (France)
2.University Paul Valéry Montpellier III (France)

When is the study starting and how long is it expected to run for?
January 2018 to December 2019

Who is funding the study?
Institut National Du Cancer (France)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
« SOFTPEERS-faisabilité », Grant INCa n°2018-030 & Grant « INCa-DGOS-Inserm 6045 »

Study information

Scientific Title
Acceptability and pilot effectiveness of a theorically and peer-based intervention to reduce binge-drinking in adolescents- SOFTPEERS program

Acronym
SOFTPEERS-feasibility

Study objectives
The study's primary hypothesis is that the SOFTPEERS program is acceptable and easy to implement. The secondary hypothesis is that the SOFTPEERS program will reduce the prevalence of binge-drinking.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/04/2018, International Review Board INSERM (8 rue de la croix Jarry, Paris, 75013, France; +33 (0)1 44 23 60 00; ceei@inserm.fr), ref: 18-481

Study design
Mixed-methods study: prospective pilot randomized control trial to assess effectiveness on main outcome and process evaluation (qualitative study with interviews and focus-group) to assess acceptability

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of binge-drinking among young people (10th and 11th grade) with no pathology

Interventions
The SOFTPEERS-feasibility project took place over 2 years from January 2018 to December 2019. Eight high schools taken as randomization units (clusters) were randomly assigned to one of two groups: intervention (n = 4) or control group (without intervention; n = 4).

Intervention:
The Softpeers program trained 10th and 11th grade high school students to become peer educators and design binge drinking prevention actions for their schoolmates. In short, peer educators were recruited among the members of the student's association in each high school. All students who took part in Softpeers as peer educators were volunteers, and the group size of peer educators was between three and seven. Each group of peer educators benefited from six guidance sessions of 1 hour provided by a professional health educator. Those sessions were implemented between January and March 2019.

In line with the principles of the trans-contextual model, the program included two main phases:

1st Phase: Motivation to limit substance use
Members of the educational staff of the school lead component aiming (i) to increase autonomous motivation for the adoption of a healthy behavior regarding substance use based on the key motivational concepts of the trans-contextual model (i.e., the perception of autonomy support and autonomous motivations), and (ii) to identify potential volunteer students to become peer-educators.

2nd Phase: No-binge behaviour promotion
A peer-to-peer component promotes the prevention of binge-drinking towards (i) peer-educators and then towards (ii) all included high school students: peer-educators then disseminate their preventive actions in their high school to their 10th and 11th grade peers. Between March and May 2019, peer educators set up their binge drinking prevention actions (e. g., posters, videos, debates, stands) for their schoolmates.

Intervention Type
Behavioural

Primary outcome(s)
For pilot effectiveness, the number of binge-drinking within the last 30 days, self-reported by questionnaire completed in class (at baseline and post-intervention, i.e. 5 to 6 months after baseline) with a standard recognized measure (Kuntsche et al., 2017), i.e., the following question: "How often in the past 12 months (or 30 days) have you had 5 drinks or more on a single occasion?"

Key secondary outcome(s))
Measured at baseline and post-intervention, i.e. 5 to 6 months after baseline:
1. Frequency of alcohol, tobacco and cannabis use assessed by questionnaire (Currie, 2010)
2. Alcohol use disorders evaluated with the AUDIT questionnaire
3. Tobacco dependence assessed with the HONC questionnaire
4. Aggressive behaviors assessed by the Brief Aggression Questionnaire (BAQ)
5. Psychosocial determinants of behavior, i.e. the core variables of the transcontextual model (i.

e., attitudes, norms, perceived control, intentions, perception of autonomy, self-determined motivations, constrained motivations) measured by questionnaires adapted to the context of binge-drinking prevention (Ajzen, 1991; Neighbors, 2003; Williams, 2006)

Completion date
01/12/2019

Eligibility

Key inclusion criteria
High schools:
1. A public high school located in the Montpellier Academy
2. Adequate human, logistical and material resources to implement the program
3. Signed the participation form

Students:
1. Be enrolled in one of the included high schools
2. In the second or first year of secondary school
3. Have been informed of the study
4. Have consented to participate (informed consent form signed by the student, and not opposed by his/her parents or legal representatives)

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit
15 years

Upper age limit
18 years

Sex
All

Total final enrolment
2021

Key exclusion criteria
High schools:
1. High schools included in another research protocol

Students:
1. Students who are unable to follow the study for its entire duration
2. Have a disability that prevents them from fully understanding the study's imperatives

3. Students (or legal representatives) who have refused (i.e., not consent) to take part in the study

Date of first enrolment
01/12/2018

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
France

Study participating centre
Academy of Montpellier (Hérault, Gard, Aude, Lozère and Pyrénées-Orientales)
France
34000 / 66000 / 30000 / 11000 / 48000

Sponsor information

Organisation
Epidaure Institute of Cancer - Montpellier

Organisation
University Paul Valéry Montpellier III

Funder(s)

Funder type
Research organisation

Funder Name
Institut National Du Cancer

Alternative Name(s)
The French National Cancer Institute, L'Institut national du cancer, INCa

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
France

Results and Publications

Individual participant data (IPD) sharing plan
The data are anonymized (identifiers assigned to participants); the anonymized data from the high-school students will be archived in the Data Archive of the Epsylon laboratory at Université Paul Valéry Montpellier 3. Access is password-protected for authorized members of the research team, under the responsibility of the laboratory director (Pr Florence Cousson-Gélie, who is also the project's principal investigator). There are no plans to make the data files public or accessible; appendices detailing the analyses may be provided if deemed appropriate when publishing results.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes