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Realist evaluation of a theory-based life skills program aiming to prevent addictive behaviors in adolescents: The ERIEAS study protocol

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ABSTRACT

Introduction

Adolescence is a sensitive life stage where tobacco, alcohol and cannabis are used as a way to learn and take on roles. Prevention programs for youths that work on changing representations about those products and helping with life skills mobilization are of interest. Unfortunately, among existing programs, few of them are evidence-based.

In France, a program named *Expériences Animées* has been developed. It is inspired by life skills development programs that have proven to be successful. EA program involves supervised animated short movies and talks with high school and secondary school pupils about the use of psychoactive substances and addictions. It aims to delay psychoactive substances initiation; prevent adolescents from becoming regular consumers; reduce the risks and harm relating to those substances use; open the way for adapted support measures.

We are interested in understanding how and under what circumstances, through which mechanisms and among which adolescents EA program works. For that purpose, we developed the ERIEAS study. The article presents its protocol, based on a realist evaluation.

Methods and analysis

EA will be conducted in 10 establishments (high schools and secondary schools). A multi-case approach will be adopted and based on the contribution analysis paradigm, the aim being to develop and adjust an intervention theory. The study comes under the theory-driven evaluation framework. The investigation methodology will include 4 stages: i) elaboration of a middle-range theory, ii) data collection for validating/adjusting the theory, iii) data analysis, iv) refinement and adjustment of the middle-range theory, and definition of the program's key functions.

Ethics and dissemination

The study will offer to health authorities' evidence-based results to help with health promotion politics roll-out in schools. It will provide knowledge about the strategic configurations most able to lead to life skills mobilization and change young people's representations about substances use.

This research has received funding from the French National Cancer Institute (INCA) n° CAMBON-2019-008. The project will be carried out with full respect of current relevant legislation (e.g. the Charter of Fundamental Rights of the EU) and international conventions (e.g. Helsinki Declaration). It follows the relevant French legislation of the research category on interventional research protocol involving the human person (3° of Article L. 1121-1 of the Public Health Code). The protocol was approved by the Comité et Protection des Personnes (CPP) i.e. Committee for the Protection of Persons CPP SUD-EST VI n°: AU 1525 and was reported to the Agence Française de Sécurité Sanitaire des Produits de Santé (ANSM) i.e. the French National Agency for the Safety of Health Products. It is in conformity with reference methodology MR003 of Bordeaux University Hospital (CNIL n° 2026779v0). This research has been registered on the site http://clinicaltrials.gov/ and in the European database ID-RCB under no 2019-A01003-54.

Strengths and limitations of this study:

- Develop alcohol, tobacco and cannabis prevention programs for youths that work on changing representations about those products and consumptions is crucial, these programs should be evidence based and focused on helping life skills mobilization such as resistance and self-regulation.

- Consistent with the « bottom-up » approaches, our study -a realist evaluation based on a natural experiment mobilizing mixed-models methods and a preference stated method (DCE)- is an innovative way of evaluating a complex intervention.
- The conclusions will be highly replicable and will offer a basis for designing other interventions using identified key functions.

KEYWORDS

Life skills; Addictions; Adolescents; Program, Realist evaluation; Complex intervention; Prevention; Public health

Word count : 6533

INTRODUCTION

Addictive behaviors are the major contributors to human morbidity and premature death; tobacco and alcohol use being the most prevalent addictive behaviors and cannabis the most prevalent "unsanctioned psychoactive drug" used worldwide (1). Adolescence is a particularly sensitive life stage where tobacco, alcohol and cannabis are used as a way to learn and take on roles. And, if tobacco, alcohol and cannabis consumption and their association with cancer risk, chronic disease and health conditions are clearly stated in the literature (2), we also know the importance of events occurring in the earliest stages of human development (before birth and during childhood) on further adult health conditions thanks to the life course approach (3). For example, because adolescence is a period during which the brain undergoes profound remodeling in areas, alcohol and cannabis consumption during this period can lead to impaired learning ability, memory and brain development and to difficulties in cognitive control and emotion regulation(4–6).

A major concern therefore is to develop alcohol, tobacco and cannabis prevention programs for youths that work on changing representations about those products and consumptions. These programs should be focused on helping life skills mobilization such as resistance and self-regulation for example.

Nowadays, there are many programs focused on addiction prevention implemented in schools. Unfortunately, among them, evidence-based and life skills programs are scarce (7,8). In France, since 2015, the organization ARIA ("Association Ressources et Initiatives Addictions"; association for initiatives and resources addictions), with a clinical psychologist and an addiction psychiatrist, have developed a program named *Expériences Animées* (animated experiences) inspired by life skills development programs that have proven to be successful such as the Life Skills Training program (9), the Unplugged program (10) and the In Media program (11).

The *Expériences Animées* (EA) program involves supervised animated short movies and talks with high school and secondary school pupils about the use of psychoactive substances and addictions. The priority is given to secondary schools in priority education areas and to vocational high schools.

The program draws on the recommendations given by Botvin and Griffin (12) and aims to:

- be draw on theoretical models and address various risk and protective factors;
- be suitable for the age group and sensitive to the changes adolescents go through;
- contain material to help adolescents recognize and resist peer pressure;
- promote the development of resistance skills;
- provide knowledge about levels of substance use to correct normative expectations;
- be based on interactive methods to stimulate participation and skills development;

- be culturally focused and contain audio-visual components and language familiar to the target group;
- be appropriately dosed;
- involve trained staff (enthusiasm, ability to adapt during implementation, etc.).

The EA program's overall purpose is to: delay initiation; prevent adolescents from becoming regular consumers; reduce the risks and harm relating to these consumptions; open the way for adapted support measures.

The EA program has never been evaluated and we are interested in understanding how, under what circumstances, through which mechanisms and among which adolescents it works. To answer these questions, we developed the ERIEAS study ("Evaluation Réaliste de l'Intervention Expériences Animées en milieu Scolaire"; Realist evaluation of the EA intervention in schools). Here, we present the ERIEAS study protocol based on a realist evaluation.

STUDY OBJECTIVES AND LOCATION

Our study aims to evaluate the EA program in order to set out an intervention theory for the program. To do so, the study has 2 main objectives:

- First objective: to characterize the effects (Outcomes) on the pupils of secondary and high schools in terms of:
  - Tobacco, alcohol and cannabis use
  - Consulting of a healthcare professional for a problematic use of substances.

- Second objective: to characterize the context and underpinning mechanisms of action (Mechanisms and Context), in order to document the conditions of effectiveness of EA in terms of contextual conditions or mechanisms triggered by the program. In other terms, it is question of identifying the program's key functions - which may be contextual conditions or action mechanisms - related to:
  - The pupils' characteristics
  - The practitioners' characteristics
  - The design of the materials and in particular the techniques employed, their use during program sessions, the activities for teaching staff and parents.
  - The macro- (e.g. classes, schools, cities) and micro- (e.g. supervised short films and talks characteristics) intervention environment.

The second objective offers a way to identify the EA's key functions with a view to transferability (13,14) (transferring key features and adapting non-key aspects) and comparison of EA with others implemented or transferred programs as *Unplugged* (10).

The EA program takes place in the French department of Charente, in 10 schools (3 high schools and 7 secondary schools).

The ERIEAS study will take place in all the 10 schools involved in the EA program. It started in January 2019 and will last until December 2022. Participants' inclusion will start at the 30th September 2019.

METHODS AND ANALYSIS

We reported this manuscript in line with the Rameses II reporting standards for realist intervention (cf. check-list in additional file) (13). ERIEAS seeks to evaluate the actual impact and the impact factors of the EA program using a realist evaluation. To this purpose, a multi-case approach will be adopted and based on the contribution analysis paradigm (14), the aim being to develop and adjust an intervention theory. The case-study method will be used as it involves exploring phenomena in context and analyzing their interactions with other elements that are meaningful to the research (15). The study comes under the theory-driven evaluation framework (16–19) where the realist evaluation method is used to explore the effects, mechanisms and the influence of context on the outcomes.

The study also comes under natural experiments in intervention research. This is because the intervention is little standardized, not undertaken for the purposes of the research (20).

Conceptual framework

In realist evaluation, developed by Pawson et Tilley (21), intervention effectiveness depends on the underlying mechanisms at play within a given context. The evaluation is about identifying context- mechanism-outcome configurations (CMOs). The aim is to understand how and under what circumstances an intervention works. What is studied in this approach is the context with the intervention as a part of it. Realist evaluation seeks to understand how an intervention brings about change, considering context and target group, and grounding the evaluation on a middle-range theory (theory that aims to describe the interactions between outcomes, mechanisms and contexts) about the mutual influences of intervention and context (22,23). It comes under the black box paradigm (24) and differs from the experimental paradigm which evaluates effectiveness without looking at the mechanism by which an intervention works and the influence of the context. Realist evaluation asks the following question: did the

intervention work in a way consistent with its underpinning theory? It seeks to understand how the intervention works by focusing on the underlying mechanisms and the influence of context. The generative causality works on three assumptions (25): i) An intervention does not work in and of itself, and it is not what produces an outcome; ii) All interventions trigger a mechanism or a set of mechanisms that produce an outcome; iii) All interventions are delivered in a context.

Hence, the evaluation is about identifying context-mechanism-outcome configurations (CMOs), called middle range theories (MRT). Hypothesizing and validating by empirical investigations, these CMO configurations (theory that aims to describe the interactions between outcomes, mechanisms and contexts) help to understand how an intervention brings about change, considering context and target group (22,23). The recurrence of CMOs is observed in successive case studies or in mixed protocols such a realist trials (23). Indeed, in order to consider context, realist evaluators observe in successive cases what Lawson (quoted in Pawson, 2006 (25)) calls demi-regularities of CMOs (i.e. regular although not necessarily permanent occurrences of an outcome when an intervention triggers one or more mechanisms in a given context) (23). According to realistic evaluators, specifically studying their recurrences in different contexts renders possible the isolation of key elements that are replicable in a family of contexts. This gives rise to middle-range theories that become stronger as progress is made through the cases. "These middle-range theories, in certain conditions, predict possible intervention outcomes in contexts different from the one in which the intervention was tested" (23).

Applied to our case

The realist principle is suitable for studying non-linear interactions in complex systems. It is the reason why we decided to adopt this approach. The intervention under investigation applies to an operational program and it is therefore important to identify its key functions (26,27), that is to say its interventional or contextual components underpinning its effectiveness. This will allow us to hypothesize about 1) the program's effectiveness, 2) its added value compared to other existing programs and 3) its specificities. Ultimately, it should enable replication (28,29).

For our purposes, here, each establishment involved in EA program with its own context will constitute a case. For each of the cases, the intervention will be studied to identify the mechanisms at play in the given context along with the variation in outcomes: the CMO configurations. CMO configurations will be identified through an analysis of each case as well as a cross-case analysis highlighting recurrent CMO configurations, thus identifying

key features for possible replication. These will be fed into secondary theories (which may be tested again in other cases/contexts).

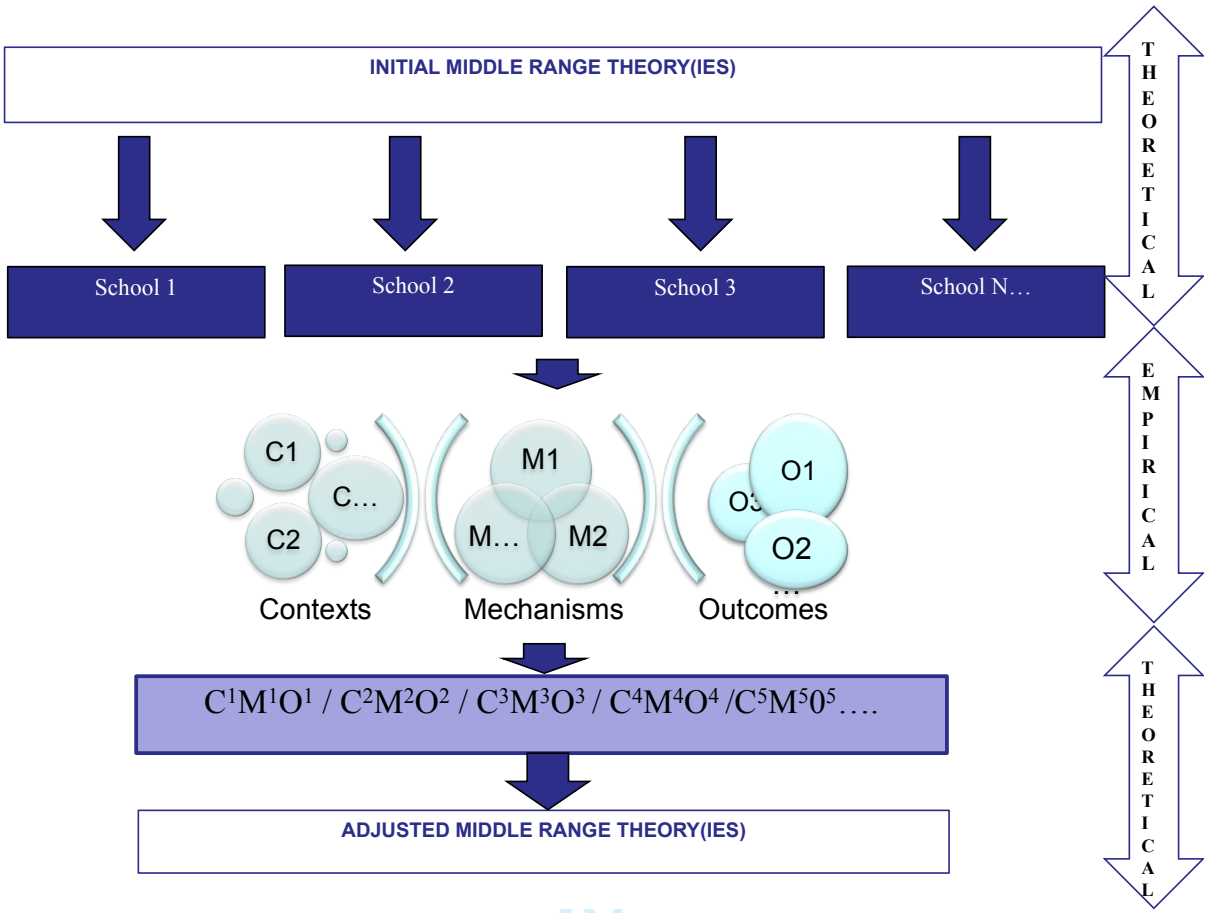
Drawing on the literature and on the experience of professionals delivering the intervention, we will first set out initial middle-range theories (21,25), that we will test in each case, by collecting data (qualitative and quantitative)(23).

The mechanisms will be identified qualitatively according to the definition by Ridde *et al*. "a mechanism is an element of reasoning and reaction of an agent with regard to an intervention productive of an outcome in a given context" (30,31). They will be divided into those relating to the session leaders and teachers in attendance and those relating to the pupils. For pupils, the literature allows us to already define two categories of mechanisms: 1) The representations about alcohol, tobacco and cannabis consumption; 2) The life skills developed/ mobilized.

Contextual elements will be included among all the elements collected qualitatively that satisfy the following definition: elements located in time and space that may affect the intervention and the outcomes produced, whether they relate to the session leaders, teachers, pupils, session delivery or the operational setting. In realistic approach, interventional elements are a part of context. So, we could distinct Ci (for Contextual factors linked to the Intervention) and Ce (for Contextual factors no linked to the intervention –External–). Each mechanism-context configuration may influence an outcome (O). In our study, outcomes are related to getting support from a health professional and using tobacco, alcohol, and/or cannabis.

Figure 1 synthesizes the principles of the realist evaluation.

Figure 1: The realistic approach and the way to refine middle range theories applied to ERIEAS study.



The *Experiences animées* program

The EA support: the short-animated movies

The EA program involves supervised short-animated movies and talks with secondary school and high school pupils about the use of psychoactive substances and more generally about all kind of addictions. To reach its target audience, the EA program uses short animated films produced by student filmmakers (second-year students at the Angoulême filmmaking school). The films are made specifically for the program and every year, new students are selected to produce new short films.

Since 2015, every year, an 8-day filmmaking workshop for students (20-26 years old) is supervised by the EA program managers. During the workshop the students are tasked with "looking at the use of psychoactive substances, their functions, and sharing their thoughts about how people become addicted – what do you have to say about it? What would you like to convey to a young audience about this issue?". The program managers in no way intervene in the actual screenwriting and aesthetics. At the end of the workshop, the students show their proposals as filmed storyboards. Following the eight days during which students think about the issues of substance

use and in some cases reflect on their own experience, the program managers select several projects to be included in *Expériences Animées*. Some 35 films have been produced since 2015.

Delivery of the sessions

The intervention during the sessions comprises 4 phases

- Diagnosis: At the first session, pupils are asked to complete a short questionnaire about their representations, normative beliefs, knowledge and use of psychoactive substances. This will be used to adapt subsequent sessions.

- Instructions: At the beginning of each session, pupils are briefly reminded about the previous sessions: what they took away from them, what the session leaders noted and remarked. Pupils are then told that "We will watch several short films and then discuss the content together, sharing our thoughts and feelings about what we have seen".

- Interaction about the films: Several films are shown during each session which include reflective dialogue, sharing thoughts and experiences (experiential approach) with everyone able to contribute knowledge. Each session is adapted according to the initial self-questionnaire, the previous session and the delivery of the current session. After a film has been shown, pupils are encouraged to freely discuss the issues raised (reminders of prevention messages already dealt with, room for emotions, feelings, interpretations, differences in point of view, etc.). Thoughts, ideas and information are noted down and are put up in real time. Afterwards, pupils are given time for critical reflection, positioning, reformulation and summarizing.

- End of the session: At the end of a session, pupils go over the keywords from the session, they summarize what was said; together they construct a prevention message based on the films shown. Discussion times are necessary in order to adapt the subsequent sessions.

The sessions are facilitated by two session leaders: a prevention officer from "Centres Jeunes Consommateurs" (centres for young substance users) and a psychologist. Their demeanor when delivering the sessions is important. They should act as clinicians who are there to listen, to help pupils reflect on the issues raised, to encourage them to express themselves while allowing others to do so, and to facilitate dialogue. A teacher, school nurse or other staff member from the school also attends the session. Each pupil is given an individual program booklet for

making notes and writing down any thoughts about what goes on during the sessions. Classroom tables are arranged in a U shape or in a rectangle (if there are many pupils in the class).

In a given secondary/high school, one session per term is delivered for each class. In the ERIEAS study, three film showings (sessions) will therefore be scheduled:

- for each 7th grade (secondary school) and 10th grade (high school) of the schools for the 2019-2020 academic year
- for each 8th grade (secondary school) and 11th grade (high school) of the schools for the 2020-2021 academic year
- for each 9th grade (secondary school) and 12th grade (high school) of the schools for the 2021-2022 academic year.

Study population

Different groups will be followed in the ERIEAS study:

- Pupils: The sample involved in the EA program will be studied. From the 2019-2020 academic year until the 2021-2022 academic year (3 academic years), the EA program will be delivered in 10 establishments (in total 39 classes and around 1000 pupils).
- Education community members: one teacher whose class is involved in the sessions, the school nurse and the headmaster, i.e. a total of 3 people per establishment will be interviewed in the study.
- Session leaders: 3 persons will be interviewed.
- Funders: 3 funders will be interviewed.

The inclusion criteria will be:

- For pupils: Pupils from the 10 secondary and high schools involved in EA program, in 7th grade and 10th grade in 2019/2020 academic year, not opposite to participate and whose holders of parental authority are not opposite to the participation of the child.
- For education community members, session leaders and funders: non-opposition to participate.

The only exclusion criteria will be to be under legal protection.

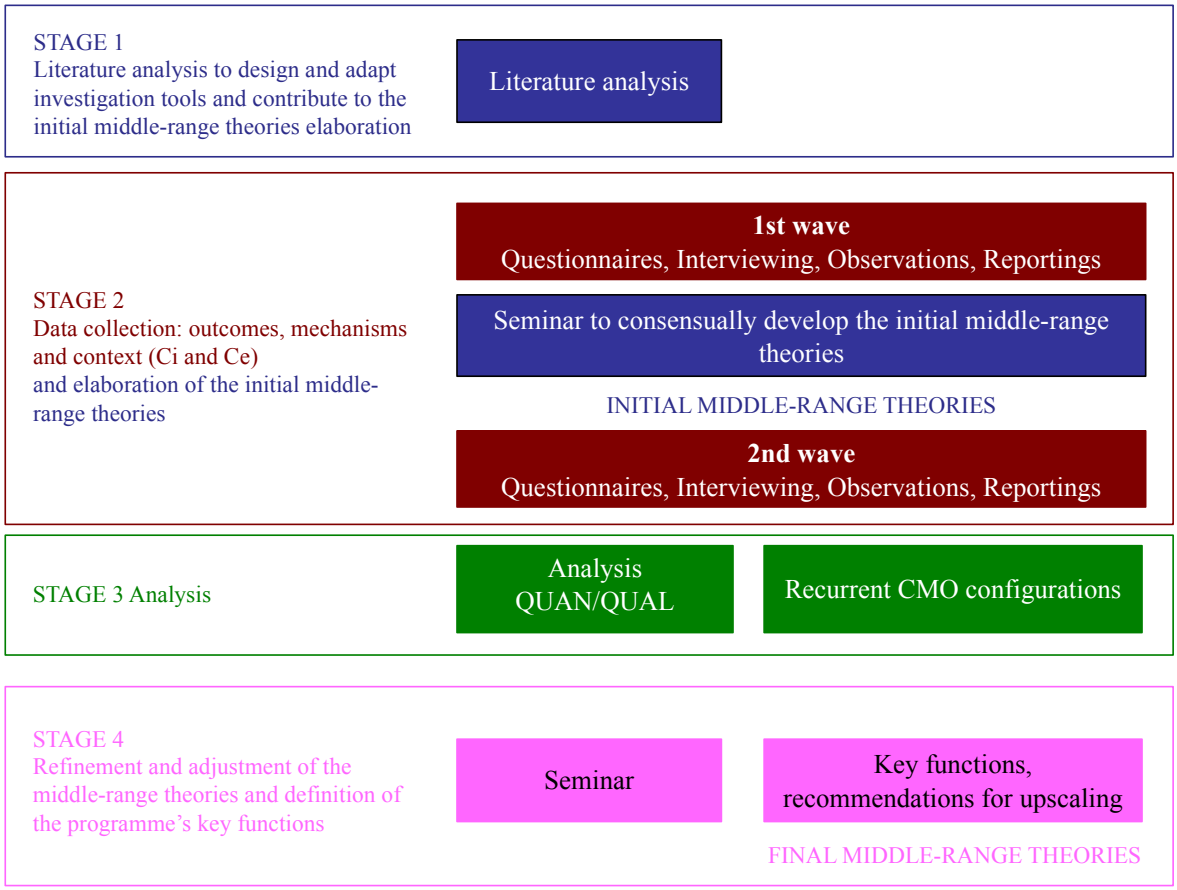
Patient and Public Involvement

The ERIEAS study does not include any patient or public involvement in terms of setting research priorities, defining research questions or outcome, providing input into study design, or disseminating the results. The research participants will be called on to answer questionnaires, or interviews.

Study design

According to theory-driven evaluation methodology (16–19), the study will be composed of 4 stages. **Figure 2** presents the 4 stages.

Figure 2: Stages of the ERIEAS study



Stage 1 – Literature analysis

The first stage involves a literature analysis to design and adapt investigation tools and contribute to the initial middle-range theories elaboration (stage 2).

A scoping review has been conducted to identify strategies that are effective in school settings in helping pupils to change their representations of alcohol, cannabis and tobacco use and to develop or mobilize life skills to prevent

addictions. The data sources used were: PsycInfo, PsycArticles, Psychology and Behavioral Sciences Collection, SocIndex, Cairn and Web of Sciences.

The keywords were “life skills” and [“adolescents” or “young adults” or “teenagers”]. Inclusion criteria were: English or French language publications from 2014 to 2019; original or methodological articles focusing on the evaluation or exploration of intervention techniques applied to school settings; interventions aimed at changing representations, life skills as a way of delaying experimentation with alcohol, tobacco and cannabis and, reducing its use.

We conducted a double-blind review of the selected papers and extracted information regarding the intervention (name, location, population, design), the evaluation design (method, main and second outcomes), the result of the intervention, its key functions and context of implementation. The purpose of this review was to extract information about the contexts, mechanisms and outcomes our study has to focus on. Our analysis questions were: what are the most effective intervention techniques? What representations and skills are they effective for? What contextual conditions influence the effectiveness of the techniques? The results have been used to design and adapt our tools (questionnaire, interview and observation grids, scorecard) and will be used for the initial middle-range theories development (stage 2). Scoping review results will be presented in a dedicated paper.

Stage 2 – Data collection and elaboration of the initial middle-range theories

Stage 2 involves data collection to appraise the outcomes, mechanisms and contextual elements (including the techniques). First wave of data collection will help to elaborate initial middle-range theories (to establish how the intervention works in context) together with literature analysis results from stage 1. Second wave of data collection will contribute to verify the initial theories (contribution analysis). In annex, in **table 1**, we exposed the variables that we will collect and the way of collection.

To collect data, the following tools will be used:

- A questionnaire to collect mechanisms and outcomes on pupils at T0 (1st wave) and T1 (2nd wave)

It will contain: descriptive variables (gender, age, socio-professional category of parents); questions on tobacco, alcohol and cannabis use; a question relating to the "use of support services" variable; questions related to the knowledge and perception of tobacco, cannabis and alcohol use; scales assessing peer pressure and life skills.

This questionnaire will be administrated at T0 (i.e. at the end of September/ beginning of October 2019) and T1 (June 2022) to all the pupils participating to the ERIEAS study. **Table 2** in annex, lists the questions/scales and their previous use in other studies.

- Pupils interviews:
    - Non-directive interviews to collect contextual factors, mechanisms and outcomes on pupils (IP1)

In the first academic year, two pupils per class will be randomly selected and interviewed, until saturation (i.e. the moment when the collected data does not add anything new to the understanding of the research topic), meaning at least 80 pupils will be monitored.

This first session of non-directive interviews will be held in November/ December 2019. These interviews will help to elaborate the initial middle range theories, to elaborate the second wave of interviews with pupils (IP2) and to configure and design a questionnaire including a DCE (Discrete Choice Experiment) set of questions.

    - Semi-directive interviews to validate CMO configurations on pupils (IP2)

At the end of the second academic year (June 2021), a second session of semi-directive interviews with pupils will be held (randomly selected and different from the previous session). This qualitative material will validate or not the framework expressed through the initial middle-range theory (CMO configurations). For each hypothesized configuration in the initial middle-range theories, there will be an open-ended question that will not allow the respondent to be guided by the expected answer (presence or not of C and M, or combinations thereof).

A total of 160 interviews of pupils will therefore be conducted during the study in two sessions.

- Semi-directive interviews to collect mechanisms and contextual factors on school professionals and EA session leaders (IE1 and IE2).

Semi-structured interviews with the education community and the session leaders will collect information related to context parameters (including Ci) and professionals' mechanisms. Three session leaders and 3 people per establishment will be surveyed: the nurse, the headmaster, a teacher whose class is involved in the intervention. Interviews will be held twice: at the end of the first academic year (June 2020) and at the end of the 3-year intervention period (June 2022). A total of 3 session leaders and 30 professionals will therefore be interviewed twice. In total, 66 interviews will be realized.

This first session of semi-directive interviews will help to elaborate the initial middle range theories, to elaborate the second wave of interviews (IE2) and to configure and design the DCE questionnaire. The second session of semi-directive interviews will validate or not the framework expressed through the initial middle-range theory.

- Semi-directive interviews to collect contextual factors on funders of the program (IF).

Semi-structured interviews with funders of the program will collect information relating to context parameters (Ce exclusively). A total of 3 funders will be interviewed once, in October 2019.These interviews will help to will help to elaborate the initial middle range theories.

- Observations to collect contextual elements of sessions notably.

The objective is to collect the following contextual elements, specific to each establishment: The intervention climate within the establishment and in each class, the reception given by the school staff as a whole, the conditions of session delivery, the motivation levels of the session leaders and teachers in attendance, the characterization of the feedback and sharing sequences (spatial organization, relations between pupils/session leaders/others).

Observations of at least 2 sessions per establishment will be conducted each academic year. 20 sessions per year will therefore be observed, making a total of 60 observations over the 3-year intervention period. Furthermore, the session leaders of non-observed sessions will produce a report following a reporting grid.

Before the program starts (in mid-October 2019), each program presentation for the school staff will be observed, thus adding 10 observation sessions. A total of 70 observation sessions will therefore take place.

- A scorecard to collect establishments characteristics (contextual elements - Ce)

Data relating to the characteristics of the establishments will be collected from the education authorities using a scorecard. These data will be : the level of urbanization of the town or city where the establishment is located (urban, quasi-urban, quasi-rural, rural), the deprivation index of the school area (FDep index from Rey et al., 2009 (32)), the number of pupils, male/female ratio, number of repeaters per establishment, the availability rate of the nurse, the type of establishment (general/vocational, priority education areas), the proximity to a center for young substance users and availability rate where appropriate, the occurrence of occasional awareness campaigns on addiction in the establishment and the fact of having been previously involved in *Expériences Animées*.

- A DCE questionnaire to validate CMO configurations and including an adaptation of discrete choice experiment (DCE).

This questionnaire will have variables based on a stated-preference method (33), named DCE (34). It will enable to better understand the pathway and the circumstances and determinants combinations that could be trigger to

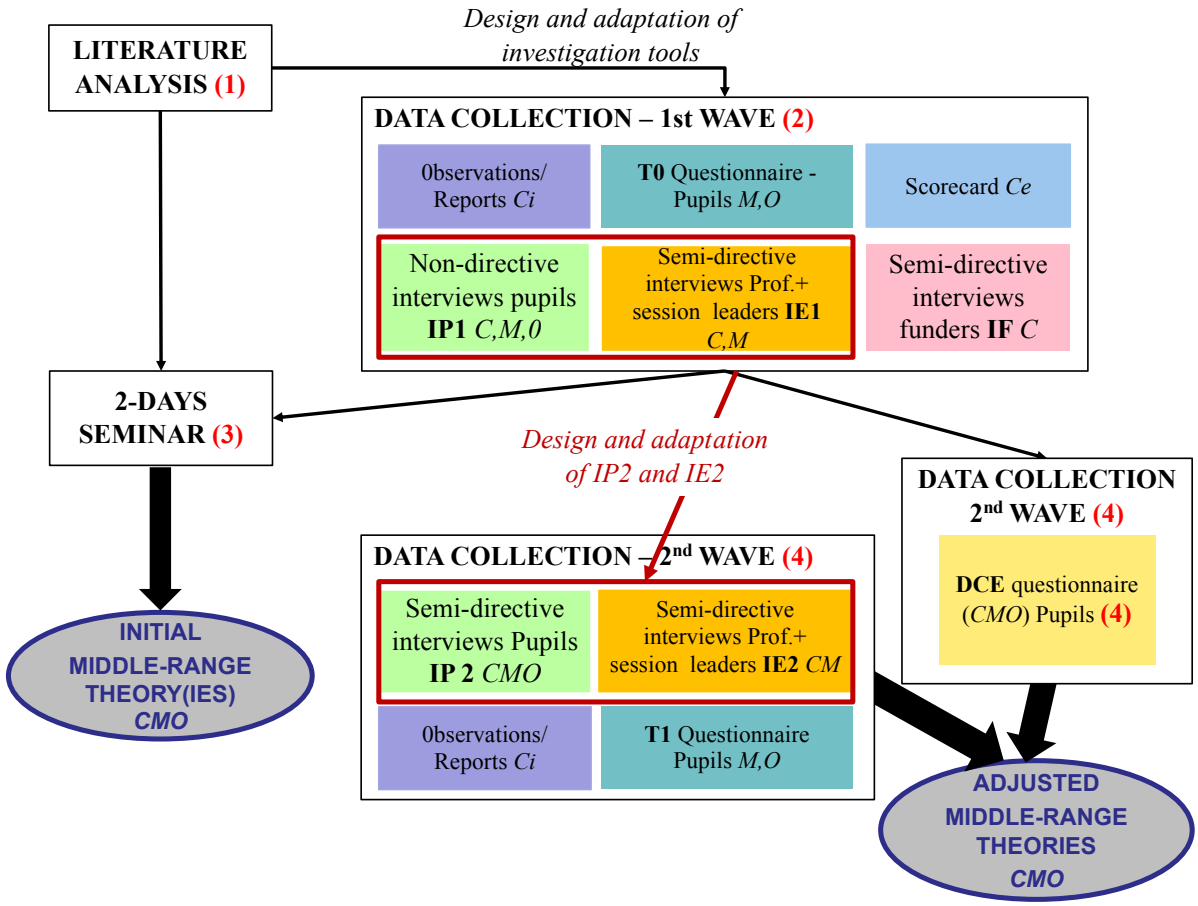
initiate or maintain or re-engage a consumption of alcohol, tobacco and / or cannabis, using. It will help to validate or not the final middle range theories.

Figure 3 presents the different modalities of data collection.

Figure 4 presents the data collection timelines.

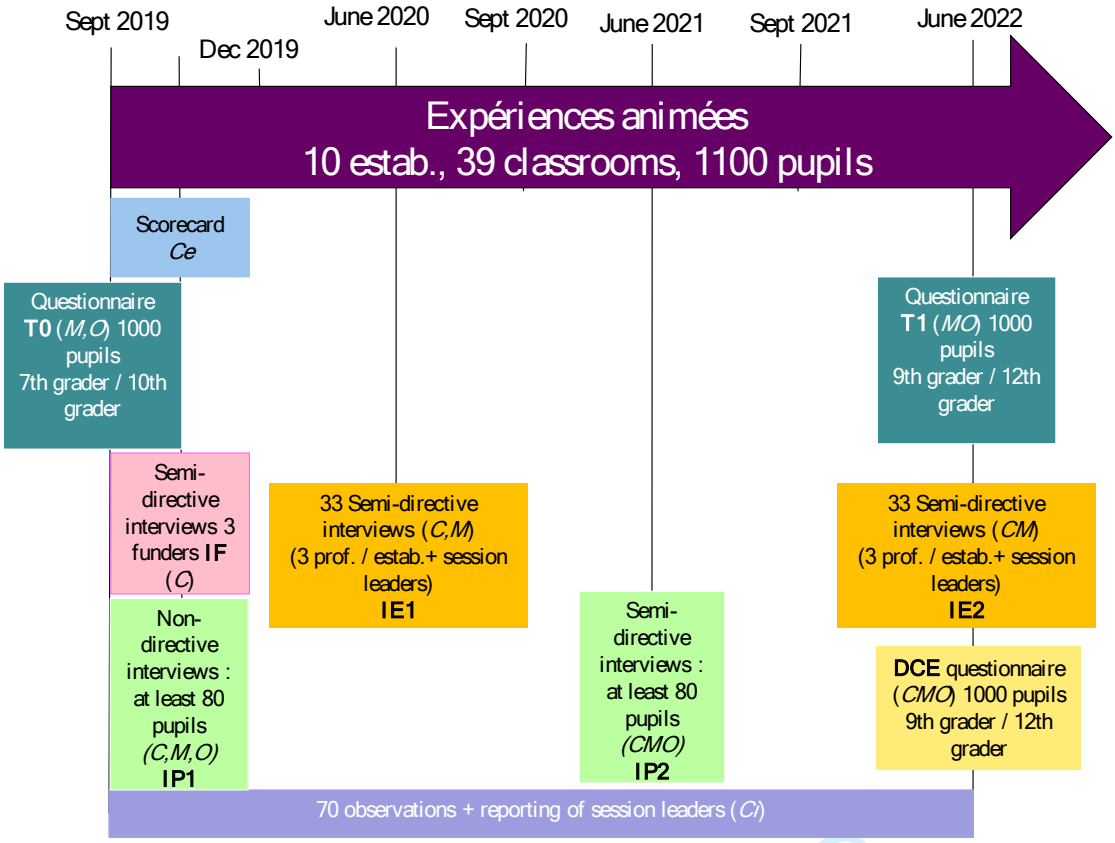
Survey instruments – questionnaires, interview guides, observation logs, and observations check lists– have been designed in line with literature analysis results (stage 1) and will be pre-tested.

Figure 3: Different modalities of data collection and their links with the middle-range theories



C, Context ; M, Mechanism ; O, Outcome; CMO, CMO configurations

Figure 4: Timeline of the data collection



Thanks to quantitative and qualitative analyses, the following outcomes will be identified:

- Tobacco, alcohol and cannabis use (Current frequency of tobacco, alcohol and cannabis consumption (every day/week/month, rarely, never); number of episodes of heavy drinking (at least 5 drinks per occasion) in the last 7 days/30 days/12 months; number of drunkenness episodes in the last 7 days/ 30 days/ 12 months)
- Consultation of a healthcare professional to discuss about a problematic use of alcohol and/or tobacco and/or cannabis (number of times in the last 12 months)

At this stage, the literature review conducted helped to identify some of the mechanisms and contextual elements. They need to be confirmed during the second stage (i.e. seminar and elaboration of the initial middle-range theories). We present here the potential M and C we aim to investigate:

- In terms of representations and attitudes (35): normative expectations or perceived norms about the use, intentions, refusal and resistance skills, risk-related attitudes and behaviors, positive and negative beliefs about consequences, reasons to use, and perceived peers' influence and friends' use.
- In terms of life skills: the aptitude to mobilize self-management skills (self-esteem, problem-solving abilities, reducing stress and anxiety), general social skills (overcoming shyness, communicating clearly, building relationships), and drug resistance skills (defenses against pressures to use alcohol and other drugs, identify the consequences of substance use, risk-taking, and the influences of the media).

The **table 1** gives details on the expected contexts and mechanisms and the time and modalities of collection.

Stage 3 - Data analysis

Data analysis will include analysis of each case (each school) and a cross-case analysis combining a QUAN/QUAL design (36) (i.e. to use quantitative and qualitative approaches in tandem and to embed one in the other to provide new insights or more refined thinking). The analysis will have to answer this question: In what contextual conditions and through which mechanisms does the program *Expériences Animées* produce outcomes? The validation of initial middle-range theories (CMOs) will allow us to answer it. This validation will go through by combining and comparing data from quantitative and qualitative analyses in monographs (an analysis of each case (establishment)) and by cross-case analysis. This analysis will identify the recurrent CMOs which will therefore be replicable.

Quantitative data (from T0 and T1 questionnaires) – Analyses of the evolution of Mechanisms and Outcomes

A first descriptive analysis will be conducted on the representations, mobilization of life skills, tobacco, alcohol and cannabis use and the use of support services at each measuring point. Trajectory modeling will be undertaken using latent class growth modeling in order to study changes in representations, life skills, products use and use of support services between the two questionnaires. The analysis will be adjusted according to the pupils' characteristics (age, gender, socio-professional category of parents) and to the establishments (level of urbanization, index of social disadvantage, number of pupils, male/female ratio, number of repeaters per

establishment, proximity to a center for young substance users/nurse, earlier involvement in *Expériences Animées*, involvement in occasional awareness campaigns on addiction, type of establishment).

This analysis will enable to verify the program's impact in context across all the pupils by studying the changes between the two collection times. As some of the variables used here are the same as for the LST (37) and Unplugged (10) programs, the findings will be compared and contrasted with those of both programs conducted in Nouvelle-Aquitaine region.

Qualitative data

The qualitative data can be divided in two groups (the two waves), with different use and aim. The firsts interview sessions and observations (i.e. IP1, IF, IE1, scorecard and firsts observations) will be mobilized to set the frame of the initial middle range theories. Following this first set of qualitative investigations, a 2-day seminar will be organized to set out the initial middle-range theories. The aim of this seminar will be to discuss the findings of the literature review and the first wave of data collection. This seminar will be interdisciplinary: epidemiologists, prevention experts, addiction, experts, psychiatrists, psychologists, sociologists, EA session leaders and ARIA staff will be present. Drawing on the participants' experiences, the literature review, the observations and the interviews, the seminar will enable to set out hypothesis about the mechanisms (M) linking Ci and Ce to the O.

The second set of qualitative investigations (i.e. IP2, IE2+lasts observations) will be mobilized to validate the final middle range theories.

All the qualitative data (i.e. data collected from pupils, funders, professionals' interviews and observations) will be analyzed by content analysis (38) which refers to "a set of techniques for systematically and objectively analyzing and describing the content of communication. The aim is to obtain indicators allowing inferences to be made about the messages and how they are produced and received (inferred variables)". Content analysis encodes, classifies and ranks the communication in order to examine its patterns, trends or distinguishing features, in our case the recurrence of C-M-O configurations in each case (establishment) and by a cross-case analysis.

Quantitative data from DCE- questionnaire – Analyses of DCE questionnaire

A DCE will be used in order to i) understand combinations of circumstances and determinants that impact on the decision of teenagers to start substances uses and/or prevent them from cessation and/or lead them to relapse if concerned, ii) validate CMO configurations.

The DCE will allow quantifying the weights individuals attach to various attributes of a situation in order to finally predict their independent impact on decisions. In other terms, the DCE approach will allow an analysis of individual stated preferences in response to hypothetical choices and enables the estimation of the relative importance of each level of attributes during the decision-making process. When presented with hypothetical options (i.e. choice scenarios) that describe alternative specifications of a situation, respondents are assumed to choose the behavior they would have. The higher a respondent's preference for certain attribute levels, the more likely they are to choose that scenario over any alternative. This method will allow the searcher to highlight situations and configurations allowing to mobilize or not life skills. Mixed logit models will be used to establish whether or not the attributes' levels presented in the scenarios are statistically significant predictors of adolescents' choices.

Combination of quantitative and qualitative data

The ERIEAS study will therefore combine quantitative and qualitative methods, mobilizing a mixed methods research. This study has a multiphase design with a first data collection combining QUAN (T0) + QUAL (i.e. IP1, IF, IE1, scorecard and firsts observations). These first data will help and guide a second qualitative phase (i.e. IP2, IE2) and the DCE questionnaire elaboration. This design seemed to be particularly relevant as it allows flexibility to address a set of research questions that will arise from each other.

The CMO configurations obtained from the qualitative data will be compared with those obtained from the DCE questionnaire. All these CMO configurations will be discussed during 1-day seminar in stage 4. Therefore, it will lead to a very complete thorough analysis of the EA complex intervention.

Stage 4 - Refinement and adjustment of the middle-range theories, and definition of the program's key functions

The different modalities of investigation and analyses will lead us to refine progressively our middle range theories. We will compare the primary theories with the CMO configurations observed in each establishment and the recurrent CMOs in order to consolidate and adjust the initial middle range theories. Furthermore, the DCE questionnaire will allow the research team to formulate strong hypotheses about the triggers to initiate or maintain or re-engage a consumption of alcohol, tobacco and / or cannabis, using among adolescents and the impact of the *Experiences Animées* intervention.

The material will be synthetized and used to refine and adjust the final middle range theories and the program's key functions. This work will be conducted during a second seminar (1 day) with the whole project team: the researchers, *Experiences Animées* professionals and ARIA staff members.

The team will carry out the following:

- a definition of the *Experiences Animées* program's key functions (configurations underpinning the program's success)
- a comparison with the elements used in other addiction prevention programs designed to develop life skills, such as the LST program (37) and Unplugged (10)
- an exploration into further strategies to complete *Expériences Animées* wherever this is necessary for ensuring optimal outcomes
- the drafting of detailed recommendations 1) to scale-up the *Expériences Animées* program's key functions to other areas with other stakeholders, and 2) for a quasi-experimental large-scale evaluation of the program (where only the key functions will be retained and freely adapted) if required (judgement criteria may not be precisely determined at this stage).

ETHICS AND DISSEMINATION

This article describes a protocol using a realist design to understand how an innovative prevention program works and, what contexts, mechanisms, and outcomes are at stake in this intervention. Realist evaluation is a valuable design allowing to highlight the triggers of an intervention and guiding its transferability.

The project will be carried out with full respect of current relevant legislation (e.g. the Charter of Fundamental Rights of the EU) and international conventions (e.g. Helsinki Declaration). It follows the relevant French legislation of the research category on interventional research protocol involving the human person (Jardé law, category 3 research on prospective data). The methods development, data collection and analysis will take account the following issues:

- Anonymity of study respondents will be preserved and ensured at all times as respondent(s) request. Unnecessary collection of personal data will be avoided, and respondents will have the right to review outputs and withdraw consent. All personal data will be coded, removed from the data for analysis and

stored separately. Only designated research staff will have access to the keys linking the data with the personal information.

- Information regarding the study and the right to refuse to participate will be distributed to all study participants and their parents or parental authority's holders, and in the case of refusal, alternative means of data collection will be explored (e.g. alternative respondents).

The protocol was approved by the Comité et Protection des Personnes (CPP) i.e. Committee for the Protection of Persons CPP SUD-EST VI n°: AU 1525 and was reported to the Agence Française de Sécurité Sanitaire des Produits de Santé (ANSM) i.e. the French National Agency for the Safety of Health Products. It is in conformity with reference methodology MR003 of Bordeaux University Hospital (CNIL n° 2026779v0).

This research has been registered on the site http://clinicaltrials.gov/.

The research project is registered in the European database ID-RCB under no 2019-A01003-54.

From a research point of view, the methodology we propose is consistent with the « bottom-up » approaches advocated in health promotion. Since this approach allows to better reflect stakeholders' views and concerns, and makes external validity workable, it becomes therefore a preferable alternative for evaluation of health promotion or programs (39). Our study is a realist evaluation based on a natural experiment mobilizing mixed-models methods and a preference stated method. Therefore, it is an innovative way of studying process of a complex intervention (40). Due to its specific methodology and its large sample, this study will provide strong and detailed information regarding the young people's consumption of tobacco, alcohol and cannabis and their representations of these consumptions. Focusing on the stated preference methods this study will highlight how pupils mobilize competences and life skills towards addictive products.

Tobacco, alcohol and cannabis consumption among adolescents are worrying, especially in France (41–44) and, prevention interventions should be tailored to this specific population. This study will explain and pinpoint the precise impact of the *Expériences Animées* program and the conditions for this impact. It will allow to define the EA program's key functions and how they work in different contexts or how they could be adapted in form; to compare and contrast the program with other programs being implemented in France, then offering fine tweaking

solutions for optimal outcomes; to define a guideline to implement *Experiences animées* elsewhere. As such, the conclusions will be highly replicable and offer a basis for designing other interventions using identified key functions. We will publish different papers in order to first describe the addictive behaviors of this population, then to analyze the impact and key functions of the EA program and eventually we will focus on what triggers the consumption of young people exposed to a prevention program. Finally, a report on the study will offer to health authorities evidence-based results to help with health promotion politics roll-out in schools. To conclude, this project will be of great interest to policy-makers, authorities and field professionals involved in the prevention and health promotion sector.

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Data statement

Not applicable

Authors' contribution

JMF and AA drafted this article and all authors revised the manuscript. The project design was developed by LC. JMF, AA, EM, RG, MT, LM, LM, VD and FA were involved in implementing the project and in developing the evaluation design, under the supervision of LC. All authors read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interests.

LIST OF ABBREVIATIONS

ANSM: "Agence Française de Sécurité Sanitaire des Produits de Santé"; the French National Agency for the Safety of Health Products

ARIA: "Association Ressources et Initiatives Addictions"; Association for initiatives and resources addictions

Ce : Contextual factor not linked to the intervention

Ci : Contextual factor linked to the intervention

CMO: Context – Mechanism – Outcomes

CPP: "Comité de Protection des Personnes"; Committee for the Protection of Person

DCE : Discrete choice experiment

EA: “Expériences Animées”; animated experiences

ERIEAS: “Evaluation Réaliste de l’Intervention Expériences Animées en milieu Scolaire”; Realist evaluation of the EA intervention in schools

LST: Life skills training

TDE: Theory driven evaluation

Annex:

Table 1: Mechanisms data (M) expected and time of collection

MECHANISMS				
Mechanisms	Variables	Data collection	Time collection	Population
Representations about drinking, tobacco and cannabis use; and what influences it	• Representations about drinking, tobacco and cannabis use • The role of social influence on consumption (initiation and use) • The short-term effects of use and abuse	Non-directive interviews (IP 1+IP2) (160)	During the 2 first academic years (September 2019 to June 2021)	At least 80 pupils the first 2 years randomly selected (i.e. 2 per class and 8 per establishment/year)

	• User rates among adolescents • Portrayal of drinking, tobacco and cannabis use: parties, fitting in, being accepted • Social acceptability of drinking, tobacco and cannabis use • The role of peers • The role of the media in encouraging alcohol, tobacco and cannabis use.	Questionnaires T0, T1	September 2019 and June 2022	Q : 1000 pupils / wave
Life skills for preventing addiction including tobacco, alcohol and cannabis use, and activated / mobilized through the sessions	• Personal self-management skills : self-esteem, problem-solving abilities, reducing stress and anxiety • General social skills: overcoming shyness, communicating clearly, building relationships • Drug resistance skills: defenses against pressure to use alcohol, cannabis and other drugs, identify the consequence of substance use, risk-taking and the influence of the media	Non-directive interviews (IP1+IP2) (160)	During the 2 first academic years (September 2019 to June 2021)	At least 80 pupils the first 2 years randomly selected (i.e. 2 per class and 8 per establishment/year)
		Questionnaires T0, T1	September 2019 and June 2022	1000 pupils / wave

Contextual data (related to *Expériences Animées* intervention - Ci)			
Variables	Data collection	Time collection	Population
• Intervention climate within the establishment • Conditions of session delivery • Characterization of the feedback and sharing sequences (spatial organization, relations between pupils/session leaders/others)	Non-directive interviews (IP1+IP2) (160)	During the 2 first academic years (September 2019 to June 2021)	At least 80 pupils the first 2 years randomly selected (i.e. 2 per class and 8 per establishment/year)
• Intervention climate within the establishment • Reception given by the school staff as a whole • Conditions of session delivery • Motivation levels of the session leaders and teachers in attendance • Characterization of the feedback and sharing sequences (spatial organization, relations between pupils/session leaders/others)	Observations (70)	September 2019 to June 2022	Program presentation for the school staff when the program starts (1 presentation per establishment) And at least 2 observation sessions per establishment and per year
	Reports by session leaders for those sessions that are not observed		Reports for all the sessions that are not observed
	Semi-structured interviews (IE1+IE2) (66 interviews at all)	June 2020 and June 2022	3 education professionals per establishment (the nurse, the headmaster, a teacher whose class is involved in

				the intervention) (30 interviews) and 3 session leaders: the same people in 2020 and in 2022
Contextual data (operational setting - Ce)				
Public	Variables	Data collection	Time collection	Population
Pupils	Characteristics • Acceptability • Acceptation of the intervention • Their role in it, support or not toward the intervention • Opinion about the intervention and its effects on pupils Facilitating/ limiting factors of change	Non-directive interviews (IP1+IP2) (160)	During the 2 first academic years (September 2019 to June 2021)	At least 80 pupils the first 2 years randomly selected (i.e. 2 per class and 8 per establishment/year)
Session leaders and education professionals	Characteristics • Acceptability • Acceptation of the intervention • Their role in it, support or not toward the intervention	Semi-structured interviews (IE1+IE2) (66 interviews at all)	June 2020/2022	3 education professionals per establishment (the nurse, the headmaster, a teacher whose class is involved in the intervention) (30 interviews) and 3 session leaders : the same people in 2020 and in 2022

	Opinion about the intervention and its effects on pupils			
Establishments	Characteristics • Type of establishment (general/vocational, priority education areas – yes/no-) • Level of urbanization of the town or city where the establishment is located • Deprivation index of the school area • Number of pupils, male/female ratio, number of repeaters per establishment • Proximity to a center for young substance users and availability rate where appropriate • Availability rate of the nurse • Establishments already involved in Expériences Animées in previous years (yes/no) Occasional awareness campaigns on addiction in the establishment (yes/no)	Scorecard from the education authorities	September 2019	Every establishment included in *Expériences Animées*

Expériences animées funders	Characteristics • Acceptation of the intervention • Opinion about the intervention and its effects on pupils • Interest about *Expériences animées* Facilities and difficulties to fund *Expériences Animées*, barriers and facilitators	Semi-structured interviews (IF) (3)	September 2019	3 people from the funding organization of *Expériences Animées*

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Table 2: Sources of questions included in T0 Questionnaire

SURVEY ITEMS	REFERENCE
General characteristics	
Sex, Age	-
Geographic Environment	-
	-
	-
Family environment	HBSC
	HBSC
	HBSC
	HBSC
	HBSC
Socio-economic situation	-
	-
School climate	HBSC/Unplugged
Substance consumption and health care use	
Use of support service	-
Alcohol consumption	HBSC (modified)
	HBSC (modified)
Heavy drinking episodes	HBSC (modified)
	HBSC (modified)
	ESPAD (modified)
Cannabis consumption	HBSC (modified)
	-
Tobacco consumption	HBSC (modified)
	-
	Unplugged
Representations about substance use and influences	
Social influences	
Cannabis	EROPP
	EMCDDA (modified)
	EMCDDA (modified)
Alcohol	ISRD (modified)
	ISRD
	EMCDDA (modified)
	EMCDDA (modified)
Tobacco	EMCDDA (modified)
	EMCDDA (modified)
Beliefs in consequences	

Alcohol	Unplugged/emcdda (modified)
Cannabis	Unplugged (modified)
Portrayal of use	
Alcohol	DMQ-R
Cannabis	DMQ-R
Knowledge	
Alcohol	EROPP (modified)
	EROPP (modified)
Cannabis	EROPP
	EROPP
History of effects of use and abuse	Unplugged/Emcdda (modified)
	-
Life Skills	
Peer pressure resistance	Unplugged
	Peer pressure Inventory
	Unplugged
Decision making and problem solving ability	Unplugged
Creative and critical thinking	Unplugged
Communication and interpersonal skills	Unplugged
Self awareness and empathy	Unplugged
Assertiveness	Unplugged
Coping with emotion and stress ability	Unplugged

HBSC, Health Behavior n School-Aged Children; ESPADD, European School Survey on Alcohol and Other Drugs; EROPP, Enquête sur les Représentations, Opinions et Perceptions relatives aux Psychotropes i.e. Survey on Representations, Views and Perceptions of Psychotropic Drugs; ISRD, International Self Report Delinquency; EMCDDA, European Monitoring Centre for Drugs and Drug Addiction; DMQ-R, Drinking Motives Questionnaire, Revised.

		TITLE	Reported in document Y/N/Unclear	Page(s) in document
1		In the title, identify the document as a realist evaluation	Y	1
SUMMARY OR ABSTRACT				
2		Journal articles will usually require an abstract, while reports and other forms of publication will usually benefit from a short summary. The abstract or summary should include brief details on: the policy, programme or initiative under evaluation; programme setting; purpose of the evaluation; evaluation question(s) and/or objective(s); evaluation strategy; data collection, documentation and analysis methods; key findings and conclusions Where journals require it and the nature of the study is appropriate, brief details of respondents to the evaluation and recruitment and sampling processes may also be included Sufficient detail should be provided to identify that a realist approach was used and that realist programme theory was developed and/or refined	Y	2
INTRODUCTION				
3	Rationale for evaluation	Explain the purpose of the evaluation and the implications for its focus and design	Y	4
4	Programme theory	Describe the initial programme theory (or theories) that underpin the programme, policy or initiative	Y	4
5	Evaluation questions, objectives and focus	State the evaluation question(s) and specify the objectives for the evaluation. Describe whether and how the programme theory was used to define the scope and focus of the evaluation	Y	5
6	Ethical approval	State whether the realist evaluation required and has gained ethical approval from the relevant authorities, providing details as appropriate. If ethical approval was deemed unnecessary, explain why	Y	2 and 22
METHODS				
7	Rationale for using realist evaluation	Explain why a realist evaluation approach was chosen and (if relevant) adapted	Y	8
8	Environment surrounding the evaluation	Describe the environment in which the evaluation took place	Y	6
9	Describe the programme policy, initiative or product evaluated	Provide relevant details on the programme, policy or initiative evaluated	Y	9
10	Describe and justify the evaluation design	A description and justification of the evaluation design (i.e. the account of what was planned, done and why) should be included, at least in summary form or as an appendix, in the document which presents the main findings. If this is not done, the omission should be justified and a reference or link to the evaluation design given. It may also be useful to publish or make freely available (e.g. online on a website) any original evaluation design document or protocol, where they exist	Y	12
11	Data collection methods	Describe and justify the data collection methods – which ones were used, why and how they fed into developing, supporting, refuting or refining programme theory Provide details of the steps taken to enhance the trustworthiness of data collection and documentation	Y	13-18
12	Recruitment process and sampling strategy	Describe how respondents to the evaluation were recruited or engaged and how the sample contributed to the development, support, refutation or refinement of programme theory	Y	11
13	Data analysis	Describe in detail how data were analysed. This section should include information on the constructs that were identified, the process of analysis, how the programme theory was further developed, supported, refuted and refined, and (where relevant) how analysis changed as the evaluation unfolded	Y	18-20
RESULTS				
14	Details of participants	Report (if applicable) who took part in the evaluation, the details of the data they provided and how the data was used to develop, support, refute or refine programme theory	Y	17 AND 28-33
15	Main findings	Present the key findings, linking them to contexts, mechanisms and outcome configurations. Show how they were used to further develop, test or refine the programme theory	y	20
DISCUSSION				
16	Summary of findings	Summarise the main findings with attention to the evaluation questions, purpose of the evaluation, programme theory and intended audience	y	21
17	Strengths, limitations and future directions	Discuss both the strengths of the evaluation and its limitations. These should include (but need not be limited to): (1) consideration of all the steps in the evaluation processes; and (2) comment on the adequacy, trustworthiness and value of the explanatory insights which emerged In many evaluations, there will be an expectation to provide guidance on future directions for the programme, policy or initiative, its implementation and/or design. The particular implications arising from the realist nature of the findings should be reflected in these discussions	y	22
18	Comparison with existing literature	Where appropriate, compare and contrast the evaluation's findings with the existing literature on similar programmes, policies or initiatives	NOT APPLICABLE	
19	Conclusion and recommendations	List the main conclusions that are justified by the analyses of the data. If appropriate, offer recommendations consistent with a realist approach	NOT APPLICABLE	
20	Funding and conflict of interest	State the funding source (if any) for the evaluation, the role played by the funder (if any) and any conflicts of interests of the evaluators	Y	26

BMJ Open

Realist evaluation of a theory-based life skills program aiming to prevent addictive behaviors in adolescents: The ERIEAS study protocol

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Realist evaluation of a theory-based life skills program aiming to prevent addictive behaviors in adolescents: The ERIEAS study protocol

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ABSTRACT

Introduction

Adolescence is a sensitive life stage during which tobacco, alcohol, and cannabis are used as ways to learn and adopt roles. There is a great deal of interest in substance use (SU) prevention programs for young people that work to change representations of these products and help with mobilization of life skills. Unfortunately, few existing programs are evidence-based.

In France, a program called Expériences Animées (EA, Animated Experiences) has been developed, inspired by life skills development programs that have been proven to be successful. The EA program uses animated short movies and talks with high school and secondary school pupils about the use of psychoactive substances and addictions. By allowing life skills mobilization and modifying representations and beliefs about SU, it is aimed at delaying initiation of use of psychoactive substances, preventing adolescents from becoming regular consumers, reducing the risks and harms related to use of these substances, and opening the way for adapted support measures.

We are interested in understanding how, under what circumstances, through which mechanisms, and among which adolescents the EA program works. Therefore, we have developed the ERIEAS study.

Methods and analysis

EA will be conducted in 10 schools. A multi-case approach will be adopted with the aim of developing and adjusting an intervention theory. The study comes under the theory-driven evaluation framework. The investigation methodology will include four stages: i) elaboration of a middle-range theory; ii) data collection for validating/adjusting the theory; iii) data analysis; and iv) refinement and adjustment of the middle-range theory and definition of the program's key functions.

Ethics and dissemination

The study will provide evidence-based results to health authorities to help in the rollout of health promotion strategies in schools. It will provide knowledge about the strategic configurations most suitable for leading to life skills mobilization and change young people's representations about SU. The project will be carried out with full respect of current relevant legislation (e.g. the Charter of Fundamental Rights of the EU) and international conventions (e.g. Helsinki Declaration). It follows the relevant French legislation of the research category

on interventional research protocol involving the human person. The protocol was approved by the Comité et Protection des Personnes (CPP) i.e. Committee for the Protection of Persons CPP SUD-EST VI n°: AU 1525 and was reported to the Agence Française de Sécurité Sanitaire des Produits de Santé (ANSM) i.e. the French National Agency for the Safety of Health Products. It is in conformity with reference methodology MR003 of Bordeaux University Hospital (CNIL n° 2026779v0). This research has been registered on ClinicalTrials.gov (No. NCT04110626). The research project is registered in the European database ID-RCB (No. 2019-A01003-54).

Strengths and limitations of this study:

- Consistent with bottom-up approaches, our study—a realist evaluation based on a natural experiment mobilizing mixed-models methods and a preference stated method (Discrete Choice Experiment [DCE])—is an innovative way to evaluate a complex intervention.
- The conclusions will be highly replicable and will provide a basis for designing other interventions using identified key functions.
- Our study will produce detailed recommendation and further strategies to develop the EA program and adapt it to various contexts.

KEYWORDS

Life skills; Addictions; Adolescents; Program, Realist evaluation; Complex intervention; Prevention; Public health

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INTRODUCTION

Addictive behaviors are major contributors to human morbidity and premature death, with tobacco and alcohol use being the most prevalent addictive behaviors and cannabis the most prevalent "unsanctioned psychoactive drug" used worldwide [1]. Adolescence is a particularly sensitive life stage where tobacco, alcohol, and cannabis are used as a means of learning and taking on roles. Consumption of these substances and their associations with cancer risk, chronic disease, and health conditions have been clearly discussed in the literature [2,3]. As adolescence is a period during which the brain undergoes profound remodeling in a number of areas, alcohol and cannabis consumption can lead to impaired learning ability, memory, and brain development and to difficulties in cognitive control and emotion regulation [4–6].

The WHO defines life skills as abilities for adaptive and positive behavior that enable individuals to deal effectively with the demands and challenges of everyday life [7]. In 2010, Botvin and Griffin reviewed school-based substance use prevention programs that have been tested and proven effective [8]. These programs focus on building drug resistance skills, general self-regulation and social skills, and/or changing normative expectations regarding inaccurate beliefs about the high prevalence of substance use [8]. A major focus is the development of alcohol, tobacco, and cannabis prevention programs for young people that work on these skills and on changing representations about these products and, therefore, their consumption.

Many programs focusing on addiction prevention have been implemented in schools [9,10]. Unfortunately, there are few evidence-based and life skills programs [9,11]. In France, since 2015, the organization Association Ressources et Initiatives Addictions (ARIA, Association for Resources and Initiatives on Addictions), with a clinical psychologist and an addiction psychiatrist, have developed a program called Expériences Animées (EA, Animated Experiences in English) inspired by life skills development programs that have proven to be successful, such as the Life Skills Training program [12], the Unplugged program [13], and the In Media Program [14]. Since January 2020, the Coreadd organization (regional coordination for addiction prevention) has assumed responsibility for the EA Program.

The EA program involves animated short movies and talks with high school and secondary school pupils about the use of psychoactive substances and addictions. Priority is given to high schools in priority education areas and to vocational high schools.

The program draws on the recommendations of Botvin and Griffin [8,15] in terms of theoretical origins, goals, and means. The EA program's overall purpose is to: delay initiation of substance use; prevent adolescents from becoming regular consumers of psychoactive substances; reduce

the risks and harm related to consumption of these products; and open the way for adapted support measures.

The EA program has not been evaluated; to understand how, under what circumstances, through which mechanisms, and among which adolescents this program works, we developed the ERIEAS study ("Evaluation Réaliste de l'Intervention Expériences Animées en milieu Scolaire"; Realist Evaluation of the EA Intervention in Schools).

STUDY OBJECTIVES AND LOCATION

Our study is aimed at evaluating the EA program to set out an intervention theory for the program. To do so, the study has two main objectives:

- First objective: To characterize the effects (Outcomes) on the pupils of high schools in terms of:
    - Tobacco, alcohol, and cannabis use.
    - Consultation with healthcare professionals for problematic substance use.

- Second objective: To characterize the context and mechanisms of action (Mechanisms and Context), and to document the conditions of effectiveness of EA in terms of contextual conditions or mechanisms triggered by the program. That is, to identify the program's key functions [16], which may be contextual conditions or action mechanisms, related to:
    - The pupils' characteristics.
    - The practitioners' characteristics.
    - The design of materials and, in particular, the techniques employed, their use during program sessions, and the activities for teaching staff and parents.
    - The macro- (e.g., classes, schools, cities) and micro- (e.g., supervised short films and talks) intervention environments.

The second objective offers a way to identify the key functions of the EA with a view to transferability (13,14) (i.e., transferring key features and adapting non-key aspects) and comparison of EA with other implemented or transferred programs, such as Unplugged [13].

The EA program takes place in 10 schools (three high schools and seven secondary schools) in the department of Charente in Western France. The ERIEAS study takes place in these 10 schools. It began in January 2019 and will run until December 2022. Inclusion of participants began on September 30, 2019.

METHODS AND ANALYSIS

This report is consistent with the RAMESES II reporting standards for realist interventions (cf. checklist in additional file) [17]. ERIEAS seeks to evaluate the actual impact and the factors involved of the EA program using a realist evaluation. For this purpose, a multi-case approach will be adopted considering each school as a "case"[18,19]. The study adheres to the theory-driven evaluation framework [20–23] where the realist evaluation method and contribution analysis [24,25] are used to explore the effects, mechanisms, and influence of context on the outcomes and to develop and adjust an intervention theory. This case-study method will help to set out the contribution "story": in light of the multiple factors influencing the result, does the intervention contribute to an observed result and in what way? [25].

The study also comes under the rubric of natural experiments in intervention research. This is because the intervention has little standardization and is not undertaken for the purposes of research [26].

Conceptual framework

In realist evaluation, developed by Pawson and Tilley [27], the effectiveness of the intervention depends on the underlying mechanisms at play within a given context. The realist evaluation is about identifying context-mechanism-outcome configurations (CMOs). The aim is to understand how and under what circumstances an intervention works. A middle-range theory (i.e., a theory that is aimed at describing the interactions between outcomes, mechanisms, and contexts) is set out to highlight the mutual influences of intervention and context [28,29]. This approach is linked to the black box paradigm [30] and differs from the experimental paradigm, which evaluates effectiveness without looking at the mechanism by which an intervention works or the influence of the context. Realist evaluation asks whether the intervention worked in a way consistent with its underpinningx theory. The generative causality works on three assumptions [31]: i) an intervention does not work in and of itself, and it is not what produces

an outcome; ii) all interventions trigger a mechanism or a set of mechanisms that produce an outcome; and iii) all interventions are delivered in a context.

Hence, the evaluation is about identifying middle-range theories. Hypothesized and validated by empirical investigations, these CMO configurations help to understand how an intervention brings about change, considering context and target group [28,29]. The recurrence of CMOs is observed in successive case studies or in mixed protocols, such a realist trials [29]. Indeed, to consider context, realist evaluators observe in successive cases what Lawson (quoted by Pawson in 2006 [31]) calls demi-regularities of CMOs (i.e., regular although not necessarily permanent occurrences of an outcome when an intervention triggers one or more mechanisms in a given context) [29]. Studying these recurrences in different contexts allows the isolation of key elements that are replicable in a family of contexts. This gives rise to middle-range theories that become stronger as progress is made through the cases. "These middle-range theories, in certain conditions, predict possible intervention outcomes in contexts different from the one in which the intervention was tested" [29].

Applied to our case

As the realist principle is suitable for studying non-linear interactions in complex systems, we adopted this approach. The intervention under investigation applies to an operational program and it is therefore important to identify its key functions [32,33], i.e., its interventional or contextual components underpinning its effectiveness. This will allow us to hypothesize about 1) the program's effectiveness, 2) its added value compared to other existing programs, and 3) its specificities. Ultimately, it should enable replication [34,35].

Here, each institution involved in the EA program, with its own context, will constitute a case. For each case, the intervention will be studied to identify the mechanisms at play in the given context along with the variation in outcomes. CMO configurations will be identified through analysis of each case. A cross-case analysis will highlight recurrent CMO configurations and thus identify key features for possible replication.

In our study, outcomes are related to using tobacco, alcohol, and/or cannabis and obtaining support from a health professional.

Drawing on the literature and on the experience of professionals delivering the intervention, we will first set out initial middle-range theories [27,31], which we will test in each case (i.e., schools), by collecting qualitative and quantitative data [29].

The mechanisms will be identified qualitatively according to the definition of Ridde et al.: "a mechanism is an element of reasoning and reaction of an agent with regard to an intervention productive of an outcome in a given context" [36,37]; and the definition of Cambon et al.: "What characterizes and punctuates the process of change and hence, the production of outcomes"[16]. The mechanisms will be divided into those related to the session leaders and teachers in attendance and those related to the pupils. For pupils, the literature allows us to define two categories of mechanisms: 1) representations about alcohol, tobacco, and cannabis consumption; and 2) life skills developed/mobilized.

Contextual elements will be included among all the elements collected qualitatively that satisfy the following definition: elements located in time and space that may affect the intervention and the outcomes produced, and whether they relate to the session leaders, teachers, pupils, session delivery, or the operational setting. In a realist approach, interventional elements are part of the context. Therefore, we could distinguish between Ci (for Contextual factors linked to the Intervention) and Ce (for Contextual factors not linked to the intervention, i.e., external factors).

Figure 1 synthesizes the principles of the realist evaluation.

The *Experiences Animées* program

The EA medium: the short-animated movies

The EA program involves showing short-animated movies followed by discussion sessions in high schools about the use of psychoactive substances and, more generally, about all types of addiction. To reach its target audience, the EA program uses short animated films produced by student filmmakers (second-year students at the EMCA animated filmmaking school in Angoulême, France). The films are made specifically for the program, and every year new students are selected to produce new short films.

A filmmaking workshop for students (20 – 26 years old) has been organized by the EA program managers and the EMCA school board every year since 2015. During the 4-day workshop, the students are tasked with looking at the use of psychoactive substances, and their functions, and sharing their thoughts about how people become addicted. They are asked "What do you have to say about it? What would you like to convey to a young audience about this issue?" The

program managers do not intervene in the actual screenwriting and esthetics of the films. At the end of the workshop, the students show their proposals as filmed storyboards. Then, the program managers select several projects for inclusion in the EA program. Some 45 films have been produced since 2015 focusing on subjects such as food and drug addiction, as well as also emotional dependence and bullying. The mean duration of the films is 3 minutes.

Delivery of the sessions

The interventions during the sessions consist of four phases.

- Presentation and instruction: In the first session, session leaders present the program and the instructions to follow during the sessions. After the first session, and at the beginning of each subsequent session, pupils are briefly reminded about the previous session (i.e., what the session leaders noted and remarked) and the instructions. Pupils are then told, "We will watch a short film and then discuss the content together, sharing our thoughts and feelings about what we have seen."

- Film: Two or three films are shown during each session. After watching each film, pupils are encouraged to discuss freely the issues raised. Films are selected by session leaders according to the previous discussion and the specific context of the session.

- Interactions about the films: These include reflective dialogue, sharing thoughts and experiences (experiential approach) with everyone able and willing to contribute. After watching each film, pupils are given time for critical reflection, positioning, reformulating, and summarizing.

- End of the session: At the end of a session, pupils go over the keywords from the session, and summarize what was said.

The sessions are facilitated by two psychologists as session leaders. Their demeanor when delivering the sessions is important. They should act as clinicians who are there to listen, to help pupils reflect on the issues raised, to encourage them to express themselves freely while allowing others to do so, and to facilitate dialogue. A teacher, school nurse, or other staff member from the school also attends the sessions. Classroom tables are arranged in a U shape or in a rectangle (if there are many pupils in the class).

In a given high school, one session per term is delivered for each class, i.e., three film showings (sessions) per academic year.

Study population

Different groups will be followed in the ERIEAS study:

- Pupils: The sample involved in the EA program will be studied. From the 2019/2020 academic year until the 2021/2022 academic year (3 academic years), the EA program will be delivered in 10 institutions (a total of 40 classes and around 1000 pupils).
- Education community members: One teacher whose class is involved in the sessions, the school nurse, and the headmaster, i.e., a total of three people per institution will be interviewed in the study.
- Session leaders: Three persons will be interviewed.
- Funders: Three funders will be interviewed.

The inclusion criteria will be:

- For pupils:
    - Pupils from the 10 secondary and high schools involved in the EA program, in 7th grade and 10th grade in the 2019/2020 academic year, willing to participate and whose parents/guardians have given consent for the child's participation.
    - Pupils of these 10 schools who will enter 8th grade and 11th grade in September 2020, and 9th grade and 12th grade in September 2021 who are willing to participate and whose parents/guardians have given consent for the child's participation.
- For education community members, session leaders, and funders: willingness to participate.

The only exclusion criteria will be to be under legal protection.

Patient and Public Involvement

The ERIEAS study does not include any patient or public involvement in terms of setting research priorities, defining research questions or outcomes, providing input into the study

design, or disseminating the results. The research participants will be called on to answer questionnaires or interviews.

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Study design

According to theory-driven evaluation methodology [20–23], the study will be composed of four stages, as outlined in Figure 2.

Stage 1 – Literature analysis

The first stage involves a literature analysis to design and adapt investigation tools and contribute to elaboration of the initial middle-range theories (stage 2).

A review has been conducted to identify strategies that are effective in school settings in helping pupils to change their representations of alcohol, cannabis, and tobacco use, and to develop or mobilize life skills to prevent addiction. The data sources used were: PsycInfo, PsycArticles, Psychology and Behavioral Sciences Collection, SocIndex, Cairn, and Web of Sciences.

The keywords were "life skills" and ["adolescents" or "young adults" or "teenagers"]. The inclusion criteria were: English or French language publications from 2014 to 2019; original or methodological articles focusing on the evaluation or exploration of intervention techniques applied to school settings; interventions aimed at changing representations; life skills as a way of delaying experimentation with alcohol, tobacco, and cannabis, and reducing their use.

Using the software Covidence®, two researchers conducted a double-blind review of the selected reports and extracted information regarding the intervention (name, location, population, design), the evaluation design (method, main and second outcomes), the result of the intervention, its key functions and context of implementation. The purpose of this review was to extract information about the contexts, mechanisms, and outcomes that were the focus of our study. Our analysis questions were: What are the most effective intervention techniques? What representations and skills are they effective for? What contextual conditions influence the effectiveness of the techniques?

The results have been used to design and adapt our tools (questionnaire, interview, and observation grids, scorecards) and will be used for the initial development of middle-range theories (stage 2). Review results will be presented in a separate paper.

Stage 2 – Data collection and elaboration of the initial middle-range theories

Stage 2 involves data collection to appraise the outcomes, mechanisms, and contextual elements (including the techniques). There will be two rounds of data collection. The first round of data collection will help to elaborate initial middle-range theories (to establish how the intervention works in context) together with the results of the literature analysis from stage 1. The second round of data collection will contribute to verifying the initial theories (contribution analysis). Table 1 shows the variables that will be collected and the manner of collection.

To collect data, the following tools will be used:

- A questionnaire to collect data on mechanisms and outcomes on pupils at T0 (1st round) and T1 (2nd round).

It will contain: descriptive variables (gender, age, socio-professional category of parents); questions on tobacco, alcohol, and cannabis use; a question relating to the "use of support services"; questions related to knowledge and perception of tobacco, cannabis, and alcohol use; and scales assessing peer pressure and life skills.

This questionnaire will be administrated twice, at T0 (i.e., at the end of September/beginning of October 2019) and T1 (June 2022) to all pupils participating in the ERIEAS study. Table 2 lists the questions/scales and their previous use in other studies.

- Pupil interviews: (IP1&IP2)

A total of 160 pupil interviews will be conducted during the study in two sessions.

  - The first session of non-directive interviews will be held in November/December 2019 (IP1). These interviews will collect contextual factors, mechanisms, and outcomes on pupils (IP1), and help to elaborate the initial middle-range theories. In the first academic year, two pupils per class will be randomly selected and interviewed, until saturation (i.e., when the collected data do not add anything new to the understanding of the research topic), meaning at least 80 pupils will be surveyed.

These interviews will collect large amounts of information allowing the elaboration of the second round of interviews with pupils (IP2) and assist the configuration and design of a questionnaire including a Discrete Choice Experiment (DCE) set of questions.

  - The second session of interviews will validate CMO configurations in pupils (IP2). At the end of the second academic year (June 2021), a session of semi-directive interviews with pupils will be held (80 pupils randomly selected, and different from

those of the previous session). This qualitative material may validate the framework expressed through the initial middle-range theory (CMO configurations). For each hypothesized configuration in the initial middle-range theories, there will be an open-ended question that will not allow the respondent to be guided by the expected answer (presence or absence of C and/or M).

- Professionals' and EA session leaders' interviews (IE1& IE2)

Semi-structured interviews with the education community and among the session leaders will collect information on mechanisms and contextual factors related to school. Three session leaders and three people per institution will be surveyed: a nurse, the headmaster, and a teacher whose class is involved in the intervention. Interviews will be held twice: at the end of the first academic year (June 2020) and at the end of the 3-year intervention period (June 2022). A total of three session leaders and 30 professionals will therefore be interviewed at each session. In total, 66 interviews will be performed.

This first session of semi-directive interviews will help to elaborate the initial middle-range theories, to design the second round of interviews (IE2), and to configure and design the DCE questionnaire. The second session of semi-directive interviews may validate the framework expressed through the initial middle-range theory.

- Funders of the program interviews (IF).

Semi-directive interviews with funders of the program will collect information related to context parameters (Ce exclusively). A total of three funders will be interviewed once, in October 2019. These interviews will help to elaborate the initial middle-range theories.

- Observation of the sessions

The objective is to collect the following contextual elements, specific to each institution: the intervention climate within the institution and in each class, the reception given by the school staff as a whole, the conditions of session delivery, the motivation levels of the session leaders and teachers in attendance, and the characterization of the feedback and sharing sequences (spatial organization, relations between pupils/session leaders/others).

Observations of at least two sessions per institution will be conducted in each academic year. Twenty sessions per year will therefore be observed, making a total of 60 observations over the 3-year intervention period. Furthermore, the session leaders of non-observed sessions will produce a report following a reporting grid.

Before the program starts (in mid-October 2019), each program presentation for the school staff has been observed, thus adding 10 observation sessions. A total of 70 observation sessions will therefore take place during the study.

- Scorecard to collect institution characteristics (contextual elements, Ce)

Data related to the characteristics of the institutions will be collected from the education authorities using a scorecard: level of urbanization of the town or city where the institution is located (urban, quasi-urban, quasi-rural, rural), the deprivation index of the school area (FDep index from Rey et al., 2009 [38]), the number of pupils, male/female ratio, number of repeaters per institution, the availability of a nurse, the type of institution (general/vocational, priority education areas), the proximity to a center for young substance users and its availability, where appropriate, the occurrence of occasional awareness campaigns on addiction in the institution, and having been previously involved in the EA program.

- DCE questionnaire

The questionnaire will have variables based on a stated-preference method [39], known as DCE [40]. It will enable us to gain a better understanding of the pathway and the circumstances and determinant combinations that could trigger initiation, maintenance, or re-engagement of consumption of alcohol, tobacco, and/or cannabis use. It may help to validate the final middle-range theories i.e. the CMO configurations.

Figure 3 presents the different modalities of data collection.

Figure 4 presents the data collection timelines.

Survey instruments: questionnaires, interview guides, observation logs, and observation checklists have been designed, consistent with the results of literature analysis (stage 1) and will be pre-tested.

Using quantitative analyses, the following outcomes will be identified at baseline and after nine EA sessions:

- Tobacco, alcohol, and cannabis use: current frequencies of tobacco, alcohol, and cannabis consumption (every day/week/month, rarely, never); number of episodes of heavy drinking (at least 5 drinks per occasion) in the last 7 days/30 days/12 months; number of episodes of drunkenness in the last 7 days/30 days/12 months.

- Consultation with a healthcare professional to discuss problematic use of alcohol and/or tobacco and/or cannabis (number of times in the last 12 months).

At this stage, the literature review will have helped to identify some of the mechanisms and contextual elements that could lead to greater effectiveness of an intervention. These factors need to be confirmed during the second stage (i.e., seminar and elaboration of the initial middle-range theories). Here, we present the potential M and C we aim to investigate at this stage of the study:

- Representations and attitudes [41]: normative expectations or perceived norms about use, intentions, refusal and resistance skills, risk-related attitudes and behaviors, positive and negative beliefs about consequences, reasons to use, and perceived peer influence and friends' use.

- Life skills: ability to mobilize self-management skills (self-esteem, problem-solving abilities, reducing stress and anxiety), general social skills (overcoming shyness, communicating clearly, building relationships), and drug resistance skills (defenses against pressures to use alcohol and other drugs, identify the consequences of substance use, risk-taking, and the influences of the media).

Both of these mechanisms have been shown in the literature to be effective in terms of addiction prevention [7,8]. Here, we use the definition of Cambon et al.: "What characterizes and punctuates the process of change and hence, the production of outcomes"[16]. In this definition, a mechanism can be psychological (motivation, self-efficacy, self-control, skills, etc.) or social (values shared in a community, power sharing perception, etc.).
Table 1 presents the details of the expected/ hypothesized contexts and mechanisms and the time and modalities of collection.

Stage 3 - Data analysis

Data analysis will include analysis of each case (each school) and a cross-case analysis allowing us to compare and see potential effects of some contexts. The analysis will answer the question: In what contextual conditions and through which mechanisms does the EA program produce outcomes? The validation of initial middle-range theories (CMOs) will allow us to answer the question. This validation will combine and compare data from quantitative and qualitative analyses in monographs (analysis of each case (institution)) and by cross-case analysis (analysis comparing these cases). We will combine a QUAN/QUAL design [42] to use quantitative and

qualitative approaches in tandem, to provide new insights and a more refined approach. This analysis will identify the recurrent CMOs that will therefore be replicable.

- Quantitative data (from T0 and T1 questionnaires): Analyses of the evolution of mechanisms and outcomes

A first descriptive analysis will be conducted on the representations, mobilization of life skills, tobacco, alcohol, and cannabis use, and the use of support services at each measurement point. Trajectory modeling will be performed using latent class growth modeling to study changes in representations, life skills, product use, and use of support services between the two questionnaires. The analysis will be adjusted according to the characteristics of the pupils (age, gender, socio-professional category of parents) and institutions (level of urbanization, index of social disadvantage, number of pupils, male/female ratio, number of teacher per institution, proximity to a center for young substance users/nurse availability, earlier involvement in the EA program, involvement in occasional awareness campaigns on addiction, type of institution). This analysis will enable verification of the program's impact in context across all the pupils by studying the changes between the two collection times (i.e., before and after nine sessions of EA). As some of the variables used here are the same as for the Life skills Training ST [43] and Unplugged [13] programs, the findings will be compared and contrasted with these programs conducted in the Nouvelle-Aquitaine region.

- Qualitative data

The qualitative data can be divided in two groups (i.e., for the two rounds), with different uses and aims. The first interview sessions and observations (i.e., IP1, IF, IE1, scorecard and first observations) will be utilized to set the frame of the initial middle-range theories. Following this first set of qualitative investigations, a 2-day seminar will be organized to set out the initial middle-range theories. The aim of this seminar will be to discuss the findings of the literature review and the first round of data collection. This seminar will be interdisciplinary, and will involve epidemiologists, prevention experts, addiction experts, psychiatrists, psychologists, sociologists, EA session leaders, and Coreadd staff. Drawing on the participants' experiences, the literature review, the observations, and the interviews, the seminar will enable us to set out hypotheses about the mechanisms (M) linking Ci and Ce to the outcomes.

The second set of qualitative investigations (i.e., IP2, IE2 and lasts observations) will be utilized to validate the final middle-range theories.

All the qualitative data (i.e., data collected from pupils, funders, professionals' interviews, and observations) will be examined by content analysis [44], which refers to "a set of techniques for systematically and objectively analyzing and describing the content of communication. The aim is to obtain indicators allowing inferences to be made about the messages and how they are produced and received (inferred variables)". Content analysis encodes, classifies, and ranks the communications to examine patterns, trends, or distinguishing features; in our case, the recurrence of C-M-O configurations in each case (institution) and by cross-case analysis.

- Quantitative data from DCE questionnaires: analyses of DCE questionnaires

A DCE will be used to: i) understand combinations of circumstances and determinants that impact the decisions of teenagers to start substance use and/or prevent them from cessation and/or lead them to relapse; ii) validate CMO configurations.

All previous materials collected and analyzed will be utilized to identify attributes and potential scenarios.

The DCE will allow quantification of the weights individuals attach to various attributes of a situation to finally predict their independent impacts on decisions. In other words, the DCE approach will allow analysis of individual stated preferences in response to hypothetical choices and will enable estimation of the relative importance of each level of attribute during the decision-making process. When presented with hypothetical options (i.e., choice scenarios) that describe alternative specifications of a situation, it is assumed respondents will choose the behavior that they would most likely adopt. The higher a respondent's preference for a certain attribute level, the more likely they are to choose that scenario over any alternative. This method will allow the researcher to highlight situations and configurations allowing the implementation of life skills. Mixed logit models will be used to establish whether the attributes' levels presented in the scenarios are statistically significant predictors of adolescents' choices.

- Combination of quantitative and qualitative data

The ERIEAS study will combine quantitative and qualitative methods to achieve mixed methods research. This study has a multiphase design with first data collection combining QUAN (T0) + QUAL (i.e., IP1, IF, IE1, scorecard and firsts observations). These first data will contribute to and guide a second qualitative phase (i.e., IP2, IE2) and the DCE questionnaire elaboration by identifying some C, M, O and, possibly, certain configurations for investigation. This design seemed to be particularly relevant as it allows flexibility to address a set of research questions that will arise from the separate parts of the study.

The CMO configurations obtained from the qualitative data will be compared with those obtained from the DCE questionnaire. All these CMO configurations will be discussed during a 1-day seminar in stage 4, which will lead to a complete analysis of the EA complex intervention.

Stage 4 - Refinement and adjustment of the middle-range theories, and definition of the program's key functions

The different modalities of investigation and analysis will allow us to progressively refine the middle-range theories. We will compare the primary theories with the CMO configurations observed in each institution and the recurrent CMOs to consolidate and adjust the initial middle-range theories. Furthermore, the DCE questionnaire will allow the research team to formulate strong hypotheses about the triggers involved in initiating, maintaining, or re-engaging in consumption of alcohol, tobacco, and/or cannabis among adolescents and the impact of the EA intervention.

The material will be synthetized and used to refine and adjust the final middle-range theories and the program's key functions. This work will be conducted during a second seminar (1 day) with the whole project team, i.e., the researchers, EA professionals, and Coreadd staff members.

The team will carry out the following activities:

- Definition of the EA program's key functions (configurations underpinning the program's success).
- Comparison with the elements used in other addiction prevention programs designed to develop life skills, such as the LST program [43] and Unplugged [13].
- Exploration of further strategies to complete the EA program wherever this is necessary to ensure optimal outcomes.
- Drafting of detailed recommendations 1) to scale-up the EA program's key functions to other areas with other stakeholders, and 2) for a quasi-experimental large-scale evaluation of the program (where only the key functions will be retained and freely adapted) if required (judgment criteria may not be precisely determined at this stage).

ETHICS AND DISSEMINATION

This article describes a protocol using a realist design to understand how an innovative prevention program works, and what contexts, mechanisms, and outcomes are involved in this intervention. Realist evaluation is a valuable approach that highlights the triggers of an intervention and guides its transferability.

The project will be carried out in full accord with current relevant legislation (e.g., the Charter of Fundamental Rights of the EU) and international conventions (e.g., Declaration of Helsinki). It follows the relevant French legislation on interventional research protocols involving the human person (Jardé law, category 3 research on prospective data). The methods development, data collection, and analysis will take into account the following issues:

- Anonymity of study respondents will be preserved and ensured at all times. Unnecessary collection of personal data will be avoided, and respondents will have the right to review outputs and withdraw consent. All personal data will be coded, removed from the data for analysis and stored separately. Only designated research staff will have access to the keys linking the data with the personal information.

- Information regarding the study and the right to refuse to participate will be distributed to all study participants and their parents or guardians and, in the case of refusal, alternative means of data collection will be explored (e.g., alternative respondents).

The protocol was approved by the Comité et Protection des Personnes (CPP) i.e., Committee for the Protection of Persons CPP SUD-EST VI No. AU 1525 and was reported to the Agence Française de Sécurité Sanitaire des Produits de Santé (ANSM) i.e., the French National Agency for the Safety of Health Products. It is in compliance with reference methodology MR003 of Bordeaux University Hospital (CNIL No. 2026779v0).

This research has been registered on ClinicalTrials.gov (No. NCT04110626).

The research project is registered in the European database ID-RCB (No. 2019-A01003-54).

This research has received funding from a national recognized research agency; the INCa. This funding has been obtained via a national competitive peer review grant application process, named “2018 Call for projects- Population health intervention research: Addressing all dimensions of cancer control”.

From a research viewpoint, our proposed methodology is consistent with the bottom-up approaches advocated in health promotion, starting with a real-world response to a pressing

problem [45]. As this approach allows better reflection of stakeholders' views and concerns, and makes external validity workable, it therefore becomes a preferable alternative for evaluation of health promotion or programs [45]. Our study is a realist evaluation based on a natural experiment mobilizing mixed-model methods and a preference stated method. Therefore, it is an innovative way of studying the process of a complex intervention [46]. Due to its specific methodology and large sample size, this study will provide strong and detailed information regarding consumption of tobacco, alcohol, and cannabis among young people and their representations of the consumption of these products. Utilizing the stated preference methods, this study will highlight how pupils use their competences and life skills in relation to addictive products.

Our study has some limitations related to its design. First, even if our study provides insights into pupils' behaviors before and after the intervention it will not allow us to take into account all factors that may play a part in the consumption of psychotropic agents in adolescence. Nevertheless, the two rounds of quantitative data acquisition and the large amount of qualitative data collected will provide a better understanding of how such an intervention could have an impact on consumption and perceptions regarding psychotropic agents. Second, our results are declarative and the ERIEAS study will not use any kind of biological or medical information. Even if declarative data could lead to underestimation, the use of an auto-administered questionnaire on drug consumption would reduce this under-declaration [47].

Tobacco, alcohol, and cannabis consumption among adolescents constitute a worrying trend, especially in France [48–51], and interventions aimed at prevention should be tailored to this specific population. This study will explain and pinpoint the precise impacts of the EA program and the conditions for this impact. It will allow definition of the EA program's key functions and how they work in different contexts and, possibly, how they could be adapted in form. We will be able to compare and contrast the program with other programs being implemented in France, with a view to creating fine adjustments of solutions for optimal outcomes. Finally, guidelines will be set out, to implement EA elsewhere. The conclusions will be highly replicable and offer a basis for designing other interventions using identified key functions. We will publish different papers describing the addictive behaviors of this population, and then go on to analyze the impacts and key functions of the EA program. We will eventually focus on what triggers consumption of psychotropic agents among young people exposed to a prevention program. Finally, a report on the study will provide health authorities with evidence-based results to help with the rollout of health promotion policies in schools. In conclusion, this

project will be of great interest to policy-makers, authorities, and field professionals involved in the substance use prevention and health promotion sector.

Figure legends:

Figure 1: The realistic approach and the way to refine middle range theories applied to ERIEAS study.

Figure 2: Stages of the ERIEAS study

Figure 3: Different modalities of data collection and their links with the middle-range theories

Figure 4: Timeline of the data collection

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Data statement

Not applicable

Authors' contribution

JMF and AA drafted this article and all authors revised the manuscript. The project design was developed by LC. JMF, AA, EM, RG, MT, LM, LM, VD and FA were involved in implementing the project and in developing the evaluation design, under the supervision of LC. All authors read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interests.

LIST OF ABBREVIATIONS

ANSM: "Agence Française de Sécurité Sanitaire des Produits de Santé"; the French National Agency for the Safety of Health Products

ARIA: "Association Ressources et Initiatives Addictions"; Association for initiatives and resources addictions

Coreadd: Regional coordination for addiction prevention

Ce : Contextual factor not linked to the intervention

Ci : Contextual factor linked to the intervention

CMO: Context – Mechanism – Outcomes

CPP: “Comité de Protection des Personnes”; Committee for the Protection of Person

DCE : Discrete choice experiment

EA: “Expériences Animées”; animated experiences

ERIEAS: “Evaluation Réaliste de l’Intervention Expériences Animées en milieu Scolaire”; Realist evaluation of the EA intervention in schools

LST: Life skills training

TDE: Theory driven evaluation

Table 1: Mechanisms data (M) expected and time of collection

MECHANISMS				
Mechanisms	Variables	Data collection	Time collection	Population
Representations about drinking, tobacco and cannabis use; and what influences it	• Representations about drinking, tobacco and cannabis use • The role of social influence on consumption (initiation and use) • The short-term effects of use and abuse • User rates among adolescents • Portrayal of drinking, tobacco and cannabis use: parties, fitting in, being accepted • Social acceptability of drinking, tobacco and cannabis use • The role of peers • The role of the media in encouraging alcohol, tobacco and cannabis use.	Non-directive interviews (IP 1+IP2) (160) Questionnaires T0, T1	During the 2 first academic years (September 2019 to June 2021) September 2019 and June 2022	At least 80 pupils the first 2 years randomly selected (i.e. 2 per class and 8 per establishment/year) Q : 1000 pupils / wave

Life skills for preventing addiction including tobacco, alcohol and cannabis use, and activated / mobilized through the sessions	• Personal self-management skills : self-esteem, problem-solving abilities, reducing stress and anxiety • General social skills: overcoming shyness, communicating clearly, building relationships • Drug resistance skills: defenses against pressure to use alcohol, cannabis and other drugs, identify the consequence of substance use, risk-taking and the influence of the media	Non-directive interviews (IP1+IP2) (160)	During the 2 first academic years (September 2019 to June 2021)	At least 80 pupils the first 2 years randomly selected (i.e. 2 per class and 8 per establishment/year)
		Questionnaires T0, T1	September 2019 and June 2022	1000 pupils / wave

Contextual data (related to *Expériences Animées* intervention - Ci)

Variables	Data collection	Time collection	Population
• Intervention climate within the establishment • Conditions of session delivery • Characterization of the feedback and sharing sequences (spatial organization, relations between pupils/session leaders/others)	Non-directive interviews (IP1+IP2) (160)	During the 2 first academic years (September 2019 to June 2021)	At least 80 pupils the first 2 years randomly selected (i.e. 2 per class and 8 per establishment/year)

• Intervention climate within the establishment • Reception given by the school staff as a whole • Conditions of session delivery • Motivation levels of the session leaders and teachers in attendance • Characterization of the feedback and sharing sequences (spatial organization, relations between pupils/session leaders/others)	Observations (70)	September 2019 to June 2022	Program presentation for the school staff when the program starts (1 presentation per establishment) And at least 2 observation sessions per establishment and per year
	Reports by session leaders for those sessions that are not observed		Reports for all the sessions that are not observed
	Semi-structured interviews (IE1+IE2) (66 interviews at all)	June 2020 and June 2022	3 education professionals per establishment (the nurse, the headmaster, a teacher whose class is involved in the intervention) (30 interviews) and 3 session leaders: the same people in 2020 and in 2022

Contextual data (operational setting - Ce)

Public	Variables	Data collection	Time collection	Population

Pupils	Characteristics • Acceptability • Acceptation of the intervention • Their role in it, support or not toward the intervention • Opinion about the intervention and its effects on pupils Facilitating/ limiting factors of change	Non-directive interviews (IP1+IP2) (160)	During the 2 first academic years (September 2019 to June 2021)	At least 80 pupils the first 2 years randomly selected (i.e. 2 per class and 8 per establishment/year)
Session leaders and education professionals	Characteristics • Acceptability • Acceptation of the intervention • Their role in it, support or not toward the intervention Opinion about the intervention and its effects on pupils	Semi-structured interviews (IE1+IE2) (66 interviews at all)	June 2020/2022	3 education professionals per establishment (the nurse, the headmaster, a teacher whose class is involved in the intervention) (30 interviews) and 3 session leaders : the same people in 2020 and in 2022
Establishments	Characteristics • Type of establishment (general/vocational, priority education areas – yes/no-)	Scorecard from the education authorities	September 2019	Every establishment included in *Expériences Animées*

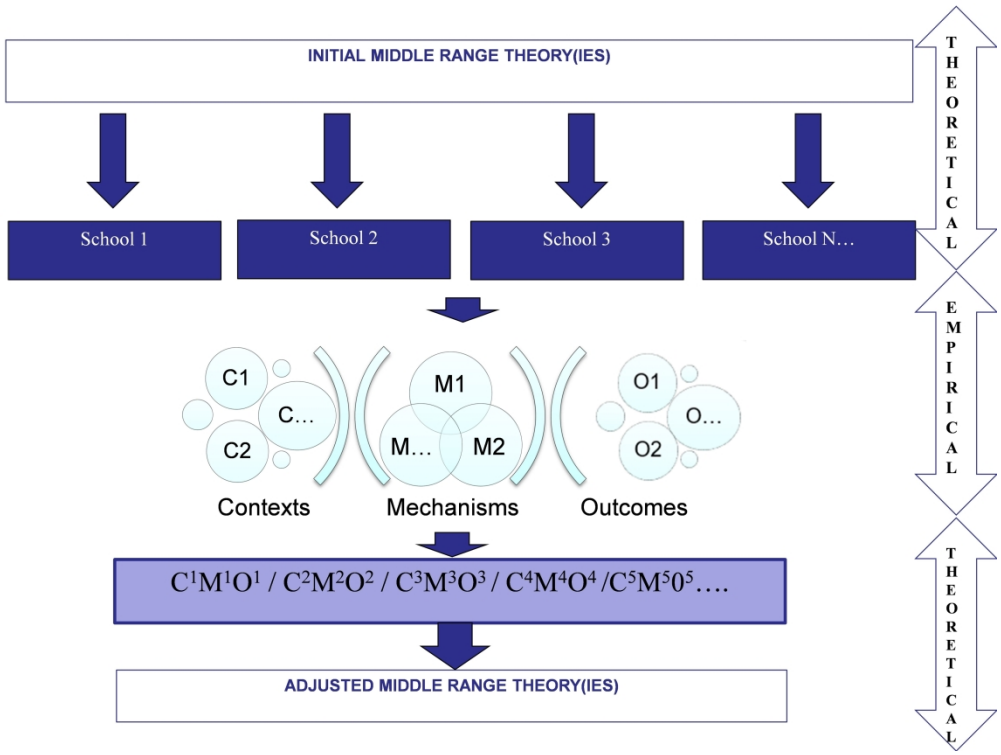
	• Level of urbanization of the town or city where the establishment is located • Deprivation index of the school area • Number of pupils, male/female ratio, number of repeaters per establishment • Proximity to a center for young substance users and availability rate where appropriate • Availability rate of the nurse • Establishments already involved in Expériences Animées in previous years (yes/no) Occasional awareness campaigns on addiction in the establishment (yes/no)			
Expériences animées funders	Characteristics • Acceptation of the intervention • Opinion about the intervention and its effects on pupils • Interest about *Expériences animées* Facilities and difficulties to fund *Expériences Animées*, barriers and facilitators	Semi-structured interviews (IF) (3)	September 2019	3 people from the funding organization of *Expériences Animées*

Table 2: Sources of questions included in T0 Questionnaire

SURVEY ITEMS	REFERENCE
General characteristics	
Sex, Age	-
Geographic Environment	-
	-
	-
Family environment	HBSC
	HBSC
	HBSC
	HBSC
	HBSC
Socio-economic situation	-
	-
School climate	HBSC/Unplugged
Substance consumption and health care use	
Use of support service	-
Alcohol consumption	HBSC (modified)
	HBSC (modified)
Heavy drinking episodes	HBSC (modified)
	HBSC (modified)
	ESPAD (modified)
Cannabis consumption	HBSC (modified)
	-
Tobacco consumption	HBSC (modified)
	-
	Unplugged
Representations about substance use and influences	
Social influences	
Cannabis	EROPP
	EMCDDA (modified)
	EMCDDA (modified)
Alcohol	ISRD (modified)
	ISRD
	EMCDDA (modified)
	EMCDDA (modified)
Tobacco	EMCDDA (modified)
	EMCDDA (modified)
Beliefs in consequences	

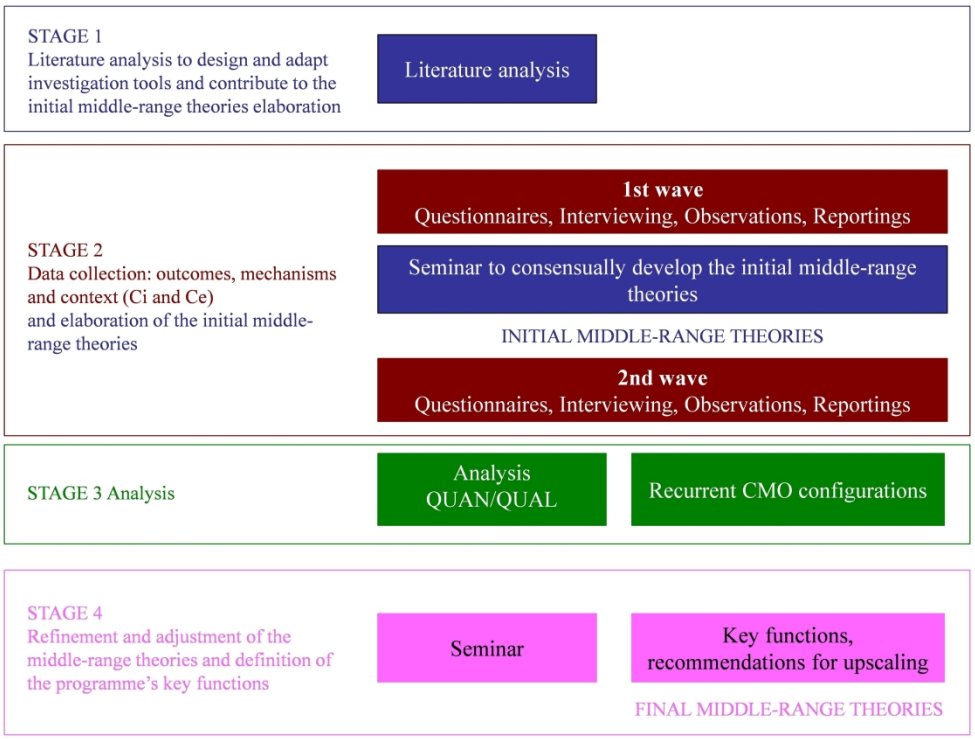
	Unplugged/emcdda
Alcohol	(modified)
Cannabis	Unplugged (modified)
Portrayal of use	
Alcohol	DMQ-R
Cannabis	DMQ-R
Knowledge	
Alcohol	EROPP (modified)
	EROPP (modified)
Cannabis	EROPP
	EROPP
	Unplugged/Emcdda
History of effects of use and abuse	(modified)
	-
Life Skills	
Peer pressure resistance	Unplugged
	Peer pressure Inventory
	Unplugged
Decision making and problem solving ability	Unplugged
Creative and critical thinking	Unplugged
Communication and interpersonal skills	Unplugged
Self awareness and empathy	Unplugged
Assertiveness	Unplugged
Coping with emotion and stress ability	Unplugged

HBSC, Health Behavior n School-Aged Children; ESPADD, European School Survey on Alcohol and Other Drugs; EROPP, Enquête sur les Représentations, Opinions et Perceptions relatives aux Psychotropes i.e. Survey on Representations, Views and Perceptions of Psychotropic Drugs; ISRD, International Self Report Delinquency; EMCDDA, European Monitoring Centre for Drugs and Drug Addiction; DMQ-R, Drinking Motives Questionnaire, Revised.



The realistic approach and the way to refine middle range theories applied to ERIEAS study.

381x285mm (300 x 300 DPI)



Stages of the ERIEAS study.

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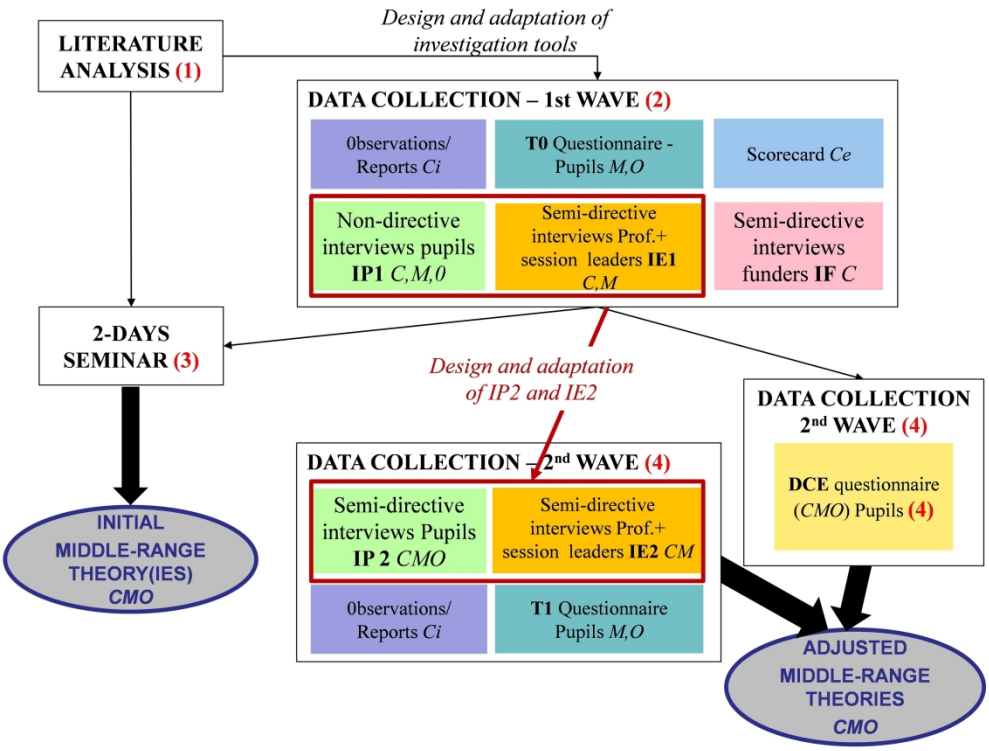
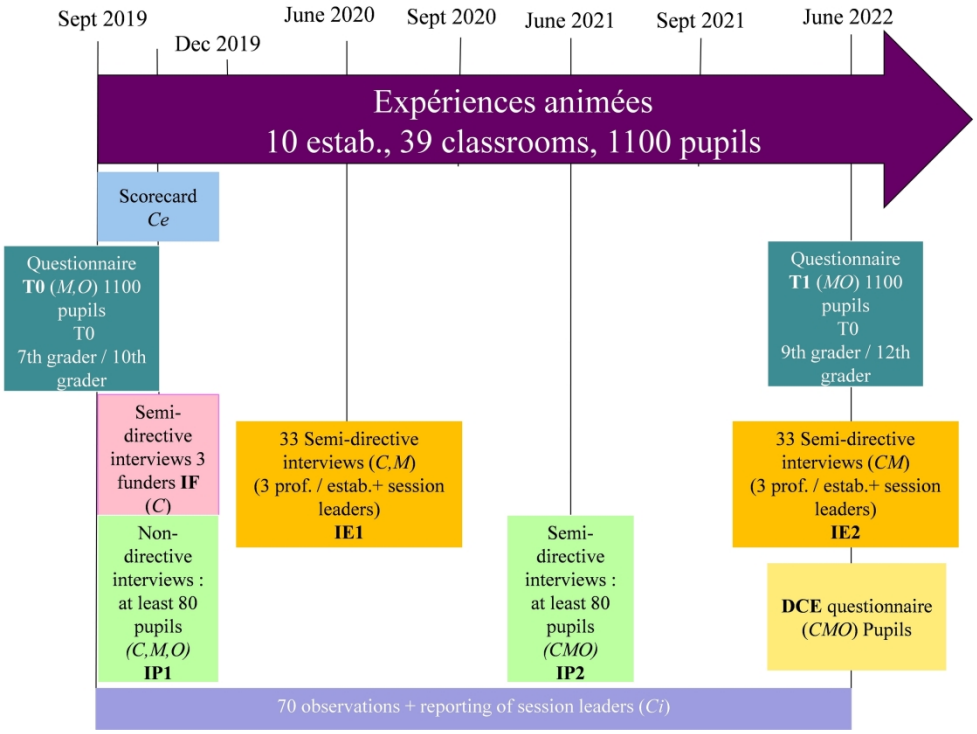


Different modalities of data collection and their links with the middle-range theories.

254x190mm (300 x 300 DPI)



Timeline of the data collection.

254x190mm (300 x 300 DPI)

		TITLE	Reported in document Y/N/Unclear	Page(s) in document
1		In the title, identify the document as a realist evaluation	Y	1
SUMMARY OR ABSTRACT				
2		Journal articles will usually require an abstract, while reports and other forms of publication will usually benefit from a short summary. The abstract or summary should include brief details on: the policy, programme or initiative under evaluation; programme setting; purpose of the evaluation; evaluation question(s) and/or objective(s); evaluation strategy; data collection, documentation and analysis methods; key findings and conclusions Where journals require it and the nature of the study is appropriate, brief details of respondents to the evaluation and recruitment and sampling processes may also be included Sufficient detail should be provided to identify that a realist approach was used and that realist programme theory was developed and/or refined	Y	2
INTRODUCTION				
3	Rationale for evaluation	Explain the purpose of the evaluation and the implications for its focus and design	Y	4
4	Programme theory	Describe the initial programme theory (or theories) that underpin the programme, policy or initiative	Y	4
5	Evaluation questions, objectives and focus	State the evaluation question(s) and specify the objectives for the evaluation. Describe whether and how the programme theory was used to define the scope and focus of the evaluation	Y	5
6	Ethical approval	State whether the realist evaluation required and has gained ethical approval from the relevant authorities, providing details as appropriate. If ethical approval was deemed unnecessary, explain why	Y	2 and 22
METHODS				
7	Rationale for using realist evaluation	Explain why a realist evaluation approach was chosen and (if relevant) adapted	Y	8
8	Environment surrounding the evaluation	Describe the environment in which the evaluation took place	Y	6
9	Describe the programme policy, initiative or product evaluated	Provide relevant details on the programme, policy or initiative evaluated	Y	9
10	Describe and justify the evaluation design	A description and justification of the evaluation design (i.e. the account of what was planned, done and why) should be included, at least in summary form or as an appendix, in the document which presents the main findings. If this is not done, the omission should be justified and a reference or link to the evaluation design given. It may also be useful to publish or make freely available (e.g. online on a website) any original evaluation design document or protocol, where they exist	Y	12
11	Data collection methods	Describe and justify the data collection methods – which ones were used, why and how they fed into developing, supporting, refuting or refining programme theory Provide details of the steps taken to enhance the trustworthiness of data collection and documentation	Y	13-18
12	Recruitment process and sampling strategy	Describe how respondents to the evaluation were recruited or engaged and how the sample contributed to the development, support, refutation or refinement of programme theory	Y	11
13	Data analysis	Describe in detail how data were analysed. This section should include information on the constructs that were identified, the process of analysis, how the programme theory was further developed, supported, refuted and refined, and (where relevant) how analysis changed as the evaluation unfolded	Y	18-20
RESULTS				
14	Details of participants	Report (if applicable) who took part in the evaluation, the details of the data they provided and how the data was used to develop, support, refute or refine programme theory	Y	17 AND 28-33
15	Main findings	Present the key findings, linking them to contexts, mechanisms and outcome configurations. Show how they were used to further develop, test or refine the programme theory	y	20
DISCUSSION				
16	Summary of findings	Summarise the main findings with attention to the evaluation questions, purpose of the evaluation, programme theory and intended audience	y	21
17	Strengths, limitations and future directions	Discuss both the strengths of the evaluation and its limitations. These should include (but need not be limited to): (1) consideration of all the steps in the evaluation processes; and (2) comment on the adequacy, trustworthiness and value of the explanatory insights which emerged In many evaluations, there will be an expectation to provide guidance on future directions for the programme, policy or initiative, its implementation and/or design. The particular implications arising from the realist nature of the findings should be reflected in these discussions	y	22
18	Comparison with existing literature	Where appropriate, compare and contrast the evaluation's findings with the existing literature on similar programmes, policies or initiatives	NOT APPLICABLE	
19	Conclusion and recommendations	List the main conclusions that are justified by the analyses of the data. If appropriate, offer recommendations consistent with a realist approach	NOT APPLICABLE	
20	Funding and conflict of interest	State the funding source (if any) for the evaluation, the role played by the funder (if any) and any conflicts of interests of the evaluators	Y	26