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**OUTCOME EVALUATION OF
SCHOOL-BASED ALCOHOL PREVENTION.
A EUROPEAN MULTI-CENTRIC TRIAL
(EU-DAP STUDY)**

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ABSTRACT

Background: Curricula aiming at preventing substance use are widespread in European schools, without formal evaluation of their effectiveness. Promising programmes based on the Comprehensive Social Influence (CSI) model have never been evaluated in Europe.

Aim: The overall aim of this thesis was to advance knowledge on the effectiveness of school-based best practice programmes on adolescents' alcohol use, as well as to elucidate the possible pathways to behavioural changes.

Methods: A cluster randomized controlled trial was carried out in 143 schools from seven European countries, involving 7079 students 12-14 years of age. Schools were randomly assigned to either control or to a 12-session standardised curriculum based on the CSI model, taught by trained teachers. Randomisation was blocked within socioeconomic levels of the school neighbourhood. Students were surveyed through a self-completed anonymous questionnaire at baseline, 6 (short term) and 18 (medium term) months thereafter. The effect of the programme on alcohol-related cognitive factors (intention to drink and to get drunk, knowledge on alcohol-related effects, skills to resist pressure to drink alcohol, normative beliefs, expectations and risk perceptions concerning alcohol) was analysed at the short term follow-up, on alcohol consumption and problematic use at the medium term. Additionally, the effect of some class characteristics on programme implementation was studied using the intervention classes as units of analysis. Given the hierarchical structure of the data all data analyses were carried out using multilevel models.

Results: The programme was associated with decreased positive expectations towards alcohol (odds ratio (OR)=0.81) and perception of peer drinking (OR=0.79), as well as with increased resistance skills against pro-alcohol pressures (OR=1.21) and knowledge (OR=2.25) at the short term follow-up. One year later the programme was associated with a decreased odds of reporting episodes of drunkenness (OR=0.79) and alcohol-related problematic behaviours (OR=0.78). There was no reduction in the frequency of alcohol use but non-drinkers and occasional drinkers at baseline progressed towards frequent drinking less often in the intervention group than in the control group. Associations were stronger among students from schools located in area of low socio economic level. Some characteristics of the class predicted the level of programme implementation: prevalence of substance use was associated with a decreased odds of implementing the programme in its entirety (OR=0.81), while students' connectedness was associated with an increased odds of teachers using role-play (OR=1.52).

Conclusions: School curricula based on the CSI model can modify cognitive factors for alcohol use and reduce occurrence of drunkenness and alcohol-related behavioural problems among students from European Countries. These programmes are likely to be particularly useful in socially disadvantaged areas. There was support for the hypothesis that resistance skills, norm perception and positive expectations may mediate the effect of school prevention on behavioural outcomes. Specific organizational strategies such as teachers' training in class management techniques may be integral to the provision of this type of programmes, in order to improve their implementation.

LIST OF PUBLICATIONS

This thesis is based on the following papers, which will be referred to in the text by their Roman numerals I-IV.

- I. Caria MP, Faggiano F, Bellocco R, Galanti MR.
Effects of a school-based prevention program on European adolescents' patterns of alcohol use.
J Adolesc Health 2011;48:182-8.
- II. Caria MP, Faggiano F, Bellocco R, Galanti MR.
The influence of socioeconomic environment on the effectiveness of alcohol prevention among European students: a cluster randomised controlled trial.
BMC Public Health 2011;11:312.
- III. Caria MP, Faggiano F, Bellocco R, Vigna-Taglianti F, Galanti MR.
Effects of a school-based prevention programme on European adolescents' intentions, perceptions and expectations towards alcohol drinking.
Manuscript.
- IV. Caria MP, Faggiano F, Bellocco R, Galanti MR.
Classroom characteristics and implementation of a substance use prevention curriculum in European countries.
European Journal of Public Health (Accepted for publication).

CONTENTS

1	INTRODUCTION.....	1
1.1	Alcohol use among young people in Europe.....	1
1.2	Prevention of alcohol use at young age.....	4
1.3	The importance of evaluation.....	7
1.4	The EU-Dap study.....	10
2	AIM.....	13
3	MATERIALS AND METHODS.....	14
3.1	Design of the EU-Dap trial.....	14
3.2	Study populations.....	16
3.3	Collection of information.....	17
3.4	Exposures and outcomes.....	18
3.5	Statistical analyses.....	19
3.6	Ethical considerations.....	21
4	RESULTS.....	23
4.1	Sample characteristics and alcohol use prevalence.....	23
4.2	Effectiveness.....	24
4.3	Programme implementation.....	28
4.4	Missing data and attrition.....	28
5	DISCUSSION.....	30
5.1	Behavioural outcomes.....	30
5.2	Cognitive domain.....	31
5.3	Methodological considerations.....	32
6	CONCLUSIONS.....	35
6.1	Suggestions for future research.....	35
6.2	Suggestions for the implementation of school-based prevention.....	36
7	ACKNOWLEDGEMENTS.....	37
8	REFERENCES.....	38
9	APPENDICES.....	45

LIST OF ABBREVIATIONS

ATOD	Alcohol, tobacco, marijuana and other illicit drugs
CI	Confidence Interval
CSI	Comprehensive Social Influence
EDDRA	Exchange on Drug Demand Reduction Action
EMCDDA	European Monitoring Centre on Drugs and Drug Addiction
ESPAD	The European School Survey Project on Alcohol and other Drugs
EU	European Union
EU-Dap	European Drug Addiction Prevention Trial
LST	Life Skills Training
LOCF	Last observation carried forward
MI	Multiple imputation
OR	Odds Ratio
US	United States
RCT	Randomized Controlled Trial
WHO	World Health Organization

1 INTRODUCTION

1.1 ALCOHOL USE AMONG YOUNG PEOPLE IN EUROPE

Alcohol is by far the most commonly used drug among adolescents in Europe [1]. For many people adolescence is characterized by the onset and escalation of alcohol use [2], along with the developmental transitions typical of this age, i.e. major changes in physical development and social circumstances (e.g. changing school, moving residence, expanding peer groups). Moreover, in many social contexts in Europe experimentation with alcohol is perceived by young people as an accepted behaviour [3, 4].

Prevalence of juvenile alcohol use

Data from European surveys indicate that by the age of 15-16 years the vast majority of youths (87%) have tried alcohol for the first time [1]. The same surveys indicate that trends of alcohol use have been fairly stable between 1995 and 2011.

In addition, many young people report alcohol consumption (57%), heavy episodic drinking (39%), and drinking to intoxication (17%) during the past thirty days. More than one in ten of 15-16 years old adolescents in European countries experience a range of problems due to alcohol consumption, from poor performance at school to serious relationship problems with friends or parents, or engaging in violent behaviour such as fighting in the past twelve months [1].

Consequences of alcohol drinking

Alcohol use by young people is correlated with both short-term (acute) and long-term (chronic) health problems, as well as negative social consequences [5].

Because of their limited experience with alcohol and limited capacity to metabolize it, adolescents are less able to recognize and compensate for the psychotropic effects of alcohol, and may become intoxicated with lower intake compared to adults [3]. Underage drinking, binge drinking in particular, is associated with the leading causes of death among adolescents and young adults: unintentional injury, homicide and suicide [3]. Consequently, more than one in four deaths among European males and one in ten deaths among females in the age 15-24 years can be attributed to alcohol [6].

Quality of life may also be impaired by underage drinking. Adolescents who use alcohol are more likely to suffer from side effects including appetite changes, weight loss, eczema, headaches and sleep disturbance [7], adverse neurodevelopmental effects [8] and brain damage leading to problems with memory, learning capacity and verbal skills [9]. There is also some evidence that alcohol may increase feelings of depression [9].

Among the social consequences poor educational performance [10], crime and disorder [11], and unprotected sex have been described, the latter frequently leading to unwanted pregnancy or sexually transmitted disease [12]. Negative consequences of alcohol use include deteriorated relationships with family, peers, or teachers [3].

Furthermore, early drinking increases the risk of developing alcohol disorders later in life [13]. In particular, regular consumption and binge drinking in adolescence is a strong predictor of alcohol dependency in adulthood [14].

Positive experiences for young people being able to drink sensibly have been also described [15]. For example, some youths may perceive improvement of mood, or increased relaxation and confidence when communicating with members of the opposite sex.

However, the adverse consequences of drinking alcohol during adolescence clearly exceed the positive ones. Overall, there is a general agreement that delaying the age of alcohol initiation and limiting the consumption is beneficial to young people's health and well-being [15].

The extent of alcohol-related harms has led to the World Health Organisation, the European Commission, and a range of stakeholders to identify juvenile alcohol consumption as a major public health issue [16, 17].

Determinants of alcohol use at young ages

The causal chain leading to alcohol use and misuse among young people is still poorly understood, although many several predictors and concurrent factors have been identified [18, 19].

Factors from different domains (e.g., individual, relational and societal) must be taken into account in order to understand patterns of risk enhancement and risk reduction in relation to alcohol drinking in adolescence (Table 1), together with their complex interplay. In fact, much of the evidence on determinants on alcohol use comes from cross sectional studies which can establish associations but are unable to determine a causal link between risk/protective factors and alcohol misuse or indeed alcohol misuse and specific consequences. For instance, some factors, such as affiliation with peers who drink, stress, and anxiety may represent both risks for and consequences of drinking [15].

Among individual factors, twin studies have demonstrated a high level of heritability across a spectrum of alcohol-related behaviours, including heavy consumption, problem drinking and alcohol dependence [20]. The influence of genetic factors on indices of progression to alcohol misuse (binge drinking, getting drunk and getting into situations regretted due to alcohol) may be stronger than the influence on initiation of alcohol use [21].

Also, children with conduct problems (e.g. bullying, fighting, truancy), aggressiveness, hyperactivity, and "sensation-seeking" personality are particularly prone to risky alcohol use [18]. Negative feelings (e.g. depressed mood, low self-esteem, and perception of low chances of success in life) have been associated with later alcohol drinking and alcohol disorders in longitudinal studies of adolescents [22-24]. Stress and anxiety have been associated with heavy and binge drinking [25]. Also, cognitions and social images regarding alcohol use that develop during middle school predict subsequent heavy drinking in high school [26]. Teens who report more positive attitudes [27], or expectancies [28] about alcohol are more likely to initiate use, as are adolescents who perceive the use of alcohol as common and tolerated [29]. Many studies have linked an early alcohol onset to heavy alcohol use in adolescence

as well as in early adulthood [30]. Some studies have found that familiar socio-economic characteristics (e.g. low parental education and income) are related to adolescent drinking habits [31], a relationship that is however still unsettled [32]. Higher prevalence of alcohol use and drunkenness has been reported among adolescents living in single-parent families [33, 34].

Among the most important protective factors at the individual level are the so-called “life skills”, i.e. personal abilities mobilized in coping with social pressures and life events predisposing to alcohol use. Among these skills decision making, problem solving, anxiety management skills, communication skills, and assertiveness have been particularly highlighted [18]. Consistently, adolescents with low skills to resist social pressure to drink are more likely to start drinking early [35]. Quality of leisure time activities may also be important in determining whether its effects are protective or deleterious. In fact, participation in structured leisure-time activities has been linked to lower levels of antisocial behaviours including alcohol use, whereas participation in activities with low structure has been related to high levels [36].

Among relational factors, a good relationship with parents seems to be an important protective factor [37]. In fact, communication and openness towards parents have been found inversely related to adolescent alcohol use [38]. Parental strategies, including monitoring and limiting availability, have been associated with delay in alcohol onset [39]. Also, it has been reported that parental guidance, rule setting, and disapproving of alcohol can prevent adolescents’ alcohol use [40, 41], and that youths who perceive strong parental disapproval of substance use are more likely to abstain from or limit heavy drinking [42]. Reverse role modeling has also been reported: for instance, in a longitudinal study parental alcohol use was found to predict their children’s use [43]. Alcohol use among peers has emerged as strongly associated with regular and heavy drinking among adolescents [44].

At the societal level, availability of alcoholic beverages has been put forward as the most important determinants of consumption. Studies have found associations between alcohol consumption and the availability of alcoholic beverages, i.e. hours or days of alcohol sale and geographical density of alcohol outlets [45]. Prohibition to sell alcohol below a minimum age makes it more difficult for youths to purchase alcoholic beverages [46]. Also, econometric studies have shown that price of alcoholic beverages is inversely correlated with consumption at the population level [45]. Consistent with the previous findings, areas where retail sales of alcohol are restricted by monopoly have been associated with lower adolescent alcohol consumption and less binge drinking compared to non-monopoly areas [47]. Finally, alcohol advertising and marketing have a significant impact on youth decisions to drink, by influencing youth expectations and attitudes [48, 49].

Table 1. Risk and/or protective factors influencing alcohol drinking in adolescence. Individual-level factors targeted by the programme evaluated in this thesis (*Unplugged*) are marked with boldface roman type.

LEVEL	RISK FACTORS	PROTECTIVE FACTORS
Individual		
	Low “Life skills” (decision making, problem solving, communication skills)	High “Life skills” (decision making, problem solving, communication skills)
	Overestimated normative beliefs	Correct normative beliefs
	Low resistance skills	High resistance skills
	Problematic personality (sensation seekers, aggressive children)	
	Low risk perceptions	High risk perceptions
	Positive cognitions	Negative cognitions
	Positive expectations	Negative expectations
	Low self-esteem	
	Unstructured leisure-time activities	Structured leisure-time activities
	High stress	
	Genetic predisposition	
	Negative feelings	
	Single-parent family	
Relational		
	Bad relationship with parents	Good relationship with parents
	Low parental monitoring	High parental monitoring
	Peers use	
	Parental use	
		Perception of parental disapproval
Societal		
	High availability	Low availability
		Presence of minimum legal age
	Low alcohol prices	High alcohol prices
	Pro-alcohol media advertising	
	Pro-alcohol cultural attitudes	Anti-alcohol cultural attitudes

1.2 PREVENTION OF ALCOHOL USE AT YOUNG AGE

Indication for universal prevention

There is no way to use the knowledge on risk- and protective factors for alcohol use to predict whether an individual will experience alcohol-related harm. Therefore *universal prevention* is the first and foremost strategy to tackle this problem among youths [50]. The expression refers to activities aiming to avoid or delay the use of

substances in the general youth population, irrespective of background risk. Universal prevention is complementary to *selective prevention* (targeting subgroups at high risk for substance use) and to *indicated prevention* (targeting individuals who are exhibiting early signs of substance abuse, conduct disorders and other problem behaviours).

The main assumption of universal prevention is that it is important to substantially reduce the recruitment of new users. While the “at risk” youth are at greatest risk for harm, they are few and account for a relatively small proportion of alcohol-related harms in a young population. In other words, the overwhelming majority of new alcohol users come from population groups which are not identifiable as “at risk”. Furthermore, universal prevention may have beneficial effects also among high-risk youths.

Strategies for universal prevention

Approaches to universal prevention of alcohol drinking at young age include a variety of strategies, from interventions limiting young people’s access to alcohol through legal and economic measures to strategies directly aiming at individual behavioural modification.

The first approach includes community-based interventions reducing availability of alcohol (price control, regulation of sale hours and of retailers’ concentration, prohibition to locate retailers near certain places like schools, recreational centres, or churches), raising the minimum legal age at which buying or drinking alcohol is permitted, tackling underage sales, and regulating alcohol marketing and advertising. Although eventually impacting on individual behaviours, these measures directly targets only the environment within which the individual choices become possible (*environmental prevention*).

The second approach includes interventions that have an explicit educational purpose. In general, alcohol prevention based on education focuses on individual-level factors to reduce risk and/or enhance protection. It may be delivered in a range of formats:

- mass media and information campaigns [51];
- school-based curricula [52];
- family-based interventions which can either involve parent training only, or include family skills training, and/or child training [53];
- community interventions which are multi-component approaches including classroom education, parental education, and wider activities aimed at changing policies and practices of community institutions [54];
- patient education provided by health professionals or social workers [55].

The role of the school

For a number of reasons, schools are considered appropriate environments for implementing universal prevention programmes directed to young people, including alcohol prevention [56]. First, the majority of alcohol drinkers begin before adulthood, therefore prevention needs to target school-age children and adolescents, before beliefs and expectations about alcohol are established [13]. Second, schools offer the most systematic and efficient way of reaching a large number of young persons every year

[57]. In Europe, schools guarantee universal coverage since all children attend compulsory school for at least eight years. Despite truancy and other causes of absenteeism, classroom-based programmes can generally count on a very good reach. Third, because of their primary vocation schools are naturally committed to pedagogic interventions and school staff needs only minimal training, if any, to implement even complex programmes. Finally, in most countries schools can easily mobilize other sectors and representatives of the community including parents, municipalities, cultural associations and volunteers.

Recognizing the importance of implementing prevention programmes at school, the Council of the European Union (EU) invites Member States (5099/01/02 Cordroge 4 Rev.1) *“to incorporate health promotion/drug prevention programmes at all schools”* and *“to promote the development of such programmes and, if necessary, adapt the government resources and organisational structures involved, in order to fully meet the previous objective”*.

Models of school-based prevention

At present, there is a large variability in the characteristics of the preventive programmes offered in schools, and specific curricula against alcohol use have employed different approaches.

Traditional approaches, represented by early interventions developed during the 1960s rely on the knowledge and on the affective model [58]. The knowledge model posits that providing adolescents with factual information about potentially harmful behaviour, such as substance use, would prevent initiation. With foundations on fear arousal, knowledge-based interventions aimed therefore to enhance awareness of effects and consequences of alcohol use, as well as to build negative attitudes towards alcohol use. The information could be presented in several different formats, such as lectures delivered by teachers or experts, videotapes, posters and pamphlets.

The so-called affective model had a wider approach [58]. It assumed that psychological factors place people at risk of use, therefore programmes accordingly address inner feelings and personality traits such as self-esteem, self-awareness and self-efficacy, through steps of personal development such as decision making and coping with stress.

Starting from the early 1980s theory-based prevention programmes have been developed based on two general approaches: the social influence and the competence enhancement models [59].

The social influence model emphasizes the importance of social pressure (i.e. influences from peers, media and advertising) in promoting the onset of adolescent substance use. The three major components of this model are psychological inoculation, normative education, and resistance skills training. The notion of “psychological inoculation” borrows its paradigm from the primary prevention of infectious disease. It suggests that inoculation of factors that acts as vaccines against social pressure will help prevent substance use in the host [60]. Therefore, an early simulated and controlled exposure to pro-alcohol social influences would build up resistance to more powerful pro-drinking messages adolescents might be expected to encounter later in life [61]. The scope of normative education, on the other hand, is to

correct the adolescents' misperception that most peers use alcohol and to downplay its social acceptability [29]. Resistance skills training focuses on providing students with instruments to resist pro-alcohol social influences, for instance by increasing awareness of media influences, teaching to recognize high-risk situations, and training assertive responses in situations of perceived pressure to drink [62].

The competence-enhancement model has its theoretical foundations in Bandura's social learning theory [63]. According to this approach, alcohol use is conceptualized as a socially learned and functional behaviour, that is the result of an interplay between social (interpersonal) and intrapersonal factors. Alcohol use is learned through a process of modelling, imitation, and reinforcement, and is mediated by an adolescent's pro-alcohol cognitions, attitudes, and beliefs. These factors, in combination with poor personal and social skills, are believed to increase an adolescent's susceptibility to alcohol use. A distinctive feature of competence-enhancement approaches is active teaching of a broad spectrum of inter-personal or intra-personal skills (so-called *life skills*) such as decision-making, goal setting, stress management, assertiveness, problem solving and communication skills.

Recently, a number of interventions have introduced elements from different approaches. In particular, programmes combining life skills education, normative education and knowledge on substances, further implemented with highly interactive methods, are known as "comprehensive social influence" (CSI) programmes [64].

1.3 THE IMPORTANCE OF EVALUATION

Comprehensive and rigorous evaluation of effectiveness in achieving stated goals is essential to prevent the proliferation of ineffective or even harmful educative programmes. In fact, since the chain of causation of alcohol misuse is still poorly understood, it is not possible to rely solely on theoretical principles in order to develop effective and safe interventions. Even the best theory-based intervention can have counterintuitive effects.

Examples are not rare. For instance, during the late 1980s it became increasingly clear that school-based programmes conveying only information on substance-related harms were not effective in modifying adolescents' behaviour, even when they were successful in increasing knowledge [65]. Also affective programmes proved to be ineffective on behavioural changes [66]. Different evaluations of Drug Abuse Resistance Education (D.A.R.E.), the most widespread substance use prevention programme in the United States (US) in the early 2000s, repeatedly reported lack of effectiveness [67, 68].

Substance use prevention can be harmful even when carried on with good intentions, e.g. may increase young people's curiosity, interest for and proneness to use psychoactive substances. Unfortunately, the case of theory-based interventions showing iatrogenic effects when submitted to a rigorous evaluation, is far from rare. For example, short-term, "moralising" programmes may stimulate young people's interest in drugs [69]. A conspicuous example of "boomerang effect" was the "Life Education" programme that in 1992 was offered to an estimated one million Australian primary schoolchildren. Its evaluation showed that the programme was associated with 40% of

boys' recent drinking and when the data were extrapolated to state-wide drinking behaviour, it was estimated that 22% of all recent drinking among males could be attributed to participation in Life Education [70]. In a recent review examining evidence that school and family alcohol education programmes prevent misuse of alcohol by young people, ten out of seventy-four evaluation studies meeting initial inclusion criteria, reported one or more adverse effects on alcohol behaviours [57]. Another well-known example is the universal school-based substance abuse prevention programme "Take Care of Your Life" that was evaluated in the Adolescent Substance Abuse Prevention Study, a 5-year study enrolling nearly 20,000 American 7th graders. The programme showed an unfavorable effect on the use of alcohol [71].

These findings suggest that educational programmes should be thoroughly evaluated prior to widespread implementation. If public health or school authorities commit themselves to carry out an intervention aimed at preventing substance abuse, there should be at least plausible evidence of its effectiveness [72].

However, evaluation of preventive interventions requires higher ethical standards than evaluation of clinical interventions, especially when adolescents are involved [73]. From the ethical point of view, it is not acceptable that such an intervention could cause harm [74].

In the United States, since 2001 the Title IV of the No Child Left Behind Act (Safe and Drug-Free Schools and Communities Act) has demanded funds be used only for programmes proven to be effective [75]. In the same year, recognizing the central role of evaluation of effectiveness in prevention sciences, the World Health Organization (WHO) recommended to provide schools with well-tested effective programmes [76]. In December 2004, the European Council endorsed the EU Drug Strategy (2005-2012) which sets the framework, objectives and priorities for the Action Plans to be brought forward by the Commission. The Action Plan proposed by the Commission among its objectives called for: *"Improve access to and effectiveness of school-based prevention programmes, in accordance with national legislation. Ensure that comprehensive effective and evaluated prevention programmes on both licit and illicit psychoactive substances, as well as poly-drug use, are included in school curricula or are implemented as widely as possible"* [EU Drugs Action Plan (2005-2008) Objective 8].

Effective components of school-based prevention

Evaluation of alcohol use prevention curricula has been reported in several studies, almost exclusively conducted in North America [77]. However, in many cases only the ability of the programme to modify intermediate variables (knowledge, intentions or some skills) was analysed, not the effectiveness in modifying the actual drinking behaviour [77]. In other cases the quality of evaluations was not optimal, leaving some methodological concerns [78].

One high-quality systematic review of prevention of alcohol misuse in young people, concluded that alcohol education has at best small positive effects [77]. However, the review reported on two classroom-based, teacher-led programmes that targeted children between the ages of 12 and 13 years, suggesting that interventions using the life skills training approach (LST) or focussing on harm reduction through skills-based activities

(SHAHRP) can produce medium to long-term reductions in alcohol use, in particular risky drinking such as drunkenness and binge drinking [77].

Programme evaluation also allows a better understanding of the successful key components of prevention.

To date, there is evidence that the most effective available preventive curricula are based on the CSI model, including personal, social, and resistance skills training, normative education and appropriate information about alcohol [55]. Curricula should also be relevant for the students and culturally sensitive, for example by including activities that require teachers' and students' input, tailored to the cultural experience of the group. Further, prevention programmes for adolescents should be delivered with appropriate interactive methods, such as discussion in peer groups, role playing, small-group work, group games [55]. The basic idea is that active participation, feedback and constructive criticisms facilitate the practice of skills being taught, compared to traditional teaching based on mono-directional communication between the teacher as knowledge-provider and the learner as recipient. In order to reach the best and most sustainable effect, it is important that the programme is implemented as planned [79, 80], that the teachers are trained to deliver the programme with the planned pedagogic methods, and that they become familiar with the underlying theory and conceptual framework of the programme [81]. Some studies suggested that classroom-based programmes taught by adult health educators and uniformed police officers external to the school have no medium- or long-term effects on alcohol use [77]. Additionally, active involvement of peers, family and community seems to enhance the effectiveness of school-based programmes [55].

Evaluation of school-based prevention in Europe

School-based substance use prevention is one of the most common preventive approaches adopted to tackle youth drinking in European countries [6]. Curricula are generally not mandatory, and they may differ greatly as to purposes, methods and implementation. There isn't, however, any national or international agreement about the type of intervention that should be carried out.

Regrettably, most of these programmes in European settings have never been evaluated with sound scientific methodology, which means that there is no information about their actual impact on the behaviour of young people [82].

Most of the adopted programmes have been developed in North America, where the corresponding evaluation research is confined. In a recent review of the effectiveness of primary prevention of alcohol misuse among young people, only four out of 56 included evaluation studies were carried out in European countries [77].

The same effectiveness cannot be assumed when programmes are implemented in cultural contexts different from those in which they were developed. Specifically, there are concerns that differences in culture and in the educational system may affect the outcome of interventions, therefore limiting their applicability to the European context [57]. In fact, US and European populations are characterized by different patterns of alcohol consumption and drinking culture. An important diversity between North American and European alcohol prevention programmes relates to the

emphasis on abstinence in the former, while emphasis on harm reduction is more common used in the latter programmes [83]. Thus, cultural transferability remains unclear and requires further piloting.

Ordinary school curricula of European countries are quite similar at least concerning the compulsory subjects, they are generally time-demanding and do not include mandatory room for health education curricula. Therefore, including complex interventions such as CSI alcohol education may entail difficulties in implementation. A recent paper from United Kingdom underlines both methodological and dissemination problems in the implementation of complex interventions such as Life Skills in an European setting [84].

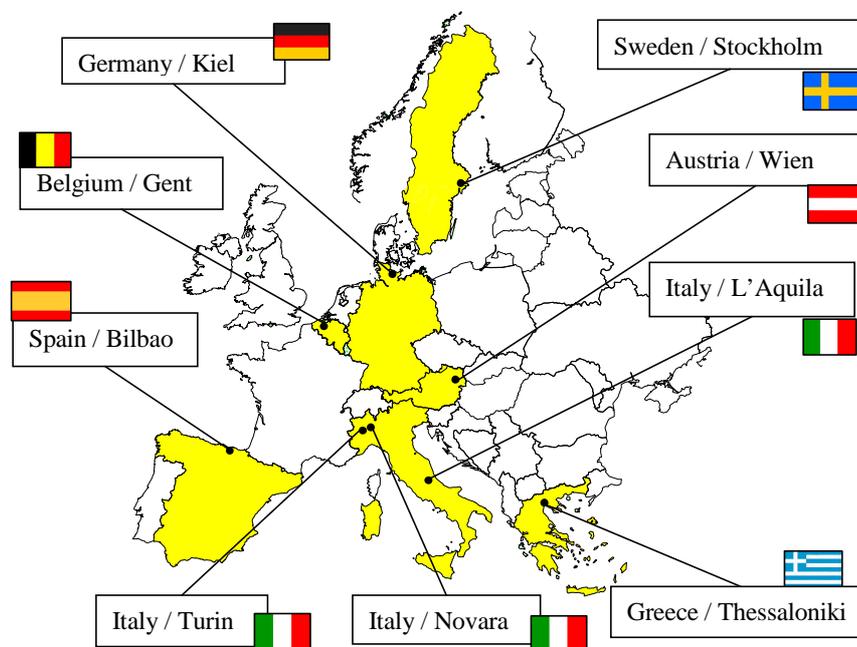
1.4 THE EU-DAP STUDY

Background

The EU-Dap (European Drug Addiction Prevention) study was designed to meet the need of scientific evaluation of a substance prevention programme carried out in European Countries. It was a multicentre study funded by the European Commission within the Community Public Health Programme for the prevention of drug dependence. The project aimed both to develop a theory-based school programme for prevention of use of tobacco, alcohol, marijuana and other illicit drugs (ATODs) and to assess its effectiveness by mean of a rigorous experimental design [85].

The collaborative project involved seven centres from nine European countries (Figure 1): Bilbao (Spain), Ghent (Belgium), Kiel (Germany), Stockholm (Sweden), Thessaloniki (Greece), Turin, Novara and L'Aquila (Italy), Vienna (Austria).

Figure 1. Geographical centres participating in the EU-Dap study.



The *Unplugged* programme

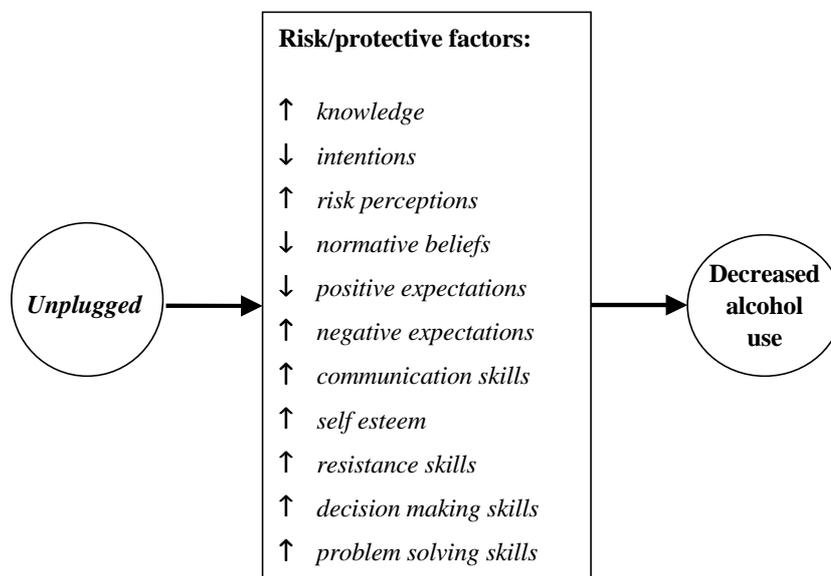
The programme being evaluated, *Unplugged*, incorporated the most recent empirical evidence on content and programme characteristics reported in the international literature to be effective in delaying the onset and in preventing progression of ATODs use.

Unplugged was developed for student populations aged 12-14 years, with teachers serving as program-deliverers, after attending a specific training.

The curriculum was specifically designed by an expert group to meet the needs of the European school, resting on similar school organization and educational systems in the participating countries. The programme duration was limited in time to accommodate the school time frame, and to fit in a single term. The duration was of approximately 12 hours over a course of 12 weeks, with each hour corresponding to a particular educational unit.

Unplugged included all recommended components of a CSI approach [64]. The curriculum consists of three modules: the first module (units 1-4) aims to improve knowledge about ATODs and about the consequences of use, as well as to encourage attitudes against substance use; the second module (units 5-8) focuses on interpersonal skills such as communication skills and on normative beliefs regarding the frequency of substance use among teens; the third module (units 9-12) aims to develop intrapersonal skills, such as coping competences, problem solving/decision making and goal setting (Figure 2).

Figure 2. The theoretical model of the *Unplugged* programme.



It also includes appropriate interactive methods, such as work in small groups, peer discussion, role-play and group-dynamic games. The structure and content of *Unplugged* is shown in Table 2.

The programme and its implementation were kept at the highest possible level of standardisation across different countries. The programme manual and materials can be accessed at www.eudap.net.

Table 2. Structure and content of the *Unplugged* programme.

UNIT	ACTIVITIES	GOALS	TARGETED RISK/PROTECTIVE FACTORS
1	Presentation, group work, contract management, homework	Introduction to the programme, setting of rules for the units, reflecting on knowledge on drugs	Knowledge
2	Group work, plenary discussion	Information on different factors influencing drug use	Knowledge, risk perception, intentions, expectations, attitudes
3	Group work, quiz	Information on positive and negative effects of drug use	Knowledge, risk perception, expectations, attitudes
4	Quiz, plenary discussion, feedback, game	Information on effects of smoking.	Knowledge, risk perception, expectations, attitudes
5	Presentation, plenary discussion, group work, game	Critical evaluation of information, reflection on differences between own opinion and actual data	Normative beliefs
6	Situation play, plenary discussion	Clarification of group influences and expectations	Relationship skills, communication skills
7	Game, plenary discussion, group work	Adequate communication of emotions, verbal and nonverbal communication	Communication skills
8	Role play, game, plenary discussion	Recognition of qualities, getting into contact with others, positive feedback	Communication skills, self-esteem
9	Discussion, group work, role play	Fostering assertiveness and respect for others	Refusal skills, assertiveness
10	Plenary discussion, group work	Expression of feelings, coping with weaknesses	Decision making, problem solving skills
11	Presentation, discussion, group work, homework	Structured problem solving, fostering creative thinking and self control	Decision making, problem solving skills
12	Game, group work, plenary discussion	Distinguishing long and short term objectives	Decision making, problem solving skills

2 AIM

The overall aim of this thesis was to advance knowledge on the effectiveness of school-based best practice programmes on adolescents' alcohol use in European settings, as well as to explore the possible pathways to behavioural influences.

The following specific questions were addressed:

- Whether a school curriculum based on comprehensive social influence is more effective in reducing alcohol consumption and alcohol-related problem behaviours among European students in the junior high grades, than usual health educational curricula (study I).
- Whether the potential beneficial effects of such school curriculum on drinking behaviour of adolescents are modified by social environment (study II).
- Whether potential behavioural changes are accompanied by changes in cognitive factors such as adolescents' intentions, perceptions, expectations, normative beliefs and knowledge on alcohol drinking (study III).
- Whether specific characteristics of the class could predict the level of implementation of the curriculum delivered by the teachers (study IV).

3 MATERIALS AND METHODS

This thesis is based on data from the cluster randomized controlled trial conducted in the EU-Dap study (ISRCTN-18092805). Details of the trial have been previously published [85] and are briefly summarized here.

3.1 DESIGN OF THE EU-DAP TRIAL

The source population consisted of students attending junior high school (12-14 years of age) in the geographical areas of the participating centres. The trial was carried out simultaneously in all centres during the school year 2004/2005.

A flow-chart of the selection of the schools and of the student populations in the EU-Dap study is displayed in Figure 3.

All schools hosting the compulsory grades corresponding to the selected age group ($n=323$) were invited to take part in the study. At this stage, the study protocol was fully disclosed to the school board.

In order to achieve a balanced representation of social composition, the school neighbourhoods were classified into three socio-economic strata, and an equal number of schools were selected within each stratum.

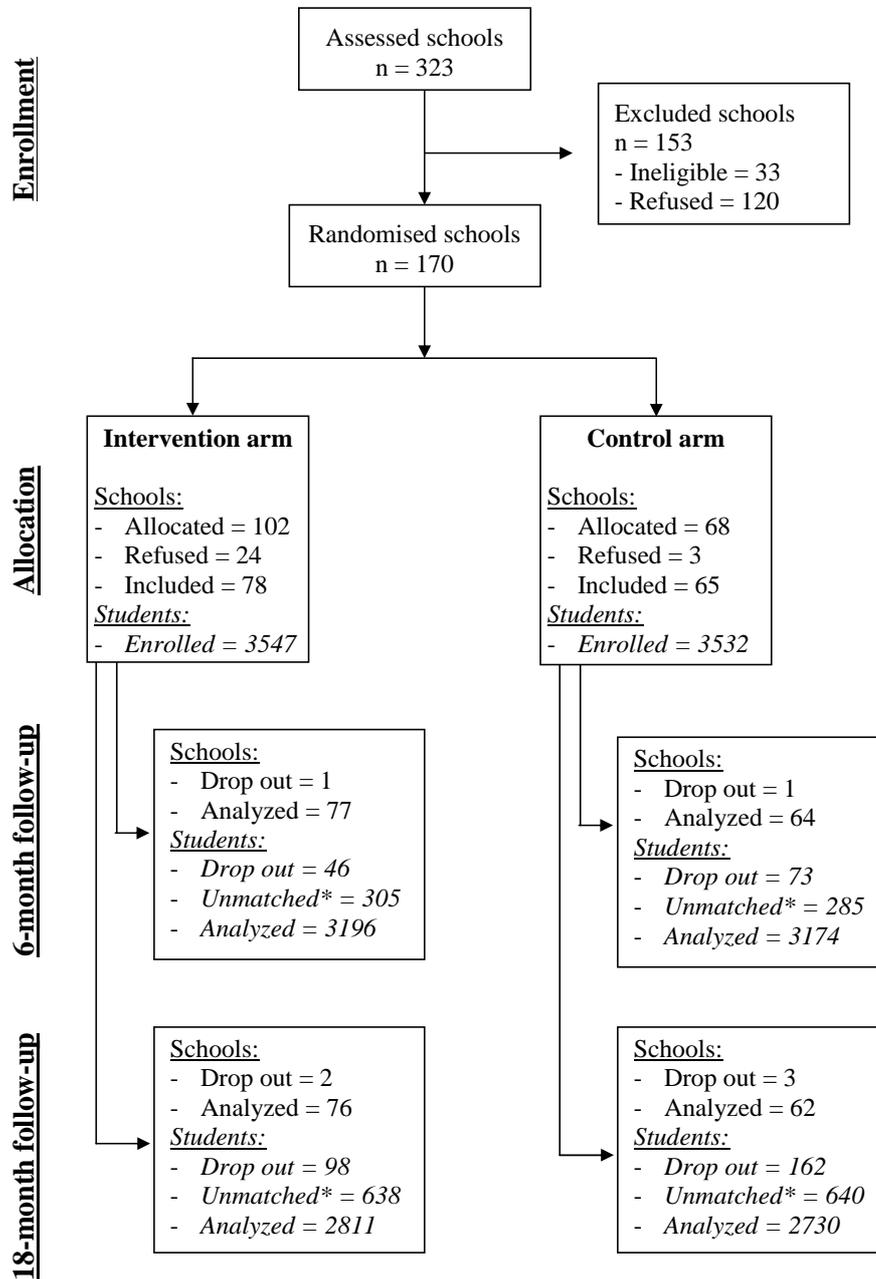
Schools were eligible if they had at least two classes in the target grade; followed the mainstream educational system (schools for students with special educational needs and confessional schools were excluded); were willing to participate in the study; and were not concurrently conducting other specific programme against substance use. Thirty-three schools were excluded because they did not meet the inclusion criteria, while 120 refused to participate, mainly because they were unable to schedule the intervention during the following school year. No differences were found on social stratification between accepting and refusing schools ($p\text{-value}=0.154$).

The remaining 170 schools were randomly assigned to intervention or to control condition, within each stratum of socio-economic condition of the neighbourhood. Two thirds of the schools in the intervention arm were further randomized to receive either a supplementary intervention conducted by peers or a supplementary intervention aimed at involving and sensitizing parents. However, these two additional components were not implemented in practice, which is the reason why this further grouping was ignored in the analysis.

To avoid contamination, all classes belonging to the same school were included in the same experimental arm.

Out of the randomized schools, 16% ($n=27$) dropped out after randomization and before the baseline survey. The withdrawal rate was higher in the intervention arm (23%) than in the control arm (4%), and was mostly caused by teachers' withdrawal during the training, along with the awareness of the heavy commitment required by the intervention. There was no association between the risk of a school dropping-out of the study and social condition ($p\text{-value} = 0.678$). No replacement of schools was allowed after randomization.

Figure 3. Schools and students flowchart of the EU-Dap cohort.



* Follow-up questionnaires not matched with baseline questionnaires among students surveyed at baseline with corresponding classes active in the follow-up survey.

The timeline of the EU-Dap trial is shown in Figure 4.
Pre-test data were collected during a baseline survey in September 2004.

Figure 4. Time-line of the EU-Dap Study.

	2004					2005		2006			
	Aug	Sep	Oct	Nov	Dec	Jan	//	May	Jan	//	May
Teachers' training	→										
Baseline survey		X									
Intervention			→								
6-month follow-up survey								X			
18-month follow-up survey											X

The school curriculum was taught from October 2004 to January 2005 in 78 intervention schools, while 65 schools acted as controls. In the EU-Dap trial, the control schools followed their usual "health" education programme, if any (usual conditions). Exclusion criteria at the students' level were: parents' did not allow participation (2.6%), or the student's incapability or refusal to participate in the baseline survey.

Post-test data were collected in May 2005 about 6 months after the baseline survey (three months after the end of the curriculum), and again in May 2006, about 18 months after the baseline survey (15 months after the end of the curriculum) [86, 87].

In total, five schools refused to continue participation during the 18-month follow-up, two from the intervention arm and three from the control arm. Reasons for schools leaving the study were lack of time (three schools), disapproving questions about inhalants (one school), and mistrust on confidentiality (one school).

In order to achieve a rigorously anonymous management of the data, while enabling the linkage of student's reports, data from baseline and follow-up surveys were matched using an individual 9-digit anonymous code. This was generated by the student based on stable personal information only known to the student (e.g. grandmother's name), in order to allow an identical code to be repeated on subsequent occasions [88].

3.2 STUDY POPULATIONS

All of the studies included in this thesis were based on the EU-Dap cohort, i.e.:

- students enrolled in the EU-Dap trial during the school-year 2004-2005
- participating in at least one follow-up survey between May 2005 and May 2006
- providing a viable anonymous code for the record matching between baseline and post-test assessments.

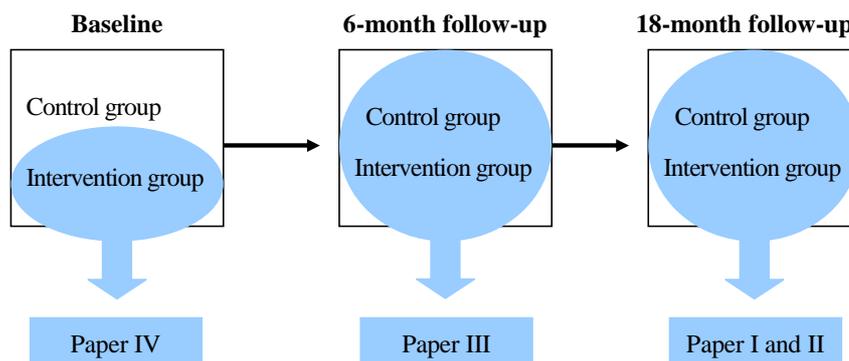
Baseline data were collected from 7079 students (Figure 3). Of these students 6604 participated in the first follow-up survey, and 6370 could be matched to their baseline data through the anonymous code described in the previous section. These latter constitute the analytic sample in paper III.

At the second follow-up data were collected from 5812 students, of whom 5541 could be matched, and represent the analytic sample in paper I and II.

Students in the intervention group participating in the baseline assessment (n = 3547) represent the study base in paper IV (Figure 5).

More detailed description of the materials are available in papers I-IV.

Figure 5. The EU-Dap study populations in papers I-IV.



3.3 COLLECTION OF INFORMATION

Information at the school level

Each centre was responsible for the classification of the socio-economic level of the schools, using the most reliable indicators available locally, such as: type of school, average income in the area, prevalence of unemployment, prevalence of individuals with only compulsory or lower education, of recipients on social welfare, and share of immigrants.

Information at the class level

A monitoring system for the programme implementation was developed. Teachers leading the programme were requested to complete a structured report soon after delivering each curriculum unit. The forms encompassed information on multiple dimensions of implementation fidelity.

Information on the students

A self-completed anonymous questionnaire with 37 items (see appendix 1) was administered in the classroom during school hours without teachers' participation. Apart from language adaptation, the questionnaire was identical in all countries and for all surveys. Questionnaire elicited answers on: (i) own substance use; (ii) knowledge and opinions about substances; (iii) substance use in the close social environment; (iv) family and social relations; (v) school environment and climate; (vi) personal skills.

Most questions were taken or adapted from the Exchange on Drug Demand Reduction Action (EDDRA) data bank of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). In a test-retest analysis the concordance for variables reporting use of alcohol was found higher than 90%, about four weeks after the first test (unpublished data).

3.4 EXPOSURES AND OUTCOMES

Exposure

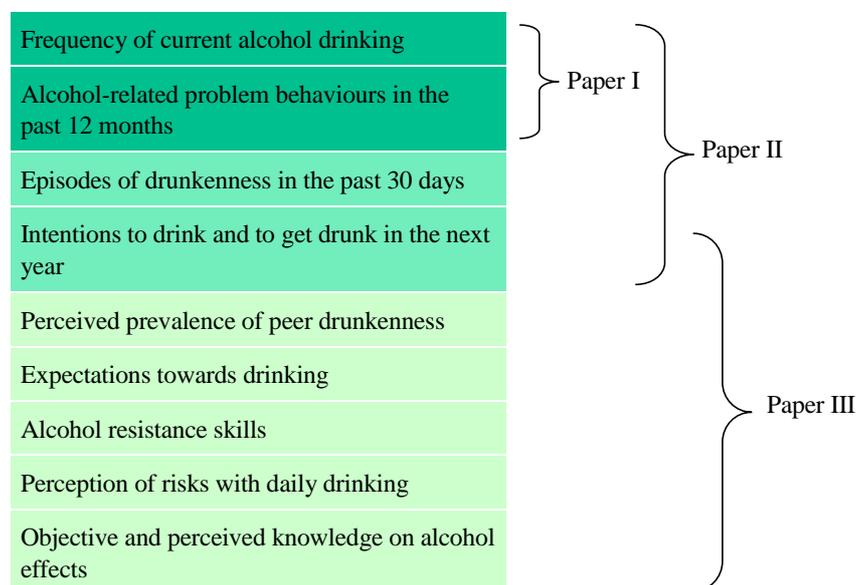
In paper I, II and III the exposure under study was the intervention status by original randomly assigned group.

Predictors of implementation in paper IV were represented by characteristics of the class, such as class size, gender composition, mean age, group prevalence of substance use and affection to school. All predictors were measured by aggregating at class level information from the baseline student survey.

Outcomes

The primary outcome in paper I and II was behavioural endpoints regarding alcohol use (Figure 6). Changes in intermediate endpoints such as alcohol-related intentions, knowledge, perceptions, expectations, and general skills were considered in paper III.

Figure 6. Alcohol-related outcomes investigated in papers I-III.



Current alcohol drinking was defined as reported consumption of even a small amount of alcoholic beverages (beer, wine or spirits) at least monthly. Alcohol-related problem behaviours referred to quarrel or argument, fighting, accident or injury, loss of money

or other valuables, damage to object or clothing, relationship problems, poor school performance, victimization by robbery, or hospitalization as a consequence of alcohol drinking.

The study outcomes in paper IV were multiple dimensions of the programme delivery at the class level:

- the completeness of implementation was investigated as per the proportion of curriculum units implemented;
- adherence, i.e. the extent to which implementation of activities and methods was consistent with the programme manual was investigated by studying the proportion of units delivered as intended, i.e. encompassing all scheduled activities, the use of the interactive role-play activities, and following the suggested duration of the units.

Other variables

Information was analysed on the following potential confounders of the relation between programme exposure and outcomes: family composition, siblings' use of alcohol, perceived parental approval, friends' misuse of alcohol. These factors were selected to represent the most important social influences to alcohol use.

3.5 STATISTICAL ANALYSES

Descriptive statistical analyses were performed to summarize the main characteristics of the study sample and to check for imbalance of potential confounders, since randomization, especially in cluster trials, is not a guarantee that potential confounders are balanced between experimental arms. Chi-square tests with the appropriate degrees of freedom were used in these analyses.

Most outcome variables were analyzed as dichotomous. Therefore, Odds Ratios (ORs) and their corresponding Confidence Intervals (95% CI), were estimated as measure of association between exposure and outcomes in logistic regression models. In paper IV duration was analysed in continuous form using linear regression models.

There were two effects for which it was necessary to adjust the regression models:

- significant differences between intervention and control group detected at baseline for some potential predictors of the outcomes (imbalance). In paper I-III the following were considered as potential confounders in all models: baseline status of the outcome under study, age, family living situation, family alcohol use, perceived school performance, and perceived parents' tolerance concerning alcohol drinking.

- the "cluster effect" due to the hierarchical structure of the data. In study I-III clustering was due to measurements of outcomes obtained from single individuals (unit of analysis), nested within classes, schools and centres. In paper IV measurements of outcomes obtained from single classes (unit of analysis) were nested within schools and centres. This data structure is also denominated "multilevel", where the term "level" identifies the position of a unit of observation within a hierarchy. Generally individuals within a cluster (class, school, or community) tend to be more similar than individuals between clusters. Therefore, clustered data tend to be correlated or

stochastically dependent. Ignoring such dependence, as in standard linear regression, may lead to incorrect statistical inference due to underestimation of standard errors, with consequent spurious statistical significance [89]. Unless the correlation in the data is accounted for in the analysis, the evaluation of the intervention effects will be biased away from the null in proportion to the magnitude of the correlation and the number of respondents in each cluster [90].

To take into account the hierarchical structure of the data in our analysis, the general framework of multilevel linear models was adopted. Multilevel models can be regarded as extensions of the linear mixed models, which allow random effects to be incorporated at more than one level [91].

In papers I-III we fitted 3-level models, with centres at level 3 (random intercept), classes at level 2 (random intercept), while students at level 1 represented the units of analysis. In paper IV we fitted 2-level models, with centres at level 2 (random intercept), while classes at level 1 represented the units of analysis.

The theoretical clusters in the hierarchy were three in papers I-III (class, school, and centre) and two in paper IV (school and centre). However, since schools and classes were highly correlated, we chose to adjust only for class because of the stronger data correlation at this level [92]. Generalized Linear Mixed Models with link function "logit" were used for binary outcomes, i.e., multilevel mixed-effects logistic regression models. Generalized Linear Mixed Models with link function "Identity" were used for continuous outcomes, i.e. multilevel mixed-effects linear regression models.

In paper II all analyses were performed separately by socioeconomic level of the school area. The presence of statistical interaction was formally tested by including in the regression model a cross-product term between the treatment condition and the socioeconomic status indicator, coded in dummy variables. A significant test statistic based on the likelihood ratio test for this interaction term would indicate that treatment effects vary by school socioeconomic level.

P-values were two-sided. Analyses were performed using the statistical package MLwiN 2.02 [93] and Stata version 12 [94]. In MLwiN a Quasi-likelihood estimation procedure was used: after linearization with marginal quasi-likelihood (MQL) including first order terms of the Taylor series expansion, the models were estimated using reweighted iterative generalised least squares (RIGLS). In Stata maximum likelihood estimation procedure approximated by adaptive Gaussian quadrature was used.

The internal reliability of multi-items variables was estimated using Cronbach's alpha.

Missing data and attrition

We analysed the association between the risk of school drop-out and social condition of the school area, using a chi square test.

At the individual level, we performed logistic regression analyses to study the association between drop-out at follow-ups and demographic characteristics or baseline drinking behaviour. We also test whether these patterns of attrition were equivalent across experimental conditions (interaction test).

In order to study a possible attrition bias in papers I-III, we conducted sensitivity analysis assessing the robustness of the main findings to different assumptions on missing data in the outcome variables. We analysed the programme effects after carrying forward the outcome status last observed of each student (Last Observation Carried Forward - LOCF), as well as under the extreme assumptions that missing values were either all negative (Best-Case scenario) or all positive (Worst-Case scenario).

In paper IV, missing data were handled by means of multiple imputation (MI) [95] as well as assuming they were all indicative of absence of implementation. We also repeated the analysis including only classes that provided complete data (listwise deletion).

3.6 ETHICAL CONSIDERATIONS

The trial was registered in the International Standard Randomised Controlled Trial Number Register.

Different ethical rules were applied in the seven countries where the study was carried on. Approval from an ethical research board was required and obtained only in Sweden (DNR 02-412; 04-553; 2007-357). All other centres released a declaration of conformity to the local regulations of ethical admission of the study. In some countries it was necessary to attain the authorization of an educational authority in order to conduct school surveys.

Confidentiality

The main ethical issue in the trial concerned the need to protect the psychological integrity of the young study participants, while complying with the requirement to inform the legal guardians about the characteristics and the implications of the study. In order to assure confidentiality all the procedures of data collection, analysis and publication were carried on preserving a rigorous anonymousness.

In fact, since names and addresses of students participating in the baseline assessment had to be collected in order to make it possible to trace them at follow-up in case of students changing school or class this was done separately from the survey data, that could link only with the help of the anonymous code described in section 3.1.

In this way, no personal information could be traced back to specific individuals.

Informed consent

Given the confidentiality of data collection and processing described above, a general policy on parental informed consent was not adopted. Three centres adopted an “opt out” consent procedure at the guardians’ level, while in other centres guardians’ consent was not mandatory. In all cases, detailed written information was delivered to both guardians and students, where the student’s right to refuse participation at any time was emphasized.

Risks with participation in the study

It was theoretically possible that the new experimental programme (*Unplugged*) had adverse effects on alcohol-related behaviours or other key outcomes. However the new the school curriculum was a best-practice incorporating principles and methods indicated by previous studies as the most promising in substance use prevention. Since there is also evidence that effective programmes need to be relevant for the students and to fit their cultural experiences, the curriculum was especially adapted by a group of experts to meet the needs of European schools.

Also, students in the control arm were not deprived of prevention programmes, because they followed the usual health educational curricula in their schools.

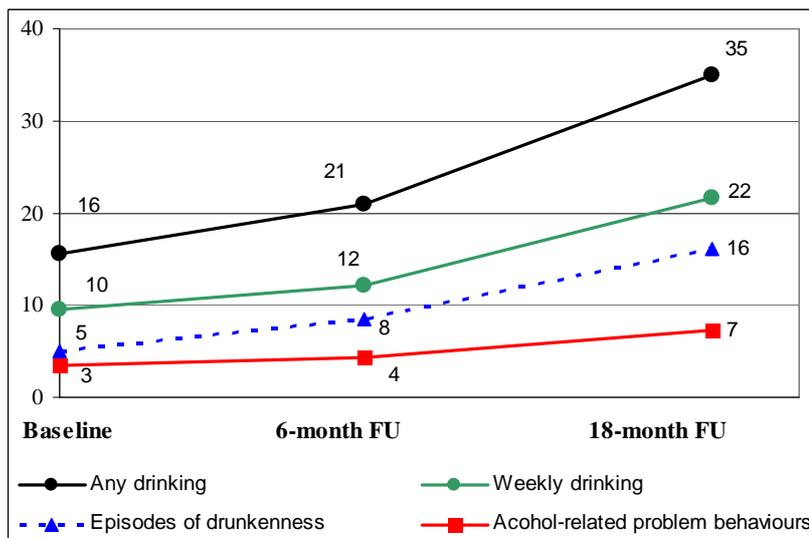
4 RESULTS

4.1 SAMPLE CHARACTERISTICS AND ALCOHOL USE PREVALENCE

At baseline the cohort was gender-balanced and the participants were in average 13.2 years old. Because of the stratification into three socio-economic levels before randomization, the sample also achieved an even representation of social strata with about one third of students in each stratum.

There was an increase in the prevalence of behavioural outcomes from baseline to the end of the follow-up period (Figure 7), in line with the uptake of substance use during developmental age. At baseline, the overall prevalence of current alcohol drinking was 16%, while 5% of the participants reported at least one episode of drunkenness during the past 30 days, and 3% reported at least one alcohol-related problem during the previous 12 months. All these figures doubled during the follow-up, and at the age of 15 years were comparable with those from European representative surveys, such as the European School Survey Project on Alcohol and other Drugs (ESPAD) survey [1].

Figure 7. Changes in prevalence of any current drinking, weekly drinking, episodes of drunkenness, and alcohol-related problem behaviours between baseline and follow-up.



Students in neighbourhoods of high socioeconomic level were more likely to drink at least monthly, while students in schools located in neighbourhoods of low socioeconomic level were more likely to report recent problem drinking.

At baseline, the control and intervention groups had similar distributions of most characteristics: gender, family living situation, perceived performance at school, own drinking behaviour and intention to drink, own resistance skills, risk perception and expectations towards alcohol drinking, siblings' drinking, and perceived parents' tolerance concerning alcohol drinking. However, compared to the intervention group

the control group had a slightly higher proportion of: students older than 14 years (42.9% vs. 34.5%), students reporting drunkenness (5.8% vs. 4.2%), intention to get drunk (21.6% vs. 18.5%) and behavioural problems related to their drinking (3.8% vs. 2.9%), high perceived prevalence of alcohol use by peers (13.7% vs. 11.2%), and knowledge about alcohol (11.2% vs. 9.1%). These differences were conventionally statistically significant at the Chi square tests, but not when multilevel models were used to test for associations.

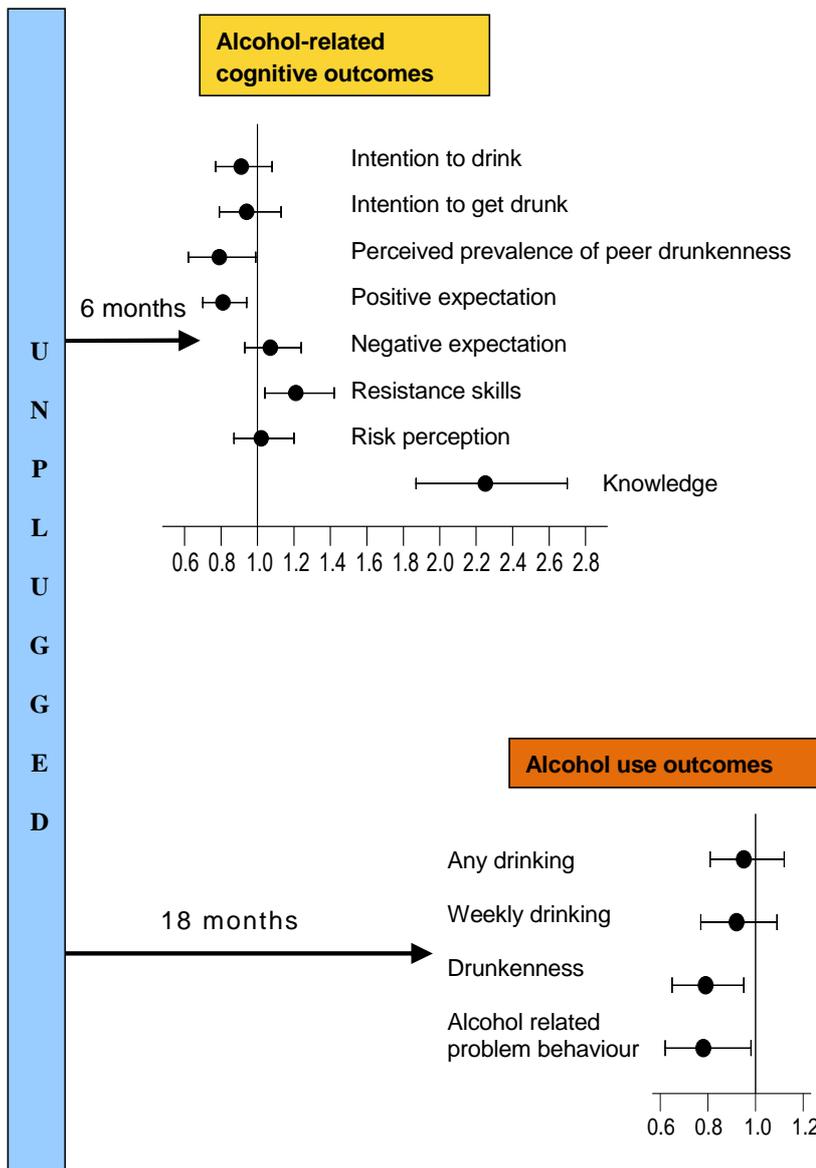
The sample of paper IV consisted of 173 classes with average size of 20 students. Prevalence of substance use at baseline ranged from 0% (in 36 classes) to 25% (in one class).

4.2 EFFECTIVENESS

At the first follow-up significant curriculum effects were detected on some of the alcohol-related cognitive outcomes. Exposure to *Unplugged* was associated with a significant 20% reduction both of perception of peer drinking (OR=0.79, 95% CI=0.62-0.99) and of positive expectations towards alcohol drinking (OR=0.81, 95% CI=0.70-0.94). Participation in the programme was also associated with a 20% increase in resistance skills against pro-alcohol pressures (OR=1.21, 95% CI=1.04-1.42) and with a two-folds increase in the probability to achieve high knowledge in alcohol-related facts (OR=2.25, 95% CI=1.87-2.70). Behavioural intentions, risk perception, and negative expectations associated with alcohol use were not affected by exposure to *Unplugged* (Figure 8).

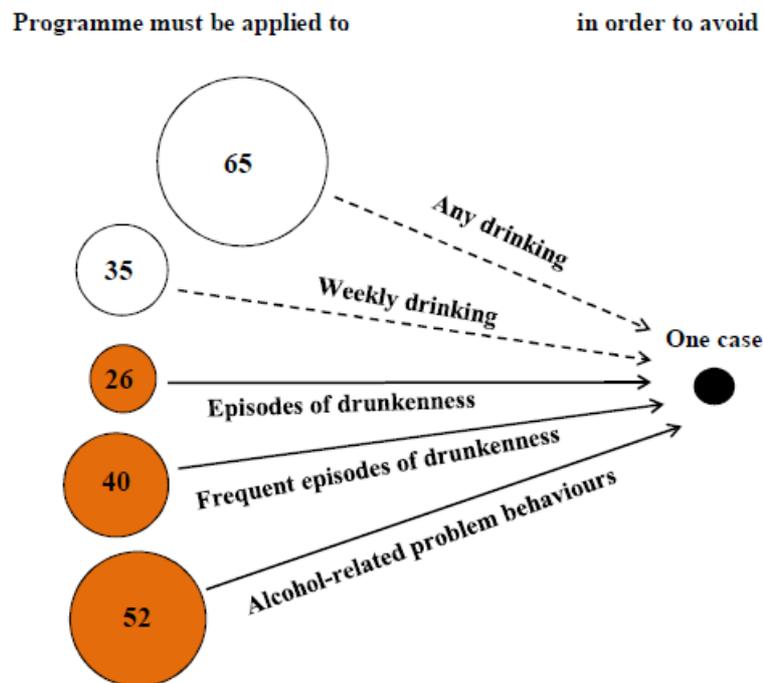
Twelve months later, beneficial effects of the programme were found for outcomes of heavy problem drinking. In fact, in the intervention group the frequency of drunkenness in the past 30 days and of alcohol-related problem behaviour in the past 12 months were reduced by 20%, compared to usual trends (Figure 8). No significant effects were found for the risk of alcohol consumption even if the intervention appeared to be effective at least in preventing non-drinkers and occasional drinkers from progressing toward frequent drinking (not shown).

Figure 8. Odds ratio (OR) and 95% confidence interval (95% CI) of alcohol-related outcomes at the 6-month and 18-month follow-up, for students in the intervention group compared to those in the control group.



Numbers Needed to Treat (NNTs) to prevent one additional event related to alcohol use ranged from 26 for any episode of drunkenness in the past 30 days to 52 for any alcohol-related problem behaviour. Delivering the programme in a class of about 25 students aged around 13-years might prevent one student from getting drunk. Delivering the programme in two classes, not only might double this success, but also might prevent one student from becoming a weekly drinker, and from experimenting with problem behaviours such as quarrels, fights, or injuries because of his/her drinking.

Figure 9. Numbers Needed to Treat (NNTs) to prevent one additional alcohol-related event at 18-month follow-up*.



* solid lines for statistically significant effects.

Socioeconomic level of the school neighbourhood

The above mentioned programme's effects were mainly driven by students attending schools in low socioeconomic context (Figures 10 and 11).

In fact, in under-privileged neighbourhoods at the short term follow-up participation in the programme was associated with a significantly lower prevalence of students reporting positive expectations, compared to controls (OR=0.75, 95% CI=0.58-0.97) and with a significantly higher prevalence of students reporting skills to refuse alcohol (OR=1.28, 95% CI=1.01-1.64) and correct knowledge about its effects

(OR=1.99, 95% CI=1.43-2.77). In the same areas at the medium term follow-up participation in the programme was associated with a significantly lower prevalence of episodes of drunkenness, compared to usual curricula, with an estimated reduction of about 40%. Also, exposure to *Unplugged* was linked to a 30% decreased risk of reporting behavioural problems due to drinking, but this effect was not statistically significant.

Among students in schools of medium or high socioeconomic level the programme was effective in doubling knowledge about alcohol but no significant programme's effects emerged for alcohol behaviours.

Figure 10. Odds ratio (OR) and 95% confidence interval (95% CI) of alcohol-related cognitive outcomes at the 6-month follow-up, for students in the intervention group compared to the controls, by socioeconomic level of the school's neighbourhood.

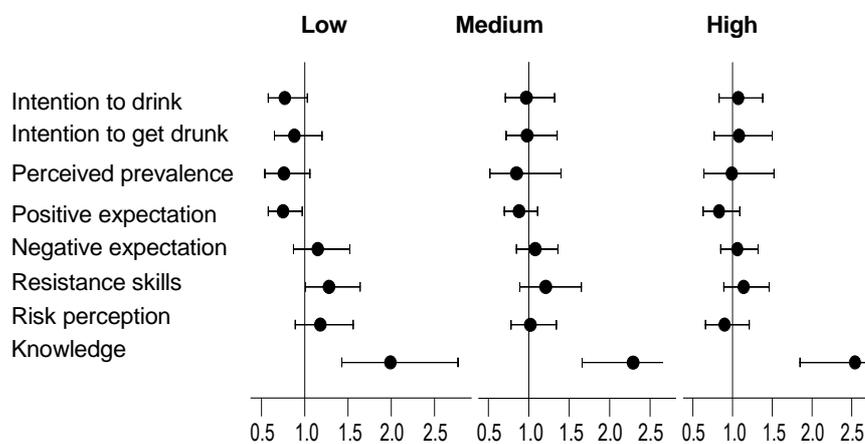
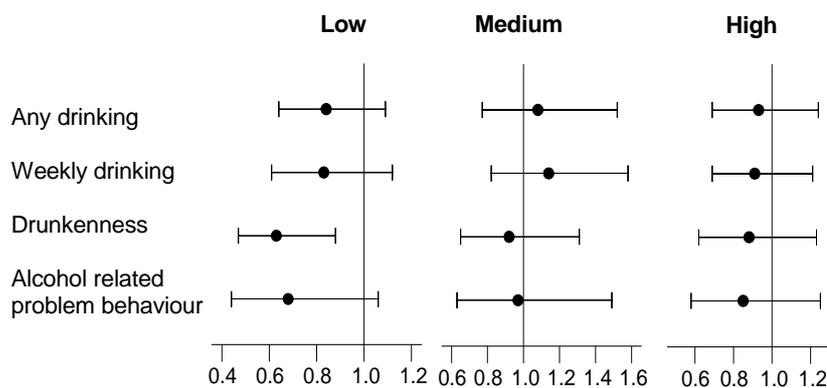


Figure 11. Odds ratio (OR) and 95% confidence interval (95% CI) of alcohol use outcomes at the 18-month follow-up, for students in the intervention group compared to the controls, by socioeconomic level of the school's neighbourhood.



Other subgroup analyses

Some explorative analyses by subgroups revealed that the beneficial effects of the programme seen in the whole sample were present only among students who did not drink at baseline and among students who perceived parents' tolerance concerning alcohol drinking. The programme effects on problematic drinking was stronger among boys than among girls, and this was paralleled by effectiveness on positive expectations and normative beliefs.

4.3 PROGRAMME IMPLEMENTATION

Overall, half of the classes in the intervention group implemented all the units in the curriculum, and used the role-play each time this activity was foreseen. Four teachers out of ten succeeded in completing all the planned activities in at least half of the units they delivered. The average duration of a unit was 62 minutes (SD=18). Implementation varied among the regional centres and among areas of different socioeconomic levels.

The level of implementation of the programme was not significantly predicted by class mean age, or by the proportion of students in the class with positive academic expectation, or liking school. On the other hand, some structural characteristics of the class did play a role. In fact, class size was inversely related to implementation: each additional student in the class was associated with a 10% decrease of the odds to implement completely at least half of the units. Also, proportion of boys in the class was associated with a shorter time devoted to each unit: for each ten percentage points increase in the proportion of boys the duration of a unit was on average two minutes shorter. Classes where students had a previous experience of substance use had a lower odds to complete the intervention compared to classes without this experience, with one-unit increase in the class prevalence of substance use associated with a 20% decrease in the odds of curriculum completion. Finally, increasing students' connectedness to their class was associated with increased odds of teachers using role-play.

4.4 MISSING DATA AND ATTRITION

Item-missingness was minimal (at the most 2.7%) for all outcomes of interest in this thesis. Therefore, missing data are mainly due to students' attrition (paper I-III) and to teachers' non-compliance with the monitoring system (paper IV).

As expected, drop out of students increased during the study period reaching the highest level at the 18-month follow-up, with retained proportions equal to 79% in the intervention group and to 77% in the control group. Attrition followed a socioeconomic gradient with higher proportions of adolescents lost to follow-up among students attending schools in the most disadvantaged neighbourhoods.

Students who dropped out were alcohol users at baseline to a larger extent than those who were retained in the study. These patterns of attrition were equivalent across experimental conditions in the whole cohort as well as within each socio-economic sub-group.

Alternative multilevel models, fitted for purpose of sensitivity analysis, showed very consistent results. All analyses performed using LOCF and the Best-Case scenario

produced results in line with the available case analysis. In the Worst-Case scenario most of the point estimates were below unity but considerably attenuated and no longer statistically significant.

In paper IV one third of the classes lacked information on programme completeness and use of role-play. Information on application fidelity and duration was missing each for 5% of the classes. Results obtained from the analyses on imputed data did not differ from those based on the original dataset.

5 DISCUSSION

A school-based programme for the prevention of substance use based on a comprehensive social influence model [64] was evaluated with reference to alcohol-related outcomes among students from junior-high schools in seven European countries. The curriculum was associated with a medium-term decreased risk for episodes of problematic drinking. No significant effects were found for frequency of alcohol consumption, but the intervention appeared to be effective at least in preventing non-drinkers to become drinkers.

The evaluation also suggested a higher preventive impact of the curriculum among students attending schools in a socially deprived context, compared to students in medium or high social contexts.

Effects on behavioural outcomes were paralleled by short term effects in the hypothesized direction on some risk factors linked to cognitive domains, such as knowledge about alcohol effects, resistance skills towards its use, normative beliefs and positive expectations. Notably, the beneficial changes on cognitive outcomes concerned again students attending schools in deprived neighbourhoods.

Finally, processes at the class level affected teachers' propensity to implement the innovative programme. In particular, class prevalence of substance use at baseline was a strong negative predictor of curriculum completeness, while class-level students' connectedness to their class showed a clear and positive impact on the use of interactive components.

5.1 BEHAVIOURAL OUTCOMES

The results on behavioural outcomes summarized above are in line with those achieved by other best practice CSI programmes, even in terms of magnitude [96]. The reported associations are considered in general indicative of small effects. However, when interpreting the strength of the effects some considerations should be borne in mind.

First, the EU-Dap study was an effectiveness trial, since the curriculum was delivered by class teachers in real-life conditions. Also, intent-to-treat analysis, warranted to avoid bias, is a conservative approach that may underestimate or even miss a possible association, because all students randomised to the intervention condition are considered equally exposed, irrespective of the actual level of programme delivery [72]. Thus, these results should not be interpreted as a measure of the ability of the programme to cause behavioural changes in ideal situations, but as an estimate of the effects that its dissemination may have on a population in naturalistic settings.

In addition, "weakness" of effects is a relative concept. In fact, the size of NNTs in the studies included in this thesis is comparable to that of several effective public health interventions such as vaccination for flu, treatment of hypertension in the elderly and statins for primary prevention of myocardial infarction.

The programme was particularly effective in areas with low socioeconomic status of the population. A possible explanation is that neighbourhood's disadvantage correlates with lack of educational resources and of social and familial support to adolescents. School-based prevention would therefore compensate for educational deficiencies at those levels making the relative "preventive gain" higher in these under-privileged

contexts [97]. It is also possible that schools in high-medium socioeconomic areas carried on other effective evidence-based programmes for the prevention of substance use, thus diluting the contrast between intervention and control condition, something that was unlikely to happen in disadvantaged areas. If this were true, then the preventive effect of the intervention on the whole population would be even greater than that observed.

The fact that the programme was associated to a reduction in risky alcohol drinking but not to a reduction of the frequency of alcohol consumption was not unexpected, and was in line with previous reports [98]. A possible explanation is that moderate alcohol consumption is a normative behaviour compared to drunkenness. Deterring youths from any alcohol use may be difficult in communities where drinking is widespread and socially acceptable, therefore prevention programmes may have a greater chance of making inroads on less socially acceptable forms of drinking, such as heavy drinking. This may be particularly true in Southern European countries, that accounted for the majority of the population enrolled in this study. This line of reasoning was also raised by Ellickson and co-workers in the United States, in their 18-month evaluation of the revised ALERT programme [98]. Another likely, but not competing explanation is that among early adolescents as those participating in the EU-Dap study the variability in frequency of alcohol drinking is very low, thus hampering the sensitivity of the study instruments to document changes, while a larger inter-individual variation may be found concerning heavy alcohol use.

5.2 COGNITIVE DOMAIN

The effectiveness of the *Unplugged* curriculum in the cognitive domain is also consistent with that reported in American studies [66].

Thus, normative beliefs, positive expectations towards future use, resistance skills, and knowledge about alcohol effects are potential mediators of the programme's effect in studies on alcohol. Whether these factors meet the requirements for actual mediation is to be explored through further analyses, revealing to which extent the programme's behavioural effects are explained by modifications in cognitive factors. Mediation analyses are important in order to identify effective components of programmes. For instance, results of this work suggest that students improving their information on alcohol are less likely to develop later problem drinking. However, it is unlikely that knowledge in itself may act as a mediator, since a bulk of previous studies failed to identify information as a predictor of behavioural change [57]. Positive expectation towards drinking, on which *Unplugged* exerted the strongest influence, deserves attention because it has been seldom studied as potential mediator of changes in teen's alcohol use. Its usefulness as cue for prevention rests on the empirical demonstration of a link between expectations, intentions and actual use, in other terms evidence that teens' re-appraisal of alcohol's function impacts on subsequent experience [28, 99, 100].

In summary, short-term modification of cognitive outcomes in the hypothesized direction, along with modification of alcohol-related behaviour at medium-term, provides strong support to the CSI theoretical model underpinning the *Unplugged* curriculum. The observation that effects on both cognitive and behavioural factors are

particularly evident in schools of low social level confers further plausibility to the model.

5.3 METHODOLOGICAL CONSIDERATIONS

Randomized controlled trials (RCT) are considered the gold-standard for effectiveness evaluation. However, in public health and community based research the degree of complexity of a field trial becomes particularly elevated, compared with the clinical setting. The EU-Dap trial constituted an exceptional endeavor in this scenario, striving to address the unavoidable organizational issues while respecting the integrity of the design.

In experimental evaluation the first basic requirements is the presence of a **control group**, representing the expected (counterfactual) outcome had the intervention not been in place [101]. In fact, comparing substance use before and after the intervention in a single group (pre-post design) would not help to rule out the influence of other factors. In addition, in this particular case the comparison would not be valid because of the expected usual increase in alcohol use during early adolescence. Ideally, the control group should be as similar as possible to the intervention group, except for the intervention to be evaluated. For instance, there should not be important differences in social class, gender, etc.

To this end, two factors are crucial: randomization and standardization.

Assignment to the experimental arms should be at random in order to assure that any possible difference in outcome predictors happens by chance [102]. In the EU-Dap study, if the allocation would have been the result of choices made by schools, those with similar characteristics would likely have selected the same experimental condition, thus opening for confounding influences (e.g. teachers' motivation and pedagogic skills). Thus, **randomization** of schools was carried out through a computerized algorithm at the central level, avoiding dissimilar procedures possibly occurring at the centre level. **Standardization** aims to ensure that the experimental groups are treated as much as possible in a similar way, particularly concerning the assessment of the outcome. In the EU-Dap trial schools in the control group received the same attention as the intervention group concerning explanation, training, motivational work, time schedule and instruments.

The separation of exposures at the level of the experimental arms is crucial to avoid contamination, i.e. the exposure to interventions similar to the one to be tested. In the EU-Dap study we had no influence on the teacher's educational choices in the control group, but three strategies were adopted to minimize this eventuality. First, all participating classes in a given school were randomized to the same experimental condition. Second, according to eligibility criteria schools intending to carry on comprehensive educational programmes, or programmes similar to *Unplugged*, were discarded. Third, we collected information on the health education actually conducted by control classes in the same academic year, allowing comparisons of methods and content with the experimental curriculum.

The cluster-based randomization (schools) with outcome measure at the individual level (students) conveys the need of an **appropriate analytical approach**. In the works included in this thesis all analyses were conducted using multilevel regression modeling [91]. In addition, the randomization of clusters implies a lower probability of achieving balanced experimental groups at the individual level, compared to the

randomization of individuals. In this latter case, homogeneity of baseline conditions between arms would be assured by randomization, thus making baseline assessment theoretically unnecessary. Therefore, in the EU-Dap study a **baseline survey** was conducted to assess the prevalence of the potential confounding factors and to verify the success of randomization.

Double blindness, usually a tenet in clinical RCT, in community studies using complex interventions is usually not possible. In the EU-Dap trial we tried to preserve at least blindness of assessors, for instance by making data collection and data imputation masked on the origin of the questionnaire.

An unequal drop-out rate just after randomization was observed in the EU-Dap trial, with intervention schools refusing participation more frequently than control schools. This was somewhat unexpected. Intuitively, this pattern could be due to initial underestimation of the necessary commitment to conduct the intervention, followed by a subsequent re-appraisal. This was indirectly confirmed by the timing of the refusals, the majority of which occurred during the teachers' training course. This school drop-out after randomization might have introduced self-selection of schools and could explain some imbalance in individual participants' characteristics, in particular the baseline prevalence of substance use. If so, it would imply that schools with higher prevalence of problem behaviours and substance use differentially refused to continue participating when assigned to active intervention rather than to controls. Although this possibility could not be excluded, it seems counter-intuitive. Moreover, there was no association between the risk of school drop-out and neighbourhood's social condition. At a closer scrutiny, imbalance appeared to be completely attributable to the contribution of a single large control school. Excluding this school, the baseline prevalence of use was very similar between arms, and the estimates of programme's effects closely overlapped those obtained with the complete data. However, in all statistical models the estimates of the programme effects were adjusted for the baseline status of the corresponding outcome.

Further strength of the EU-Dap trial was its large **sample size**, providing higher statistical power than previous experimental studies. However, given the hierarchical nature of the data the sample size was not large enough to study **subgroups** (e.g. age, socio-economic status, centre) with sufficient precision. All analyses on subgroups could only be conducted with an exploratory intent.

The large size of the sample was possible through the involvement of seven countries and nine regional centres, gathering data from **diverse socio-cultural contexts**, an advantage in handling the "context shift" from the original US-conceived skills programmes. To ensure comparability across countries, all partners were involved in the planning and organization of the study from the very beginning. This collaboration produced highly standardised programme and study protocol while allowing the discussion and monitoring of local adaptations. This latter was accomplished through a continuous flow of standardized information from the enrolment of schools, classes and students, to the implementation of the programme activities.

A critical issue in the evaluation of the effects of prevention is the choice and assessment of **end-points**. Clearly, a variety of measures are required to match the variety of objectives [57]. In the EU-Dap study we had the possibility to study both

intermediate attitudinal end-points and behavioural end-points, along the theoretical chain of programme's effects.

Self-reports of outcomes is a clear limitation of the studies included in this thesis. Adolescents may not be willing to reveal behaviours and attitudes that are perceived as unacceptable or even unlawful, such as substance use. This is a common concern in all studies in this domain. There are at least two reasons for placing confidence on the results reported in this work. First, an effective procedure to ensure anonymity can reduce the tendency to biased reports [103, 104]. In the EU-Dap study confidentiality was underlined as one of the most important features and assured by the anonymous linkage of the questionnaires. Second, there is no reason to suspect that under-reporting, if any, would be different in the two experimental groups. Even if bias towards socially desirable reports could in principle affect the intervention group to a larger extent than the control group, this is unlikely to have happened in the EU-Dap trial where all children were reached by some kind of health education programmes, and where the study hypothesis was not disclosed to the students. Information bias due to awareness of allocation remains a common concern in all studies where double blindness cannot be assured.

In order to keep the survey instruments as short as possible and to increase reliability of reports limited or no information was collected on some **potential confounding variables**, such as parents' socio-economic status (paper II) or teachers' characteristics (paper IV). Therefore, some degree of residual confounding cannot be ruled out.

Length of follow up is of concern, since previous evaluations of alcohol use prevention have been criticized for providing little evidence of the long-term effectiveness of the corresponding interventions [77]. In the EU-Dap trial a mid-term follow up was deemed acceptable, as most of the students in the study cohorts would have changed school during the following school year, thus impairing the possibility of effective tracing. This would have increased the **loss to follow-up**, with possible threat to internal validity and reduction of the statistical power.

Attrition of about 20% eighteen months after baseline is acceptable in large-scale social interventions [96]. Since the patterns of drop-out at the short and medium term were fairly comparable across experimental conditions, attrition should not have undermined the validity of our findings. If the slightly higher attrition in the control group entailed a differential retention of high risk students the protective effect of the curriculum would rather be underestimated. Besides, results from sensitivity analyses did not support the probability of important bias.

Last, but not least, the question remains of how generalizable the presented results are to the underlying school population (**external validity**). As usual in most community-based study both eligibility criteria and willingness to participate played a role in selection, making the participating schools and students a non-representative sample of the potential target. To which extent participating and non-participating schools differed in structural, functional and student characteristic could not be evaluated due to lack of information from non-participating schools. However, the observation that the prevalence of alcohol use in the student sample included in the EU-Dap trial was similar to that estimated by the ESPAD surveys for the European student populations renders the concern for external validity less worrisome.

6 CONCLUSIONS

An overarching conclusion from the studies included in this thesis, as well as the major lesson from the EU-DAP trial, is that a structured prevention curriculum based on a CSI model can be conducted in European schools, with levels of implementation and effectiveness similar to those obtained in North American countries.

Specifically, the presented work suggests that the CSI model of school-based prevention affects as intended both proximal and distal outcomes, and may lead to decreasing rates of problematic drinking and related problem behaviours among young people.

What this thesis adds

1. Findings lend support to the theoretical Comprehensive Social Influence (CSI) model, achieving the hypothesized modifications of both alcohol-related cognitive aspects and alcohol-related behaviours.
2. CSI-based prevention programmes against alcohol use can be implemented in European countries, replicating the results of similar programmes in North America.
3. CSI prevention programmes may have a greater chance of making inroads on less socially acceptable forms of drinking, such as heavy drinking, than on moderate consumption.
4. Alcohol prevention based on CSI models in European schools might be particularly beneficial to adolescents in under-privileged social contexts.
5. Resistance skills, norm perception and positive expectations may mediate the effect of alcohol prevention CSI programmes on behavioural outcomes.
6. Characteristics of the class might impact on the ability of the teachers to deliver the CSI programmes as intended.

6.1 SUGGESTIONS FOR FUTURE RESEARCH

Some valuable general lessons were learned throughout the work of design and analysis of this multi-centric trial, beyond the outcome evaluation presented in this thesis.

Evaluation of public health interventions is much more complex than evaluation of clinical treatments, within which the paradigms of Evidence Based Medicine were developed [105]. Specific features of this complexity are: need of large samples, calling for multicentre studies; length of the path of causation between intervention and outcome, with interplay of diverse socio-cultural factors; challenges to implementation; departure from pure experimental design (e.g. lack of blindness). Modest results of alcohol use prevention in youths presented in an extensive review of forty-one trials [77] may raise the question whether we have the proper tools to measure the

effectiveness of this kind of programmes, and whether evaluation of public health interventions might require different scientific standards [72]. For instance, hypothesis-testing based on conventional statistical significance may be questioned as the only criterion to make inference about the causal relation between an intervention and the proposed outcomes. Consistency of effects on several outcomes, stages of behaviour and susceptible subgroups as well as mediation analysis, can provide useful insights and enhance the plausibility of an association [106]. Other study designs that incorporate adequacy and plausibility approaches may also represent a valid complement for evaluation of large-scale public health interventions.

Concerning experimental evaluation of school-based prevention in particular, a few important strategies to enhance validity of the results and understanding of effects mechanisms can be summarized as follows:

1. complete understanding of the study protocol and corresponding workload at the level of the provider should be achieved before allocation to experimental conditions
2. the importance of collecting baseline data should be repeatedly emphasized
3. analytical methods appropriate to the hierarchical structure of the data should be applied both to the evaluation of effects and to the evaluation of imbalance between experimental groups
4. finally, analysis of teacher- and class- groups characteristics should deserve more attention in future studies, since they may affect both the implementation of preventive programmes and substance use at follow-up, therefore constituting potential confounders in *per protocol* analyses of experimental studies.

6.2 SUGGESTIONS FOR THE IMPLEMENTATION OF SCHOOL-BASED PREVENTION

We suggest that some class characteristics investigated in this work are useful general indicators of the difficulties that a teacher may encounter in implementing highly interactive educational programmes. For example substance use problems in the class may prompt the decision to adopt a preventive curriculum, but at the same time they may hamper its implementation. On the other hand, this may be facilitated by incorporating in teachers' training group management techniques, aimed at building positive relationships in the class. Specific organizational strategies, such as using two or more implementation groups in a large class, should also be considered.

Overall, a realistic perspective about what schools can reasonably achieve is recommendable. School-based programmes cannot be conceived and carried on in a vacuum, but need to be combined with extracurricular, family, and community activities to produce sustained decreases in alcohol consumption among youth [55].

Universal prevention may see useful complements in indicated or selective prevention, as it is the case for promising family-based interventions [107]. Prevention initiatives at the societal/community level such as controlling both the price and the availability, including opening hours and legal buying age, of alcohol have been demonstrated to have a large potential to reduce the overall level of problems related to alcohol use [108]. Above all, the interaction between community interventions and educational interventions seems of paramount importance. In fact, reducing environmental availability as well as community tolerance towards young people's consumption of alcohol appears to enhance the effectiveness of school and family education programmes [57].

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9 APPENDICES

Appendix 1: EU-Dap questionnaire
Papers I – IV



Appendix 1

EU-Dap questionnaire

EU-Dap questionnaire

8. At present, how often do you drink anything alcoholic, such as beer, wine or spirits?

Try to include even those times when you only drink a small amount.

Every Day	Every week	Every month	Seldom	Never
<input type="checkbox"/>				
1	2	3	4	5

9. How many times (if any) have you been drunk from drinking alcoholic beverages?

Mark one box for each line.

	Number of times						
	0	1-2	3-5	6-9	10-19	20-29	30 or more
a) In your lifetime	<input type="checkbox"/>						
b) During the last 12 months	<input type="checkbox"/>						
c) During the last 30 days	<input type="checkbox"/>						
	1	2	3	4	5	6	7

10. How likely is that each of the following would happen to you if you drink alcohol in the next month? Mark the answer that is closest to your opinion.

	Very Likely	Likely	Unlikely	Very Unlikely
a) Do badly in school.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Get into trouble with parents.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Have problems with my friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Become an addict	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Have money problems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Feel more relaxed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Have more fun	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Be more popular.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Forget my troubles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Be more confident and outgoing.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4

11. How many times (if any) have you sniffed a substance (glue, petrol, paint thinner etc) to get high? Mark one box for each line.

	Number of times						
	0	1-2	3-5	6-9	10-19	20-29	30 or more
a) In your lifetime	<input type="checkbox"/>						
b) During the last 12 months	<input type="checkbox"/>						
c) During the last 30 days	<input type="checkbox"/>						
	1	2	3	4	5	6	7

12. Have you ever heard of any of the following substances? Mark one box for each line.

	Yes	No
a) Tranquillisers or sedatives	<input type="checkbox"/>	<input type="checkbox"/>
b) Marijuana or hashish.....	<input type="checkbox"/>	<input type="checkbox"/>
c) LSD.....	<input type="checkbox"/>	<input type="checkbox"/>
d) Amphetamines.....	<input type="checkbox"/>	<input type="checkbox"/>
e) Crack.....	<input type="checkbox"/>	<input type="checkbox"/>
f) Cocaine	<input type="checkbox"/>	<input type="checkbox"/>
g) Relevin	<input type="checkbox"/>	<input type="checkbox"/>
h) Heroin.....	<input type="checkbox"/>	<input type="checkbox"/>

EU-Dap questionnaire

i) Ecstasy	<input type="checkbox"/>	<input type="checkbox"/>
j) GHB.....	<input type="checkbox"/>	<input type="checkbox"/>
k) Methadone.....	<input type="checkbox"/>	<input type="checkbox"/>
l) "Magic mushrooms"	<input type="checkbox"/>	<input type="checkbox"/>
m) Ketamine	<input type="checkbox"/>	<input type="checkbox"/>
	1	2

13. How many times (if any) have you used marijuana or hashish.....? (never=0)

Mark one box for each line.

	Number of times						
	0	1-2	3-5	6-9	10-19	20-29	30 or more
a) In your lifetime	<input type="checkbox"/>						
b) During the last 12 months	<input type="checkbox"/>						
c) During the last 30 days	<input type="checkbox"/>						
	1	2	3	4	5	6	7

14. Have you ever used any of the following drugs?

Mark one or more boxes for each line.

	No	Yes, during the last 30 days	Yes, during the last 12 months	Yes, during lifetime
a) Tranquillisers/sedatives (without a doctor's prescription).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) LSD or some other hallucinogens.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Amphetamines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Crack.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Cocaine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Relevin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Heroin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Ecstasy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) GHB	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Methadone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k) "Magic mushrooms".....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l) Ketamine.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	1	1	1

15. How likely is that each of the following would happen to you if you take marijuana or other illegal substances in the next month? Mark the answer that is closest to your opinion.

	Very Likely	Likely	Unlikely	Very Unlikely
a) Get into trouble with police	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Have problems in school.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Get into trouble with parents.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Have problems with my friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Become an addict	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Have money problems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Feel more relaxed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Have more fun	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Be more popular.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Be more confident and outgoing.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4

EU-Dap questionnaire

16. How likely is it that you will be doing each of the following A YEAR FROM NOW?

Mark one box for each line.

	Very Likel	Likely	Not Unlikely	Very Unlikely
a) smoke cigarettes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) drink alcoholic beverages (beer, wine, spirits)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) get drunk	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) smoke marijuana or hashish (pot, grass)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) sniff a substance (glue etc) to get high ..	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) take illegal substances	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4

17. Here are some statements that people have made about illegal substances.

How much do you agree with the following opinions on drugs?

Mark the answer that is closest to your opinion.

	Strongly Agree	Agree	Disagree	Strongly Disagree
a) Using drugs can be a pleasant activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) A young person should never try drugs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Using drugs is fun	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Many things are much more risky than trying drugs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Everyone who tries drugs eventually regrets it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) The laws about drugs should be made stronger	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Drug use is one of the biggest evils in the country	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Drugs help people to have experience life in full	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Schools should teach about the real hazards of taking drugs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) The police should not be annoying young people who are trying drugs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k) To experiment with drugs is to give away control of your life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4

18. For each statement below, please mark whether you think it is correct or not by checking the appropriate box.

	Yes	No	Don't know
a) Nicotine is the substance in cigarettes that causes lung cancer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) One needs to smoke several cigarettes per day during many years to become addicted	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Women have lower tolerance to alcohol than men	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) It takes about half an hour to eliminate from the body the amount of alcohol contained in a can of strong beer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Smoking marijuana does not cause physical dependence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) High consumption of hash or marijuana decreases the production of sexual hormones	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3

19. Here are some statements about your knowledge about some substances.

How much do you agree with the following?

Mark the answer that is closest to your opinion.

	Strongly agree	Agree	Disagree	Strongly disagree
a) I know all I need to know about nicotine and its effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) I know all I need to know about alcohol and its effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

EU-Dap questionnaire

c) I know all I need to know about other drugs and their effects 1 2 3 4

20. **How much do you think PEOPLE RISK harming themselves (physically or in other ways), if they..... Mark one box for each line.**

	No risk	Slight risk	Great risk	Don't know
a) smoke cigarettes occasionally	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) smoke one or more packs of cigarettes per day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) have one or two drinks nearly each week	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) drink alcohol every day.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) try inhalants (glue etc) once or twice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) try marijuana or hashish (cannabis, pot, grass) once or twice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) smoke marijuana or hashish regularly ..	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) use other drugs occasionally	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4

21. **Do any of the following people smoke cigarettes? Mark one box for each line.**

	Smokes daily	Smokes sometimes	Does not smoke	Don't know	Don't have or see this person
a) Mother	<input type="checkbox"/>				
b) Father	<input type="checkbox"/>				
c) Best friend	<input type="checkbox"/>				
d) Siblings	<input type="checkbox"/>				
	1	2	3	4	5

22. **When you answer this question, think about the friends with whom you spend most of your leisure time. Mark one box for each line.**

	None	Less than half of them	About half of them	More than half of them	All of them	Don't know
a) How many of them like school?	<input type="checkbox"/>					
b) How many of them do well at school?	<input type="checkbox"/>					
c) How many of them smoke cigarettes?	<input type="checkbox"/>					
d) How many of them get drunk?	<input type="checkbox"/>					
e) How many of them use marijuana or Other drugs?	<input type="checkbox"/>					
	1	2	3	4	5	6

23. **Does any of your siblings? Mark one box for each line.**

	Yes	No	Don't know	Don't have any siblings
a) drink alcoholic beverages (beer, wine, spirits)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) get drunk	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) smoke marijuana or hashish (pot, grass)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) sniff substances (glue, petrol, paint thinner...)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) take other drugs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4

EU-Dap questionnaire

24. Do the following descriptions fit people around you? Mark the answer that is closest to your opinion.

	Strongly Agree	Agree	Disagree	Strongly Disagree
a) My parents set clear rules	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) My parents know where I am in the evenings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) I can easily get support from my father and/or mother	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) It is very important for me not to disappoint my parents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) I can really get support from my best friend	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4

25. In the following questions, you are to say whether you agree or disagree with each statement about your family. Mark the answer that is closest to your opinion.

	Strongly Disagree	Disagree	Agree	Strongly Agree
a) In my family we really help and support one another	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) My family does not discuss its problems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) We don't often fight in my family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Each person's duties are clearly set out in my family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) In my family you can get away with almost anything	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) In my family we are full of life and good spirits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) In my family its important for everyone to express their own opinion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) In my family we hardly ever lose our tempers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) There is strict punishment for anyone breaking the rules in my family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) We can do whatever we want in my family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k) My family always does things together	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l) There are a lot of discussions in my family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m) In my family we never hit each other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n) "Work before play" is the rule in my family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o) In my family we aren't punished or told off when we do something wrong	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p) We really get along well with each other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
q) We don't tell each other about our personal problems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
r) In my family we don't often criticize each other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
s) Family members have strict ideas about what is right and what is wrong	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
t) We come and go as we want to in my family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4

EU-Dap questionnaire

26. **If you wanted to drink alcohol (or already do), do you think your father and mother would allow you to do so?** Mark one box for each line.

Would allow (allows me) to drink alcohol	Would not (does not) allow drinking at home	Would not (does not) allow drinking at all	Don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4

27. **If you wanted to smoke (or already do), do you think your father and mother would allow you to do so?** Mark one box for each line.

Would allow (allows me) to smoke	Would not (does not) allow smoking at home	Would not (does not) allow smoking at all	Don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4

28. **How did your grades compare with those of your classmates during the last school year?**

1 Much better 2 Better 3 The same as most of them 4 Worse

29. **In your opinion, will you have improved your grades at the end of this school year?**

1 Yes 2 Probably yes 3 Probably no 4 No

30. **How do you feel about school at present?**

1 I like it a lot
 2 I like it a bit
 3 I don't like it very much
 4 I don't like it at all

31. **How much do you agree with the following descriptions of your school?**

Mark one box for each line.

	Strongly agree	Agree	Disagree	Strongly disagree
a) The students in my class enjoy being together	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Most of the students in my class are kind and helpful	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Other students accept me as I am	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) How I do in school matters a lot to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) I have great respect for what my teachers tell me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4

32. **Have you ever had any of the following problems in the last 12 months?**

Mark all that applies for each line.

	Never	Yes, because of my alcohol use	Yes, because of my drug use	Yes for reasons other than alcohol or drug use
a) Quarrel or argument	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Scuffle or fight	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Accident or injury	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Loss of money or other valuable items	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

EU-Dap questionnaire

e) Damage to objects or clothing you owned	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Problems in your relationship with (your) parents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Problems in your relationship with (your) friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Problems in your relationship with (your) teachers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Performed poorly at school	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Victimized by robbery or theft	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k) Hospitalised or admitted to an emergency room.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	1	1	1

33. **There are several possible way to take decisions. How well do the following apply to you?**
 Mark the answer that is closest to your opinion.

	Strongly Agree	Agree	Disagree	Strongly Disagree
a) When I have decided to do something, I always carry it through	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) I often make up my mind without thinking of the consequences	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) I weigh up all the choices before I decide on something	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) I often regret something that I had decided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) When I decide on something it doesn't matter what my friends think	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4

34. **Imagine yourself in each of the following situations. Some of them may be very familiar to you, some others less, so that you may feel less secure in answering. It is enough you do your best. Mark the answer that is closest to your opinion.**

	Very likely	likely	unlikely	very unlikely
a) You and your best friend are at a party where you meet new people, and you feel you really want to get to know them. Someone offers you to smoke hash together. Your friend accepts. Do you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) You and the same friend are studying hard for an important test at school the day after. Both of you feel stressed and need to calm down. Your friend suggests a cigarette would help, and offers one. Do you accept?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) The day after, you both pass the test, and feel now it is time to celebrate. Have still some pocket-money left, and the liquor store is nearby. Would you buy some alcohol (beer, wine) to celebrate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1	2	3	4

35. **How much do you agree with the following descriptions of yourself?**

Mark the answer that is closest to your opinion.

	Strongly Agree	Agree	Disagree	Strongly Disagree
a) I feel that I have a number of good qualities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

EU-Dap questionnaire

- | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| b) I am able to do things as well as most other people | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) At times I think I am no good at all | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| d) Most boys and girls of my age are smarter than I am | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| e) I am quite good at sports | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| f) I feel very embarrassed when I have to say something in class | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| g) My being happy is important to my parents | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| h) I worry a lot about silly things | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| i) I often feel nervous over nothing at all | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| j) I have plenty of interests and hobbies | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 1 | 2 | 3 | 4 |

36. **Here are some statements about dealing with other people. Mark the answer that is closest to your opinion.**

- | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| | Strongly Agree | Agree | Disagree | Strongly Disagree |
| a) When someone tries to make you feel small, you should do the same to them | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) There is point in letting people know you're angry with them | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) The only way to deal with bullies is to let them know who is in charge | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| d) There are always ways of dealing with problems without having to fight | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| e) It is much better to 'fly off the handle' than to explain things calmly | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 1 | 2 | 3 | 4 |

37. **Imagine you would like to do the following things. How easy or difficult would you find it? Mark one box for each line.**

- | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| I would like to... | very Easy | easy | difficult | very difficult |
| a) Say something nice to a friend. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Ask for a favour. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) Show someone that I like him/her. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| d) Say "no" when someone asks me to do something I do not want to. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| e) Call for help when I have got problems. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| f) Help someone who needs help. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 1 | 2 | 3 | 4 |